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Cooley LLP / Eurand
ATTN: Patent Group
1299 Pennsylvania Avenue, Suite 700
Washington, DC 20004

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MILLIGAN, ADAM C	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GOPI M. VENKATESH, VIJAYA SWAMINATHAN, JIN-WANG LAI, and JAMES M. CLEVENGER

Appeal 2020-002049
Application 13/310,632
Technology Center 1600

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and ULRIKE W. JENKS, *Administrative Patent Judges.*

JENKS, *Administrative Patent Judge.*

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from Examiner's decision to reject claims 1–4, 6, 8, and 24 as obvious and on the grounds of non-statutory obviousness type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as Adare Pharmaceuticals, Inc. Appeal Br. 2.

STATEMENT OF THE CASE

The Specification describes pharmaceutical compositions incorporated into an orally disintegrating tablet (ODT) that disintegrates in the oral cavity of a mammal, without the need of water or other fluids. Spec. 1:8–10. Aged persons or children who are unwilling or individuals with dysphagia have difficulty swallowing tablets and capsules and would benefit from such an ODT. *Id.* at 2:4–6. While oral formulations such as suspensions, syrups, and sachets are known, they often suffer from bitter taste and unpleasant mouthfeel making compliance difficult. *See id.* at 2:5–6.

CLAIMED SUBJECT MATTER

The claims are directed to rapidly disintegrating microgranules. Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. Rapidly dispersing microgranules, which microgranules have a median particle size in the range of about 100 μm to about 300 μm, comprising at least one sugar alcohol, saccharide, or a mixture thereof, at least one super disintegrant, and at least one multifunctional additive, wherein the at least one multifunctional additive is pregelatinized starch, and is present in an amount of 1-3 weight% of the microgranules, and *the microgranules are without an active ingredient*.

Appeal Br. 22 (Claims App.) (emphasis added).

REJECTIONS

Examiner rejects the claims as follows:

1. Claims 1–4, 6, 8, and 24 are rejected under 35 U.S.C. 103(a) as unpatentable over Venkatesh,[2] in view of Hsu[3] and Beatch.[4]

[2] Venkatesh et al., US 2009/0092672 A1, publ. Apr. 9, 2009 ("Venkatesh").
[3] Hsu et al., US 2005/0147670 Al, publ. July 7, 2017 ("Hsu").
[4] Beatch et al., US 2008/0188547 A1, publ. Aug. 7, 2008 ("Beatch").

2. Claims 1–4, 6, 8, and 24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–13 of US 8,545,881 in view of Beatch.
3. Claims 1–4, 6, 8, and 24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–18 of US 8,747,895 in view of Beatch.
4. Claims 1–4, 6, 8, and 24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–48 of US 8,962,022 in view of Beatch.
5. Claims 1–4, 6, 8, and 24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–15 of US 9,089,490 in view of Beatch.
6. Claims 1–4, 6, 8, and 24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–13, 23, and 24 of US 9,730,896 in view of Beatch.
7. Claims 1–4, 6, 8 and 24 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–18 of US 9,884,014 in view of Beatch.

OPINION

1. Obviousness over Venkatesh, Hsu, and Beatch

Examiner finds that Venkatesh teaches rapidly dispersing granules containing disintegrant, sugar alcohol and/or saccharide, where the granules are not greater than 300 µm. *See* Final Act.[5] 2–3 (citing Venkatesh ¶¶ 31, 43–45, 69, 72, 99). Examiner finds that "[t]he microgranules [of Venkatesh] can also contain a binder such as corn starch at about 1%–2% (Klucel®

[5] Final Office Action mailed January 28, 2019 ("Final Act.").

LF).” *Id.* at 3 (citing Venkatesh ¶ 40). Examiner acknowledges that “Venkatesh does not teach that the corn starch is pregelatinized” as recited in the rejected claims. *Id.*

Examiner finds that Hsu teaches corn starch and pregelatinized starch are suitable binders for use in oral disintegrating dosage forms, and that starches and modified starches additionally have disintegration properties. Final Act. 3 (citing Hsu ¶¶ 46, 47, 50, 55). In addition, Examiner finds that “Beatch teaches that pregelatinized starch (i.e. Starch 1500) is known as a glidant and a disintegrant.” *Id.* (citing Beatch (Table 5)).

Based on these teachings, Examiner concludes:

> It would have been obvious to one of ordinary skill in the art making the granules of Venkatesh to substitute the corn starch of Venkatesh for the pregelatinized starch of Hsu, given Hsu teaches that both corn starch and pregelatinized starch are suitable starch binders for use in oral disintegrating formulations. See MPEP 2144.06. Further, one of ordinary skill in the art would expect better oral disintegration upon substitution of pregelatinized starch for a non-disintegrant binder because pregelatinized starch is also known as a disintegrant.

Final Act. 3.

Appellant contends that Examiner failed to make a prima facie case for the production of rapidly dispersing granules containing pregelatinized starch and no drug. *See* Appeal. Br. 8–9.

“[E]xaminer bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

Upon review of the evidence in light of Examiner’s articulated rationale, we agree with Appellant that Examiner has not made out a prima facie case. In presenting the prima facie case, Examiner relies on substituting

equivalents known for the same purpose. *See* Final Act. 3 (citing MPEP 2133.06); Ans. 4. Specifically, Examiner relies on substituting the corn starch taught in Venkatesh with the pregelatinized starch taught in Hsu. *See* Ans. 4. We agree with Appellant that substitution of the corn starch in Venkatesh for the pregelatinized of Hsu would not result in microgranules as presently claimed.

Claim 1 recites that the pregelatonized starch is present in the microgranules, but the microgranules are expressly required by the claim to be "without an active ingredient." Thus, active ingredients are excluded from the claim. Venkatesh teaches the production of orally disintegrating tablets containing lamotrigine. Venkatesh, Abstract. "Lamotrigine is an anticonvulsant drug used in the treatment of epilepsy and bipolar disorder." *Id.* ¶ 5. According to the Specification, "active ingredients" is reasonably interpreted to encompass pharmaceutical drug actives. *See* Spec. 10:12–20. Therefore, Venkatesh's lamotrigine is reasonably considered an "active ingredient" as recited in the present claims and is thereby an excluded ingredient from the rapidly disintegrating granules.

Venkatesh teaches the production two types of lamotrigine containing orally disintegrating tablets: tablets containing only lamotrigine granules (Venkatesh ¶ 7) or tablets containing lamotrigine granules in conjunction with disintegrating granules containing no active ingredient (*id.* at 9). Venkatesh teaches using film-forming binder in the lamotrigine containing granules, and the film forming binder includes corn starch. *Id.* ¶ 40. Venkatesh teaches that the lamotrigine containing granules can include other ingredients such as modified starch. *Id.* ¶ 41. Additionally, Venkatesh teaches that "[t]he lamotrigine-containing layer comprises about 90%-99% lamotrigine, and about 1 % to about 10% binder." *Id.* ¶ 50. Thus, the use of

corn starch and modified starch in Venkatesh is limited to the lamotrigine containing granules. Based on these disclosures, we agree with Appellant that Examiner has not sufficiently articulated a rationale to arrive at the rapidly disintegrating granules that contain no active ingredient as claimed. *See* Appeal Br. 14; Reply Br. 2. Examiner relies on substitution of corn starch with pregelatinized starch, but such a substitution would only result in granules that contain active ingredient. Examiner has not articulated a rationale for removing the active ingredient from these granules. The evidence of record, therefore, does not support Examiner's position that the combination of Venkatesh, Hsu, and Beatch renders the claims obvious. Accordingly, we reverse the rejection relying on the combination of Venkatesh, Hsu, and Beatch.

2–7. Non-statutory double patenting

Examiner rejected claims 1–4, 6, 8, and 24 on the basis of non-statutory obviousness type double patenting over Patent Nos.: US 8,545,881, US 8,747,895, US 8,962,022, US 9,089,490, US 9,730,896, and US 9,884,014. *See* Final Act. 9; Ans. 5–8.

Appellant does not argue the merits of these non-statutory double patenting rejections, but notes that they will consider submitting a terminal disclaimer upon the indication of allowable subject matter. *See* Appeal Br. 21 ("Appellant requests that these rejections be held in abeyance until the pending claims are otherwise allowable, at which time Appellant may file a terminal disclaimer to obviate [these] rejection[s]."). We therefore summarily affirm these rejections. *See* Manual of Patent Examining Procedure § 1205.02 (9th Ed., Rev. 08.2017, Jan. 2018) ("If a ground of rejection stated by the examiner is not addressed in the appellant's brief, appellant has waived any challenge to that ground of rejection and the Board

may summarily sustain it, unless the examiner subsequently withdrew the rejection in the examiner's answer.").

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–4, 6, 8, 24	103	Venkatesh, Hsu, Beatch		1–4, 6, 8, 24
1–4, 6, 8, 24		Non-statutory double patenting over US 8,545,881	1–4, 6, 8, 24	
1–4, 6, 8, 24		Non-statutory double patenting over US 8,747,895	1–4, 6, 8, 24	
1–4, 6, 8, 24		Non-statutory double patenting over US 8,962,022	1–4, 6, 8, 24	
1–4, 6, 8, 24		Non-statutory double patenting over US 9,089,490	1–4, 6, 8, 24	
1–4, 6, 8, 24		Non-statutory double patenting over US 9,730,896	1–4, 6, 8, 24	
1–4, 6, 8, 24		Non-statutory double patenting over US 9,884,014	1–4, 6, 8, 24	
Overall Outcome			1–4, 6, 8, 24	

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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED