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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HANS-RAINER HOFFMANN,
BODO ASMUSSEN, HOLGER PIOTROWSKI,
and MARKUS MÜLLER

Appeal 2018-002254
Application 14/293,418
Technology Center 1700

Before MICHAEL P. COLAIANNI, GEORGE C. BEST, and
N. WHITNEY WILSON, *Administrative Patent Judges*.

WILSON, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants¹ appeal under 35 U.S.C. § 134(a) from the decision of the Examiner finally rejecting claims 1 and 3–14. We have jurisdiction over the appeal under 35 U.S.C. § 6(b).

We affirm.

¹ The real party in interest is said to be LTS Lohmann Therapie-Systeme AG (Appeal Br. 3).

BACKGROUND

Appellants' invention is directed to edible, film-shaped preparations with cola flavor which, on contact with moisture, are said to disintegrate quickly without leaving any residue (Spec. 1:19–20).

Independent claims 1, 4, and 11 are representative of the claims on appeal and are reproduced below from the Claims Appendix to the Appeal Brief (*emphasis added*):

1. An edible, water-soluble, wafer containing *cola flavouring, wherein said preparation dissolves quickly upon contact with moisture, does not leave a residue, and has a pleasant mouthfeel and wherein said preparation contains a film-forming polymer being a hydroxypropylated starch derivative selected from the group consisting of hydroxypropylated pea starch and hydroxypropylated tapioca starch in combination with further film-forming polymers,*

said cola flavo[u]ring present in said preparation in an amount ranging from 5 to 20 %-wt[.],

said hydroxypropylated starch derivative present in an amount ranging from 55 to 65 %-wt[.],

said one or more further film-forming polymers present in an amount ranging from 0.01 to 10 [%-wt[.], all %-wts[.] relative to dry matter,

from 2 to 5 %-wt[.] acidifier,

and said one or more further film-forming polymers selected from the group consisting of cellulose derivatives, partially hydrolysed polyvinyl alcohols, polyvinyl pyrrolidone, and polyethylene glycols.

4. The preparation according to Claim 1, wherein the film-forming polymer mixture comprises

a) *55 to 65%-wt. of a hydroxypropylated starch derivative, and*

- b) *4.7 to 10%-wt. of further film-forming polymer consisting of partially hydrolysed polyvinyl alcohols*
- c) 5 to 18%-wt[.] glycerine
- d) 0[.]%-wt. filler(s), and
- e) 2 to 5 %-wt[.] acidifier and
stabilizer is not required.

11. An edible, water-soluble, film-shaped preparation containing 5 to 20 %-wt[.] *cola flavouring*, wherein said preparation dissolves quickly upon contact with moisture, does not leave a residue, and has a pleasant mouthfeel, and wherein said preparation contains a film-forming polymer being a hydroxypropylated starch derivative in an amount in the range of about 55 – 65[.]%-wt[.] selected from the group consisting of hydroxypropylated pea starch and hydroxypropylated tapioca starch in combination with a further film-forming polymer consisting essentially of partially hydrolysed polyvinyl alcohol in an amount of 4.7 – 10[.]%-wt[.] and 2 to 5 %-wt[.] acidifier, all relative to dry matter, and stabilizer is not required.

(App. A 1, 2, 4–5).

REJECTIONS

(1) Claim 4 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.²

(2) Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

² The Examiner has withdrawn the rejection of claims 9–12 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 14).

(3) Claims 1, 3–8, and 11–14 are rejected under 35 U.S.C. § 103(a) as unpatentable over Corriveau³ in view of Fadden,⁴ as evidenced by Saxena.⁵

(4) Claim 9 is rejected under 35 U.S.C. § 103(a) as unpatentable over Corriveau in view of Fadden, as evidenced by Saxena, and in further view of Heath.⁶

(5) Claim 10 is rejected under 35 U.S.C. § 103(a) as unpatentable over Corriveau in view of Fadden, as evidenced by Saxena, in view of Heath, and in further view of Pearce.⁷

DISCUSSION

Rejection (1) under 35 U.S.C. § 112, ¶ 1

The Examiner finds that the limitations of claim 4 reciting “0 %[-wt.] filler(s)” and “stabilizer is not required” were not described in the Specification as filed within the meaning of § 112 (Ans. 3).

To satisfy the written description requirement of § 112, the Specification must allow a person of ordinary skill in the art to recognize that the inventor invented what is claimed. *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989). The Specification must reasonably convey to a person of ordinary skill in the art that the inventor had possession of the

³ Corriveau et al., US 2004/0043134 A1, published March 4, 2004.

⁴ Fadden et al., US 2004/0247648 A1, published December 9, 2004.

⁵ Saxena, S.K., *POLYVINYL ALCOHOL (PVA)*, Chemical and Technical Assessment, 61st JECFA 1–3 (2004).

⁶ Heath, Henry B., *Source Book of Flavors*, The AVI Publishing Co., Inc. 779–92 (1981).

⁷ Pearce et al., US 2003/0224090 A1, published December 4, 2003.

claimed subject matter as of the filing date. *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985); *see also Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). The Specification, however, need not describe the claimed subject matter word-for-word. *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976).

The Examiner notes that the Specification “states that fillers are ‘thickeners, disintegration enhancers, or stabilizers’” (Ans. 3). The Examiner finds that because claim 4 “has already excluded fillers,” Appellants are “not considered to have support to ‘not require’ stabilizers (*id.*). According to the Examiner, “‘not requiring’ a stabilizer does not exclude the presence of a stabilizer” (*id.*).

However, we agree with Appellants that the disputed limitations are supported by the Specification (Appeal Br. 10). We note that the Specification discloses that “20[]%-wt. of one or more fillers, e.g.[,] . . . stabilisers, . . . may be contained in the wafers” (Spec. 13:20–26) (emphasis added). The Specification further discloses that a preferred embodiment of the described wafers includes 0–20 %-wt. filler(s) (*id.* at 14:1–8) (emphasis added). Thus, the Specification describes instances in which the claimed composition may not require stabilizers *and* excludes filler(s). Based on this disclosure, we find that the Specification describes, within the meaning of § 112, the claimed composition containing “0 %-wt. filler(s)” and a “stabilizer,” which “is not required.”

Accordingly, we reverse the rejection of claim 4 under 35 U.S.C. § 112, first paragraph.

Rejection (2) under 35 U.S.C. § 112, ¶ 2

In the examination context, the relevant inquiry under 35 U.S.C. § 112, second paragraph, “is to determine whether the claims do, in fact, set out and circumscribe a particular area with a *reasonable* degree of precision and particularity.” *In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971) (emphasis added); *see also In re Packard*, 751 F.3d 1307, 1310 (Fed. Cir. 2014) (“[a] claim is indefinite when it contains words or phrases whose meaning is unclear”). “[T]he definiteness of the language employed must be analyzed—not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.” *Moore*, 439 F.2d at 1235.

In this instance, the Examiner determines that the limitation “stabilizer is not required” as recited in claim 4 is construed to mean that the “stabilizer is optionally present” (Ans. 4). The Examiner further determines that “if [A]ppellant[s] ha[ve] already claimed the preparation comprising 0[%-wt.] filler, [then] it is unclear what [A]ppellant[s] intended the ‘not required’ stabilizer to encompass” (*id.*).

In response, Appellants argue that because the Specification describes “stabilizers” as an example of “fillers,” “a person having ordinary skill in the art would understand that the recitation ‘0[%-wt. fillers(s)’ limits the scope of Claim 4 to recite that the preparation as claimed includes 0[%-wt. of stabilizer” (Appeal Br. 15). Appellants further argue that “contrary to the Examiner’s urgings, the recitations of Claim 4 cannot be read as ‘a stabilizer is optionally present’” (Reply Br. 5).

This argument is insufficient to show error in the rejection as Appellants do not explain the meaning of the claim language “stabilizer is not required.” The disputed language is particularly unclear if, as Appellants assert, it cannot mean that the claimed stabilizer is optionally present.

Accordingly, we affirm the rejection of claim 4 under 35 U.S.C. § 112, second paragraph.

Rejections (3), (4), and (5) under 35 U.S.C. § 103(a)

Upon consideration of the evidence of record and each of Appellants’ contentions as set forth in the Appeal and Reply Briefs, we determine that Appellants have not demonstrated reversible error in any of the Examiner’s rejections under 35 U.S.C § 103(a) in the Final Office Action and Answer. We sustain the rejections under 35 U.S.C. § 103(a) as obvious over the applied prior art, essentially for the reasons expressed by the Examiner in the Final Office Action and the Answer (Final Act. 2–15; Ans. 3–26). We add the following for emphasis.

Rejection (3)

The Examiner finds that Corriveau’s rolled, edible, rapidly dissolving thin film products teach each of the limitations of independent claims 1 and 11, with the exception that, *inter alia*, Corriveau is silent with respect to the claimed hydroxypropylated starch types (Ans. 6). However, the Examiner relies on Fadden for “teach[ing] that hydroxypropylated tapioca starch is known to be utilized in fast dissolving orally consumable films” (*id.* (citing Fadden ¶ 14)). The Examiner concludes that “it would have been obvious to have selected [Fadden’s] hydroxypropylated tapioca starch where hydroxypropylated starches, generally, are taught as suitable for use in the

invention of Corriveau[] as hydroxypropylated tapioca starches were known in the art to be included in oral films” (Ans. 6).

Appellants make the following arguments urging reversal of the rejection of claims 1, 3, 4, and 11: (1) “Corriveau’s alleged . . . 52.6% by weight of hydroxypropylated starch in Example 6 is still less than the claimed range of 55% to 65% by weight as claimed” and the film of Example 6 actually teaches 47.35 % by wt. of hydroxypropylated starch of the finished film (Appeal Br. 21); (2) the Examiner does not provide a rationale why the ordinarily skilled artisan would have randomly combined the hydroxypropylated starch of Corriveau’s Example 6 with the polyvinyl alcohol ingredient of Example 13, which does not include any hydroxypropylated starch (*id.* at 19–20; Reply Br. 12); (3) Corriveau fails to teach that its dissolved composition does not leave a residue and Fadden’s moisture resistant modified starches would have dissolved more slowly (Appeal Br. 24, 28; Reply Br. 13–14); (4) Saxena’s disclosure that polyvinyl alcohol imparts barrier film properties teaches away from the claimed combination of polyvinyl alcohol with hydroxypropylated starch (Appeal Br. 29–30; Reply Br. 14); and (5) Examples 1–3 of the Specification provide evidence that “the present invention is significant (and thus unexpected)” (Appeal Br. 33) and the Rule 132 Declaration of Dr. Müller provides “comparisons with the closest prior art and the invention” (Reply Br. 12–13 (citing Rule 132 Declaration ¶¶ 13–16; 17–21)).

Appellants’ arguments are not persuasive.

With respect to arguments (1) and (2), the claims at issue each require that the recitations of %-wts. are “relative to dry matter.” Thus, Appellants have not identified error in the Examiner’s subtraction of the 10 %-wt.

contributed by water to derive the 52.6 %-wt. of hydroxypropylated starch relative to the dry film of Example 6 (*see* Ans. 7). Furthermore, Corriveau explicitly discloses that “[s]uitable film-formers include but are not limited to . . . modified starches such as those that have been acid modified, bleached, oxidized, esterified, etherified, crosslinked, and treated enzymatically” (Corriveau ¶ 82; *see also In re Fritch*, 972 F.2d 1260, 1264 (Fed. Cir. 1992) (explaining that “[i]t is well settled that a prior art reference is relevant for all that it teaches to those of ordinary skill in the art”). Thus, we are not persuaded that the claimed hydroxypropylated starch derivative, which is a modified starch, is not disclosed as a suitable film-former in Corriveau’s list of modified starches.

Corriveau further teaches that “[i]n an embodiment, the concentration of the film-forming agent constitutes between 5% to about 60% by dry weight” (Corriveau ¶ 82). Therefore, the claimed hydroxypropylated starch derivative ranges are *prima facie* obvious over the teachings of Corriveau. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (“[a] *prima facie* case of obviousness typically exists when the ranges of . . . [the] claimed composition overlap the ranges disclosed in the prior art”); *see also In re Malagari*, 499 F.2d 1297, 1303 (CCPA 1974) (concluding that a claimed invention was rendered *prima facie* obvious by a prior art reference whose disclosed range (0.020–0.035% carbon) overlapped the claimed range (0.030–0.070% carbon)).

With regard to argument (2), we are not persuaded because Corriveau is relevant for all that it teaches to those of ordinary skill in the art. *See Fritch*, 972 F.2d at 1264. As the Examiner finds, Corriveau teaches “combinations of film forming polymers, including all of the claimed film-

forming polymers, as suitable for inclusion in their invention . . . , as well as specific examples with amounts of hydroxypropylated starch in combination with smaller amounts of additional film-forming polymers including gelatin” and polyvinyl alcohol (Ans. 5 (citing *Corriveau* ¶ 82; Example 6); *see also* Ans. 7 (citing *Corriveau* Example 13)). Based on these teachings, Appellants’ arguments have not identified reversible error in the Examiner’s conclusion that it would have been obvious for the ordinary skilled artisan “to have utilized a large amount of a hydroxypropylated starch in combination with a smaller amount of an additional film-forming polymer as claimed with the reasonable expectation that a suitable water-soluble wafer would [have] be[en] provided” (Ans. 5).

We are not persuaded by Appellants’ argument (3) because the cited prior art, which is directed to quick-dissolving oral film, discloses each limitation recited in claims 1 and 11 (*see id.* at 18, 20). It is well established that when claimed and prior art products are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). This is true whether the rejection is under 35 U.S.C. § 102 (anticipation) or 35 U.S.C. § 103 (obviousness), and is based on the fact that the PTO is not in a position to manufacture products or to obtain and compare prior art products. *Id.*

In this instance, Appellants have not met their burden in demonstrating that the edible, water-soluble wafer composition resulting from the Examiner’s proposed combination does not possess the claimed

capability to dissolve quickly upon contact with moisture and does not leave a residue.

Appellants' argument (4) is not persuasive because the Examiner relies on Saxena only as evidence that teaches that Corriveau's polyvinyl alcohol would have been inherently partially hydrolyzed (*see* Ans. 7, 21).

Argument (5) is not persuasive because Appellants have failed to establish that the ordinary skilled artisan would not have expected that the claimed wafer provides quick dissolution properties. *See In re Freeman*, 474 F.2d 1318, 1324 (CCPA 1973) (holding that to establish the existence of unexpected results, Appellants must establish: (1) that there actually is a difference between the results obtained through the claimed invention and those of the closest prior art and (2) that the difference actually obtained would not have been expected by a person of ordinary skill in the art at the time of the invention.).

Appellants have not shown error in the Examiner's finding that both the applied prior art and the instant claims are similarly directed to fast dissolving orally consumable films (*see* Ans. 18, 20). Furthermore, our review of Examples 1–3 of the Specification and paragraphs 13–16 and 17–21 of the Rule 132 Declaration of Dr. Müller finds that Appellants have not made any comparisons with the closest prior art.

Accordingly, we affirm the rejection of claims 1, 3, 4, and 11 for the reasons set forth above and explained in the Examiner's Final Action and the Answer. Dependent claims 5–8 and 12–14 fall with each of their respective independent claims. 37 C.F.R. § 41.37(c)(1)(iv).

Rejection (4)

The Examiner finds that the combination of Corriveau and Fadden “is silent as to the edible films comprising caramel coloring, caffeine or lime flavoring” (Ans. 11). However, the Examiner finds that Heath teaches a variety of cola syrup formulations (*id.*). The Examiner concludes that because “all of the claimed ingredients are known to be used in edible films and to provide cola flavors it is considered obvious to combine the claimed ingredients to provide a cola-flavored edible film” (*id.* at 12).

Appellants make the following arguments urging reversal of the rejection of claim 9: (1) Heath does not teach or suggest the claimed wafer containing sucralose cola flavoring because Heath requires the combination of saccharin and calcium cyclamate (Appeal Br. 33–34); and (2) the Examiner’s proposed combination does not teach the required amounts of sucralose and the optional sorbitol syrup (*id.* at 35–36).

Appellants’ arguments are not persuasive. We agree with the Examiner that the ordinary skilled artisan would have gleaned from Corriveau that an edible, water-soluble, wafer may include any known flavor, including Heath’s cola flavoring (*see* Ans. 23, citing Corriveau ¶ 88 (disclosing that “[a]ny suitable amount and type of artificial and/or natural flavoring agents can be used in any sensorially acceptable fashion.”)). Furthermore, Corriveau teaches a number of high intensity sweeteners for inclusion in oral films, including sucralose, saccharin, and cyclamate (Corriveau ¶ 92; Example 6 (disclosing sucralose at 1.4 %-wt.)). Therefore, in the absence of any showing of unexpected results, Appellants have not identified reversible error in the Examiner’s determination that it would have

been obvious to combine the claimed ingredients to provide a cola-flavored edible film.

Accordingly, we affirm the rejection of claim 9 for the reasons set forth above and explained in the Examiner's Final Action and the Answer.

Rejection (5)

The Examiner finds that the combination of Corriveau, Fadden, and Heath "is silent as to the edible films comprising polyoxyethylene sorbitan monooleate[and] macrogol glycerol hydroxystearate" (Ans. 13). However, the Examiner finds that Pearce "teach[es] plasticizers for edible films including polyoxyethylene sorbitan monooleate (i.e.,] polysorbate) and macrogol glycerol hydroxystearate (i.e.,] polyoxyethylene castor oil derivative) in a mixture in an amount ranging from 0.1 to 5 % total by weight" (*id.* (citing Pearce ¶ 50)). The Examiner concludes that because "all of the claimed ingredients are known to be used in edible films and to provide cola flavors it is considered obvious to combine the claimed ingredients to provide a cola-flavored edible film" (Ans. 14).

Appellants urge reversal of the rejection of claim 10 by arguing that Pearce: (1) teaches that film-forming agents other than pullulan, such as those presently claimed, give rise to a slimy filler (Appeal Br. 37–38); and (2) cautions against the addition of the claimed glycerin or sorbitol to avoid producing an overly moist film (*id.*).

These arguments are not persuasive because Appellants do not point to anything in Pearce that criticizes, discredits, or discourages employing either non-pullulan film-forming agents, glycerin, or sorbitol. Without such an express teaching, it cannot be said that the art teaches away from the

necessary modification. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004).

With regard to argument (1), the Examiner finds that Pearce's exemplary Base Film Formulation A does not comprise pullulan (Ans. 25, citing Pearce ¶ 197). Furthermore, Pearce provides a list of film-forming agents which are essentially the same as those of Corriveau (*compare* Pearce ¶ 28 *with* Corriveau ¶ 82).

Appellants' argument (2) is not persuasive because we agree with the Examiner that Pearce only teaches that "it may be useful" to avoid substantial amounts of sorbitol and/or glycerin (Ans. 25 (citing Pearce ¶ 33)). In other words, Pearce does not teach that these compounds cannot be included in oral films.

Accordingly, we affirm the rejection of claim 10 for the reasons set forth above and explained in the Examiner's Final Action and the Answer.

CONCLUSION

We REVERSE the rejection of claim 4 under 35 U.S.C. § 112, ¶ 1, for failing to comply with the written description requirement.

We AFFIRM the rejection of claim 4 under 35 U.S.C. § 112, ¶ 2, as indefinite.

We AFFIRM the rejection of claims 1, 3–8, and 11–14 under 35 U.S.C. § 103(a) as unpatentable over Corriveau in view of Fadden, as evidenced by Saxena.

We AFFIRM the rejection of claim 9 under 35 U.S.C. § 103(a) as unpatentable over Corriveau in view of Fadden, as evidenced by Saxena, and in further view of Heath.

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We AFFIRM the rejection of claim 10 under 35 U.S.C. § 103(a) as unpatentable over Corriveau in view of Fadden, as evidenced by Saxena, in view of Heath, and in further view of Pearce.

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