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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOSEPH FOURNELL, SCOTT EAKER, and
ARMANDO MONTOYA¹

Appeal 2018-006809
Application 13/566,753
Technology Center 1700

Before N. WHITNEY WILSON, CHRISTOPHER C. KENNEDY, and
MERRELL C. CASHION, JR., *Administrative Patent Judges*.

KENNEDY, *Administrative Patent Judge*.

DECISION ON APPEAL

This case is an appeal under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 1, 3–5, 7–9, 14, 16, 18–21, 31, and 34–39. An oral hearing was held on September 12, 2019. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

BACKGROUND

The subject matter on appeal relates to methods for producing human milk products with reduced bacteria content. *E.g.*, Spec. 1:14–16; Claim 1.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. The Appellant identifies the real party in interest as Prolacta Bioscience, Inc. *See* App. Br. 2.

Claim 1 is reproduced below from page 20 (Claims Appendix) of the Appeal Brief:

1. A method for treating raw human milk to obtain microfiltered human milk having lower bacteria content compared to raw human milk, comprising:
 - (a) providing raw human milk;
 - (b) separating the raw milk into a cream fraction and a skim milk fraction, wherein the skim milk fraction contains about 1.0% to about 0.1 % fat content;
 - (c) pre-filtering the skim milk fraction using a filter aid through one or more pre-filters to produce pre-filtered skim milk, wherein said filter aid is added to said skim milk fraction in a concentration of from about 20 g/L to about 50 g/L, and wherein said filter aid has a permeability of from about 0.100 D to about 0.300 D; and
 - (d) microfiltering the pre-filtered skim milk obtained in step (c) through one or more microfilters to obtain microfiltered human skim milk.

REJECTIONS ON APPEAL

The claims stand rejected under 35 U.S.C. § 103(a) as follows:

1. Claims 1, 3–5, 7, 9, 14, 16, 18–21, 31, and 34–39 over Gregory (US 5,707,678, issued Jan. 13, 1998), Schmidt (US 2,155,843, issued Apr. 25, 1939), and Lindquist (US 6,652,900 B2, issued Nov. 25, 2003);
2. Claim 8 over Gregory, Schmidt, Lindquist, and Medo (US 2008/0124430 A1, published May 29, 2008).

ANALYSIS

The Examiner finds that Gregory discloses a method similar to that of claim 1, including, *inter alia*, the use of a diatomaceous earth filter aid, but the Examiner does not specify at what step of Gregory's method the filter

aid is used. Ans. 2–3. As to the permeability of Gregory’s filter aid, the Examiner finds that Gregory discloses the use of commercial products Dicalite 215 and Hyflo Supercell as filter aids. *Id.* at 3. Although Gregory itself says nothing about permeability, the Examiner finds that the permeability of Dicalite 215 is 0.02 D and that the permeability of Hyflo Supercell is 1.00 D. *Id.* The Examiner finds that Gregory therefore “teaches a range” of permeabilities, i.e., 0.02 D to 1.00 D, “that overlaps the claimed permeability” range of 0.100 D to about 0.300 D. *Id.* As to the concentration of the filter aid, Gregory discloses a concentration of 4 g/L, and the Examiner acknowledges that Gregory “does not disclose the claimed amount of filter aid used.” *Id.* However, the Examiner finds that Schmidt teaches the use of “0.05 % or 50g/l” filter aid in a milk treatment process. *Id.* The Examiner determines that it would have been obvious to use Schmidt’s 50 g/L filter aid concentration in Gregory’s process because Schmidt “teaches that the filter aids provides [sic] a good result at 0.05 % or 50g/l.” *Id.*

In view of those and other findings less material to the disposition of this appeal, the Examiner concludes that the subject matter of claim 1 would have been obvious to a person of ordinary skill in the art.

We reverse the Examiner’s rejection for three reasons. First, as argued by the Appellant, claim 1 specifically requires the use of a filter aid during the prefiltering step. In the Final Action, the Examiner does not appear to address that requirement of claim 1. *See* Final Act. 3. In the Appeal Brief, the Appellant repeatedly argues that Gregory teaches the use of a filter aid only in the microfiltration step rather than in a prefiltration step as claimed. *See* App. Br. 6, 12–13, 15, 18. In the Answer, the Examiner

acknowledges that argument but fails to address it. *See* Ans. 14 (finding that “the claims do not exclude additional prefiltering [steps]” without making findings as to whether Gregory teaches or suggests the use of a filter aid during prefiltering). On this record, the Examiner has not established a *prima facie* case of obviousness because the Examiner has not made adequate fact findings concerning the step during which the filter aid is used. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) (“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.”).

Second, as argued by the Appellant, App. Br. 8–10, the Examiner has not adequately established that the prior art teaches or suggests the claimed filter aid permeability range of 0.100 D to about 0.300 D. Specifically, the Examiner has not adequately established that Gregory’s mere disclosure of two commercially available filter aids, Dicalite 215 and Hyflo Supercell, *see* Gregory at 2:43–48, should be considered to disclose a range of undisclosed permeabilities. The Examiner identifies no disclosure at all in Gregory concerning permeabilities.

The Examiner cites *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004), for the proposition that a reference need not individually and explicitly disclose a range in order for the prior art as a whole to suggest a range. *See* Ans. 10–11. In that case, the claim at issue recited a weight plate comprising, *inter alia*, “a triad of spaced apart elongated handle openings.” *Iron Grip Barbell*, 392 F.3d at 1319. “The prior art [collectively] disclosed weight plates with one, two and four elongated handles,” and the prior art appears to have expressly disclosed the number of handles and the purpose of the handles. *See id.* at 1320–22. The

Federal Circuit held that the claimed number of three handles fell within the range of handles (i.e., 1–4) disclosed by the collective prior art and would have been *prima facie* obvious. *Id.*

In this case, by contrast, the Examiner identifies no specific disclosure in Gregory, Schmidt, or Lindquist of any suitable permeability value for filter aids. Although Gregory discloses two specific filter aids, Dicalite 215 and Hyflo Supercell, and an independent reference discloses that those filter aids have permeabilities of 0.02 D and 1.00 D, respectively, *see* App. Br. 23 (Exhibit A), the Examiner does not adequately establish that Gregory’s disclosure of two exemplary filter aids, with no reference whatsoever to permeability, constitutes the disclosure of a desirable filter aid permeability range of 0.02 D to 1.00 D. By the Examiner’s reasoning, Gregory would be viewed as implicitly disclosing a “range” of every individual property of those two filter aids. The Examiner fails to show that Gregory’s disclosure should be viewed so broadly. *Cf. In re Stepan Co.*, 868 F.3d 1342, 1346 (Fed. Cir. 2017) (“[T]he Board must provide some rational underpinning explaining why a person of ordinary skill in the art would have arrived at the claimed invention . . .”).

Additionally, because the Examiner identifies no evidence in the record that filter aid permeability was a known result-effective variable, the record before us does not adequately support a rejection on the basis of a “routine optimization” rationale. *See In re Antonie*, 559 F.2d 618, 620 (CCPA 1977) (stating that cases “in which the parameter [to be] optimized was not recognized to be a result-effective variable” are an “exception” to “the rule that the discovery of an optimum value of a variable in a known process is normally obvious”).

On this record, the Examiner has not adequately established that the prior art teaches or suggests the claimed filter aid permeability range.

Third, as argued by the Appellant, App. Br. 13–14, the Examiner has not adequately established that a person of ordinary skill would have had reason to increase the filter aid concentration disclosed by Gregory by more than an order of magnitude (from 4 g/L to 50 g/L) in view of Schmidt.

Gregory teaches that a filter aid concentration of “about 4 g/l” is “effective to increase the filter capacity to desired levels.” Gregory at 2:47–49. The Examiner relies on Schmidt’s disclosure of using a filter aid at a concentration of “0.05 % or 50g/l.” Ans. 3; *see also* Schmidt at 2:1–20. Even assuming that Schmidt’s milk has a density of 1 g/cm³, so that 0.05 weight % corresponds to 50 g/L as the Examiner finds (*e.g.*, Ans. 3 (“SCHMIDT teaches that the filter aids provide[] a good result at 0.05 % or 50g/l”)), one of Schmidt’s primary concerns is using concentrations of filter aid that are sufficient to remove bacteria while minimizing loss of fat during filtration. *E.g.*, *id.* at 1:19–31. Gregory, by contrast, specifically teaches removal of fat by centrifugation prior to filtration. *E.g.*, Gregory at 3:26–33. Thus, the processes disclosed by Gregory and Schmidt have noteworthy differences. The Examiner fails to establish that the concentration of filter aid used in Schmidt would have been desirable in Gregory’s process. Moreover, the Examiner fails to establish why a person of ordinary skill in the art would have been motivated to increase the concentration of Gregory’s filter aid by more than tenfold from 4 g/L to 50 g/L when Gregory discloses that 4 g/L is effective to achieve Gregory’s goals.

On this record, the Examiner has not adequately established that a person of ordinary skill would have had reason to increase the filter aid concentration disclosed by Gregory (4 g/L) to the 50 g/L of Schmidt.

For those three reasons, we reverse the Examiner’s rejection of claim 1. Claims 3–5, 7–9, 14, 16, 18–21, and 31 depend from claim 1, directly or indirectly, and the Examiner’s analysis of those claims does not remedy the errors identified above. We likewise reverse the Examiner’s rejection of claims 3–5, 7–9, 14, 16, 18–21, and 31.

Independent claim 34 does not include the filter aid permeability limitation of claim 1, but, like claim 1, claim 34 does require the use of a filter aid during the prefiltering step, and it requires the same concentration of filter aid as claim 1. The Examiner’s analysis of claim 34 does not remedy the errors discussed above concerning those two limitations. Nor does the Examiner’s rejection of claims 35–39, which depend from claim 34. Accordingly, we reverse the Examiner’s rejection of claims 34–39.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
1, 3–5, 7, 9, 14, 16, 18–21, 31, 34–39	§ 103(a) Gregory, Schmidt, Lindquist		1, 3–5, 7, 9, 14, 16, 18–21, 31, 34–39
8	§ 103(a) Gregory, Schmidt, Lindquist, Medo		8
Overall Outcome			1, 3–5, 7–9, 14, 16, 18–21, 31, 34–39

REVERSED