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Harness Dickey (Troy)
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOEP VAN DEN BRENK,
KOEN CORNELIS VAN DIJKE,
ADRIANA MARTINA LAMBERTA VAN DER STEEN,
RAOUL CHARLES JOHAN MOONEN, and
ANTONIE VAN BAALEN

Appeal 2019–000385
Application 14/385,044
Technology Center 1700

Before MICHAEL P. COLAIANNI, GEORGE C. BEST, and
DEBRA L. DENNETT, *Administrative Patent Judges*.

DENNETT, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

STATEMENT OF THE CASE

[1] In this Decision, we refer to the Specification filed September 12, 2014 ("Spec."); the Final Office Action dated September 8, 2017 ("Final Act."); the Appeal Brief filed March 5, 2018 ("Appeal Br."); the Examiner's Answer dated August 16, 2018 ("Ans."); and the Reply Brief filed October 12, 2018 ("Reply Br.").

Appellant appeals under 35 U.S.C. § 134(a) from the Examiner's final rejection of claims 1–17 and 21–24.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

The claims are directed to a process for preparing a lipid and protein component-containing composition for feeding infants and young children. Claims 1 and 22, reproduced below from the Claims Appendix of the Appeal Brief, illustrate the claimed subject matter with disputed terms italicized:

> 1. *A process for preparing a lipid and protein component-containing composition*, which is an infant or follow-on formula or a growing up milk and *comprises lipid globules*, comprising:
>
> a) providing an aqueous phase with a dry matter content of 10[wt.]% to 60 wt.% (based on total weight of the aqueous phase), the aqueous phase including at least one protein component;
>
> b) providing a liquid lipid phase having at least one lipid; and
>
> c) mixing the lipid phase with the aqueous phase in a ratio of 5[]% to 50 % (w/w) *using an inline mixer with at least one mixing head at a pressure of no greater than 10 bar so as to obtain a lipid and protein component-containing composition comprising lipid globules having a volume-weighted mode diameter of at least 1.0 μm,*
>
> *wherein the process does not include the use of a homogeniser [sic]*.
>
> 22. *A process for preparing a lipid and protein component-containing composition, which* is an infant or

[2] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as N.V. Nutrica. Appeal Br. 3.

follow-on formula or a growing up milk and *comprises lipid globules*, comprising:

a) providing an aqueous phase with a dry matter content of 10[wt.]% to 60 wt.% (based on total weight of the aqueous phase), the aqueous phase including at least one protein component;

b) providing a liquid lipid phase having at least one lipid;

c) dispersing the liquid lipid phase into the aqueous phase in a ratio of 5[]% to 50% (w/w) *using an inline mixer with at least one mixing head at a pressure of no greater than 10 bar to generate an emulsion comprising lipid globules having a volume-weighted mode diameter of at least 1.0 μm*; and

d) atomizing the emulsion with a spray dryer to obtain the lipid and protein component-containing composition,

wherein the process does not include the use of a homogeniser.

REFERENCES

The Examiner relies on the following prior art in rejecting the claims on appeal:

Brown	US 2004/0052156 A1	Mar. 18, 2004
Sarma et al. ("Sarma")	US 2008/0113067 A1	May 15, 2008
Trophardy	US 2009/0252789 A1	Oct. 8, 2009
Van Baalen et al.[3]	WO 2010/027258 A1	Mar. 11, 2010

[3] The Examiner relies on Van Baalen et al., US 2011/0206743 A1, published Aug. 25, 2011 ("Van Baalen") as the English language equivalent of Van Baalen et al. Final Act. 2. Appellant stated no objection. In our Decision, citations to Van Baalen are to the published US application.

REJECTIONS

The Examiner maintains the following rejections under 35 U.S.C. § 103(a):[4] (1) claims 1–14, 16, and 21–24 as unpatentable over Van Baalen in view of Brown and further in view of Sarma; and (2) claims 15 and 17 as unpatentable over Van Baalen in view of Brown and Sarma, and further in view of Trophardy. Final Act. 2–18.

OPINION

Rejection of claims 1–14, 16, and 21–24 as unpatentable over Van Baalen in view of Brown, and further in view of Sarma

Appellant argues that the Examiner fails to make a prima facie case of obviousness with respect to independent claims 1 and 22. *See, e.g.*, Appeal Br. 10. Appellant does not make separate patentability arguments for the dependent claims. We select claims 1 and 22 as representative of the claims. *See* 37 C.F.R. § 41.37 (c)(1)(iv).

With respect to claims 1 and 22, the Examiner finds that, *inter alia*, Van Baalen's homogenizer provides lipid globules having overlapping ranges of volume-weighted mode diameters. Final Act. 3–8, 9 (citing Van Baalen ¶ 139; Tables 1, 2). The Examiner finds that Van Baalen teaches most of the steps of each method, but does not teach that an inline mixer with at least one mixing head provides lipid globules having the volume-weighted mode diameters recited in step c. *Id.* at 9, 13.

The Examiner finds that Sarma teaches subjecting a protein-containing product to liquid grinding in a high-shear inline mixer to reduce

[4] Because this application claims priority to an application filed before the March 16, 2013, effective date of the America Invents Act, we refer to the pre-AIA version of the statute.

the particle size of protein particles. *Id.* at 9 (citing Sarma ¶ 51). Such disclosure, the Examiner finds, illustrates that inline mixing results in a finished lipid-protein complex emulsion which exhibits a particle size distribution that overlaps the claimed amount. *Id.* at 10 (citing Sarma Fig. 4). The Examiner concludes that it would have been obvious for the ordinarily skilled artisan at the time of the invention "to have included the inline mixer without the homogenizer as an addition to the process[,] as suggested by Sarma selected from the overlapping portion of the range taught by the reference[,] because overlapping ranges have been held to establish prima facie obviousness." *Id.* (citing MPEP § 2144.05). According to the Examiner, inline mixers are interchangeable with homogenizers because each apparatus mixes two phases to create an emulsion. Ans. 20.

Claims 1 and 22, however, each require "*using an inline mixer* . . . so as to obtain a lipid and protein component-containing composition *comprising lipid globules* having a volume-weighted mode diameter of at least 1.0 μm" (emphasis added). Appellant argues persuasively that Sarma's resulting lipid-protein complex does not comprise lipid globules. Appeal Br. 13–14. Rather, Sarma's inline mixer produces "a solid mixture containing protein particles with a size of 30–70 μm." *Id.* at 14 (citing Sarma ¶¶ 15, 21). As Appellant argues, Sarma teaches that "[t]he lipid will surround each protein particle" in the finished lipid-protein complex. *Id.* (citing Sarma ¶ 29).

On the other hand, the Specification describes "the production of lipid globules having a volume-weighted mode diameter more close to the diameter of natural human milk lipid globules." Spec. 6:10–12. The

Specification provides that the desired natural human milk lipid globules contain "triglycerides contained within emulsified globules . . . surrounded by a structural membrane composed of phospholipids . . . , glycolipids, cholesterol, enzymes, *proteins*, and *glycoproteins*." Spec. 1:16–20 (emphasis added). The Specification describes that "[t]he lipid globules produced by the present process preferably comprise a core and preferably a coating, wherein the core comprises a lipid," and "[t]he coating preferably comprises polar lipids, in particular phospholipids." Spec. 19:5–10.[5]

On these facts, Sarma does not teach or suggest preparing a lipid and protein component-containing composition comprising *lipid globules* using an inline mixer. Rather, Sarma merely suggests that an inline mixer can be used to provide lipids surrounding each protein particle core in the finished lipid-protein complex. Thus, the Examiner's reason for combining the disclosures of Van Baalen with those of Sarma to teach claims 1 and 22 is unsupported.

The Examiner finds inline mixers with at least one mixing head are interchangeable with homogenizers because Van Baalen teaches the use of a variety of mixing equipment, which is not limited to homogenizers. Ans. 21 (citing Van Baalen ¶¶ 108, 110); *see also* Final Act. 13. The Examiner finds that Brown's inline mixer with at least one mixing head produces mixing by low stress or low shear, which Appellant desires. Ans. 21. The Examiner

[5] The Specification provides that the preferred "weight ratio [of] phospholipids to protein is above 0.10, more preferably above 0.20, even more preferably above 0.3," which suggests that these ratios facilitate the presence of proteins within the coating. Spec. 18:24–26; *see also id.* 2:11–17 (disclosing that insufficient amounts of phospholipids leads to undesired increased protein amounts covering the liquid globules).

determines that it would have been obvious to one of ordinary skill in the art at the time of the invention "to produce the claimed inline mixer and head step including the rate and any properties therefrom because as suggested by [Van Baalen], any mixer can be used, and the rates and properties such as low shear rates and times are provided by Brown." Final Act. 14.

However, our review of the Examiner's relied-upon disclosure finds that although Van Baalen vaguely teaches that homogenization can be "performed with a variety of mixing equipment," only a specific Niro Suavi NS 2006 H Homogenizer is disclosed as suitable. Van Baalen ¶¶ 110, 112. Furthermore, the Examiner's remaining relied-upon paragraph merely provides that minerals, vitamins, and stabilizing gums may be added to a nutritional composition and mixed therein using an agitator. *Id.* ¶ 108. The record before us does not establish sufficiently that inline mixers with at least one mixing head are interchangeable with homogenizers. *See* Reply Br. 4. Thus, the Examiner provides no motivation for one of ordinary skill in the art at the time of the invention to modify Van Baalen with the teachings of Sarma and Brown.

Therefore, Appellant argues persuasively that the Examiner's proposed combination of references lacks the requisite articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *See* Appeal Br. 16; *see also In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."). In the instant case, the reason to combine the references appears to be based only on hindsight reconstruction of the disclosed

invention, which "we cannot allow . . . to be the thread that stitches together prior art patches into something that is the claimed invention." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

The Examiner fails to show prima facie obviousness of claims 1 and 22 over Van Baalen, Brown, and Sarma. We, therefore, do not sustain the Examiner's rejection of claims 1 and 22. For the same reasons, we do not sustain the rejection of: (i) claims 2–14, 16, and 21, which depend from claim 1; and (ii) claims 23 and 24, which depend from claim 22.

Appellant shows that the Examiner reversibly errs in concluding that the pending claims would have been obvious over the cited references.

Rejection of claims 15 and 17 as unpatentable over Van Baalen in view of Brown, Sarma, and further in view of Trophardy

Claims 15 and 17, which depend from claim 1, were rejected as obvious over Van Baalen in view of Brown, Sarma, and further in view of Trophardy. Final Act. 17. The additional Trophardy reference does not remedy the deficiency of the Examiner's proposed combination of Van Baalen, Brown, and Sarma, in the rejection of claim 1. Although Appellant did not argue separately against the rejection of claims 15 and 17 (*see* Appeal Br. 10), we do not sustain the rejection of the parent claim, and, therefore, do not sustain the rejection of claims 15 and 17.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–14, 16, 21–24	103(a)	Van Baalen, Brown, Sarma		1–14, 16, 21–24
15, 17	103(a)	Van Baalen, Brown, Sarma, Trophardy		15, 17
Overall Outcome				1–17, 21–24

REVERSED