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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MARCEL BRAUN and CAROLINE NIEDERREITER

Appeal 2019-004652
Application 13/379,185
Technology Center 1700

Before ROMULO H. DELMENDO, BEVERLY A. FRANKLIN, and
MONTÉ T. SQUIRE, *Administrative Patent Judges*.

DELMENDO, *Administrative Patent Judge*.

DECISION ON APPEAL

The Appellant¹ appeals under 35 U.S.C. § 134(a) from the Primary Examiner’s final decision to reject claims 1, 4–6, 9, and 27–31.² We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. The Appellant identifies “Nestec S.A.” as the real party in interest (Appeal Brief filed November 8, 2018 (“Appeal Br.”) at 2).

² See Appeal Br. 4–10; Reply Brief filed May 21, 2019 (“Reply Br.”) at 2–5; Final Office Action entered August 8, 2018 (“Final Act.”) at 2–8; Examiner’s Answer entered March 22, 2019 (“Ans.”) at 3–8.

I. BACKGROUND

The subject matter on appeal relates to a process for manufacturing a milk powder composition in which lactase is stabilized such that the symptoms of gastro-intestinal intolerance in mammals caused by lactose are alleviated (Specification filed December 19, 2011 (“Spec.”) 1, ll. 3–16; 8, ll. 5–8). Representative claim 1 is reproduced from the Claims Appendix to the Appeal Brief, as follows:

1. A process for the manufacture of a milk powder composition comprising 5-70% lactose and 0.05-0.5% lactase based on dry weight, the process comprising:

mixing, a lactase solution consisting of water and lactase in an amount corresponding to a lactase activity of 500-5000 IU/100 g powder, with a milk composition; and

spray-drying the mixture to form the milk powder composition, the drying step occurring within 0.1 to 120 minutes from the mixing of the lactase with the milk composition in the presence of water, and ***an outlet temperature of the spray-drying being 72-75°C.***

(Appeal Br. 11 (emphasis added)).

II. REJECTION ON APPEAL

On appeal, the Examiner maintains a rejection under pre-AIA 35 U.S.C. § 103(a) of claims 1, 4–6, 9, and 27–31 as unpatentable over Vasiljevic et al.³ (“Vasiljevic”), Clark et al.⁴ (“Clark”), and *Enzyme*

³ T. Vasiljevic & P. Jelen, *Retention of β -Galactosidase Activity in Crude Cellular Extracts from Lactobacillus delbrueckii ssp. Bulgaricus 11842 Upon Drying*, 56 INT’L J. DAIRY TECH. 111–16 (2003).

⁴ US 6,835,402 B1, issued December 28, 2004.

*Development Corporation: A Buyer's Guide to Enzymes*⁵ (“Buyer’s Guide”)
(Ans. 3–8; Final Act. 2–8).

III. DISCUSSION

1. *Grouping of Claims*

The Appellant relies on the same arguments for all claims on appeal, focusing primarily on independent claim 1 (Appeal Br. 5–10). Although claim 28 is discussed under a separate subheading (*id.* at 9), the arguments are the same as those offered for claim 1. Therefore, we decide this appeal on the basis of claim 1, which we designate as representative pursuant to 37 C.F.R. § 41.37(c)(1)(iv). Claims 4–6, 9, and 27–31 stand or fall with claim 1.

2. *The Examiner's Position*

The Examiner finds that Vasiljevic describes a method (i.e., a process) for preparing a stabilized lactase preparation by spray-drying a milk composition containing added lactase (Ans. 3–4; Final Act. 3–4). Regarding the contested claim limitation highlighted in reproduced claim 1 above (“an outlet temperature of the spray-drying being 72–75°C”), the Examiner acknowledges that Vasiljevic’s process differs from the claimed subject matter in that it controls the spray-drying outlet temperature to 45, 55, or 65°C (Ans. 5; Final Act. 4). The Examiner asserts, however, that:

[i]t is well established in the art that the outlet temperature in spray drying is determined by a number of factors, the most important being the required residual moisture content of the powder, the temperature and humidity of the drying air, total solids content of the feed and the design of the dryer; and the inlet temperature is selected such that the temperature of powder

⁵ Publication date unknown.

particles do not exceed the point where protein denaturation which results in a loss in enzyme activity occurs.

(*Id.*). Based on these findings, the Examiner concludes that “it would have been obvious to one of ordinary skill in the art to adjust such conditions in spray drying to suit the water content in the feed and the desired moisture content of the final product, the added adjuncts and the type of lactase enzyme used” (*id.*). According to the Examiner,

it would have been obvious to one of ordinary skill in the art to have experimentally optimized these conditions to obtain a dried product with a lower residual moisture content for example, in the range of 2%-5%, by employing higher temperatures than those applied in Vasiljevic in spray drying by the use of appropriate adjuncts and an appropriate lactase preparation as a residual moisture content in this range is reported in the prior art . . . to be conducive to retention of lactase activity in the dried product during prolonged storage.

(Ans. 8).

The Examiner also finds that Vasiljevic does not disclose a specific lactase content of 0.05–0.5% in the dry milk composition, as required by claim 1 (Ans. 6; Final Act. 5). To resolve this difference, the Examiner relies on Clark and concludes that a person having ordinary skill in the art would have arrived at such contents (*id.*). As for Buyer’s Guide, the Examiner merely relies on this reference as evidentiary support for the presence of a standardizing agent, also known as a carrier or filler (Ans. 4; Final Act. 4).

3. *The Appellant’s Contentions*

The Appellant contends that the Examiner’s rejection is flawed because Vasiljevic teaches away from “an outlet temperature of the spray-drying being 72–75°C” as specified in claim 1 (Appeal Br. 6). According to

the Appellant, Vasiljevic teaches spray-drying at outlet temperatures of 45–65°C or freeze-drying, but that spray-drying at 65°C “substantially lowered” β -galactosidase activity in whey and skim milk (*id.* (citing Vasiljevic 112 (Fig. 1), 115). The Appellant argues that, therefore, Vasiljevic would have dissuaded a person having ordinary skill in the art from substantially increasing the outlet temperature of the spray-drying to 72–75°C, as required by claim 1 (*id.*). In the Appellant’s view, “one would not have been led to substantially exceed the outlet temperature of Vasiljevic to achieve the claimed process . . . unless the outlet temperature is recognized as a result-effective variable and the optimization is purposeful” (*id.* at 7) (emphasis omitted).

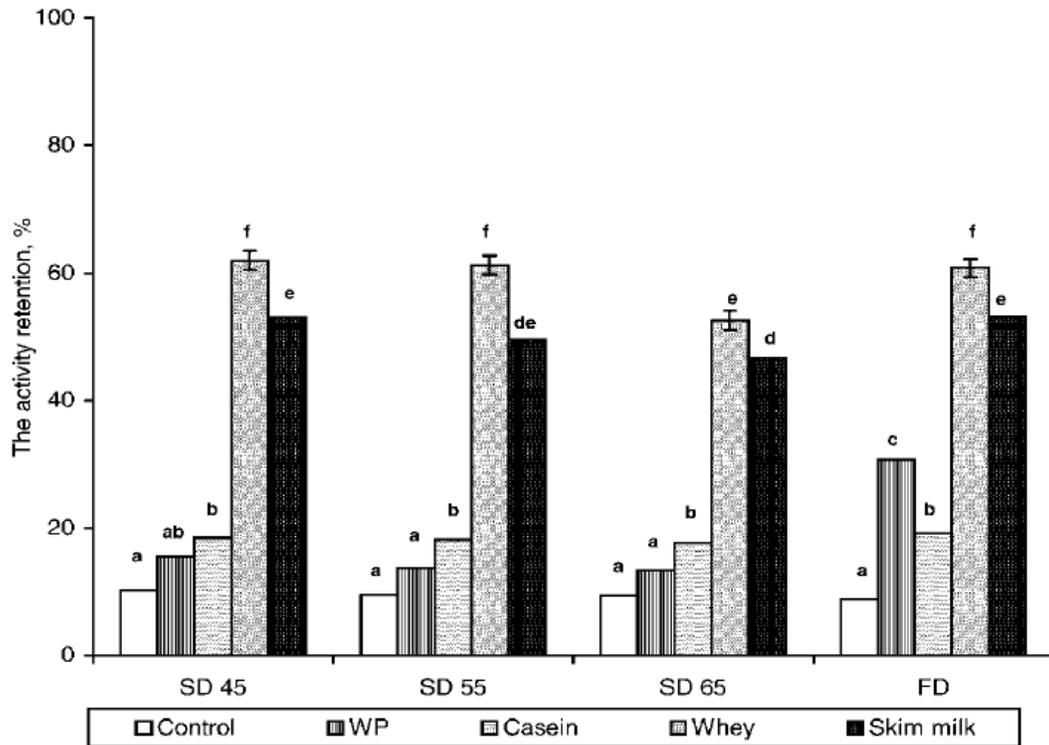
As for Clark and Buyer’s Guide, the Appellant argues that these references do not remedy the perceived deficiencies of Vasiljevic relative to claim 1’s subject matter (*id.* at 7–8). According to the Appellant, Clark is silent regarding spray-drying and is not reasonably pertinent to the particular problem addressed by the Inventors (*id.* at 7). Similarly, the Appellant argues that Buyer’s Guide does not disclose or suggest spray-drying (*id.* at 8).

4. *Opinion*

The Appellant’s arguments fail to identify reversible error in the Examiner’s rejection. *In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011).

Vasiljevic discloses the effect of various spray-drying outlet temperatures (45, 55, or 65°C) or freeze drying on the activity retention of β -galactosidase extract from *Lactobacillus delbrueckii* ssp. *bulgaricus* 11842 (Vasiljevic Abstract, 113–15), which is undisputedly a lactase (Ans. 3).

Specifically, the effects are summarized in Vasiljevic's Figure 1, reproduced as follows:



Vasiljevic's Figure 1 reproduced above shows the effects of adding skim milk components, whey, or skim milk on the activity retention of crude β -galactosidase extract from *Lactobacillus delbrueckii* ssp. *Bulgaricus* 11842 at three different spray-drying outlet temperatures (45, 55, or 65°C) and freeze-drying (Vasiljevic 113).

As shown in Vasiljevic's Figure 1, the activity retentions of crude β -galactosidase extract at a spray-drying temperature of 65°C appear to be well over 40% for skim milk and over 50% for whey. Thus, although Vasiljevic states that a spray-drying outlet temperature of "65°C substantially lowered the retained β -galactosidase activity in whey and skim milk CCEs [crude cellular extracts] *as compared to freeze-dried*

preparations” (*id.* at 115, left column (emphasis added)), the reference does not say that a spray-drying outlet temperature of 65°C is an absolute upper limit for spray-drying outlet temperature or that temperatures at or even somewhat above this level (e.g., 72°C) provide unsuitable results or otherwise render the prior art process inoperable. *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) (“[C]ase law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide [the] motivation [or reason] for the current invention.”); *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (“Even reading [the prior art]’s description as discouraging use of epoxy for this purpose, Gurley asserted no discovery beyond what was known to the art.”).

Given the general guidance in *Vasiljevic*—i.e., activity retention may be affected by different enzyme origin, the presence of mineral salts, final moisture content achieved, drying conditions such as selection of drying adjuncts, and processing parameters used during drying (*Vasiljevic* 114–115), a person having ordinary skill in the art would have determined, through routine experimentation, the outer limits of the operating parameters (e.g., spray-drying outlet temperature) that provide successful, useful results. Indeed, as the Examiner aptly finds (Ans. 8), *Vasiljevic* encourages such experimentation (*Vasiljevic* 115, right column (“Further investigation is required to elucidate the putative effect of lactose on the activity retention of β -galactosidase in CCE preparations and to clarify the influence of different drying adjuncts, as well as the processing parameters used during drying.”)). *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (quoting *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) (“[W]here the general

conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.”)).

Thus, contrary to the Appellant’s allegation, Vasiljevic explicitly informs one skilled in the relevant art that spray-drying outlet temperature is a result-effective variable. *Applied Materials*, 692 F.3d at 1297 (“A recognition in the prior art that a property is affected by the variable is sufficient to find the variable result-effective.”).

The Appellant’s arguments that Clark and Buyer’s Guide do not disclose spray-drying is ineffective, because the Examiner’s rejection is based on the collective teachings found in the prior art, including Vasiljevic, which teaches spray-drying. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (“Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references.”).

Finally, we discern no persuasive merit in the Appellant’s cursory argument that Clark does not address the problem with which the Inventors were concerned. That approach was criticized by the Supreme Court of the United States, and, therefore, is no longer dispositive in an obviousness analysis. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007) (“The first error of the Court of Appeals in this case was to foreclose this [obviousness] reasoning by holding that . . . patent examiners should look only to the problem the patentee was trying to solve.”).

For these reasons, and those well-stated by the Examiner, we uphold the Examiner’s rejection.

IV. CONCLUSION

In summary:

| Claims Rejected | 35 U.S.C. § | Reference(s)/Basis | Affirmed | Reversed |
|------------------------|--------------------|----------------------------------|------------------|-----------------|
| 1, 4-6, 9, 27-31 | 103(a) | Vasiljevic, Clark, Buyer's Guide | 1, 4-6, 9, 27-31 | |

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