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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ZIHUA AO, JOHN D. ALVEY,
JUAN M. GONZALEZ, and JENNIFER VILLEGAS

Appeal 2019-002130
Application 13/775,202
Technology Center 1700

Before LINDA M. GAUDETTE, MERRELL C. CASHION, JR., and
SHELDON M. McGEE, *Administrative Patent Judges*.

CASHION, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the
Examiner's decision to reject claims 21–38, 40, and 41. Appeal Br. 3.
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. Appellant identifies the real party in interest as Mead
Johnson Nutrition Company. Appeal Br. 3.

The invention is generally directed to “nutritional compositions comprising an emulsion system comprising a waxy starch or a waxy starch and citric acid esters of mono- and di-glycerides.” Spec. ¶ 1. The invention also includes hypoallergenic nutritional compositions. Spec. ¶ 3; Appeal Br. 11; Ans. 15. According to the Specification, hypoallergenic compositions contain hydrolyzed protein, extensively hydrolyzed protein, or free amino acids. Spec. ¶ 3. Claim 21 illustrates the invention (formatting added):

21. A powdered nutritional composition comprising:

a protein equivalent source comprising a hydrolyzed protein and free amino acids, wherein the hydrolyzed protein comprises a degree of hydrolysis of at least 50%, further wherein the protein equivalent source is present in an amount of from about 1 g/100 kcal to about 7 g/100 kcal,

a fat source,

a carbohydrate source, wherein the carbohydrate source is present in an amount of from about 5 g/100 kcal to about 25 g/100 kcal, and

an emulsifier system comprising a waxy potato starch and citric acid esters of mono- and di-glycerides, wherein the waxy potato starch is present in an amount of 6% to 15% of the total weight of the nutritional composition, and wherein the citric acid esters of mono- and di-glycerides are present in an amount of between 0.1% and 2% by weight of the total weight of the nutritional composition.

Independent claim 41 is directed to a specific nutritional composition having additional components not recited in claim 21.

Appellant requests review of the following rejections maintained by the Examiner:

I. Claims 21–25, 27, 30–35, 38, and 40 rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Martinez (US 6,099,871, issued August 8, 2000), Vurma (WO 2013/101400 A1, published July 4, 2013),

Donnet-Hughes (WO 2006/108824 A1, published October 19, 2006), and Euber (US 6,436,464 B1, issued August 20, 2002).

II. Claim 26 rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Martinez, Vurma, Donnet-Hughes, Euber, and Duarte (MX 2011010299 A, published March 29, 2013, and relying on an English translation of the Abstract only, dated December 4, 2014).

III. Claim 28 rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Martinez, Vurma, Donnet-Hughes, Euber, and Mower (US 2006/0210697 A1, published September 21, 2006).

IV. Claim 29 rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Martinez, Vurma, Donnet-Hughes, Euber, and Wittke (US 2011/0293784 A1, published December 1, 2011).

V. Claims 36 and 37 rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Martinez, Vurma, Donnet-Hughes, Euber, and Russell (US 2010/0074871 A1, published March 25, 2010).

VI. Claim 41 rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Martinez, Vurma, Donnet-Hughes, Euber, and Weizman (Weizman, Z. et al., *Effect of a probiotic infant formula on infections in child care centers: comparison of two probiotic agents*, 115(1) Pediatrics (January 2005) (Abstract only)).

Appellant relies on the same line of arguments to address the separate rejections of independent claims 21 and 41 (Appeal Br. 18–19). Appellant presents separate arguments for claims 22 and 23 (*id.*). Appellant also contends that the Examiner does not address the specific limitations of claims 24–29 and 35–37 (*id.* at 19). We note that the Examiner rejected claims 24, 25, 27, 30–35, 38, and 40 in Rejection I while claims 26, 28, 29, 36, and 37 were rejected separately (Rejections II–V). Appellant’s argument for claims 24–29 and 35–37 is tantamount to “merely point[ing] out what [the] claim[s] recite[and] will not be considered an argument for separate

patentability of the claim[s].” 37 C.F.R. § 41.37(c)(1)(iv) (2017).

Accordingly, we consider the patentability of the claims subject to grounds of Rejections I–VI based on the arguments made in support of patentability of claim 21 as representative of the subject matter claimed. We address the arguments for claims 22 and 23 separately.

OPINION

After review of the respective positions the Appellant provides in the Appeal and Reply Briefs and the Examiner provides in the Final Action and the Answer, we affirm the Examiner’s prior art rejections of claims 21–38, 40, and 41 based on the fact-finding and the reasons the Examiner provides. We add the following for emphasis.

Independent claim 21

The Examiner finds that Martinez suggests a powdered nutritional composition (an infant formulation) comprising native and pre-gelatinized starch and emulsifiers that differs from the subject matter of claim 21 in that Martinez does not disclose an emulsifier system comprising (1) the use of a waxy potato starch, (2) the use of citric acid esters of mono- and di-glycerides, and (3) the claimed amount of emulsifier. Final Act. 3–6.

Regarding difference (1), the Examiner finds that Vurma teaches that it was known to use waxy potato starch as a starch source for a stabilizing material in nutritional compositions, including infant formulations. Final Act. 5; Vurma ¶¶ 8–10, 54. The Examiner determines that it would have been obvious to one of ordinary skill in the art to use a waxy potato starch as the waxy starch in Martinez’s infant formulation because both references are

directed to nutritional infant formulations.² Final Act. 5.

Regarding difference (2), the Examiner finds that Martinez discloses the use of soy lecithin as an emulsifier for infant formulations. Final Act. 5; Martinez col. 4, ll. 61–66. The Examiner finds that Donnet-Hughes teaches an infant nutritional composition can comprise emulsifiers such as soy lecithin, citric acid esters of mono- and diglycerides, and the like. Final Act. 5; Donnet-Hughes 7. The Examiner determines that it would have been obvious for one skilled in the art to modify Martinez’s nutritional composition by using Donnet-Hughes’s citric acid esters of mono- and diglycerides in place of Martinez’s soy lecithin because both references are directed to infant nutritional compositions and such substitution would have amounted to nothing more than the use of a known emulsifier for its intended use in a known environment to accomplish an entirely expected result. Final Act. 5.

Regarding difference (3), the Examiner finds that Martinez discloses an infant formulation that is shelf stable (i.e. remains in a single homogenous phase and does not separate into more than one phase) after reconstitution. Final Act. 5–6; Martinez col. 5, ll. 15–25. The Examiner determines that it would have been obvious to one of ordinary skill in the art to adjust the amount of emulsifier, through routine experimentation, to arrive at the desired emulsion stability in view of Martinez’s teachings. Final Act. 6.

² We note that Martinez discloses using potato starch in the disclosed invention but does not expressly disclose using waxy potato starch. Martinez col. 1, l. 8.

The Examiner also finds that Martinez does not disclose (4) a protein source including free amino acids. Final Act. 3–4, 5–6.

Regarding difference (4), the Examiner finds that Euber teaches an infant nutritional composition comprising a protein source selected from any appropriate nitrogen source including free amino acids and an emulsifier system comprising octenyl succinic anhydride (OSA) modified starch and an acetylated monoglyceride. Final Act. 6; Euber Abstr., col. 4, ll. 23–27, 56–59. The Examiner determines that it would have been obvious to one of ordinary skill in the art to have used free amino acids as an added protein source in Martinez’s infant formulation to make a formulation compatible for babies with protein allergies because both references are directed to infant nutritional compositions and Euber teaches that free amino acids were known to be used as a protein and/or nitrogen source for infant formulations to make a hypoallergenic formulation for babies. Final Act. 6; Euber col. 1, ll. 32–34.

Appellant argues that the combined teachings of the cited art do not recognize that a combination of waxy potato starch and citric acid esters of mono- and di-glycerides is a particularly useful emulsifier system for hypoallergenic nutritional formulations comprising hydrolyzed protein and free amino acids because waxy potato starch contains only trace amounts of protein. Appeal Br. 11; Spec. ¶¶ 35–41.

Appellant’s argument does not identify error in the Examiner’s determination of obviousness for the reasons the Examiner presents. Final Act. 6; *see* Ans. 16. Moreover, while Appellant argues that part of the discovery is the use of a waxy potato starch containing only trace amounts of protein (Appeal Br. 11 (citing Spec. ¶¶ 35–41)), claim 21 does not recite that

the waxy potato starch must be one that has only trace amounts of protein.

Appellant argues that the Examiner is benefitting from impermissible hindsight because Martinez, while disclosing the inclusion of hydrolyzed proteins, puts equal or more focus on intact proteins as the protein source in providing an anti-regurgitation infant formulation to address postprandial gastroesophageal reflux (“GER”) in infants and not a hypoallergenic formulation. Appeal Br. 12; Martinez col. 3, ll. 61–66. In support of this argument, Appellant contends that Martinez includes examples of formulations with intact proteins (Examples 1–3), an example of a formulation with hydrolyzed protein (Example 4), and examples with both (Examples 5 and 6), as well as a comparative example utilizing intact protein formulations (Example 7). *Id.* Thus, Appellant asserts that Martinez’s focus is not a hypoallergenic formulation because the concerns surrounding emulsification of a hypoallergenic formulation without adding intact protein do not arise in the Martinez arena. *Id.*

These arguments also lack persuasive merit.

As the Examiner explains, Martinez discloses an infant formulation comprising a protein component made up of entirely hydrolyzed protein. Ans. 16; Martinez col. 3, ll. 61–64, col. 7, ll. 15–25 (Example 4). In fact, Appellant’s acknowledgement that Martinez’s disclosure includes examples of nutritional compositions comprising hydrolyzed proteins is an acknowledgement that Martinez’s disclosure encompasses hypoallergenic nutritional compositions. *See Spec.* ¶ 3.

While Appellant’s claimed invention aims to provide hypoallergenic properties in addition to providing desirable anti-regurgitation properties (as Martinez’s does (Appeal Br. 12; Spec. ¶ 39; Ans. 17)), it is well settled that

a chemical composition and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709 (Fed. Cir. 1990) (“Products of identical chemical composition can not have mutually exclusive properties.”). Appellant has not directed us to objective evidence showing that Martinez’s nutritional compositions comprising hydrolyzed proteins do not possess hypoallergenic properties. Nor has Appellant explained adequately why Martinez’s nutritional compositions comprising hydrolyzed proteins would not also be hypoallergenic.

Appellant asserts that Martinez is not focused on hypoallergenic nutritional compositions because Martinez prefers nutritional compositions that contain intact proteins and not hydrolyzed proteins. Appeal Br. 12.

As we note above, Appellant acknowledges that Martinez’s disclosure encompasses hypoallergenic nutritional compositions comprising hydrolyzed proteins.

Further, it is well settled that a reference may be relied upon for all that it discloses and not merely the preferred embodiments as suggested by Appellant. *See Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (“[A]ll disclosures of the prior art, including unpreferred embodiments, must be considered.” (quoting *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976))). Appellant has not explained adequately why Martinez’s examples of nutritional formulations comprising intact proteins limits Martinez’s broader disclosure that expressly includes nutritional compositions comprising hydrolyzed proteins.

Appellant argues that, contrary to the Examiner’s assertions, Martinez does not teach including an amount of waxy starch based on the total dry weight of the composition. Appeal Br. 13. Appellant contends that nothing

in Martinez provides enough information to suggest including waxy potato starch in an amount of 6% to 15% of the total weight of the nutritional composition because Martinez does not address emulsifying a protein-free formulation. *Id.* Appellant asserts that, while Martinez teaches adjusting for viscosity, Martinez does not address emulsification of a protein free composition or provide a teaching which would lead the artisan to the amount of starch needed for emulsifying a hypoallergenic formulation. *Id.*

This argument fails to identify reversible error in the Examiner's determination of obviousness for the reasons the Examiner presents. Ans. 17. The Examiner's position is that Martinez, like Appellant, describes nutritional compositions comprising hydrolyzed proteins that have desirable anti-regurgitating properties. Ans. 17; Appeal Br. 12; Spec. ¶ 39; Martinez col. 1, ll. 48–52. Appellant discloses that the total amount of waxy starch used can be advantageously adjusted based on desired viscosity and that the total amount of starch contributes to desirable anti-regurgitation properties of the nutritional composition. Ans. 17; Spec. ¶ 39; Martinez col. 3, ll. 26–32. Similarly, Martinez discloses that the use of waxy starches achieves anti-regurgitation effects and the need to control viscosity of infant formula so that it is sufficiently high to be effective in treating regurgitation, but not so high as to inhibit pourability. Martinez col. 3, ll. 20–23, 26–32. Thus, there is a reasonable basis to support the Examiner's assertion that the functionality of the starch in the claimed invention and in Martinez is to serve as a component of an emulsifying system and as a thickener. Ans. 17. Therefore, we agree with the Examiner that Martinez provides sufficient

guidance to one skilled in the art to arrive at the claimed amount of waxy potato starch based on the total weight of the nutritional composition.

Appellant's argument that adjusting for viscosity does not address emulsification of a protein free composition is not persuasive because, as we note above, Martinez's disclosure encompasses nutritional compositions comprising hydrolyzed proteins. Appeal Br. 13. Appellant has not explained adequately why Martinez fails to address emulsification of nutritional compositions containing hydrolyzed proteins.

Appellant argues that the Examiner does not provide any reference that supports the contention that the artisan would undertake "routine experimentation" to determine the amount of emulsifier and, instead, merely states that one of skill in the art would have been motivated to adjust the amount of emulsifier. Appeal Br. 16. Appellant further argues that, absent impermissible hindsight, the Examiner has not shown or explained that the amount of emulsifier is recognized by the art as a result effective variable. *Id.*

As the Examiner explains, Martinez discloses the need to produce an infant formulation that is shelf stable after reconstitution. Ans. 19; Martinez col. 5, ll. 15–25. Indeed, Martinez discloses that the formulation is in a form ready to consume in a single homogenous phase (i.e., does not separate into more than one phase upon visual inspection) or that the thickener does not settle out as a sediment upon visual inspection after storage overnight in the refrigerator. Martinez col. 5, ll. 16–21. Martinez also discloses that its formulation has the advantage of remaining fluid. *Id.* at col. 5, ll. 21–25. Thus, Martinez's disclosure provides sufficient guidance for one skilled in the art to determine the amount of emulsifier needed for a suitable

formulation. Given this disclosure, Appellant has not adequately explained why one skilled in the art, using no more than ordinary creativity, would not have been capable of determining the appropriate amount of emulsifier to obtain a desirable nutritional composition from Martinez’s teachings. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”); *see also In re Sovish*, 769 F.2d 738, 743 (Fed. Cir. 1985) (presuming skill on the part of one of ordinary skill in the art).

Appellant argues that Martinez does not teach the inclusion of free amino acids (or extensively hydrolyzed casein protein³) in the protein source. Appeal Br. 17. Appellant further argues that the Examiner’s reliance on Euber for the missing element is misplaced because Euber does not teach the claimed waxy potato starch. Appeal Br. 17; Euber col. 1, ll. 9–10. Thus, one skilled in the art would not have been able to combine Euber with Martinez and just include the extensively hydrolyzed proteins and free amino acids without also including the unique emulsifying system Euber teaches. Appeal Br. 17. That is, Appellant contends that the skilled artisan would have been led to utilize an acetylated monoglyceride in combination with a starch for a nutritional composition having such a protein component,

³ The limitation of “or extensively hydrolyzed casein protein” is not recited by independent claim 21 (or independent claim 41). It is recited in dependent claim 27, which Appellant has not specifically argued. *See generally* Appeal Br. To the extent that Appellant argues this limitation, our discussion with respect to the addition of free amino acids is applicable to the addition of this component given that the Examiner relies on Euber to address both, the free amino acids and the extensively hydrolyzed casein protein. Final Act. 6.

but not the waxy potato starch and citric acid esters of mono- and di-glycerides claimed herein. *Id.*

These arguments also lack persuasive merit.

As the Examiner explains, the language in claim 21 is drafted with the open transitional language of “comprising” that does not exclude additional unrecited components including the components of the emulsifying system of Euber. Ans. 19. In fact, Appellant acknowledges that Euber’s octenyl succinic anhydride modified starch, can be an additional element of the claimed emulsification system. Appeal Br. 17. Thus, Appellant has not explained adequately why one skilled in the art would not have used an acetylated monoglyceride in combination with a starch for nutritional composition having such a hydrolyzed protein component such as the waxy potato starch and citric acid esters of mono- and di-glycerides claimed.

We have also considered Appellant’s arguments that Vurma is not directed to a hypoallergenic composition and its combination with Martinez does not teach or suggest the claimed weight percentages of waxy potato starch claimed herein. Appeal Br. 15. We find these arguments unpersuasive for the reasons the Examiner presents, which we adopt as our own. Ans. 17–18.

Dependent claims 22 and 23

Claim 22 recites that the waxy potato starch comprises a combination of native and pre-gelatinized potato starches.⁴ Claim 23 recites that the weight ratio of native to pre-gelatinized waxy starch is from 0.1:1 to 2:1.

⁴ We understand that Appellant’s arguments for claim 22 are also directed to independent claim 41. Appeal Br. 18. Accordingly, our discussion of claim 22 is equally applicable to independent claim 41.

Regarding claim 22, the Examiner finds that Martinez discloses that the waxy starch can be used in its native state or with additional pre-treatments such as pre-gelatinization. Final Act. 11; Martinez col. 2, l. 11.

Appellant argues that, while Martinez teaches the use of either of the native and pre-gelatinized starches, Martinez does not teach the combined use of these starches. Appeal Br. 14.

We are unpersuaded by this argument for the reasons the Examiner presents. Ans. 17. “It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.” *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980). Appellant has pointed to no objective evidence showing criticality resulting from the use of a starch blend of native and pre-gelatinized starches.

Regarding claim 23, the Examiner asserts that, while Martinez discloses that either of the native and pre-gelatinized starches can be used in nutritional compositions, Martinez does not necessarily teach away or discourage the combination. Final Act. 4; Ans. 17. The Examiner also asserts that Appellant has not provided evidence that the claimed ratio of native and pre-gelatinized starch is critical. Ans. 17.

Appellant argues that there is nothing in any of the cited references that teaches the claimed ratio of native to pre-gelatinized starches, even if waxy potato starch was substituted for Martinez’s starches, and a combination of native and pre-gelatinized starches was used. Appeal Br. 14.

Appellant’s argument fails to identify reversible error in the Examiner’s determination of obviousness for the reasons presented by the Examiner. Ans. 17.

Moreover, Appellant's invention contemplates using a combination of the same starch in native and pre-gelatinized forms. *See* Spec. ¶ 83 (Example 2). The Specification does not describe any advantage in using a native versus a pre-gelatinized form of the same starch. *See id.* ¶ 34. Nor does Appellant direct us to any evidence of the criticality of the claimed ratio range. Thus, absent a showing that the claimed weight ratio of native to pre-gelatinized waxy starch is critical, one skilled in the art would not expect a combination of the native and pre-gelatinized starches, particularly native and pre-gelatinized forms of the same starch, to perform any differently than when used individually.

Arguments not specifically addressed are deemed not persuasive for the reasons the Examiner presents.

Accordingly, we affirm the Examiner's prior art rejections of claims 21–38, 40, and 41 for the reasons the Examiner presents and we give above.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
21–25, 27, 30–35, 38, 40	103(a)	Martinez, Vurma, Donnet-Hughes, Euber	21–25, 27, 30–35, 38, 40	
26	103(a)	Martinez, Vurma, Donnet-Hughes, Euber, Duarte	26	
28	103(a)	Martinez, Vurma, Donnet-Hughes, Euber, Mower	28	
29	103(a)	Martinez, Vurma, Donnet-Hughes, Euber, Wittke	29	
36, 37	103(a)	Martinez, Vurma, Donnet-Hughes, Euber, Russell	36, 37	
41	103(a)	Martinez, Vurma, Donnet-Hughes, Euber, Weizman	41	
Overall Outcome			21–38, 40, 41	

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED