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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ADAM BURBIDGE, JAN ENGMANN, and
SIMINA POPA NITA¹

Appeal 2019-004051
Application 14/365,731
Technology Center 1600

Before ERIC B. GRIMES, RICHARD M. LEBOVITZ, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method for promoting safe swallowing of nutritional products, which have been rejected for obviousness and provisionally rejected for obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM the provisional double patenting rejection.

¹ Appellant identifies the Real Party in Interest as Nestec S.A. Appeal Br. 2.

STATEMENT OF THE CASE

“Dysphagia is the medical term for the symptom of difficulty in swallowing.” Spec. ¶ 2. The inability to properly swallow food or liquids can lead to aspiration and infection. *Id.* ¶ 7. “Mild to moderate oral pharyngeal dysphagia may require the texture of foods to be modified in order to minimize the likelihood of choking or aspiration.” *Id.* ¶ 103.

“A know[n] treatment for beverages and liquid foods is to increase the viscosity of the food/beverage by adding starch or gum thickeners. . . . It is, however, often disliked by patients because of the extra swallowing effort and may also leave residues at high levels of viscosity.” *Id.* ¶ 111.

The Specification discloses that

providing inventive nutritional products to dysphagic patients having increased bolus cohesion due to its extensional viscosity, without dramatically modifying other physical properties of the material such as, for example, its shear viscosity, dramatically reduces the amount of swallowing effort for the patient, as well as the risk of residue build-up in the oropharyngeal and/or esophageal tracts.

Id. ¶ 116.

“Shear viscosity, often referred to as simply viscosity, describes the reaction of a material to applied shear stress.” *Id.* ¶ 107. “Another rheological property of a material is its extensional viscosity.” *Id.* ¶ 108. “Extensional viscosity is generally only relevant in flows where a fluid is ‘stretched’/extended (e.g., when a flowing through a constriction such as an esophageal sphincter), or when compressed (e.g., between . . . the tongue and pharynx).” *Id.* ¶ 112.

A “Capillary Breakup Extensional Rheometer (CaBER) is an example for a rheometer applying extensional stress.” *Id.* ¶ 109.

During the CaBER experiment as performed herein for measuring the relaxation time of the nutritional product, a drop of said product is placed between two vertically aligned and parallel circular metal surfaces. . . . The metal surfaces are then rapidly separated linearly. . . . The filament formed by this stretching action subsequently thins under the action of interfacial tension.

Id. “The relaxation time in a CaBER experiment is determined” based on a plot of the filament thickness versus time during the thinning process. *Id.*

“[T]he nutritional products of the present disclosure aim to improve the cohesion of food boluses to prevent a food bolus from being broken up into smaller fragments, which may enter the airway.” *Id.* ¶ 113. “[T]he incorporation of food grade polymers . . . increas[es] the cohesiveness of the food bolus.” *Id.*

Claims 26, 51–57, and 59–65 are on appeal. Claim 26 is the only independent claim and reads as follows:

Claim 26: A method for promoting safe swallowing of nutritional products in a patient in need of same, the method comprising administering to the patient a liquid nutritional product comprising an aqueous solution of a food grade biopolymer comprising at least one of okra gum or cactus mucilage, the food grade biopolymer providing to the liquid nutritional product:

a shear viscosity less than about 100 mPas when measured at a shear rate of 50s^{-1} ; and

a relaxation time, determined by a Capillary Breakup Extensional Rheometry (CaBER) experiment, of more than 10 ms (milliseconds) at a temperature of 20°C ,

wherein the liquid nutritional product comprising the food grade polymer has an increased cohesiveness.

The claims stand rejected as follows:

Claims 26, 51–55, 57,² 59, 60, and 63–65 under 35 U.S.C. § 103(a) as obvious based on Holahan,³ Ghadimi,⁴ Grönlund,⁵ De Block,⁶ Stillman,⁷ Ramsden,⁸ and Guil-Guerrero⁹ (Ans. 3–4);

Claims 26, 56, and 59–61¹⁰ under 35 U.S.C. § 103(a) as obvious based on Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, and Ramsden¹¹ (Ans. 10);

² The statement of the rejection does not include claim 57, but claim 57 is addressed in the body of the opinion. Ans. 4. Thus, we assume that the omission of claim 57 from the statement of the rejection was a typographical error.

³ Holahan, WO 03/011051 A1, published February 13, 2003.

⁴ Ghadimi, *Free Amino Acids of Different Kinds of Milk*, 13 AMER. J. CLIN. NUTR. 75–81 (1963).

⁵ Grönlund et al., *Maternal breast-milk and intestinal bifidobacteria guide the compositional development of the Bifidobacterium microbiota in infants at risk of allergic disease*, 37 CLIN. EXP. ALLERGY 1764–72 (2007).

⁶ De Block et al., *Evaluation of Two Methods for the Determination of Lactulose in Milk*, 6 INT. DAIRY JOURNAL 217–222 (1996).

⁷ Stillman, US 7,115,297 B2, issued Oct. 3, 2006.

⁸ Lawrence Ramsden, “*Plant and Algal Gums and Mucilages*,” in CHEMICAL AND FUNCTIONAL PROPERTIES OF FOOD SACCHARIDES, CRC Press LLC, Piotr Tomasik (ed.) (2003). The copy of record does not include page numbers, so our citations are to the relevant subsection of the reference.

⁹ Guil-Guerrero, *Nutritional composition of Plantago species (P-major L., P-lanceolata, L., and P-media L.)*, ECOL. FOOD NUTR. 1–17 (Aug. 2010).

¹⁰ The Examiner states that some of the rejections include claim 58. *See* Ans. 10, 17, 21. However, claim 58 has been cancelled. *See* Adv. Action mailed Oct. 11, 2018, at 2.

¹¹ This rejection is based on the same evidence as the first rejection (with Ramsden being cited twice) but because the rejections are based on different rationales, we address them as separate rejections.

Claims 26 and 60 under 35 U.S.C. § 103(a) as obvious based on Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, and Cárdenas¹² (Ans. 16);

Claim 56 under 35 U.S.C. § 103(a) as obvious based on Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, and Fukui¹³ (Ans. 12);

Claims 26 and 60–62 under 35 U.S.C. § 103(a) as obvious based on Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, Clarke¹⁴ and Redgwell¹⁵ (Ans. 14);

Claims 26, 60, and 61 under 35 U.S.C. § 103(a) as obvious based on Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, and Hussein¹⁶ (Ans. 17);

Claims 26, 55, 59, and 60 under 35 U.S.C. § 103(a) as obvious based on Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, and Hyldon¹⁷ (Ans. 18); and

¹² Cárdenas, *Rheology and Aggregation of Cactus (Opuntia ficus-indica) Mucilage in Solution*, J PACD 152–159 (1997).

¹³ Fukui, US 6,277,395 B1, issued Aug. 21, 2001.

¹⁴ Clarke, US 6,271,001 B1, issued Aug. 7, 2001.

¹⁵ Redgwell, *Structural Features of the Mucilage from the Stem Pith of Kiwifruit (Actinidia deliciosa): Part I, Structure of the Inner Core*, 153 CARBOHYDRATE RES. 97–106 (1986).

¹⁶ Hussein, *Utilization of some plant polysaccharides for improving yoghurt consistency*, 56(2) ANNALS OF AGRIC. SCI. 97–103 (2011).

¹⁷ Hyldon, US 3,664,847, issued May 23, 1972.

Claims 26, 51, 52, 59, 60, and 65, provisionally, for obviousness-type double patenting based on claims 43, 47, and 49–52 of application 14/002,052 (Ans. 21).

I

The Examiner has rejected claims 26, 51–55, 57, 59, 60, and 63–65 as obvious based on Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, and Guil-Guerrero. The Examiner finds that “Holahan teaches a method of promoting effective swallowing by a person with dysphagia comprising of feeding an aqueous concentrated xanthan gum thickener composition (a food grade polymer) with a liquid food.” Ans. 4. The Examiner finds that “Stillman teaches a similar method of promoting safe swallowing of nutritional products by administering a nutritional product comprising an aqueous solution of a food grade biopolymer” such as psyllium gum. *Id.* at 5–6.

The Examiner cites Ghadimi, Grönlund, and De Block as evidence of components (which do not include okra gum or cactus mucilage) inherently found in milk or breast milk. *Id.* at 4–5. The Examiner cites Ramsden and Guil-Guerrero as evidence that “psyllium gum comes from plants of the genus *Plantago* which includes ribwort.” *Id.* at 6.

The Examiner finds that “Holahan teaches the method where the nutritional product containing a thickener and lists many examples of thickeners.” *Id.* The Examiner concludes that it would have been obvious “to modify the teachings of Holahan in such a way that *the food grade polymer is psyllium mucilage or ribwort mucilage as recited in claims 26 and 60* for

the purpose being able thicken a nutritional composition for the promotion of safe swallowing.” *Id.* (emphasis added).

Claim 26, however, is limited to a method of administering a product that comprises okra gum or cactus mucilage, not psyllium mucilage or ribwort mucilage. The Examiner has not pointed to any disclosure in any of the cited references that would have led a skilled artisan to modify Holahan’s method to include a composition comprising either okra gum or cactus mucilage, and therefore has not shown that the cited references would have made obvious a method meeting the limitations of claim 26. We reverse the rejection of claims 26, 51–55, 57, 59, 60, and 63–65 under 35 U.S.C. § 103(a) based on Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, and Guil-Guerrero.

II

The Examiner has rejected claims 26, 56, and 59–61 as obvious based on Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, and Ramsden. The Examiner has rejected claims 26 and 60 as obvious based on Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, and Cárdenas. The same issue is dispositive for both rejections.

The Examiner finds that “neither Holahan or Stillman teach . . . okra gum” but Ramsden teaches that okra gum was a well-known source of food grade polymers used in food and pharmaceuticals as a thickening and gelling agent. Ans. 11. Similarly, the Examiner finds that “Holahan does not teach the method wherein the food grade biopolymer is . . . cactus mucilage.

However, cactus mucilage was a known source of food grade polymers in food as taught by Cárdenas.” *Id.* at 16.

The Examiner concludes that it would have been obvious “to modify the teachings of Holahan and Stillman in such a way that the food grade polymer was okra gum . . . for the purpose [of] being able [to] thicken a nutritional composition for a patient with a swallowing disorder” because okra gum was known for use as a thickening agent. *Id.* at 11–12. Similarly, the Examiner concludes that it would have been obvious “to modify the teachings of Holahan in such a way that the food grade polymer is cactus mucilage for the purpose [of] being able [to] thicken a nutritional composition for a patient with a swallowing disorder” because “food was known to contain such polymers for it[s] rheological properties as taught by Cárdenas.” *Id.* at 16–17.

The Examiner acknowledges that Holahan and Stillman are silent with regard to the shear viscosity, relaxation time, and cohesiveness of the nutritional composition as recited in claim 26. *Id.* at 7. The Examiner reasons, however, that “the dilution or thickness of the nutritional product is a result effective variable and that the amount of diluting or thickness of the nutritional product would be [a] matter of routine optimization.” *Id.* at 10.¹⁸

Appellant argues that “*Holahan* does not present a selection of specific biopolymers that are able to confer a high extensional viscosity

¹⁸ The Examiner also finds that the recited properties are “inherent to the composition as taught by Holahan and Stillman.” Ans. 8. This finding is not supported by the evidence because the compositions of Holahan and Stillman do not comprise either okra gum or cactus mucilage, which are required by all of the claims.

(cohesiveness) to a liquid product while maintaining a ‘thin liquid’ texture with the shear viscosity as recited in independent claim 26.” Appeal Br. 7. “In contrast, *Holahan* only describes the ‘thickening’ of liquid foods.” *Id.*

Appellant argues that “*Declaration II*, [19] Annex 3 . . . presents data with regard to the shear viscosity and relaxation time of ‘Resource ThickenUp clear’ solutions . . . contain[ing] the biopolymers xanthan and hydrolysed starch.” *Id.* at 6. Appellant argues that the results of the experiments in the declaration show that, in contrast to okra gum or cactus mucilage, “the use of xanthan/starch can merely serve to ‘thicken’ a liquid, i.e. to increase its shear viscosity. However, it cannot provide any significant level of cohesiveness, i.e. extensional viscosity, to the product.” *Id.* at 6–7.

Appellant argues that, “[a]s demonstrated by the experimental data submitted in *Declaration II*, okra and cactus mucilages are **not** functionally equivalent and actually have **superior** cohesiveness to other biopolymers disclosed in *Holahan*, such as xanthan.” *Id.* at 8–9. That is, okra gum and cactus mucilage “actually had **superior** cohesiveness to the preferred thickener of *Holahan* and *Stillman*, i.e., xanthan.” *Id.* at 7.

We agree with Appellant that the rejection is not supported by a preponderance of the evidence of record. *Holahan* teaches a “treatment for dysphagia . . . which comprises feeding a concentrate thickener composition contained within a food to a patient having the condition of dysphagia.” *Holahan* ¶ 13. *Holahan* discloses a variety of thickeners, but does not

¹⁹ Declaration under 37 C.F.R. § 1.132 of Jan Engmann, dated May 18, 2018.

disclose okra gum or cactus mucilage. *Id.* ¶ 20. “In a preferred aspect, the thickener selected comprises xanthan gum.” *Id.* ¶ 21.

Stillman discloses modified “fiber-water”: “an invention composed specifically of water and soluble fiber (that’s simple enough) that is tasteless, odorless and colorless, much like water itself,” containing one or more additional elements. Stillman 7:15–23. Stillman discloses that its fiber-water can include “[v]iscosity changing additives . . . for those with swallowing difficulties.” *Id.* at 31:27–30. Stillman discloses that viscosity changing additives include gums. *Id.* at 31:34–37. Stillman lists numerous gums, but does not include okra gum or cactus mucilage. *See id.* at 31:55 to 33:39.

Ramsden discusses “the structure and functional properties of the gums and their value in food applications.” Ramsden § 15.1. Ramsden teaches that “[o]kra gum is only a weak emulsifiant but can act as a thickener.” *Id.* § 15.5.1.5.

Cárdenas states that cactus mucilage in solution forms “large aggregates [that] may underlie some of the special functional properties already identified for the use of cactus mucilage in food and other products.” Cárdenas 152, abstract. “[L]ittle is known about the molecular and rheological characteristics underlying specialized functional properties as an additive for food.” *Id.* at 153. “Cactus mucilage may find applications in the food, cosmetics, pharmaceutical and other industries.” *Id.* at 155–156.

The Examiner concludes that the disclosures of Ramsden and Cárdenas would have led a skilled artisan to use okra gum or cactus mucilage in Holahan’s composition, as a “substitution of one known type of

food grade plant-based polymer for another for the purpose of thickening food for administration to a patient with a swallowing disorder.” Ans. 12, 17. Regarding the properties recited in claim 26, the Examiner concludes that

one of ordinary skill in the art would recognize that the dilution or thickness of the nutritional product is a result effective variable and that the amount of diluting or thickness of the nutritional product would be matter of routine optimization depending on the properties of the aqueous solution and the subject being administered the nutritional product.

Id. at 10.

The Examiner finds that Stillman discloses a “nutritional product [that] is diluted prior to administering,” Ans. 9–10, but does not cite any evidence showing that the degree of dilution or thickness of a nutritional product was a result-effective variable. However, even if the degree of thickness of a liquid nutritional product was recognized as a result-effective variable, and therefore obvious to optimize, Appellant has provided evidence to show that the thickness of a composition relates only to its shear viscosity and not to relaxation time as claimed.

Appellant’s Declaration II describes biopolymer solutions comprising cactus, okra, or flax seed extracts as follows: “[T]hese liquid foods have a low shear viscosity and thus, they still have the texture of a ‘thin liquid.’” Declaration II ¶ 6. *See also id.* ¶ 9 (discussing shear viscosity ranges that progressively increase for nectar-like, honey-like, and pudding-like foods).

Declaration II supports the position that shear viscosity and relaxation time, as recited in claim 26, can vary independently. The declaration “presents data with regard to the shear viscosity and relaxation time of

‘Resource ThickenUp clear’ solutions in mineral water (6 g/l and 12 g/l).” *Id.* ¶ 11. “‘ThickenUp Clear’ . . . contains the biopolymers xanthan and hydrolysed starch.” *Id.* The data show that the shear viscosity of the solutions increased from 40 mPas at 6 g/l to 180 mPas at 12 g/l, but the “relaxation time (CaBER, ms)” was “not measurable” for either solution. *Id.*

The declaration also states that the data show that xanthan/starch can merely thicken a liquid—i.e., increase its shear viscosity—but it “cannot provide any significant level of cohesiveness . . . to the product.” *Id.* ¶ 12. Claim 26 requires a “liquid nutritional product comprising [a] food grade polymer” and having “an increased cohesiveness.”

In short, while the evidence supports the Examiner’s position that “Holahan, Ramsden and Cárdenas are directed to thickening food” (Ans. 23), the evidence also shows that the parameters recited in claim 26 require more than simply thickening—increasing the shear viscosity—of a food. Rather, claim 26 requires increasing the cohesiveness of the composition, as reflected by the low shear viscosity and the relaxation time (as measured by a CaBER experiment) recited in the claim. The Examiner has not shown that a method comprising administering a product with the properties recited in claim 26 would have been obvious based on the cited references.

III

The Examiner has rejected claims 26, 55, 56, and 59–62 as obvious based on Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guill-Guerrero, and (a) Fukui, (b) Hussein, (c) Hyldon, or (d) the combination of Clarke and Redgwell. The Examiner concludes that claim 26 would have been obvious based on Holahan, Ghadimi, Grönlund, De Block, Stillman,

Ramsden, and Guil-Guerrero, for the reasons discussed in the first rejection, and cites Fukui, Hussein, Hyldon, or the combination of Clarke and Redgwell for their disclosures of additional food grade polymers recited in claims 55, 56, and 59–62.

As discussed above, however, the Examiner’s first rejection did not set out a prima facie case of obviousness for a method meeting all of the limitations of claim 26. The Examiner does not point to any disclosure of okra gum or cactus mucilage in Fukui, Hyldon, or the combination of Clarke and Redgwell, and does not provide any reason why these references would have led a person of ordinary skill in the art to modify Holahan’s composition to include okra gum or cactus mucilage. Therefore, the Examiner has not shown that Fukui, Hyldon, or the combination of Clarke and Redgwell make up for the deficiency discussed above.

The Examiner finds that Hussein does disclose okra gum: “Hussein teaches okra and Jew’s mallow contain polysaccharides useful for thickening yogurt.” Ans. 17. The Examiner concludes that it would have been obvious “to modify the teachings of Holahan in such a way that the food grade polymer is okra gum or mallow mucilage for the purpose [of] being able [to] thicken a nutritional composition for a patient with a swallowing disorder” because the modification is “the substitution of one known type of food grade plant-based polymer for another for the purpose of thickening food for administration to a patient with a swallowing disorder.” *Id.* at 18.

The Examiner’s reliance on Hussein, however, suffers from the same deficiency discussed above with regard to Ramsden and Cárdenas; i.e., claim 26 requires increasing the cohesiveness of a composition, not simply

thickening it. The Examiner has not pointed to any disclosure in Hussein that would have made obvious a composition with the properties recited in claim 26.

IV

The Examiner has provisionally rejected claims 26, 51, 52, 59, 60, and 65 for obviousness-type double patenting based on claims 43, 47, and 49–52 of application 14/002,052. Ans. 21.

Appellant presents no argument in the Appeal Brief disputing the merits of the provisional rejection. We therefore affirm it. *See* 37 C.F.R. § 41.37(c)(1)(iv) (The Appeal Brief must include “[t]he arguments of appellant with respect to each ground of rejection.”); *Hyatt v. Dudas*, 551 F.3d 1307, 1314 (Fed. Cir. 2008) (“When the appellant fails to contest a ground of rejection to the Board, . . . the Board may treat any argument with respect to that ground of rejection as waived.”).

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
26, 51–55, 57, 59, 60, 63–65	§ 103(a) Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guill-Guerrero		26, 51–55, 57, 59, 60, 63–65
26, 56, 59–61	§ 103(a) Holahan, Ghadimi, Grönlund, De Block, Stillman,		26, 56, 59–61

Claims Rejected	Basis	Affirmed	Reversed
	Ramsden, Guil-Guerrero, Ramsden		
26, 60	§ 103(a) Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, Cárdenas		26, 60
56	§ 103(a) Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, Fukui		56
26, 60–62	§ 103(a) Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, Clarke, Redgwell		26, 60–62
26, 60, 61	§ 103(a) Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, Hussein		26, 60, 61
26, 55, 59, 60	§ 103(a) Holahan, Ghadimi, Grönlund, De Block, Stillman, Ramsden, Guil-Guerrero, Hyldon		26, 55, 59, 60
26, 51, 52, 59, 60, 65	obviousness-type double patenting (provisional) 14/002,052	26, 51, 52, 59, 60, 65	
Overall Outcome		26, 51, 52, 59, 60, 65	53–57, 61–64

Appeal 2019-004051
Application 14/365,731

TIME PERIOD FOR RESPONSE

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-IN-PART