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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte ADAM STEWART BURBIDGE, JAN ENGMANN, and SIMINA POPA NITA[1]

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Appeal 2019-004040
Application 14/002,052
Technology Center 1600

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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 treating a patient having a swallowing disorder, 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.

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[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. "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.* ¶ 82.

"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.* ¶ 87.

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. ¶ 90.

"Shear viscosity, often referred to as simply viscosity, describes the reaction of a material to applied shear stress." *Id.* ¶ 85. "Extensional viscosity is the ratio of the stress required to extend a liquid in its flow direction to the extension rate." *Id.* ¶ 86.

"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.* ¶ 88. "The difference between shear and extensional viscosity is usually expressed in terms of a 'Trouton ratio,' which is the ratio between the extensional viscosity and the shear viscosity

at the same rate of deformation." *Id.* The Specification discloses that, "[b]ecause of the presence of both shear and extensional forces, . . . it is important to consider the extensional viscosity and Trouton ratio of nutritional products for patients having difficulty swallowing." *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.* ¶ 89. "[T]he incorporation of food grade polymers . . . increas[es] the cohesiveness of the food bolus." *Id.*

Claims 43, 44, 46, 47, 49, 50, and 52 are on appeal. Claim 43 is the only independent claim and reads as follows:

> Claim 43: A method for treating a patient having a swallowing disorder, the method comprising:
>
> administering to the patient having the swallowing disorder a liquid nutritional product comprising a nutritional composition and a food grade polymer selected from the group consisting of okra gum, cactus mucilage, and combinations thereof, the liquid nutritional product having a Trouton ratio that is 6 to 15 and an extensional viscosity greater than 100 mPa s,
>
> wherein the liquid nutritional product comprising the food grade polymer has an increased cohesiveness relative to the nutritional composition.

The claims stand rejected as follows:

Claims 43, 44, 46, 47, 50, and 52 under 35 U.S.C. § 103(a) as obvious based on Stillman,[2] Ramsden,[3] Guil-Guerrero,[4] Chan,[5] Fukui,[6] and Dufresne[7] (Ans. 3);

Claims 43, 49, and 50[8] under 35 U.S.C. § 103(a) as obvious based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, and Ramsden[9] (Ans. 7–8);

Claims 43 and 50 under 35 U.S.C. § 103(a) as obvious based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, and Cárdenas[10] (Ans. 9);

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[2] US 7,115,297 B2, Oct. 3, 2006.
[3] Lawrence Ramsden, "15. Plant and Algal Gums and Mucilages," in CHEMICAL AND FUNCTIONAL PROPERTIES OF FOOD SACCHARIDES, Piotr Tomasik, ed. (2003). The copy of record does not include page numbers, so our citations are to the relevant subsection of the reference.
[4] J. L. Guil-Guerrero, *Nutritional composition of Plantago species (P. major L., P. lanceolata L., and P. media L.)*, 40(5) Ecology of Food and Nutrition 481–495 (2001).
[5] Philip Shiu-Kin Chan et al., *Study of the shear and extensional rheology of casein, waxy maize starch and their mixtures*, 21 Food Hydrocolloids 716–725 (2007).
[6] US 6,277,395 B1, Aug. 21, 2001.
[7] US 2004/0258823 A1, Dec. 23, 2004.
[8] The Examiner states that some of the rejections include claim 51. *See* Ans. 7, 9, 12. However, claim 51 has been cancelled. *See* Adv. Action mailed Oct. 11, 2018, at 2.
[9] 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.
[10] A. Cárdenas et al., *Rheology and Aggregation of Cactus (Opuntia ficus-indica) Mucilage in Solution*, J. PACD 152–157 (1997).

Claims 43 and 50 under 35 U.S.C. § 103(a) as obvious based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, and Sliwinski[11] (Ans. 10);

Claims 43, 49, and 50 under 35 U.S.C. § 103(a) as obvious based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, and Hussein[12] (Ans. 12);

Claims 43 and 50 under 35 U.S.C. § 103(a) as obvious based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, and Hyldon[13] (Ans. 13);

Claims 43 and 50 under 35 U.S.C. § 103(a) as obvious based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, and Turker[14] (Ans. 14); and

Claims 43, 44, 49, 50, and 52, provisionally, for obviousness-type double patenting based on claims 25, 59, 60, 64, and 65 of application 14/365,731 (Ans. 16).

I

The Examiner has rejected claims 43, 44, 46, 47, 50, and 52 as obvious based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, and

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[11] WO 2006/054886 A1, May 26, 2006.
[12] M. M. Hussein et. al., *Utilization of some plant polysaccharides for improving yoghurt consistency*, 56(2) Annals of Agricultural Science 97–103 (2011).
[13] US 3,664,847, May 23, 1972.
[14] Arzu Ucar Turker & Ekrem Gurel, *Common Mullein (Verbascum thapsus L.): Recent Advances in Research*, 19(9) Phytotherapy Research 733–739 (2005).

Dufresne. The Examiner finds that "Stillman teaches administering a nutritional composition comprising a soluble fiber with viscosity changing characteristics to a patient with a swallowing disorder (dysphagia)." Ans. 4. The Examiner finds that Stillman teaches soluble fiber from plant sources, including psyllium gum. *Id.* The Examiner cites Ramsden and Guil-Guerrero as evidence that "psyllium gum comes from plants of the genus *Plantago* which includes ribwort." *Id.*

The Examiner acknowledges that "Stillman is silent as to the Trouton's ratio and the extensional viscosity of the nutritional product," and does not disclose "increased cohesiveness." *Id.* at 5. The Examiner finds, however, that the recited properties would have been inherent in Stillman's product because it "is either identical or sufficiently similar to the claimed nutritional product." *Id.* at 6.

Alternatively, the Examiner finds that, as evidenced by Chan, Fukui, and Dufresne, the Trouton's ratio and extensional viscosity of a nutritional product are result effective variables subject to routine optimization. *Id.* The Examiner concludes that "the invention as a whole was prima facie obvious to one of ordinary skill in the art." *Id.* at 7.

Appellant argues that "the Examiner admits that *Stillman* does not disclose such a specific plant mucilage as okra gum." Appeal Br. 7. Appellant argues that "*Stillman* does not present a selection of specific biopolymers that are able to confer a high extensional viscosity (cohesiveness) to a liquid product while maintaining a 'thin liquid' texture (low shear viscosity). In contrast, *Stillman* only describes the 'thickening' of liquid foods." *Id.* Appellant argues that, "[a]s demonstrated by the

experimental data submitted in *Declaration III*,[15] okra and cactus mucilages have **superior** cohesiveness and therefore, are **not** functionally equivalent to other biopolymers disclosed in *Stillman*, such as xanthan." *Id.* at 8.

We agree with Appellant that the Examiner has not established a prima facie case of obviousness. In particular, claim 43 requires a composition comprising either okra gum or cactus mucilage. The Examiner does not point to any disclosure in the cited references of either okra gum or cactus mucilage, and does not provide any reason why a person of ordinary skill in the art would have modified Stillman's composition to include okra gum or cactus mucilage.

Because the Examiner has not shown that the cited references would have made obvious a method meeting the limitations of claim 43, we reverse the rejection of that claim, and dependent claims 44, 46, 47, 50, and 52, under 35 U.S.C. § 103(a) based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, and Dufresne.

II

The Examiner has rejected claims 43, 49, and 50 as obvious based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, and Dufresne, and Ramsden. The Examiner has rejected claims 43 and 50 as obvious based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, and Dufresne, and Cárdenas. The same issue is dispositive for both rejections.

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

The Examiner finds that "Stillman does not 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. 8. Similarly, the Examiner finds that "Stillman does not teach . . . cactus mucilage. However, cactus mucilage was a known source of food grade polymers in food as taught by Cárdenas." *Id.* at 9.

The Examiner concludes that it would have been obvious "to modify the teachings of 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 8–9. Similarly, the Examiner concludes that it would have been obvious "to modify the teachings of Stillman 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 10.

Appellant argues that "*Stillman* does not present a selection of specific biopolymers that are able to confer a high extensional viscosity (cohesiveness) to a liquid product while maintaining a 'thin liquid' texture (low shear viscosity). In contrast, *Stillman* only describes the 'thickening' of liquid foods." Appeal Br. 7.

Appellant argues that "*Declaration III* 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 III*, okra and cactus mucilages have **superior** cohesiveness and therefore, are **not** functionally equivalent to other biopolymers disclosed in *Stillman*, such as xanthan." *Id.* at 8. That is, okra gum and cactus mucilage "actually had **superior** cohesiveness to the preferred thickener of *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. 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 Stillman'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. 9, 10. Regarding the Trouton ratio and extensional viscosity recited in claim 43, the Examiner finds that "one of ordinary skill in the art would recognize that the Trouton's ratio and extensional viscosity of the nutritional product are a result effective variables" that would be routinely optimized, "as evidenced by Chan, Fukui, and Dufresne." *Id.* at 6.

Chan states that proteins and polysaccharides are commonly used in foods as, among other things, thickening agents. Chan 716, left col. Chan describes "the shear and uniaxial extensional flow behaviour of aqueous casein and phosphated waxy maize starch systems." *Id.*, abstract. "Trouton ratios were calculated to compare different responses of biopolymers to the shear and extensional deformation." *Id.* The Examiner does not point to any disclosure in Chan indicating that there is an optimal range of Trouton ratios

or extensional viscosities for nutritional compositions, especially those for people with a swallowing disorder.

Fukui discloses "an assistive-drink to facilitate swallowing medicines characterized in that it contains water and an adhesive paste to make viscous liquid or gelatinoid." Fukui 1:62–64. "Specifically, the viscosity at 20° C. is preferably 1,000–25,000 cP if it is a viscous liquid, and the jelly strength at 20° C. is preferably 10–100 g/cm^2 if it is a gelatinoid." *Id.* at 3:43–46. Fukui states:

> If the jelly strength is less than 10 g/cm^2 or the viscosity is less than 1,000 cP, misswallowing is apt to occur in swallowing medicines. On the other hand, if the jelly strength exceeds 100 g/cm^2 or the viscosity exceeds 25,000 cP, swallowing becomes difficult for those who have difficulty in swallowing. Thus both cases are unpreferable.

Id. at 3:47–52.

Thus, Fukui teaches a desirable range of viscosities, for viscous liquids, for people with difficulty swallowing medicines. Fukui, however, does not specify whether the viscosity is shear viscosity, volume viscosity, or extensional viscosity. *See* Spec. ¶¶ 85–86. The Specification states that shear viscosity is "often referred to as simply viscosity." *Id.* ¶ 85.

Dufresne discloses "a method for preparing an adapted food composition for facilitating the act of swallowing in dysphagic patients," comprising the step of "allowing the incorporation of at least one binding and/or gelling and/or thickening compound capable to modulate the rheological profile of the transformed food substance." Dufresne ¶¶ 15–16. "[T]he rheological profile or the serving rheological profile consists in a

combination of rheological parameters defined as firmness, cohesiveness, springiness, adhesiveness, gumminess, chewiness and consistency." *Id.* ¶ 19.

The Examiner has not, however, pointed to any disclosure in Dufresne of an optimal range of firmness, cohesiveness, springiness, adhesiveness, gumminess, chewiness or consistency for patient having a swallowing disorder, nor has the Examiner explained how those parameters relate to the Trouton ratio or extensional viscosity recited in claim 43. The Examiner does point to specific viscosity ranges suggested by Dufresne "to quantify and standardize the thickened liquids used in the treatment of dysphagia." Dufresne ¶ 90, *see also* Ans. 7. As with Fukui, however, the Examiner does not explain why a skilled artisan would read Dufresne's disclosure to relate to extensional viscosity rather than shear viscosity, which is "often referred to as simply viscosity." Spec. ¶ 85.

Appellant's Declaration III supports the position that shear viscosity and extensional viscosity 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)." Declaration III, ¶ 10. "'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.* "CaBER experiments are useful to assess whether biopolymers can confer a high extensional viscosity to a nutritional product, such as a liquid." *Id.* ¶ 6.

The declaration also states that the data show that xanthan/starch can thicken a liquid—i.e., increase its shear viscosity—but it "cannot provide

any significant level of cohesiveness to the product." *Id.* ¶ 11. Claim 43 requires a "liquid nutritional product comprising [a] food grade polymer" and having "an increased cohesiveness relative to the nutritional composition."

In short, while the evidence supports the Examiner's position that "Stillman, Ramsden and Cárdenas are directed to thickening food" (Ans. 19), the evidence also shows that the parameters recited in claim 43 require more than simply thickening—increasing the shear viscosity—of a food. Rather, claim 43 requires increasing the cohesiveness of the composition, as reflected by the extensional viscosity and Trouton ratio (extensional viscosity/shear viscosity; Spec. ¶ 88). The Examiner has not shown that a method comprising administering a product with the properties recited in claim 43 would have been obvious based on the cited references.

III

The Examiner has rejected claims 43, 49, and 50 as obvious based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, and one of Sliwinski, Hussein, Hyldon, or Turker. The Examiner concludes that claim 43 would have been obvious based on Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, and Dufresne, for the reasons discussed in the first rejection, and cites Sliwinski, Hussein, Hyldon, and Turker for their disclosures of additional food grade polymers recited in claims 49 and 50.

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 43. The Examiner does not point to any disclosure of okra gum or cactus mucilage in any of Sliwinski, Hyldon, or Turker, and

does not provide any reason why these references would have led a person of ordinary skill in the art to modify Stillman's composition to include okra gum or cactus mucilage. Therefore, the Examiner has not shown that Sliwinski, Hyldon, or Turker make up for the deficiencies 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. 12. The Examiner concludes that it would have been obvious "to modify the teachings of Stillman 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 12–13.

The Examiner's reliance on Hussein, however, suffers from the same deficiency discussed above with regard to Ramsden and Cárdenas; i.e., claim 43 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 43.

IV

The Examiner has provisionally rejected claims 43, 44, 49, 50, and 52 for obviousness-type double patenting based on claims 25, 59, 60, 64, and 65 of application 14/365,731. Ans. 16.

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
43, 44, 46, 47, 50, 52	§ 103(a) Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne		43, 44, 46, 47, 50, 52
43, 49, 50	§ 103(a) Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, Ramsden		43, 49, 50
43, 50	§ 103(a) Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, Cárdenas		43, 50
43, 50	§ 103(a) Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, Sliwinski		43, 50
43, 49, 50	§ 103(a) Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, Hussein		43, 49, 50

Claims Rejected	Basis	Affirmed	Reversed
43, 50	§ 103(a) Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, Hyldon		43, 50
43, 50	§ 103(a) Stillman, Ramsden, Guil-Guerrero, Chan, Fukui, Dufresne, Turker		43, 50
43, 44, 49, 50, 52	obviousness-type double patenting (provisional) 14/365,731	43, 44, 49, 50, 52	
Overall Outcome		43, 44, 49, 50, 52	46, 47

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