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DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

NATURE OF THE INVENTION

The oropharyngeal physiology involved in a normal swallow is an exceedingly complex series of coordinated actions. A host of very different medical conditions, both physical and neurological in nature, can alter normal swallowing. For example, patients suffering stroke, Alzheimer's disease, amyotrophic lateral sclerosis, or traumatic brain injury can exhibit abnormal swallowing.

1 According to Appellants, the real party in interest is the Wisconsin Alumni Research Foundation. App. Br. 2.
Spec. 1. Abnormal swallowing is called “dysphagia.” Spec. 2.

STATEMENT OF THE CASE

The following claim is representative.

15. A method of providing sustenance to a dysphagic subject comprising feeding to the subject one or more edible compositions of matter having an apparent viscosity of from about 150 cP to about 2000 cP at about 30 s⁻¹; a yield stress of from 0 Pa to about 20 Pa at 1 s⁻¹; and a flow index of from about 0.2 to about 0.6.

Cited References


Grounds of Rejection

Claims 15–24 remain rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Germain in view of Garcia.

FINDINGS OF FACT

The Examiner’s findings of fact are set forth in the Answer at pages 3–10. The following facts are highlighted.


Title.
2. Germain discloses that,

The North American Dietetic Association (2000) presented a 4-level scale for the beverages used in the treatment of dysphagia. The terminology refers to nectar-like for the thin liquids, honey-like and spoon-thick for the thickened fluids. Thus, the terminology used during this protocol was very similar to what is found in the literature except for the thickest samples which were referred to as pudding.

p. 65.

3. Germain, Table 3 is reproduced below.

<table>
<thead>
<tr>
<th>Product of honey consistency</th>
<th>m Index</th>
<th>SD</th>
<th>n Index</th>
<th>SD</th>
<th>R²</th>
<th>VS</th>
<th>SD</th>
<th>Viscosity*</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bovine supplement</td>
<td>4.96</td>
<td>0.73</td>
<td>6.66</td>
<td>0.67</td>
<td>0.94</td>
<td>15.3</td>
<td>2.26</td>
<td>507</td>
<td>9.30</td>
</tr>
<tr>
<td>Vanilla supplement</td>
<td>9.18</td>
<td>1.65</td>
<td>0.51</td>
<td>0.04</td>
<td>9.94</td>
<td>29.6</td>
<td>4.38</td>
<td>2720</td>
<td>130</td>
</tr>
<tr>
<td>Strawberry supplement</td>
<td>5.96</td>
<td>1.05</td>
<td>0.65</td>
<td>0.04</td>
<td>9.98</td>
<td>22.4</td>
<td>1.72</td>
<td>2120</td>
<td>54.2</td>
</tr>
<tr>
<td>Chocolate supplement</td>
<td>9.30</td>
<td>0.29</td>
<td>0.60</td>
<td>0.04</td>
<td>9.77</td>
<td>25.3</td>
<td>1.50</td>
<td>2245</td>
<td>47.1</td>
</tr>
<tr>
<td>Milk/juice</td>
<td>8.18</td>
<td>0.29</td>
<td>0.53</td>
<td>0.04</td>
<td>9.76</td>
<td>25.2</td>
<td>0.59</td>
<td>1240</td>
<td>17.7</td>
</tr>
<tr>
<td>Milk 2%</td>
<td>16.5</td>
<td>0.18</td>
<td>0.42</td>
<td>0.04</td>
<td>9.76</td>
<td>1.68</td>
<td>0.76</td>
<td>1750</td>
<td>53.3</td>
</tr>
</tbody>
</table>

High protein group average: 8.49, SD 0.57, VS 0.96, Viscosity 16.5, SD 1750

High protein group std. dev: 4.77, SD 0.10, VS 0.92, Viscosity 11.0, SD 578

<table>
<thead>
<tr>
<th>Juice</th>
<th>m Index</th>
<th>SD</th>
<th>n Index</th>
<th>SD</th>
<th>R²</th>
<th>VS</th>
<th>SD</th>
<th>Viscosity*</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prune juice</td>
<td>7.28</td>
<td>0.70</td>
<td>0.71</td>
<td>0.02</td>
<td>9.98</td>
<td>18.4</td>
<td>0.76</td>
<td>2700</td>
<td>44.0</td>
</tr>
<tr>
<td>Vegetable juice</td>
<td>2.93</td>
<td>0.68</td>
<td>0.44</td>
<td>0.04</td>
<td>9.94</td>
<td>4.88</td>
<td>1.28</td>
<td>427</td>
<td>17.5</td>
</tr>
<tr>
<td>Orange juice</td>
<td>10.3</td>
<td>1.74</td>
<td>0.25</td>
<td>0.02</td>
<td>9.88</td>
<td>4.14</td>
<td>0.86</td>
<td>417</td>
<td>59.9</td>
</tr>
<tr>
<td>Apple juice</td>
<td>3.14</td>
<td>0.22</td>
<td>0.76</td>
<td>0.02</td>
<td>9.79</td>
<td>18.3</td>
<td>0.61</td>
<td>850</td>
<td>68.7</td>
</tr>
<tr>
<td>Cranberry juice</td>
<td>10.9</td>
<td>0.89</td>
<td>0.21</td>
<td>0.01</td>
<td>9.85</td>
<td>3.40</td>
<td>0.95</td>
<td>840</td>
<td>90.4</td>
</tr>
<tr>
<td>Juice group average</td>
<td>4.91</td>
<td>0.17</td>
<td>0.47</td>
<td>0.03</td>
<td>9.86</td>
<td>9.06</td>
<td>1.69</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Juice group std. dev</td>
<td>3.78</td>
<td>0.26</td>
<td>0.45</td>
<td>0.03</td>
<td>7.83</td>
<td>969</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group average</td>
<td>7.77*b</td>
<td>0.52*b</td>
<td>0.95</td>
<td>15.3**</td>
<td>1489**</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Std. dev.</td>
<td>4.22</td>
<td>0.18</td>
<td>0.04</td>
<td>9.83</td>
<td>390</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Significance refers to data from Tables 2-4: "Products of nectar versus honey consistency, p < 0.05. "Products of honey versus pudding consistency, p < 0.05. "Products of pudding versus nectar consistency, p < 0.05. High protein versus juice group, pudding consistency, p < 0.05.

* Consistency coefficient.
| Flow behavior index.
| Yield stress,
| Apparent viscosity calculated with H. Bolley equation.

Germain, Table 3 shows 2% milk with a viscosity of 1750 mPa s; a yield stress of 1.68; and a flow index of 0.42.
PRINCIPLES OF LAW

In making our determination, we apply the preponderance of the evidence standard. See, e.g., *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int'l Co. v. Telex Inc.*, 550 U.S. 398, 416 (2007).

*Obviousness Rejection*

The Examiner finds that Germain discloses wide varieties and/or possibilities of such compositions using specific values of apparent viscosities, consistency coefficient, flow behavior index and yield stress values. However, it is not specified in Germain why would a person having ordinary skill in the art prefers to provide food/drink having the ranges of the rheological parameters such as those recited in the instant claims.

Garcia teaches that dysphagia has diverse causes (introduction), and that the degree of dietary modification should be based on each patient’s swallowing capacity and must be regularly evaluated and adjusted (page 30). Garcia also teaches that food texture is often modified according to a patient’s oral motor control. The NDD prescribes four levels of modification, with level 1 for patients with significant impairment in control, levels 2 and 3 for patients with some ability to chew, and level 4 for patients able to eat an unrestricted, regular diet (table 2, page 30). The reference states that the NDD includes standard labels and suggested ranges for various liquid consistencies. Measured in units of viscosity called centipoises (cP), these consistencies are classified as follows: thin (1 to 50 cP), nectar-like (51 to 350 cP), honey-like (351 to 1,750 cP), and spoon thick (greater than 1,750 cP).
Note that these well-known suggested values of **apparent viscosities** are within or overlapping with the ranges recited in the instant claims. Garcia teaches that incompliance with administering the proper consistency of food to the proper condition may lead to aspiration of an overly thickened fluid which can increase the risk of aspiration pneumonia (see page 31). Further, thin fluids are more desired by patients although these thin fluids also have aspiration risks (see page 32).

**Final Act 4–5. The Examiner concludes that**

It would have been obvious to a person having ordinary skill in the art to choose from the specified apparent viscosities disclosed by Germain wherein the choice would vary for each patient according to the etiology of the condition, the level of advancement of the condition, and the consistency of formulation being provided as taught by Garcia since both references are in the same field of endeavor. Appropriate values of such parameters in any given instance will be readily apparent to those skilled in the art or capable of determination by routine experimentation. The person having ordinary skill would further be motivated because Garcia states that both thick or very thin liquids lead to high risk of aspiration pneumonia; however, it is important to note that nearly 55% of patients who aspirate don’t cough or show any overt symptoms of aspiration (silent aspiration); (page 28). Thus, without an accurate decision of the proper consistency of food or drink for EACH PATIENT, those patients will have a high risk of complications - e.g. aspiration pneumonia- from the food and/or drink. Further, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art.

**Final Act 5.**

Appellants contend that, “Germain and Garcia do not recognize apparent viscosity, yield stress, and flow index as result-effective variables.” App. Br. 3 (emphasis omitted); *see also id.* at 5. Appellants contend that “the rejection is improper and reversible because the claimed parameters are
not known in the art as being important for dysphagic patients.”  *Id.*

(emphasis omitted). Appellants argue that, “Germain et al. found ‘a limited correlation between apparent viscosity... and the consistency levels established with the Bostwick consistometer,’ and that ‘the flow behavior index showed no correlation with the Bostwick consistency.’”  *Id.* at 4.

Appellants further argue that

The apparent viscosity measurements in Germain were the calculated using the Herschel Bulkley model at 50 sec-1. See Germain at page 67, right-hand column, penultimate paragraph. In short, the Germain reference does not contain a single value of apparent viscosity measurements at 30 sec-1 as required by Claim 1.

This is critical because the compositions tested in Germain are non-Newtonian fluids. One cannot simply extrapolate the apparent viscosity at 50 sec-1 as presented in Germain to a corresponding value at 30 sec-1 as required by the present claims. This is because in a non-Newtonian fluid, the relation between the shear stress and the shear rate is non-linear. In a non-Newtonian fluid, the strain experienced by the fluid is related to the stress and shear rate in a highly complex, non-linear fashion. Thus, none of the data presented in Germain at Tables 2-4 can be compared, apples-to-apples, with the positive limitations of the present claims because the apparent viscosity values in Germain were calculated at 50 sec-1. See Germain at page 67, right-hand column, first full paragraph.


The issue is: Does the preponderance of evidence relied upon by the Examiner support a conclusion of obviousness?

**ANALYSIS**

Appellants do not argue individual claims separately in the Appeal Brief. Therefore, we select claim 15 as representative claim for purposes of
this Decision. We agree with the Examiner’s fact finding, statement of the rejection and responses to Appellants’ arguments as set forth in the Answer. We find that the Examiner has provided evidence to support a prima facie case of obviousness. We provide the following additional comment to the Examiner’s argument set forth in the Final Rejection and Answer.

Germain discloses, “Rheological characterization of thickened beverages used in the treatment of dysphagia.” FF1. Germain discloses that,

The North American Dietetic Association (2000) presented a 4-level scale for the beverages used in the treatment of dysphagia. The terminology refers to nectar-like for the thin liquids, honey-like and spoon-thick for the thickened fluids. Thus, the terminology used during this protocol was very similar to what is found in the literature except for the thickest samples which were referred to as pudding.

FF2. According to the Examiner, Germain discloses thickened beverage having “nectar thick” or “HONEY thick” consistencies characterized by rheological parameter values (apparent viscosity, yield stress, and flow index) falling within or overlapping with the ranges presently defined in the claims. Regarding the apparent viscosity, the reference teaches values (average± SD) were 615 ± 260 m Pa s for the nectar, 1480 ± 790 m Pa s for the honey and 3340 ± 1240 m Pa s for the pudding consistency (abstract). Further, Germain teaches within the nectar consistency group, only the cranberry juice corresponded to the suggested standard of less than 351 mPa s. For the honey-like products (351-1750 mPa s). Also, pudding consistency group was considered, and met the 1751 mPa's boundary.

Ans. 4. Thus, Germain discloses viscosity ranges, and other food/beverage values associated with the North American Dietetic Association level scale
for the beverages used in the treatment of dysphagia that overlap with the claimed viscosity range. See also Garcia 30–31.

Furthermore, Germain, Table 3, shows 2% milk with a viscosity of 1750 mPa s; a yield stress of 1.68; and a flow index of 0.42. Germain additionally describes a Ste. Anne’s Hospital study for the clinical management of dysphagia. Germain, p. 65, col. 2. According to Germain, Ste. Anne’s Hospital has been producing a wide selection of thickened beverages for the clinical management of dysphagia to liquids. SAH is the permanent residence of 550 veterans with an average age of 82 years old. Nearly 10% of these residents require thickened beverages on a daily basis. Gradually, all that would be consumed by a resident was thickened form of juices (apple, orange, cranberry, prune and tomato), milk (regular 2% and lactose free), liquid dietary supplements (chocolate, vanilla, strawberry and banana flavors), lemonade, soft drinks as well as coffee and tea.

Germain, p. 65. Thus, Germain discloses that 2% milk is appropriate for administration to dysphagia patients. Because Germain discloses broader, accepted viscosity ranges and other food characteristics appropriate for dysphagia patients, and Germain specifically teaches an embodiment of 2% milk, which overlaps the claimed viscosity, yield stress, and flow index values (and therefore is appropriate for administration to patients with dysphagia), it would have been obvious to one of ordinary skill in the art to administer 2% milk, an edible composition, to a dysphagic patient, as claimed. Ans. 4.

Ultimately, Appellants have failed to indicate why the viscosity, yield stress, and flow index values of Germain, including the 2% milk values cited
by the Examiner, do not meet all limitations of the claim. “The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims…. In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.” In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990). “[A] prima facie case of obviousness arises when the ranges of a claimed composition overlap the ranges disclosed in the prior art. … Even without complete overlap of the claimed range and the prior art range, a minor difference shows a prima facie case of obviousness.” In re Harris, 409 F.3d 1339, 1341 (Fed. Cir. 2005). The Examiner has established an overlap between the claim ranges and those of the cited prior art, sufficient to establish a prima facie case of obviousness. Appellants have failed to rebut the Examiner’s prima facie case of obviousness by a preponderance of the evidence.

We adopt the Examiner’s responses to Appellants’ other arguments of record, including the manner in which the Examiner addressed Appellants’ Bostwick consistency, and Herschel-Buckley viscosity measurement arguments. See Answer 3–10.

CONCLUSION OF LAW

The cited references support the Examiner’s obviousness rejections, which are affirmed for the reasons of record. All pending, rejected claims fall.
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