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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* ANNICK MERCENIER, SOPHIE NUTTEN, and  
GUENOLEE PRIOULT

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Appeal 2015-003179  
Application 13/319,943  
Technology Center 1600

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Before RICHARD M. LEOVITZ, JEFFREY N. FREDMAN, and  
RYAN H. FLAX, *Administrative Patent Judges*.

LEOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed to an oral nutritional supplement. The Examiner finally rejected the claims as obvious under 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 134. The Examiner's decision is affirmed.

STATEMENT OF CASE

Claims 1–4, 6, 12, 14–16, and 25 stand finally rejected by the Examiner as follows:

1. Claims 1–4, 6, 12, 14, 15, and 25 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Hougee (U.S. Pat. Appl. Publ. 2010/0278781

A1, pub. Nov. 4, 2010), Schmitt (U.S. Pat. Appl. Publ. 2009/0263537 A1, pub. Oct. 22, 2009), Arigoni (U.S. Pat. No. 7,183,101 B2, patented Feb. 27, 2007), and Arulampalam (U.S. Pat. Appl. Publ. 2010/0254956 A1, pub. Oct. 7, 2010).

2. Claim 16 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Hougee, Schmitt, Arigoni, Arulampalam, and Nishihara (U.S. Pat. Appl. Publ. 2003/0149061 A1, pub. Aug. 7, 2003).

Claim 1 is representative and reads as follows:

Claim 1: Oral nutritional supplement designed to be administered to children, having a caloric density of 0.9 - 1.6 kcal/ml, an osmolality of 380 - 420 mOsm/kg water, and comprising a protein source comprising about 10 – 13 % of the calories of the composition, a carbohydrate source comprising about 43 – 55 % of the calories of the composition, a lipid source accounting for about 33 – 46 % of the calories of the composition and probiotic micro-organisms rendered non-replicating by heat treatment at 120 °C to 140 °C for 1-30 seconds, the probiotic microorganisms are selected from the group consisting of *Bifidobacterium longum* NCC 3001, *Bifidobacterium longum* NCC 2705, *Bifidobacterium breve* NCC 2950, *Bifidobacterium lactis* NCC 2818, *Lactobacillus johnsonii* La1, *Lactobacillus paracasei* NCC 2461, *Lactobacillus rhamnosus* NCC 4007, *Lactobacillus reuteri* DSM17938, *Lactobacillus reuteri* ATCC55730, *Streptococcus thermophilus* NCC 2019, *Streptococcus thermophilus* NCC 2059, *Lactobacillus casei* NCC 4006, *Lactobacillus acidophilus* NCC 3009, *Lactobacillus casei* ACA-DC 6002 (NCC 1825), *Escherichia coli* Nissle, *Lactobacillus bulgaricus* NCC 15, *Lactococcus lactis* NCC 2287, and combinations thereof.

## DISCUSSION

Claim 1 is directed to an oral nutritional supplement to be administered to children. The supplement comprises 1) protein, 2) carbohydrate, and 3) lipid, each in specifically recited caloric percentages of the supplement. In addition, the supplement comprises 4) a probiotic microorganism selected from a specific list of microorganisms. The probiotic microorganism is 5) “rendered non-replicating by heat treatment at 120°C to 140°C for 1–30 seconds.” The elected species of probiotic microorganism is *Bifidobacterium longum* NCC 2705.

The Examiner found, and Appellants did not dispute, that Hougee describes an oral supplement comprising 1) protein, 2) carbohydrate, and 3) lipid, in the same amounts recited in the claims. Final Rej. 3. The Examiner found that Hougee teaches 4) a probiotic microorganism in the oral supplement which is *Bifidobacterium breve*, not the elected *Bifidobacterium longum* NCC 2705. *Id.* The Examiner also found that Hougee teaches that the *Bifidobacterium breve* are made 5) non-viable by heat treatment. *Id.* at 4. Hougee does not describe the recited temperature and time period for heat treatment, but Hougee discloses “UHT treatment,” i.e., ultra-high temperature treatment. Hougee ¶ 26.

To meet the claimed heat treatment conditions, the Examiner further cited Arulampalam. Final Rej. 6. Arulampalam describes heat treatment of *Bifidobacterium* utilized in various oral products, including in a dietary supplement. Arulampalam ¶ 93. Arulampalam specifically discloses the elected *Bifidobacterium longum*. *Id.* at ¶¶ 83, 87. As found by the Examiner, Arulampalam describes UHT conditions that fall within the recited temperatures and times of claim 1:

Ultra-high temperature processing or (less often) ultra-heat treatment (both abbreviated UHT) is the partial sterilization of food or beverages by heating it for a short time, at a high temperature exceeding 115° C. In a preferred embodiment the ultra-heat treatment process is performed at 115-180° C. for 0.1-20 sec, 120-150° C. for 0.5-15 sec, 125-140° C., or most preferred 125-135° C. for 2-10 sec.

*Id.* at ¶ 77.

The Examiner determined it would have been obvious to have applied Arulampalam's UHT conditions to Hougee since Hougee teaches utilizing UHT for the same purpose. Final Rej. 7.

The Examiner also cited additional prior art publications for teaching *Bifidobacterium longum*. The Examiner found that Schmitt describes an oral supplement for children comprising 1) protein, 2) carbohydrate, and 3) lipid, in the same amounts recited in the claims, and 4) *Bifidobacterium longum*. Final Rej. 5. Additionally, the Examiner found that Arigoni discloses *Bifidobacterium longum* in foods and pharmaceutical compositions, providing further reason to have used it in Hougee's oral composition. *Id.*

Appellants contend that, unexpectedly, as shown in the Specification, "anti-inflammatory profiles of live micro-organisms such as *B. longum* NCC 2705 can be enhanced by UHT-like and HTST-like heat treatments. See specification, page 26, lines 11–14." Appeal Br. 6. Appellants state that Hougee would not have led the skilled worker to expect "that anti-inflammatory profiles of the claimed probiotics are enhanced or generated by UHT-like and HTST-like treatments relative to live cells or pasteurization-inactivated cells." *Id.*

Upon review of the experimental results described in the Specification, and as discussed in the Briefs (*e.g.*, Appeal Br. 9–11), we agree with the Examiner that they are insufficient to establish the non-obviousness of the claimed subject matter. Ans. 9. The legal principle enunciated in *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991) is particularly pertinent.

In *Baxter*, the applicant argued that the claimed plasticized blood donor bag comprised of DEHP had unexpected properties in suppressing hemolysis of red blood cells stored inside it. *Baxter*, 952 F.2d at 389. The court found that such evidence did not rebut *prima facie* obviousness because the prior art disclosed a DEHP-plasticized donor bag, and therefore, Baxter’s blood bag had the same hemolytic-suppressing function as the prior art – albeit unappreciated at the time of the invention. *Baxter*, 952 F.2d at 391. The court concluded that “[m]ere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention.” *Baxter*, 952 F.2d at 392.

In this case, Arulampalam teaches UHT treated probiotic bacteria, including *Bifidobacterium longum*. Arulampalam ¶¶ 77, 93. The heat treatment conditions described by Arulampalam meet the conditions recited in rejected claim 1. Appellants did not challenge the obviousness of utilizing UHT treated *Bifidobacterium longum* in Hougee’s method. Arulampalam’s UHT treated *Bifidobacterium longum*, when included in a supplement as taught by Arulampalam’s (¶ 93), would have possessed the same anti-inflammatory properties that are relied upon by Appellants to establish the non-obviousness of the claimed subject matter. As held in *Baxter*, simply recognizing that the UHT-treated *Bifidobacterium longum*

possessed anti-inflammatory when administered in a food supplement as taught by Arulampalam is not an adequate basis to demonstrate that the claimed subject matter is non-obvious in view of Hougee, Schmitt, Arulampalam, and Arigoni.

The examined subject matter, as reflected also in claim 14, is drawn to *Bifidobacterium longum* NCC 2705. Arulampalam describes UHT treatment of *Bifidobacterium longum*, but not the specific species NC 2705 of *Bifidobacterium longum* which is claimed. However, Arulampalam discloses treating the genus of *Bifidobacterium longum* microorganisms under UHT conditions as recited in the claims. Arulampalam ¶¶ 77, 83, 87. Each member of this genus, absent evidence to the contrary, would possess the unrecognized anti-inflammatory properties. One of ordinary skill in the art would necessarily have to choose a specific *Bifidobacterium longum* to UHT heat treat in accordance with Arulampalam. For this reason, the disclosure in Arulampalam of UHT treated *Bifidobacterium longum* reasonably suggests the specifically claimed species, which was a known *Bifidobacterium longum* as established by Arigoni.

#### Claim 15

Claim 15 depends from claim 1, and further recites that the supplement comprises “about 0.005 mg – 1000 mg of the probiotic microorganisms rendered non-replicating per daily dose.”

Appellants contend that the Examiner did not address this claim element. Appeal Br. 12.

We do not agree. The Examiner found that Hougee teaches that its composition comprises “ $10^3$  to  $10^{13}$  cfu [of *Bifidobacterium breve*] per g dry

weight of the composition or  $10^4$  to  $10^{14}$  cfu per 100 ml of the liquid composition.” Final Rej. 3. The Examiner also found that Schmitt describes “an amount of lactic acid producing bacteria (e.g., *Bifidobacterium longum*, *B. breve*), either living or dead (inactivating living bacteria by heat treatment and/or sonication) equivalent of  $10^2$  to  $10^{13}$  cfu per g dry weight of the composition.” *Id.* at 5.

The Specification discloses “the therapeutically effective dose and/or the prophylactic effective dose is in the range of about 0,005 mg – 1000 mg probiotic micro-organisms,” the same amounts recited in claim 15. Spec. 9:19–22. The Specification also discloses: “In terms of numerical amounts, the ‘short-time high temperature’ treated non-replicating micro-organisms may be present in the composition in an amount corresponding to between  $10^4$  and  $10^{12}$  equivalent cfu/g of the dry composition.” *Id.* at 9:23–26. Thus, the Specification reasonably conveys to one of ordinary skill in the art that a range of “0.005 mg – 1000 mg probiotic micro-organisms” overlaps with “ $10^4$  and  $10^{12}$  equivalent cfu/g of the dry composition.”

The cfu/g quantities described in Hougee and Schmitt fall, or overlap, with the equivalent amounts described in the Specification. The Examiner made this point on pages 12–13 of the Answer. Consequently, the Examiner’s findings addressed claim 15.

#### Claim 25

Claim 25 depends from claim 1, and further recites “wherein the heat treatment is performed at 120 °C to 140 °C for 5-15 seconds.” Appellants contend that these conditions further distinguish the claimed invention.

Appeal Br. 13.

These values fall within the ranges disclosed by Arulampalam: “In a preferred embodiment the ultra-heat treatment process is performed at 115–180° C. for 0.1–20 sec, 120–150° C. for 0.5–15 sec . . .” Arulampalam ¶ 77. Appellants have not explained how their narrow range distinguishes the claims.

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. These cases have consistently held that 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) (internal citations omitted.)

#### Claim 16

Claim 16 depends from claim 1, and further comprises “lipid source comprising medium chain triglycerides (MCT) and long chain triglycerides (LCT) with an MCT : LCT ratio in the range of 12:88 to 8:92.” The Examiner found that Nishihara suggested a ratio that overlaps with the claimed range and that it would have been obvious to have utilized it for the advantages described in Nishihara and Schmitt. Final Rej. 8–9. Appellants did not identify an error in the Examiner’s findings, but instead reiterate the arguments they made over the rejection of claim 1. Appeal Br. 13.

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#### SUMMARY

The obviousness rejections of claims 1, 15, 16, and 25 are affirmed. Claims 1–4, 6, 12, and 14 were not argued separately and fall with claim 1. 37 C.F.R. 41.37(c)(1)(iv).

#### TIME PERIOD

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