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**Datasheet for the decision  
of 6 June 2007**

**Case Number:** T 1503/05 - 3.3.04

**Application Number:** 95932570.5

**Publication Number:** 0778778

**IPC:** A61K 35/66

**Language of the proceedings:** EN

**Title of invention:**  
Probiotic compositions

**Patentee:**  
THE UNIVERSITY OF NEW SOUTH WALES, et al

**Opponent:**  
Cerestar Holding B.V.

**Headword:**  
Probiotic compositions/CERESTAR

**Relevant legal provisions:**

-

**Relevant legal provisions (EPC 1973):**

EPC Art. 54, 56

**Keyword:**

"Main request: novelty (no)"

"Auxiliary request: novelty (yes) - Inventive step (yes)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 1503/05 - 3.3.04

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.04  
of 6 June 2007

**Appellant I:** THE UNIVERSITY OF NEW SOUTH WALES  
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**Appellant II:** Cerestar Holding B.V.  
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**Representative:** Wilkinson, Stephen John  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
11 October 2005 concerning maintenance of  
European patent No. 0778778 in amended form.

**Composition of the Board:**

**Chair:** U. Kinkeldey  
**Members:** R. Gramaglia  
D. S. Rogers

## Summary of Facts and Submissions

I. European Patent No. EP-B-0 778 778 (application No. 95 932 570.5, published as WO-A-96/08261) having the title "Probiotic compositions" was granted with 18 claims, of which claim 1 read as follows:

"1. A probiotic composition comprising one or more probiotic microorganisms and a carrier which will function to transport the one or more probiotic microorganisms to the large bowel or other regions of the gastrointestinal tract, the carrier comprising a modified or unmodified resistant starch or mixtures thereof, which carrier acts as a growth or maintenance medium for microorganisms in the large bowel or other regions of the gastrointestinal tract."

Independent claim 2 related to a two part probiotic composition. Dependent 3 to 14 related to specific embodiments of the probiotic compositions according to claim 1 or 2. Claim 15 was directed to a food composition including a probiotic composition according to the preceding claims. Claims 16 to 18 were to a method of forming the probiotic composition.

II. The following documents are cited in the present decision:

D1 W0-A-91/17672;

D2 W0-A-94/14342;

D3 EP-A-0 564 893;

- D4 EP-A-0 202 409;
- D7 EP-A-0 550 060;
- D8 W0-A-90/15147;
- D10 W0-A-97/35889;
- D13a Food Carbohydrates, edited by D.R Lineback and G.E. Inglett, Basic Symposium Series, AVI Publishing Company, Westport, CT, USA, pages 257, 259 and 269 (1982);
- D13b Starch: Chemistry and Technology, edited by R.L. Whistler, J.N. Bemiller and E.F. Paschall, Academic Press, Inc, USA, pages 581-583 (1984).
- D14a English translation of JP-A-61-231966;
- D15a English translation of JP-A-61-151127.

III. Notice of opposition was filed by the opponent requesting the revocation of the European patent on the grounds of Article 100(a) and (b) EPC on the grounds that the claims did not fulfil the requirements of Articles 54, 56 and 83 EPC 1973. The objection by the opponent under Article 83 EPC 1973 was withdrawn (see point 11 of the decision under appeal).

IV. The opposition division came to the conclusion that granted claim 1 lacked novelty in view of document D7 and maintained the patent on the basis of the auxiliary request then on file, wherein claim 1 differed from granted claim 1 in that the wording "a modified or

unmodified resistant starch or mixtures thereof" in the latter had been replaced with **"a chemically modified resistant starch"**.

- V. Both appellant I (patentee) and appellant II (opponent) filed appeals against the decision of the opposition division.
- VI. Oral proceedings were held on 6 June 2007.
- VII. The submissions on its Main Request, that the patent be maintained as granted, by appellant I (patentee), insofar as they are relevant to the present decision, can be summarized as follows:

*Novelty (Article 54 EPC 1973)*

*Document D7*

- Document D7 disclosed a yoghurt composition comprising a resistant starch. However, this document merely mentioned "yoghurt", not "live yoghurt".

*Document D2*

During the oral proceedings, appellant I admitted that claim 1 of the Main Request lacked novelty over the disclosure in document D2. There is therefore no need to consider further the parties' submissions on appellant I's Main Request.

- VIII. The submissions by appellant I (patentee) on its request that the appeal of appellant II be dismissed, can be summarized as follows:

*Novelty (Article 54 EPC 1973)*

*Document D7*

- Even assuming that document D7 disclosed a resistant starch which could be combined with a yoghurt containing alive bacteria, claim 1 as maintained by the opposition division was nevertheless rendered novel by the restriction to "chemically modified starch".
  
- It is true that according to page 3, line 38 of document D7, the resistant starch could be a dextrin obtained by cleavage of the 1, 6-bond of amylopectin, however, dextrin was a degradation product of starch which was soluble in water. Owing to this property, the skilled person would understand that dextrin could not function as a carrier to transport the probiotic microorganism(s) to the large bowel. Therefore, dextrin could be defined neither as a resistant starch nor as a "chemically-modified resistant starch".

*Inventive step (Article 56 EPC 1973)*

- Document D2 merely aimed at using resistant starch as a source for dietary fibre in foods, without addressing the issue of providing a material capable of transporting the probiotic microorganism(s) to the large bowel and without dealing with the problem of providing a material which was capable of behaving as a growth or maintenance medium for the microorganism(s) in the large bowel.

- Document D4 dealt with compositions which contained viable bacteria and a bulking agent which acted as a carrier and which could be starch. Therefore, this document did not address the issue of providing a material capable of transporting probiotic microorganisms to the large bowel, nor with the problem of providing a material which was capable of behaving as a growth or maintenance medium for the microorganisms in the large bowel.
  
- The above conclusion also applied to document D15a, which related to capsules suitable for protecting Bifidobacterium from the acidic environment of the stomach, which capsules could comprise starch.
  
- Document D1 taught the ability of dietary fibre to carry and protect probiotic microorganisms as they passed through the digestive tract. However, this document did not investigate whether dietary fibre was further able to act as a growth or maintenance medium for said microorganisms in the large bowel or other regions of the gastrointestinal tract. Hence, the skilled person would not have been encouraged to replace the undecomposable fiber of document D1 with resistant starch, known from document D8 to undergo decomposition in the large bowel.
  
- Departing from document D14a as closest prior art, this document described a mixture of soluble dietary fibre and sugars which were not digested and absorbed within the stomach and intestines. It would not have been obvious to replace the soluble dietary fibre and sugars of document D14a by either unmodified resistant starch or by the chemically

modified resistant starch of document D3. This is because the disclosure of resistant starch having a high content of soluble fiber could not be derived from the Table on page 10 of document D3.

IX. The submissions by appellant II (opponent) in support of its request that decision under appeal be set aside and that patent be revoked, can be summarized as follows:

*Novelty (Article 54 EPC 1973)*

*Document D7*

- Document D7 disclosed a resistant starch which could be combined to a yoghurt containing live bacteria. According to page 3, line 38 of this document, the resistant starch could be a dextrin obtained by cleavage of the 1, 6-bond of amylopectin. The present patent's description, which disclosed the ways a resistant starch could be modified, also included "acidification" of necessity resulting in dextrin. Therefore, dextrin could be defined as a "chemically-modified resistant starch" and hence claim 1 as maintained by the opposition division lacked novelty in view of document D7.

*Inventive step (Article 56 EPC 1973)*

- Starting from document D2 as the closest prior art, the difference between the teaching in document D2 and the claimed invention was the replacement of chemically modified resistant starch for resistant starch. However, Fig. 9 and 10 of the patent in suit did not show any improvement over using unmodified



starch. The problem to be solved was thus to provide an alternative to unmodified starch. But this was obvious over document D3 (see Example 5, page 5)

- Document D1 disclosed a food product comprising dietary fibre, for instance cereal bran, and live microorganisms. Starting from document D1 as closest prior art, the problem posed in the contested patent was thus to provide means capable of carrying probiotic microorganisms to the large bowel without undergoing enzymatic breakdown in the small intestine of man, while being capable of behaving as a growth or maintenance medium for the microorganism(s) in the large bowel. According to the claim 1 of this request, the technical problem was solved by using a chemically-modified resistant starch as carrier for the microorganisms, which chemically-modified resistant starch would also act as a growth or maintenance medium for the microorganisms.
  
- However the above solution was obvious to the skilled person in the light of document D8, which taught that resistant starch was acted upon by the microorganisms present in the large intestine to produce by-products which were of significance in improving colon function.
  
- Starting from document D14a as closest prior art, this document dealt with a mixture of soluble dietary fibre and sugars which were not digested and absorbed within the stomach and intestines. The differences between the disclosure in document D14a and the claimed subject-matter lay thus in the type

of material used in the composition, namely a chemically modified resistant starch as proposed by the patent. However, it would have been obvious to replace the soluble dietary fibre and sugars of document D14a by either unmodified resistant starch or by the chemically modified resistant starch known from document D3 (no benefit had been shown by the patentee in using chemically modified resistant starch instead of unmodified resistant starch) having a high content of soluble fiber (as could be derived from the Table on page 10 of document D3), in order to obtain an alternative formulation having the same function as that described in document D14a.

X. The appellant I (patentee) requested that:

1. The decision under appeal be set aside and that the patent be maintained as granted; or
2. The appeal of appellant II (opponent) be dismissed.

The appellant II (opponent) requested that the decision under appeal be set aside and that the European patent No. 0 778 778 be revoked.

## **Reasons for the Decision**

*Appellant I's Main Request that the patent be maintained as granted*

*Novelty (Article 54 EPC 1973)*

*Document D2*

1. Document D2 (see the table on page 12: "Batch" Nos. 2 to 6) discloses baking formulations comprising inter alia starch A.958 and yeast. Starch A.958 is a "H-maize-high amylose starch 80%" (see *ibidem*, page 6, lines 2-3), namely a "resistant starch" according to present claim 1 and paragraph [0024] of the patent in suit. Yeasts such as *Saccharomyces* falls under the definition of the probiotic microorganism(s) according to claim 1 as granted and paragraph [0011] of the patent in suit. Moreover, the claimed probiotic composition can, inter alia, be an intermediate product to be incorporated into a variety of foods and beverages such as baked products (see paragraph [0034] of the patent in suit). This definition also applies to the baking formulations described in document D2.
  
2. Claim 1 as granted also requires that the carrier including resistant starch should function to transport the probiotic microorganism(s) to the large bowel or other regions of the gastrointestinal tract and act as a growth or maintenance medium for microorganisms in the large bowel or other regions of the gastrointestinal tract. However, appellant I admitted in his letter dated 5 April 2004 (see page 11, lines 1-3) that all types of resistant starch exhibit the capacity to transport microorganisms and to act as

a growth medium. Therefore, the references in claim 1 as granted to the implicit action of resistant starch as carrier and growth/maintenance medium for the probiotic microorganism(s) have no further limiting effect on the wording in claim 1 as granted "a modified or unmodified resistant starch or mixtures thereof".

3. In view of the foregoing, the board concludes that the subject-matter of claim 1 as granted lacks novelty in view of the disclosure in document D2.

4. At the oral proceeding, the patentee admitted that document D2 was novelty destroying for the subject matter of claim 1 of the main request. In view of this statement the board will treat this admission as a withdrawal of its main request/appeal by appellant I (patentee).

*Appellant II's request that the decision under appeal be set aside and that the patent be revoked*

*Novelty (Article 54 EPC 1973)*

5. Claim 1 of the patent as maintained in amended form by the opposition division differs from granted claim 1 in that the wording "a modified or unmodified resistant starch or mixtures thereof" in the latter has been replaced with **"a chemically modified resistant starch"**.

6. Document D7 discloses a resistant starch which can be combined with a yoghurt (see page 4, lines 1-5, wherein "RS" is an acronym for resistant starch). It is argued by appellant II that a yoghurt contains live (probiotic) bacteria. As for the resistant starch, the latter can

be a dextrin obtained by cleavage of the 1, 6-bond of amylopectin (see page 3, line 38 of document D7). Appellant II maintains that dextrin falls under the definition of the term "chemically-modified resistant starch".

7. To buttress the view that dextrin is a chemically modified resistant starch, appellant II relies on paragraph [0027] of the patent in suit, which discloses the ways a resistant starch can be chemically modified and which include "acidification". It is argued by appellant II that acidification of necessity results in dextrin (see e.g. documents D13a and D13b).
  
8. However, a critical property of resistant starch is that it resists enzymatic breakdown and thus escapes digestion in the small intestine of man (see e.g., document D8, page 1, lines 10-11 and document D2, bottom of page 1), while it is acted upon in the large intestine to produce by-products (see document D8, page 1, lines 24-25). This property follows from the matrix structure/ crystallinity of resistant starch (see document D10, page 1, lines 4-8) and hence from its insolubility in water. That resistant starch exhibits this property is confirmed in document D8 (see page 2, line 34 to page 3, line 6), illustrating the separation of the water-insoluble resistant starch from water-soluble non-resistant starch fractions by centrifugation.
  
9. In contrast to the above situation, dextrin is a degradation product of starch which is soluble in water (see document D13a, under the heading "Dextrinisation": "soluble in cold water" and "cold water solubility").

Owing to the solubility in cold water of dextrin (which solubility is expected to be even higher at the 37°C prevailing in the small intestine) and hence to the impossibility of dextrin forming a matrix structure (and thus escaping digestion), the skilled person would understand that dextrin cannot function as carrier to transport the probiotic microorganism(s) to the large bowel. Therefore, the board considers that dextrin referred to on page 3, line 38 of document D7 can be defined neither as a resistant starch nor as a "chemically-modified resistant starch".

10. Therefore, even assuming, in favour of appellant II, that a yoghurt contains live (probiotic) bacteria (see point 6 supra), document D7 fails to directly and unambiguously disclose a formulation comprising one or more probiotic microorganisms and a carrier comprising "a chemically modified resistant starch".
11. Appellant II argues that the "acidification" referred to in paragraph [0027] of the patent in suit would of necessity result in dextrin. However, in the board's view, the purpose of this treatment is to "alter the charge density or hydrophobicity of the **granule** and/or **granule surface** to enhance the attachment compatibility between the microorganism and the resistant starch" (see paragraph [0027]; emphasis by the board). The board concludes that this "acidification" treatment should not be so strong as to destroy the insoluble matrix structure of the granules, which are still made of resistant starch.
12. In conclusion, the subject-matter of claim 1 satisfies the requirements of Article 54 EPC 1973. This

conclusion extends to claims 2 to 18, all directly or indirectly relying on the probiotic composition of claim 1.

*Inventive step (Article 56 EPC 1973)*

*Closest prior art*

13. Appellant II provides different lines of reasoning for each of documents D1, D2, D4, D14a or D15a as the closest prior art document.
14. The established case law of the boards of appeal identifies the closest prior art as a teaching in a document conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e., requiring the minimum of structural modifications to arrive at the claimed invention.
15. As for document D2, this document discloses (see point 1 supra) baking formulations comprising a resistant starch ("starch A.958") and a probiotic microorganism (yeast). The difference between the formulation described in document D2 and the claimed invention lies in the chemically modified resistant starch instead of resistant starch.

However, document D2 merely aims at using resistant starch as a source for dietary fibre in foods, without addressing the issue of providing a material capable of transporting the probiotic microorganism(s) to the large bowel without undergoing enzymatic breakdown in the small intestine of man. Nor does document D2 deal with the problem of providing a material which is capable of behaving as a growth or maintenance medium

for the microorganism(s) in the large bowel. Therefore, the teaching in document D2 is not aiming at any of the objectives envisaged by the claimed invention.

16. As regards document D4, it deals with compositions which contain viable bacteria and a bulking agent which acts as a carrier and which can be starch. It, further, discloses that when such compositions are intended for use as probiotic compositions, the viability of the bacteria needs to be protected from the harsh environment of the stomach, such that the bacteria are delivered to the intestines in a viable state. Protection from the gastric environment is provided by an enteric coating which remains undissolved in the stomach. Starch is mentioned (see document D4, column 5, lines 30 and 34) as a suitable enteric coating material.

However, document D4 deals with protection of the microorganisms from the harsh gastric environment only. This does not necessarily implies resistance to enzymatic breakdown in the small intestine of man (by e.g.,  $\alpha$ -amylases). Therefore, this document does not address the issue of providing a material capable of escaping digestion in the small intestine and transporting these probiotic microorganism(s) to the large bowel. Document D4 is also silent as to the provision of a growth or maintenance medium for the microorganism(s) in the large bowel. Therefore, the teaching in document D4 does not aim at any of the objectives targeted by the claimed invention.

17. The conclusion of point 16 supra also applies to document D15a, which relates to capsules suitable for protecting Bifidobacterium from the acidic environment



of the stomach, which capsules may comprise starch (see page 4, line 10).

18. As for document D1, it discloses the ability of dietary fibre to carry and protect probiotic microorganisms, as they pass through the digestive tract (see page 1, lines 29-35 and page 6, lines 13-16). This document does not investigate whether dietary fibre are further able to act as growth or maintenance medium for said microorganisms in the large bowel or other regions of the gastrointestinal tract.

The differences between the disclosure in document D1 and the claimed subject-matter lies in (i) the type of material used in the composition, namely a chemically modified resistant starch as proposed by the patent and (ii) in that claim 1 as maintained by the opposition division deals with the problem of finding a growth or maintenance medium for the microorganism(s) carried to the large bowel.

19. In view of the foregoing, the board considers document D1 as a more promising springboard to the claimed subject-matter than documents D2, D4 and D15a.
20. Starting from document D1 as closest prior art, the problem posed in the contested patent is thus to provide means capable of carrying probiotic microorganisms to the large bowel without undergoing enzymatic breakdown in the small intestine of man, while being capable of behaving as a growth or maintenance medium for the microorganism(s) in the large bowel.

21. The solution proposed in claim 1 as maintained by the opposition division is chemically modified resistant starch.
  
22. Appellant II maintains that this solution was obvious to the skilled person in the light of document D8, which taught (see page 1, lines 24-26) that resistant starch was "undigestible in the small intestine but is acted upon by microorganisms present in the large intestine to produce by-products, such as short-chain fatty acids, which are of significance in improving colon function". Hence, according to appellant II, resistant starch was an obvious alternative to the dietary fibre of document D1, which alternative the skilled person would have considered in view of these properties. Appellant II further argues that no benefit has been shown by the patentee in using chemically modified resistant starch (known from document D3) over resistant starch *simpliciter*.
  
23. In the board's judgement, the technical teaching which can be derived from page 6, lines 12-14 of document D1 ("fibrous material which is undecomposable in the digestive system serves as a protector and vehicle for the bacteria"; see also the passage on page 3, line 30 to page 4, line 3, in particular the wording "remaining intact") is that the protective/carrier effects of the dietary fibre on the beneficial bacteria are linked to the undecomposable nature of the dietary fibre throughout the whole digestive system (including the large bowel). Hence, the skilled person wishing to solve the problem emphasised under point 20 *supra* would not have been encouraged to replace the undecomposable

fiber of document D1 with resistant starch, known from document D8 to undergo decomposition in the large bowel.

24. The skilled person wishing to solve the problem underlined in point 20 supra would face further uncertainty from the lack of information in document D8 regarding whether resistant starch was capable not only of escaping digestion in the small intestine **but also** of transporting probiotic microorganisms to the large bowel. Whereas the skilled person might have been aware (from the generally accepted definition of resistant starch and from document D2 (see page 1, lines 32-35)) that resistant starch could pass through the upper regions of the gastrointestinal tract unscathed, this did not necessarily imply that resistant starch could protect and carry microorganisms as they passed through the small intestine. This latter property followed from the ability of the microbes to attach to the fiber surface (see document D1, page 3, last line) and the skilled person could not take for granted that microbes would attach to resistant starch.
25. But even assuming in favour of appellant II that the skilled person considered it implicit that resistant starch was able to protect/transport microorganisms on their way to the large bowel, the skilled person had nevertheless to combine the teaching of three documents (documents D1, D8 and D3; the latter disclosing the chemically modified resistant starch) in order to arrive at the claimed subject-matter. This fact, in the board's view, speaks against the obviousness of the claimed formulations, once the skilled person departs from document D1 as closest prior art.

26. In a different line of argument, appellant II starts from document D14a as closest prior art. This document deals with a mixture of soluble dietary fibre (guar gum, psyllium, alginic acid or pectin) and sugars which are not digested and absorbed within the stomach and intestines (fructo-oligosaccharide, raffinose, stachyose or inulin). It is stated on page 3 (see under "[Operation]") of this document that "there is an effect which promotes a reproduction of a useful microbe with the sugars which is not absorbed within the stomach and intestines".

The differences between the disclosure in document D14a and the claimed subject-matter lie in (i) the type of material used in the composition, namely a chemically modified resistant starch as proposed by the patent and (ii) in that present claim 1 deals with the problem of providing a material capable of transporting the probiotic microorganisms to the large bowel without undergoing enzymatic breakdown in the small intestine of man.

27. Appellant II argues that it was known at the priority date of the patent in suit that resistant starch reached the large bowel unscathed, where it behaved as a growth and maintenance medium for faecal bacteria (see the literature cited in paragraph [0004] of the patent in suit). Therefore, in the view of appellant II, it would have been obvious to replace the soluble dietary fibre and sugars of document D14a by either unmodified resistant starch or by the chemically modified resistant starch of document D3, having a high content of soluble fiber (as can be derived from the Table on page 10 and Example 5 of document D3), in

- order to obtain an alternative formulation having the same function as that described in document D14a.
28. However, the disclosure of resistant starch having a high content of soluble fiber cannot be derived from the Table on page 10 of document D3. This is because the above passages merely refer to "TDF", namely the total dietary fiber contents (see *ibidem*, line 14), i.e., both soluble and insoluble dietary fibers. Therefore the skilled person would not have been encouraged to replace the soluble dietary fiber of document D14a by a possibly insoluble dietary fiber of document D3.
29. Moreover, the uncertainty facing the skilled person and conclusions of the board under points 24 and 25 *supra* also apply, *mutatis mutandis*, to the situation where the skilled person wishing to obtain an alternative formulation having the same function as that described in document D14a, departs from document D14a as closest prior art.
30. In summary, the subject-matter of claim 1 as maintained by the opposition division satisfies the requirements of Article 56 EPC 1973. This conclusion extends to claims 2 to 18, all relying on the probiotic composition of claim 1.

**Order**

**For these reasons it is decided that:**

The appeal of appellant II is dismissed.

Registrar:

Chair:

P. Cremona

U. M. Kinkeldey