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Datasheet for the decision of 1 March 2007

T 0690/04 - 3.3.09 Case Number:

Application Number: 97203997.8

Publication Number: 0862863

IPC: A23K 1/16

Language of the proceedings: EN

Title of invention:

Cereal product containing probiotics

Patentee:

SOCIETE DES PRODUITS NESTLE S.A.

Opponent:

Chr. Hansen A/S Mars UK Limited

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 158

Keyword:

- "Main request (novelty no, prior public use)"
- "Auxiliary request 1 (novelty yes; inventive step yes)"

Decisions cited:

G 0001/92

Catchword:



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Boards of Appeal

Chambres de recours

Case Number: T 0690/04 - 3.3.09

DECISION
of the Technical Board of Appeal 3.3.09
of 1 March 2007

Appellant: SOCIETE DES PRODUITS NESTLE S.A.

(Patent Proprietor) Case postale 353 CH-1800 Vevey (CH)

Representative: Rupp, Christian

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted 13 April 2004 revoking European patent No. 0862863 pursuant

to Article 102(1) EPC.

Composition of the Board:

Chairman: P. Kitzmantel
Members: J. Jardón Álvarez
W. Sekretaruk

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Summary of Facts and Submissions

- I. The grant of European patent No. 0 862 863 in respect of European patent application No. 97203997.8 in the name of SOCIETE DES PRODUITS NESTLE S.A., which had been filed on 18 December 1997, was announced on 17 October 2001 (Bulletin 2001/42) on the basis of 10 claims. Claim 1 read as follows:
 - "1. A dried, ready-to-eat cereal product comprising a gelatinised starch matrix which includes a coating or filling containing a probiotic micro-organism."

Claims 2 to 10 were dependent claims.

II. Two Notices of Opposition were filed against this patent by:

Chr. Hansen A/S, (Opponent I) on 8 July 2002 and by

Mars UK Limited (Opponent II) on 16 July 2002.

Both Opponents requested the revocation of the patent in its full scope based on Article 100(a) EPC (lack of novelty and inventive step); Opponent I additionally based its opposition on Article 100(b) EPC (insufficiency of disclosure).

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

O11: JP - A - 04-169179;

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012: Translation into English of 011;

O13: WO - A - 97/16077;

014: US - 3 997 675;

O23: EP - A - 0 241 441;

0210:GB - A - 1 503 094;

- O213:Photographs of pack: "Wysong International Vitality Dry Kattefoder Vitality Feline; attached to O222
- O215:Fuller, R. A Review. Probiotics in man and animals.

 Journal of Applied Bacteriology, 1989, 66,

 pages 365 378;
- O217: Affidavits from J. Marsman concerning the Eagle Pack Products;
- O220: Affidavit from Dr R. L. Wysong dated December 2003 + Exhibits RLW1 and RLW2:
 - RLW1 Invoice copies for "Feline Vitality 4 lb." and "WY Jr. Growth 20# box",
 - RLW2 Texas Agricultural Experiment Station,
 letter dated 21 October 1994 concerning
 Wysong Professional Diet Growth Canine Diet
 (dry).
- O221:Affidavit from M. M. Jensen dated 18 December 2003 + Exhibits MMJ1 and MMJ2:

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- MMJ1 Microbiological Analysis of cat feed product J821,
- MMJ2 English translation of MMJ1;
- O222: Affidavit from M. L. Møller and its English translation, certification of translation, photographs of "Vitality Dry Kattefoder" pack: see O213;
- O223:Declaration from B. Hermansen, its English translation and certification thereof;
- O224:Copy of invoice Nr. 675 from DanSip Wysong to Maxsø Dyrehandel, dated 7 November 1996;
- O225:Copy of invoice Nr. 0018 from Wysong Danmark ApS to Kennel Hirsholmen; dated 15 April 1997;
- 0226:EP A 0 088 574 and
- O228:Witness statement of Dr R. L. Wysong dated

 16 January 2005 + Exhibits RLW3 and RLW4:
 - RLW3 Copy of the final frame from the video "Rationale for Animal Nutrition - An Interview with Dr R. L. Wysong",
 - RLW4 Copy of the transcript excerpt of the video RLW3, published as a book entitled "Rationale for Animal Nutrition An Interview with Dr R. L. Wysong" in 1993.
- IV. By its decision announced orally on 26 February 2004 and issued in writing on 13 April 2004, the Opposition Division revoked the patent.

The Opposition Division held that the application disclosed the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person, essentially because the examples in the contested patent illustrated how the claimed invention could be worked and that the technical problem of improvement of the storage stability of probiotic micro-organisms was solved. Furthermore, the Opponents have failed to bring any evidence which could establish that a filling comprising probiotic micro-organisms could not be prepared by the skilled person. In the Opposition Division's view, the specification contained enough information about how to prepare such a cereal product.

The Opposition Division, however, revoked the patent because the subject-matter of Claim 1 of the then pending main request lacked novelty over the disclosure of the prior art document Ol1/Ol2 and the subject-matter of Claim 2 lacked novelty over Ol3 and Ol4, and because the subject-matter of Claim 1 of the auxiliary request lacked inventive step having regard to the disclosure of Ol4 alone, or in combination with O226, or in view of the disclosure of Ol1/Ol2 in combination with O23.

V. On 27 May 2004 the Patent Proprietor (Appellant) lodged an appeal against the decision of the Opposition Division and paid the appeal fee on the same day.

In the Statement of Grounds of Appeal filed on 12 August 2004, the Appellant requested that the decision under appeal be set aside and that the - 5 - T 0690/04

European patent be maintained on the basis of the claims according to a main request or according to the auxiliary requests I to IV filed therewith.

VI. By letters dated 23 December 2004 and 21 October 2005
Respondent I (Opponent I), and by letters dated
22 December 2004, 7 March 2006, 24, 25 and 29 January
and 1 February 2007 Respondent II (Opponent II),
disputed all the arguments submitted by the Appellant
concerning novelty and inventive step.

Respondent II also filed several pieces of evidence in support of its case.

VII. During the oral proceedings held on 1 March 2007 the Board and the Respondents raised several objections to the amendments made to the claims and in particular concerning their compliance with the requirements of Rule 57a EPC. After discussion, the Appellant withdrew its previous main request and auxiliary request I and filed amended sets of claims for a main request and an auxiliary request I taking account of the objections. Independent Claims 1 and 2 of these requests read as follows:

MAIN REQUEST:

"1. A dried, ready-to-eat, cereal product comprising a gelatinised starch matrix which includes a filling containing a probiotic micro-organism.

2. For the designation GB only:

A dried, ready-to-eat cereal product comprising a gelatinised starch matrix which includes a coating containing a probiotic micro-organism, the coating comprising a carrier substrate which contains the micro-organism.

2. For all other designation states:

A dried, ready-to-eat cereal product comprising a gelatinised starch matrix which includes a coating containing a probiotic micro-organism, the gelatinised starch matrix being in expanded form, the coating comprising a carrier substrate which contains the micro-organism."

AUXILIARY REQUEST I:

"1. A dried, ready-to-eat, cereal product comprising a gelatinised starch matrix which includes a filling containing a probiotic micro-organism the filling comprising a carrier substrate which contains the micro-organism.

2. For the designation GB only:

A dried, ready-to-eat cereal product comprising a gelatinised starch matrix which includes a coating containing a probiotic micro-organism, the coating comprising a carrier substrate which contains the micro-organism, wherein the product contains 0.5-20% by weight of the mixture of the probiotic micro-organism and carrier substrate.

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2. For all other designation states:

A dried, ready-to-eat cereal product comprising a gelatinised starch matrix which includes a coating containing a probiotic micro-organism, the gelatinised starch matrix being in expanded for

the gelatinised starch matrix being in expanded form, the coating comprising a carrier substrate which contains the micro-organism.

wherein the product contains 0.5-20% by weight of the mixture of the probiotic micro-organism and carrier substrate."

The Respondents did not raise any formal objections to these amended sets of claims under Rule 57a EPC. They also did not resist their admittance into the appeal proceedings at this stage of the proceedings.

- VIII. The arguments presented by the Appellant in its written submissions and at the oral proceedings may be summarized as follows:
 - The subject-matter of the claims is limited to "probiotic micro-organisms", that is to say, to "live microbial feed supplement which beneficially affect a host by improving its intestinal microbial balance" (cf. 0215). The probiotic activity of a given micro-organism is strain specific and the list of micro-organisms recited in paragraph [0018] of the specification includes probiotic and non-probiotic micro-organisms. However, the claimed subject-matter is limited only to the specific strains having probiotic activity.

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- As a consequence of this limitation, the prior art documents cited by the Respondents, which did not specify if the strain used was probiotic, were not novelty destroying for the claimed subject-matter. In particular 014, which used inactive yeast, did not disclose an embodiment falling within the scope of any claim of the patent in suit.
- Document 012 did not anticipate the claimed subjectmatter because in this document the live sporulating microbial cells were <u>mixed</u> with gelatinised starch. This mixing with starch was different from the filling claimed in Claim 1, which implied the presence of a cavity (to be filled with the microorganism).
- Also, in its opinion the alleged prior uses "Eagle pet food" (O217) and "Wysong pet food" (O213) filed by the Respondents were not prejudicial to the novelty of the patent in suit. Concerning the Wysong Vitality Dry Kattefoder, the Appellant pointed out that the sale of this product constituted prior art only if the skilled person could analyse the product and reproduce it without undue burden. He stated that the skilled person would not be able to analyse the kibbles of O213 without undue burden and consequently this prior art was not novelty destroying.
- Concerning inventive step, the Appellant considered the formulations which had already been proven to be proper carriers for live probiotics such as yogurts (see [0003]) to be the closest prior art. The problem to be solved by the patent in suit was then

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to find a suitable mechanism for introducing probiotic micro-organisms along with dried cereal products, the resulting products having a long shelf-life. The solution to this problem, namely the claimed cereal products, could not be derived from the prior art cited by the Respondents and therefore involved an inventive step. In particular none of the cited documents recognized that probiotic survival could be achieved by using a carrier substrate which conferred protection on the probiotic micro-organisms. The probiotic micro-organism remained viable for extended periods of time when formulated into a coating on or filling for a dried cereal product.

- IX. The arguments presented by the Respondents in its written submissions and at the oral proceedings may be summarized as follows:
 - The Respondents considered the subject-matter of Claim 1 of the main request as lacking novelty over the disclosures of O12, O24 and O210 and that of Claim 2 as lacking novelty over the disclosure of O14. The Respondents denied any difference between the probiotic character of micro-organisms, including yeasts such as Saccharomyces cereviseae, as used in the current specification and in the prior art.
 - Respondent II further relied on the previously filed and now supplemented prior public use evidence concerning the Eagle (O217) and the Wysong (O213, O228) products, which, in its opinion destroyed the

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novelty of the subject-matter of Claim 2 of the main request.

- Concerning auxiliary request I, the Respondents acknowledged the novelty of the subject-matter of Claim 1 but denied the novelty of Claim 2 in view of O14. Moreover the subject-matter of Claim 1 lacked inventive step over the disclosure of O14 or O213 combined with O226 and the subject-matter of Claim 2 lacked inventive step having regard to the combined teaching of O14 and O210.
- X. The Appellant (Patent Proprietor) requested that the decision under appeal be set aside and that the European patent be maintained on the basis of the main request or the auxiliary request I both filed during the oral proceedings on 1 March 2007.

The Respondents (Opponents) requested that the appeal be dismissed.

Reasons for the Decision

- 1. The appeal is admissible.
- 2. Preliminary remark
- 2.1 The sets of claims according to both the main request and auxiliary request I include two different versions of independent Claim 2, namely a first version for the designation GB only and a second version for all the other designated states.

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2.2 The Appellant has limited the subject-matter of Claim 2 in its version for the designated states other that GB in view of the earlier PCT application 013, published after the filing date of the present application. This limitation, however, is not necessary for the designation GB because when 013 entered the European phase no designation fee was paid for GB, so that this document does not belong to the prior art according to Article 54(3),(4) EPC for GB (Article 158(1),(2) EPC).

MAIN REQUEST

- 3. Novelty (Article 54 EPC)
- 3.1 Claim 2 of the patent in its version for Great Britain is directed to a cereal product having the following features:
 - a) a dried
 - b) ready-to-eat cereal product comprising
 - c) a gelatinised
 - d) starch matrix which includes
 - e) a coating containing
 - f) a probiotic micro-organism, wherein
 - g) the coating comprises a carrier substrate which contains the micro-organism.

Claim 2 for all other designated states further specifies that:

f) the gelatinised starch matrix is in expanded form.

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- 3.2 Respondent II denied the novelty of the subject-matter of Claim 2 of the main request over the prior public uses of the Eagle Pack Products (O217) and the Wysong Products (O213).
- 3.3 According to EPO practice concerning the determination of whether an invention has been made available to the public by prior use it is necessary to clarify when the act of prior use occurred, what was made available to the public through that use and the circumstances of the act of use, i.e. where, how and by whom the subject-matter was made public through that use (see Case Law of the Boards of Appeal of the European Patent Office, 5th edition 2006, page 561).
- 3.4 The Wysong International Vitality Feline product (O213)
- 3.4.1 The "when" issue

This prior use objection is based essentially on the affidavit of Dr Randy L. Wysong, founder and director of the Wysong Corporation, Midland, Michigan, United States of America, (0220), and the clarifications filed with letter dated 29 January 2007 (0228).

Dr Wysong stated that Wysong Corporation had been selling dry pet food containing probiotics since the 1980s. These products included the "Vitality Feline" product (also called "Vitality Dry Kattefoder" when sold in Denmark) which is considered to anticipate the subject-matter of Claim 2 of the main request.

Respondent II filed photographs of a package of a "Vitality Feline" product (O213) and several invoices showing that the product was available to the public

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before the priority date of the patent in suit, ie before 9 January 1997.

Document 0213 includes pictures of the front and back of the packaging for the "Vitality Feline" product. The package was sold in Denmark and is referred to as Vitality Feline on the back side and had been relabelled as "Vitality Dry Kattefoder" on the front side. Dr Wysong explained in point 17 of his affidavit 0220 that the reference "951106" on the reverse side of the package referred to the date 6 November 1995 and the Board has no reason to doubt the accuracy of this statement as this manner of codifying a date on a printed publication is conventional. Respondent II further filed two invoices (0224 and 0225) showing that "Vitality Dry Kattefoder" had been sold in Denmark on 7 November 1996 (0224) and 26 March 1996 (0225) and submitted two declarations by Ms M. L. Møller (0222, points 4 - 6 of the English translation) and Ms B. Hermansen (0223, points 4 and 5 of the English translation) which state that they recognised with complete certainty the packages of "Vitality Dry Kattefoder" as those which they had purchased in various pet shops in Ballerup and Roedrove in 1995 or 1996.

The Appellant questioned whether the product O213 could have been sold in Denmark because the batch code and the expiration date of the product were not given on the package. Without this information the product could not have been sold legally in any EU country.

The Board notes that the evidence provided by Respondent II undoubtedly shows that the product was

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marketed before the priority date of the patent. The absence of an adequate selling authorisation by the competent administrative EU bodies cannot impair the accuracy of the available evidence. In fact, Respondent II actually confirmed during the oral proceedings that the product had later to be withdrawn from the market due to the absence of such authorisation.

Respondent II provided further evidence that certain Wysong products, including the Vitality Feline product now under consideration, were available also in the United States (see RLW1, an invoice of Wysong Corporation dated 31 January 1995, and RLW2, a letter of the Texas Agricultural Experimental Station dated 21 October 1994 showing that it lacked the necessary registration in Texas).

In summary, the evidence filed by Respondent II establishes that the product "Vitality feline" was produced and sold by Wysong Corporation before the priority date of the patent.

3.4.2 The "what" issue

It remains to decide if this product anticipates the subject-matter of Claim 2.

The Vitality Feline product is a dried (moisture max. 12%) ready-to-eat (see feeding guide) cereal product containing several starch sources (wheat, rice, corn and extruded soybeans) and a source of live (viable) naturally occurring micro-organisms (Streptococcus faecium, Lactobacillus acidophilus, Lactobacillus casei, Lactobacillus lactis and Saccharomyces cerevisiae)

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having a probiotic activity which has not been quantified (see O213). Thus, the Vitality Feline product shows features a), b), d) and f) of Claim 2 of the patent in suit.

It remains to be established whether this product also anticipates the remaining features of Claim 2, namely that the starch is gelatinised (feature c)) and that it includes a coating (feature e)) which contains the probiotic micro-organism (feature g)).

To prove that the Vitality Feline product also anticipates features c), e) and g) Respondent II relied essentially on the declarations by Dr R. L. Wysong (O220, O228), explaining the process of preparation of the Wysong products and on an information video produced in 1991 (RLW3) and its transcript published in 1993 (RLW4), also explaining how the Wysong products were prepared. This video film is mentioned on the package O213 together with the information that it could be purchased from Wysong Corporation.

Respondent II filed a copy of the final frame of this video showing that it was made in 1991 (RLW3) and a transcript excerpt of the video including the preparation process of the Wysong products (RLW4; while the filed transcript corresponds to the third printing dated 1998, the first edition was printed in 1993, as can be seen from the first page of the transcript).

The process as described in RLW4 indicates (see paragraph bridging pages 78 - 79) that the Wysong products were prepared by extrusion cooking to produce gelatinized starches (feature c)). The extruded product

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was dried and could have various liquids and powder applied to it before it was finally put into its final package (page 83, last two lines). On page 85 it is explained that fragile ingredients such as essential fatty acids and probiotic and enzymes could be incorporated after processing to prevent their destruction. The addition of a fatty acid and a probiotic after the extrusion step results in a coating containing the probiotic micro-organism (features e) and g)).

The disclosure of RLW4 is confirmed by page 2 of the affidavit of Dr Wysong (O220) explaining that the Wysong process involves the extrusion cooking of, amongst other ingredients, cereal grains resulting in a kibble product having a gelatinised starch matrix. The extruded kibbles are then dried and coated with the heat-sensitive products (O220, points 6 to 11).

The Appellant pointed out that the sale of a product constituted prior art only if the skilled person could analyse the product and reproduce it without undue burden (G 1/92). It doubted that an analysis of the product would reveal to a skilled person all the features of a product falling within the scope of the patent, in particular because in its opinion the identity of the micro-organism, the amount of viable micro-organism present and the presence of a carrier substrate could not be determined without ambiguity.

The Board cannot accept this argument of the Appellant. As explained above, the subject-matter of Claim 2 lacks novelty because the product Vitality Feline and a process for its production were available to the public

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before the priority date of the patent. Under these circumstances, it is not necessary that the skilled person could analyse the product, because he would know its constitution from the ingredients listed in O213 and the method of preparation described in the prepublished transcript RLW4.

Notwithstanding the above and for the sake of completeness, the Board notes that it considers that the skilled person could analyze the "Vitality Feline" in order to confirm its constitution. It is within the knowledge of the skilled person how to determine the degree of gelatinization of a given starch by using physical, chemical and biochemical methods such as loss of birefrigerance, increase in viscosity, differential scanning calorimetry, etc. It is also within the skilled person's capacity to find out if the product includes a coating containing the probiotic microorganism.

This analysis was in fact made on the product O213 by Ms Jensen, the Laboratory Manager in Chr. Hansen during 1996 and 1997, who, notwithstanding her cautious language, confirmed in her affidavit, O221, that the "Vitality Dry Kattefoder" is coated and contained a large quantity of lipid and that the bacteria were ("suspected to be") incorporated into the fatty substance (see points 11 and 12). (The use of the word "suspected" in this statement cannot detract from the fact that verifying this "suspicion", if wished, would not go beyond routine analysis techniques)

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- 3.5 Thus, the product Vitality Feline shows all the features of Claim 2 of the patent in suit in its version for Great Britain. The subject-matter of this Claim 2 lacks therefore novelty (Article 54 EPC).
- Glaim 2 for all the other designated states differs from Claim 2 for the Great Britain designation only in that the gelatinised starch matrix is in "expanded form" (feature h)). As explained above, the Wysong process includes the extrusion cooking of cereal grains to produce a gelatinised starch product, such process resulting in an expanded product (see RLW4, page 83, penultimate paragraph). Consequently, the prior use of Vitality Feline is also novelty destroying for the subject-matter of Claim 2 for all the other designated states.
- 3.7 Both versions of Claim 2 of the main request lack novelty with regard to the prior use O213.
- 3.8 Under these circumstances there is no need to discuss the further alleged prior public use, the Eagle Pack Products, O217.

AUXILIARY REQUEST I

- 4. Novelty (Article 54 EPC)
- 4.1 Claim 1
- 4.1.1 Claim 1 of the first auxiliary request is directed to a cereal product comprising a gelatinised starch matrix which includes a <u>filling</u> comprising a carrier substrate which contains a probiotic micro-organism. Its subject-

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matter is identical to the subject-matter of Claim 1 of the auxiliary request before the Opposition Division.

- 4.1.2 The novelty of this claim was already acknowledged by the Opposition Division, essentially because none of the cited prior art documents discloses the combination of a gelatinised starch matrix including a filling comprising a carrier substrate containing the microorganisms. Concerning 012 the Opposition Division pointed out that no carrier substrate was present in the products disclosed there (see working example 1).
- 4.1.3 The Respondents did not raise any novelty objection to the subject-matter of Claim 1 of the auxiliary request I during the present appeal proceedings.
- 4.1.4 The Board agrees with the finding of the Opposition Division that the subject-matter of Claim 1 is novel. It is also pointed out that the subject-matter of Claim 1 further differs from the disclosure of O12 by the presence of the carrier substrate containing the micro-organism as a filling in the gelatinised starch matrix, that is to say, the carrier containing the micro-organism is "filled" into the (eg central) bore of the starch matrix [see 0037] resulting in a different product from the product disclosed in O12, where the gelatinized starch and the micro-organism are mixed together (O12, Claim 1).
- 4.1.5 For these reasons the subject-matter of Claim 1 is novel.

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4.2 Claim 2

- 4.2.1 Compared to Claim 2 of the main request discussed under point 3.1, the subject-matter of both versions of Claim 2 of auxiliary request I has been limited by specifying that the product contains 0.5-20 % by weight of the mixture of the probiotic micro-organism and carrier substrate. This feature is not disclosed in the prior use O213.
- 4.2.2 The Respondents did not dispute the novelty of the subject-matter of Claim 2 over 0213 but contested its novelty over 014.

Document O14 discloses a process for improving the palatability of dry cat food kibs comprising 30 to 65% by weight of farinaceous material and 25 to 40% by weight of proteinaceous material which are coated with 0.5 to 20% by weight of dry yeast (see Claim 1). The yeast is applied to the animal food as a dry coating or mixed with a carrier such as a fat or other edible material (column 6, line 64 - column 7, line 4). Commercially available dried yeast is used as the yeast (column 3, lines 18 - 26), the preferred yeasts comprising Torulopsis, Candida and Saccharomyces (Claims 3 - 7); in the example Saccharomyces cereviseae is used.

The Respondents argued that the species of the microorganisms used in 014 and in the patent in suit, for instance *Saccharomyces cereviseae*, were the same and concluded that they should be probiotic and therefore novelty destroying. It is however noted that in 014 only dried yeasts which do not contain viable, live - 21 - T 0690/04

cells are used (see column 3, line 34, specifying that the fermenting power is inactive). The probiotic nature of a micro-organism is strain specific and cannot be extrapolated to other strains of the same micro-organism. The fact that the disclosure of 014 is not restricted to the specified inactive yeasts because other yeasts might also be considered (see column 4, lines 37 - 52) does not justify the conclusion, in the absence of a positive disclosure in that direction, that these "other" yeasts would be active ones; rather it is conspicuous from 014's focus on palatability that viability of the yeasts is not an issue of concern.

Thus, the subject-matter of Claim 2 of the patent differs from the disclosure of O14 by the use of a probiotic micro-organism, which is not part of O14's explicit or implicit disclosure.

- 4.2.3 The subject-matter of Claim 2 of the auxiliary request I is novel (Article 54 EPC).
- 5. Inventive step (Article 56 EPC)
- 5.1 The patent in suit relates to ready-to-eat cereal products comprising a gelatinized starch matrix and containing probiotic micro-organisms.

Probiotic micro-organisms are live non-pathogenic micro-organisms that, when ingested, beneficially affect the host animal by improving its microbial balance. Therefore there is a considerable interest in including probiotic micro-organisms in foodstuffs. The introduction of the probiotic micro-organisms is normally accomplished by the ingestion of the organisms

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in drinks, dairy products, capsules, etc., in such a way that the micro-organism arrives in a viable condition at the intestine.

The incorporation of probiotic micro-organisms into ready-to-eat cereal products is problematic as the cereal products are required to have long storage lives, for example at least a year, while the cell-counts for many probiotic micro-organisms can drop rapidly over a few days.

- 5.2 Closest prior art
- 5.2.1 In accordance with the established case law the closest prior art is usually a document having the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common with the invention. Having this in mind, the closest prior art document in the present case must also be a document dealing with the incorporation of probiotic micro-organisms into foodstuffs.
- 5.2.2 Among the prior art cited by the Respondents, in addition to the prior uses O213 and O217, the documents O12 (see Claim 1 and page 5, lines 10 14), O24 (see Claim 1) and O210 (see Claim 7), relate to feeds including probiotic micro-organisms and a product of starch, and any of them could be taken as an appropriate starting point in the assessment of inventive step.
- 5.2.3 The Respondents considered document O14 as the closest prior art. O14 discloses a process for improving the

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palatability of dry animal food by coating such food with yeast (see Claim 1). As discussed above in relation with novelty (see 4.2.2), the yeast disclosed in O14 is inactive and it is not a probiotic microorganism.

Taking into account that the background of the invention lies in keeping the micro-organisms alive during storage, document 014, in which the survival of micro-organisms does not play any role, cannot qualify as the closest prior art document.

- 5.3 The problem to be solved and its solution
- 5.3.1 Independently of which of the documents mentioned above under 5.2.2 is considered as the closest prior art, the technical problem underlying the patent in suit consists in providing a further (alternative) cereal product containing probiotic micro-organisms which remain viable during storage.
- 5.3.2 The patent in suit proposes two solutions to the above stated problem:
 - a cereal product comprising a gelatinised starch matrix including a filling comprising a carrier substrate which contains the micro-organism (Claim 1), and
 - a cereal product comprising a gelatinised starch
 matrix which includes a coating comprising a carrier
 substrate which contains the micro-organism wherein
 the product contains 0.5 20% by weight of the

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mixture of carrier substrate and micro-organism (Claim 2).

5.3.3 Having regard to the worked examples of the patent in suit the Board accepts that the problem has been credibly solved. The examples show that cell counts remain substantially constant indicating good storage stability. The results from the storage at 37 °C for eight weeks indicate that the micro-organisms are likely to be viable after one year of storage at normal conditions. These findings were not contested by the Respondents.

5.4 Inventive step

It remains to be decided whether or not the claimed solutions are obvious over the cited prior art.

5.5 Claim 1.

5.5.1 The Respondents considered that the subject-matter of Claim 1 directed to a filling was obvious having regard to the prior art products wherein the micro-organism was present as a coating (014 or 0213). The application of the carrier substrate which contains the probiotic micro-organism as a filling was regarded merely as a trivial modification of the known products having a coating and, in the absence of any unexpected effect, lacking inventive step. Respondent II pointed out that the patent in suit presented both alternatives as equally valuable and that feed products comprising a filling were already well known, for instance from 0226, which disclosed an animal foodstuff comprising a first food formulation including a cereal component as

external shield filled with a second formulation (see Claim 1).

- 5.5.2 The Board finds these arguments unconvincing. First of all it is noted that none of the documents cited by the Respondents discloses the use of both coatings and fillings as alternative variants for incorporating a substance to a cereal product. The prior art uses a coating or a filling depending of its intended use. The fact that they were presented in the patent in suit as alternatives is irrelevant for the assessment of inventive step as the patent itself does not represent the state of the art.
- 5.5.3 Document O226 also gives no hint about the claimed solution. This document relates to dry dog food of improved breakability, which is attractive to dogs by smell and can be stored and handled without unpleasant odour to humans (see page 2, lines 6 11). The food is produced by co-extrusion under increased pressure, at a temperature above 100°C and under high shear conditions (page 8, lines 21 -27), that is to say, under conditions which are not viable for living probiotic micro-organisms. O226 can therefore give no hint towards the solution of present Claim 1.
- 5.5.4 In summary, there is no indication either in O226 or in the other available documents as to the use of a filling comprising a carrier substrate which contains the micro-organism so as to impart good storage stability to a cereal product. The subject-mater of Claim 1 involves an inventive step.

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5.6 Claim 2

- 5.6.1 The Respondents considered the subject-matter of
 Claim 2 obvious having regard to the combined teaching
 of documents 014 and 0210.
- 5.6.2 Document O14 discloses dry animal food having improved palatability obtained by coating such food with yeast (see abstract). The yeast can be mixed with a binder (see column 6, lines 64 66). The amount of binder (carrier) and yeast used in O14 overlap to a great extent with the amounts used in Claim 2 of the patent in suit, the only difference between O14 and Claim 2 being the use of a probiotic micro-organism to replace yeast.
- 5.6.3 Document O210 relates to a method for the prophylaxis and treatment of diarrhoea in dogs by administering Bifidobacterium pseudolongum or/and Bifidobacterium adolescentis isolated from the intestines and/or faeces of dogs (see Claim 1). O210 further teaches a preparation obtained by mixing the Bifidobacterium into a gelatinized starch paste containing an amino acid, vacuum drying the mixture and then crushing it to granules (Claim 2). No carrier is used in O210 to protect the micro-organisms.
- 5.6.4 The Board cannot accept the argument of the Respondents that it would be obvious to replace the yeast of O14 by the probiotic micro-organism of O210 and thus arrive at the claimed invention. As already pointed out above (see 5.2.3), O14 aims to solve a different problem, namely to improve the palatability of dry animal food. Consequently, there is no reason for the skilled person

to combine the teaching of O210, which relates to the administration of live bacteria to dogs, with the teaching of O14, which relates to the improvement of palatability of animal food.

- 5.6.5 There is therefore no indication in the prior art that probiotic survival could be improved by using a carrier substrate which confers protection to the micro-organism. It is also noted that the 0.5 to 20% by weight limitation of the subject-matter of Claim 2 over the disclosure of the prior use 0213 is not an arbitrary limitation. According to the Appellant an amount lower than 0.5% by weight could not guarantee a homogeneous coating of the kibbles during the production process and an amount greater than 20% by weight would have negative consequences on the kibbles, since such a thick coating could suffer delamination or easily get chipped off through handling.
- 5.7 For these reasons the subject-matter of Claim 2 also involves an inventive step (Article 56 EPC).
- 6. It thus follows that auxiliary request I of the Appellant Respondent is allowable, and that the decision under appeal must be set aside.

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Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of Claims 1 to 10 of the auxiliary request I as filed on 1 March 2007 during the oral proceedings, after any necessary consequential amendment of the description.

The Registrar: The Chairman:

D. Sauter P. Kitzmantel