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Datasheet for the decision of 22 March 2019

Case Number: T 1686/13 - 3.3.08

Application Number: 05706788.6

Publication Number: 1720974

IPC: C12N1/00, C12N1/04, A23K1/00

Language of the proceedings: EN

Title of invention:

Frozen lactic acid bacteria culture of individual pellets

Patent Proprietor:

Chr. Hansen A/S

Opponents:

DuPont Nutrition Biosciences ApS Dutch Dairy Ingredients B.V.

Headword:

Pellet-frozen Lactococcus culture/CHR. HANSEN

Relevant legal provisions:

EPC Art. 54, 56, 83, 84, 123(2), 123(3) EPC R. 115(2) RPBA Art. 12(4), 15(3)

Keyword:

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Main request - admission (yes);
Main request - requirements of the EPC met (yes);
Admission of new evidence (no);
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Decisions cited:

G 0003/14, T 1374/07, T 2017/07

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 1686/13 - 3.3.08

DECISION
of Technical Board of Appeal 3.3.08
of 22 March 2019

Appellant I:

(Patent Proprietor)

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Chr. Hansen A/S

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Party as of right:

(Opponent 01) appeal withdrawn

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Appellant II:

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Representative:

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Decision under appeal:

Interlocutory decision of the Opposition

Division of the European Patent Office posted on

13 June 2013 concerning maintenance of the European Patent No. 1720974 in amended form.

Composition of the Board:

Chairman P. Julià
Members: M. Montrone

R. Winkelhofer

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Summary of Facts and Submissions

- I. Appeals were lodged by the patent proprietor and opponents 01 and 02 against the interlocutory decision of an opposition division concerning European patent No. 1 720 974, having the title "Frozen lactic acid bacteria culture of individual pellets". The patent is based on European application No. 05 706 788.6, which was filed as an international application and published as WO 2005/080548 (hereinafter the "patent application").
- II. In the decision under appeal, the opposition division held that the subject-matter of claims 1 of the main request (claims as granted) and of auxiliary request 1 was anticipated by the disclosure of *inter alia* document D2 (Article 54 EPC). Auxiliary request 2 was found to meet the requirements of the EPC.
- III. With its statement of grounds of appeal, the patent proprietor submitted three auxiliary requests.

 Auxiliary requests A1 and A2 were new to the proceedings, while auxiliary request A3 was identical to auxiliary request 2 dealt with in the decision under appeal.
- IV. With their statements of grounds of appeal, opponents 01 and 02 submitted arguments as to why auxiliary request 2 (auxiliary request A3 in the appeal proceedings) did not fulfil the requirements of the EPC. In support of their case on inventive step, the opponents filed document D20 (opponent 02) and documents D21 and D22 (opponent 01).
- V. The parties replied to their respective statements of grounds of appeal. The patent proprietor submitted

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auxiliary requests B1 to B6, while the opponents submitted arguments as to why the main request and auxiliary requests A1 and A2 contravened the requirements of the EPC.

- VI. In a further submission, the patent proprietor argued that, in view of decision G 3/14 (OJ EPO 2015, A102), the amendments in auxiliary requests A1 and A2 were excluded from an assessment under Article 84 EPC. In reply thereto, the opponents contested the patent proprietor's view on this issue.
- VII. With submission dated 23 March 2018, opponent 01 withdrew its appeal, and thus remained as party as of right in the appeal proceedings. In view thereof, the patent proprietor and opponent 02 are referred to in the present appeal proceedings as appellants I and II, respectively.
- VIII. The parties were summoned to oral proceedings. In a communication pursuant to Article 15(1) RPBA, the parties were informed of the board's provisional, non-binding opinion on some of the legal and substantive matters of the case.
- IX. In reply thereto, appellant I submitted also auxiliary requests C1 and C2.
- X. Oral proceedings were held on 22 March 2019, in the absence of the party as of right. At the oral proceedings, appellant I withdrew all pending sets of claims and made auxiliary request B6, submitted with a letter dated 10 March 2014, its main and sole request in the appeal proceedings.

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XI. Claims 1, 4 and 7 of the main (sole) request read as follows:

"1. A pellet-frozen lactic acid bacteria (LAB) culture wherein the LAB is a Lactococcus spp. including Lactococcus lactis subsp. lactis and Lactococcus lactis subsp. cremoris in a commercially relevant package that has a weight of at least 50g frozen material, wherein the frozen material is present in the form of individual pellets, having a content of viable bacteria of at least 10⁹ colony forming units (CFU) per g frozen material and comprising from 0.5% to 13% of an additive compound measured as w/w of the frozen material, wherein the additive compound is an additive compound that is selected from the group of additive compounds consisting of Trehalose and Maltodextrine, and which further is characterized by,

when using an amount of 10% of the additive compound measured as w/w of the frozen material, the compound is able to increase the Tm' (onset temperature of ice melting) of the frozen lactic acid bacteria (LAB) culture, which without the additive compound has a Tm' value from $-70\,^{\circ}\text{C}$ to $-46\,^{\circ}\text{C}$, to a Tm' value above $-46\,^{\circ}\text{C}$, such as from $-45\,^{\circ}\text{C}$ to $-15\,^{\circ}\text{C}$ (measured by DSC)

and wherein the frozen lactic acid bacteria (LAB) culture is characterized by that when stored at approximately -46°C for 7-14 days the individual pellets of the frozen culture are not sticking together and therefore substantially remain as individual pellets where this is measured by following test

the individual pellets of the frozen culture are pellet frozen in liquid nitrogen and 100 individual pellets (around 5-100 g of pellets) are poured into a

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petridish, thus forming a thin layer of loose individual single pellets, the layer being characterized in that the majority of the pellets are in physically contact with one or more, of its neighbor pellets, placed at approximately -46°C for 7-14 days and examined to see if the pellets are still loose or if the pellets had made clumps or are sticking together wherein the criteria for that the individual pellets of the frozen culture substantially remain as individual pellets are that at least 80 of the 100 individual pellets remain as loose individual single pellets;

with the exception of a frozen lactic acid bacteria (LAB) culture that comprises LAB that are able to utilize sucrose.

- 4. A method for making a pellet-frozen lactic acid bacteria (LAB) culture of any of the claims 1 to 3 comprising the following steps:
- (i) adding an additive compound to viable bacteria to get at least 50~g of material with a content of viable bacteria of at least 10^9 colony forming units (CFU) per g material and comprising the additive compound in an amount from 0.5% to 13% measured as w/w of the material,
- (ii) freezing the material to get pellet-frozen material, and $% \left(\frac{1}{2}\right) =\frac{1}{2}\left(\frac{1}{2}\right) +\frac{1}{2}\left(\frac{1$
- (iii) packing the pellet-frozen material in a suitable way to get a packed frozen lactic acid bacteria (LAB) culture of any of the claims 1 to 3.
- 7. Use of the pellet-frozen lactic acid bacteria (LAB) culture of any of claims 1-3 in a process for making a food or feed product".

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Dependent claims 2-3 and 5-6 define specific embodiments of the product or method of claims 1 and 4, respectively.

- XII. The following documents are cited in this decision:
 - D2: WO 2004/065584 (publication date: 5 August 2004);
 - D20: Chr. Hansen "Emmenthal Cheese Types", First revised edition, March 2002;
 - D21: API 50 CHL Medium kit instructions, 1998;
 - D22: H. de Roissart and F. M. Luquet, "Bactéries Lactiques", 1994, Vol. 1: 70, 71, 74 and 82.
- XIII. Appellant I's submissions, insofar as relevant to the present decision, may be summarised as follows:

Admission of the main request (Article 12(4) RPBA)

The main request should be admitted into the appeal proceedings, since it had been filed (as auxiliary request B6) in reply to the opponents' statement of grounds of appeal.

Admission of documents D20 to D22 (Article 12(4) RPBA)

Documents D20 to D22 should not be admitted into the appeal proceedings. They were late filed and were not submitted as a direct response to issues raised by the opposition division in the decision under appeal but as further evidence. They could have been filed before the opposition division and all documents lacked relevance too.

Main request

Article 123(2) EPC - claim 1

The subject-matter of claim 1 was amended by deleting members of two lists relating either to equally preferred microorganisms or additive compounds. Such an amendment amounted to a mere shrinkage of two lists of a certain size, but not to a selection of members from two lists, and hence, did not comprise added subjectmatter. Furthermore, the patent application provided on page 11, lines 20 to 24 a basis for the specific socalled "O-culture" lactic acid bacteria (LAB) frozen pellet, i.e. Lactococcus spp. including Lactococcus lactis subsp. lactis and Lactococcus lactis subsp. cremoris, and for the disclaimer cited in claim 1. LAB that were not able to use sucrose were cited throughout the patent application. Further, Examples 1 and 2 of the patent application disclosed the specifically LAB species cited in claim 1, including the use of trehalose and maltodextrin as additive compounds.

Article 123(3) EPC - claim 1

The deletion of members from the list of additive compounds referred to in claim 1 did not broaden the scope of protection of that claim compared to that of claim 1 as granted, since the parts of the claim relevant for defining its scope had not changed. Accordingly, the situation dealt with in decision T 2017/07 of 26 November 2009 did not apply to the present case.

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Claim construction - claim 1

Claim 1 was directed to a pellet-frozen LAB culture requiring inter alia that, when 10% additive compound was used, the onset temperature of ice melting (Tm') was increased to a value above -46°C, and that, when stored at approximately -46°C for 7-14 days, the individual frozen pellets of the LAB culture did not stick together. These functional features in claim 1 excluded additive compounds that, in the concentration range of "0.5% to 13%", did not prevent frozen pellets of LAB cultures from sticking together under the defined storage conditions, i.e. non-functional embodiments were excluded from the scope of the claim.

Article 84 EPC - claim 1

The terms "LAB culture" and "LAB" as referred to in claim 1 were clear. The former related to a culture that comprised either several or single LAB species, while the latter defined the particular species that was/were contained in that culture.

Article 83 EPC - claim 1

Claim 1 required that pellet-frozen LAB cultures did not stick together when stored at -46°C for 7-14 days as determined by a specific test indicated in the claim. The patent taught the skilled person how this result could be achieved, namely by using an additive compound that increased the Tm' of the frozen Lactococcus culture to a value above -46°C, i.e. the storage temperature. The experimental data in the patent demonstrated that this effect was achieved for a pellet-frozen LAB "O-culture" (a mixture of Lactococcus lactis subsp. lactis and Lactococcus lactis subsp.

cremoris) when using either maltodextrin or trehalose as additive compounds (see e.g. page 11, lines 20-24, page 16, lines 12-15, page 20, lines 1-3, and Tables 2, 3 and 6 of the patent application). Moreover, the skilled person was able to obtain non-sticky pelletfrozen Lactococcus cultures kept under the storage conditions recited in claim 1 over substantially the whole breadth of the claim without undue burden by performing standard tests and using the specific concentrations of maltodextrin or trehalose indicated in claim 1. The results shown in Table 6 were fully in line with the teaching disclosed in the patent application and informed the skilled person that nonsticking frozen pellets of Lactococcus cultures could be obtained - by using concentrations of maltodextrin falling within the range given in claim 1 - in the presence of a Tm' increasing effect. No undue burden was required from the skilled person to determine and measure the Tm' of a frozen Lactococcus culture by using standard methods well-known in the art (see page 18, line 11 to page 19, line 2, and Example 1 of the patent application). Lastly, non-functional embodiments were explicitly excluded from the claim by the functional features present in the claim.

Article 56 EPC - claim 1

Although document D2 was identified in the decision under appeal as the closest prior art for the claimed pellet-frozen LAB cultures, this document concerned the viability of stored frozen LAB cultures and there was no reference to the need for preventing the stickiness or clumping of pellet-frozen LAB cultures. Document D2 did not deal with the problem underlying the patent and it had thus a purpose different from that of the patent. Therefore, according to the established case

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law, it was not an appropriate starting point for a problem-solution approach.

In any case, starting from document D2, the technical problem to be solved was considered as the provision of an improved pellet-frozen LAB culture. The claimed pellet-frozen LAB culture provided a non-obvious solution to this problem. Document D2 did not point at the use of trehalose or maltodextrin in the concentration range recited in claim 1 for preventing stickiness of pellet-frozen LAB cultures under the storage conditions specified in claim 1. Indeed, document D2 was silent on the relevance of sticking or clumping of stored pellet-frozen LAB cultures.

Moreover, the disclosure of document D2 addressed solely pellet-frozen LAB cultures of strains that were able to utilise sucrose, while the cultures of claim 1 were limited to strains that were not able to use sucrose. In view thereof, hindsight knowledge of the patent was required for a skilled person to look at LAB strains that were not able to utilise sucrose when starting from document D2, even though these strains formed part of the common general knowledge of the skilled person. Thus, document D2 did not provide any suggestion, let alone a motivation, directing a skilled person to a pellet-frozen LAB culture according to claim 1.

XIV. Appellant II's submissions, insofar as relevant to the present decision, may be summarised as follows:

Admission of the main request (Article 12(4) RPBA)

The main request was late filed and reasons why it could not have been filed at earlier stages of the

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proceedings or with the statement of grounds of appeal were not provided. Furthermore, the submission of the main request at this late stage extended the appeal proceedings, the request did not overcome the deficiencies of previous requests and introduced new, complex issues.

Admission of documents D20 to D22 (Article 12(4) RPBA)

Documents D20 to D22 should be admitted into the appeal proceedings since they were all submitted with the statements of grounds of appeal and hence, at the earliest possible time in the proceedings. They were filed in direct response to a decision taken by the opposition division during the oral proceedings in the context of inventive step and concerning the non-ability of certain LABs referred to in the closest prior art document D2 to utilise sucrose. Documents D21 and D22 were relevant for the subject-matter of claim 1 since they addressed the issue that LAB strains utilising sucrose were excluded from the claim by way of a disclaimer. Document D22 related to a textbook which represented the common general knowledge of the skilled person.

Main request

Article 123(2) EPC - claim 1

Claim 1 related *inter alia* to a restricted set of pellet-frozen LAB species and additive compounds. These restrictions resulted from a two-fold selection of individual members derived from two different lists, which according to the case law (see "Case Law of the Boards of Appeal of the EPO", 8th edition 2016, II.E. 1.4.2, 420; T 1374/07 of 13 January 2009), amounted to

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a new combination of LAB species and additive compounds. Claim 1 further comprised an amended disclaimer that was broader than that disclosed on page 6, lines 5 to 11 of the patent application. The combination of the specific LAB organisms, additive compounds and the amended disclaimer as referred to in claim 1 was neither individualised nor indicated as preferred in the patent application. Thus, claim 1 encompassed added subject-matter.

Article 123(3) EPC - claim 1

Claim 1 was directed to a pellet-frozen LAB culture composition in which, inter alia, the amount of additive compounds was defined by the range of "0.5% to 13%". This range excluded the presence of the specific additive compounds cited in the claim in amounts outside of the range. However, by deleting some of the individual additive compounds from the list referred to in claim 1 as granted, claim 1 of the main request allowed the presence of the deleted additive compounds in amounts outside the range of 0.5% to 13%. This was so because the pellet-frozen LAB culture was defined in claim 1 as "comprising" additive compounds and thus, it was open to, and allowed for, the presence of other additive compounds. Indeed, the presence of any of these compounds in the LAB culture medium was not excluded in claim 1. Accordingly, the restriction in claim 1 of additive compounds to maltodextrin and trehalose broadened the scope of protection of the claim when compared to that conferred by claim 1 as granted. This interpretation was supported by the case law (see "Case Law", II.E.2.4.13, 469; T 2017/07, supra).

Claim construction - claim 1

The pellet-frozen LAB culture according to claim 1 was defined *inter alia* by two functional features, namely (i) when using an amount of 10% additive compound, the Tm' of the LAB culture was increased to a value above -46°C, and (ii) when storing the LAB culture at approximately -46°C for 7-14 days, the individual pellets did not substantially stick or clump together. Although claim 1 required that a 10% concentration of additive compounds achieved an increase of the Tm' above -46°C, the claim allowed a concentration range of 0.5% to 13% and thus, encompassed amounts of additive compounds below 10% that did not necessarily achieve this effect.

Article 84 EPC - claim 1

The terms "LAB culture" and "LAB" as recited in claim 1 were unclear because the former related to a plural form of LAB species, while the latter to a single species. In other words, both terms had an inconsistent meaning.

Further, the recited storage temperature of "approximately -46°C" in feature (ii) was inconsistent with the value of "above -46°C" in feature (i), since it comprised temperatures lower than -46°C, for example, -46.1°C. However, it was not clear how sticking or clumping was prevented at these lower temperatures.

Article 83 EPC - claim 1

The skilled person could not obtain pellet-frozen Lactococcus spp. across the whole breadth of the claim without undue burden. It was necessary to test the Tm' increasing effect of trehalose and maltodextrin on all individual pellet-frozen Lactococcus species in the concentration range of 0.5% to 13% as indicated in the claim, in particular between 0.5% to below 10%. This included their testing in the presence of other compounds (such as cryoprotective agents, etc.), which were not excluded from claim 1. The patent application did not provide guidance regarding which concentration of additive compounds achieved the Tm' increasing effect, except for a 10% concentration. As regards concentrations below 10%, the patent application disclosed that 5% trehalose failed to increase the Tm' of a pellet-frozen Lactococcus culture to a value above -46°C (see Figure 1); there were thus serious doubts that a Tm' increasing effect could be achieved with even lower amounts. Likewise, as shown in Table 6 of the patent application, no Tm' increasing effect was achieved with 4.0% maltodextrin.

Table 6 further showed that concentrations of maltodextrin falling within the range of 0.5% to 10% failed to increase the Tm' of various pellet-frozen LAB cultures to a value above -46°C when glycerine as a conventional cryoprotective agent was present, even though Table 3 showed that this agent alone (here named "glycerol") had no effect on the Tm' of a pellet-frozen Lactococcus culture. The data shown in Tables 3 and 6 were all obtained by using maltodextrin "DE 12" ("DE" stands for "dextrose equivalent", while the number indicates the amount of individual D-glucose units in maltodextrin, or in other words its chain length;

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comment added by the board). According to the patent application, maltodextrins in the range of "DE 2" to "DE 19" were preferred (see e.g. page 14, lines 18 and 19). However, the patent application provided neither information nor guidance regarding the Tm' effect of each type of maltodextrin on pellet-frozen LAB cultures, not even for the preferred ones.

Moreover, Lactococcus organisms were known to be very heterogenous and that different Lactococcus species could produce, depending on culture medium and substrate, different types and amounts of organic acids, which themselves could influence the Tm' of the frozen pellets. However, the patent application was silent on how the impact of organic acids on the Tm' was to be reduced, for example, by a washing step of Lactococcus strains before freezing.

In view of the reported failures of the additive compounds to achieve the required Tm' effect and the lack of information and guidance in the patent application, the skilled person had to embark on a research program in order to obtain the claimed pelletfrozen LAB cultures across the whole breadth of the claim.

Article 56 EPC - claim 1

Document D2 represented the closest prior art for the pellet-frozen LAB culture according to claim 1. The claimed cultures differed from those disclosed in document D2 only in that they were limited to "O-cultures", and in that LAB cultures utilising sucrose were excluded. However, there was no technical effect associated with these differences, since the evidence on file showed that no effect could be attributed to

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the alteration from one LAB strain to another.

Accordingly, the technical problem was the provision of an alternative pellet-frozen LAB culture.

The subject-matter of claim 1 as a solution to this problem was obvious to the skilled person, since it merely constituted an arbitrary selection of lactic acid bacteria. The teaching in document D2 was focused on the provision of stable pellet-frozen LAB cultures. Although this document mentioned that the ability of various LAB strains to use sucrose was a cause of their instability when stored in pellet-frozen form, document D2 was not bound by this theory.

The skilled person was well aware in view of his or her common general knowledge at the relevant date of the patent that some of the Lactococcus strains comprised in O-cultures were able to use sucrose, although document D2 explicitly stated that they were incapable of doing so. Consequently, the skilled person would have recognised that the theory in document D2 as set out above was not correct and could be ignored. In doing so, the skilled person would have arrived at the pellet-frozen Lactococcus cultures according to claim 1, i.e. comprising Lactococcus that were not able to utilise sucrose, in an obvious manner.

- XV. Appellant I requests that the decision under appeal be set aside and that a patent be maintained on the basis of the claims of the main request submitted as auxiliary request B6 on 10 March 2014. Furthermore, it requests that documents D20 to D22 not be admitted into the appeal proceedings.
- XVI. Appellant II requests that the decision under appeal be set aside and that the patent be revoked. It further

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requests that documents D20 to D22 be admitted into the proceedings.

Reasons for the Decision

1. The duly summoned party as of right (opponent 01) did not attend the oral proceedings, which in accordance with Rule 115(2) EPC and Article 15(3) RPBA took place in its absence.

Admission of the main request (Article 12(4) RPBA)

- 2. The main request was filed as auxiliary request B6 by appellant I in reply to the statements of grounds of appeal of the other parties in these proceedings (see section V above). According to Article 12(1) and (4) RPBA, the request would therefore normally be, as a rule, part of the appeal proceedings. With reference to Article 12(4) RPBA, however, this rule does not apply under all circumstances, since the provision refers to the power of the boards of appeal to hold inadmissible, i.e. exclude, inter alia, requests filed for the first time in reply to the statements of grounds of appeal of the other parties which could have been filed during the first instance proceedings.
- 3. In its communication in preparation of the oral proceedings, the board observed that the reference to fungal species had been deleted in claim 1 of auxiliary request B6 (now the main request). This amendment aims at remedying a possible lack of clarity issue that had been raised by the opponents for the first time at the oral proceedings before the opposition division, and which the opposition division decided in the patent proprietor's favour (see page 14, point 4.3 of the

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decision under appeal). In these circumstances, the board concludes that this amendment could not have been introduced earlier by appellant I.

- 4. Further and contrary to appellant II's view, the board considers that the deletion of fungal species from claim 1 is a straightforward amendment that does not extend the appeal proceedings. Nor does this amendment raise any new complex issues.
- 5. Consequently, the main request is considered in the appeal proceedings.

Admission of documents D20 to D22 (Article 12(4) RPBA)

- 6. With their statements of grounds of appeal, appellant II and the party as of right (opponent 01) submitted document D20 and documents D21 and D22, respectively.
- 7. As set out above, according to Article 12(4) RPBA these documents are normally, as a rule, part of the appeal proceedings. The boards however have a discretion according to Article 12(4) RPBA to exclude documents from the appeal proceedings when account is taken, inter alia, on whether or not a convincing case has been made as to why the documents could not have been filed earlier, and as to why they are prima facie relevant.
- 8. In its communication in preparation of the oral proceedings, the board observed that document D20 was submitted by appellant II in support of a new and independent line of attack with regard to inventive step. Moreover, whilst claim 1 is directed to pelletfrozen lactic acid bacteria (LAB) cultures wherein the

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LAB is a *Lactococcus* spp., the pellet-frozen LAB cultures referred to in document D20 are mixtures of several *Lactococcus* spp. and *Leuconostoc cremoris* (see page 4, point 3 of document D20), i.e. a LAB culture different from that referred to in claim 1.

- 9. Documents D21 to D22 were submitted by the party as of right (opponent 01) in support of its case on inventive step in relation to document D2 as closest prior art. The party as of right submitted inter alia that documents D21 to D22 provided evidence that strains of Lactococcus lactis subsp. lactis and cremoris were able to utilise sucrose (see column "31" in the Table of document D21; and Tables 3 and 11 of document D22).
- 10. Considering the relevance of documents D21 and D22, it may be acknowledged that they have been filed as documentary evidence of the common general knowledge of a skilled person at the relevant date of the patent. In the board's view, this common general knowledge was already well established in the art and, as stated in the patent itself, the skilled person was well aware in relation to LAB species that "Even though some of these species in general are described as capable of utilising sucrose mutants that are not able to utilise sucrose, have been, and will continuously be isolated" (see paragraph [0050] of the patent). The same principle applies to those species which in general are described as not being able to utilise sucrose.
- 11. In the board's view, there is thus no need to provide further evidence of this common general knowledge for assessing the teaching of document D2 in the eyes of a skilled person. The relevant fact rather is that, regardless of whether the LAB strain is a wild-type or

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a mutant thereof, document D2 clearly and explicitly emphasises throughout the document that its teaching applies only to "LAB that are able to utilize sucrose" (see e.g. page 1, line 5 or page 6, line 5), thereby excluding LAB species that are not able to utilise sucrose, i.e. those referred to in claim 1 (see section XI above).

12. Thus, the disclosures of documents D20 to D22 lack relevance and, accordingly, these documents are not admitted into the appeal proceedings.

Article 123(2) EPC - claim 1

- 13. The issue to be assessed is whether or not the features: i) "wherein the LAB is a Lactococcus spp. including Lactococcus lactis subsp. lactis and Lactococcus lactis subsp. cremoris", ii) "an additive compound that is selected from the group of additive compounds consisting of Trehalose and Maltodextrine", and iii) "with the exception of a frozen lactic acid bacteria (LAB) culture that comprises LAB that are able to utilize sucrose", as referred to in claim 1, can be directly and unambiguously derived by the skilled person, using common general knowledge, from the patent application as a whole.
- 14. The patent application reads on page 10, lines 16 to 18 in relation to a pellet-frozen LAB culture that it "may be any in particular commercial relevant LAB that do not utilize sucrose ..." (emphasis added by the board). Page 10, lines 22 to 27 in the patent application further discloses in this context that "Preferably, the LAB is a LAB selected from the group comprising Bifidobacterium spp., Brevibacterium spp., Propionibacterium spp., Lactococcus spp. including

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Lactococcus lactis subsp. lactis and Lactococcus lactis subsp. cremoris, Lactobacillus spp. including Lactobacillus acidophilus, Streptococcus spp., Enterococcus spp., Pediococcus spp., Leuconostoc spp., Oenococcus spp. and fungal spp. including Pencillium spp., Cryptococcus spp., Debraryomyces spp., Klyveromyces spp. and Saccharomyces spp." (emphasis added by the board).

- 15. Furthermore, page 11, lines 20 to 24 in the patent application reads as follows: "The culture as described herein may comprise LAB that are not able to utilize sucrose. An so-called O-culture is used to make cheese without holes (Cheddar, Cheshire, Feta) and typically comprises one or more organisms selected from the group comprising Lactococcus lactis subsp. lactis and Lactococcus lactis subsp. cremoris. In general O-cultures are considered not to utilize sucrose" (emphasis added by the board).
- 16. In the board's view, the skilled person would directly derive from the passages of the patent application indicated above that all LAB species are equally preferred and that, in particular, an "O-culture" comprising various Lactococcus species, namely those cited in claim 1, are not able to utilise sucrose. In other words, the specific LAB organisms and the disclaimer referred to in claim 1 are disclosed in combination in an individualised form in the patent application. Accordingly, a two-fold selection from any list concerning these two features of claim 1 is not required (see "Case Law", II.E.1.4.2, 420; T 1374/07).
- 17. With regard to the additive compounds, claim 6 as originally filed reads as follows: "The pellet-frozen culture of any of the preceding claims, wherein the

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additive compound is an additive compound selected from the group consisting of Cyclodextrin, Maltitol, Trehalose, Fish gelatin, Maltodextrine, Yeast Extract and Spray gum" (emphasis added by the board).

- 18. Furthermore, regarding a combined disclosure of "O-culture" and additive compounds, Example 1 in the patent application reports on page 16, lines 10 to 15:

 "R604-E (a commercially available frozen O-culture, Chr. Hansen A/S, Denmark) tends to form sticky pellets during frozen storage. In the present study this problem is approached by taking a closer look at the melting temperature, and trying to increase it by adding caseinate, sucrose or maltodextrin" (emphasis added by the board).
- 19. Also, Example 2 discloses a combination of the O-culture "R604-E" and additive compounds, including maltodextrin and trehalose, for assessing the effect of such a compound on the Tm' of a pellet-frozen Lactococcus culture. The patent application reads in this context: "In working example 2 it can be seen that Cyclodextrin increased Tm' to -44°C, Maltitol increased Tm' to -42°C, Trehalose increased Tm' to -38°C, Fish gelatin increased Tm' to -37°C, Maltodextrine increased Tm' to -32°C and Spray gum increased Tm' to -31°C" (see page 13, lines 19 to 21, emphasis added by the board).
- 20. In view of theses passages, the patent application discloses that also all of the additive compounds recited in the claim are equally preferred alternatives. Furthermore, the working examples in the patent application explicitly mention some of them, including those recited in claim 1. Thus, there is likewise no two-fold selection from different lists

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required for the specific LABs and the additive compounds referred to in claim 1.

- As set out above, the patent application discloses a combination of Lactococcus spp. including Lactococcus lactis subsp. lactis and Lactococcus lactis subsp. cremoris that are all not able to utilise sucrose (i.e. the disclaimer) as referred to in claim 1. Furthermore, compositions comprising "O-culture" pellet-frozen LAB cultures and trehalose or maltodextrin as additive compounds are disclosed in the working Examples 1 and 2 of the patent application. In the light of these considerations, the board is convinced that the patent application discloses the combination of specific LAB organisms, additive compounds and the disclaimer as referred to in claim 1 in an individualised form.
- 22. Therefore, the claimed subject-matter does not extend beyond the content of the application as filed and Article 123(2) EPC is complied with.

Article 123(3) EPC - claim 1

- 23. Article 123(3) EPC requires that the claims of a patent as granted may not be amended during opposition/appeal proceedings in such a way as to extend the protection conferred. In order to decide whether or not an amendment of the patent in suit satisfies that requirement, it is necessary to compare the protection conferred by the claims before amendment, i.e. as granted, with that of the claims as amended (see "Case Law", II.E.2 et seq., 459).
- 24. <u>Claim 1 as granted</u> is directed to a pellet-frozen LAB culture <u>comprising</u> inter alia a concentration "from 0.5% to 13% of an additive compound measured as w/w of

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the frozen material", wherein the additive compound "is selected from the group of additive compounds consisting of Cyclodextrin, Maltitol, Trehalose, Fish gelatin, Maltodextrine, Yeast Extract and Spray gum".

- In other words, claim 1 as granted defines that a pellet-frozen LAB culture of any type comprises an amount of additive compound that must not be lower than 0.5% or exceed 13% by weight of the frozen material, wherein the additive compound is selected from cyclodextrin, maltitol, trehalose, fish gelatin, maltodextrin, yeast extract and spray gum.
- Thus, while the pellet-frozen LAB culture according to claim 1 as granted contains as "additive compound" those limited to the specific compounds in the concentrations recited in claim 1, it may comprise other compounds (such as those present in the culture medium, for example, nutrients, cryoprotectants, stabilisers, etc.) due to the "open" definition of the pellet-frozen LAB culture composition in the claim. These other compounds are undefined and may be present in any concentration under the proviso that they are not "additive compounds" as functionally defined in the claim.
- Accordingly, due to the "open" definition, claim 1 as granted does not limit the amount of the specific "additive compounds" in an absolute sense, but only in relation to their function as "additive compounds", namely by increasing the Tm' of the frozen LAB culture which prevents sticking/clumping of the individual frozen pellets under the storage conditions defined in the claim. In these circumstances, the pellet-frozen LAB culture of claim 1 as granted may also encompass cyclodextrin, maltitol, trehalose, fish gelatin,

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maltodextrin, yeast extract and spray gum in concentrations exceeding those cited in claim 1.

- Claim 1 as amended is directed to a pellet-frozen LAB culture wherein the LAB is a Lactococcus spp. including L. lactis subsp. lactis and L. lactis subsp. cremoris, comprising a concentration "from 0.5% to 13% of an additive compound measured as w/w of the frozen material", wherein the additive compound "is selected from the group of additive compounds consisting of Trehalose and Maltodextrine".
- 25.1 In other words, <u>claim 1 as amended</u> specifies that in a pellet-frozen *Lactococcus* culture the amount of an additive compound consisting of trehalose or maltodextrin has to fall within the recited concentration range of 0.5% to 13% by weight of the frozen material.
- 25.2 Accordingly, <u>claim 1 as amended</u> is more restricted compared to claim 1 as granted, because it is directed to *Lactococcus* organisms only compared to all LAB organisms, and it is limited to trehalose and maltodextrin as additive compounds.
- Otherwise, claim 1 as amended defines, like claim 1 as granted, the claimed pellet-frozen LAB culture composition "openly". Thus, for the same reasons as those set out above, the pellet-frozen LAB culture may contain cyclodextrin, maltitol, trehalose, fish gelatin, maltodextrin, yeast extract and spray gum in any concentration exceeding the range of 0.5% to 13%, if their function is different from that of an "additive compound" as required by the claim.

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- 26. Appellant II relied in support of its case on decision T 2017/07 (supra). In that decision, claim 1 as granted was directed to a hair dye composition that required inter alia the presence of from 0.5% to 50% of an alkylene carbonate having 3 to 5 carbon atoms. Contrary thereto, the composition in claim 1 as amended was defined as comprising only one of the alkylene carbonates encompassed by claim 1 as granted, namely propylene carbonate. Furthermore, neither in claim 1 as granted nor in amended claim 1, the alkylene carbonate was associated with a functional limitation or any other restriction, i.e. its concentration in both claims was limited in an absolute sense by the indicated range. However, the definition of the hair dye composition in amended claim 1 (like in granted claim 1) was "open" and thus allowed for the presence of additional compounds in any concentration, such as for example, the other alkylene compounds encompassed by claim 1 as granted. In other words, the concentration of alkylene compounds in the hair dye composition of amended claim 1, except for propylene carbonate, was no longer restricted by the range as defined in granted claim 1. In these circumstances, the scope of protection of claim 1 as amended was broader compared to that of claim 1 as granted.
- 27. This situation however, for the reasons set out above, differs from that of the present case. Accordingly, appellant II's argument is not convincing.
- 28. In view of these considerations, the board concludes that the subject-matter of claim 1 does not extend the scope of protection conferred by claim 1 as granted. Thus, Article 123(3) EPC is complied with.

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29. Claim 1 is directed to a pellet-frozen LAB culture wherein the LAB is a Lactococcus spp. including Lactococcus lactis subsp. lactis and Lactococcus lactis subsp. cremoris. The culture is further specified by its weight ("at least 50 g frozen material"), the amount of viable bacteria ("at least 109 colony forming units (CFU) per g frozen material"), and in that it comprises trehalose and maltodextrin as additive compounds in a defined concentration range ("0.5% to 13% w/w of the frozen material"). These additive compounds are further functionally defined in that, when used in a specific concentration ("10%"), they increase the onset temperature of ice melting ("Tm'") of the frozen LAB culture to a value "above -46 °C". Furthermore, the claim functionally defines that, when the pellet-frozen LAB culture is stored at defined conditions ("at approximately -46°C for 7-14 days"), sticking/clumping of the pellets is substantially lacking. Lastly, claim 1 excludes by way of a disclaimer "LAB cultures that comprise LAB that are able to utilize sucrose".

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30. Thus, claim 1 relates to a pellet-frozen LAB culture, i.e. a composition, consisting of Lactococcus spp. organisms only. The composition has a specified weight and viable bacterial content, and further encompasses at least an additive compound consisting of either trehalose or maltodextrin in a defined concentration range. Further, the claim requires that (i) a concentration of 10% of the additive compound increases the Tm' to a value above -46°C, and (ii) the frozen pellets remain "clump-free" when stored at defined conditions. In other words, the functional requirement (ii) excludes from claim 1 those pellet-frozen LAB

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cultures, that clump or stick together when stored under the specified conditions.

Article 84 EPC - claim 1

- 31. Appellant II argued that claim 1 as amended lacked clarity because the terms "LAB culture" and "LAB" referred either to plural or singular forms of LAB, which rendered their meaning inconsistent. Furthermore, it was unclear whether or not the term "LAB culture" referred to a mixed culture containing two or more different LAB species or a single LAB species only.
- 32. The board is not convinced by this argument. As set out above, the term "LAB culture" in claim 1 is to be construed to relate to at least one Lactococcus spp. organism ("spp." stands for "species pluralis", comment added by the board), which may be either a single Lactococcus species or a mixture of two or more Lactococcus species, including but not limited to the two explicitly recited subspecies L. lactis subsp. lactis or L. lactis subsp. cremoris. Thus, the term "LAB culture" in claim 1 cannot be construed to encompass bacteria which are not Lactococcus species, irrespective of whether they belong to the group of lactic acid bacteria or not, since the claim reads explicitly "wherein the LAB is a Lactococcus spp.". In view of these considerations, there is also no discrepancy between the meaning of the terms "LAB culture" and "LAB" as referred to in claim 1.
- 33. In a further line of argument with regard to lack of clarity, appellant II submitted that the storage temperature of "approximately $-46\,^{\circ}$ C" and the Tm' value of "above $-46\,^{\circ}$ C" had an inconsistent meaning in claim 1, since due to the term "approximately" also

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values lower than -46°C, such as for example -46.1°C, were encompassed as storage temperature. This inconsistency left it unclear, how sticking or clumping of the individual frozen pellets was prevented at these lower storage temperatures.

- The board notes that claim 1 as granted already contains the identical wording in relation to the storage temperature and the Tm' value when compared to claim 1 of the main request, in other words, these terms have not been amended in present claim 1.

 Furthermore, since Article 84 EPC is not a ground for opposition, according to established case law (see decision G 3/14 (OJ EPO 2015, A102, catchword), the assessment of this issue under Article 84 EPC is excluded.
- 35. Consequently, the subject-matter of claim 1 is clear, and Article 84 EPC is met.

Article 83 EPC - claim 1

- 36. Several lines of arguments were put forward by appellant II with regard to insufficiency of disclosure including that the skilled person could not obtain the pellet-frozen LAB culture according to claim 1 across the whole breadth of the claim without undue burden. In this context, it was contested that the patent application sufficiently disclosed how pellet-frozen LAB cultures could be obtained that remained "clumpfree" when stored under the conditions recited in claim 1, in particular, at concentrations of maltodextrin or trehalose between 0.5% to below 10%.
- 37. As set out above, claim 1 comprises two functional features. The first requires that in the presence of

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either trehalose or maltodextrin in a concentration of 10%, the Tm' of the pellet-frozen LAB culture is increased to a value of above -46°C. It was uncontested that the data in the patent application demonstrate that an amount of 10% of these two additive compounds achieves this effect under the experimental conditions described in the patent application.

- 38. With regard to the second functional feature, i.e. that the frozen pellets of the LAB culture remain "clump-free" when stored at the conditions referred to in claim 1 over the whole breadth of the claim and, in particular, in the presence of either trehalose or maltodextrin in a concentration below 10%, the following is noted:
- The patent application discloses Differential Scanning Calorimetry (DSC) as a standard method for determining the Tm' value of frozen LAB pellets (see page 9, lines 13 and 14, Example 1 on page 18, line 11 to page 19, line 2). Furthermore, the concentration of trehalose and maltodextrin in the range of 0.5% to below 10% may be determined by standard methods well-known in the art. It was further uncontested that Lactococcus spp. organisms are generally available to the public, and that the test as defined in claim 1 allowed the skilled person to assess the sticking/clumping behaviour of the frozen pellets.
- The patent application discloses in Table 6 that 6%, 6.1%, 6.6% and 10.1% maltodextrin as additive compound increase the Tm' of various pellet-frozen LAB samples to a value above -46°C, and that sticking/clumping of these cultures is prevented when stored at -46°C (see samples designated as "HP B", "LP B" and "LL-2B" in column 1 of Table 6 in conjunction with page 23, line

22 and 23 of the patent application), i.e. maltodextrin achieves the desired effects at a concentration of 10% and below 10%. Table 6 further discloses that in the presence of 10% glycerine, maltodextrin fails to increase the Tm' to a value above -46°C, which accordingly causes clumping of the pellet-frozen Lactococcus samples stored at -46°C. In other words, the data in Table 6 demonstrate that maltodextrin effects on the Tm' and the clumping behaviour of pellet-frozen Lactococcus cultures depend on the presence/absence of glycerine, i.e. a condition that can be readily tested by standard methods in the art, and accordingly, avoided to obtain the claimed pelletfrozen LAB cultures. Furthermore, Table 3 discloses that both 10% trehalose and 10% maltodextrin increase the Tm' of a pellet-frozen Lactococcus culture to a value above -46°C (see first and second rows). The fact that 10% glycerine alone shows no Tm' increasing effect on pellet-frozen Lactococcus cultures as disclosed in Table 3 is considered irrelevant, since glycerine is not specified as additive compound in claim 1.

Thus, the patent application teaches the skilled person that an increase of the Tm' of the pellet-frozen Lactococcus culture to a value above -46°C is the prerequisite for preventing pellet sticking/clumping under the storage conditions specified in claim 1. The patent application further teaches conditions in which the additive compounds referred to in claim 1 either achieve this effect or fail. The skilled person's attention is drawn thereby to the relevance of this prerequisite and to the requirement to carry out appropriate tests for measuring it for the particular Lactococcus spp. culture used. The same applies to the various types of maltodextrins in the range of "DE 2" to "DE 19" as disclosed in the patent application (see

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e.g. page 14, lines 18 and 19). As set out above, tests for determining a potential increase of the Tm' and the assessment of the sticking/clumping of the frozen *Lactococcus* pellets are carried out by methods well-known in the art.

- The board agrees with appellant II that the term

 Lactococcus relates to a group of bacterial species
 that may produce organic acids heterogeneously.

 Appellant II further argues that these organic acids
 may have a negative impact on the Tm'-increasing effect
 of trehalose and maltodextrin on pellet-frozen

 Lactococcus and that the patent application is silent
 on this issue, not teaching how such an impact might be
 minimised, for example, by washing the strains to
 remove the organic acids before freezing them.
- The board notes, however, that there is also no evidence on file showing that the impact of these organic acids on the Tm' of the frozen pellets of LAB cultures is to such an extent that the skilled person cannot obtain, under the specified storage conditions, "non-clumping" frozen LAB pellets according to claim 1 at all or in a significant large number of cases. On the contrary, as set out above, the working examples demonstrate that maltodextrin and trehalose achieve this effect in a commercially available "O-culture".
- 38.6 Similar considerations apply to the fact that 4% maltodextrin or 5% trehalose as shown in Table 6 and in Figure 1, respectively, of the patent application fail to increase the Tm' of the commercial "HP B" and "R604E" cultures above the value of -46°C. Although these commercial cultures contain Lactococcus strains, the single reported failures of the additive compounds on a specific Lactococcus culture is no evidence that

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maltodextrin and trehalose at concentrations below 5% in general do not increase the Tm' of pellet frozen Lactococcus spp. cultures to a value above -46°C.

- 38.7 In these circumstances, the skilled person, by screening different Lactococcus cultures in the presence of trehalose or maltodextrin at the concentrations defined in claim 1, is able to obtain the claimed "non-clumping" frozen LAB pellets over substantially the whole breadth of the claim by performing the routine methods mentioned above. Although this might be a laborious task for the skilled person, carrying out methods well-known in the art that require no inventive skill, does not amount to an undue burden. In this context, it is also of relevance that sticking or clumping frozen LAB pellets, i.e. non-working embodiments, are explicitly excluded from the scope of claim 1.
- 39. Therefore, the guidance provided in the patent application is sufficient to allow the skilled person to obtain "non-clumping" pellet-frozen LAB cultures according to claim 1 across the whole scope of the claim. Consequently, Article 83 EPC is met.

Article 54 EPC - claim 1

40. It was uncontested that the subject-matter of claim 1 is not anticipated by the disclosure of the available prior art documents. Consequently, Article 54 EPC is complied with.

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Article 56 EPC - claim 1

Closest prior art

- 41. The board agrees with the opposition division and appellant II that document D2 represents the closest prior art for the pellet-frozen LAB culture of claim 1. Although, as agreed by all parties, document D2 is silent on the issue of sticking or clumping of pellet-frozen LAB cultures and means for its prevention, the document shares a more general purpose with the patent, namely the provision of pellet-frozen LAB cultures that are stable during storage.
- Document D2 discloses pellet-frozen LAB cultures that utilise sucrose and have a weight of at least 50 g frozen material containing an amount of at least 10⁹ viable CFU per g frozen material (see claim 1, page 10, line 15 to page 11, line 20, and page 13, line 24 to page 14, line 16). The document reports further that these LAB cultures contain cryoprotectants, including trehalose or maltodextrin, in amounts of between 4% to 10% (see page 12, lines 4, 11, 17 and 18).
- 43. The pellet-frozen LAB cultures according to claim 1 differ from those in document D2 in that: i) they are limited to Lactococcus species only, ii) these Lactococcus species are unable to utilise sucrose, and iii) trehalose and maltodextrin, in a limited concentration range, are used as additive compounds to increase the Tm' of the frozen LAB culture to above -46°C. These differences have the effect that pellet-frozen Lactococcus cultures do not stick or clump together when stored at -46°C for 7 to 14 days.

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- 44. Appellant II asserted that no technical effects could be ascribed to the differences indicated above. The board however, in view of the considerations set out above, does not concur with appellant II, since these differences achieve an anti-clumping or anti-sticking effect of individual pellet-frozen *Lactococcus* cultures stored at the conditions defined in claim 1.
- 45. Thus, starting from the teaching of document D2, the technical problem underlying the claimed invention is defined as the provision of an improved pellet-frozen LAB culture composition.
- 46. The subject-matter of claim 1 solves this problem across the whole scope of the claim for the reasons set out above in the context of sufficiency of disclosure.

Obviousness

- 47. It was uncontested that document D2 does not mention the problem of "clumping" or "sticking" of pellet-frozen LAB cultures during storage. Therefore, document D2 does not point at possible solutions of this problem, let alone at the use of maltodextrin or trehalose as "additive compounds" for solving the technical problem defined above. Thus, the subjectmatter of claim 1 cannot be considered obvious in the light of the teaching of document D2 alone.
- 48. With reference to the common general knowledge, appellant II argued that a skilled person would be well aware at the relevant date of the patent that a Lactococcus "O-culture", characterised in document D2 as not being able to utilise sucrose, contains bacteria that are able to utilise sucrose. Therefore, it would have been obvious for the skilled person that the

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storage stability problems of the LAB cultures reported in document D2 are not caused by the bacteria's ability to use sucrose, contrary to the explicit statement in document D2. Consequently, the skilled person would consider the teaching of document D2 to apply also to LAB cultures that are not able to utilise sucrose, such as the LAB cultures cited in claim 1 of the main request.

- 49. The board is not convinced by this argument. Even when account is taken of the common general knowledge of a skilled person as referred to by appellant II, hindsight would have been required in order to set aside the numerous explicit indications given in document D2 - consistently repeated throughout the whole document - that its teaching applies solely to LAB cultures containing bacteria that are able to utilise sucrose (see e.g. a "LD-culture" on page 8, lines 19 to 21 and page 9, lines 1 to 3). Furthermore, as set out above, document D2 is silent on trehalose and maltodextrin playing a role or affecting as "additive compounds" the Tm' of a frozen LAB culture, a role which requires the presence of these compounds in a defined concentration range. Document D2 provides no hint thereto, let alone to the associated anti-clumping or anti-sticking effects on frozen pellets of these LAB cultures.
- 50. Thus, neither the use of LAB cultures that are not able to utilise sucrose nor the presence of maltodextrin and trehalose to achieve a Tm' increase and the associated anti-sticking/anti-clumping effect on frozen pellets of these LAB cultures are obviously derivable from document D2 alone or in combination with the common general knowledge of the skilled person. Hence, Article 56 EPC is complied with.

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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 7 of the main request, submitted as auxiliary request B6 on 10 March 2014, and a description to be adapted thereto.

The Registrar:

The Chairman:



B. ter Heijden

P. Julià

Decision electronically authenticated