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Datasheet for the decision of 9 July 2015

Case Number: T 0112/11 - 3.3.08

Application Number: 99935013.5

Publication Number: 1100868

IPC: C12N1/20, C12N1/04

Language of the proceedings: EN

Title of invention:
PROCESS FOR PREPARING STARTER CULTURES OF LACTIC ACID BACTERIA

Patent Proprietor:
INSTITUT NATIONAL DE LA RECHERCHE AGRONOMIQUE (INRA)

Opponent:
DuPont Nutrition Biosciences ApS

Headword:
Porphyrin starter culture medium Lactococcus/INRA

Relevant legal provisions:
EPC Art. 114(2), 56
RPBA Art. 12(4), 13(1)

Keyword:
Main Request - admissibility (yes); inventive step (no)

Decisions cited:

Catchword:

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Case Number: T 0112/11 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 9 July 2015

Appellant: (Patent Proprietor)	INSTITUT NATIONAL DE LA RECHERCHE AGRONOMIQUE (INRA) 147, rue de l'Université 75338 Paris Cédex 07 (FR)
Representative:	Rançon, Xavier Lucien Abel Cabinet Orès 36, rue de Saint Pétersbourg 75008 Paris (FR)
Respondent: (Opponent)	DuPont Nutrition Biosciences ApS Langebrogade 1 P.O. Box 17 1001 Copenhagen K (DK)
Representative:	Williams, Aylsa D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 November 2010 revoking European patent No. 1100868 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman M. Wieser
Members: P. Julià
J. Geschwind

Summary of Facts and Submissions

I. European patent no. 1 100 868 was opposed on the grounds as set forth in Articles 100(a),(b) and (c) EPC. The opposition division considered the Main Request (claims as granted) and Auxiliary Requests 1-2 to contravene Article 54 EPC and Auxiliary Request 3 to contravene Article 56 EPC.

II. An appeal was lodged by the patentee (appellant). With the statement of Grounds of Appeal, the appellant filed a new Main Request (almost identical to Auxiliary Request 1 filed at first instance) and Auxiliary Requests 1-13.

III. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to Summons to oral proceedings, the parties were informed of the board's preliminary, non-binding opinion on the issues of the case.

IV. With letter dated 7 May 2015, the appellant replied to this communication filing new Auxiliary Requests 14-19.

V. Oral proceedings were held on 9 July 2015. During these proceedings, the appellant withdrew all its previous requests and filed a new Main Request.

VI. Claim 1 of the new **Main Request** reads as follows:

"1. Process for preparing a Lactococcus starter culture, which comprises:

- culturing at least one strain of Lactococcus bacteria under aeration and in an appropriate nutrient medium,

in which at least one porphyrin compound is present or is added;

- harvesting the bacteria at the end of the said culture;

- packaging the harvested bacteria;

- storage of said harvested bacteria, at approximately 4°C, or in frozen or lyophilized form."

Claims 2 to 5 are directed to preferred embodiments of the process of claim 1.

VII. The following documents are cited in this decision:

D1: T. Kaneko et al., Applied and Environmental Microbiology, September 1990, Vol. 56, No. 9, pages 2644 to 2649;

D2a: JP-A-04 36180 (publication date: 6 February 1992);

D2b: English translation of D2a provided by the opponent/respondent with its Notice of opposition;

D6: W.E. Whitehead et al., J. Dairy Sci., 1993, Vol. 76, pages 2344 to 2353;

D7: A.K. Supesteijn, Antonie van Leeuwenhoek, 1970, Vol. 36, pages 335 to 348;

D18: G. Wolf et al., Int. J. Food Microbiol., 1991, Vol. 12, pages 133 to 140;

D26: J.S. Yadav et al., in "A Comprehensive Dairy Microbiology", First edition 1993, "Chapter

13. Starter Cultures", pages 350 to 422;

D39a: H. de Roissart and F.M. Luquet ed., "Bactéries Lactiques", January 1994, Vol. 1, page 540;

D39b: English translation of D39a provided by the respondent in its reply to appellant's Grounds of Appeal;

D47: Declaration of I. Auzanneau (filed by the respondent with letter dated 3 July 2014).

VIII. Appellant's arguments, insofar as they are relevant for this decision, may be summarized as follows:

Admissibility of the Main Request

The claims of the Main Request were identical to claims 1-5 of Auxiliary Request 10 filed with the Grounds of Appeal and thus, they were in the appeal proceedings from the beginning. The Main Request was filed in reply to the board's communication for reasons of procedural efficiency and economy. It simplified the appeal procedure.

Admissibility of documents D26, D39 and D47

Whereas documents D26 and D39 represented the common general knowledge of a skilled person, the late-filed document D47 contained new experimental evidence with non-pertinent data that were never before in the procedure. The filing of this evidence at such a late stage of the proceedings (one month before the oral proceedings) precluded the appellant from performing a detailed analysis, reproduce the experiments and, if necessary, provide experimental counter-evidence.

Main Request
Article 100(a) EPC (Article 56 EPC)

The closest prior art document D6 was concerned with the same purpose as the patent, described the general knowledge in the art of designing dairy starter cultures for industry, indicated products and conditions for achieving these cultures and addressed some of the problems encountered thereto.

Starting from this prior art, the technical problem was the provision of an alternative process for preparing a *Lactococcus* starter culture. This problem was solved by the invention over the entire breadth of the claims. The term "*starter culture*" had the meaning normally given to it in the art (such as in documents D6, D26 and D39), namely a culture that, when inoculated in a fermentation medium, was capable of initiating bacterial growth on an industrial scale. For a starter culture to be useful in a commercial environment, it had to have reproducible properties, such as cell viability and the ability to acidify the fermentation medium.

There was no reason for the skilled person to combine the teaching of document D6 with document D1, since document D1 was concerned with a different purpose, namely to study the role of hemin in aerobically grown *Lactococcus* cultures. Although the stimulation of *Lactococcus* growth under aerobic conditions by incorporation of hemin into the growth medium was known since 1968 (document D7), there had been no incentive for a skilled person to use these conditions in the preparation of starter cultures.

On the contrary, some of the results disclosed in document D1 would have kept the skilled person away from using the conditions described therein for preparing stater cultures. As shown in Figure 1 of document D1, the presence of hemin in the growth medium resulted in a decrease of lactic acid production (with associated pH increase) and an increase of the anti-microbial agent diacetyl. It was known in the art that a good stater culture had to produce lactic acid at steady rate so as to provide sufficient acidity in the fermentation medium. Moreover, a high concentration of an anti-microbial agent could hinder the growth of the starter bacteria. Indeed, document D6 already referred to some problems of *Lactococcus* starter cultures arising from a production of pathogen inhibitors and from the non-maintenance of appropriate pH in the fermentation medium. Although document D1 reported the production of more biomass, the growth of a cell population and the final biomass of the culture were not indicative of its viability. A good starter culture should show good and reproducible cell viability and re-acidification upon inoculation for fermentation, none of these properties was mentioned in document D1. Thus, the combination of documents D6 and D1 was not obvious and required hindsight knowledge of the patent.

Although packaging and storage of starter cultures were known in the art, it was known that these processes caused stress and diminished the viability of these cultures. It could not be expected that, after packaging and storage, *Lactococcus* cultures produced under the conditions of document D1 could be good starter cultures with high viability, the less so in view of the low level of lactic acid produced before

packaging and storage and the presence of anti-microbial agents.

IX. Respondent's arguments, insofar as they are relevant for this decision, may be summarized as follows:

Admissibility of the Main Request

The Main Request was filed only at the oral proceedings. Although it was based on the Auxiliary Request 10 filed with the Grounds of Appeal, no reasons had been given why it could not be filed at an earlier stage of the procedure. It did not *prima facie* overcome the objections raised before the opposition division and should not be admitted into the procedure.

Admissibility of documents D26, D39 and D47

Documents D26 and D39 represented the common general knowledge of the skilled person. Document D47 was *prima facie* highly relevant as it provided experimental evidence to support arguments that were already on file. According to the case law of the Boards of Appeal, one reason for not allowing late-filed experimental evidence was a lack of time for analyzing the evidence, reproduce the experiments and provide counter-evidence. However, the experiments in document D47 reproduced only what allegedly had been done in the patent and thus, there was no need for the appellant to provide any counter-evidence but only to put forward the data obtained when performing the experiment described in Example 1.3 of the patent.

Main Request
Article 100(a) EPC (Article 56 EPC)

Several documents, such as documents D2 or D18 which disclosed almost all technical features characterizing the process of claim 1, could be regarded as representing the closest state of the art. Also document D6 was a candidate for the closest prior art, since it addressed the relevant steps and conditions for preparing bacterial starter cultures for dairy fermentation and identified the advantageous properties of *Lactococcus* bacteria, such as flavour/aroma production and ability to reduce the pH.

Starting from document D6, the technical problem was the provision of an alternative process for preparing a *Lactococcus* starter culture. If the term "*starter culture*" was understood as implying the presence of specific technical features (such as cell viability, reproducibility, etc.), the problem was not solved over the whole breadth of the claims, since the process of claim 1 was not characterized by the use of a specific type of porphyrin, a certain range of porphyrin concentration, specific aeration conditions, oxygen concentrations, bacteria harvesting time, etc. It was not plausible that all embodiments falling within the scope of claim 1 solved the technical problem. If, however, the term "*starter culture*" was broadly understood without requiring any specific technical feature, the underlying technical problem was solved, however, the solution was obvious from the disclosure in the prior art, in particular from document D1.

The advantageous properties of *Lactococcus lactis* bacteria used for the studies reported in document D1 were known in prior art concerned with dairy fermentation, such as documents D6 and D26. Since the presence of hemin under aerobic conditions resulted in enhanced growth of *Lactococcus* culture (higher

biomass), increased production of flavour (acetoin, diacetyl) compounds, and advantageous pH maintenance, the skilled person, when reading document D6, would have immediately realized the relevance of the studies reported in document D1. The information obtainable from Figure 1 of document D1, in particular the concentration of lactic acid during the aerobic fermentation, allowed the skilled person to select appropriate harvesting times. Indeed, claim 1 was not limited to any specific harvesting time. No prejudice was derivable from document D1 that would have prevented a skilled person to use hemin in the production of *Lactococcus* starter cultures under aerobic conditions. Certainly not a prejudice satisfying the strict criteria established in this respect in the case law of the Boards of Appeal. Likewise, according to the case law, the age of documents known long before the filing date was not a criterium on which to base an inventive step.

The packaging and storage steps of the process of claim 1 did not represent a selection from a number of possible alternatives. They were standard, known and generally carried out in the field of dairy starter cultures as shown in the prior art, such as document D39. In fact, the patent itself referred to these steps as well-known techniques and failed to provide evidence for any effect associated therewith.

X. The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of claims 1-5 of the Main Request filed on 9 July 2015 at the oral proceedings before the board.

XI. The respondent requested that the appeal be dismissed.

Reasons for the Decision

Admissibility of the Main Request

1. The Main Request, filed at the oral proceedings, consists of claims 1 to 5, which are identical to claims 1 to 5 of the Auxiliary Request 10 filed with appellant's statement setting out the Grounds of Appeal. Although this request, as such, has been filed only at the latest possible stage of the appeal procedure, all its subject-matter - literally present in former Auxiliary Request 10 - has been in the appeal procedure from the beginning. The respondent, in its reply, did not object to the admissibility of Auxiliary Requests 1 to 13 submitted with the Grounds of Appeal.

2. The amendments made do not add complexity to the case or raise issues which the board or the respondent could not be expected to deal without adjournment of the oral proceedings. On the contrary, they simplify the case and improve the efficiency of the appeal procedure.

3. Thus, the board, in exercising its discretion under Article 114(2) EPC and Article 13(1) RPBA, admits the Main Request into the appeal proceedings.

Admissibility of documents D26, D39 and D47

4. Document D26 was filed by the appellant with its statement of Grounds of Appeal, document D39 by the respondent in reply thereto, thus at the onset of the appeal procedure. Both documents represent the skilled person's common general knowledge as defined in the "Case Law of the Boards of Appeal of the EPO", 7th

edition 2013 (see section I.C.1.6.1, page 74). The board decides to admit them into the appeal procedure.

5. Document D47 was filed by the respondent at a later stage of the appeal procedure and constitutes an amendment to the respondent's case in the meaning of Article 13(1) RPBA. It is an expert declaration with new comparative experimental data which, allegedly, result from a reproduction of Example 1 of the patent.

5.1 The document was filed to support respondent's arguments on insufficiency of disclosure and lack of inventive step, based on an alleged overly broad scope of claim 1, which was not limited to any type and concentration of porphyrin. However, these objections had already been raised at the very beginning of the opposition procedure. Regarding the nature and disclosure of document D47, the board sees no reason why it could not have been filed at an earlier point in time during the opposition procedure in order to give the patentee/appellant a fair chance to defend its patent and the opposition division the opportunity to decide on it (Article 12(4) RPBA). To admit document D47 into the appeal procedure would not be in line with the purpose and function of an appeal, namely to review the decision taken by the department of first instance (cf. "Case Law", *supra*, IV.E.1, page 934).

5.2 Thus, the board, in exercising its discretion under Article 114(2) EPC and Article 12(4) RPBA, does not admit document D47 into the appeal proceedings.

Main Request

6. In view of the decision taken by the board with regard to Article 56 EPC (cf. point 7 onwards), there is no

need to elaborate in this decision on the examination of the requirements of the other articles of the EPC mentioned in the written procedure (Articles 123(2), 83 and 54 EPC).

Article 100(a) EPC (Article 56 EPC)
The closest prior art document

7. Documents D2 and D18 have been cited by the respondent as possible candidates for representing the closest state of the art (cf. point IX *supra*).

7.1 Document D18 discloses studies on the heme-dependent catalase activity of *Lactobacilli* when grown under aerobic conditions in the presence of hematin. Although reference is made to the possible relevance of these studies for selecting appropriate starter organisms and cultures (cf. page 134, second paragraph and page 139, second paragraph), the document mainly focuses on the kinetics and conditions of catalase production and its physiological role for protecting the bacteria against endogenously produced hydrogen peroxide. Document D18 does not refer to the specific *Lactococcus* bacteria of claim 1.

7.2 Document D2 discloses "*a method for increasing the proliferation of lactic acid bacteria and also increasing the antimicrobial substance productivity ... by adding a small quantity of iron porphyrin to a culture medium ... and culturing under aerobic conditions*" (cf. page 3, fourth paragraph of document D2b). The method is exemplified by using a "*diacetyl-producing bacteria belonging to the Lactococcus genus*", in particular a *Lactococcus lactis* subspecies *lactis* (cf. paragraph bridging pages 3-4, pages 6-7, Test Example 2 of document D2b). Haem, haemin and haematin

are mentioned as preferred iron porphyrins (cf. page 4, third paragraph of document D2b). However, there is no reference in document D2 to starter cultures and to the possible relevance of this method for preparing them.

8. According to the case law of the Boards of Appeal, a document does not qualify as closest prior art merely because it discloses a product with a similar composition as a claimed product or because it has the most technical features in common with the claimed subject-matter. The first and foremost consideration in the selection of the closest prior art is that it must be directed to the same purpose or effect as the invention (cf. "Case Law", *supra*, I.D.3.1-3.2, pages 167-168). In line with these criteria, the board considers neither document D2 nor document D18 to represent the closest state of the art.

9. Document D6 is directed to the same purpose as the invention, namely the preparation of starter cultures, in particular dairy starter cultures. The document refers to *Lactococcus* bacteria and to several of its sub-species (*L. lactis* ssp. *lactis*, *L. lactis* ssp. *cremoris*) and to the importance of considering the differences between them when designing media for the preparation of starting cultures (cf. *inter alia*, page 2346, left-hand column). Particular interest is given to the conditions and parameters that have to be considered to optimize bacterial growth and the suitability for the intended use, namely "*to inoculate milk for cheese making*".

10. In line with the established case law (cf. point 8 *supra*), the board decides that document D6 represents the closest state of the art.

The objective technical problem and proposed solution

11. Starting from the disclosure in document D6, the technical problem is seen in the provision of an alternative process for the preparation of a *Lactococcus* starter culture. This problem is convincingly solved by the claimed subject-matter over the entire scope of the claims.

12. The appellant argues that the term "*starter culture*" in claim 1 must be read as a technical feature which, even though implicitly, requires the product resulting from the claimed process to have several specific properties, such as a high quality and reproducible viability. In appellant's view, these properties differentiate a "*starter culture*" from other "*microbial factory cultures*". The purpose of preparing a "*starter culture*" is directly linked to its subsequent use in food (dairy) fermentation in industrial settings and therefore, it underlies more stringent requirements than other factory type of cultures (cf. point VIII *supra*).

13. The board does not share appellant's view. The process of claim 1 is characterized by four steps (culturing, harvesting, packaging and storage) defined in a general manner. No particular degree of quality (purity), viability and/or reproducibility is required in claim 1. It is not appropriate to rely on additional steps and/or specific conditions, not explicitly mentioned in claim 1, for differentiating the claimed process from other methods known in the art. If such additional steps and/or conditions were essential for achieving the desired effect, they had to be mentioned in the claim (cf. "Case Law", *supra*, II.A.3.2, page 252). In the present case, there is no reason for interpreting

the term "*starter culture*" in a narrow manner. In line with the criteria established in the case law of the Boards of Appeal (cf. "Case Law", *supra*, I.C.3.8, page 114), the term *"starter culture"* does not necessarily imply the presence of the optimal properties referred to by the appellant but has to be interpreted in a broad manner.

14. Accordingly, there is no need for the board to consider respondent's arguments regarding the objection that the technical problem has not been solved over the entire scope of the claims, as these arguments are all based on a narrow interpretation of the term *"starter culture"* (cf. point IX *supra*).

Obviousness and expectation of success

15. Document D1 discloses studies on the growth of a *Lactococcus lactis* subsp. *lactis* culture under aerobic conditions in the presence of hemin. It is shown that bacterial growth under these conditions results in the production of more biomass and in an enhanced production of the flavor compounds diacetyl and acetoin instead of lactate (cf. page 2644, abstract and left-hand column). Reference is made to "*great differences in growth, pH, glucose utilization, and end product formation by ... L. lactis subsp. lactis 3022 aerobic cultures with and without hemin (Fig. 1)*". In particular, it is stated that "*cells in hemin-containing culture grew faster and produced more biomass*" and "*the production of diacetyl and acetoin in the culture with hemin after a 48-h incubation was about 10-fold higher*" (cf. page 2645, left-hand column, last paragraph to right-hand column, second paragraph, and page 2646, Figure 1).

16. Although document D1 does not refer to a "*starter culture*", the bacterial strain used is the same as the strain mentioned in document D6 (*Lactococcus lactis* ssp. *lactis*). Whereas document D6 is concerned with the design of starter media to "*maximize the growth of starter bacteria*" (cf. page 2344, right-hand column, third paragraph; page 2346, right-hand column, lines 5-10), document D1 shows the significant differences in both, rate and amount of growth for this bacterial strain under aerobic conditions in the absence and presence of hemin. Although the amount of bacterial cell biomass cannot be directly equated to cell viability, the former is indirectly related to the latter, as at some point during culture, the viability must be high enough to achieve a high biomass.

17. Document D6 also refers to the relevance of maintaining or controlling the pH in the starter medium, in particular to "*prevent the pH from going to ≤5*" (cf. page 2348, second paragraph) which belongs to the skilled person's general knowledge (cf. page 374, paragraph bridging left and right-hand column of document D26). Document D1 reports a pH increase (due to lactate consumption) when the bacterial strain is cultured under aerobic conditions in the presence of hemin (cf. page 2645, right-hand column, second paragraph and page 2646, Figures 1C-1D).

18. Despite this disclosure in documents D6 and D1, the appellant points to several issues that, allegedly, would have prevented a skilled person to combine their teaching and to arrive at the claimed subject-matter in an obvious way (cf. point VIII *supra*).

18.1 As regards an increase in the production of diacetyl and acetoin, it is undisputed that the levels of these

substances are much higher when *L. lactis* subsp. *lactis* is grown under areobic conditions in presence of hemin (cf. Figures 1A and 1B in document D1) and that the anti-microbial properties of diacetyl might inhibit the growth of both non-desirable pathogens and the starter culture itself. However, the skilled person was well-aware of this problem and knew possible means to deal with it (cf. page 2346, right-hand column of document D6), which allowed him/her to conduct the fermentation process at advantageous conditions (i.e. using the advantageous anti-microbial activity against non-desired pathogens and at the same time producing the desired amounts of flavour compounds). The information derivable from Figures 1A and 1B of document D1 also helped a skilled person to achieve these conditions.

18.2 With regard to the decreasing level of lactic acid referred to by the appellant, shown in Figures 1C and 1D of document D1, this level remains identical for more than 24 hours in media with and without hemin. Only after 24 hours there is a significant lactate decrease in the media containing hemin which causes a pH increase. Also with regard to this issue, the information derivable from Figures 1C and 1D of document D1 allows a skilled person to find out and select optimal conditions for the starter culture and to achieve an optimal compromise between decrease in lactic acid production (with increased diacetyl/acetoin production) and pH maintenance.

18.3 Concerning appellant's argument that the high age of some of the cited documents was indicative of an inventive step, it is correct that, according to the case law of the Boards of Appeal, the age of documents known long before the filing date may be an indication of an inventive step. However, this is only used as a

secondary indication in the assessment of inventive step and it does not always have to support it (cf. "Case Law", *supra*, I.D.10.3, page 226). In the present case, it was already known in 1968 that the growth of *Lactococcus lactis* "*is greatly stimulated by incorporation of hemin in the growth medium*" (cf. document D7, page 346, third paragraph). This very old prior art, however, does not contain any information concerning other important parameters, besides growth, which have been disclosed more than thirty years later in the detailed studies of document D1.

19. Thus, the board denies that any of the issues referred to by the appellant would indeed have prevented a skilled person, trying to solve the underlying technical problem, to combine the teaching of documents D6 and D1 and to arrive at the claimed subject-matter in an obvious way. Moreover, the board, in the here relevant prior art, sees no indication of the existence of a technical prejudice as defined in the case law that would have barred him/her from doing so (cf. "Case Law", *supra*, I.D.10.2, page 224).

20. Finally, the features "*packaging*" and "*storage*" indicated in claim 1 are standard in the field of starter cultures and they do not require any inventive contribution (cf. *inter alia*, page 378, point 11, page 387, Figure 13.6, page 389 of document D26, and page 540, second paragraph and Figure 1 of document D39). Indeed, the patent itself refers to these methods as well-known to the person skilled in the art and no particular, let alone surprising or unexpected, effect is shown in the patent to be associated with these specific features or steps in the process of claim 1 (cf. page 4, paragraph [0035] of the patent).

21. As regards the expectation of success, very ambitious problems, like the provision of an improved process, might require the consideration of very specific factors, parameters and conditions, such as those referred to in point 13 *supra*. However, less ambitious problems, i.e. the provision of an alternative process, are generally associated with a higher expectation of success. In view of the underlying, less ambitious technical problem (cf. point 11 *supra*) and the features defining the process of claim 1, a reasonable expectation of success is given.

22. The claimed subject-matter does not involve an inventive step. The Main Request does not fulfil the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Wolinski M. Wieser

Decision electronically authenticated