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Datasheet for the decision of 28 May 2021

Case Number: T 2137/16 - 3.3.09

Application Number: 08801419.6

Publication Number: 2207428

IPC: A23C9/123, A23C19/032, A23C19/076, A23C9/12, A23C9/142

Language of the proceedings: EN

Title of invention:
PROCESS FOR PRODUCING LACTOSE-FREE MILK

Patent Proprietor:
Arla Foods Amba

Opponents:
Valio Ltd
AB Tetra Pak

Headword:
Process for producing lactose-free milk/VALIO

Relevant legal provisions:
EPC Art. 56, 83, 123(2)

Keyword:
Main request: inventive step - (no)
Auxiliary request: added subject-matter - (no); sufficiency of disclosure - (yes); inventive step - (yes)

Decisions cited:
T 0457/02

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 2137/16 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 28 May 2021

Appellant: (Patent Proprietor)	Arla Foods Amba Sønderhøj 14 8260 Viby J (DK)
Representative:	Plougmann Vingtoft a/s Strandvejen 70 2900 Hellerup (DK)
Appellant: (Opponent 1)	Valio Ltd Meijeritie 4 00370 Helsinki (FI)
Representative:	Kolster Oy Ab (Salmisaarenaukio 1) P.O. Box 204 00181 Helsinki (FI)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 20 July 2016 concerning maintenance of the European Patent No. 2207428 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	A. Veronese
	D. Rogers

Summary of Facts and Submissions

I. This decision concerns the appeals filed by opponent 1 and the patent proprietor against the opposition division's decision finding that European patent No. EP 2 207 428 B1 as amended according to auxiliary request 2 meets the requirements of the EPC.

II. With their notices of opposition, the two opponents had requested revocation of the patent in its entirety on the grounds under Article 100(a) (lack of novelty and lack of inventive step), 100(b) and 100(c) EPC.

III. Claim 1 of auxiliary request 2 reads:

"*1. A process for producing lactose-free or substantially lactose-free milk, wherein the pH is not adjusted, comprising the steps of:*

a) Ultrafiltration of original milk to obtain a first permeate and a first retentate;
b) Nanofiltration of said first permeate to obtain a second permeate and a second retentate;
c) Mixing said first retentate with said second permeate to obtain a mixture; and
d) Hydrolysing remaining lactose in said mixture to obtain a hydrolysed milk;

wherein the concentration of lactose in the mixture of said first retentate and said second permeate is 2-4% weight/weight, and wherein no water is added during the process."

IV. The documents submitted during the opposition proceedings included:

D1: US 2007/0166447 A1

D8: WO 00/45643

D15: D. A. Bender et al., Bender's Dictionary of Nutrition and Food Technology, Woodhead Publishing Limited, 7th Edition, 2007, p. 228

D19: Grahn T., "Reduction of lactose content in milk using membrane filtration and enzymatic treatment", Master of Science Thesis, 20 June 2007, Lund University, Sweden

V. With its reply to opponent 1's grounds of appeal, the proprietor filed the following documents:

D22: Printout from http://www.alibaba.com/showroom/lactase-enzyme-powder.html

D23: Product specification for powdered lactase from Biocon

D24: T. Finocchiaro et al., Adv. Biochem. Eng., 2005, vol. 15(71), pp. 71-88

VI. The opposition division found *inter alia* that the subject-matter of auxiliary request 2, which required a lactose concentration of 2-4% wt before hydrolysis and included the requirement that no water is added during the process, met the requirements of Article 123(2) EPC, was sufficiently disclosed and involved an inventive step over D19.

VII. Opponent 2 withdrew its opposition. In the present decision, for improved readability, the appellants are referred to as the proprietor and the opponent.

VIII. With a letter dated 1 October 2020 the proprietor filed a main request and an auxiliary request. The auxiliary request corresponds to auxiliary request 2 which was found allowable by the opposition division.

IX. Claim 1 of the main request differs from claim 1 of the auxiliary request in that the lactose concentration in the mixture of step d) is 2.3% weight/weight and in that the wording "and wherein no water is added during the process" is not present.

X. The proprietor's arguments which are relevant for the decision can be summarised as follows:

- the range 2-4% wt of lactose, and the requirement that no water is added, which characterised the auxiliary request, were disclosed in lines 4 to 5 and 31 to 33 of page 9 and in claim 2 as filed;

- the claimed process was sufficiently disclosed; lactose could be hydrolysed using known methods, even without adding water; the patent described one way of carrying out the process and determining the concentration coefficient of step b); the data on page 8 related to non-hydrolysed milk; since preserving the taste of milk was not a feature characterising the claims, the issue of whether a certain concentration of lactose or potassium was suitable to achieve this effect was irrelevant;

- the claimed subject-matter involved an inventive step; the addition of water during the process was excluded implicitly in claim 1 of the main request and explicitly in that of the auxiliary request; the process claimed in the two requests differed from that described in D19, the closest prior art,

in that no water was added; the problem was the provision of a simpler process for preparing lactose-free milk; D19 did not hint at the claimed solution, because it disclosed a process requiring the addition of water;

- the process of claim 1 of the main request further differed from that of D19 in that the lactose concentration in step d) was lower; in view of this difference, a further problem was the provision of an alternative process for preparing lactose-free milk preserving the taste and sweetness of original milk; this lower concentration could not be obtained following the instructions in D19;

- D1 and D8 did not hint at the claimed solution either; the lactose concentration before hydrolysis in the process of D1 was below the claimed concentration; D8 could not be combined with D19, because it related to a substantially different process.

XI. The opponent's arguments which are relevant for the present decision can be summarised as follows:

- the main request had been filed late and should not be admitted into the appeal proceedings;

- without an indication of the feature of the concentration coefficient of step b) in claim 1 of the auxiliary request, the feature requiring that no water is added during the process added subject-matter; these two features were inextricably linked in the application as filed;

- the claimed invention was insufficiently disclosed; the patent did not teach how to hydrolyse the residual lactose without adding water; hydrolysis had not taken place in the milk in table 1 of the patent, which still contained lactose; the concentration coefficient in step b), essential to avoid the addition of water, was not specified in claim 1; taste and sweetness could not be preserved across the entire range defining the lactose concentration in step d); the potassium content, also important for these properties, was not specified either;

- the claimed invention did not involve an inventive step over D19, the closest prior art, alone or combined with D1 or D8; D19 and D1 pointed to avoiding the addition of water in a process for preparing lactose-free milk; furthermore, D19 and D8 taught carrying out the hydrolysis in step d) in a mixture comprising 3% wt of lactose.

XII. The requests

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, or, alternatively, the auxiliary request, both filed with the letter dated 1 October 2020.

The opponent requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

Main request

1. The opponent requested that the main request not be admitted into the appeal proceedings. In view of the negative finding, set out below, concerning the main request and inventive step, there is no need to deal with this issue.

2. *Inventive step*

2.1 Both parties agreed that, as decided by the opposition division in the decision under appeal, D19 was the closest prior art. The board does not see any reason to deviate from this choice. In the same way as the opposed patent, D19 focuses on processes for reducing the lactose content in milk using membrane filtration steps and enzymatic hydrolysis of the residual lactose. Figure 3 on page 7 of D19 describes a process in which, as in claim 1 of the main request, the milk is subjected to ultrafiltration, nanofiltration and to a step in which the remaining lactose is hydrolysed. The process provides for the addition of water before ultrafiltration or, alternatively, to the mixture comprising the retentate of the ultrafiltration and the permeate of the nanofiltration: see page 3, first paragraph, and figure 3 on page 7. The concentration of lactose before the hydrolysis is not indicated.

2.2 According to the proprietor, the process defined in claim 1 of the main request differs from that of D19, first of all, in that no water is added. In its

opinion, the wording used in claim 1 - "said first permeate", "said first retentate", "said second permeate", "said mixture" - excludes any step which is not explicitly mentioned in the claim. In particular, it excludes any step involving the addition of water.

2.3 This argument is not persuasive. Claim 1 defines a process for producing lactose-free milk "comprising" the steps a), b), c) and d). As stated in point 4.3 of the reasons of decision T 457/02, in patent claims the expression "comprising" is interpreted as "including", "containing" or "comprehending". Consequently, the wording of claim 1 of the opposed patent, in general, does not rule out the presence of further steps beyond those which are explicitly mentioned.

2.4 The proprietor argued that, since the word "said" was used in claim 1, instead of a simple "the", the presence of further steps in the process was excluded. In its opinion, point 4.4 of the reasons of T 457/02 supported this interpretation. Thus, the reference to "said mixture" in step d) excluded the mixture obtained in step c) by mixing the first retentate and the second permeate being mixed further with water prior to the hydrolysing step.

2.5 While the board agrees with the proprietor that, in line with the findings in T 457/02, the reference to "said mixture" in step d) refers to the mixture obtained in step c), the expression "mixing said first retentate with said second permeate" does not exclude further components being added in order to arrive at the mixture referred to in step c). Thus, step c) does not exclude the mixture referred to therein being obtained by mixing the first retentate, the second permeate and water. However, this is what is disclosed

in D19 (see figure 3), where the first retentate, the second permeate and water are mixed prior to subjecting "said mixture" to hydrolysis. In other words, even when applying the rationale of T 457/02, the board arrives at the conclusion that the subject-matter of claim 1 does not differ from the process disclosed in D19 in that no water is added. This interpretation of claim 1 also makes sense considering that claim 2, which depends on claim 1, explicitly excludes the addition of water.

2.6 This means that the process of claim 1 differs from that disclosed in D19 only in that the concentration of lactose in the mixture of steps c) and d), before hydrolysis, is 2-3% weight/weight. This concentration is not specified in the process shown on page 7 of D19 (figure 3).

2.7 As stated in paragraphs [0009] and [0012] of the opposed patent, it is highly desirable to manufacture lactose-free milk retaining the taste and sweetness of the original milk. Paragraphs [0066] and [0072] teach that, when the concentration of the residual lactose before hydrolysis is within the claimed range, the milk has the sweetness and taste of the original milk.

2.8 Starting from D19, the objective technical problem may thus be seen as the provision of a process for producing a milk which is substantially lactose-free, but maintains the sweetness and taste of the original milk.

2.9 The relevant issue is whether, when confronted with this problem, the skilled person would have considered adjusting the concentration of lactose before the hydrolysis step to a value within the claimed range.

2.10 Annex D on page XIII of D19 indicates that, in order to obtain milk having the same sweetness and taste as ordinary milk, the amount of lactose present in the mixture before hydrolysis should be 3.1% wt. Annex D only mentions ultrafiltration. However, it is readily apparent that the teaching of this annex is general and applies to all processes described in D19, including that described on page 7.

2.11 It is also readily apparent from Annex D that the value 3.1% wt is calculated relying on "approximative values" of sweetness: see page XIII, second paragraph. Therefore, the calculated value is also approximative. Furthermore, as conceded by the proprietor, the amount of lactose present in ordinary milk, conferring its sweetness, depends on the animals used, their feed and other factors. This means that, despite being presented as a single value, 3.1% wt is an approximation of the concentration of lactose which the author expects to afford the "same sweetness of ordinary milk". The value of 3% wt in claim 1 is so close to this value that it would be considered to fall within this approximation and to result in a milk having the same properties.

2.12 The proprietor asserted that, following the instructions on pages 14 and 24 of D19, it would be impossible to obtain a residual concentration of lactose within the claimed range of 2-3% wt. Page 24 recommends not exceeding the concentration coefficient of 2 during nanofiltration. According to the proprietor's calculations, working under the recommended operating conditions, the lactose concentration before hydrolysis would be at least 3.75% wt. The board does not agree with these figures, because in its calculations the proprietor ignores the

fact that water is added during the process described in D19. By adding water, the lactose concentration can easily be lowered to the 3.1% wt, or below, mentioned in Annex D.

2.13 For these reasons, the board considers that, when confronted with the underlying problem, the skilled person would have carried out the process described in figure 3 on page 7 of D19, adjusting the concentration of lactose before hydrolysis to 3% weight/weight, i.e. within the range of claim 1.

2.14 A further pointer to the selection of this concentration is found on page 3, lines 1 to 20, and on page 7, lines 3 to 12, of D8. Here, it is confirmed that, to retain the sweetness of the original milk, the residual content of lactose in milk processed by filtration steps, before the final step of enzymatic hydrolysis, should be about 3% by weight. The fact that the process of D8 differs from the claimed process, because it does not involve nanofiltration, does not undermine the relevance of this document's teaching.

2.15 It can thus be concluded that, when confronted with the underlying technical problem, the skilled person would have carried out the process described in figure 3 on page 7 of D19, so that the concentration of lactose in the mixture before hydrolysis would be in the range of 2-3% weight/weight specified in claim 1.

2.16 Consequently, the subject-matter of claim 1 of the main request does not involve an inventive step (Article 56 EPC).

Auxiliary request

3. *Amendments*

3.1 According to the opponent, the requirement in claim 1 that "no water is added during the process" infringes Article 123(2) EPC. In its opinion, in the application as filed this requirement is inextricably linked with the selection of a specific concentration coefficient in step b). The omission of this coefficient in claim 1 creates originally undisclosed subject-matter.

3.2 The board does not share this view. The requirement that no water is added during the process is disclosed in several parts of the application as filed, independently of the selection of a particular concentration coefficient: see for example claim 2 and page 9, lines 4 and 5, as filed.

3.3 Therefore, the requirement that no water is added during the process does not extend beyond the content of the application as filed (Article 123(2) EPC).

4. *Sufficiency of disclosure*

4.1 The opponent argued that the claimed invention is not sufficiently disclosed, because the patent does not teach how to hydrolyse the residual lactose without adding water. Furthermore, the skilled person would not be able to determine the scope of claim 1 or whether work carried out is within or outside that scope. This applies in particular as the lactase used for the hydrolysis described in the patent is dispersed in a solution of glycerol and water.

4.2 These arguments are not persuasive. The hydrolysis of lactose is a well-known process, as shown in the documents cited during the proceedings, e.g. D15 (page 228) and D19 (pages 18 to 19). The skilled person would not consider trace amounts of water used to disperse the lactase used for the hydrolysis to be "water added during the process" within the meaning of claim 1. Moreover, lactase is commercially available in powder form, see D22-D24. Thus, it can be added to the reaction mixture without the addition of any water. Furthermore, the issue of assessing the precise scope of the claims concerns the clarity of the claimed subject-matter rather than sufficiency of disclosure (Case Law of the Boards of Appeal, 9th edition 2019, chapter II.C.8.2).

4.3 The opponent drew attention to the fact that the product shown in table 1 on page 8 of the patent, relating to example 2, contains 2.8% wt lactose. In its opinion, this is evidence that no hydrolysis has taken place during the described process and that the claimed invention cannot be carried out.

4.4 This argument is not persuasive either. Example 1 on page 7 of the patent describes in detail a process for carrying out the invention. The amount of lactose in the original milk is 4.8% wt and that in the final product is less than 0.01% wt. From this information, and taking into account the teaching of the patent, it is evident that, whereas the product in example 1 is the final product of a process according to the invention, the product described in example 2 is that which is obtained in the mixing step c), before the hydrolysis.

4.5 The opponent also argued that claim 1 does not refer to the concentration coefficient in step b), which is an essential feature for carrying out the invention without adding water. However, the skilled person finds, in paragraphs [0038], [0040] and [0042] of the patent, sufficient information to determine the concentration coefficient necessary to avoid the addition of water. Example 1 shows that a concentration coefficient of 5 is suitable to carry out the claimed process.

4.6 Finally, the opponent argued that there is no evidence that maintaining the lactose concentration before hydrolysis within the range of 2-4% wt preserves the original taste and sweetness of the milk. In particular, it disputed that this effect can be achieved across the entire range claimed. However, preserving the sweetness and taste of milk is not a feature characterising claim 1; therefore, it is not an issue concerning sufficiency of disclosure (see Case Law of the Boards of Appeal, 9th edition 2019, chapter II.C.3.2). Furthermore, the opponent did not provide any evidence that the purported effect cannot be achieved. The same considerations apply to the argument that the potassium concentration, which may affect the taste of milk, is not specified in claim 1.

4.7 For these reasons, it is concluded that the claimed invention is sufficiently disclosed (Article 83 EPC).

5. *Inventive step*

5.1 As in the case of the main request, D19 is the closest prior art. The process of claim 1 of the auxiliary request differs from that described in figure 3 on page 7 of D19 in that no water is added and in that the mixture before hydrolysis contains 2-4% wt of lactose. This concentration is not mentioned on page 7. As argued by the proprietor, the effect of avoiding the addition of water is that the process is simpler to perform. The aspect of providing a simpler process is set out on page 2, lines 1-3 and 14-17, of the application as filed, corresponding to paragraphs [0008] and [0011] of the patent. Paragraphs [0075] to [0079] of the patent confirm that the process can be carried out so that loss of water from the original milk is minimised and the addition of water avoided. Paragraphs [0066] and [0072] make it credible that the milk retains the taste and sweetness of the original milk. No evidence to the contrary was provided by the opponent.

5.2 Accordingly, starting from D19, the underlying problem is the provision of a simpler process for preparing a substantially lactose-free milk having a taste and sweetness similar to the original milk.

5.3 The opponent considered that D19 (abstract, page 7, first paragraph, and page 29, second paragraph) would prompt the skilled person to avoid the addition of water because it teaches that water can be recovered from the nanofiltration permeate so that the loss of water during the process is minimised. In the opponent's opinion, the skilled person would thus consider avoiding the addition of water.

5.4 The board does not concur with this view. The opponent's assessment clashes head-on with the teaching of figure 3 on page 7 of D19, which unequivocally provides for the addition of water, either before the ultrafiltration step or before the enzymatic hydrolysis. This means that, according to D19, the addition of water is an absolute requirement, and that this document does not lead the skilled person to the claimed solution.

5.5 The opponent also referred to a combination of D19 with D1. D1 is a document relating to the preparation of lactose-free milk products. The opponent drew attention to paragraphs [0098] and [0099] of D1, which disclose a filtration process for preparing milk-related products not involving the addition of water. In its opinion, these paragraphs provide an incentive to avoid the addition of water during the process. However, as noted by the proprietor, the concentration of lactose in the mixture obtained before hydrolysis according to this passage is 1.6% wt, which is outside the claimed range. Thus, even if considering combining D19 with D1, the skilled person would not have arrived at the claimed solution.

5.6 The opponent argued that paragraphs [0098] and [0099] of D1 should be read in combination with paragraphs [0025], [0026] and [0038], which had more general scope and pointed to the use of higher concentrations of lactose. The board does not agree. These paragraphs cannot be relied on in order to read a broader teaching into the embodiment disclosed in paragraphs [0098] and [0099]; in particular, as noted by the proprietor, paragraph [0038], which is the only one mentioning lactose, discusses the concentration of lactose in the

final product rather than in the mixture prepared before the final hydrolysis.

5.7 Therefore, the board concludes that, as decided by the opposition division, the subject-matter of claim 1 of the auxiliary request involves an inventive step. The same applies to the dependent claims, which are more limited in scope.

Order

For these reasons it is decided that:

1. The appeals are dismissed.

The Registrar: The Chairman:

G. Magouliotis A. Haderlein

Decision electronically authenticated