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**Datasheet for the decision
of 29 May 2013**

Case Number: T 0116/10 - 3.3.10

Application Number: 04724921.4

Publication Number: 1622652

IPC: A61L15/36, A61K35/74,
A45D37/00, A61F13/15

Language of the proceedings: EN

Title of invention:

Hygiene product comprising probiotic composition

Patent Proprietor:

SCA Hygiene Products AB

Opponent:

Ellen Aktiebolag

Headword:

Relevant legal provisions:

EPC Art. 56
RPBA Art. 12(2), 13(1)

Keyword:

Inventive step
(no), main request and auxiliary requests 1 to 5.
Sixth auxiliary request not admitted into the proceedings.

Decisions cited:

Catchword:



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Chambres de recours**

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Case Number: T 0116/10 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 29 May 2013

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
23 November 2009 concerning maintenance of the
European Patent No. 1622652 in amended form.**

Composition of the Board:

Chairman: P. Gryczka
Members: R. Pérez Carlón
F. Blumer

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division to maintain European Patent No. 1 622 652 in amended form upon the basis of the then pending main request, claim 2 thereof reading:

"A hygiene product, such as a sanitary napkin, panty-liner, tampon, diaper, incontinence guard, hygiene tissue, etc. characterized in that said hygiene product is provided with a probiotic composition containing a dispersion of a bacterial preparation in a lipid phase, said bacterial preparation containing at least one lactic acid producing bacterial strain and starch as contact sorption drying carrier."

- II. Notice of opposition had been filed by the appellant requesting revocation of the patent in its entirety on the grounds that the invention was not sufficiently disclosed for it to be carried out (Article 100(b) EPC) and that the subject-matter claimed was not novel and lacked an inventive step (Article 100(a) EPC).

- III. *Inter alia*, the following documents were submitted during opposition proceedings:

D1a: WO 02/28446

D18: Kudra and Mujumdar, Advanced Drying Technologies, Marcel Dekker, Inc. New York, Basel 2002, pages 157-185.

- IV. The opposition division considered document D1a as the closest prior art. In the light of D1a, the problem to be solved by the claimed invention was the provision of a hygiene product containing a bacterial composition

with prolonged shelf life, and the solution proposed was not obvious, as starch was not a usual additive for drying and there was no indication that it could lead to an improved shelf life. The subject-matter claimed was, therefore, inventive.

Document 18, which was then numbered as document D12, was not admitted into the proceedings since it had been late filed and was considered *prima facie* not relevant.

- V. With a letter dated 3 August 2010, the respondent (proprietor) filed five sets of claims as auxiliary request 1 to 5, the main request corresponding to the main request pending before the opposition division. During the oral proceedings held before the board on 29 May 2013, the respondent submitted a sixth auxiliary request.
- VI. Independent claim 2 of the main request is present in auxiliary requests 1 to 5, in the form of claim 2 of the first to the fourth auxiliary request, and in the form of claim 1 of the fifth auxiliary request.
- VII. The arguments of the appellant relevant for the present decision can be summarised as follows:

The embodiment on page 17, lines 3-10 of document D1a represented the closest prior art, and differed from the subject-matter claimed since it disclosed the genus carbohydrates whereas claim 2 required the more specific embodiment "starch". The data on file did not show any improvement associated to this distinguishing feature, so that the problem to be solved was merely the provision of an alternative hygiene product. Since the choice of starch was a non-purposive selection among carbohydrates, the subject-matter of claim 2 was

not inventive. Even if an improvement in terms of shelf life would be acknowledged, the subject-matter of claim 2 was obvious in the light of the combination *inter alia* of documents D1a, which disclosed that carbohydrates were both suitable nutrients for bacteria dispersions in absorbing sanitary articles and additives which could be mixed with said bacteria before freeze drying, and D18, which disclosed starch as a contact sorption drying agent (in the form of wheat bran) and as a lactic acid bacteria nutrient (in the form of corn meal). The subject-matter of claim 2 was, hence, not inventive. Since auxiliary requests 1 to 5 contained a claim identical to claim 2 of the main request, none of them was allowable.

With respect to auxiliary request six, filed during the oral proceedings before the board, the appellant argued that in the absence of any new issue such a late filing could only be due to strategic reasons. Claim 1 referred to a new combination of features which had not been put forward before, and the appellant was not prepared to react to this new procedural situation. For these reasons, the appellant requested that the sixth auxiliary request was not admitted into the proceedings.

VIII. The arguments of the respondent relevant for the present decision are as follows:

The closest prior art was document D1a, in particular the embodiment disclosed on page 7, lines 3-9. This embodiment differed from the subject-matter of claim 2 of the main request in the nature of the nutrients added. The problem to be solved was providing an absorbent article containing lactic acid producing bacteria with improved shelf life, and the solution,

which was using starch as a contact sorption drying carrier, was not obvious since no incentive could be found in the prior art for using starch in order to achieve such an improvement. The combination of documents D1a and D18 did not lead to the claimed invention since not every starch was a contact sorption drying carrier. The skilled person would not consider adding a nutrient such as starch to bacteria before drying, and D18 failed to disclose starch as a suitable contact sorption drying carrier for bacteria. For these reasons, the subject-matter of claim 2 of the main request and of the first to fourth auxiliary requests and of claim 1 of the fifth auxiliary request was inventive.

With respect to the sixth auxiliary request, the appellant argued that it should be admitted into the proceedings as it represented its last opportunity to defend its case. Since the subject-matter of this request resulted from the combination of the features of claim 2 of the main request with a feature which had been present in independent claim 1 from the beginning of the proceedings, and which had been thoroughly discussed, it did not introduce any new, unexpected issue.

IX. The final requests of the parties were as follows:

- The appellant requested that the decision under appeal be set aside and the patent be revoked.
- The respondent requested that the appeal be dismissed or, subsidiarily, that the patent be maintained on the basis of any of the first to sixth auxiliary requests, the first to fifth auxiliary requests as filed with a letter dated

3 August 2010, the sixth auxiliary request as filed during the oral proceedings before the board.

- X. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request:

2. Since the board arrived to the conclusion that the subject-matter of claim 2 of the main request is not inventive, it is not considered necessary to discuss whether the subject-matter of any of claims 1 and 3-11 is novel, or whether the subject-matter of these claims is sufficiently disclosed.
3. Neither the opposition division nor the appellant had any objection with regard to the novelty of the subject-matter of claim 2 of the main request, and the board sees no reason to depart from this view in the light of the available prior art, as D1a fails to disclose a hygiene product comprising starch.

The sufficiency of the disclosure of the subject-matter of claim 2 has not been challenged in these appeal proceedings.

Inventive step:

4. Claim 2 of the main request is directed to a hygiene product comprising a probiotic composition containing a

dispersion of a bacterial preparation in a lipid phase, said bacterial preparation containing at least one lactic acid producing bacterial strain and starch as contact sorption drying carrier.

5. Closest prior art:

- 5.1 In agreement with the opposition division and the parties, document D1a is considered the closest prior art.

D1a discloses absorbent articles containing a dispersion of lactic acid producing bacteria in a lipid phase, said dispersion comprising carbohydrates added to said bacteria before freeze drying (see page 17, lines 3-10). D1a does not closer define the type of carbohydrates suitable as additives.

D1a fails thus to disclose a hygiene product comprising the specific carbohydrate starch.

6. Technical problem underlying the invention:

The respondent defined the technical problem underlying the invention as the provision of a hygiene product comprising lactic acid producing bacteria strain with improved shelf life in terms of bacteria viability.

7. Solution:

The solution proposed in claim 2 of the patent in suit is a hygiene product which comprises starch.

8. Success:

It was in dispute between the parties whether the

afore-mentioned problem had been effectively solved.

In the following analysis of inventive step, the board takes the most favourable situation for the respondent, namely that said problem has been credibly solved by the subject-matter of claim 2.

9. Finally, it remains to be examined whether the claimed solution was obvious for the person skilled in the art:

D1a discloses hygiene articles bearing a suspension of bacteria, to which carbohydrates have been added before the drying of said bacteria (page 17, lines 3-10).

Document D1a further discloses (page 16, lines 9-18; page 7, lines 3-9) that the presence of nutrients such as carbohydrates in a bacteria dispersion increases the survival and reproduction of said bacteria and its production of lactic acid and other metabolites in a hygiene product. Hence, the skilled person is taught by D1a that carbohydrates are suitable additives before drying, and that they increase the shelf life of the bacteria added to a hygiene product.

Document D18 had not been admitted into the proceedings by the opposition division. This document has been filed again with the notice of opposition. Since both parties had relied on its content during the appeal proceedings, and it merely reflects the general technical knowledge in the field of drying, document D18 is considered as part of these appeal proceedings.

Document D18 discloses starch as a suitable nutrient for lactic acid bacteria (page 169, lines 4-6, corn meal, as acknowledged by the respondent, mainly consists of starch) and as a suitable active contact

sorption drying sorbent (page 158, first line).

Document D1a discloses that carbohydrates are both suitable additives for drying and suitable nutrients, and that nutrients are beneficial for the shelf life. It is common general knowledge that starch is both a suitable nutrient for lactic acid bacteria, and a suitable contact sorption drying sorbent. The skilled person would combine the teaching of document D1a and the general knowledge in the field of drying lactic acid bacteria represented by D18, and add, as a carbohydrate, starch to the lactic acid producing bacteria before drying expecting to improve the survival and reproduction of said bacteria, and hence their shelf life, arriving thus to the present invention without using inventive skills.

The subject-matter of claim 2 is therefore not inventive in the sense of Article 56 EPC.

10. The respondent argued that starch, when intended as a nutrient could be used in moisture saturated form. Such a moisture saturated starch did not fulfill the functional feature in claim 2 requiring that starch was a "contact sorption drying carrier". Hence, even the combination of documents D1a with D18 would not lead to the present invention, since not every starch could act as a contact sorption drying carrier as required by claim 2.

However, according to paragraph [12] of the patent in suit, "*by contact sorption drying carriers are meant substances that have the ability to take up moisture from the ambient environment*". Document D1a explains on page 11, lines 23-28 that the hydrophobic carrier used (which corresponds to the lipid phase as in claim 2)

protects the bacteria from air and humidity, so that a better stability of bacteria is achieved. The skilled person knows, thus, that moist impairs the stability of the bacteria suspension. Therefore, when combining the teaching of D1a and the general knowledge in the art reflected by D18, the skilled person would only consider adding non moist starch, which is a contact sorption drying carrier as defined in paragraph [12] of the patent in suit, since it has the ability to take up moisture from the ambient environment.

This argument of the respondent must, thus, be rejected.

11. The respondent argued that following the teaching on page 169 of document D18, the skilled person would try to reduce the metabolism of the bacteria so that they are kept stable and, for this reason, would not add a nutrient before drying them.

However, document D1a discloses that the use of nutrients is beneficial. The cited passage of document D18 explains that corn meal (starch) could induce the undesired growth of lactic acid bacteria in some dried products but, in the present case, the growth of said bacteria on the final product upon use is not only desirable but the very purpose of the invention.

Additionally, the respondent acknowledged that glucose, which is a nutrient according to D1a, is a known cryoprotecting agent added often to bacteria before freeze drying. The argument that it is generally known that nutrients shall not be added to bacteria before drying must, therefore, be dismissed.

12. The respondent argued that document D18 did not disclose starch in connection with the drying of bacteria.

As mentioned by the appellant in its written submissions, document D18 discloses in table 12.3, the drying of bacterial preparations such as *L. plantarum*, which is a lactic acid producing bacteria according to paragraph [26] of the patent in suit, in the presence of wheat bran, which comprises starch. Hence, document D18 already discloses the drying of lactic acid producing bacteria with a composition comprising starch.

This argument of the respondent must also fail.

13. The respondent argued that an improvement in shelf life had been achieved by the combined effect of the lipid phase forming the dispersion and starch, which went beyond the effect of each of them separately. This unexpected synergy could not be derived from the state of the art, with the consequence that the subject-matter of claim 2 was inventive.

However, the use of a lipid phase for protecting the bacteria from air and moist had been already described in document D1a. Any alleged effect (longer shelf life) should be derivable from the distinguishing feature (starch), and such an effect is obvious having regard at the art, for the reasons explained above.

This argument is, hence, rejected.

14. The respondent argued that the water content of dried *L. plantarum* according to table 12.3 of document D18 (page 181) was too high for a product suitable for

hygiene purposes and concluded that for this reason the skilled person would not consider combining the teaching of D18 with document D1a.

However, table 12.3 of D18 indicates that the drying disclosed had been carried out to an "optimum moisture content of biomass", which appears to have been purposively chosen. D18 fails to disclose that a lower moisture content could not have been achieved.

This argument of the respondent must, therefore, fail.

15. The respondent further argued that starch could have been added in forms such as granules which, although still fulfilling the requirements of "nutrient", were not a "contact sorption drying carrier" as required by claim 2.

However, there is no evidence on file which could support this fact. There is no apparent reason why granules of starch could not absorb moisture from the ambient environment and, hence, could not act as a contact sorption drying carrier as defined in paragraph [12] of the patent in suit.

This argument of the respondent must, thus, also be rejected.

16. The board concludes that the subject-matter of claim 2 of the main request is not inventive in the sense of Article 56 EPC, even considering the most favourable situation for the respondent that the subject-matter of claim 2 solved the problem of providing a hygiene product with improved shelf life.

First to fifth auxiliary requests:

17. Since claim 2 of the first to fourth auxiliary requests and claim 1 of the fifth auxiliary request are identical to claim 2 of the main request, their subject-matter is not inventive (Article 56 EPC) for the same reasons explained with respect to the main request, with the consequence that these requests are not allowable.

Admissibility of the sixth auxiliary request:

18. The sixth auxiliary request has been filed at a very late stage of the proceedings, namely at the beginning of the oral proceedings before the board.
19. The respondent explained that the sixth auxiliary request merely introduced into claim 2 of the main request the feature *"said bacterial preparation is obtainable by mixing at least one lactic acid producing bacterial strain with said contact sorption drying carrier followed by drying the bacterial preparation comprising said at least one lactic acid producing bacterial strain and said contact sorption drying carrier"*, which had been present in claim 1 of the main request from the beginning of the proceedings and had been thoroughly discussed. This request, therefore, did not raise any new issue which could take the appellant by surprise.

The respondent further argued that it should be allowed to file such a request since it was its last chance to properly defend its patent.

20. The purpose of the appeal procedure in inter partes proceedings is mainly to give a party being adversely

affected the possibility of challenging the decision of the first instance. According to Article 12(2) of the Rules of Procedure of the Boards of Appeal, the statement of grounds of appeal and the reply shall contain a party's complete case. If, at a later stage of the proceedings, the respondent wants other request to be considered, admission of this request into the proceedings is a matter of discretion of the board of appeal and not a matter of right of the proprietor of the patent (Article 13(1) of the Rules of Procedure of the Boards of Appeal).

In the present case, the objection which may have prompted the filing of the sixth auxiliary request, namely lack of inventive step, had been known to the respondent from the statement of grounds of appeal. Therefore, the filing of this request is not induced by objections, facts or evidence freshly raised.

Additionally, claim 1 of the sixth auxiliary request defines a combination of features which had not been put forward before. The appellant could not be expected to provide during the oral proceedings sufficient counter arguments to support its case without a detailed analysis of the art, and without the possibility of providing further evidence.

Thus, the board concludes that if this new request, filed at a very late stage, i.e. during the oral proceedings before the board, would be admitted into proceedings, the appellant could not be expected to deal with it so that the oral proceedings could have to be postponed which, according to Article 13(3) of the Rules of Procedure of the Boards of Appeal, should be avoided.

The board, therefore, uses its discretion under Article 13(1) of the Rules of Procedure of the Board of Appeal not to admit the sixth auxiliary request into the proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated