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Datasheet for the decision of 7 May 2013

Case Number: T 0153/10 - 3.3.10

Application Number: 01967903.4

Publication Number: 1322346

IPC: A61L15/36, A61F13/15, A61F13/20

Language of the proceedings: EN

Title of invention:
PROCESS FOR PRODUCTION OF AN ABSORBING SANITARY ARTICLE COMPRISING LACTIC ACID PRODUCING BACTERIA

Patent Proprietor:
ELLEN AB

Opponent:
SCA Hygiene Products AB

Headword:

Relevant legal provisions:
EPC Art. 100(a), 100(b), 100(c), 54(2), 56, 123(2), 123(3), 84, 111(1)

Keyword:
Main request: Added subject-matter (no); sufficiency of disclosure (yes); novelty (yes); inventive step (no).
Inventive step - (no) First to fourth auxiliary requests
Remittal to the department of first instance - (yes)
Fifth auxiliary request

Decisions cited:
T 0020/81

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0153/10 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 7 May 2013

Appellant: (Patent Proprietor)	ELLEN AB Svärdvägen 27 182 33 Danderyd (SE)
Representative:	Berglund, Magnus Ström & Gulliksson AB Studentgatan 1 P.O. Box 4188 203 13 Malmö (SE)
Respondent: (Opponent)	SCA Hygiene Products AB 405 03 Göteborg (SE)
Representative:	HOFFMANN EITLE Patent- und Rechtsanwälte Arabellastrasse 4 81925 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 November 2009 revoking European patent No. 1322346 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appeal lies from the decision of the opposition division to revoke European patent No. 1 322 346.

II. An opposition had been filed requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC), that the invention was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC) and that the patent in suit contained added subject-matter (Article 100(c) EPC).

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

D2: WO 92/13577
D5: WO 99/12583
D7: WO 99/12504

IV. The opposition division decided that the patent as granted (main request) contained added subject-matter, that the subject-matter of claim 1 of the first and second auxiliary request was not novel over the disclosure of document D2, and that the subject-matter of claim 1 of the third to fifth auxiliary request was not inventive over the combination of D2, which was the closest prior art, and D5.

V. *Inter alia*, the following experimental reports were submitted by the appellant (patent proprietor):

D9: "Stability potential of lactobacilli in sanitary tampons for different application

methods"

D19: "Stability study of lactic acid bacteria blended with different hydrophobic carriers and applied to tampons by different techniques such as dipping, brushing and extrusion"

VI. With the statement of grounds of appeal, the appellant submitted a main request (patent as granted) and first to eleventh auxiliary requests. The independent claims of the requests relevant for this decision read as follows:

Main request (patent as granted):

Claim 1: *"A process for the production of an absorbing sanitary article comprising lactic acid producing bacteria characterised in that it comprises the following steps:*

- *dispersion of viable lactic acid producing bacteria in an essentially hydrophobic carrier, resulting in a dispersion of bacteria,*
- *application of the dispersion of bacteria by continuous or discontinuous extrusion on and/or in at least one component that are to form part of the final article, providing at least one continuous and/or discontinuous string of dispersion of bacteria on and/or in the final sanitary article."*

Claim 16: *"An absorbing sanitary article comprising lactic acid producing bacteria, characterised in that viable lactic acid producing bacteria are dispersed in an essentially hydrophobic carrier, and that the dispersion of bacteria forms at least one continuous or*

discontinuous string on and/or in the final sanitary article."

First auxiliary request:

Claim 1 of the first auxiliary request is identical to claim 1 of the main request.

Claim 16: *"An absorbing sanitary article, obtainable by a process according to any one of the claims 1 to 15, comprising lactic acid producing bacteria, characterised in that viable lactic acid producing bacteria are dispersed in an essentially hydrophobic carrier, and that the dispersion of bacteria forms at least one continuous or discontinuous string on and/or in the final sanitary article."*

Second auxiliary request:

Claim 1: *"A process for the production of an absorbing sanitary article comprising lactic acid producing bacteria characterised in that it comprises the following steps:*

- *dispersion of viable lactic acid producing bacteria in an essentially hydrophobic carrier, resulting in a dispersion of bacteria,*
- *application of the dispersion of bacteria by gentle feeding on and/or in at least one component that are to form part of the final article, providing at least one continuous and/or discontinuous string of dispersion of bacteria on and/or in the final sanitary article, wherein the gentle feeding is performed by continuous or discontinuous extrusion."*

Claim 16 of the second auxiliary request is identical to claim 16 of the first auxiliary request.

Third auxiliary request:

Claim 1: *"A process for the production of an absorbing sanitary article comprising lactic acid producing bacteria characterised in that it comprises the following steps:*

- *dispersion of viable lactic acid producing bacteria in an essentially hydrophobic carrier, resulting in a dispersion of bacteria, wherein the carrier has a viscosity of 200-20 000 mPas measured at 30°C with a shear rate of 100 1/s with a cone (diameter 50 mm, 2°);*
- *application of the dispersion of bacteria by gentle feeding on and/or in at least one component that are to form part of the final article, providing at least one continuous and/or discontinuous string of dispersion of bacteria on and/or in the final sanitary article, wherein the gentle feeding is performed by continuous or discontinuous extrusion."*

Claim 16: *"An absorbing sanitary article comprising lactic acid producing bacteria, characterised in that viable lactic acid producing bacteria are dispersed in an essentially hydrophobic carrier, and that the dispersion of bacteria forms at least one continuous or discontinuous string on and/or in the final sanitary article, wherein the carrier has a viscosity of 200-20 000 mPas measured at 30°C with a shear rate of 100 1/s with a cone (diameter 50 mm, 2°)."*

Fourth auxiliary request:

Claim 1 of the fourth auxiliary request is identical to claim 1 of the third auxiliary request.

Claim 16: *"An absorbing sanitary article, obtainable by a process according to any one of the claims 1 to 15, comprising lactic acid producing bacteria, characterised in that viable lactic acid producing bacteria are dispersed in an essentially hydrophobic carrier, and that the dispersion of bacteria forms at least one continuous or discontinuous string on and/or in the final sanitary article, wherein the carrier has a viscosity of 200-20 000 mPas measured at 30°C with a shear rate of 100 1/s with a cone (diameter 50 mm, 2°)."*

Fifth auxiliary request:

Claim 1: *"A process for the production of an absorbing sanitary article comprising lactic acid producing bacteria characterised in that it comprises the following steps:*

- *dispersion of viable lactic acid producing bacteria in an essentially hydrophobic carrier, resulting in a dispersion of bacteria, wherein the carrier is an at least partially saturated fat, with a viscosity of 200-20 000 mPas measured at 30°C with a shear rate of 100 1/s with a cone (diameter 50 mm, 2°) and a melting temperature between approximately 25 and 45°C;*
- *application of the dispersion of bacteria by gentle feeding on and/or in at least one component that are to form part of the final article, providing at least one continuous and/or discontinuous string of dispersion of bacteria on and/or in the final sanitary article, wherein the gentle feeding is performed*

by continuous or discontinuous extrusion."

Claim 16: *"An absorbing sanitary article comprising lactic acid producing bacteria, characterised in that viable lactic acid producing bacteria are dispersed in an essentially hydrophobic carrier, and that the dispersion of bacteria forms at least one continuous or discontinuous string on and/or in the final sanitary article, wherein the carrier is an at least partially saturated fat, with a viscosity of 200-20 000 mPas measured at 30°C with a shear rate of 100 1/s with a cone (diameter 50 mm, 2°) and a melting temperature between approximately 25 and 45°C."*

VII. The arguments of the appellant (patent proprietor) relevant for the present decision were the following:

The application as filed disclosed extrusion as a particular type of gentle feeding, so that claim 1 of the main request, in which the feature "gentle feeding" was replaced by "extrusion" did not contain added subject-matter.

The invention was disclosed in a manner sufficiently clear and complete for it to be carried out, since the patent in suit contained enough examples and there was no technical difficulty in performing the claimed invention.

Document D2 disclosed applying a suspension of bacteria on a tampon by coating or dipping into a bacteria suspension. However, the sanitary article thus obtained did not have a string of bacteria suspension as required by claim 16 of the main request. Additionally, D2 failed to disclose an essentially hydrophobic carrier. The subject-matter of claim 16 of the main

request was, therefore, novel.

The method for obtaining a tampon disclosed on page 7 of D2 by dipping it into a bacteria suspension and the tampon thus obtained was the closest prior art. The problem underlying the claimed invention was providing absorbing sanitary articles easier to produce, more absorbent, with a better controlled amount and concentration of bacteria with an increased viability, and a method for producing such absorbing sanitary articles. Although D7 disclosed applying hydrophobic compositions on absorbent articles, it was silent on compositions comprising bacteria, so that the skilled person would not combine its teaching with the disclosure of D2. Additionally, extrusion allowed applying the lactic acid producing bacteria inside a tampon, and not only on its surface. The subject-matter claimed was, therefore, inventive.

The feature "gentle feeding" in independent claim 1 of the second to fifth auxiliary requests was clear in the light of the whole disclosure of the patent in suit, since the skilled reader would only consider within the scope of the claimed invention those feeding methods compatible with a bacteria suspension, and, hence, necessarily gentle.

The independent claims of the third to fifth auxiliary requests defined the hydrophobic carrier of the invention in terms of their properties. Since none of the documents on filed disclosed hydrophobic carriers with the claimed viscosity, the subject-matter of these requests was necessarily inventive.

VIII. The arguments of the respondent (opponent) relevant for the present invention were the following:

The feature "gentle feeding", which was present in claim 1 as filed, was essential for the invention. As this limitation was not a feature of claim 1 as granted, said claim contained added subject-matter.

The extrusion step in the method subject-matter of claim 1 was not limited to any particular pump, although, according to the description of the patent in suit, not every pump was suitable for carrying out such extrusion. Additionally, although oils and fats fell within the definition of a carrier as in claim 1, they could not be extruded. Since the method subject-matter of claim 1 embraced embodiments which would not lead to obtaining an absorbing sanitary article comprising lactic acid producing bacteria, the subject-matter claimed was not sufficiently disclosed for it to be carried out.

The respondent considered that the tampon disclosed in document D2, obtained by coating it or by dipping it into a bacteria suspension, was an absorbent sanitary article in which the bacteria suspension formed a string, so that the subject-matter of claim 16 of the main request was not novel.

With regards to inventive step, if the embodiment of D2 where a tampon was dipped in a bacteria suspension was the closest prior art, no improvement with respect to such an embodiment had been proven, so the problem underlying the invention was merely to provide alternative absorbent articles, and the solution was obvious in the light of the teaching of D7.

Claim 1 of the first auxiliary request was identical to claim 1 as granted, and the same objections thus apply.

Claim 16, which was drafted as the product obtainable by the process of claim 1, was not inventive for the same reasons as claim 1 of the main request.

Claim 1 of the second auxiliary request merely differed from claim 1 as granted by the feature "gentle feeding performed by continuous or discontinuous extrusion", which did not represent any further limitation over the feature "continuous or discontinuous extrusion" in claim 1 of the main request. The same difference was apparent between claims 16 of the first and second auxiliary request, and the objection directed to lack of inventive step applied to the later in the same manner.

The viscosity range in claims 1 and 16 of the third and fourth auxiliary requests was so broad that it could not represent any further limitation with respect to the disclosure of D2, so that its subject-matter was not inventive for the same reasons as the main request.

Finally, the feature "gentle feeding" in the second to fifth auxiliary requests was not clear due to the vague term "gentle".

IX. Oral proceedings before the board took place on 7 May 2013.

X. The final requests of the parties were the following:

- The appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or, subsidiarily, on the basis of any of the first through eleventh auxiliary requests, all

requests as filed with the statement setting out the grounds of appeal.

- The respondent requested that the appeal be dismissed.

XI. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request:

Added subject-matter:

2. The opposition division decided that the feature "extrusion" had been disclosed in the application as originally filed only in combination with the feature "gentle feeding". Since claim 1 of the patent as granted only contained "extrusion" without the additional limitation "gentle feeding", said claim contained subject-matter which extended beyond the disclosure of the application as filed.

3. The application as filed discloses that (page 4, lines 14-15) "application by gentle feeding, preferably extrusion, is a gentle application method". Page 10, line 1 mentions "gentle feeding, by for instance extrusion". These paragraphs thus disclose "extrusion", without any additional limitation, as a particular example of "gentle feeding", with the consequence that the ground under Article 100(c) EPC does not preclude the maintenance of the patent as granted.

4. The respondent alleged that it was clear from the passage on page 19, lines 5-7 that not every extrusion was gentle. Said passage reads:

"The pumping of the dispersion was performed using a hydraulic piston pump. This type of pump is preferred since it does not affect the dispersion mechanically".

Since an extrusion could only be gentle if specific pumps were used for this purpose, not every extrusion was a gentle feeding. Hence, introducing in claim 1 the feature "extrusion" while removing the limitation "gentle feeding", so that the process of claim 1 included every possible extrusion, gentle or not, contravened the requirements of Article 123(2) EPC.

However, the passage quoted discloses which type of pump is suitable for carrying out the invention and provides valuable information to the skilled reader as to how to carry it out. It does not disclose that the process could not have been carried out with other pumps since then the extrusion would not be "gentle".

This argument of the respondent is, therefore, rejected.

Sufficiency of disclosure:

5. The respondent objected that the invention was not sufficiently disclosed, since paragraph [66] of the patent in suit disclosed that the carrier "Acosoup" was squeezed out from the tampon during the compression step, whereas coconut butter diminished the liquid absorption of the fibres. Therefore, although these two carriers were substantially hydrophobic carriers as required by claim 1, an absorbing sanitary article

containing a string of bacteria dispersion could not be obtained with them.

Occasional lack of success of a claimed process, for example when using "Acosoup" or coconut butter as carriers, does not necessarily impair its feasibility if some experimentation is still to be done to transform the failure into success, provided that such experimentation is not undue and does not require inventive activity.

In the present case, the patent in suit contains sufficient examples, and provides sufficient technical information with regard to the carriers suitable for the claimed invention (paragraph [75] to [93]) and to the extrusion step (paragraphs [19] to [22]).

In addition, the first of the embodiments on paragraph [66] mentioned by the respondent relates to the application of a string of bacteria suspended on "Acosoup" on a tampon component during the tampon manufacture before the compression step, and does not prove that the same carrier could not be applied to a tampon during a different step of the production procedure, or to a different type of absorbing sanitary article.

The other embodiment on paragraph [66] referred to the use of coconut butter as carrier, and the absorbing sanitary article obtained had an impaired absorbance. However, said paragraph fails to disclose that an absorbing article could not be obtained at all.

This argument of the respondent is, hence, rejected.

6. The respondent argued that the passage on paragraph [131] of the patent in suit, whose wording is as quoted in paragraph 4. above, proved that not every pump could perform an extrusion of a bacteria suspension. Since the type of pump was not a feature of claim 1, the subject-matter of said claim embraced embodiments which would not lead to an absorbing sanitary article comprising lactic acid producing bacteria, with the consequence that the invention was not sufficiently disclosed.

The board considers, however, that, by disclosing which type of pump is suitable for carrying out the claimed process, this passages actually gives the skilled person a useful information for carrying out the invention. The important point under sufficiency of disclosure is whether the claimed method can be carried out following the teaching of the contested patent and the information about the suitable pumps is, in fact, a proof of the sufficiency of the disclosure of the patent and not of the lack thereof.

This argument of the respondent is, hence, rejected.

7. The respondent finally argued that oils and fats, which were hydrophobic carriers, could not be extruded because they were either too fluid or too hard. Since the subject-matter of claim 1 included non workable embodiments, the claimed invention was not sufficiently disclosed.

The important point under sufficiency of disclosure is that the claimed object can be produced following the teaching of the patent in suit. The fact that the patent indicates that care should be taken when choosing the carrier since some do not give the best

result is, in the the present case, more a proof that the invention is sufficiently disclosed since the skilled person gets by this teaching a valuable information to prepare the claimed absorbing articles and to carry out the claimed method.

These arguments of the respondent are, thus, dismissed.

8. The board concludes that the objections brought forward by the respondent do not preclude that the invention is sufficiently disclosed for it to be carried out by a person skilled in the art.

Novelty:

Absorbing sanitary article, claim 16:

9. Product claim 16 is directed to an absorbing sanitary article comprising viable lactic acid producing bacteria dispersed in an essentially hydrophobic carrier, wherein said dispersion forms at least one string on and/or in the final sanitary article.

10. Document D2 discloses an absorbing sanitary article comprising lactic acid producing bacteria dispersed in a carrier (claim 6). In relation with the preparation of the absorbing article, D2 discloses that:

"According to the second method the desired amount of bacterial powder is applied in the form of a suspension wherein the bacterial powder is finely distributed in the adhesive agent to a homogeneous suspension. The application can take place e.g. by coating of the suspension or by dipping the tampon in the suspension" (page 7, lines 2-7)

11. The appellant argued that document D2 failed to disclose an essentially hydrophobic carrier, as required by claim 16. The passage on page 7 of D2 quoted above did not mention any specific adhesive agent, and not every adhesive agent was hydrophobic, since water was also known as a bacteria adhesive.

However, the passage quoted above discloses a suspension in "the" adhesive agent. Only one passage in document D2, namely page 4, lines 31-33, defines the adhesive agents as being "any compound having adhesive properties, such as coco fat, vegetabilic oil, or other glyceride or wax or other compound having the similar properties and a good skin and mucous membrane tolerance at the use in the urogenital region". Both coco fat and vegetabilic oil are essentially hydrophobic carriers as required by claim 16 of the main request, so that the nature of the carrier is not a distinguishing feature vis-à-vis D2.

12. The appellant has further argued that the subject-matter of claim 16 of the main request amounted to a selection from two independent lists within the disclosure of D2: a first selection from the list of possible methods for applying bacteria suspensions, and a second selection from the list formed by the embodiments "no adhesive - non hydrophobic adhesives - hydrophobic adhesives".

However, document D2 already discloses, in combination, the formation of a suspension in an adhesive agent, whereas the adhesive agent is as defined on page 4, for the reasons explained under point 11. No such a selection from different lists is thus required in order to arrive at the subject-matter claimed.

This argument of the appellant is, therefore, dismissed.

13. It remains to be examined whether in the sanitary article disclosed in D2 "the dispersion of bacteria forms at least one continuous or discontinuous string on and/or in the final sanitary article", as required by claim 16 of the main request.

13.1 Interpretation of the feature "string":

On paragraph [55] and on the last sentence on paragraph [97], the patent in suit defines a string as a continuous line, which can also be a layer or a film, or as a discontinuous line of dots, spots or shorter lines. Paragraph [97] also discloses that the amount and the area of the applied carrier should be minimised. Hence, the term string has not its normal meaning since it also covers layers or films. Although the term string does not imply in the patent in suit any precise limitation in terms of the length, breadth or width of the applied bacteria suspension, such a string can not cover completely the surface of the claimed absorbing article, since the covered area should be minimised in the light of paragraph [97].

13.2 The question arises whether the absorbent article on page 7 of document D2 contains a string of dispersion of bacteria, as required by claim 16.

According to document D2, the suspension of bacteria is applied by coating with the suspension or by dipping the tampon in the suspension. However, document D2 does not disclose the area of the absorbent article covered by the hydrophobic suspension after coating or dipping, whereas a string in the sense of the patent in suit

cannot completely cover the surface of the absorbent article. For this reason, D2 does not disclose a tampon bearing a string of bacteria suspension in the sense of the claimed invention, with the consequence that the absorbing sanitary article subject-matter of claim 16 of the main request is novel over the tampon of D2 (Article 54(2) EPC).

Process claim 1:

14. Claim 1 relates to a process for the production of an absorbing sanitary article comprising dispersion of viable lactic acid producing bacteria in an essentially hydrophobic carrier and applying said suspension via extrusion forming a string on and/or in the final sanitary article.

It has not been disputed that D2 fails to disclose the feature of claim 1 "extrusion" and at least for this reason the subject-matter of claim 1 of the main request is already new. In addition, D2 does not disclose a process which provides a string of dispersion of bacteria on/in the final sanitary article for the reasons explained under point 13. The subject-matter of process claim 1 is thus also novel.

Inventive step:

Absorbing sanitary article, claim 16:

15. Closest prior art:

In agreement with both parties and the opposition division, document D2 is considered the closest prior art.

Document D2 discloses a tampon which has been dipped into a suspension of lactic acid producing bacteria in a hydrophobic carrier (page 7, lines 2-7), and this embodiment of D2 represents the closest prior art.

As explained above, this embodiment of D2 differs from the subject-matter of claim 16 in that D2 fails to disclose that the dispersion of bacteria forms a string on and/or in the final sanitary article.

16. Technical problem underlying the invention:

The appellant defined the problem underlying the present invention as providing an absorbing sanitary article which is easier to produce, in which the content and concentration of bacteria is better controlled, and having an increased bacteria viability and an improved absorbency.

17. Solution:

The solution proposed by claim 16 of the main request is an absorbing sanitary article containing a string of bacteria suspension in a hydrophobic carrier.

18. Success:

18.1 The problem as defined by the appellant refers to four different aspects, namely absorbance, bacteria viability, control of the amount and concentration of bacteria, and ease of manufacture.

a) Improved absorbance:

It has not been disputed that a hydrophobic composition impairs the water absorbance of an absorbing sanitary

article. There is, therefore, a link between the absorbing capacity of the article and the part of its surface covered by the hydrophobic bacteria suspension.

Document D2 does not disclose the relative area of the tampon surface covered by hydrophobic bacteria suspension, so that a direct comparison between the absorbance of the tampon of D2 and of the absorbing sanitary articles subject-matter of claim 16 cannot be made.

However, when compared with the article disclosed in D2, the claimed article is characterised by the fact that the bacteria suspension forms a string, i.e. that the whole surface of the article is not covered by the hydrophobic suspension. Assuming in favour of the appellant that by dipping or by coating, the articles of D2 are fully covered by the hydrophobic suspension, it can be acknowledged that the absorbance of the partly coated claimed article is improved and that consequently the absorbing sanitary article subject-matter of claim 16 credibly solves this part of the problem.

b) Ease of manufacture:

The appellant argued that an absorbing sanitary article containing a string of bacteria dispersion in an hydrophobic carrier was easier to manufacture than the absorbent of D2.

However, it has not been shown that dipping an absorbent article into a bacteria suspension or coating it as disclosed in D2 was technically more complex than the extrusion step used to prepare the claimed article. Such an advantage in terms of ease of manufacture is,

hence, not apparent comparing the process of D2 and that of the patent in suit. The appellant has not provided any experimental evidence in this respect, so that the alleged advantage in terms of ease of manufacture is also devoid of experimental evidence.

This part of the problem is, therefore, considered not solved by the subject-matter of claim 16.

c) Better control of the amount and concentration of the bacteria in the absorbent article:

The appellant argued that the concentration and the amount of bacteria applied to the absorbing sanitary articles was better controlled when a string of bacteria suspension was applied.

However, such an advantage is not obvious to the skilled reader when comparing an absorbing sanitary article having a string of bacteria suspension with the tampon obtained by dipping disclosed in D2, and no experimental evidence in this respect has been provided.

This part of the technical problem cannot be considered, hence, solved by the subject-matter of claim 16.

d) Increased viability of the bacteria:

The appellant attempted to rely on the data provided in document D9, in particular on the example labelled "application method 2 - dipping/coating" for showing that the bacteria viability was higher in the absorbing sanitary articles of the invention, which contained a string of bacteria suspension, than in a tampon

obtained by dipping as in D2.

In application method 2 of of D9, a tampon was dipped into a melted hard fat (adhesive) and then coated with a powder of lyophilized bacteria. In contrast, the closer embodiment of document D2 implies dipping the tampon into a previously formed suspension of bacteria in an adhesive agent. Therefore, the data provided in document D9 do not reflect the closest embodiment of D2, with the consequence that these data do not represent a fair comparison with the closest prior art.

The appellant also relied on the experimental evidence provided as D19. Comparison of entries 1.a and 1.c in figure 1 allegedly proved that an improvement in terms of bacteria viability linked to applying the bacteria suspension in the form of a stripe had been achieved.

The string of bacteria in example 1.a of D19 had been extruded into the tampon, whereas the bacteria suspension is placed on the surface of the absorbent article of example 1.c. Therefore the absorbing sanitary articles of entries 1.a and 1.c on figure 1 of D19 differ not only in that the bacteria suspension forms a string, which is the distinguishing feature of the invention, but also on the location of said string. The bacteria in the claimed and comparative absorbents are thus differently exposed to those external agents (air, moisture) affecting bacteria viability. For this reason, the results provided on table 1 of document D19 do not represent a fair comparison with respect to the closest prior art.

The appellant argued that the inner part of a tampon had a residual moisture content, so that the comparison in D19 was in disfavour of the case of the appellant.

However, there is no corroborating evidence on file showing that the inside of the absorbent article is a more disfavourable environment for the bacteria. This argument is, thus, dismissed.

The part of the problem defined as improving the viability of the bacteria in the absorbing sanitary article is thus considered not solved by the subject-matter of claim 16.

18.2 In the absence of evidence that the alleged technical problems have effectively been solved, it cannot be considered, as argued by the appellant, that the later has discharged its burden of proof and that it was the duty of the respondent to demonstrate that the alleged effects were achieved by the claimed articles.

18.3 According to the jurisprudence of the Boards of Appeal, alleged unsupported advantages cannot be taken into consideration in respect of the determination of the problem underlying the invention (see e.g. decision T 20/81, OJ EPO 1982, 217, point 3, last paragraph of the reasons). As the alleged improvement in terms of ease of manufacture, control of the amount and concentration of bacteria and of bacteria viability lacks the required support, the technical problem as defined in point 16. above needs reformulation.

The objective technical problem underlying the invention can thus only be the provision of an absorbent article with increased absorbency.

In favour of the appellant, it will be considered that this problem has been effectively solved.

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

Trying to improve the absorbency of a sanitary article containing bacteria in a hydrophobic carrier with respect to the tampon of D2, which had been obtained by dipping it into a bacteria dispersion in a carrier such as coco fat or vegetabilic oil, the skilled person would turn to document D7, which relates to the application of skin beneficial hydrophobic (page 40, line 1), melted (page 40, line 16) compositions on absorbing sanitary articles.

On page 40, lines 15-20, document D7 discloses that slot extrusion is a preferred application method for adding a melted lotion into an absorbent article. It continues stating that it was particularly preferred applying such lotion in a plurality of spaced apart stripes so as to minimize its effect on the absorbency.

As acknowledged by the appellant during the oral proceedings, a stripe is a particular embodiment of a string according to the claimed invention.

From document D7, the skilled person knows that hydrophobic compositions forming stripes on absorbing sanitary articles minimise the effect of the hydrophobic composition on the sanitary article absorbency. The skilled person would, then, extract this information from D7 and apply it to the tampons of D2 arriving thus to the claimed solution without using inventive skills.

The subject-matter of claim 16 of the main request is therefore not inventive in the sense of Article 56 EPC.

The appellant argued that document D7 did not refer to bacteria containing suspensions. Documents D2 and D7 belonged, hence, to different technical fields with the consequence that the skilled person would not consider combining their teachings.

However, the decrease in absorbency is only related to the hydrophobicity of the composition added to the absorbing sanitary article, and not to the presence or absence of bacteria. Document D7 deals with the addition of hydrophobic compositions to absorbing sanitary articles, and addresses the problem posed by the claimed invention. For these reasons, D7 does not belong to a remote, unrelated technical field, and the skilled person would consider combining its teaching with the disclosure of document D2.

This argument is therefore dismissed.

Process claim 1:

20. Closest prior art:

It was not contested that document D2 remains the closest prior art for the assessment of inventive step of the process according to claim 1.

D2 discloses a process for producing a tampon by dipping said tampon into a bacteria suspension in a hydrophobic carrier. The features distinguishing the process subject-matter of claim 1 from that disclosed in document D2 are:

- the fact that the bacteria dispersion is applied by extrusion, and

- that the process leads to a sanitary article which contains a string of bacteria dispersion (see point 14. above).

21. Technical problem underlying the invention:

In relation with the process claimed, the appellant formulated the technical problem as providing an easier process for the production of an absorbing sanitary article which allowed a better control of the volume and concentration of the bacteria suspension applied, improved the viability of said bacteria in the final product, led to a product with enhanced absorbency, and allowed applying the bacteria inside the absorbing article.

22. Solution:

The solution proposed by claim 1 of the main request is the process characterised in that a dispersion of bacteria in a hydrophobic carrier is applied by extrusion in such a manner that said dispersion forms a string in or on the final absorbing sanitary article.

23. Success:

For the same reasons as for the product claim 16, the problems of providing an easier process for the production of an absorbent article, with better control of the concentration and of the amount of bacteria and higher bacteria viability cannot be considered to be solved (see point 18.1, points b) to d) above).

For the reasons explained under point 18.1 a) the problem of producing an absorbing sanitary article with increased absorbance will be considered solved, in

favour of the appellant.

With respect to the alleged advantage that the process subject-matter of claim 1 allowed applying the bacteria into the internal part of a tampon, this problem is considered solved by the subject-matter of claim 1, since neither dipping nor coating allow applying a composition in the internal part of a tampon, whereas such an application is possible via extrusion.

Consequently, the objective problem underlying the claimed invention must be reformulated as the provision of a process which allows the preparation of a more absorbing sanitary article containing bacteria, which allows applying said bacteria inside said absorbing sanitary article.

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

Trying to obtain a method for manufacturing a sanitary article more absorbing than those of D2, the skilled person would turn to document D7, which relates to the application of hydrophobic skin beneficial compositions on sanitary articles (page 40, lines 1 and 16).

On page 40, lines 15-20, document D7 discloses that slot extrusion in the form of stripes is a preferred application method for adding a melted lotion into an absorbent article. As acknowledged by the appellant during the oral proceedings, a stripe is a particular embodiment of a string according to the present invention.

The skilled person would apply the technical information on methods for applying hydrophobic, melted

substances to sanitary articles disclosed in D7 to the bacteria containing compositions of D2 and arrive to the claimed process without using inventive skills.

Although D7 discloses adding a hydrophobic suspension to the top sheet of a diaper, this choice is not due to the application method (extrusion) but to the intended use of the hydrophobic suspension. The skilled person would recognise that extrusion is not limited to the surface of the absorbing article, but also allows adding such a suspension inside said article. Thus, the skilled person, by choosing the method of D7 for applying the suspension of bacteria as in claim 1, solves simultaneously both parts of the problem underlying the invention.

The subject-matter of claim 1 is thus not inventive.

25. As the subject-matter of claims 1 and 16 of the main request is not inventive in the sense of Article 56 EPC, even considering, in favour of the appellant, that the problem of providing an absorbing sanitary article and a method for obtaining said article with an improved absorbency has been solved, the ground of opposition mentioned under Article 100(a) EPC precludes the maintenance of the patent as granted.

First auxiliary request:

26. Claim 1 of the first auxiliary request is identical to claim 1 as granted and its subject-matter is not inventive for the reasons explained with respect to the later (see points 20. to 25. above)

27. Claim 16 of the first auxiliary request has been amended in the form of a "product by process" claim.

The appellant has not provided any additional distinguishing feature derivable from the method of obtention which was not present in the absorbing sanitary article subject-matter of claim 16 of the main request, nor is any such difference apparent from the mere wording of said claim. In the absence of additional distinguishing features, the inventive step analysis remains the same as for claim 16 of the main request (see points 15. to 19. above).

28. The subject-matter of claims 1 and 16 of the first auxiliary request is not inventive, with the consequence that said request is not allowable.

Second auxiliary request:

29. Process claim 1 of the second auxiliary request includes the feature "application ... by gentle feeding ... wherein the gentle feeding is performed by continuous or discontinuous extrusion". Absorbing sanitary article claim 16 is drafted in the form of a product by process claim.

As explained in point 4. above, every extrusion within the context of the present invention is a gentle feeding, with the consequence that this feature does not provide any additional distinguishing feature vis-à-vis document D2. The subject-matter of process claim 1 and of absorbing sanitary article claim 16 is not inventive for the reasons explained with respect to claims 1 and 16 of the main request (see points 15. to 25. above).

30. Since the subject-matter of claims 1 and 16 of the second auxiliary request are not inventive, this

request is not allowable.

Third auxiliary request:

Inventive step:

Absorbing sanitary article, claim 16:

31. The subject-matter of claim 16 of the third auxiliary request differs from that of claim 16 of the main request in the additional limitation defining that "the carrier has a viscosity of 200-20000 mPas measured at 30˚C with a shear rate of 100 1/s with a cone (diameter 50 mm, 2˚)".

32. Closest prior art:

Document D2 remains the closest prior art. This was not contested by the parties.

It has been a point of dispute between the parties whether cocoa oil, which is disclosed in D2 as a carrier, had the viscosity required by claim 16 of the third auxiliary request. This question could not be clarified during the proceedings before the board. However, even when considering, to the advantage of the appellant that said viscosity represents an additional distinguishing feature, the claimed article nevertheless lacked an inventive step for the following reasons:

Under the assumption that cocoa oil does not have the viscosity required by claim 16, the claimed absorbing sanitary article differs from the tampon disclosed in D2 in that

- it bears a bacteria suspension in form of a string, and
- the hydrophobic carrier of said suspension has a viscosity of 200-20 000 mPas in the conditions defined in the claim.

33. Technical problem underlying the invention:

The technical problem formulated by the appellant remains the same as that defined for claim 16 of the previous requests, namely providing an absorbing sanitary article which is easier to manufacture, in which the volume and concentration of the bacteria suspension applied is better controlled, the viability of said bacteria and the absorbency of the sanitary article being improved.

34. Solution:

The solution proposed by claim 16 of the third auxiliary request is an absorbent article containing a string of a suspension of bacteria into a hydrophobic carrier having the viscosity defined in clam 16.

35. Success:

As for the main request, it will be considered that the absorbance of the claimed articles had been improved, but that the problems of simpler manufacture and of better control of concentration and amount of bacteria have not been credibly solved for the reasons already explained (see 18. b) and 18. c)) since no evidence has been provided that an additional effect on these problems was linked to the viscosity of the hydrophobic carrier.

It remains, however, to be examined whether the viscosity of the hydrophobic carrier as defined in claim 16 provides an effect in terms of the bacteria viability in the absorbing sanitary article.

The appellant relied on the results provided on Figure 3 of D19, in which coconut fat (entry 2.c), which allegedly did not have the viscosity required by claim 16, was used.

However, there is no difference in bacteria viability (about 30% CFU) when said bacteria are dispersed in Lipex Sheasoft, whose viscosity lays within the claimed viscosity range (entry 5.c) and in coconut fat (entry 2.c), which allegedly has a viscosity outside said range. From this data, it can then only be concluded that the problem of improving bacteria viability has not been solved, as no difference in viability is apparent between absorbent articles having bacteria dispersions in carriers with the required viscosity and in carriers with a viscosity falling outside the range defined in claim 16.

The objective technical problem has, therefore, to be reformulated in a less ambitious manner as providing absorbent articles with an improved absorbency. In favour of the appellant, this problem is considered solved (see point 18.1 a) above).

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

As already explained with respect to the main request, improving the absorbency by applying the hydrophobic composition in the form of a stripe does not involve an inventive step (see point 19. above). In addition, the

viscosity range defined in claim 16 is very broad, and no effect has been shown which could be associated to the defined viscosity range. Therefore, this range of viscosity can only be regarded as a mere random, non inventive selection within the suitable viscosities of hydrophobic carriers.

Consequently, the subject-matter of claim 16 of the third auxiliary request is not inventive in the sense of Article 56 EPC.

Process claim 1:

37. Process claim 1 of the third auxiliary request differs from process claim 1 of the main request since it contains the feature "gentle feeding", and the feature "wherein the carrier has a viscosity of 200-20000 mPas measured at 30˚C with a shear rate of 100 1/s with a cone (diameter 50 mm, 2˚)".

As explained in connection to the second auxiliary request, the feature "gentle feeding" does not introduce any additional limitation with respect to the subject-matter of claim 1 of the main request.

38. Closest prior art:

Document D2 remains the closest prior art.

The parties were divided as to whether cocoa oil, disclosed in D2 as a carrier, had a viscosity within the range defined in claim 1. In the following analysis it would be considered, in favour of the appellant, that none of the hydrophobic carriers of D2 have the viscosity required by claim 1, with the consequence that the distinguishing features between the claimed

process and the process of D2 are:

- the presence of an extrusion step,
- that the bacteria suspension is applied forming a string on the final product, and
- that the viscosity of the hydrophobic carrier ranges from 200 to 20 000 mPas at the conditions defined in the claim.

39. Technical problem underlying the invention:

The technical problem as formulated by the appellant was providing an easier process for the production of an absorbing sanitary article, which allowed a better control of the volume and concentration of the bacteria suspension applied, improved the viability of said bacteria in the final article, led to a product with improved absorbency, and allowed applying the bacteria suspension inside the absorbing sanitary article.

40. Solution:

The solution proposed by claim 1 of the third auxiliary request is applying a dispersion of bacteria in a hydrophobic carrier with a viscosity from 200 to 20 000 mPas by extrusion, so that said dispersion forms a string in and/or on the absorbing sanitary article.

41. Success:

For the reasons already explained with respect to claim 16, it cannot be considered that the process subject-matter of claim 1 of the third auxiliary request solves the problems of providing an easier process, and of controlling the amount and concentration of the bacteria suspension applied and improving viability

(see point 35. above).

The problem of allowing to apply the bacteria suspension inside the absorbing sanitary article is also solved by the extrusion step defined in claim 1 (see point 23. above).

In favour of the appellant, it is considered that the problem of providing a method for producing an absorbing article with improved absorbency is solved by the subject-matter of claim 1 as well (see point 18.1 a) above).

For these reasons, the technical problem as defined by the appellant shall be reformulated in a less ambitions manner as the provision of a process for the production of an absorbing sanitary article, which allowed applying a bacteria suspension inside said absorbing sanitary article and leading to a product with improved absorbency. This problem, in favour of the appellant, will be considered solved.

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

Document D7 discloses a method for producing absorbing sanitary articles while minimising the effect on its absorbency by applying an hydrophobic (page 40, line 1) melted composition by using slot extrusion (page 40, lines 15-20) and applying such a composition in a plurality of spaced apart stripes. D7 refers to the same technical problem (minimising the effect on absorbency), and discloses an application method (extrusion) which allows adding a composition inside an absorbing sanitary article. The skilled person, trying to solve the problem posed by the patent in suit, would

combine the teaching of D7 and of the closest prior art D2 and arrive to the claimed solution without using inventive skills, as explained already with respect to the main request (see points 20. to 25. above).

The broad range of viscosities introduced in claim 1 of the third auxiliary request, in the absence of any effect which could be linked to this choice, can only be considered as a random selection within the suitable hydrophobic carriers and, as such, does not contribute to the solution of the technical problem.

43. The subject-matter of claims 1 and 16 of the third auxiliary request is thus not inventive, with the consequence that the third auxiliary request is not allowable.

Fourth auxiliary request:

44. Process claim 1 of the fourth auxiliary request is identical to claim 1 of the third auxiliary request and is not inventive for the same reasons as the later.

45. Absorbent article claim 16 is drafted as a "product by process claim". However, the appellant has not put forward any additional difference in the final product which could be derived from its manufacture method, nor is any such difference evident. Since claim 16 does not include any additional distinguishing feature with respect to the product disclosed in D2, the inventive step analysis remains the same as for the subject-matter of claim 16 of the third auxiliary request.

46. The subject-matter of claims 1 and 16 of the fourth auxiliary request is not inventive in the sense of Article 56 EPC, with the consequence that this request

is not allowable.

Fifth auxiliary request:

Process claim 1 of the fifth auxiliary request differs from process claim 1 of the fourth auxiliary requests insofar as the carrier is an at least partially saturated fat having a melting temperature between approximately 25 and 45°C.

47. Amendments:

47.1 Claim 1 of the fifth auxiliary request finds a basis on the combination of claim 8 as originally filed, and the passages in the description on page 12, lines 20-25, and on page 4, lines 13-14.

Dependent claims 2-14 find a basis on claims 3-6, 9, 10 and 12-18 as filed.

Claim 15 of the fifth auxiliary request finds a basis on claim 25 as filed and the passage in the description on page 12, lines 20-25.

Dependent claims 16-24 find a basis on claims 26-34 as originally filed.

The requirements of Article 123(2) EPC are therefore fulfilled.

47.2 Independent claim 1 results from the combination of claims 1 and 8 as granted, with the addition of the feature "gentle feeding". Independent claim 15 results from the combination of granted claims 16 and 21. In both independent claims the scope of the claims has been, hence, narrowed.

The subject-matter claimed does not extend beyond the scope of the claims as granted, so that the requirements of Article 123(3) EPC are also fulfilled.

48. Clarity of the feature "gentle feeding":

The respondent argued that the feature "gentle feeding" now in claim 1 was not clear in the sense of Article 84 EPC. "Gentle" was a relative, vague term which did not allow to draw the line between "gentle" and "non gentle".

The original application disclosed "extrusion" as a particular embodiment of "gentle feeding". Since the narrower limitation "extrusion" is also incorporated into claim 1, its meaning cannot be rendered unclear by the broader term "gentle feeding" which in fact does not limit the subject-matter of the claim (see point 3. above).

The feature "gentle feeding performed by ... extrusion" is therefore clear.

49. Remittal:

The opposition division had not dealt with the patentability of claims directed to absorbing sanitary articles and a method for its manufacture in which the carrier fulfills the conditions set out in claims 1 and 15 that the carrier is at least partially saturated fat, with a viscosity of 200-20 000 mPas measured at 30°C with a shear rate of 100 l/s with a cone (diameter 20 mm, 2°) and a melting temperature between approximately 25 and 45°C.

A number of new issues arise with respect to the fifth auxiliary request, such as whether said parameters are clear, whether the claimed invention is disclosed in a manner sufficiently clear and complete for it to be carried out, and whether they bring any additional difference with respect to the state of the art, in particular since the board has arrived to the conclusion that the subject-matter of the independent claims of the third and fourth auxiliary requests was not inventive considering, to the advantage of the appellant, that coco fat did not have a viscosity within the range defined in the claims, without having been able to clarify whether it actually fulfilled said parameter.

In order to allow *inter alia* these issues to be examined by two instances, the board considers it appropriate to exercise the power conferred to it by Article 111(1) EPC to remit the case to the opposition division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of the fifth auxiliary request as filed with the statement setting out the grounds of appeal.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated