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**Datasheet for the decision
of 8 February 2022**

Case Number: T 2769/18 - 3.3.10

Application Number: 11182779.6

Publication Number: 2572737

IPC: A61L15/46

Language of the proceedings: EN

Title of invention:

Improved wound dressing

Patent Proprietor:

BSN medical GmbH

Opponents:

Schmitt-Nilson, Gerhard, Waibel, Stefan

Headword:

Wound dressing / BSN

Relevant legal provisions:

EPC Art. 123(2), 56

Keyword:

Amendments - allowable (yes) - intermediate generalisation (no)
Inventive step - (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 2769/18 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 8 February 2022

Appellant:

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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
7 September 2018 concerning maintenance of the
European Patent No. 2572737 in amended form.**

Composition of the Board:

Chairman

P. Gryczka

Members:

M. Kollmannsberger

F. Blumer

Summary of Facts and Submissions

I. The patent proprietor as well as the opponent filed an appeal against the decision of the Opposition Division to maintain European Patent No. 2 572 737 under Article 101(3)(a) EPC in amended form.

II. Documents relevant for the present decision are:

D18: WO 2006/089551

D19: WO 2006/127292

III. Opposition proceedings were based on the grounds under Article 100(a) EPC for lack of novelty and inventive step and 100(c) EPC for unallowable amendments.

The Opposition Division decided that the granted patent did not contain unallowable amendments and complied thus with the requirements of Article 123(2) EPC. The novelty objection based on D18 was not considered justified. Regarding inventive step, the Opposition Division found D18 to be the closest prior art. Starting from D18 the subject matter of claim 1 of the granted patent was obvious when considering the general knowledge as well as the teaching of D19. The claims of the first auxiliary request on the other hand were found to fulfil the requirements of the EPC.

IV. The appellant-patent proprietor requests to set aside the decision of the Opposition Division and to maintain the patent as granted, i. e. to reject the opposition. As auxiliary request he requests maintenance of the patent in amended form according to one of the eight claim sets filed with the statement of grounds of appeal. These auxiliary requests had already been

submitted during the opposition procedure. The first auxiliary request is the one on which the Opposition Division maintained the patent.

V. The appellant-opponent requests to set aside the decision of the Opposition Division and to revoke the patent.

VI. Independent claim 1 of the granted patent reads as follows:

"A unitary wound dressing comprising:

an absorbent core,

a backing layer, and

a woven or non-woven fabric layer comprising an agent having an effect against pathogenic microbial colonization of a wound,

wherein the woven or non-woven fabric layer is bonded to at least a part of the border portion to the proximal surface of the backing layer bordering the center portion.

wherein the non-woven or woven fabric is not bonded to the absorbent core.

said wound dressing further comprising a carrier layer secured to the woven or non-woven fabric in at least a part of the border portion thereof and having at least an opening through which fluid can pass from the wound into the absorbent core."

- VII. In relation to the patent as granted the appellant-patent proprietor submitted during the appeal proceedings that the Opposition Division's assessment of inventive step was incorrect. To arrive at the claimed wound dressing starting from D18 as closest prior art several selections needed to be made and the carrier layer needed to be added at the claimed position. These modifications were neither obvious from general knowledge nor from the teaching of D19. On the other hand, the Opposition Division's finding that the granted claims complied with Article 123(2) EPC was correct.
- VIII. In relation to the patent granted the appellant-opponent defended the Opposition Division's assessment of inventive step. Starting from D18 the claimed wound dressing was obvious from general knowledge and D19. Also starting from D19 the claimed wound dressing lacked an inventive step. Furthermore, the granted claims extended beyond the originally filed disclosure; technical features from the description had been taken out of context and introduced into claim 1. The novelty objection over D18 was not maintained in appeal.
- IX. A communication under Article 100(2) EPC was sent to the parties on 9 April 2021.
- X. On 17 September 2021 the parties were summoned to oral proceedings for the 8 February 2022. These oral proceedings were held in the form of a videoconference. At the end of the oral proceedings the Board announced its decision.

Reasons for the Decision

1. The appeals are admissible.

Patent as granted

2. Amendments (Article 123(2) EPC)

- 2.1 Claim 1 of the granted patent is a combination of originally filed claims 1 and 3. Additionally the feature "*wherein the non-woven or woven fabric is not bonded to the absorbent core*" has been taken from par. [0009] of the original description as published. This feature further defines the fabric layer comprising an antibacterial agent which is the layer facing the wound upon application of the dressing.

This was undisputed.

- 2.2 The opponent's view was that this feature has been taken out of context. In particular he argued that the disclosure of paragraph [0009] required the backing layer of the wound dressing to be water-impervious and vapor-permeable. Although this was not disclosed as obligatory but as preferred, it would nevertheless have to be read together with the previous sentence since the previous sentence did not contain any reference to a backing layer at all. Furthermore, other features mentioned after the word "preferably" were not optional but obligatory, such as the carrier layer and the presence of a skin adhering facing layer.
- 2.3 The Board does not follow the opponent's conclusions. The feature "*wherein the non-woven or woven fabric is not bonded to the absorbent core*" is disclosed in par.

[0009] at the beginning of the summary of the invention where the wound dressings of the invention are described in a general way. The other structural features of the wound dressing defined in this first sentence are likewise present in claim 1 of the granted patent. The properties of the backing layer, on the other hand, are clearly marked as a preferred feature. Introducing the disputed feature from the general description of the claimed wound dressing into claim 1 does not add any previously undisclosed information. The original disclosure does not necessarily require a water-impervious and vapor-permeable backing layer in case the fabric is not bonded to the absorbent core. The nature of the backing layer and the fabric layer not being bonded to the absorbent core are not presented as being linked in any way. The fact that also obligatory features of the wound dressing are mentioned after the word "preferably" does not change this assessment; the combination of the obligatory features with the properties of the backing layer discussed above is still a preferred, not an obligatory, configuration of the claimed wound dressing.

Thus, in the Board's view the Opposition Division has correctly assessed this question in the impugned decision (point 1.1 of the reasons for the decision).

3. Inventive step (Article 56 EPC)

3.1 The claimed invention

The claims of the granted patent are directed to a multilayer unitary wound dressing. The independent claim defines an absorbent core and three additional

layers, namely a backing layer, a fabric layer and a carrier. The fabric layer comprises an antimicrobial agent and is bound to at least a part of the border portion of the proximal surface of the backing layer, but not to the absorbent core. The carrier layer is secured to at least a part of the border portion of the fabric layer and contains at least an opening which allows fluid to pass from the wound to the absorbent core.

The location of the carrier layer is not directly specified in the claim, however, since the fabric layer is bonded to the proximal layer of the backing layer the carrier layer must itself be secured to the proximal side of the fabric layer, as shown e. g. in figures 1 and 7.

During oral proceedings the parties agreed on this claim interpretation, i. e. that the layers are directly bound to each other and the carrier layer is situated beneath the fabric layer. In the following, the fabric layer will also be referred to as "skin facing layer".

3.2 Closest state of the art

- 3.2.1 The Opposition Division chose D18 as closest prior art document and reasoned this choice, see pages 10 and 11 of the decision. During the oral proceedings before the Opposition Division all parties agreed thereto (see point 1.4 of the minutes). The choice of D18 as closest prior art does not appear to have been contested in the parties' appeals. The opponent referred to his submissions in the notice of opposition (see point IV.4 of the statement setting out the grounds of appeal) and stated that D19 was an equally valid starting point.

However, no arguments against the reasoning made by the Opposition Division have been brought forward. During oral proceedings before the Board no inventive step attack starting from D19 was made.

The Board thus considers D18 to represent the closest state of the art.

3.2.2 D18 discloses a wound dressing similar to the one defined in the present claims. The idea underlying D18 is to create an envelope between a backing layer (1) and a skin facing layer (2) in which an absorbent element (4) can freely float and expand once it absorbs body fluids from the wound. Such a wound dressing is generally described in the last paragraph on page 3 and the first paragraph on page 4 and individual embodiments are depicted e. g. in figures 1 and 2.

3.2.3 It was uncontested that the wound dressing of D18 lacks a carrier layer as defined in claim 1 of the granted patent. It may additionally contain an adhesive flange (10) corresponding to the skin adherent layer defined in claim 4 of the granted patent, but a carrier layer is not described in D18.

Thus, one difference between the claimed wound dressing and that disclosed in D18 is the feature

"said wound dressing further comprising a carrier layer secured to the woven or non-woven fabric in at least a part of the border portion thereof and having at least an opening through which fluid can pass from the wound into the absorbent core".

- 3.2.4 The Opposition Division considered this to be the only difference and based the problem-solution approach on this difference alone.

The patent proprietor was, however, of the opinion that also the claimed structure of the skin facing layer is not directly and unambiguously disclosed in D18.

The claim requires this layer to be made of a woven or non-woven fabric and to comprise an agent having an effect against pathogenic microbial colonisation of a wound.

D18 describes the structure of this layer in various passages; no particular importance is given to the type of material to be used. On page 7, lines 13-15 the layer is described as being made of e. g. a foam, a non-woven, a polymer film or a laminate. A similar disclosure can be found on page 9, lines 6-10 where additionally knits are mentioned, i. e. a woven fabric.

According to page 13, lines 15ff the dressing may comprise an active ingredient. Various possible types of activities are listed. Zinc or salts thereof are mentioned as an example for bacteriostatic or bactericidal compounds in line 28. On page 14 lines 8/9 it is stated that the skin facing layer may be impregnated with "*zinc paste or other skin conditioning or healing enhancing materials*".

The patent proprietor argued that these passages do not amount to a disclosure of the layer as defined in claim 1, i. e. a woven or non-woven fabric impregnated with an antibacterial agent. In particular (i) the location of the bacteriostatic or bactericidal agent was not specifically described in D18, (ii) "Zinc paste" was

not disclosed as having, and does in fact not have, an antibacterial effect and (iii) woven or non-woven fabrics were only one possibility out of several mentioned in D18. Thus, various selections had to be made to arrive at the layer as claimed.

The opponent, on the other hand, argued that from the disclosure of D18 only a very limited number of selections, if at all, had to be made concerning the material of the skin facing layer. Zinc salts, and thus also zinc paste were disclosed as antibacterial agents present in the skin facing layer. In any case, an active agent aimed to be delivered to the wound, would have been placed by a skilled person immediately in the skin facing layer even if this location was not specifically mentioned.

3.2.5 The Board follows the patent proprietor in this assessment insofar as there is no single embodiment disclosed in D18 from which the present claims would differ only in the presence of the carrier layer. The general disclosure, e. g. in claim 1 of D18, does not define the skin facing layer. In the embodiment shown in figure 1 the skin facing layer is a film, not a fabric, and there is no mention of any active agent; furthermore the skin facing layer may have an aperture in order to allow the wound to have direct contact to the absorbent core. Similar considerations apply to the other embodiments shown in the figures. The properties of the skin facing layer as claimed in the disputed patent (woven or non-woven fabric, containing an antibacterial agent) are not disclosed in combination within one embodiment.

3.2.6 Thus, claim 1 of the granted patent differs from the disclosure of D18 in that (i) the wound dressing

additionally contains a carrier layer as defined above and (ii) the skin facing layer is specifically a woven or non-woven fabric layer comprising an agent having effect against pathological microbial colonization of a wound.

3.3 Objective technical problem and solution

3.3.1 The effect of the carrier layer is explained in paragraph [0049] of the description as providing additional security against delamination during wearing and making the dressing application easier by increasing the stiffness of its border portion.

3.3.2 The patent proprietor's view was that there is a functional interaction between the additional carrier layer and the skin facing fabric comprising an antimicrobial agent. In his view the combination of these features lead to less wound infection; the former by preventing delamination of the dressing with the corresponding opening of infection channels, the latter by preventing the microbial colonisation of the wound. These two effects synergistically work together in order to improve wound healing.

3.3.3 The Board does not agree. The patent does not disclose any link between the effects of the carrier layer and the impregnation of the skin facing layer with an antimicrobial agent. The effects of the carrier layer are described in paragraph [0049] and relate to an increase in stiffness and to provide additional security against delamination. The effects of the impregnated fabrics are described in paragraphs [0050] to [0055]. Any effect of the impregnated fabric layer on dressing deformation is attributed to the fact that it is not bonded to the absorbent core (see paragraph

[0055], see also the description of the prior art in paragraph [0008]) and not on an interaction with the carrier layer.

- 3.3.4 Thus, the technical problem to be solved relating to the first difference can be formulated as how to modify the dressing of D18 in a way to increase its stiffness and reduce its tendency for delamination.

The Opposition Division had formulated this technical problem in a similar way (see page 12, fourth paragraph of its decision) and also the opponent's formulation of the technical problem related to the mechanical stability of the wound dressing.

- 3.3.5 This problem has been solved by the claimed wound dressing which is characterized by having a carrier layer secured to at least a part of the border of the fabric layer. In the interpretation discussed in point 3.1 above this layer is situated at the proximal side of the skin facing fabric layer.
- 3.3.6 It was uncontested that the claimed wound dressing indeed solves the stated technical problem.
- 3.3.7 According to the Opposition Division's decision and the opponent's arguments, this problem was solved in an obvious way. This question will be addressed next. Since, as will be shown below, the claimed solution was not obvious, there is no need to address any technical problem based on the structure and effect of the antimicrobial skin facing layer.

- 3.4 Obviousness of the solution

- 3.4.1 The opponent referred to D19. D19 discloses a wound dressing carrier layer (26) placed between the backing layer and the skin facing layer, see figure 2. According to the paragraph bridging pages 16 and 17 the carrier layer may have a greater stiffness than the backing layer so as to prevent curling, wrinkling or sticking of parts of the skin facing layer upon repeated administration. The opponent argued that this was the same solution to the same problem as in the disputed patent. The choice of the location of the carrier layer in the claimed dressing was obvious starting from D18, since otherwise the envelope would have to be opened. Thus, a skilled person would not have needed any inventive activity to solve the technical problem stated above.
- 3.4.2 The patent proprietor pointed to the structural differences between the dressing of D18 and D19. A skilled person would not have combined these two documents. Moreover, the carrier layer in D19 was not located in the same position as in the claims of the patent.
- 3.4.3 In the Board's view, starting from D18, D19 does not lead the skilled person to the solution of the technical problem as claimed.

Firstly, D18 and D19 deal with wound dressings that have substantial structural differences. The dressing of D18 is an envelope structure having a freely floating absorbent core. In the dressing of D19 the absorbent core, on the other hand, is secured to the backing layer and, as is apparent from figures 2 and 10-12, also to the skin facing layer in case there is such a layer covering the absorbent core. Expansion of the absorbent core upon uptake of liquids will thus not

necessarily have the same consequences on mechanical stability of the wound dressing in D18 and in D19.

Secondly, D19 deals with the problem of skin adhesion, in particular in the region of the wound opposed to the boarder portions, see pages 2/3, summary of the invention. It is proposed to provide a dressing with two different skin facing layers with different adhesive properties. These may preferably be silicone sheets, as shown in figure 2, or the center portion may be formed by the adhesive core itself, like in figures 10-12 referred to by the opponent.

A skilled person, starting from D18 and aiming at reducing delamination would not have turned to a document as D19, dealing with structurally different dressings and aiming at a different goal, in order to solve the technical problem posed. It is correct that D19 proposes, for some of its embodiments, a carrier layer in order to improve the mechanical stability. However, D19 is not primarily concerned with improvements of mechanical properties, and mechanic properties of the dressing of D19 may be different than in D18 due to the difference in structure. A skilled person would not, without knowing the claimed invention, take an isolated disclosure in D19 and apply it to the structurally different dressings of D18.

Moreover, as pointed out by the patent proprietor, in D19 the carrier layer is located between the backing layer and the skin adhesive layer whereas starting from D18 to arrive at the claims of the patent, the carrier layer would have to be located at the proximal side of the two layers forming the envelope. The opponent argued that the locations are the same, in both cases being at the distal side of the skin adhesive layer

(layer 10 in D18, layer 28 in D19). This is formally correct, however, since in D18 the adhesive flange 10 does not form part of the envelope whereas in D19 the adhesive layer 28 is located below the backing layer and the carrier layer, the locations are not the same. The opponent had countered that, anyway, a skilled person, seeing the wound dressing of D18, would have placed an additional carrier layer below the envelope, since otherwise, if placed at the position as in D19, the envelope would have to be opened again. However, this is a modification of the teaching of D19 rather than an application of it to D18 and thus, in the Board's view, speaks against a combination of D18 and D19 to lead to the claimed wound dressing.

- 3.4.4 The Opposition Division and the opponent also argued that it was general knowledge that carrier layers improved the mechanical properties of wound dressings.

No such general knowledge has been substantiated and the Board notes that the only specific disclosure dealing with carrier layers referred to by the opponent is D19. D19 does not qualify as general knowledge.

In any case the question is not whether it was general knowledge that carrier layers may improve mechanical properties, but whether and where a skilled person would have introduced such a layer into the wound dressing of D18.

- 3.5 Thus, starting from the wound dressing disclosed in D18 a skilled person would not have arrived at the subject-matter defined in the claims of the patent without applying hindsight knowledge. Various selections would have had to be made to arrive at the structure of the claimed skin facing layer and an additional carrier

layer would have had to be added at the claimed location. At least the addition of the carrier layer was not obvious from the cited prior art. Whether the additional selections which had to be made within the teaching of D18 with regard to the nature of the skin facing layer were obvious for the skilled person is thus not decisive.

The claims of the granted patent involve thus an inventive step in the sense of Article 56 EPC.

4. In summary, no ground of opposition prejudices the maintenance of the patent as granted. The opposition is therefore to be rejected (Article 101(2) EPC).

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is maintained as granted.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated