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Datasheet for the decision of 12 April 2016

Case Number: T 0266/15 - 3.3.10

Application Number: 04739725.2

Publication Number: 1638620

IPC: A61L15/46, A61L15/18, B32B15/14, A61F13/15

Language of the proceedings: EN

Title of invention:
ANTIMICROBIAL WOUNDDRESSING

Patent Proprietor:
Beiersdorf AG

Opponent:
Paul Hartmann AG

Headword:

Relevant legal provisions:
EPC Art. 123(2), 54(2), 56

Keyword:

Amendments - allowable (yes) - main request
Novelty - (no) - main request - (yes) - first auxiliary request
Clarity - first auxiliary request - not open to examination in opposition appeal
Sufficiency of disclosure - not part of appeal proceedings
Inventive step - (yes) - first auxiliary request

Decisions cited:

Catchword:

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Case Number: T 0266/15 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 12 April 2016

Appellant: (Opponent)	Paul Hartmann AG Paul-Hartmann-Strasse 12 89522 Heidenheim (DE)
Representative:	DREISS Patentanwälte PartG mbB Postfach 10 37 62 70032 Stuttgart (DE)
Respondent: (Patent Proprietor)	Beiersdorf AG Unnastraße 48 20253 Hamburg (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 15 January 2015 concerning the maintenance of European patent No. 1638620 in amended form.**

Composition of the Board:

Chairman	P. Gryczka
Members:	R. Pérez Carlón
	C. Schmidt

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the interlocutory decision of the opposition division maintaining European patent No. 1 638 620 in the form of the then pending main request.

II. Notice of opposition had been filed on the ground of lack of novelty and inventive step (Article 100(a) EPC).

III. The documents filed during the opposition proceedings included the following:

D10: DE 89 07 218 U1
D11: DE 101 08 083 A1
D12: WO 86/05971

IV. The opposition division concluded that the feature "wherein the antimicrobial metal in elemental form is coated on the first layer on the side which faces the second layer" in claim 1 of the main request, which is also the main request in these appeal proceedings, found a basis in the application as originally filed. It also concluded that the claimed subject-matter was novel, *inter alia* as document D12 disclosed impregnation and not coating. It considered that either of documents D11 or D12 was the closest prior art, that the problem underlying the claimed invention was providing an alternative antimicrobial composite, and that the solution, which was a composite characterised by having an antimicrobial metal coated on its surface, was not obvious having regard to the prior art. For those reasons, the claimed subject-matter was inventive.

V. Claim 1 of the main request reads as follows:

"An antimicrobial composite comprising a first, liquid-permeable layer and a second layer arranged on the first layer, wherein the first layer comprises a foramenous material and wherein an antimicrobial metal in elemental form is present between the first and second layers, wherein the antimicrobial metal in elemental form is coated on the first layer on the side which faces the second layer and substantially no antimicrobial metal in elemental form being present on exterior surfaces of the composite."

VI. The first auxiliary request corresponds to the first auxiliary request before the opposition division on 8 October 2014.

Claim 1 of this request contains all the features of claim 1 of the main request and, in addition, specifies that:

"the antimicrobial metal is present in an amount of from 10 mg/m2 to 600 mg/m2 of composite."

VII. The arguments of the appellant relevant for the present decision were the following:

The feature of claim 1 of the main request "wherein the antimicrobial metal in elemental form is coated on the first layer on the side which faces the second layer" did not find a basis in the application as originally filed. For that reason, the main request contained added subject-matter.

Document D12 disclosed a wound dressing having a layer (3) in the form of a silver-impregnated open mesh and

having no silver on its outer surfaces. For that reason, claim 1 of the main request was not novel.

With respect to the first auxiliary request, the appellant argued that the patent in suit did not disclose, in a manner sufficiently clear and complete, how to obtain a composite comprising the required amount of silver. Furthermore, that feature, which was not present in the claims as granted, was not clear.

Both D10 and D12 disclosed wound-covering articles, but D12 had more features in common with the claimed invention than D10 and so, for that reason, was the closest prior art.

If, nevertheless, document D10 were to be considered closer, the problem underlying the claimed invention was merely to provide an alternative antimicrobial composite. The solution, which was a composite characterised by not containing any metal on its outer surfaces, was obvious, as D10 taught covering an active layer with a gauze. The subject-matter of claim 1 of the first auxiliary request was for that reason not inventive.

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

Claim 1 of the main request found a basis in claim 1 as originally filed in combination with paragraph [0067] of the description, according to which the antimicrobial metal required by claim 1 was preferably present as a coating on one of the surfaces of the first layer.

Document D12 failed to disclose an antimicrobial metal

in elemental form, as it only referred to "silver", elemental silver was difficult to use in impregnation processes, and the presence of saline was required for ensuring conductivity, which hinted that "silver" in the context of D12 referred to Ag^+ ions. D12 also failed to disclose a product in which silver was coated, as required by claim 1. For those reasons, the subject-matter of claim 1 of the main request was novel.

Document D10 was the closest prior art, as D12 referred to a different type of composite to be used in combination with an electric current. D10 did not disclose the absence of antimicrobial metal in elemental form from the exterior surfaces of the composite. Even if the problem underlying the claimed invention were to be considered as merely to provide a further antimicrobial composite, the solution, which was characterised by having no antimicrobial metal in elemental form on exterior faces of the composite, was inventive.

IX. Oral proceedings before the board of appeal took place on 12 April 2016.

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

The appellant requested that the decision under appeal be set aside and that European patent No. 1 638 620 be revoked.

The respondent requested that the appeal be dismissed or, subsidiarily, that the patent be maintained upon the form of one of the first to seventh auxiliary requests,

- the first and second auxiliary requests being identical to those before the opposition division, filed with letter dated 8 October 2014, and submitted again with a letter dated 23 December 2015,
- the third to fifth auxiliary requests having also been filed under cover of a letter dated 23 December 2015, and
- the sixth and seventh auxiliary requests having been filed with a letter received on 18 January 2016.

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

Reasons for the Decision

1. The appeal is admissible.

Main request

2. Amendments

2.1 The appellant argued that the feature of claim 1 "wherein the antimicrobial metal in elemental form is coated on the first layer on the side which faces the second layer", which had been added during the opposition proceedings, did not find the required basis in the application as originally filed.

2.2 However, paragraph [0067] of the application as originally filed provides such basis. This paragraph discloses that the antimicrobial metal is preferably present as a coating (at least) on one of the surfaces of the first layer. Claim 1 as originally filed requires an antimicrobial metal to be present between

the first and second layers. The combination of the two requirements results in the feature of claim 1, according to which the metal is coated on the first layer on the side which faces the second layer.

The argument of the appellant that claim 1 of the main request contained added subject-matter is thus dismissed.

3. Novelty

3.1 Claim 1 relates to an antimicrobial composite comprising an antimicrobial metal in elemental form coated on a first, foramenous, liquid-permeable layer on the side which faces the second layer. Substantially no antimicrobial metal in elemental form is present on exterior surfaces of the composite.

3.2 Claim 6 of document D12 refers to a wound dressing having multiple layers (1) to (5). Layer (3) is an electrically-conductive open mesh which comprises a silver-impregnated material. On page 4, lines 19-24, document D12 discloses that said open mesh may be of a material such as nylon which has been treated by impregnation with a metal such as silver.

3.2.1 The respondent argued that "silver" did not necessarily mean elemental silver, and that represented a distinction with respect to D12. In fact, impregnation with elemental silver was difficult, and page 5, lines 5-8 disclosed that, in order to ensure good conductivity, the dressing of D12 needed to be hydrated with isotonic saline prior to use, which hinted that silver was in the form of silver salts. For these reasons, the respondent concluded that document D12 did not disclose an antimicrobial metal in elemental form,

as required by claim 1.

Elemental silver is usually designated, simply, silver, whereas Ag^+ is normally indicated as "ionic silver" "silver ions" or "silver salts", as on page 5, line 2 of document D12. For this reason alone, it is concluded that document D12, on page 4, lines 19-24, refers to an open mesh impregnated with elemental silver.

The respondent has not provided evidence which could prove that elemental silver is difficult to use in impregnation. This argument is thus a mere allegation, devoid of proof.

With respect to the argument that, according to page 5, lines 5-8 of D12, saline was required for ensuring conductivity, this passage relates to the chemical conductivity of the full dressing, i.e. to the capacity of the dressing to transport silver ions into the wound, which is undoubtedly enhanced by saline, and not to the electrical conductivity of the mesh. Thus, the board fails to see how this passage could indicate that silver salts, and not elemental silver, were present on the mesh of D12.

3.2.2 The appellant saw a further difference in that impregnation could not lead to a product in which an antimicrobial metal in elemental form was coated, as required by claim 1.

During the oral proceedings before the board, the respondent interpreted this feature as requiring the presence of metal on the surface of the first layer, but not excluding its presence either within the first layer or on any other surface of the first or further layers. The board and the appellant agreed with this

interpretation.

Document D12 discloses treating a nylon mesh by impregnation with a metal such as silver (page 4, lines 19-24). Although document D12 does not provide further details on how to carry out this impregnation, taking into account that nylon fibers have a low absorbency, it can only be concluded that at least part of the silver remains on the surface of the open mesh structure which, according to the repondent's interpretation, corresponds to a mesh in which silver is coated on the first layer, as required by claim 1.

3.2.3 For these reasons, the board concluded that document D12 discloses all the features of claim 1 of the main request, which therefore lacks novelty (Article 54 EPC). Consequently, this request is not allowable.

First auxiliary request

4. Amendments

The appellant has not raised any objections under Article 123(2) EPC further to those already examined with respect to the main request, which the board considered not convincing for the reasons already explained (see point 2. above).

5. Clarity and sufficiency of disclosure

The appellant argued that the patent in suit did not disclose, in a manner sufficiently clear and complete, how to obtain the claimed antimicrobial composite, in which the antimicrobial metal in elemental form was present in an amount of from 10 mg/m^2 to 600 mg/m^2 of composite. It further argued that this feature was not

clear.

Claim 11 as granted already required a (different) specific amount of antimicrobial metal in elemental form per surface of composite. Thus, any lack of clarity which could derive from that relative amount was already present in the claims as granted, and cannot be examined in these opposition appeal proceedings (G 3/14).

Article 100(b) EPC was not invoked by the appellant in its notice of opposition. Such a fresh ground could only be examined during these appeal proceedings with the consent of the respondent (G 10/91), which had not been given.

For those reasons, these objections are not admissible.

6. Inventive step

Claim 1 of the first auxiliary request is directed to an antimicrobial composite comprising a first, foramenous, liquid-permeable layer, a second layer arranged on the first layer, and an antimicrobial metal, coated on the first layer on the side which faces the second, in an amount of from 10 mg/m^2 to 600 mg/m^2. Claim 1 further requires substantially no antimicrobial metal in elemental form to be present on exterior surfaces of the claimed composite. The claimed composites are intended as part of wound-covering articles, antimicrobial skin care articles or diapers.

6.1 Closest prior art

The parties were divided as to whether document D10 or D12 was closer to the claimed antimicrobial composites.

The appellant argued that document D12 had more features in common with the claimed invention than document D10.

However, document D12 relates to multi-layer bactericidal wound dressings to which an electrical current is applied in order to enhance wound healing and to release bactericidal silver ions into the wound (page 4, line 25 to page 5, line 4). Although claim 1 does not exclude that an electric current could be applied to the claimed antimicrobial composites, it is apparent from the patent in suit that such a current is not required.

Document D10 refers to multi-layer wound dressings containing an active substance in the form of a thin layer of metal or metallic compound on one of the layers (page 1, last paragraph), which can be made of cellulose, plastic or fabric, and a further layer of non-woven on the side of the previous layer opposite to the metal. By perforating this composite with nails, a part of the non-woven is pushed through the composite and forms a layer over the thin layer of metal or metallic compound. This layer of non-woven protects the metal from direct contact, but does not cover its surface completely (page 2, lines 1-2). Document D10 thus discloses a composite suitable as a wound-covering article comprising an active metal layer, which does not require the application of any current and which aims at avoiding direct contact of the active metal with the wound or the skin. For those reasons, the board considers that document D10 is closer than D12 to the claimed invention.

The antimicrobial composites of document D10 differ

from those of claim 1 at least in that those of D10 contain silver in elemental form on exterior surfaces, which is excluded from claim 1, as the non-woven layer only partially covers the outer layer of silver.

6.2 Technical problem underlying the invention

The parties had different views as to the formulation of the technical problem effectively solved by the claimed invention.

In the following, it will be examined whether the subject-matter of claim 1 is inventive under the assumption that the technical problem underlying the claimed invention is merely that of providing a further antimicrobial composite. Since the solution to this problem is not obvious, it is not necessary to examine whether a more ambitious problem has also been solved.

6.3 Solution

The solution to this technical problem is the claimed antimicrobial composite, characterised in that substantially no antimicrobial metal in elemental form is present on exterior surfaces of the composite.

6.4 Success

The board agrees with the opposition division that, having regard to the data provided in the examples of the patent in suit, the problem of providing a further antimicrobial composite is credibly solved by the composite of claim 1.

6.5 It thus remains to be decided whether or not the proposed solution to the objective problem defined

above is obvious in view of the state of the art.

6.5.1 The key feature of the antimicrobial composites of D10 is a layer of non-woven which protects the metal from direct contact, but which does not completely cover said metal.

In contrast, the present invention requires the absence of metal from the outer surfaces of the composite.

6.5.2 The appellant argued that document D10 already taught away from any direct contact of the wound or the skin with the metal and, for that reason, it was obvious to increase the thickness of the layer over the metal.

However, the board considers that the skilled person would not modify the feature which document D10 considers essential in the absence of a reason for doing so or of a specific hint towards the claimed subject-matter.

6.5.3 The appellant further argued that document D10 disclosed that it was known to completely cover the metal layer with a gauze. For this reason, an antimicrobial composite which did not contain any metal on its outer surfaces was an obvious option for a skilled person.

However, document D10 refers to covering with a gauze an active layer of unknown composition, and discloses that an antimicrobial composite having an only partially covered metallic layer is preferred. The skilled person would thus infer that fully covering such a metal layer was not efficient.

6.5.4 The appellant has not relied on any further passages of the prior art which could render the claimed subject-matter obvious, nor is any such passage apparent in the prior art opposed to the patent in suit.

7. Starting from D10, the board considers that the skilled person would not have omitted its essential feature, which is that the metal not be completely covered.

For this reason, it is concluded that document D10 does not provide a hint towards the claimed solution, with the consequence that the subject-matter of claim 1 is inventive, as required by Article 56 EPC.

8. Claims 14-21 refer to a process of making an antimicrobial composite which does not necessarily lead to obtaining an antimicrobial composite according to claim 1. Although the statement of ground of appeal includes a section allegedly directed to these claims (see page 12), it only contains arguments with respect to claims 2 to 13. Thus, the appellant has not raised objections against process claims 14 to 21 going beyond those which also relate to the antimicrobial composite of claim 1, which the board rejects for the reasons explained above.

9. The board thus concludes that none of the objections raised by the appellant precludes the maintenance of the patent in suit in the form of the first auxiliary request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the first auxiliary request, filed on 8 October 2014, and a description to be adapted.

The Registrar: The Chairman:

M. Schalow P. Gryczka

Decision electronically authenticated