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Datasheet for the decision of 2 February 2017

Case Number: T 0387/15 - 3.3.10

Application Number: 07021890.4

Publication Number: 1882482

IPC: A61L15/28, A61L15/46

Language of the proceedings: EN

Title of invention:
Antibacterial wound dressing

Patent Proprietor:
ConvaTec Limited

Opponent:
Smith & Nephew plc

Headword:

Relevant legal provisions:
EPC Art. 100(c), 76(1), 123(2), 123(3), 84, 83, 54(2), 111(1)
RPBA Art. 13(1), 13(3)
EPC R. 80

Keyword:
Amendments - added subject-matter (yes) - Main request including corrections, main request without corrections, auxiliary requests 1-16
Auxiliary request 17 - added subject-matter (no), clarity (yes), sufficiency of disclosure (yes), novelty (yes), remittal (yes)

Decisions cited:
T 0337/95, T 0409/91, T 0435/91, G 0003/14

Catchword:

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Case Number: T 0387/15 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 2 February 2017

Appellant: (Patent Proprietor)	ConvaTec Limited GDC First Avenue Deeside Industrial Park Deeside Flintshire CH5 2NU (GB)
Representative:	Mays, Julie Venner Shipley LLP 200 Aldersgate London, EC1A 4HD (GB)
Respondent: (Opponent)	Smith & Nephew plc Group Patents & Trademarks 15 Adam Street London WC2N 6LA (GB)
Representative:	Uno, Jennifer Elizabeth Hayes HGF Limited Saviour House 9 St Saviourgate York, YO1 8NQ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 12 December 2014 revoking European patent No. 1882482 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	P. Gryczka
Members:	R. Pérez Carlón
	T. Bokor

Summary of Facts and Submissions

I. The appeal lies from the decision of the opposition division to revoke European patent No. 1 882 482.

II. Notice of opposition had been filed on the grounds of added subject-matter (Article 100(c) EPC), insufficiency of disclosure (Article 100(b) EPC), and lack of novelty and inventive step (Article 100(a) EPC).

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

D2: WO 02/43743
D4: WO 02/24240
D8: US 6,087,549
D9: US 4,728,323
D10: US 5,681,575
D11: US 5,180,585
D12: US 2,887,088

IV. The opposition division concluded that the invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and that none of the requests then pending contained added subject-matter. However, the wound dressing of claim 1 of the patent as granted and of the auxiliary request then pending was not novel over those disclosed in document D4.

V. With a letter dated 8 November 2016, the appellant (patent proprietor) filed a "main request including corrections", a "main request without corrections", which corresponds to the claims of the patent as granted, and auxiliary requests 1 to 16. Auxiliary

request 17 was filed during the oral proceedings before the board, which took place on 2 February 2017.

VI. Claim 1 of the main request including corrections reads as follows:

"An antibacterial wound dressing derived from gel-forming fibres having silver ions linked thereto at some but not all exchangeable sites, characterised in that the gel-forming fibres are obtainable by dunking the fibres in an unconstrained manner into a silver-containing solution so that the distribution of silver ions over the exchangeable sites is uniform, and the silver ions are linked to not more than 20% of the exchangeable sites on the gel-forming fibres."

VII. Claim 1 of the main request without corrections and of auxiliary requests 1 to 16 contains, like claim 1 of the main request including corrections, the feature

"the gel-forming fibres are obtainable by dunking the fibre(s) in an unconstrained manner into a silver-containing solution so that the distribution of silver ions over the exchangeable sites is uniform",

wherein *"fibre(s)"* indicates that some of these requests, like the patent as granted, refer to "fibre" in the singular, and some to "fibres" in the plural.

VIII. Claim 1 of auxiliary request 17 reads as follows:

"An antibacterial wound dressing derived from gel-forming fibres having silver ions linked thereto at some but not all exchangeable sites, characterised in that the gel-forming fibres are obtainable by dunking the fibres in an unconstrained manner into a silver-

containing solution by lowering the fibres directly into the silver-containing solution and pushing the fibres immediately below the surface of the silver-containing solution so that the distribution of silver ions over the exchangeable sites is uniform, and the silver ions are linked to not more than 20% of the exchangeable sites on the gel-forming fibres and the silver content of the fibres is 0.9 to 1.5% by weight."

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

The feature "obtainable by dunking the fibre" or "obtainable by dunking the fibres" which was present in claim 1 of the main request including corrections, the main request without corrections and auxiliary requests 1-16, found a basis in the parent application, page 7, lines 7-8, since claim 1 should be read in the context of the description of the patent in suit, and was thus limited to the specific types of dunking disclosed in the earlier application. For this reason, none of these requests contained added subject-matter.

Auxiliary request 17 should be admitted into the proceedings, as it had been filed in response to an objection raised during the oral proceedings before the board.

The feature "pushing the fibres immediately below the surface of the silver-containing solution" in claim 1 of auxiliary request 17 was clear.

There was no difficulty in pushing fibres immediately below the surface of a solution, as required by claim 1. For that reason, the claimed subject-matter was sufficiently disclosed for it to be carried out by

a person skilled in the art.

Claim 1 required fibres containing silver ions linked to no more than 20% of the exchangeable sites, obtainable by dunking, having a uniform silver distribution, and containing from 0.9 to 1.5% by weight of silver. Neither D2 nor D4 disclosed a wound dressing having fibres as required by claim 1 of auxiliary request 17, which was thus novel.

The appellant requested that the case be remitted to the opposition division if inventive step needed to be examined.

X. The arguments of the respondent (opponent) relevant for the present decision were the following:

The parent application of the patent in suit only disclosed a specific type of dunking, as disclosed on page 4, lines 20-25; page 5, line 25, to page 6, line 1, and page 7, lines 7-8. However, claim 1 of the main request including corrections, the main request without corrections and auxiliary requests 1-16 required fibres obtainable by any kind of dunking, and thus contained added subject-matter.

Auxiliary request 17, filed towards the end of the oral proceedings before the board, should not be admitted into the proceedings as it had been filed very late.

Claim 1 of auxiliary request 17 was not clear due to the feature "immediately", not present in the claims as granted, which did not specify a clear time interval.

The claimed invention was not sufficiently disclosed for it to be carried out by a person skilled in the

art. The description indicated that the volume of silver solution used should be as small as possible, but did not teach how to dunk the fibres in such a case. In addition, the relative terms "uniform" and "immediately" did not allow the skilled person to carry out every embodiment of claim 1.

Claim 1 of auxiliary request 17 did not exclude a wound dressing containing mixtures of fibres. For that reason, the dressing resulting from blending silvered and non-silvered fibres disclosed in example 1 of document D4, which contained 1.0% by weight of silver, was novelty-destroying for the wound dressing of claim 1.

The embodiment of D2 on page 8, lines 5-18, explicitly disclosed all the features of claim 1 with the exception of the uniform distribution of silver ions over the exchangeable sites. However, this feature was disclosed implicitly, as the dressing obtained was found to be photostable. Thus, the claimed wound dressing was not novel over that disclosed in D2.

At the oral proceedings before the board, the respondent did not object the case being remitted to the opposition division for further prosecution.

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

- The appellant requested that the decision under appeal be set aside and the patent maintained in the form of the "main request including corrections" or, subsidiarily, of the "main request without corrections", which is identical to the claims of the patent as granted, or on the basis of any of auxiliary requests 1 to 16, filed with a

letter dated 8 November 2016, or of auxiliary request 17, filed during the oral proceedings before the board. It further requested that the case be remitted to the opposition division for further prosecution if inventive step was to be examined, and that documents D8 to D12 be admitted into the proceedings.

- The respondent requested that the appeal be dismissed, and that documents D8 to D12 not be admitted into the proceedings.

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

Reasons for the Decision

1. The appeal is admissible.

Amendments; main request including corrections, main request without corrections, auxiliary requests 1-16

2. The main request including corrections, the main request without corrections and auxiliary requests 1-16 contain the feature "*the gel-forming fibres are obtainable by dunking the fibre(s) in an unconstrained manner into a silver-containing solution so that the distribution of silver ions over the exchangeable sites is uniform*", wherein "fibre(s)" indicates that some of these requests, like the patent as granted, refer to "fibre" in the singular, and some to "fibres" in the plural.

2.1 The patent in suit is based on a divisional application of European patent application No. 1 425 050.

2.2 Claim 1 of the patent in suit does not contain any limitation of the feature "dunking", which merely means dipping or submerging.

2.3 In contrast, the earlier application discloses contacting fibres with silver salt solutions in a particular manner, namely "in such a way that the entire solution for silvering is contacted essentially simultaneously with the entire amount of gel-forming fibres" (page 4, lines 20-25) or "by lowering the fibres directly into the solution and pushing the fibres immediately below the surface of the solution" (passage bridging pages 5 and 6). These limitations are not included in claim 1, which only requires fibres obtainable by dunking, in general, and is not limited to fibres obtainable by the specific dunking of the earlier application.

2.4 For this reason, claim 1 of the main request including corrections, of the patent as granted (main request without corrections) and of auxiliary requests 1-16, contains subject-matter extending beyond the content of the earlier application as filed, with the consequence that the ground of opposition under Article 100(c) EPC precludes the maintenance of the patent as granted (main request without corrections), and that neither the main request including corrections nor auxiliary requests 1-16 are allowable (Article 76(1) EPC).

2.5 The appellant argued that dunking in claim 1 of these requests was limited by its meaning in the description of the patent in suit, which was the same as in the earlier application, and therefore that claim 1 of said requests did not contain added subject-matter.

However, it is well-established case law (see for

example T 197/10, not published in the OJ of the EPO, point 2.3 of the Reasons) that if a claim is worded clearly there is no need to use the description to interpret it.

"Dunking" is a clear term meaning dipping or submerging, and there is no need to read into claim 1 any specific meaning or restriction given to it in the description. Thus, the definition of dunking in the description of the patent in suit does not limit the meaning of dunking to the types disclosed in the earlier application.

2.6 Although Article 100(c) EPC had been a ground of opposition, the respondent's argument in points 2.1 to 2.3 above was only raised during the oral proceedings before the board. The appellant neither objected to this argument being discussed and decided upon, nor argued that it was not prepared to address it during the oral proceedings (Article 13(3) RPBA), and the objection is very relevant for the outcome of these appeal.

Under these circumstances, the board made use of its discretion to admit the respondent's new line of argument into the proceedings (Article 13(1) RPBA).

Auxiliary request 17

3. Admission

3.1 Auxiliary request 17 was filed towards the end of the oral proceedings before the board of appeal.

The respondent argued that this request had been filed very late, and should therefore not be admitted into

the proceedings.

However, this request was a reaction to the respondent's argument on added subject-matter, put forward for the first time during the oral proceedings before the board, and to which the appellant could not have responded earlier. The respondent did not argue that it could not deal with this request during the oral proceedings (Article 13(3) RPBA), and the board is satisfied that is able to deal with it too. For all these reasons, the board made use of its discretion to admit auxiliary request 17 into the proceedings (Article 13(1) RPBA).

4. Amendments

The respondent had no added-matter objection to auxiliary request 17.

4.1 Claim 1 of auxiliary request 17 finds a basis in the combination of claims 1 and 2 as originally filed, page 8, lines 12-13, page 7, lines 7-8 and page 5, lines 25 to page 6, line 1. Claims 2-4 find a basis in pages 3-5 as filed, combined with the passages mentioned with respect to claim 1.

By requiring the claimed wound dressing to be derived from fibres obtainable by a specific type of dunking so that the distribution of silver ions over the exchangeable sites is uniform, instead of obtainable by dunking in general, claim 1 of auxiliary request 17 does not extend the scope of protection conferred by the patent as granted.

The requirements of Article 123(2) and (3) EPC are thus

fulfilled.

4.2 Claim 1 of auxiliary request 17 finds a basis in the combination of claims 1 and 2 of the earlier application as originally filed, and the passages on page 8, lines 12-13, page 7, lines 7-8 and page 5, lines 25 to page 6, line 1.

Claims 2 and 3 find a basis in claims 3 and 4 combined with the passages already mentioned with respect to claim 1.

Lastly, claim 4 finds a basis on page 11, lines 8-10. Although this passage discloses the feature of claim 4 that the uniform distribution of silver ions over the exchangeable sites is shown by the uniform colouration of the dressing in the context of a specific embodiment for obtaining silvered fibres, the skilled person will understand from the earlier application that the method for evaluating the uniformity of silver distribution on fibres is independent of the method used for obtaining them.

The requirements of Article 76(1) EPC are thus also fulfilled.

4.3 The board raised an objection under Rule 80 EPC directed at "the main request including corrections", as the amendments in said request were not a response to a ground of opposition.

Although claim 1 of auxiliary request 17 also contains these amendments, this claim has been further amended with respect to the patent as granted. There is no reason why Rule 80 EPC should prevent the appellant from replacing "derived form" with "derived from" and

"by dunking the fibre" with "by dunking the fibres", once the claim is amended in response to a ground of opposition. The latter amendment finds a basis in page 5, line 25 of the description, the former is derivable from the whole content of the application as filed and, as such, neither of them is in breach of Article 123(2) EPC. No objection under Article 123(3) EPC is apparent, either.

5. Clarity

5.1 Article 84 in conjunction with Rule 43(1) EPC stipulates that the claims must be clear and must define the matter for which protection is sought in terms of the technical features of the invention. These requirements serve the purpose of ensuring that the public is not left in any doubt as to which subject-matter is covered by a particular claim and which is not (see T 337/95, OJ EPO 1996, 628, Reasons 2.2 to 2.5).

5.2 The respondent argued that the word "immediately", which had been added to claim 1 during these opposition appeal proceedings, was not clear, contrary to Article 84 EPC. The description of the patent in suit indicated that "immediately" in the sense of claim 1 included 10 seconds but not 15 seconds, but lacked any further information setting clear limit to the dunking time.

5.3 Claim 1 requires fibres which are obtainable by dunking them in an unconstrained manner into a silver-containing solution. Such dunking step is carried out by lowering the fibres directly into the silver-containing solution and pushing the fibres, i.e. all of them, *immediately* (i.e. without waiting) below the

surface of the silver-containing solution (i.e thard enough to immerse the fibres in the solution). Thus, this feature is sufficiently clear in the context of claim 1, even in the absence of a reference to a specific time interval.

The board thus concludes that claim 1 of auxiliary request 17 is clear, as required by Article 84 EPC.

6. Sufficiency of disclosure

6.1 According to the case law of the boards of appeal, the requirements of sufficiency of disclosure are met only if the claimed invention can be performed by a person skilled in the art without undue burden over the whole area claimed, using common general knowledge and having regard to the information in the patent in suit (T 409/91, OJ 1994, 653, Reasons 3.5; T 435/91, OJ 1995, 188, Reasons 2.2.1).

6.2 The respondent considered that the claimed invention was not sufficiently disclosed for it to be carried out by a person skilled in the art. The features "uniform" and "immediately" were relative terms which did not allow the skilled person to operate throughout the whole scope of the claim. Paragraph [0017] of the patent in suit indicated that the volume of silver solution should be as small as possible, which necessarily made the dunking of fibres difficult and hence slower, but no instruction beyond the examples had been provided.

6.3 However, the board is convinced that the skilled person would not have any difficulty in dunking fibres into a silver solution by lowering them directly into said solution and pushing them immediately below its

surface, even in the absence of specific instructions in the description.

6.4 The respondent also argued that the patent in suit did not sufficiently disclose the degree of uniformity of the silver distribution. For that reason, the claimed invention was not sufficiently disclosed for it to be carried out by a person skilled in the art.

Although the evaluation of the uniformity of the silver distribution could leave some uncertainty with respect to the subject-matter of claim 1, that is a clarity issue which is not open to examination in these opposition appeal proceedings since this feature was already present in claim 1 as granted (G 3/14, OJ 2015, A102, order).

7. Novelty

7.1 Claim 1 of auxiliary request 17 is directed to an antibacterial wound dressing derived from gel-forming fibres.

7.2 The board interprets claim 1 as relating to a wound dressing which contains one or more types of gel-forming fibres. The claimed dressing, however, has to contain fibres which fulfil the following criteria:

- silver ions are linked to them at some but not all exchangeable sites,
- they are obtainable by dunking in an unconstrained manner into a silver-containing solution by being lowered directly into it and pushed immediately below the solution's surface, so that the distribution of silver ions over the exchangeable sites is uniform,

- silver ions are linked to not more than 20% of the exchangeable sites of the gel-forming fibres, and
- the silver content of the fibres is 0.9 to 1.5% by weight.

All these conditions should be fulfilled by the same fibres, due to the use of the article "the" throughout the claim.

7.3 It is undisputed that documents D2 and D4 are prior art as defined in Article 54(2) EPC.

7.4 D4

7.4.1 The respondent argued that example 1 of document D4 disclosed all the features of claim 1 of auxiliary request 17. On page 6, line 4, in the context of example 1, D4 disclosed blends of silvered and unsilvered carboxymethyl cellulose which contained 1.0% by weight silver. This amount of silver inevitably required less than 20% of the exchangeable sites to be bound to silver, irrespective of the carboxymethylation degree of cellulose. Claim 1 did not exclude blends of fibres and, for that reason, example 1 of D4 disclosed an embodiment having all the features of claim 1 of auxiliary request 17.

7.4.2 However, the blend disclosed in D4 containing 1.0% by weight silver cannot be obtained by dunking "the" fibres (i.e. all of them) in a silver-containing solution, as such a process could not lead to a mixture of 12.5% silvered fibres containing 8% by weight of silver and 87.5% unsilvered fibres. Such a blend has been obtained from silvered fibres which were obtainable by dunking but contain 8% by weight silver, which is higher than required by claim 1. Thus, none of

these fibres fulfil the conditions of the fibres set in claim 1.

For this reason, claim 1 of the main request is novel over D4, as required by Article 54(2) EPC.

7.4.3 The respondent argued that, according to example 1 of the patent in suit, the calculation of the percentage of tow remaining uncoloured according to the claimed invention referred to the whole tow and, for that reason, the skilled person would understand that the properties required by claim 1 could refer to a blend of fibres, not only to those containing silver.

However, it is not apparent why the skilled person would consider that the percentage of silver could refer to a blend of fibres, one of them lacking any silver, as an uncoloured fibre does not necessarily lack any silver, and, in any case, example 1 refers to fibres obtained by dunking, not to a blend of fibres.

7.5 D2

The respondent argued that the embodiment of D2 on page 8, lines 5-18, disclosed an Aquacel wound dressing, which was a carboxymethyl cellulose dressing, subjected to silver nitrate (page 8, lines 11-12) so that the final concentration of silver in the dressing could be 1% by weight (page 8, lines 10-11), which was lower than required for 20% of the exchangeable sites to be occupied by silver. The dressing was found to be photostable (page 8, line 17), which indicated a uniform distribution of silver ions. For these reasons, this embodiment disclosed all the features of claim 1 of auxiliary request 17.

However, the embodiment on page 8, lines 5-18, fails to disclose that the product obtained has a uniform distribution of silver ions over the exchangeable sites of the fibres. There is no direct link between being photostable (i.e. not changing under the influence of light) and having a homogeneous distribution. In addition, example 1 of the patent in suit shows that not every method for applying silver ions to fibres necessarily results in a uniform distribution thereon, and there is no evidence on file which could show whether or not the process of D2 leads to a uniform distribution. For these reasons, it is concluded that document D2 fails to disclose all the features of claim 1 of auxiliary request 17.

7.6 It is thus concluded that the wound dressing of claim 1 of auxiliary request 17 is novel over the prior art cited against it (Article 54(2) EPC).

8. Admission of documents D8 to D12

These documents were not admitted into the proceedings by the opposition division. The appellant requested that they be admitted in these appeal proceedings.

As none of these documents has any bearing on the present decision, it is not necessary to decide on this point. Should their admission be considered relevant in the further proceedings, the issue can be decided, either by the first instance or in any subsequent appeal.

9. Remittal

9.1 The opposition division revoked the patent in suit due to lack of novelty, but did not deal with all the

grounds for opposition. Under these circumstances, the board considers it appropriate to remit the case to the opposition division for further prosecution on the basis of the claims according to auxiliary request 17 (Article 111(1) EPC). Neither party has objected to remittal.

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 for further prosecution.

The Registrar: The Chairman:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated