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Datasheet for the decision of 21 November 2013

Case Number: T 0449/13 - 3.3.02

Application Number: 01998356.8

Publication Number: 1343510

IPC: A61K31/74, A61K9/70, A61F13/00

Language of the proceedings: EN

Title of invention:
LIGHT STABILIZED ANTIMICROBIAL MATERIALS

Patent Proprietor:
ConvaTec Technologies Inc.

Opponent:
Smith & Nephew plc

Headword:
Antimicrobial materials / CONVATEC

Relevant legal provisions:
EPC Art. 56, 107, 111

Keyword:
Appeal of the patent proprietor not admissible - not adversely affected
Inventive step - main request and first auxiliary request (no) arbitrary choice
Appeal decision - remittal to the department of first instance (yes)
further auxiliary requests not yet subject of discussion

Decisions cited:

Catchword:
./.

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Case Number: T 0449/13 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 21 November 2013

Appellant: (Opponent)	Smith & Nephew plc Group Patents & Trademarks 15 Adam Street London WC2N 6LA (GB)
Representative:	Drysdale, Douglas Standen Harrison Goddard Foote LLP Delta House 50 West Nile Street Glasgow G1 2NP (GB)
Respondent: **(Patent Proprietor)**	ConvaTec Technologies Inc. 6100 Neil Road, Suite 500 Reno NV 89511 (US)
Representative:	Mays, Julie Venner Shipley LLP 200 Aldersgate London EC1A 4HD (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 December 2012 concerning maintenance of the European Patent No. 1343510 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
R. Cramer

Summary of Facts and Submissions

I. European patent No. 1 343 510, filed as application No. 01 998 356.8 based on international patent application PCT/US2001/044773 and published as WO 2002/043743, was granted with 8 claims. The priority of US 250182 P dated 29 November 2000 was claimed.

Independent claim 1 as granted read as follows:

"A method of preparing a light stabilized antimicrobial material, characterised in that the method comprises the steps of:

a) preparing a solution comprising an organic solvent and a source of silver in a quantity sufficient to provide a desired silver concentration in said material;

b) subjecting a polymer to said solution for a time sufficient to incorporate said desired silver concentration into said polymer, wherein said polymer comprises a polysaccharide or modified polysaccharide, a polyvinylpyrrolidone, a polyvinyl alcohol, a polyvinyl ether, a polyurethane, a polyacrylate, a polyacrylamide, collagen, or gelatin or mixtures thereof; and

c) subjecting said polymer, during or after step (b) to one or more agents selected from the group consisting of ammonium salts, thiosulphates, chlorides and peroxides which facilitate the binding of said silver on said polymer, which material is substantially photostable upon drying, but which will dissociate to release said silver upon rehydration of said material."

II. Opposition was filed against the granted patent under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC on the grounds that it contained subject-matter which had not originally been disclosed.

III. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

(1) WO 01/24839

(2) US 2396514

IV. The opposition division held that the set of claims of the main request filed during the oral proceedings met the requirements of the Convention.

Even if the proprietor had withdrawn its priority claim with letter of 11 October 2012 and, consequently, document (1) was prior art under Article 54(2) EPC, novelty could be acknowledged with respect to all documents on file. The range for the concentration of the agent introduced in step c) of the claimed method and differing from example 25m of document (1) was the technical feature which rendered the subject-matter of claim 1 of the main request novel.

Based on this difference, the teaching of claim 1 of the main request was not obvious in the light of document (1) alone or in combination with document (2).

V. Both the opponent and the patent proprietor filed appeals against the decision of the opposition division. The patent proprietor's notice of appeal was

filed in the knowledge of the opponent's notice of appeal and contained the indication that the requests filed during the proceedings before the opposition division were maintained.

Admissibility of the patent proprietor's appeal, however, was questioned by the opponent on the grounds that the proprietor was not adversely affected by the decision of the opposition division.

VI. As indicated in its notice of appeal, the patent proprietor filed, together with its statement of grounds of appeal, nine sets of claims as main request and auxiliary requests 1 to 8.

Based on the former main request, dated 11 October 2012 and filed before the opposition division, the new main request filed with the grounds of appeal reinstated dependent claims 4, 5 and 6 together with an additional correction or amendment replacing the word "halide" by "chloride" in claim 4.

Auxiliary request 1 was identical to the main request upheld by the opposition division.

Auxiliary requests 2 to 8 were the renumbered auxiliary requests submitted during the opposition proceedings.

The wording of claim 1 of the patent proprietor's main request reads (changes with respect to claim 1 as granted marked):

"A method of preparing a light stabilized antimicrobial material including gel forming fibers characterised in that the method comprises the steps of:

a) preparing a solution comprising an organic solvent and a source of silver in a quantity sufficient to provide a desired silver concentration in said material;

b) subjecting a polymer to said solution for a time sufficient to incorporate said desired silver concentration into said polymer, wherein said polymer comprises a polysaccharide or modified polysaccharide, a polyvinylpyrrolidone, a polyvinyl alcohol, a polyvinyl ether, a polyurethane, a polyacrylate, a polyacrylamide, collagen, or gelatin or mixtures thereof; and

c) subjecting said polymer, during or after step (b) to one or more agents selected from the group consisting of ammonium salts, thiosulphates, chlorides and peroxides which facilitate the binding of said silver on said polymer,
the agent being present in a concentration between 1% and 25% of the total volume of treatment,
which material is substantially photostable upon drying, but which will dissociate to release said silver upon rehydration of said material."

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

VII. Oral proceedings took place on 21 November 2013.

VIII. The appellant (opponent)'s arguments during the proceedings may be summarised as follows:

The patent in suit did not disclose any advantage of its teaching over the prior art, in particular example 25m of document (1). Under these circumstances, the

choice of a concentration of 1 to 25% of the agent facilitating the binding of the silver to the polymer was arbitrary and did not support the assumption of inventiveness.

As far as a possible remittal of the case was concerned, the appellant (opponent) disagreed because the request for acceleration had been filed for good reasons and would be thwarted by remittal. The appellant (opponent) would give the patent proprietor as much time as it wanted to consider all the arguments necessary to assess auxiliary requests 2 to 8, in particular with respect to experiments to be presented and showing that the problem was not solved over the whole scope of the claims.

IX. The patent proprietor contested the arguments of the appellant (opponent):

Document (1) had to be read as a whole. There was nothing in this document that would cause the skilled person to single out example 25m and, if this example was looked at, the product of example 25n was disclosed to be more stable and contained no chloride. Moreover, example 25m of document (1) did not result in a photostable product. To enhance photostability, in view of example 25n, the conclusion was that the chloride concentration had to be reduced.

In addition, there were concerns that more chloride would negatively influence the gel-forming properties of the resultant material, in particular of a wound dressing.

The skilled person would need to overlook the colour instability of the product of example 25m and increase

the salt concentration way above the significant molar excess already present in that example to arrive at patentee's claims.

The appellant (opponent)'s submissions during the UK proceedings on the same subject-matter showed that the necessary considerations were much more complicated than those it had presented before this board.

Provided that the identical claims 1 of the main request and auxiliary request 1 were not found allowable by the board, the patent proprietor would ask for remittal of the case for assessment of auxiliary requests 2 to 8.

X. The appellant (opponent) requested that the appeal of the patent proprietor be declared inadmissible, and that the decision under appeal be set aside and that European patent No. 1 343 510 be revoked.

XI. The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims filed as main request with the grounds of appeal, or alternatively that the appeal of the opponent be dismissed, or more alternatively that the decision under appeal be set aside and that the patent be maintained on the basis of one of the sets of claims of auxiliary requests 2 to 8, all filed with the grounds of appeal.

Reasons for the Decision

1. The opponent's appeal is admissible.

2. The opposition division maintained the patent in suit according to the proprietor's main request filed during

the oral proceedings. Therefore, its decision did not adversely affect the patent proprietor.

The patent proprietor has filed no arguments as to why this legal principle should not apply in the present case.

Therefore, its appeal is not admissible in view of Article 107 EPC.

3. Claim 1 of the main request (identical to claim 1 of auxiliary request 1); Article 56 EPC

3.1 Closest prior art

The patent proprietor had withdrawn its priority claim with letter of 11 October 2012 and, consequently, document (1) was considered prior art under Article 54(2) EPC in the opposition division's decision.

The patent proprietor declared that it did not wish to discuss before the board the considerations of the opposition division in its annex to the summons to its oral proceedings that had led to said withdrawal.

It still accepted document (1) as prior art under Article 54(2) EPC which was relevant for the assessment of inventive step.

3.2 Inventive step; identical claims 1 of the main request and auxiliary request 1

3.2.1 The closest state of the art is document (1).

3.2.2 The subject-matter of claim 1 of the main request and auxiliary request 1 relates to a method of preparing a

light stabilised antimicrobial material including gel forming fibers, in that the method comprises the steps of

a) preparing a solution comprising an organic solvent and a source of silver in a quantity sufficient to provide a desired silver concentration in said material;

b) subjecting a polymer to said solution for a time sufficient to incorporate said desired silver concentration into said polymer, wherein said polymer comprises *inter alia* a polysaccharide or modified polysaccharide; and

c) subjecting said polymer, during or after step (b), to one or more agents selected from the group consisting of … chlorides and … which facilitate the binding of said silver on said polymer,

the agent being present in a concentration between 1% and 25% of the total volume of treatment,

which material is substantially photostable upon drying, but which will dissociate to release said silver upon rehydration of said material.

3.2.3 The subject-matter of example 25m of document (1) relates to a method of preparing a

light stabilised antimicrobial material including gel forming fibers, (see page 44, lines 12 to 14; aquacel, the polymer used in this example and in the example of

the patent in suit, includes gel forming fibers) in that the method comprises the steps of

a) preparing a solution comprising an organic solvent and a source of silver in a quantity sufficient to provide a desired silver concentration in said material; (see page 44, lines 10 to 11 together with page 45, line 19, text before "add dressing")

b) subjecting a polymer to said solution for a time sufficient to incorporate said desired silver concentration into said polymer, wherein said polymer comprises a modified polysaccharide (see page 44, lines 10 to 11 together with page 45, line 19, text including "add dressing"; aquacel is a carboxymethyl cellulose according to page 44, line 21); and

c) subjecting said polymer, during or after step (b), to one or more agents selected from the group consisting of … chlorides … which facilitate the binding of said silver on said polymer, (see page 45, lines 19 to 21 together with page 44, lines 15 to 17);

which material is substantially photostable upon drying, but which will dissociate to release said silver upon rehydration of said material (see page 45, lines 30 to 31 together with page 44, lines 15 to 17).

In the patent in suit, in column 6, lines 38 to 40, the term "photostable" is defined as "controlled colour change to a desired colour with minimal change thereafter". Samples of example 25 in document (1) "that contained higher concentrations of silver discolored more quickly in light with most samples eventually turning a purplish color". This means a controlled colour change to a particular colour, "the

desired colour", because the overall amount of discolouration is not indicated as negative. Further discoloration was not mentioned and therefore cannot be more than minimal in the sense of the patent in suit. Therefore, the patent's definition for photostability is fulfilled by the material resulting from examples 25 in document (1).

The only feature not disclosed in example 25m is that the agent used in step c) (sodium chloride in example 25m) be "present in a concentration between 1% and 25% of the total volume of treatment". 1% w/v sodium chloride under the circumstances of example 25m, namely in 50g ethanol and 2.1ml of water, would amount to around 0.65g of agent and 0.0888g of the agent sodium chloride being present in example 25m.

3.2.4 There are no experiments on file that compare the method of the patent in suit to the method set out in example 25m of document (1). With regard to photostability, only the statements set out under point 3.2.3 above comparing the claimed teaching with example 25m are possible. Accordingly, photostability or any other effect resulting from the application of the method of the patent in suit cannot be regarded as equal or improved with respect to the results disclosed in document (1), example 25m.

3.2.5 As a consequence, the problem to be solved is to provide a further method to produce a light stabilised antimicrobial material.

3.2.6 The proposed solution according to the patent in suit is to use the agent which facilitates the binding of silver to the polymer in a concentration between 1% and 25% of the total volume of treatment.

In view of the experiment set out in the patent in suit, the problem can be considered to be plausibly solved.

3.2.7 The skilled person working on methods for preparing light stabilised antimicrobial materials learns from document (1) that the concentration of sodium chloride in the total volume of treatment can be varied (sodium chloride is the agent which facilitates the binding of silver to the polymer in both example 25 and the example set out in the patent in suit, and is applied in different amounts in example 25, namely e.g. 0.0888g in 25m and 0.1777g in 25a to 25d.

3.2.8 Moreover, it is even indicated on page 44, lines 17 and 18 that the stability of the material to light is controlled by the amount of sodium chloride … . The stability-enhancing effect of the amount of sodium chloride (see explanation on page 21, lines 19 to 27, in particular lines 25 to 27) must inevitably relate to the amount of sodium chloride present in the final material and not to the concentration in the bath (volume of treatment). The indication, mentioned in example 25, can only be based on the fact that any excess of chloride ions in the final material can only be achieved by an excess of chloride ions in the bath (volume of treatment), even if not all of it is present in the final material because, in the preparatory step before drying, a dressing is taken out of the bath and blotted (see document (1), page 45, lines 26 to 27).

Consequently, the hint in example 25 to the amount of sodium chloride has to be understood as that amount which is necessary to provide for enough excess chloride ions in the bath to be able to retain

sufficient chloride in the final material to ensure stability to light, even after the losses on blotting. Because of these losses, the concentration of sodium chloride in the bath is independent of the amount of chloride in the final material, as long as a minimum amount is guaranteed.

Accordingly, excess sodium chloride provided by the concentration of sodium chloride in the bath in some freely chosen amount is generally foreseen on the basis of example 25, the excess amount mandatorily being higher in the bath than in the final product.

3.2.9 Even in this situation, no evidence has been provided in the patent in suit or the entire proceedings of any correlation between any particular effect and a concentration of 1% or up to 25% of the agent in the total volume of treatment according to claim 1 of the main request.

3.2.10 Consequently, such a concentration must be seen as an arbitrary choice which is not inventive and the subject-matter of claim 1 of the main request (identical to claim 1 of auxiliary request 1) does not fulfil the provisions of Article 56 EPC.

4. Under these circumstances the patent proprietor's further arguments on file cannot succeed:

Most of these arguments are based on the assumption that the products of the state of the art were of poor quality in terms of photostability and therefore there was a need to enhance the photostability of the material produced by the method of example 25m, and the person skilled in the art had to derive from the overall document (1) or from other prior art how to

achieve it. This, however, according to the board's considerations and conclusions on inventive step, is not the case. The product according to example 25m is at least as photostable as the products according to the method of claim 1 of the main request.

In addition, it must be pointed out that a higher concentration of sodium chloride in the total volume of treatment does not necessarily result in a higher content of sodium chloride in the final material. Depending on the treatment of samples (dressings) after "subjecting said polymer" to the agent(s) "facilitating the binding of said silver on said polymer" more or less of the sodium chloride contained in the total volume of treatment is separated from the dressing. This occurs for instance by blotting, as is realised in example 25m.

Since the teaching of claim 1 of the patent in suit (and all of the text of the patent) is silent on the treatment of the dressings after step c) with respect to the fluid of the bath, no valid conclusion about the content of sodium chloride in the material and no further conclusion about any characteristics that might be influenced by that content can be drawn.

Further, as far as the ability to form gels is concerned, particular attention has to be paid to the fact that claim 1 of the main request does not relate to the final **material** (and not only dressings) to be able to form gels but only that it includes gel-forming fibers, e.g. fibers that are capable of forming a gel, no matter what they do in reality.

The complexity of considerations and reasoning in the UK proceedings relating to the subject-matter of the

patent in suit is not relevant in the proceedings before the EPO because it is mainly caused by the different legal system applicated there.

5. Remittal

Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered at two instances, it is well recognised that any party may be given an opportunity for two readings of the important elements of a case.

The opposition division decided on the maintenance of the patent according to the main request as amended in oral proceedings. Consequently, the auxiliary requests already on file were not to be assessed.

Even in the knowledge that these auxiliary requests would necessarily become an issue in the appeal proceedings if the board were to find the request decided upon by the opposition division not to be allowable (see notice of appeal and grounds of appeal filed by the patent proprietor) and after requesting accelerated prosecution, the appellant (opponent) never commented on either their admissibility or their allowability.

Concluding that the set of claims of the request dealt with by the opposition division is not allowable, creates a new situation for the board with respect to auxiliary requests 2 to 8. Therefore, they should now be examined on their own merits.

Thus, the board exercises its discretion under Article 111 EPC and remits the case to the first instance for further prosecution.

6. To conclude: the subject-matter of the main request and auxiliary request 1 lacks inventive step. Because of the further auxiliary requests which have been filed but not yet examined as to their admissibility and allowability, the case is remitted.

Order

For these reasons it is decided that:

1. The appeal filed by the patent proprietor is inadmissible.

2. The decision under appeal is set aside.

3. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated