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**Datasheet for the decision
of 18 December 2012**

Case Number: T 1729/09 - 3.3.10

Application Number: 96944824.0

Publication Number: 876165

IPC: A61L27/00, A61L31/00

Language of the proceedings: EN

Title of invention:

CROSSLINKED POLYMER COMPOSITIONS AND METHODS FOR THEIR USE

Patentee:

AngioDevice International GmbH

Opponent:

Kuros Biosurgery AG

Headword:

Relevant legal provisions:

EPC Art. 123(2), 111(1)

RPBA 13(1)

Keyword:

Added subject-matter - yes (main and auxiliary requests 1-12)
Auxiliary requests 12-18 not admitted into the proceedings
Remittal for further prosecution

Decisions cited:

G0005/83, G0010/91

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 1729/09 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 18 December 2012

Appellant: AngioDevice International GmbH
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 16 July 2009
revoking European patent No. 876165 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairwoman: C. Komenda
Members: R. Pérez Carlón
D. Rogers

Summary of Facts and Submissions

- I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to revoke European patent No. 876 165.
- II. An opposition was filed, on the grounds that the subject-matter of the patent as granted was not novel and did not involve an 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 subject-matter of the claims related to a treatment by therapy or by surgery (Article 100(a) and 53(c) EPC).
- III. The opposition division decided that the then pending main and second auxiliary request were not novel, and that the amendments made to the claims of the auxiliary requests 1 and 1B did not fulfill the requirements of Article 123(2) EPC.
- IV. With a letter dated 15 November 2012, the appellant filed a new main request and a first to sixth auxiliary request. The relevant independent claims of these requests read as follows:

Main request:

Claim 1: *"A composition comprising a first synthetic polymer having m nucleophilic groups, and a second synthetic polymer having n electrophilic groups of which two or more groups are succinimidyl groups; wherein said nucleophilic groups and said electrophilic groups are capable of reacting to form covalent bonds between the first synthetic polymer and the second*

synthetic polymer which results in formation of a three-dimensional matrix; wherein each synthetic polymer has an alkylene oxide backbone and wherein m and n are each greater than or equal to 3."

First auxiliary request:

Claim 1: "A composition comprising a first synthetic polymer having m nucleophilic groups, and a second synthetic polymer having n electrophilic groups, wherein said electrophilic groups are succinimidyl groups and wherein said nucleophilic groups and said electrophilic groups are capable of reacting to form covalent bonds between the first synthetic polymer and the second synthetic polymer which results in formation of a three-dimensional matrix; wherein each synthetic polymer has an alkylene oxide backbone and wherein m and n are each greater than or equal to 3."

Second auxiliary request:

Claim 1: "A composition comprising as first synthetic polymer polyethylene glycol having m nucleophilic groups of which two or more groups are selected from a primary amino group and a thiol group, and a second synthetic polymer having n electrophilic groups of which two or more groups are succinimidyl groups; wherein said nucleophilic groups and said electrophilic groups are capable of reacting to form covalent bonds between the first synthetic polymer and the second synthetic polymer which results in formation of a three-dimensional matrix; wherein the second synthetic polymer has an alkylene oxide backbone and wherein m and n are each greater

than or equal to 3."

Third auxiliary request:

Claim 1: "A composition comprising as first synthetic polymer polyethylene glycol having m nucleophilic groups, and a second synthetic polymer having n electrophilic groups; wherein said nucleophilic groups are selected from a primary amino group and a thiol group, wherein said electrophilic groups are succinimidyl groups and wherein said nucleophilic groups and said electrophilic groups are capable of reacting to form covalent bonds between the first synthetic polymer and the second synthetic polymer which results in formation of a three-dimensional matrix;

wherein the second synthetic polymer has an alkylene oxide backbone and wherein m and n are each greater than or equal to 3."

Fourth auxiliary request:

Claim 1: "A composition comprising as first synthetic polymer polyethylene glycol having m nucleophilic groups of which two or more groups are selected from a primary amino group and a thiol group, and as second synthetic polymer polyethylene glycol having n electrophilic groups of which two or more groups are succinimidyl groups; wherein said nucleophilic groups and said electrophilic groups are capable of reacting to form covalent bonds between the first synthetic polymer and the second synthetic polymer which results in formation of a three-dimensional matrix;
wherein m and n are each greater than or equal to 3."

Fifth auxiliary request:

Claim 1: *"A composition comprising as first synthetic polymer polyethylene glycol having m nucleophilic groups, and as second synthetic polymer polyethylene glycol having n electrophilic groups, wherein the nucleophilic groups are selected from a primary amino group and a thiol group, wherein the electrophilic groups are succinimidyl groups and wherein said nucleophilic groups and said electrophilic groups are capable of reacting to form covalent bonds between the first synthetic polymer and the second synthetic polymer which results in formation of a three-dimensional matrix; wherein m and n are each greater than or equal to 3".*

Sixth auxiliary request:

Claim 1: *"A composition comprising a first polyethylene glycol having m primary amino groups, and a second polyethylene glycol having n succinimidyl groups, wherein m and n are each greater than or equal to 3."*

Claim 2: *"Use of a composition according to claim 1 for the preparation of a medical device for use in a method of preventing the formation of adhesions following surgery or injury."*

Claim 3: *Use of a composition according to claim 1 for the preparation of a medical device for use as a biosealant."*

Together with its statement of grounds for appeal dated 25 November 2009, the appellant filed a seventh to twelfth auxiliary requests, whose relevant independent claims read as follows:

Seventh auxiliary request:

Claim 1: *"Use of a composition [following wording is as in claim 1 of auxiliary request 4] for the preparation of a medical device for use in a method of preventing the formation of adhesions following surgery or injury."*

Claim 2: *"Use of a composition [as in claim 1 of auxiliary request 4] for the preparation of a medical device for use as biosealant."*

Eight auxiliary request:

Claim 1: *"Use of a composition [as in claim 1 of auxiliary request 5] for the preparation of a medical device for use in a method of preventing the formation of adhesions following surgery or injury."*

Claim 2: *"Use of a composition [as in claim 1 of auxiliary request 5] for the preparation of a medical device for use as biosealant."*

The only claim of the ninth auxiliary request is identical to claim 2 of the seventh auxiliary request.

The only claim of the tenth auxiliary request is identical to claim 2 of the eighth auxiliary request.

Eleventh auxiliary request:

Claim 1: *"Use of a composition [as in claim 1 of auxiliary request 6] for the preparation of a medical device for use in a method of preventing the formation of adhesions following surgery or injury."*

Claim 2: *"Use of a composition [as in claim 1 of auxiliary request 6] for the preparation of a medical device for use as biosealant."*

The only claim of the twelfth auxiliary request is identical to claim 2 of the eleventh auxiliary request.

During the oral proceedings held on 18 December 2012 before the board, the appellant filed further auxiliary requests thirteenth to nineteenth.

Claims 1 and 2 of the thirteenth to eighteenth auxiliary requests were identical, respectively, to those of the main request and the first to fifth auxiliary requests, claims 3 and 4 of each of these requests having been deleted.

The nineteenth auxiliary request contained only claim 1 of the sixth auxiliary request.

- V. The appellant stated that the feature "m and n are each greater than or equal to three" found a basis in claim 5 and on page 10, lines 9-10 of the description as originally filed, whereas the feature "a polymer having succinimidyl groups" was disclosed on page 11, line 30 to page 14, line 10. No new subject-matter was present since the subject-matter claimed resulted from the combination of most preferred embodiments.

Claim 1 of the sixth and of the nineteenth auxiliary requests found a basis in claims 23, 24 and 27 as filed, and the subject-matter of these claims corresponded to the combination of claims 20, 21 and 24 as granted.

The feature "medical device" had been introduced for formal reasons in order to avoid an objection under Article 53(c), and therefore it did not need a basis in the application as originally filed.

The appellant considered that the respondent could not raise objections under Article 123(2) EPC during the oral proceedings before the board against those sets of claims where this objection had not been raised before, and requested that new objections be rejected as late filed.

- VI. The respondent argued that the application as originally filed failed to disclose the combination of the features of the main request and of the first to fifth and seven to tenth auxiliary requests, which resulted from a cherry picking of different embodiments within the application as filed.

The term "medical device" could not be found in the application as filed, and it could not be added merely to avoid an objection under Article 53(c) EPC.

- VII. The appellant requested that the decision under appeal be set aside and the patent be maintained upon the basis of:
- the main request; or alternatively
 - any of auxiliary requests 1-6; all the above having been filed under cover of a letter dated 15 November 2012; or alternatively
 - any of auxiliary request 7-12, filed under cover of a letter dated 25 November 2009; or alternatively,
 - any of auxiliary request 13-19, filed at the oral proceedings before the board on 18 December 2012.

VIII. The respondent requested that the appeal be dismissed.

IX. At the end of the oral proceedings before the board, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Added subject-matter (Article 123(2) EPC):

2. Main request:

2.1 Claim 1 of the main request is based on claim 1 as granted, wherein the synthetic polymers have been restricted to contain "m nucleophilic" and "n electrophilic" groups, two or more of the electrophilic groups being "succinimidyl groups" and "m and n are each greater than or equal to 3". Due to the amendments made, the claim includes *inter alia* the combination of features of "polymer having succinimidyl groups" and "m and n are each greater than or equal to three".

2.2 The appellant provided as a basis the disclosure on page 10, lines 9-10, claim 5 as filed; and page 11, lines 30 to page 14, line 6 of the application as filed.

2.3 It has not been disputed that the wording of each of the features can be found in the application as originally filed.

The parties were, however, of different views as to whether said features had been disclosed in combination.

2.4 The description includes on page 9, line 11 and following, a chapter under the heading "synthetic polymers", at the end of which it mentions:

"most preferably, both the first and the second synthetic polymer contain at least three functional groups" (page 10, lines 9-10).

This feature is, however, not disclosed in combination with any specific functional group.

2.5 On page 11, line 30, the description refers to "synthetic polymers containing multiple electrophilic groups". This paragraph discloses that "multi-electrophilic polymers of the claimed invention may contain two or more succinimidyl groups" (page 12, line 5), but it is silent on the *total* amount of electrophilic groups (n) of said polymer, which may be different from the total amount of succinimidyl groups, and does not indicate any amount of nucleophilic (m) groups of the nucleophilic polymer. This passage does not disclose the features relating to "polymer having succinimidyl groups" and "m and n are each greater than or equal to three" in combination and, therefore, does not provide a basis for the subject-matter of claim 1.

2.6 The next passage, starting on page 12, line 20 under the heading "hydrophilic polymers" discloses polyethylene glycol polymers containing succinimidyl groups, but neither in combination with the total amount of electrophilic groups (n) of said polymer, nor with the amount (m) of nucleophilic groups in the nucleophilic polymer.

2.7 Claim 5 as filed discloses the feature "m, n are each greater than or equal to three". However, this claim is

not combined with the additional feature that the electrophilic groups are succinimidyl as required by claim 1 of the main request, and the combination of the features of a claim and a passage of the description is only possible if said combination was originally disclosed.

There is, however, no disclosure of the combination of the amounts n and m of the nucleophilic and electrophilic groups of the polymer as in claim 5 and the chemical structure of the electrophilic groups being succinimidyl groups.

2.8 Claim 27 of the application as originally filed was dependent from claim 23. Claim 27 disclosed the combination of the features "m and n are each greater than or equal to three" and "succinimidyl groups". However, these features are, additionally, combined with the nature of the nucleophilic groups (amino) and the backbone of both polymers (polyethylene glycol), whereas neither said backbones nor the chemical structure of the nucleophilic groups are features of claim 1.

2.9 It remains to be addressed whether, although the passages mentioned above do not explicitly disclose the specific combination of features of claim 1, such a combination would be implicitly disclosed in the light of the teaching of the application as filed.

Even if the skilled person would combine the aforementioned features "a polymer having succinimidyl groups" and "n greater than or equal to three", such a combination could result in two different embodiments, namely:

- a polymer having 3 or more electrophilic groups (n), from which 2 or more (n') are succinimidyl, and the remaining n-n' groups are not defined (see claim 1 of the main request) or
- a polymer having 3 or more electrophilic groups (n) which are all succinimidyl (see claim 1 of the first auxiliary request).

However, none of these embodiments were disclosed in the application as originally filed. Linking these features in a technically meaningful manner requires adding undisclosed information, not present in the application as filed, namely whether all the electrophilic groups in the second polymer, or only two or more of them are succinimidyl. For these reasons the disclosure of the passages cited by the respondent cannot be read as a single, combined disclosure in the light of the general technical information provided in the application as filed.

2.10 The board concludes, therefore, that the combination of features in present claim 1 of "polymer having succinimidyl groups" and "m and n are each greater than or equal to three" does not find a basis in the application as originally filed. The main request contravenes the requirements of Article 123(2) EPC and is therefore not allowable.

2.11 The appellant argued that the skilled person would have combined these features since they were most preferred embodiments, whose combination should always be allowed.

A combination of preferred embodiments fulfills the requirements of Article 123(2) EPC only if these embodiments have been disclosed in combination, which

is not the case here for the reasons given above. Labelling an embodiment as preferred does not mean that this embodiment could be combined with another preferred embodiment or any other parts of the description, unless the general disclosure of the application provides a basis for this combination.

This argument of the appellant must, therefore, fail.

- 2.12 The appellant also mentioned that the application contained examples falling within the subject-matter claimed.

However, the presence of an example falling within the subject-matter of claim 1, in which both n and m are 4, is not sufficient to provide a basis for the broader scope of claim 1, which requires " m and n are each greater than or equal to three".

Therefore, this argument must also fail.

- 2.13 The board concludes, thus, that the subject-matter of claim 1 of the main request does not find a basis in the application as originally filed (Article 123(2) EPC), with the consequence that this request is not allowable.

3. First to fourth and seventh to tenth auxiliary requests:

- 3.1 Due to the amendments made during the appeal proceedings, claim 1 of the first to fourth and seventh to tenth auxiliary requests also contains the combination of features "polymer having succinimidyl groups" and " m and n are each greater than or equal to three".

Therefore, the same argumentation and considerations as brought forward with respect to the main request also apply to the first to fourth and seventh to tenth auxiliary requests. Consequently, the board concludes that the amendments made to claim 1 of these requests do not satisfy the requirements of Article 123(2) EPC.

- 3.2 The respondent did not raise any objection of added subject-matter against the claims of the first, third, fifth, sixth and eighth to twelfth auxiliary requests during the written procedure, and the appellant requested that the arguments brought forward during the oral proceedings before the board be considered late filed and not admitted into the proceedings.

However, if the claims of a patent are amended in the course of opposition or appeal proceedings, such amendments are to be fully examined *ex officio* by the board as to their compliance with the provisions of Article 123 EPC (G 10/91, point 19 of the reasons), even if the parties to the proceedings had not raised such an objection.

Therefore, the board finds that the first to fourth and seventh to tenth auxiliary request do not fulfill the requirements of Article 123(2) EPC.

4. Fifth auxiliary request:

- 4.1 Claim 1 of the fifth auxiliary request is based on granted claim 1 and has been further restricted to the first and second synthetic polymers being polyethylene glycol and having m nucleophilic groups selected from a primary amino and a thiol group and n electrophilic groups, which are succinimidyl groups. Further, m and n

is restricted to be each greater than or equal to three.

Due to the amendments made, claim 1 specifically claims a composition comprising a first polyethylene glycol having three thiol groups in combination with a second polyethylene glycol having three succinimidyl groups.

- 4.2 The appellant referred to page 11, lines 11 to 15, which disclosed as preferred embodiments polyethylene glycols having two or more thiol groups and to page 12, lines 4 to 6, which disclosed a preferred polyethylene having two or more succinimidyl groups. Original claims 5 and 17 disclose that m and n are each greater than or equal to three.

However, the disclosure of the first polyethylene glycol having two or more thiol groups is not a specific disclosure of a polyethylene having *three* (or more) thiol groups. Thus, no basis can be found for the particular combination of a polyethylene glycol having three thiol groups with a polyethylene having three succinimidyl groups.

Consequently, the board concludes that the amendments made to claim 1 of the fifth auxiliary request do not satisfy the requirements of Article 123(2) EPC.

5. Sixth auxiliary request:

- 5.1 Claims 2 and 3 of the sixth auxiliary request contain the feature "medical device". It is accepted by the parties that this feature cannot be found literally in the application as originally filed.

5.2 The appellant argued that the amendments made to claims 2 and 3 of the sixth auxiliary request were in reaction to an objection under Article 53(c) EPC raised during the opposition proceedings. Since the term had been introduced in order to disclaim subject-matter excluded from patentability for non-technical reasons, a basis thereof was not necessary.

5.3 The board considers, however, that claims 2 and 3 of the sixth auxiliary request are not Swiss type claims in the sense of G5/83, since they are directed to the use of a composition for the manufacture of a medical device rather than of a medicament. The feature "medical device" has not been, therefore, introduced in order to disclaim subject-matter excluded from patentability for non-technical reasons and, hence, needs a basis in the application as filed in order to fulfill the requirements of Article 123(2) EPC.

5.4 It remains to be examined whether such a basis can be found in the application as originally filed:

The paragraph "field of the invention" on page 1 of the application as filed does not disclose medical devices, it merely indicates that the compositions of the invention can be used as bioadhesives, for tissue augmentation, in the prevention of surgical adhesions and for coating surfaces of synthetic implants, as drug delivery matrices and for ophthalmic applications.

Page 22, lines 12-23 discloses a "double barreled syringe" containing the claimed compositions. Page 27, line 16 discloses "syringes", and page 27, lines 31-32 discloses "a spray can, and a nozzle or other application devices". However, these embodiments do not provide a basis for the broader feature "medical

device", which thus represents an unallowable generalisation.

The appellant has argued that the feature "medical device" was within the technical field of the invention. However, it is not sufficient that an embodiment is not contradictory to the wording of the claim in order to provide a basis for the later. This argument must, therefore, fail.

5.5 The board concludes that the sixth auxiliary request contains added subject-matter in the sense of Article 123(2) EPC, with the consequence that this request is not allowable.

6. Eleventh and twelfth auxiliary requests:

All the claims of the eleventh to twelfth auxiliary request contain the feature "medical device" for which no basis can be found in the application as filed for the reasons explained with respect to the sixth auxiliary request. These requests do not satisfy, therefore, the requirements of Article 123(2) EPC with the consequence that they are not allowable.

7. Thirteenth to eighteenth auxiliary requests:

The thirteenth to eighteenth auxiliary requests have been filed during the oral proceedings before the board, and, hence, it falls within the discretion of the board whether to admit these requests into the proceedings (Article 13(1) of the Rules of Procedure of the Boards of Appeal).

Independent claim 1 of the thirteenth to eighteen auxiliary requests are identical, respectively, to

independent claim 1 of the main and first to fifth auxiliary requests. These requests do not address the outstanding objections under Article 123(2) EPC explained in points 2 to 4 of this decision. For this reason, the board makes use of its discretion under Article 13(1) of the Rules of Procedure of the Boards of Appeal not to admit these requests into the proceedings.

8. Nineteenth auxiliary request:

8.1 This request contains only one claim, which is identical to claim 1 of the sixth auxiliary request.

8.2 The subject-matter of claim 1 is based on the combination of claims 23, 24 and 27 as originally filed, and, therefore fulfills the requirements of Article 123(2) EPC. The respondent did not have any objection with respect to added subject-matter against this request.

8.3 As regards Article 123(3) EPC, the subject-matter of claim 1 results from the combination of the subject-matter of granted claims 20, 21 and 24.

The respondent has argued that the last part of claim 24 as granted, namely the feature "3." could not be found in the published granted patent. The board notes that this feature was present in the text forming the basis of the decision to grant under Article 97(2) EPC. This is the legally binding text of the grant of the patent against which the requirements of Article 123(3) EPC are to be assessed. This argument, therefore, fails to convince the board that the inclusion of this feature means the requirements of Article 123(3) EPC are not complied with.

The board therefore concludes that the nineteenth auxiliary request fulfills the requirements of Article 123(3) EPC.

9. Remittal:

9.1 As regards the product claims, the appealed decision of the opposition division dealt exclusively with the issue of added subject-matter. None of the other requirements of the EPC were dealt with in this decision. Under these circumstances, 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 upon the basis of claim 1 of auxiliary request 19, filed at the oral proceedings before the board on 18 December 2012.

The Registrar:

The Chairwoman:



C. Rodríguez Rodríguez

C. Komenda

Decision electronically authenticated