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**D E C I S I O N**  
**of 30 June 2003**

**Case Number:** T 1058/00 - 3.3.3

**Application Number:** 91911862.0

**Publication Number:** 0536223

**IPC:** C08G 18/48

**Language of the proceedings:** EN

**Title of invention:**

Polyurethane or polyurethane-urea elastomeric compositions

**Applicant:**

AorTech Biomaterials Pty Ltd

**Opponent:**

-

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 84, 123(2)

**Keyword:**

"Claims - clarity (yes)"  
"Amendments - agreed by Boards of Appeal"

**Decisions cited:**

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**Catchword:**

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**Case Number:** T 1058/00 - 3.3.3

**D E C I S I O N  
of the Technical Board of Appeal 3.3.3  
of 30 June 2003**

**Appellant:** AorTech Biomaterials Pty Ltd  
126 Greville Street  
Chatswood,  
New South Wales 2067 (AU)

**Representative:** Kyle, Diana  
Elkington and Fife  
Prospect House  
8 Pembroke Road  
Sevenoaks, Kent TN13 1XR (GB)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 16 May 2000  
refusing European patent application  
No. 91 911 862.0 pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** R. Young  
**Members:** A. Däweritz  
E. Dufrasne

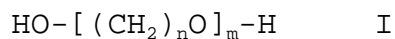
## Summary of Facts and Submissions

- I. European patent application No. 91 911 862.0, based on International application No. PCT/AU91/00270, filed on 26 June 1991, claiming the priority of 26 June 1990 of an earlier application in Australia (PK0817) and published under No. WO-A-92/00338 on 9 January 1992, was refused by a decision of the Examining Division, dated 16 May 2000, subsequent to a letter from the Applicants dated 29 October 1999 wherein it had not approved the text on the basis of an auxiliary request filed by letter of 23 March 1999, communicated to it under Rule 51(4) EPC on 29 April 1999.
- II. The decision was based on a set of five claims, filed as main request with the letter dated 23 March 1999 and resubmitted with the letter of 29 October 1999, and an amended description of 21 pages. Pages 1, 2 and 5 to 21 of the description, as filed with the said letter of 23 March 1999, had been communicated to the Applicants with the Communication under Rule 51(4) EPC in modified form with some amendments on pages 5 and 6 by the Examining Division. Pages 3 and 4 in further modified form were submitted by the Applicants with the letter of 29 October 1999.

Claim 1 of the refused main request read as follows:

"1. A medical device or medical implant which is composed wholly or partly of a polyurethane or polyurethane-urea elastomeric composition which comprises a reaction product of:

- (A) a soft segment macrodiol homopolymer represented by formula I,



wherein n represents an integer greater than 5 and less than 13, m is a number such that the number average molecular weight of the compound of formula I falls in the range from 218 to 5000 and optionally at least one hydrogen atom represented in formula I is substituted by a C<sub>1</sub> to C<sub>3</sub> alkyl group or a halogen atom;

- (B) an aromatic diisocyanate which is 4,4'-diphenylmethane diisocyanate (MDI), and
- (C) optionally an agent to act as a chain extender selected from

- 1,4-butanediol (BDO),
- 1,6-hexanediol (HDO),
- 1,2-ethylenediamine (EDA),
- 1,6-hexanediamine (HDA) and
- 1,2-propanediamine (1,2-PDA),

which is a pacemaker lead, a catheter, an implantable prosthesis, a cardiac assist device, a heart valve, a suture, a vascular graft, an extra-corporeal device which is intended to come into contact with cells or body fluids of living animals or humans or an artificial heart."

Claim 1 of the said auxiliary request had differed from the claim quoted above by the wording of its last paragraph reading as follows:

"which is a pacemaker lead, a catheter, an implantable prosthesis, a cardiac assist device, a heart valve, a suture, a vascular graft, an extra-corporeal [device] for blood contacting applications or an artificial heart."

The word "device" had been inserted in this paragraph by the Examining Division in the version of the text which had been annexed to the Communication under Rule 51(4) EPC.

In each of these two requests, the remaining Claims 2 to 5 were dependent claims of identical wording.

According to the decision, Claim 1 of the said main request did not meet the requirements of Article 123(2) EPC and the amendments on newly filed pages 3 and 4 were not allowable under Article 84 EPC.

It was held that the extra-corporal medical devices disclosed in the application as filed were used in contact with blood, so that the original text of the application did not support the generalisation to the formulation "which is intended to come into contact with cells or body fluids of living animals or humans" in the above main request.

The modifications on pages 3 and 4 as suggested by the applicant were not deemed allowable, because the claims were directed to a medical device or a medical implant but not to biomaterials as such.

III. On 14 July 2000, a Notice of Appeal against the above decision was lodged by the Appellants (Applicants), including the request that the above decision be set

aside and the application be allowed including claim 1 and page 3, as submitted on 29 October 1999. The prescribed fee was paid on 14 July 2000.

In the statement of grounds of appeal, submitted on 14 September 2000, the Appellants modified their request in that three sets of claims, each containing five claims, and new pages 3 and 4 were filed. The sets of claims were identified as main request and as auxiliary requests 1 and 2.

- IV. By letters of 25 October 2000 and 19 June 2001, the EPO was informed of a transfer of the application to a new Applicant (Appellant) and a change of name of the latter. The registration of the change of name took effect on 21 June 2001.
  
- V. By letter dated 7 August 2002, the Appellant withdrew its main request and first auxiliary request, as filed on 14 September 2000, requested that the proceedings be based on former auxiliary request 2 and referred to the comments in support of former auxiliary request 2, in the statement of grounds of appeal.
  - (i) In these comments, the Appellant pointed to the fact that the Examining Division had expressed its intention to base a European patent on Claim 1 according to the auxiliary request 1 during the examination proceedings, identical to the new Main Request. This claim would not offend against Article 123(2) EPC, because extra-corporeal devices for blood contacting applications were specifically described in the application as filed on page 1.

The amendment on page 4, on which part of the objection under Article 84 EPC had been based, had been deleted. The passage on page 3 had been amended so that it was clear that the claimed subject-matter as defined in Claim 1 might function as a biomaterial. Consequently, the definition of this term, which was within the meaning of the originally defined invention, was still required in the description.

VI. On 6 February 2003, a conversation by telephone took place between the Representative and the Rapporteur. In this conversation, a further objection under Article 123(2) EPC was raised with respect to the use of the verb "to comprise" instead of "to be" at line 2 of Claim 1 under consideration.

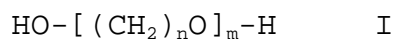
Additionally some editorial issues were discussed.

VII. By letter dated 2 April 2003, the Appellant requested the claims as on file to be replaced by Claims 1 to 4 filed with this letter and pages 1, 3, 4, 17 and 18 of the description to be replaced by the enclosed version amended in handwriting.

The set of claims as amended now reads:

"1. A medical device or medical implant which is composed wholly or partly of a polyurethane or polyurethane-urea elastomeric composition which is a reaction product of:

(A) a soft segment macrodiol homopolymer represented by formula I,



wherein n represents an integer greater than 5 and less than 13, m is a number such that the number average molecular weight of the compound of formula I falls in the range from 218 to 5000 and optionally at least one hydrogen atom represented in formula I is substituted by a C<sub>1</sub> to C<sub>3</sub> alkyl group or a halogen atom;

- (B) an aromatic diisocyanate which is 4,4'-diphenylmethane diisocyanate (MDI), and
- (C) optionally an agent to act as a chain extender selected from
  - 1,4-butanediol (BDO),
  - 1,6-hexanediol (HDO),
  - 1,2-ethylenediamine (EDA),
  - 1,6-hexanediamine (HDA) and
  - 1,2-propanediamine (1,2-PDA),

which is a pacemaker lead, a catheter, an implantable prosthesis, a cardiac assist device, a heart valve, a suture, a vascular graft, an extra-corporeal for blood contacting applications or an artificial heart.

2. A medical device or medical implant according to claim 1 which is composed of a material comprising not less than 10% of the polyurethane or polyurethane-urea elastomeric composition.

3. A medical device or medical implant according to claim 1 or 2, wherein at least one hydrogen atom is substituted by fluorine atom in the homopolymer.



4. A medical device or medical implant according to any of claim 1 to 3, wherein the elastomeric composition further comprises one or more of a cross-linking agent, a catalyst, an antioxidant, a stabilizer and a processing aid."
- VIII. In reply to two further conversations by telephone on 7 May 2003 and 26 June 2003, the Appellant filed new pages 4 and 17, further amended in handwriting (letters dated 22 May 2003 and 26 June 2003).
- IX. According to the three letters of the Appellant dated 7 August 2002, 2 April 2003 and 22 May 2003, the Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of above Claims 1 to 4 submitted with the letter of 2 April 2003 under the heading "Auxiliary request 2".

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Wording of the claims*
  - 2.1 By letter dated 7 August 2002, the Appellant requested that the claims of the main request and auxiliary request 1, filed with the statement of grounds of appeal, should be disregarded and the appeal should proceed on the basis of the claims of auxiliary request 2 as filed at the same time. These latter claims were then resubmitted with the letter of 2 April 2003 in an amended version.

In view of these facts and in accordance with the

request in the letter of 7 August 2002, the set of claims submitted by letter of 2 April 2003 forms the basis for this decision.

## 2.2 Article 84 EPC

The Board has no reason to deviate from the point of view implicitly derivable from the Communication under Rule 51(4) EPC issued on 29 April 1999 indicating that the version of application documents annexed thereto complied with the requirements of the EPC, since the present set of claims differs from the version in the above Communication only by the replacement of the word "comprises" by "is" at line 2 of Claim 1 and the deletion of the word "device" inserted by the Examining Division in the penultimate line of this claim. This deletion does not render the claim unclear or ambiguous.

Additionally, previous Claim 3, undisputedly redundant, has been deleted and the following claims have been adapted and renumbered accordingly.

## 2.3 Article 123(2) EPC

As pointed out in the previous section, the broader expression "comprises" has been replaced by the original term "is" in Claim 1.

Furthermore, the present Claims are based on the following parts of the original application:

Claim 1: Claims 1, 5, 10 and 12; page 1, lines 17 to 19 and page 2, lines 17 to 20 in combination with page 3, lines 10 to 17; page 4, line 27 and the experimental results in Examples 10 to 12.

Claims 2, 3 and 4: Claims 11, 3 and 6, respectively.

In view of these facts, the Board is satisfied that the requirements of Article 123(2) EPC are met by the claims.

3. *Description*

The present version of the description is based, in part, on pages 2 and 5 to 16, as communicated to the Applicant with the Communication under Rule 51(4) EPC on 29 April 1999, to which consent had been given by letter dated 29 October 1999. Furthermore, it contains replacement sheets of pages 1, 3 and 18, submitted with the letter of 2 April 2003, of page 4, dated 22 May 2003, and of page 17, annexed to the letter dated 26 June 2003. The amendments in these application documents, which comply with the requirements of Article 123(2) EPC, have brought the description into line with the amended claims which form the basis for this decision.

4. *Conclusion*

4.1 By amendment of the claims and of the description, the reasons for the refusal of the application in suit have been removed.

- 4.2 Moreover, in view of the present wording of the claims, the Board sees no reason to take a position as regards novelty and inventive step different from that implicitly derivable from the Communication under Rule 51(4) EPC dated 29 April 1999 (as mentioned in section 2.2).
- 4.3 It follows that the subject-matter of Claims 1 to 4 is novel and involves an inventive step.
- 4.4 Since the request to set aside the decision under appeal and to grant a patent on the sole set of claims in the file is successful, it is not necessary to hold the oral proceedings requested by the Appellant as an auxiliary request (letter of 7 August 2002).

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division with the order to grant a patent on the basis of
  - Claims 1 to 4, submitted with the letter of 2 April 2003 (with the heading "Auxiliary Request 2"), and
  - Description:
    - pages 2 and 5 to 16, as communicated to the Applicant with the Communication under Rule 51(4) EPC on 29 April 1999,
    - pages 1, 3 and 18, submitted with the letter of 2 April 2003,
    - page 4, dated 22 May 2003, and
    - page 17, submitted with the letter of 26 June 2003.

The Registrar:

The Chairman:

E. Görgmaier

R. Young

**Internal distribution code:**

- (A) [ ] Publication in OJ  
(B) [ ] To Chairmen and Members  
(C) [X] To Chairmen  
(D) [ ] No distribution

DECISION of 29 June 2004  
correcting an error in the  
D E C I S I O N  
of 30 June 2003

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**Applicant:**

AorTech Biomaterials Pty Ltd

**Opponent:**

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**Headword:**

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**Relevant legal provisions:**

EPC R. 89

**Keyword:**

"Request for correction (allowable)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 1058/00 - 3.3.3

**DECISION of 29 June 2004  
correcting an error in the  
D E C I S I O N  
of the Technical Board of Appeal 3.3.3  
of 30 June 2003**

**Appellant:** AorTech Biomaterials Pty Ltd  
126 Greville Street  
Chatswood,  
New South Wales 2067 (AU)

**Representative:** Kyle, Diana  
Elkington and Fife  
Prospect House  
8 Pembroke Road  
Sevenoaks, Kent TN13 1XR (GB)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 16 May 2000  
refusing European patent application  
No. 91 911 862.0 pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** R. Young  
**Members:** A. Däweritz  
E. Dufrasne

In application of Rule 89 EPC, the Decision given on 30 June 2003 is hereby corrected as follows:

On page 9, the first to third lines of the paragraph under the heading "3. Description" are corrected to read:

"The present version of the description is based, in part, on pages 2, 5 to 16 and 19 to 21, as communicated to the Applicant with the Communication under Rule 51(4) EPC"

On page 11, the passage relating to the description of Point 2 of the Order is corrected to read:

"- Description:

pages 2, 5 to 16 and 19 to 21, as communicated to the Applicant with the Communication under Rule 51(4) EPC on 29 April 1999,

pages 1, 3 and 18, submitted with the letter of 2 April 2003,

page 4, dated 22 May 2003, and

page 17, submitted with the letter of 26 June 2003."

The Registrar:

The Chairman:

G. Rauh

R. Young