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**D E C I S I O N**  
of 22 October 1997

**Case Number:** T 0738/93 - 3.3.4

**Application Number:** 86105465.8

**Publication Number:** 0204931

**IPC:** A61L 31/00

**Language of the proceedings:** EN

**Title of invention:**

Resorbable surgical composite material and method of producing it

**Patentee:**

Biocon OY

**Opponent:**

Aesculap AG  
Akzo Faser AG

**Headword:**

Osteosynthesis/BIOCON

**Relevant legal provisions:**

EPC Art. 123(2)(3), 84, 111

**Keyword:**

"Added subject-matter (no) - after amendments"  
"Remittal (yes)"

**Decisions cited:**

G 0002/88

**Catchword:**



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Boards of Appeal

Chambres de recours

Case Number: T 0738/93 - 3.3.4

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.4  
of 22 October 1997

**Appellant:**  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 11 March 1993  
revoking European patent No. 0 204 931 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** U. M. Kinkeldey  
**Members:** L. Galligani  
S. C. Perryman

## Summary of Facts and Submissions

I. The appeal was lodged by the appellants-patentees against the decision of the opposition division issued on 11 March 1993 whereby the patent was revoked pursuant to Article 102(1) EPC on the ground that the amended claims then on file offended against Article 123(2) EPC. The granted patent had been opposed by two parties (opponents 01 and 02) under Article 100(a) and (b) EPC. With letter dated 1 September 1993, opponents 02 withdrew their opposition.

The claims as granted read as follows:

"1. Surgical, osteosynthesis composite material which is at least partially absorbable in tissue conditions, characterized in that the osteosynthesis material is self-reinforced, i.e. it is formed about the absorbable polymer or copolymer matrix which is reinforced with the absorbable polymeric reinforcement units which have essentially the same chemical element percentage composition as the matrix has.

2. Osteosynthesis material as claimed in Claim 1, characterized in that the reinforcement units are in the form of fibers, threads, twists, cords, films, ribbons, woven fabrics or corresponding.

3. Osteosynthesis material as claimed in Claims 1 and 2, characterized in that the absorbable matrix and reinforcement units are manufactured of polyglycolide or of its copolymer.

4. Osteosynthesis material as claimed in Claims 1 and 2, characterized in that the absorbable matrix and reinforcement units are manufactured of polylactide or of its copolymer.

5. Osteosynthesis material as claimed in Claims 1 and 2, characterized in that the absorbable matrix and reinforcement units are manufactured of glycolide/lactide copolymer.

6. Osteosynthesis material as claimed in Claims 1 and 2, characterized in that the absorbable matrix and reinforcement units are manufactured of poly- $\beta$ -hydroxybutyric acid.

7. Osteosynthesis material as claimed in Claims 1 and 2, characterized in that the absorbable matrix and reinforcement units are manufactured of polydioxanone.

8. Osteosynthesis material as claimed in Claims 1 and 2, characterized in that the absorbable matrix and reinforcement units are manufactured of polyvinylalcohol.

9. Osteosynthesis material as claimed in Claims 1 and 2, characterized in that the absorbable matrix and reinforcement units are manufactured of polyesteramide.

10. Osteosynthesis material as claimed in any of Claims 1-9, characterized in that the material forms in the shape of a three-dimensional solid, an osteosynthesis implant, such as plate, pin, nail, medullary rod, screw, balk or like, or the material forms at least part of an osteosynthesis implant.

11. Method for manufacturing material for osteosynthesis devices in accordance with Claims 1-10, characterized in that the part of the material which will form the matrix is subjected to heat and/or pressure in such a way that the physical condition of the part of the material which will act as matrix phase allows the development of adhesion between the nearby reinforcement units and the matrix.

12. Method for manufacturing material as claimed in Claim 11, characterized in that the melt of absorbable polymer or copolymer and the absorbable reinforcement units are mixed together, the mixture is formed into the desired shape and cooled down.

13. Method for manufacturing material as claimed in Claim 11, characterized in that the absorbable fiber, thread, twist, cord, film, ribbon, woven fabric or corresponding material is heated in such a way that the material is softened or melted and coalesced at least partially and the material is formed into the desired shape by means of pressure and cooled down."

II. With the statement of grounds, the appellants submitted new claims 1 to 8 which were objected to by the respondents (opponents 01) in their reply to the appeal on the ground that they offended against Article 123(3) EPC. With their reply, the respondents filed two new documents, among them the following:

(a) J.Appl.Chem, USSR, Vol. 42, 1969, pages 1788-1791.

III. On 4 August 1995 the appellants filed new claims 1 to 8 and requested that the new filed documents be disregarded.

IV. On 23 April 1997 the board sent a communication in which formal objections under Article 84 and 123 EPC were raised against the claims on file. With letter of 22 August 1997, in reply to this communication, the appellants filed new claim requests together with a corresponding amended description, namely claims 1 to 8 as a main request and claims 1 to 10 as an auxiliary request.

V. The respondents objected to the new claim requests with letter dated 7 October 1997.

VI. Oral proceedings took place on 22 October 1997. During oral proceedings, the appellants filed a **new main claim request** in substitution of the previous one. This consisted of claims 1 to 8 as follows:

"1. Surgical osteosynthesis composite material formed in the shape of an osteosynthesis implant or part thereof, wherein the composite material is at least partially absorbable in tissue conditions,

wherein the composite material is self-reinforced, i.e. it is formed from an absorbable polymer or copolymer matrix which is reinforced with an absorbable polymeric reinforcement fibers having essentially the same chemical element percentage composition as the matrix has,

wherein the polymer or copolymer from which the reinforcement fibers are manufactured is not polyvinylalcohol (PVA) and

wherein the fiber content in the self-reinforced material is at least 30% in weight.

2. Material according to claim 1, wherein the polymer or copolymer from which the reinforcement fibers are manufactured is selected from the group consisting of

- polyglycolide (PGA) or its copolymer
- polylactide (PLG) or its copolymer
- glycolide / lactide copolymer
- poly- $\beta$ -hydroxybutyric acid (PHB)
- polydioxanone (PDS)
- polyesteramide (PEA).

3. Material according to claim 1 or 2, wherein the fibers are provided in the form of threads, twists, cords, ribbons, or woven fabrics.

4. Material according to any of claims 1 to 3, wherein it is formed in the shape of a plate, pin, nail, medullary rod, or screw.

5. Use of a surgical osteosynthesis composite material which is at least partially absorbable in tissue conditions and which is self-reinforced, i.e. is formed from a polymer or copolymer matrix reinforced with absorbable polymeric reinforcement fibers having essentially the same chemical element percentage composition as the matrix has, to manufacture a surgical osteosynthesis implant or part thereof having a fiber content of at least 30% in weight.

6. Method for manufacturing material for osteosynthesis implants or parts thereof in accordance with claims 1 to 4, characterized in that the part of the material which will form the matrix is subjected to heat and/or pressure in such a way that the physical condition of the part of the material which will act as matrix phase allows the development of adhesion between the nearby reinforcement fibers and the matrix, and that the material is cooled rapidly after the development of such adhesion.

7. Method for manufacturing material as claimed in claim 6, characterized in that the melt of absorbable polymer or copolymer and the absorbable reinforcement fibers are mixed together, the mixture is formed into the desired shape and cooled down rapidly.

8. Method for manufacturing material as claimed in claim 6, characterized in that the absorbable fiber, thread, twist, cord, ribbon, or woven fabric is heated

in such a way that the material is softened or melted and coalesced at least partially and the material is formed into the desired shape by means of pressure and cooled down rapidly."

- VII. The respondents raised formal objections under Article 84 and 123(2) EPC against the newly filed claims.
- VIII. The appellants request that the decision under appeal be set aside and that the patent be maintained on the basis of the main request submitted at the oral proceedings or of the auxiliary request submitted with letter dated 22 August 1997.

The respondents request that the appeal be dismissed.

### Reasons for the Decision

*Formal admissibility of the main request: Articles 84 and 123(2) and (3) EPC.*

Article 123(3) EPC

- 1. Comparison of claims 1 to 8 on file with claims 1 to 13 as granted brings out the following:
  - (a) Claim 1 differs from claim 1 as granted in that:
    - (i) it specifies that the claimed material is "formed in the shape of an osteosynthesis implant or part thereof"; (ii) it specifies that the reinforcement units are "fibers"; (iii) it specifies the fiber content (30% in weight); (iv) it contains a disclaimer in respect of polyvinylalcohol.



- (b) Dependent claim 2, which specifies the polymer or copolymer from which the reinforcement fibers are manufactured, derives from granted claims 3 to 7 and 9;
- (c) Dependent claim 3 derives from granted claim 2, some of the **alternative** embodiments of the latter being deleted;
- (d) Dependent claim 4 derives from granted claim 10, some of the **alternative** embodiments of the latter being deleted;
- (e) Independent claim 5 is a new claim in the form "use of a surgical osteosynthesis material...to manufacture a surgical osteosynthesis implant or part thereof". This corresponds to the reformulation of the granted product claims 1 and 10 in terms of the use of the product, with the further limitation to the use of a product having a fiber content of at least 30% in weight;
- (f) Independent method claim 6 corresponds to granted claim 11 and, apart from the fact that it now refers to amended product claims 1 to 4, it contains the additional feature "and that the material is cooled rapidly after the development of such adhesion";
- (g) Dependent method claims 7 and 8 correspond to granted claims 12 and 13, respectively, but contain the further feature "rapidly" in relation to the cooling step.

2. The above analysis reveals that all the amendments introduced in the claims at issue in comparison with the claims as granted result in a limitation of the extent of protection conferred. This applies also to

the new use claim 5 (cf in this respect decision G 2/88 of the Enlarged Board of Appeal, OJ EPO 1990, 93). Thus, there is no violation of Article 123(3) EPC.

*Article 123(2) EPC*

3. As regards the compliance of the new claims with Article 123(2) EPC, the respondents object to the new feature "wherein the fiber content in the self-reinforced material is at least 30% by weight", which in their opinion has no fair basis in the application as filed, and to the omission from claim 1 of the expression "a three dimensional solid" that qualified in granted claim 10 the shape of the osteosynthesis implant, as, in their view, said omission results in the creation of new matter not previously disclosed.
4. As regards the fiber content, the board accepts that the new feature finds its implicit basis in the application as filed for the following reasons:
  - (a) the application as filed emphasizes the high content of fibers in the claimed product (cf eg page 6, second and fourth paragraph);
  - (b) Examples 1, 4 and 5 report a fiber content of 30, 40 and 50% in weight, respectively;
  - (c) The remaining examples all refer to embodiments in which the fiber material is partially fused together within a thin matrix as a consequence of application of pressure. Therefrom it can be deduced that the final fiber content in percentage in weight is very high and thus at least 30% in weight;

(d) Thus, since the lowest value reported in the application as filed is 30% in weight and all other values are above it, it is concluded that the contested feature "having a fiber content of at least 30% in weight" finds indirect, but unambiguous basis in the application as filed.

5. As regards the omission of the expression "a three dimensional solid" in respect of the shape of the osteosynthesis implant of claim 1, it is noted that, as any implant is intrinsically a three dimensional solid, no question of added matter can arise from the omission of a superfluous qualification.
6. As regards the remaining amendments, they all find support in the application as filed, as most of them result from the rearrangement of the claims as filed. In particular, the change from units to fibers finds support on page 5, line 2, the feature "cool rapidly" or "cooled down rapidly" in the method claims finds support on page 6, first paragraph and in the examples. As for the disclaimer in claim 1, which has been introduced in view of the citation of document (a) by the respondents (see Section II supra), this is not an addition of subject-matter, but merely the exclusion from protection of subject-matter that was previously covered (cf. granted claim 8).
7. In conclusion, no objection under Article 123(2) EPC is seen by the board.

*Article 84 EPC*

8. The respondents object to the clarity of the term "essentially" in claims 1 and 5. Moreover, they object to the feature related to the fiber content, because in their view the patent specification does not give any clear indications in respect of the initial fiber

content, and to the feature "cooled rapidly" or "cooled down rapidly", because no indications are given as to the temperatures meant and to the time needed for cooling.

9. As for the term "essentially", the board observes that it was in the claims as granted and thus is not open to objection under Article 84 EPC. At any rate, in the context of the claims the term is not unclear as it emphasizes the substantial identity in the chemical composition between the fibers and the matrix.
10. The feature specifying the minimum fiber content of the implant is not unclear as it relates to a measurable parameter (eg by X-ray determination of density) of the claimed product. The respondents acknowledged that the skilled person knew how to measure this parameter and the board sees no reason to doubt this even though no method is described. It appears to the board that the skilled person would have no difficulties in determining by a reasonable amount of routine trials the initial amount of fiber material which should be used in order to achieve a given final fiber content, taking into account possible losses due to melting during heating and/or compression.
11. As for the cooling step, no specific instructions need to be given in respect of rapid cooling down as any person of average skill knows by which means any high temperature of a given product can be reduced to lower temperature (cooling) in a short time (rapidly).
12. Therefore, no clarity objections under Article 84 EPC against the amended claims of the request at issue are seen by the board.

*Remittal of the case to the first instance (Article 111 EPC)*

13. The patent in suit had been revoked by the first instance on the ground that the amended claims then on file offended against Article 123(2) EPC, only summary statements being made in the appealed decision in respect of novelty and inventive step. At oral proceedings before the board, at least one party (the respondents) indicated their preference for a referral of the case to the first instance under Article 111 EPC, the other party (the appellants) not being opposed thereto.

14. During the appeal proceedings the respondents submitted inter alia the new citation (a). This prompted the appellants to introduce a disclaimer into claim 1. In order to ensure that the parties have the opportunity of having the substantial questions of patentability decided by the opposition division also on the basis of the new document, and with the possibility of a further appeal remaining open, the board considers it appropriate to make use of the power granted to it under Article 111(1) EPC to remit the case to the first instance for further prosecution.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside;
2. The matter is remitted to the first instance for further examination on the basis of the main request submitted at the oral proceedings on 22 October 1997.

The Registrar:

The Chairperson:

D. Spigarelli

U. M. Kinkeldey