**BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS**

**BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE**

**CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS**

**Internal distribution code:**
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen

# D E C I S I O N
# of 26 April 1999

**Case Number:** T 0415/97 - 3.2.2

**Application Number:** 92106241.0

**Publication Number:** 0508452

**IPC:** A61B 17/064

**Language of the proceedings:** EN

**Title of invention:**
Reduced mass absorbable surgical fastener and retainer

**Applicant:**
United States Surgical Corporation

**Opponent:**
-

**Headword:**
-

**Relevant legal provisions:**
EPC Art. 54(2), 56

**Keyword:**
"Novelty and inventive step (yes)"

**Decisions cited:**
-

**Catchword:**
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 0415/97 - 3.2.2

**D E C I S I O N**
**of the Technical Board of Appeal 3.2.2**
**of 26 April 1999**

**Appellant:** United States Surgical Corporation
150 Glover Avenue
Norwalk
Connecticut 06856 (US)

**Representative:** Marsh, Roy David
Hoffmann Eitle
Patent- und Rechtsanwälte
Postfach 81 04 20
81904 München (DE)

**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted 2 December 1996 refusing European patent application No. 92 106 241.0 pursuant to Article 97(1) EPC.**

**Composition of the Board:**

**Chairman:** W. D. Weiß
**Members:** M. G. Noel
J. C. M. De Preter

## Summary of Facts and Submissions

I. European patent application No. 92 106 241.0 (publication No, 0 508 452) was refused by decision of the Examining Division issued on 2 December 1996, in particular on the grounds that the subject-matter of claim 1 according to the main request lacked novelty and inventive step having regard to the disclosure of document (1) US-A-4 932 960.

II. The reasons for the refusal were essentially that the wording of claim 1 only differed from document (1) by a parameter (total mass less than 4 mg per transverse millimeter) which, however, was implicitly disclosed by said document and that its selection for making surgical fasteners was considered as a mere optimization lying within craft skills without requiring any inventive activity.

III. The appellant lodged an appeal against the first instance's decision and paid the appeal fee on 3 February 1997. A statement of grounds was filed on 7 April 1997.

IV. The appellant requested that the decision under appeal be set aside and that the patent application go forward on the basis of claim 1 in accordance with proposal B (main request) or go forward with claim 1 in accordance with proposal A (auxiliary request) both filed with letter of 5 November 1996. The decision under appeal is based on these two requests. As a further auxiliary request, that oral proceedings be arranged.

V. In its statement of grounds of appeal the appellant

argued essentially that the characterising feature of claim 1 in suit was not specifically mentioned in document (1). Instead, the surgical fastener described in this document appeared to be about 25% more bulky than the bulkiest fastener permitted by claim 1. Moreover, since document (1) recited the best mode embodiment according to a US patent practise, the skilled person would never have seriously contemplated slimming the known fastener to the extent required by claim 1. Therefore, the subject-matter of claim 1 was neither suggested by the disclosure of document (1).

VI. Claim 1 under appeal (main request) reads as follows:

"A two-part bioabsorbable surgical fastener comprising:

(a) a fastener member (100) comprising

(i) a backspan (101) defining a transverse axis;

(ii) at least two substantially parallel prongs (104) extending substantially perpendicularly from said backspan; and

(b) a retainer member (202) having

(i) a base (204)

(ii) at least two columnar members (206), each columnar member having an aperture (212) adapted to receive a respective one of the fastener prongs, and, when engaged on tissue, being effective to achieve hemostatis; and wherein:

the backspan (101) has transversely-projecting extrusions (102) to improve hemostatis;

each of the prongs (104) has at least one barb (106) which projects from an edge of the shank (120) of the prong at the distal end of the prong;

each of the prongs (104) is supported by a

triangular buttress (108) disposed between the backspan and the shank of the prong; and

each of the columnar members has an expansion slot (208) to permit transverse expansion of the said aperture when the barb of the corresponding prong enters the retainer member;

the fastener member being obtainable by molding: the fastener being **characterised** in that:
said fastener member and retainer member when engaged have a total mass of less than 4 mg per transverse millimeter of the overall transverse dimension of the fastener."

## Reasons for the Decision

1. The appeal is admissible.

2. *Closest prior art and novelty (main request)*

2.1 The two-part bioabsorbable surgical fastener according to the invention comprises a fastener to be inserted by penetration into an interlocking retainer, with body tissues interposed therebetween. In the patent application two embodiments of preferred surgical fasteners A and B are proposed, which differ from each other only by the longitudinal dimension of their respective fastener prongs (cf. application, page 5). In the following paragraph referred to as "Example" a comparison is made between the preferred "fastener A" and other prior art "Control fasteners" known from the appellant at the time the invention was made.

2.2 Document (1) originates from the same applicant and same inventors as in the present application. The drawings are identical and use the same coordinate system, identified by arrows X, Y, Z. In column 5 of said document it is specified that surgical fasteners of the type described therein may be of any size appropriate to their function of fastening body tissue. As an example, a preferred embodiment is given with dimensions in inches.

2.3 In the following table a comparison is made between dimensional features (converted into millimeters) of the fasteners and retainers according to, respectively, the prior art "Control fasteners", the fastener A of the present invention and the fastener according to document (1). The total mass per transverse millimeter is given by the ratio: total mass / transverse dimension.

| | | X<br>Transverse | Y<br>longitudinal | Z<br>lateral | Total mass and total mass per transverse millimeter |
|---|---|---|---|---|---|
| Prior art "Control fasteners" | Fastener prongs<br>retainer | 6,2<br>6,6 | 5,6 | ? | 33,8 mg<br>5.1 mg/mm<br>(33,8/6,6) |
| Invention "Fastener A" | Fastener prongs<br>retainer | 4,85<br>5,15 | 5,64 | 0,76 | 18,2 mg<br>3,52 mg/mm<br>(18,2/5,15) |

| | | | | | |
|---|---|---|---|---|---|
| Document (1) Fastener | Fastener prongs retainer | 4,10 5,10 | 3,78 2,66 | 1,14 | ? |

2.4 When comparing the "Control fasteners" with fastener A, it appears that a reduction in the total mass per millimeter from 5,1 mg/mm to 3,52 mg/mm is actually obtained with the fasteners according to the invention, in accordance with the purpose set in the present application although the lateral dimensions of the prior art fasteners are not specified.

Document (1) discloses all the features contained in the precharacterising portion of claim 1 in suit. However, there is no mention of any mass. Therefore, the features in the characterising portion are not explicitly disclosed in document (1).

The question then to be answered is whether document (1) implicitly discloses these features. A comparison between the two last fasteners of the above table shows that the transversal and longitudinal dimensions of the fastener of document (1) are slightly less than the corresponding dimensions of the fastener A of the invention. Since both surgical fasteners are made of the same material, the Examining Division arrrived at the conclusion that both fasteners have approximately the same total mass.

This conclusion, however, neglects the fact, that the fasteners are three-dimensional bodies of which the volumes have to be compared. Having this in mind, the table above further shows that the lateral dimension of the fastener according to document (1) (1,14 mm) is

well above (+50%) the lateral dimension of fastener A (0,76 mm). But, as was seen before, since the two other dimensions of the known fastener are smaller than the corresponding dimensions of fastener A, the total mass of the known fastener in relation to that of fastener A cannot be assessed with certainty.

From the foregoing, it results that the mass of fastener (1) cannot be derived from document (1) directly and unambiguously. As a consequence, the characterising feature of claim 1 according to which "fastener member and retainer member when engaged have a total mass of less than 4 mg per transverse millimeter of the overall transverse dimension of the fastener", is not implicitly disclosed by document (1) either.

Therefore, the subject-matter of claim 1 is novel within the meaning of Article 54(2) EPC.

3. *Inventive step (main request)*

3.1 The problem underlying the present invention is to provide a two-part bioabsorbable surgical fastener having a mass as reduced as possible so as to minimize the foreign matter introduced to the body and to facilitate absorption thereof without detrimentally affecting the efficacy of the fastener in achieving hemostasis (cf. page 2, lines 53 to 57 and page 4, lines 51 to 52). The solution is given in particular by the characterising feature of claim 1 by which the subject-matter thereof is distinguished from the disclosure of document (1).

3.2 Document (1) is not only silent about any mass indication but does not suggest that a fastener having a reduced mass should be aimed at either. The problem upon which document (1) is based was rather to provide a fastener which permits elastic expansion of the retainer in the lengthwise direction (cf. column 2, lines 17 to 19). Although it is desirable to have a staple which is as narrow as possible, a lower limit is imposed by the mechanical resistance required. This lower limit is referred to in the table above by a retainer having a lateral dimension of 1,14 mm (0,045 inch) which, according to the Board, is to be considered as a lower limit value that the skilled person certainly would have not exceeded.

The first instance's argument that a person skilled in the art would have slimmed the fastener disclosed in document (1) in order to solve the problem set in the present application is not accepted because document (1) does not give any hint in this respect. The present invention reduces the lower limit value for the lateral dimension to 0,76 mm for both fasteners A and B. This value is about half the minimal value recommended by document (1). Therefore, there is no reasonable basis for the assumption that the range for total mass per transverse millimeter of the known surgical fastener according to document (1) might overlap with the range as claimed, i.e. less than 4 mg/mm.

3.3 For these reasons the Board is satisfied that the characterising feature of claim 1 according to the main request is not suggested by the disclosure of document (1) either. Therefore, the subject-matter of

claim 1 is inventive within the meaning of Article 56 EPC.

4. Since the main request is acceptable, the other auxiliary requests need no further consideration by the Board.

5. The dependent claims and the description do not yet take into account the amendments made to claim 1 according to the main request. The Board, therefore, makes use of the power conferred upon it by Article 111(1) EPC and remits the case to the Examining 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 Examining Division for further prosecution on the basis of claim 1 according to the main request (proposal B filed with letter dated 5 November 1996).

The Registrar: The Chairman:

S. Fabiani W. D. Weiß