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D E C I S I O N
of 9 April 2002

Case Number: T 0948/98 - 3.2.2

Application Number: 92116976.9

Publication Number: 0541950

IPC: A61B 17/064

Language of the proceedings: EN

Title of invention:

Malleable, bioabsorbable, plastic staple and method and apparatus for deforming such staple

Applicant:

Sherwood Services AG

Opponent:

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Headword:

-

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

"Amended claims allowable on formal aspects"
"Remittal for further prosecution"

Decisions cited:

-

Catchword:

-



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Boards of Appeal

Chambres de recours

Case Number: T 0948/98 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 9 April 2002

Appellant: Sherwood Services AG
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Representative: Wächtershäuser, Günter, Prof. Dr.
Patentanwalt
Tal 29
D-80331 München (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 15 May 1998
refusing European patent application
No. 92 116 976.9 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiss
Members: M. G. Noël
J. C. M. De Preter

Summary of Facts and Submissions

I. The Examining Division refused European patent application No. 92 116 976.9 (publication No. 0 541 950) on the grounds of lack of inventive step of any of the four requests submitted at the oral proceedings, vis a vis the state of the art represented by documents

D1: GB-A-2 233 903, and

D2: WO-A1-83/00614.

II. The appellant lodged an appeal against this decision on 15 July 1998 and filed a statement of grounds along with new sets of claims according to two requests, the main request being similar to the main request as refused.

III. In a communication dated 28 November 2001 the Board objected against clarity and adequate support of the newly filed claims under Articles 84 and 123(2) EPC and suggested a formally acceptable set of claims as a basis for the discussion at the oral proceedings.

The appellant replied on 11 March 2002 by the submission of an additional second auxiliary request.

IV. Oral proceedings were held on 9 April 2002. Following a discussion on the merits of the invention with respect to the prior art documents D1 and D2, the appellant submitted a replacement single request focused to the stapling device considered as a whole.

The appellant finally requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 3 submitted at the oral proceedings.

V. The appellant argued that the now claimed subject-matter referred to the specific combination of a polymeric surgical staple having sufficient stiffness but capable of being plastically deformed into a precise shape that securely joined tissues together with minimal damage to the tissues and to the staple itself, with an anvil made of the same material as the staple and formed according to the embodiment of Figures 10 to 17. In particular, the configuration of the guiding grooves inside the pocket depressions of the anvil allowed for preventing the staple points from engaging the bottom of the grooves and thus from breaking. Also the use of polymeric materials allowed for precisely making complicatedly shaped anvil pockets, using precise yet inexpensive injection moulding techniques as compared with conventional expensive machining techniques. All now claimed features were adequately supported by the application as filed.

VI. Claim 1 reads as follows:

"Stapling device for applying a surgical staple comprising in combination:

(a) an anvil for said staple, with its first and second legs (14') extending in one direction from opposite ends of the back span (12') and substantially perpendicularly thereto in an undeformed state; said anvil comprising: a

supporting body (44) having a longitudinal axis (C-C) and including a bioabsorbable polymeric surgical staple-receiving face (46); first and second pocket depressions (48) each beginning with an entry end (52) located at said staple-receiving face (46), continuing to a depressed portion within said body (44) below said staple-receiving face (46), and terminating in an exit end (54) at said staple-receiving face (46), said first and second pocket depressions (48) extending in non-collinear relation with the entry end (52) of each located substantially on the longitudinal axis and the exit end (54) of each located on a side of the longitudinal axis opposite the side on which the exit end (54) of the other pocket depression is located, said entry ends (52) of said first and second pocket depressions (48) being spaced by a distance substantially equal to the distance between the first and second legs (14') of the staple in the undeformed state; whereby the first and second legs (14') of a staple driven toward said anvil and received in the entry ends (52) of the respective first and second pocket depressions (48) are guided to said exit ends (54) thereof to be deformed toward the back span (12') and to extend toward opposite sides of the back span (12') to suture tissue received therein; and

- (b) one-piece, bioabsorbable, malleable, polymeric surgical staples, loaded in an undeformed state in that stapling device and comprising a back span (12') and first and second legs (14') at opposite ends of the back span whereby for receiving tissue therebetween the first and second

legs extend in an initial undeformed configuration from opposite ends of the back span (12') in one direction substantially perpendicular to the longitudinal axis of the back span and whereby each leg terminates in an end point (16'), whereby the first and second legs (14') are capable of being plastically deformed initially inwardly toward each other and then toward said back span (12') in a direction generally opposite said one direction to locate the two end points (16') laterally at opposite sides of said back span (12'), wherein further the first and second legs (14') and the back span (12') each has a noncircular cross-section shape, whereby the first and second pocket depressions (48) each have a contoured staple-guiding groove (50) having a floor (56) and being bounded on its lateral sides at its center near its lowest section and extending toward the exit end by stepped sloping walls that narrow the pocket in that region, whereby the floor (56) of the groove (50) lies below the extreme of the surfaces of the walls such that the apex of the chiseled staple point is prevented from engaging and thereby digging into the floor (56)."

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

Claim 1 relates to a stapling device for applying a surgical staple comprising in combination staples loaded in the stapling device and an anvil for

deforming the staples into their suturing configuration.

The staple is defined in its undeformed state and then in a deformed configuration which is achieved by its cooperation with the associated anvil, in accordance with features referred to in part (a) (first five lines and last eight lines) and in part (b) (first twenty lines) of claim 1. These features are fairly supported by the application as filed (version as published), in particular on page 4, lines 36 to 54 in connection with Figures 4 to 6, as well as on page 3, lines 11 to 16, lines 23 to 26 and lines 38 to 40.

The anvil is defined by features also referred to in part (a) (following the third line) and by features placed at the end of part (b) ("whereby...into the floor"). All these features are also correctly supported by the application as filed, in particular on page 7, lines 26 to 45 in connection with Figures 10 to 17, as well as on page 3, lines 30 to 45.

Claim 2 is supported on page 6, lines 55 to 56.

Claim 3 is supported on page 7, lines 19 to 20.

Therefore, the amendments are clear and do not extend beyond the application as filed, as required by Articles 84 and 123(2) EPC.

3. *Remittal*

After a number of successive amendments, the subject-matter of claim 1 is now confined to a stapling device according to the specific embodiment of Figures 10

to 17 of the application. Since the new claims, to a large extent, rely on features originating from the description and the figures as filed, the subject-matter of which has not yet been examined or at last not been commented upon by the Examining Division, the Board finds it appropriate to remit the case to the Examining Division for further prosecution of the new subject-matter on the basis of the cited prior art, possibly supplemented by an additional research at the discretion of the first instance.

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.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß