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D E C I S I O N
of 31 March 1995

Case Number: T 0969/92 - 3.2.2

Application Number: 87302157.0

Publication Number: 0238264

IPC: A61B 17/08

Language of the proceedings: EN

Title of invention:

Improved surgical fastening systems made from polymeric materials

Applicant:

Ethicon Inc

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 54, 56

Keyword:

"Novelty - state of the art, availability"

"Novelty (yes)"

"Inventive step (yes)"

Decisions cited:

T 0763/89, T 0666/89

Catchword:

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Case Number: T 0969/92 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 31 March 1995

Appellant: Ethicon Inc
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Representative: Jones, Alan John et al
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Decision under appeal: Decision of the Examining Division of the European Patent Office dated 2 June 1992 refusing European patent application No. No. 87 302 157.0 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: H. Seidenschwarz
Members: P. Dropmann
J.-C. De Preter

Summary of Facts and Submissions

- I. A Notice of Appeal was filed against the decision of the Examining Division refusing application No. 87 302 157.0 on the ground that the claimed subject-matter lacked an inventive step having regard to document EP-A-0 136 949 (D1).
- II. Following a telephone conversation between the Appellant's representative and the Rapporteur raising objections under Article 84 and Rules 27 and 29(1) and (7) EPC, the Appellant filed, with its letter of 30 March 1995, an amended set of Claims 1 to 3 together with an adapted description.
- III. The Appellant requested that the decision under appeal be set aside and a patent granted on the basis of Claims 1 to 3 and description pages 1 to 8 as both filed with the letter of 30 March 1995 and Figures 1 to 9 as originally filed.
- IV. Claims 1 to 3 read as follows:
- "1. A surgical fastening system for joining tissue (46), said system comprising a plurality of parallel rows of staples (15, 20) and a plurality of parallel rows of receivers (17, 30, 40, 45), each of said staples (15, 20) comprising a pair of legs (16, 21), said legs (16, 21) being joined at one end thereof by a linking member (22), the opposite end of each leg (16, 21) being adapted to penetrate tissue (46) so the linking member (22) lies adjacent the tissue (46) penetrated by said legs (16, 21), each receiver (17, 30, 40, 45) having a body portion (31) and a plurality

of openings (32) disposed in said body portion (31), said openings (32) being located so as to engage the legs (16, 21) of the staple (15, 20) after said legs (16, 21) have penetrated the tissue (46) so that the receiver (17, 30, 40, 45) lies on the opposite side of the tissue (46) to be joined, and means (24, 34) on said legs (16, 21) and on said receivers (17, 30, 40, 45) for interlocking the staple (15, 20) and the receiver (17, 30, 40, 45) together, each receiver (17, 30, 40, 45) being connected to two receivers (17, 30, 40, 45) in an adjacent row by flexible linkages (41) capable of maintaining the integrity of the receivers (17, 30, 40, 45), characterized by each connection between two adjacent receivers (17, 30, 40, 45) comprising a plurality of parallel linkages (41) which are sufficiently flexible and strong to maintain the receivers (17, 30, 40, 45) connected during both the application of the fastening system when joining the tissue (46) and the use of the fastening system to hold the tissue (46) until such tissue (46) has healed.

2. A surgical fastening system according to Claim 1 wherein the openings (32) in the receiver (17, 30, 40, 45) each have an oval shape.

3. A surgical fastening system according to Claim 1 wherein each connection between receivers (17, 30, 40, 45) comprises three parallel linkages (41)."

Reasons for the Decision

1. The appeal is admissible.

2. No formal objections arise against Claim 1 under Articles 123(2) and 84 EPC and Rule 29 EPC. The description complies with Rule 27 EPC.

3. *Novelty*

Document D1 (see, in particular, Figures 1, 4 and 5, Claims 1, 2 and 5 and description page 5, lines 18 to 31) discloses a surgical fastening system comprising all the features specified in the pre-characterising portion of Claim 1 of the application. This document, however, does not anticipate the characterising feature of Claim 1 that each connection between two adjacent receivers comprises a plurality of parallel linkages for the following reasons.

It is stated in Claim 1 of document D1 (and, similarly, in the paragraph bridging pages 2 and 3) as follows: "each of said retainer members being connected by at least one such link to at least one other retainer member so that all the retainer members are connected to each other to form a unitary assembly" (the terms "retainer member" and "link" used in the document are synonymous to the terms "receiver" and "linkage", respectively, used in the application).

This statement could be interpreted to mean that each connection consists of at least one link, the consequence being that the feature of Claim 1 of the application that each connection between two adjacent receivers comprises a plurality of parallel linkages falls within the scope of the quoted general statement in document D1.

However, this does not mean that the afore-mentioned feature of Claim 1 concerning the plurality of linkages per connection has been made available to the public by document D1 in the sense of Article 54(2) EPC. In order to determine what was made available to the public, the remainder of document D1 must be carefully considered for guidance to find out what is really taught in the prior document, i.e. its real express and implicit information content:

The embodiments of the invention of document D1 which are illustrated in Figures 4 to 6A to E clearly show that in all cases each retainer member is connected to one or more other retainer members, each connection consisting of a single link. Nowhere in the figures or description of document D1 is there any sign that there could be more than one link per connection between two adjacent retainer members. Indeed, the purpose of the links disclosed in document D1 is, as stated at the end of its Claim 1 and in the description, to connect all the retainer members to each other to form a unitary assembly. This purpose is completely achieved by single-link connections as disclosed in document D1. There is no suggestion in the document that a plurality of links may be provided per connection between two adjacent retainer members. In particular, there is no support in document D1 for the argument of the Examining Division (cf. point 2.3, first and second paragraphs, of the decision under appeal) that it is apparent from or indicated in document D1 that one or more linkages may be provided between **two** adjacent retainer members.

The statement "connected by at least one such link" in Claim 1 of document D1 clearly covers the situation where, if there is more than one retainer member in the first row and/or if there is more than one other retainer member, there is necessarily more than one link as shown in the figures. The recitation in Claim 1 of document D1 of "one or more yieldable links" merely gives expression to the fact that each retainer member may be connected to one or more adjacent retainer members.

The above considerations concerning the disclosure of document D1 are in line with the case law of the Boards of Appeal of the EPO, cf. T 763/89 (not published) and T 666/89 (OJ EPO 1993, 495).

It follows from the preceding considerations that the characterising feature of Claim 1 of the application concerning the plurality of linkages per connection between two adjacent receivers was not made available to the public by document D1. Since, furthermore, the other documents cited in the European Search Report and in the application do not disclose this feature, the subject-matter of Claim 1 is novel within the meaning of Article 54(1) and (2) EPC.

4. *Inventive step*

In the light of the state of the art known from document D1, which represents the state of the art that is closest to the subject-matter of Claim 1, the technical problem underlying the present invention can be seen as rendering the connection between the receivers, while maintaining the desired flexibility of

the connection, sufficiently strong to maintain the receivers connected until the tissue has healed.

The problem is solved in accordance with Claim 1 by providing a plurality of parallel linkages per connection between two adjacent receivers. The probability of complete accidental breakage of a connection is thereby reduced while maintaining the flexibility of the connection.

As already pointed out under section 3 above, document D1 discloses that each connection between two adjacent retainer members consists of a single link. There is no indication in this document that each connection might advantageously be formed from a plurality of parallel linkages. Nor do the other documents cited in the European Search Report and in the application suggest the use of more than one linkage between two adjacent receivers instead of a single linkage per connection.

The Examining Division argued that the skilled person, starting from the state of the art known from document D1 and being faced with the problem that the one link depicted in the figures of document D1 was considered to be too weak, or liable to break too soon or too often, would routinely consider the provision of a stronger connection between the receivers and, following the disclosure of document D1, would provide more than one linkage, ie a plurality of linkages. However, in the view of the Board, the obvious solution to this problem would be to make the single-link connections disclosed in document D1 stronger, eg by increasing the cross-section of the links. In the

absence of any relevant suggestion in the state of the art considered in the proceedings, the skilled person would not, in an obvious manner, replace the single-link connection by a connection consisting of a plurality of links.

The subject-matter of Claim 1 thus cannot be derived in an obvious manner from the state of the art cited in the Search Report and the description and, therefore, involves an inventive step in accordance with Article 56 EPC.

5. Hence, the subject-matter of Claim 1 is patentable having regard to Articles 52(1), 54 and 56 EPC.

Dependent Claims 2 and 3 define particular embodiments and meet likewise the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent in the version set out in point III above.

The Registrar:

The Chairman:

S. Fabiani

H. Seidenschwarz