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Datasheet for the decision of 18 October 2013

Case Number: T 0581/10 - 3.2.02

Application Number: 99904160.1

Publication Number: 1051114

IPC: A61B 17/10

Language of the proceedings: EN

Title of invention:
TISSUE ANCHORING SYSTEM AND METHOD

Applicant:
Orthodyne, Inc.
Cole, J., Dean

Headword:
-

Relevant legal provisions:
EPC Art. 56, 111(1), 123(2)

Keyword:
"Added subject-matter (no)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0581/10 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 18 October 2013

Appellant: (Applicant)
Orthodyne, Inc.
Suite 204B,
1118 South Orange Avenue
Orlando, FL 32806 (US)

Cole, J., Dean
500 Lakeview Street
Orlando, FL 32804 (US)

Representative:
Höhfeld, Jochen
Klunker Schmitt-Nilson Hirsch
KSNH Patentanwälte
Destouchesstrasse 68
D-80796 München (DE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 4 November 2009 refusing European patent application No. 99904160.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: E. Dufrasne
Members: D. Ceccarelli
M. Stern

Summary of Facts and Submissions

I. The appellant lodged an appeal against the decision of the Examining Division, dispatched on 4 November 2009, to refuse European patent application No. 99 904 160.1.

II. The notice of appeal was received on 4 January 2010 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 12 March 2010.

III. In the statement setting out the grounds of appeal, the appellant requested that the application be allowed in the version refused by the Examining Division.

The appellant also requested oral proceedings if the application could not be allowed on the basis of the written submissions.

IV. The Board summoned the appellant to oral proceedings and provided its provisional opinion.

V. Oral proceedings took place on 18 October 2013. During the oral proceedings, the appellant filed claims 1 to 11, an adapted description and figures according to a new main request.

The appellant's final requests were that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed during the oral proceedings.

VI. The following documents are of importance for the present decision:

D1: EP-A-0 464 480;
D2: US-A-5,116,340;
D3: US-A-5,643,289;
D4: EP-A-0 669 101.

VII. Claim 1 of the main request reads as follows:

"A system for joining tissue segments, comprising:

an elongated flexible member (20) having a distal portion and a proximal portion;

a first anchor (30, 32) fixedly attached to said distal portion, said anchor (30, 32) adapted to engage a first tissue section;

a second anchor having an aperture for slidably receiving said elongated flexible member (20), said second anchor including a deformable portion adjacent said aperture and a washer (14, 93), said deformable portion deformable to securely engage said elongated flexible member (20), said second anchor adapted to engage a second tissue section; and

a crimping tool (50, 900) having a crimping mechanism that comprises:

an inner cylindrical member (54, 901) having a bore (541, 917) dimensioned to permit the elongated flexible member (20) to slide therethrough; and

an outer cylindrical member (52, 902) with an inner passage and a distal end and positioned in surrounding relation to the inner cylindrical member (54, 901) and rotatable relative thereto about a common longitudinal axis between a holding position and a crimping position;

wherein the inner and outer cylindrical member have cooperating distal ends (502, 905) adapted to hold the

deformable portion in the holding position and to crimp the deformable portion in the crimping position;

said crimping mechanism being disposed within said inner passage adjacent said distal end and having an inner chamber sized to receive said deformable portion, whereby actuation of said crimping mechanism deforms said deformable portion to securely engage said flexible member (20)."

The other claims of the main request are dependent claims.

VIII. The appellant's arguments are summarised as follows.

The claims according to the main request were based on original claims 33 to 44, with its claim 1 including the features of original claims 33 and 35 as well as the washer according to original claim 34. The remaining features of original claim 34 were not technically relevant. Hence claim 1 of the main request complied with Article 123(2) EPC.

Document D1 did not disclose a crimping tool and was, therefore, not relevant.

None of documents D2 to D4 disclosed a crimping tool with inner and outer cylindrical members that were rotatable about a common longitudinal axis between a holding position and a crimping position.

The crimping mechanism according to the invention was able to crimp the deformable element along the axis of the flexible member, which permitted "a surgical procedure to be carried out through a small unitary

incision without removing surrounding tissue". Therefore, the objective technical problem was to provide a system for joining tissue segments, including a crimping tool that allowed minimally invasive surgery or at least improved minimally invasive surgery. All crimping tools disclosed in documents D2 to D4 would require significant changes in their design in order to obtain the crimping tool of the present invention. Hence the subject-matter of claim 1 was inventive in view of the cited prior art.

Reasons for the Decision

1. The appeal is admissible.

2. *Basis in the original application (Article 123(2) EPC)*

With respect to claim 1 on which the impugned decision was based, claim 1 of the main request has been amended to comprise all the features of originally filed claims 33 and 35 as well as the washer of original claim 34. As the appellant correctly remarks, in the second paragraph of the "Reasons for the Decision" of the impugned decision, the Examining Division found that adding only the washer from the subject-matter of claim 34 was acceptable in view of Article 123(2) EPC, since the change from "elongated flexible member" (as in claim 1) to "cable" (as in original claim 34) as well as from the "deformable portion" (as in claim 1) to the "ferrule" (as in original claim 34) was not considered "technically significant". The Board additionally remarks that a basis for a general "elongated flexible member" is also present on original

page 9, lines 15 to 20, and that a basis for a general "deformable portion" is also present on original page 19, lines 12 to 14. The Board is therefore satisfied that the requirements of Article 123(2) EPC are met by claim 1 of the main request.

3. Although the only ground on which the impugned decision is based was non-compliance with Article 123(2) EPC, in an "obiter dictum" of the impugned decision, the Examining Division expressed the view that "inclusion of all the features of originally filed claims 33-35 would result in subject-matter for which a positive argument for novelty, inventive step, industrial applicability and original disclosure could be made". In other words, also in view of the remarks made in the second paragraph of the "Reasons for the Decision" of the impugned decision, as explained in point 2 above, the appellant and the Board were given to understand that the Examining Division would allow the subject-matter of claim 1 according to the present main request.

In view of these circumstances, in accordance with Article 111(1) EPC, the Board decides to exercise the competence of the Examining Division and continue with the examination of all the requirements of the EPC for the main request.

4. *Patentability (Articles 52(1) and 56 EPC)*

4.1 Document D1 concerns a device for arthroscopic surgical procedures involving a small insertion opening (column 2, lines 33-36) and aiming at anchoring a suture to body tissue, the device comprising an anchor

(10) and an opposite locking member (52, 74, 90) for holding torn or fractured pieces of body tissue together until they are reattached or healed (figures 7, 8, 12A and 12B, in particular).

Each of documents D2 to D4 concerns a crimping tool for applying a cinch member to the ends of a suture loop. They do not however foresee the use of two opposite members for joining tissue segments between them.

As also derivable from the wording of claim 1, the system of the invention is intended for use in surgical procedures for securely holding together two tissue segments, the procedure involving a possibly small insertion opening (page 2, lines 3-6 of the original application). The Board therefore considers that the device of document D1 more closely matches the purpose of the system according to claim 1 and is therefore the most promising starting point towards the invention.

Hence, document D1 is the closest prior art.

4.2 Referring in particular to figures 7, 8, 12A and 12B, document D1 discloses a system for joining tissue segments, comprising an elongated flexible member (suture 20) having a distal portion and a proximal portion; a first anchor (anchor 10) fixedly attached to said distal portion, said anchor adapted to engage a first tissue section; a second anchor (either of washers 52, 74, 90) having an aperture for slidably receiving said elongated flexible member (20), said second anchor including a deformable portion adjacent said aperture (respective parts through which stop

members 50, 72, 92 pass) and a washer, said second anchor adapted to engage a second tissue section.

4.3 Document D1 fails in particular to disclose a crimping tool having a crimping mechanism with an inner cylindrical member and an outer cylindrical member positioned in surrounding relation to the inner cylindrical member and rotatable relative thereto about a common longitudinal axis, the cylindrical members having co-operating distal ends for crimping a deformable portion of the anchor as claimed.

Hence, the subject-matter of claim 1 is novel within the meaning of Article 54 EPC.

4.4 This differentiating feature makes it possible to suitably crimp the deformable element along the axis of the flexible member at a desired distance.

4.5 The objective technical problem to be solved can therefore be regarded as being how to more effectively hold together the tissue segments in order to promote the healing process.

4.6 With the device of document D1 the distance between the two anchors is determined by the position of the stop members and can therefore only be adjusted at discrete steps. The above-mentioned objective technical problem is not addressed.

The devices of documents D2 to D4 do not comprise a crimping mechanism with co-operating inner and outer cylindrical members as claimed in claim 1.

The skilled person would therefore not arrive at the subject-matter of claim 1 in an obvious way.

Hence, the subject-matter of claim 1 is inventive within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of:

- claims 1 to 11 of the main request;

- pages 1 to 29 of the adapted description;

- figure sheets 1/17 to 17/17;

all filed during oral proceedings.

The Registrar: The Chairman:

D. Hampe E. Dufrasne