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D E C I S I O N
of 5 July 2001

Case Number: T 1046/98 - 3.2.2

Application Number: 92104875.7

Publication Number: 0504915

IPC: A61F 2/08

Language of the proceedings: EN

Title of invention:
Orthopaedic fastener

Patentee:
United States Surgical Corporation

Opponent:
Smith & Nephew Plc

Headword:
-

Relevant legal provisions:
EPC Art. 100(a), 100(b)

Keyword:
"Insufficient disclosure (no)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1046/98 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 5 July 2001

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 13 August 1998 rejecting the opposition filed against European patent No. 0 504 915 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
J. C. M. De Preter

Summary of Facts and Submissions

I. The appellant (opponent) filed an appeal against the decision of the opposition division to reject the opposition, paid the appeal fee and filed the statement of Grounds in due time.

II. The patent was opposed on the grounds of Article 100(a) (lack of novelty and of inventive step) and 100(b) (insufficient disclosure).

III. The following documents cited in the opposition proceedings were still discussed at the appeal stage.

D1: EP-B-0 270 704 (equivalent to DE-U-8 633 339 cited in the description of the patent in suit, page 1, line 9, as representing the precharacterizing part of claim 1);

D3: EP-A-0 238 223;

D4: PCT/US/85/00639;

D6: US-A-2 490 364;

D7: PCT/US/88/03041.

IV. On request of both parties oral proceedings were held on 5 July 2001. At the end of the oral proceedings the requests of the parties were as follows:

- The appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked.

- The respondent (patentee) requested that the appeal be dismissed.

V. Claim 1 as granted reads as follows:

"A surgical fastener which comprises:
a) a rivet (100) having an axial bore (104), distal locking means (116) for frictionally engaging a bone to secure the rivet thereto and a proximal head portion (101); and
b) a pin (200) receivable into said bore and proximally slidable therein, said pin having means (206) for activating said rivet locking means in response to a proximal locking movement of said pin within said bore, in which locking movement the pin is retracted within the axial bore of the rivet in a direction against the proximal head portion of said rivet,
characterized by means (110) for holding soft tissue to said bone, said holding means projecting distally from the proximal head portion of the rivet, whereby the fastener is apt for securing said soft tissue to said bone."

VI. The parties presented the following arguments:

(a) Insufficient disclosure

The appellant argued that - regarding the barbs - the description, page 3, lines 34 to 37, stated that different configurations than the barbs were contemplated that could achieve the function assigned to them. This statement of purpose was not sufficient to describe the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

The respondent argued that this was a new ground of opposition, since in the opposition stage the objection against insufficiency of disclosure was based on the wording: "blind rivet" whereas in appeal proceedings it was based on the shape of the barbs.

(b) Inventive step

According to the appellant the choice of the closest prior art was crucial for the assessment of inventive step in the present case. The device according to document D1 - which had the greatest number of structural features in common with the claimed subject-matter - should be considered as the closed prior art here instead of the one disclosed in document D7 which was preferred by the decision under appeal because it concerned the fastening of soft tissue to the bone. In fact, also the device according to document D1 was capable of performing the function of the claimed invention of fastening soft tissue to the bone. Therefore, the choice of document D1 did not even violate the principles set out in decision T 506/95.

The subject-matter of claim 1 differed from the fastener disclosed in document D1 only by the holding means. Both document D1 and the invention related further to surgical fasteners. The problem to be solved by the invention when starting from document D1 as the closest prior art was to provide a better attachment between the head of the rivet and the soft tissue to be kept in place.

Document D7, which belonged to the same technical field of the invention, taught to add projections (170a) to the lower surface (160a) of the head (110a) to enhance

engagement of the fastener's head to a ligament, see page 14, end of paragraph 2 and Figure 9. This teaching rendered the subject-matter of claim 1 obvious. Alternatively, document D3, which also belonged to the same technical field of the invention (see patentee's response of 13 June 1997, page 2), taught in Figure 4 the use of barb-like projections on the underside of the head of the rivet. Alternatively, document D4, which also belonged to the same technical field (see patentee's letter of 13 June 1997, page 2), Figure 8 and page 10, lines 32 to 35, taught the use of projecting barbs for fastening the head to ligaments, tendons and the like. Document D6 belonged also to a strongly related technical field and disclosed using serration to improve contact with the bone.

In conclusion, starting from document D1, all the further four documents cited above disclosed the problem and the solution of the invention. Accordingly the subject-matter of claim 1 did not involve an inventive step.

Starting alternatively from document D3, Figure 2, as the closest prior art, the distinguishing features of claim 1 were that: a) the locking pin was retracted (rather than advanced, see column 4 and Figure 2, post 24 and legs 22), and: b) the device comprised means projecting distally from the proximal head portion of the rivet. Feature a) solved the technical problem of providing an alternative method of frictionally engaging a bone to secure the rivet thereto using a pin receivable into the bore of said rivet. Feature b) solved the technical problem to provide a better attachment between the head of the rivet and the material with which it was in contact. The two

technical problems and their solutions were unrelated; accordingly they could be considered separately (see T 130/89). Feature a) was disclosed in document D1, Figures 5 and 6. Regarding feature b), a solution to the problem was disclosed in the same document D3, Figure 4 (barbs 38) and claims 7 and 8. It was obvious to add holding means according to Figure 4 to the rivet according to Figure 2. there was no prejudice against it, see also T 19/91, T 104/83, T 321/87.

Accordingly the subject-matter of claim 1 lacked inventive step having regard to D3 and D1.

The respondent argued that in the EPO Boards of Appeal Case Law 1997 (special edition of the OJ EPO 1998, page 26) it was stated that the criterion for choosing the closest state of the art was the suitability for the purpose of the invention and not purely superficial structural similarities, see also T 506/95, point 4.1.

The fastener according to document D1 was applied in the manner of a blind rivet, i.e. when the central pin was retracted the head of the fastener acted as a countersupport and is simultaneously pressed firmly against the osteosynthesis plate (see D1, column 4, lines 2, 10 to 55). The fixation pressure was therefore determined by the tensile strength of the central pin and might not be chosen according to the discretion of the surgeon. For the fixation of soft tissue ligaments, be it natural or artificial, the fixation pressure may be applied progressively by the surgeon during the surgery. Screws had, therefore, been used instead of fixation pins in the art to allow for the progressive adjustment of the fixation pressure (see document D3, Figure 4). Consequently, a person skilled in the art

would not have envisaged to apply the teaching of document D1 for the fixation of soft tissue ligaments and therefore not modified the known fastener by respective holding means. The basic idea of the invention was (see EP-B-0 504 915, page 4, second paragraph) to first insert the orthopaedic fastener into the predrilled hole and press it in such that the barbs bite into the tissue to hold the tissue in close proximity to the surface of the bone. Maintaining the predetermined fixation pressure, the pin was then pulled proximally by the surgeon until the fastener was held in its place in the hole by lateral friction. This implies that not the head of the fastener but the surroundings of the hole were used as a countersupport during the retraction of the central pin.

Document D3 could not be considered as the closest prior art because it did not concern the securing of living tissue to bone but of a strap-like artificial ligament which was designed for taking the load during the repair or reconstruction of a ligament or tendon.

Reasons for the Decision

1. The appeal is admissible.

2. Insufficient disclosure

The appellant filed new arguments to further substantiate its original ground of opposition of insufficient disclosure. The submission of new arguments does not establish a new ground of opposition. The arguments of the appellant are however not convincing. To meet the requirements of

Article 100(b) EPC in the present case, it is sufficient that at least one way to hold soft tissue to the bone is disclosed. The barbs contained in the description meet this requirement.

3. *Novelty*

None of the documents cited discloses, in combination, all the features of claim 1.

Since the novelty was no longer disputed at the appeal stage this issue need not to be further investigated.

4. *Inventive step*

4.1 The German equivalent of Document D1 is cited in the description of the patent in suit (see page 2, line 9) as the document which represents the closest prior art disclosing all the features in the preamble of claim 1.

Also the appellant insisted in that document D1 should be rated as the closest prior art and the Board, for the sake of argument, sees no reason for not adopting this position either.

4.2 It is uncontested that the subject-matter of claim 1 differs from the disclosure of document D1 by the features in its characterizing part, that is by providing means for holding soft tissue to the bone, said holding means projecting distally from the proximal head portion of the rivet. It is also uncontested that this distinguishing feature is known from document D3.

Document D1 is directed to using surgical fasteners to

fix a plate to the two pieces of a broken bone in order to keep them together during the healing process. Traditionally such plates were made of metal and were fastened to the bone by means of metal screws. Document D1 discloses using plates and fasteners made of materials which are reabsorbable by the body, such as polylactit (see column 4, from line 7). Reabsorbable materials are however too soft for making screws because the screws could be torn by the torsional force applied during screwing (see document D1, description, column 1, lines 1 to 65). In order to avoid this drawback, document D1 suggests using fasteners consisting of a rivet and a pin having all the features of the claimed invention, except that they are adapted to secure soft tissues to the bone and that they comprise holding means distally projecting from the rivet head.

The question therefore arises whether the person skilled in the art would have considered to transfer the teaching of document D1 concerning the securing of two broken bones, to the securing of soft tissues such as ligaments and tendons to the bone, and, if the answer to the first question is yes, whether he, for this purpose, would have added projecting means to the rivet head of the fastener of document D1 without any inventive skill being involved.

The Board has reached the conviction that the skilled person in the field would not take in consideration to transfer the teaching of document D1 to the securing of soft tissues for the following reasons.

Document D1 leads away from the claimed invention because it discloses a fastening procedure which is not

suitable for securing soft tissue to the bone. In order to develop the pulling force required to break the fasteners pin leaving the distal end of it in the axial bore of the fasteners rivet and therewith frictionally engaging the bone to the fasteners rivet, the abutment is chosen on the head of the fasteners rivet, see document D1, column 4, lines 33 to 40. From there the abutment force is transferred on the underlying plate and finally to the bone surface. The result is that the plate is pressed between the rivet head and the bone surface by a fixed force equal to the breaking force of the pin.

This method is not suitable for holding soft tissue according to the requirements of the invention where the pressure on the ligament to be held should be progressively adjustable in order to avoid damage of the ligament. A precondition for such adjustment is that the abutment is positioned on the bone surface surrounding the rivet head instead of on the rivet head. The fact that document D1 explicitly suggests a fastening procedure not suitable for soft tissue is a strong circumstantial evidence that the person skilled in the field would not consider the teaching of document D1 as relevant for fastening soft tissue.

But even if he would have considered to modify the teaching of document D1 to adapt it to hold soft tissues, he would not have added to the device of document D1 distal projections on the rivet head, because document D1 leads away from it. Distal projections are well known in the field, see document D3, however it makes no sense to add in the device of document D1 projections under the head of the rivet because these projections would lie against the plate

and possibly are crushed against it by the fastening force on the rivet head.

The disclosure of documents D4 and D7 is similar to the one of D3. Document D6, in particular Figure 7, relates to bone fasteners with a pushing mechanism and is even more remote to the invention.

Accordingly the subject-matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare W. D. Weiß