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Datasheet for the decision of 10 April 2008

Case Number: T 0425/06 - 3.2.02

Application Number: 95901937.3

Publication Number: 0755228

IPC: A61B 17/70

Language of the proceedings: EN

Title of invention:
Variable locking stabilizer anchor seat and screw

Patentee:
CROSS MEDICAL PRODUCTS, INC.

Opponents:
Synthes AG Chur
Stryker Spine

Headword:
-

Relevant legal provisions:
EPC Art. 123

Relevant legal provisions (EPC 1973):
EPC Art. 54(1)(2), 56

Keyword:
"Added subject-matter (no)"
"Novelty, inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0425/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 10 April 2008

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 29 December 2005 revoking European patent No. 0755228 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal on 22 February 2006 against the decision of the opposition division posted on 29 December 2005 revoking the European patent 755 228. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 8 May 2006.

II. The opposition division held that the subject-matter of the main request and of the second to fourth auxiliary requests then on file did not meet the requirements of Article 123(2) EPC 1973 and that the subject-matter of the first auxiliary request lacked novelty (Article 54 EPC 1973), having regard to:

D7 = DE - U - 93 02 700, or
D8 = EP - A - 613 664.

III. Additionally the following documents are relevant for the present decision:

D2 = US - A - 4 805 602
D4 = DE - U - 92 02 745
D6 = WO - A - 91/16020
D10 = EP - A - 0 558 883
D11 = US - A - 4 648 388
D12 = US - A - 4 887 595
D13 = US - A - 4 655 199.

IV. Oral proceedings were held on 10 April 2008.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside

and the patent be maintained on the basis of the claims according to the main request (filed as auxiliary request 4 with the letter of 4 April 2008) or according to the auxiliary request (filed as auxiliary request 5 with the letter of 4 April 2008).

The respondents I and II (opponents I and II) requested that the appeal be dismissed.

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

"A bone interface anchor (12) for use with an elongate stabilisation rod (20), said anchor comprising; seat means (14) having retaining means (17) for retaining a said stabilisation rod (20) in use, compression means comprising a compression member (25) adapted to bear upon said rod (20) for compressively securing the rod (20) in the retaining means (17) of the seat means (14) in use, and a bone screw (15) for securing the anchor (12) relative to a bone interface in use, the seat means (14) having means (22) to form a mating cooperation with a head (40) of said bone screw (15) which allows for the seat means (14) to be variably angularly oriented relative to said bone screw (15), said bone screw head (40) being convexly rounded and said seat means (14) including a concavely rounded socket (22) which receives said bone screw (15) so as to form a ball and socket joint with the convexly rounded head (40) thereof; the seat means (14) and bone screw head (40) being thereby adapted to form a locking interface whereby said relative angular orientation of the seat means (14) and the bone screw (15) is locked, when in use a said stabilisation rod (20) is selectively compressively secured in the seat means

(14) as aforesaid, in direct contact with said bone screw head (40), the seat means (14) and bone screw head (40) being compressed together at said locking interface, and the top of the bone screw head (40) having a projection which has a convexly rounded rod interface surface (50) for contact with the stabilisation rod (20) and is engageable by a driver to screw the bone screw (15) into bone in use."

Claim 1 of the first auxiliary request reads as follows (additions with respect to the main request are underlined):

"A bone interface anchor (12) for use with an elongate stabilisation rod (20), said anchor comprising; seat means (14) having retaining means (17) for retaining a said stabilisation rod (20) in use, compression means comprising a compression member (25) adapted to bear upon said rod (20) for compressively securing the rod (20) in the retaining means (17) of the seat means (14) in use, and a bone screw (15) for securing the anchor (12) relative to a bone interface in use, the seat means (14) having means (22) to form a mating cooperation with a head (40) of said bone screw (15) which allows for the seat means (14) to be variably angularly oriented relative to said bone screw (15), said bone screw head (40) being convexly rounded and said seat means (14) including a concavely rounded socket (22) which receives said bone screw (15) so as to form a ball and socket joint with the convexly rounded head (40) thereof; the seat means (14) and bone screw head (40) being thereby adapted to form a locking interface whereby said relative angular orientation of the seat means (14) and the bone screw (15) is locked,

when in use a said stabilisation rod (20) is selectively compressively secured in the seat means (14) as aforesaid, in direct contact with said bone screw head (40), the seat means (14) and bone screw head (40) being compressed together at said locking interface, and the top of the bone screw head (40) having an external hex projection which has a convexly rounded rod interface surface (50) for contact with the stabilisation rod (20) and is engageable by a driver to screw the bone screw (15) into bone in use."

VI. The appellant argued as follows.

The newly filed claims of the main and auxiliary request did comply with Article 123 EPC. With respect to the features concerning the projection on the bone screw head the skilled person reading the original disclosure, would recognize that the hexagonal shape of the projection and the provision of knurls on the contact surface were inessential features which could be neglected in the claims without violating Article 123(2) EPC.

The subject-matter of the claims according to both requests did also involve an inventive step. The subject-matter of claim 1 of both requests differed from the bone interface anchor according to D7 and D4 (or D10) by a locking interface between the rod (40) and the head of the fixation member (14) of Figure 3, and by the provision of a projection on the tip of the bone screw head for engagement by a driver and for contact with the stabilisation rod. Both features were not suggested by the state of the art. In particular

none of the documents cited by the respondents showed a projection on the top of a bone screw head.

VII. The respondents argued as follows.

Claim 1 of both requests did not comply with Article 123 (2) EPC. A bone screw having a projection on its head was exclusively described on page 6, lines 8 to 14 of the published application (WO - A - 95/13753), where only a projecting external hex having a rounded exterior surface which included a knurl was disclosed. Since claim 1 of the main request and claim 1 of the auxiliary request did not contain all these features they referred to an unallowable intermediate generalisation.

Furthermore, the subject-matter of claim 1 of both requests did not involve an inventive step having regard to the combination of the teaching of documents D7, D2 and D11 to D13 or D4 (or D10), D6 and D11 to D13.

D7 taught that the shaft portion 54 shown in Figure 4 was preferably provided with tool engaging surfaces to operate the bone screw when the head was outside reach (see page 9, middle paragraph). That meant that the screw head had to be provided with a further driver engaging element for use when the screw could be operated from above. Starting from this teaching, it was obvious to provide an internal hex in the screw head as shown in D2. Furthermore, it was obvious that the internal hex could be replaced by an external hex as suggested by each of the documents D11 to D13.

In addition to this argumentation, the respondent II pointed out that, the present requests should not be admitted into the proceedings, since the appellant had plenty of time to present them at an earlier time, and since the new claims 1 comprised essential amendments. In particular the replacement of the term "being" by "is" in the last sentence of the claim resulted in that only the projection of the screw head and no longer the screw head itself was engageable by the driver. Moreover the expression "external hex projection" was not disclosed in the published application. Hence these amendments amounted to further violations of Article 123 EPC.

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility of the latest filed requests*

The requests on file, even if late filed, are considered admissible since they represent a serious attempt to overcome the objections raised by the board and the opponents and do not contain modifications which could surprise the opposing parties. The respondents also conceded that they had enough time to study the new requests.

3. *Main request*

Claim 1 of the main request contains the following feature:

"the top of the bone screw head having a projection which has a convexly rounded rod interface surface for contact with the stabilisation rod and is engageable by a driver to screw the bone screw into bone in use"

This feature is taken out of a single example described on page 6, lines 8 - 14 of the published application (WO - A - 95/13753). According to this passage the top of the screw head includes a projecting external hex 48 having a rounded exterior surface, whereby the external hex can be used to drive the screw into the bone. However, there is no support in the whole application that the projection may have another shape than a projecting external hex. Consequently claim 1 represents a generalisation of the original teaching since it covers not only an external hex to be engaged by a driver, but also other embodiments such as for example a slit head engageable with a flat-bladed driver or a cross slit head engageable with a cross point bladed driver, or a hex socket to be used with an Allen driver, to name just a few possibilities. Independent of the question whether or not the hexagonal shape of the projection is essential, the present generalisation goes beyond the scope of the explicit or implicit disclosure of the original application.

Hence claim 1 of the main request does not comply with Article 123(2) EPC.

4. *First auxiliary request*

4.1 Amendments

With respect to the main request claim 1 of the first auxiliary request contains the further specification that the projection is an external hex projection. It is true that the expression "external hex projection" is not to be found in the published application. However, the respondent II failed to show any difference between the expression "a projecting external hex" used on page 6, line 9 of WO - A - 95/13753 and the expression "external hex projection" used in claim 1 of the auxiliary request. Both expressions describe exactly the same feature and the use of the term "external hex projection" does not amount to a violation of Article 123(2) EPC. Moreover, the objection of insufficient disclosure raised against the main request in section 3 above is overcome by the restriction of the "projection" to an "external hex projection"

It is correct that WO - A - 95/13753 describes on page 6 further features of the hex projection, as for example that the rounded exterior surface includes a knurl. However the skilled person recognizes that the external hex projection has the purpose of providing engagement with a driver in order to drive the screw into the bone, while the further features of the hex projection have different purposes. For example, the knurl on the rod interface surface provides a high friction between the projection and the rod. That means that these further features are not functionally linked in the original disclosure and that the inclusion of

the external hex projection without these further features is not an intermediate generalisation.

Finally, the replacement of the term "being" by the term "is" in the last sentence of claim 1 results in that now the projection of the screw head and not just the complete screw head is engageable with the driver. The result is therefore a restriction of the protection sought which, additionally, brings the claim closer to the disclosed embodiment.

4.2 Novelty and inventive step

Each of D7 and D4 (see in particular Fig. 15) or D10 discloses a bone interface anchor for use with an elongate stabilisation rod (D7: 40, D4: 14), said anchor comprising: seat means (20/72) having retaining means (D7: 24) for retaining a said stabilisation rod in use, compression means (44/ 38d) comprising a compression member adapted to bear upon said rod for compressively securing the rod in the retaining means of the seat means in use, and a bone screw (52/32a) for securing the anchor relative to a bone interface in use, the seat means having means to form a mating cooperation with a head (56/70) of said bone screw which allows for the seat means to be variably angularly oriented relative to said bone screw, said bone screw head being convexly rounded and said seat means including a concavely rounded socket which receives said bone screw so as to form a ball and socket joint with the convexly rounded head thereof. Contrary to the appellant's opinion each of D7 and D4 (or D10) additionally discloses that the seat means and bone screw head are thereby adapted to form a locking

interface whereby said relative angular orientation of the seat means and the bone screw is locked, when in use a said stabilisation rod is selectively compressively secured in the seat means as aforesaid, in direct contact with said bone screw head, the seat means and bone screw head being compressed together at said locking interface. This effect of the arrangement shown in D7 and D4 (or D10) is clearly described in D7 (see page 8, full paragraph).

Starting form the state of the art according to D7 or D4 (or D10) the object to be achieved by the subject-matter of claim 1 is to be seen in facilitating the insertion of the screw without deterioration of the even loading of the compressive forces from the rod on the screw.

This object is achieved by the provision of a bone screw wherein the top of the bone screw head has an external hex projection which has a convexly rounded rod interface surface for contact with the stabilisation rod and is engageable by a driver to screw the bone screw into bone in use.

There is no suggestions in the available prior art which could lead the skilled person in an obvious way to the claimed device.

D7 or D4 (or D10) both disclose a bone screw where the shaft and not the head comprises means (54a/68d) which are engageable by a driver to screw the bone screw into bone in use. The fact that D7 describes that the tool engaging surfaces are provided in order to rotate the pedicle screw while the ball head sits in the ball

receiving portion and is out of reach does not necessarily mean that a further tool engaging surface has to be provided in the screw head. On the contrary, since the screw head according to D7 or D4 (or D10) has a ball shape for contact with a rod, it has to be concluded that the screw head has no tool engaging means, and that the engaging surfaces of the shaft portion are used in all circumstances.

Moreover, the skilled person would avoid the provision of a hexagonal socket as shown in D2 or D6 in the screw head according to D7 or D4 (or D10), since this would be detrimental for the desired contact between the ball shaped screw head and the rod aimed at an even distribution of the force transmitted from the rod to the screw. For the same reason the skilled person would also avoid the provision of a hexagonally shaped head as desired in D11, D12 or D13.

Therefore the provision of a hex projection having a convexly rounded contact surface on the top of a bone screw head according to D7 or D4 (or D10) in order to achieve the object cited above cannot be regarded as an obvious measure.

Accordingly, the subject-matter of claim 1 of the first auxiliary request and of its dependent claims 2 to 6 is novel and involves an inventive step.

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 maintain the patent on the basis of:

   – Claims: 1 to 6 according to the first auxiliary request filed as auxiliary request 5 with the letter dated 4 April 2008;
   – Description: pages 1 to 3 filed during the oral proceedings;
   – Drawings: Figures 1 to 7 as granted.

The Registrar: The Chairman:

V. Commare T. Kriner