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D E C I S I O N
of 20 August 2002

Case Number: T 0319/00 - 3.2.2

Application Number: 95500028.6

Publication Number: 0729732

IPC: A61F 2/36

Language of the proceedings: EN

Title of invention:
Modular design osseous substitution prosthesis

Applicant:
INDUSTRIAS QUIRURGICAS DE LEVANTE, S.A.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52, 56

Keyword:
"Novelty and inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0319/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 20 August 2002

Appellant: INDUSTRIAS QUIRURGICAS DE LEVANTE, S.A.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 29 October 1999 refusing European patent application No. 95 500 028.6 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
R. T. Menapace

Summary of Facts and Submissions

I. The appellant (applicant) filed an appeal against the decision of the examining division to refuse the application for lack of novelty of the amended claim 1. The further dependent claims 2 to 5 were also considered not to involve an inventive step.

II. The following documents have been cited in the decision under appeal:

D1 = DE-A-4 320 086

D2 = EP-A-382 429

D3 = EP-A-382 395

D4 = WO-A-94/07438.

In the communication of 18 January 2002 the Board cited further the following document, mentioned in D1:

D1A = DE-A-4 031 520.

III. Following the communication of the Board on 18 January 2002 and a telephonic conversation on 13 May 2002, the appellant requested with letter of 13 May 2002 the grant of a patent in the following amended version:

Claims:

- claim 1 and claim 2 (first part) as filed with letter of 13 May 2002;
- claim 2 (second part) to claim 7 as filed with letter of 25 March 2002;

Description:

- pages 1 to 7 and 3a as filed with letter of 25 March 2002;
- page 3b as filed with letter of 13 May 2002.

Drawings:

- sheets 1/3 to 3/3 as filed with letter of 25 March 2002.

IV. Claim 1 as filed with letter of 13 May 2002 reads as follows:

"Osseous substitution prosthesis of a modular design for the osseous substitution in the femur proximal zone covering up to two thirds of the femur bone, said prosthesis comprising

- a metaphysis component (1) having an axial central bore for receiving a screw;

- one or more than one accumulable selectable diaphysis component(s) (3) having equal or different lengths so as to adapt the prosthesis length to the length of the resection to be effected, said diaphysis component(s) (3) having an axial bore for receiving a screw and having, at either of its two axial ends either a male or female hexagonal screw nut permitting six different positions and immobilizing the rotation of one component against another;

- an intramedullar stem (4) having a diameter and length depending upon the diameter and length of the medullar channel into which it is to be inserted, said intramedullar stem (4) having at its end proximal to the diaphysis component(s) (3) an axial threaded bore for receiving a screw, a hexagonal screw nut permitting

six different positions and immobilizing the rotation of one component against another, and having a lateral tongue allowing a transversal fixation of the stem to the healthy portion of the femoral bone by means of cortical screws (6); and

- a screw (5) adapted in length so as to join said metaphysis component (1), said one or more than one diaphysis component(s) (3) and said intramedullar stem (4) via their central axial bores and holding the prosthesis screwed in the intramedullar stem (4)."

Claim 2 as filed with letters of 25 March 2002 and 13 May 2002 reads as follows:

"Osseous substitution prosthesis of a modular design for the osseous substitution in the femur diaphysis covering up to two thirds of the femur bone, said prosthesis comprising

- one selectable diaphysis component (3) adapting the prosthesis length to the length of the resection to be effected, said diaphysis component (3) having, at either of its two axial ends a female hexagonal screw nut permitting six different positions and immobilizing the rotation of one component against another;

- a distal intramedullar stem (4) having a diameter and length depending upon the diameter and length of the medullar channel into which it is to be inserted, said distal intramedullar stem (4) having at its end proximal to the diaphysis component (3) a male hexagonal screw nut permitting six different positions and immobilizing the rotation of one component against another, and having a lateral tongue allowing a transversal fixation of the stem to the healthy portion

of the femoral bone by means of cortical screws (6); and

- a proximal intramedullar stem (9) having a diameter and length depending upon the diameter and length of the medullar channel into which it is to be inserted, said proximal intramedullar stem (9) having at its end proximal to the diaphysis component (3) a hexagonal screw nut permitting six different positions and immobilizing the rotation of one component against another, and having a lateral tongue allowing a transversal fixation of the stem to the healthy portion of the femoral bone by means of cortical screws (6)."

V. The appellant argued that - in contrast to document D1 - the present invention relied upon a "male" and "female" hexagonal screw nut at the connection portion of the parts/components forming the prosthesis of the invention. The "male" and "female" hexagonal screw nut system of the invention had the advantage of allowing 6 different positions and yet effectively preventing rotation around the central axis of the prosthesis even in a state where the screw is not yet strengthened. Document D1 aimed at overcoming the disadvantages of the complicated system of document D1A, Figure 3, by providing conical connections. The "extension conus" with a multiple step recess system of document D1A was replaced in document D1 by a system always consisting of three components. In the prosthesis system of document D1 there was no need for the variable connectors of document D1A, so that a combination of the teaching of both documents would never have been envisaged by a person skilled in the art.

Reasons for the Decision

1. The appeal is admissible

2. *Amendments*

The new claim 1 is composed of a combination of features contained in the original claims 1 and 3 to 5, in the description, page 4, lines 23 to 25, page 5, lines 6 to 29, page 6, lines 5 to 26, and in Figures 1 and 2. Claim 2 derives from the original claims 2 and 7, from the description, page 6, lines 5 to 26, and page 7 lines 14 to 26 and from Figure 3. Claim 3 derives from claim 2, from the description, page 5 from line 31 to page 6, line 4, and from the Figures 1 and 2. The feature of claim 4 is contained in the original description, page 5, lines 8 to 12. Claims 5 and 6 are based on the original claim 6. Claim 7 derives from the description, page 6, lines 19 to 21. The amendments in the description are limited to minor corrections, to the evaluation of documents D1 and D1A, and to the adaptation to the wording of the new claims. Accordingly Article 123 (2) EPC is met.

3. *Novelty*

The Board concurs with the appellant (see letter of 25 March 2002, paragraph (7)) that document D1 represents the closest state of the art and discloses an osseous substitution prosthesis of a modular design for the osseous substitution in the femur proximal zone. Said prosthesis comprises a metaphysis component (3) having an axial central bore for receiving a screw and one or more than one accumulable selectable diaphysis components (5) so as to adapt the

prosthesis length to the length of the resection to be effected. Said diaphysis components have an axial bore for receiving a screw. The known prosthesis further comprises an intramedullar stem (2) having a diameter and length depending upon the diameter and length of the medullar channel into which it is to be inserted. Said intramedullar stem (2) has at its end proximal to the diaphysis components an axial threaded bore for receiving a screw (12) which is adapted in length so as to join said metaphysis component, said one or more than one diaphysis components and said intramedullar stem via their central axial bores and holding the prosthesis screwed in the intramedullar stem.

The subject-matter of claim 1 differs from this state of the art in that said diaphysis components have, at either of its two axial ends either a male or female hexagonal screw nut permitting six different positions and immobilizing the rotation of one component against another and in that said intramedullar stem (2) has at its end proximal to the diaphysis components a hexagonal screw nut permitting six different positions and immobilizing the rotation of one component against another, and a lateral tongue allowing a transversal fixation of the stem to the healthy portion of the femoral bone by means of cortical screws (6).

Claim 2 represents a further embodiment of the invention suitable for the osseous substitution (of an intermediate part) of the femur diaphysis and therefore has a further (proximal) intramedullar stem instead of the metaphysis component according to Claim 1.

Accordingly the subject-matter of claims 1 and 2 are novel.

4. *Inventive step*

Starting from the teaching of document D1, the technical problem underlying the invention has to be seen in providing a flexible and yet precise positioning of the prosthesis with respect to the bone and a reliable connection of the prosthesis with the bone.

The solution provided by the distinguishing features of the independent claims 1 and 2, namely a hexagonal screw nut, which allows a precise lateral positioning of the prosthesis, and a lateral tongue for the intermedullar stem which assures a reliable connection to the bone are not made obvious by the available prior art.

Documents D1 and D1A disclose a tapered, conical connection between the elements of the prosthesis which - because of the frictional force on the contact surfaces of the connection - is difficult to adjust. Document D1A discloses further a lateral tongue 80, in Figure 1, but not for a pure intramedullar stem like the invention and not in combination with a hexagonal connection.

The further documents of the available prior art are farther away from the claimed invention.

It follows from these considerations that the subject-matter of claims 1 and 2 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 Examining Division with the order to grant a patent with the following version:

Claims:

- claim 1 and claim 2 (first part) as filed with letter of 13 May 2002;
- claim 2 (second part) to claim 7 as filed with letter of 25 March 2002;

Description:

- pages 1 to 7 and 3a as filed with letter of 25 March 2002;
- page 3b as filed with letter of 13 May 2002

Drawings:

- sheets 1/3 to 3/3 as filed with letter of 25 March 2002.

The Registrar: The Chairman:

V. Commare W. D. Weiß