Case Number: T 0662/01 - 3.2.2
Application Number: 94500193.1
Publication Number: 0655229
IPC: A61F 2/30
Language of the proceedings: EN
Title of invention:
Straight non-hardened stem for total hip prostheses
Applicant:
INDUSTRIAS QUIRURGICAS DE LEVANTE, S.A.
Opponent:
-
Headword:
-
Relevant legal provisions:
EPC Art. 52(1), 56, 84, 123(2)
Keyword:
"Clarity (yes, after amendment)"
"Inventive step (yes, after amendment)"
Decisions cited:
-
Catchword:
-
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DECISION
of the Technical Board of Appeal 3.2.2
of 20 July 2004

Appellant: INDUSTRIAS QUIRURGICAS DE LEVANTE, S.A.
Islas Baleares, 50
P.I. Fuente del Jarro
E-46988 Paterna - Valencia (ES)

Representative: Koepe, Gerd L., Dipl.-Chem.
Koepe & Partner
Robert-Koch-Strasse 1
D-80538 München (DE)

Decision under appeal: Decision of the Examining Division of the European Patent Office posted 14 March 2000 refusing European application No. 94500193.1 pursuant to Article 97(1) EPC.

Composition of the Board:
Chairman: T. K. H. Kriner
Members: S. S. Chowdhury
U. J. Tronser
Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 14 March 2000 to refuse European patent application No. 94 500 193.1.

The ground of refusal was that the subject-matter of the claims was not clear and the description was full of linguistic errors which rendered the comprehensibility of the claims very difficult. Moreover, the scope of protection had been extended beyond that originally filed contravening Article 123(2) EPC.

II. On 12 May 2000 the appellant (applicant) lodged an appeal against the decision, and paid the prescribed fee on the same day. On 14 July 2000 a statement of grounds of appeal was filed. Oral proceedings took place on 20 July 2004.

III. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

Claims 1 to 3, description pages 1 to 3, 3a, 3b, 3c, and 4 to 6, and Figures 1 and 2 submitted at the oral proceedings.

IV. Claim 1 of this request reads as follows:

"A non-cemented straight stem for total hip prosthesis consisting of a first neck zone (1) with European Morse cone 12-14 that allows accepting femoral heads of different sizes and lengths, thus affording a modular
character; and a supporting collar (2) extending medially; a second proximal zone (8) affording forced implant bone fitting, with a constant thickness cross-section in the anterior-posterior plane and inclination widening in the lateral zone, and having applied an embedded coating, with the exception of the lateral zone; and a third distal zone (6) having a rounded terminal tip; characterized in that the supporting collar (2) in the first neck zone (1) extends at an angle of 30° with the horizontal, the widening in the lateral portion of the second proximal zone (8) can present two endings or terminations in the posterior proximal zone, bevelled at 15° or straight; the embedded coating is applied on the calcar triangle (5); at the first neck zone (1), the cervical-diaphysial angle is 140°; and the embedded coating in the second proximal zone (8) is composed of poropatite (titanium spherules (poropros) + hydroxyapatite), or hydroxyapatite."

Claims 2 and 3 are dependent on claim 1.

V. The following documents from the European Search Report were of interest in the appeal procedure:


D2: FR-A-2 619 707

Reasons for the Decision

1. The appeal is admissible.

2. Amendments

2.1 In response to the impugned decision and a communication from the Board to the effect that the entire application reads in poor technical English the appellant had the application, which was initially filed in Spanish, re-translated. According to Article 14(2) EPC the translation of an application filed in an official language of a Contracting State may be brought into conformity with the original text of the application throughout the proceedings before the EPO. This also includes the case where the entire text is re-translated if the original translation was very poor as in the present case.

The application as filed at the oral proceedings is based on the re-translation which was filed on 6 July 2004 and is accompanied by a declaration of the translator that she is well acquainted with English and Spanish and that the re-translation is a true and correct translation of the original Spanish text. The translation filed on 6 July 2004 is, therefore, accepted as the authentic English text of the European application.

2.2 The claims filed at the oral proceedings are based on the claims of the re-translation. Claim 1 is a combination of the features of claims 1 and 4 of the re-translation, but is narrower in scope in that the angle between the supporting collar and the horizontal
is restricted to 30° and the cervical-diaphysial angle is restricted to 140°, which specific angles are supported by page 4, line 13 and page 5, line 11, respectively. Also, the option of titanium for the embedded coating in the second proximal zone has been cancelled. The description has been amended for consistency with claim 1 filed at the oral proceedings. The application meets the requirement of Article 123(2) EPC, accordingly.

3. Clarity

Borland's Medical Dictionary defines "calcar femorale" as the plate of strong tissue which strengthens the neck of the femur. In the application the expression "calcar triangle" clearly refers to a triangular zone adjacent the calcar and this is shown in Figure 2 as the roughly triangular zone 5 to which the embedded coating is applied, and its location is consistent with the dictionary definition of this term. There is no objection to the use of the expression "calcar triangle" in claim 1, accordingly.

Claim 1 now defines the direction in which the second proximal zone has a constant thickness. The claim further defines an inclination widening in the lateral zone, which can present two endings or terminations in the posterior proximal zone, bevelled at 15° or straight. This clearly refers to the fact that the stem tapers toward the distal end, as viewed in the anterior-posterior direction, and the wider (proximal) end of the second proximal zone adjacent the collar has a portion which may be straight or bevelled at 15°. All
the objections as to clarity in the impugned decision have, therefore, been met.

4. **Novelty**

The closest prior art document is D1, over which claim 1 is correctly divided into the two-part form, so that the non-cemented hip prosthesis stem of claim 1 is novel by virtue of the features in the characterising part of the claim.

5. **Inventive step**

The claimed invention relates to a non-cemented straight stem for total hip prosthesis. Since the stem is not cemented it is important to secure it firmly in place in the medullary canal by other means. A porous structure on the stem for promoting bone growth into the structure constitutes a biological stem fixation means which is well known in the prior art. In the present application the embedded coating on the calcar triangle corresponds to this feature (see page 3, last paragraph).

In the prior art different configurations of such porous structures were known. D1 describes a porous structure in the form of a metal alloy surface structure (column 7, lines 52 to 55). In D2 a porous pad of titanium fibre metal is wrapped about the stem (page 6, last paragraph), and in D3 a porous matrix formed of spherical beads of titanium alloy is employed. These exemplify the different types of porous structures known in the prior art.
The non-cemented hip prosthesis stem of claim 1 of the application requires the use of materials not known in this context, namely poropatite (titanium spherules (poropros) + hydroxyapatite), or hydroxyapatite. These have the advantage that they provide a combination of porosity and crystalline structure which promotes bone growth (see the paragraph linking pages 3 and 4) since these materials have a chemical composition and a crystalline structure which are closely related to those of the bone structure. The rapid growth of bone into the porous structure is clearly of advantage where the stem is non-cemented.

The use of these materials in the present context is not known in the prior art, for which reason their incorporation in a non-cemented hip prosthesis stem involves an inventive step. Claim 1 meets the requirement of Article 52(1) EPC, accordingly.
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 an order to grant a patent on the basis of claims 1 to 3, description pages 1 to 3, 3a, 3b, 3c, and 4 to 6, and Figures 1 and 2 submitted at the oral proceedings.

The Registrar:     The Chairman:

A. Vottner       T. K. H. Kriner