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DECISION
of 10 March 2004

Case Number: T 0988/01 - 3.2.2
Application Number: 91913303.3
Publication Number: 0530323
IPC: A61F 2/36

Language of the proceedings: EN

Title of invention:
Femoral stem prosthesis

Patentee:
MIKHAIL, Michael W.E.

Opponent:
1. SMITH & NEPHEW GROUP RESEARCH CENTRE
2. DePuy International Limited
3. Spierings, Petrus Tarasius Josephus

Headword:
-

Relevant legal provisions:
EPC Art. 123, 56

Keyword:
"Extended scope of protection (no, after amendments)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0988/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 10 March 2004

Appellant: MIKHAIL, Michael W.E.
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Respondents: SMITH & NEPHEW GROUP RESEARCH CENTRE
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 26 June 2001
revoking European patent No. 0530323 pursuant
to Article 102(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
U. J. Tronser

Summary of Facts and Submissions

- I. Following the decision of revocation of the European patent dated 26 June 2001, on the grounds of extension of the protection (Article 123(3) EPC) and lack of inventive step of its subject-matter (Article 100a EPC), the appellant (patentee) lodged an appeal on 4 September 2001 and filed a statement of grounds for appeal on 5 November 2001.
- II. Only the opponents 1 and 2 (respondents) replied to the appellant's statement. They reiterated their original objections on the grounds of Article 100(a) EPC (lack of novelty and inventive step) and Article 100c EPC (added subject-matter and extension of protection conferred). But did not maintain the original objection on the ground of insufficient disclosure (Article 100(b) EPC). Opponent 3 did not react at all and neither was present at the subsequent oral proceedings even though summoned according to the rules.
- III. Oral proceedings were held on 10 March 2004 during which finally the following single claim was filed:

"1. A collarless femoral hip joint prosthesis (50) adapted to be cemented into an intramedullary canal, the prosthesis having an elongated stem (51) which has a proximal end and a distal end (52) extending along a first axis (C), the stem being convergently tapered towards its distal end and having its proximal end extending to an area of juncture with a neck portion (53) extending along a second axis (D) disposed at an obtuse angle to the first axis, the area of juncture forming a smooth arcuate contour (55) in

the included angle between the first and second axes and an enlarged shoulder (56) on the opposite side, the shoulder including a lower portion (57) which follows a straight line path aligned with the stem and an upper portion (58) which follows a smooth curved path merging with the neck portion and a straight line path from one edge (58A) to the opposite edge (58B) across its width, the area of juncture between the lower portion and the upper portion providing a line of demarcation (59) at the outermost portion of the shoulder, the stem having a circular cross-sectional configuration near its distal end (52) and an oval cross-sectional configuration in the area approaching the arcuate contour (55) and the shoulder (56), the cross-sectional configurations in intermediate areas merging between circular and oval, the prosthesis being formed of cobalt-chromium-molybdenum alloy and the stem having a smooth polished surface with a surface roughness equal to or less than 102 nm (4 microinches)."

IV. At the end of the oral proceedings the requests of the parties were as follows:

The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the single claim according to the main request submitted at the oral proceedings and the description as submitted at the oral proceedings (columns 1 to 9) and the figures as granted.

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

V. Of the documents cited in the opposition proceedings the following were still considered at the appeal stage:

D6: "Experience with the Exeter Total Hip Replacement Since 1970", J. L. Fowler, A. J. C. Lee and R. S. M. Ling, Orthopaedic Clinics of North America, Vol. 19, No. 3, July 1988, pages 477-489.

D10: US-A-4 865 608.

D11: "Localised Endosteal Bone Lysis in Relation to the Femoral Components of Cemented Total Hip Arthroplasties". P. P. Antony et al., The Journal of Bone and Joint Surgery, Vol. 72-3, No. 6, November 1990, pages 971 to 979.

D12: US-A-4 179 758.

D17: "1984 Annual Product Catalog", Howmedica Orthopaedics Division, 5 pages of which pages A-1 and A-34 (The Exeter 30 mm Total Hip System).

D21: US-A-4 808 186.

VI. Arguments presented by the parties.

(i) the appellant

The schematic drawing of an Exeter endoprosthesis displayed in document D17 does not allow to identify the structural features of the prosthesis as claimed. Even if document D6 may disclose the phenomenon of subsidence upon which the invention is based, it fails to disclose the use of cobalt-chromium-molybdenum alloy

or of the specific degree of polishing required for the surface of the prosthesis. Document D11 was published after the priority date of the present patent and, therefore, is not part of prior art. Moreover, the passage on page 978 which refers generally to an Exeter polished stem according to Fowler (D6) does not clearly disclose which specific stem design actually had the measured roughness of 0.03 micrometer.

D21 proposes another stem concept having a channel for reducing its stiffness in relation to the mass for thereby producing a more flexible stem. Therefore, there is no reason for considering this document alone or in combination. Document D10 discloses a stem having a circular cross-section at its distal end, which is, however, not merging into an oval configuration towards its proximal end. The skilled person, therefore, would have to combine at least three documents for only approaching the claimed subject-matter, which is clearly an indication of inadmissible *ex-post* reasoning.

(ii) the respondents

The catalog Howmedica (D17) discloses an Exeter femoral prosthesis having the same profile and most of the structural features of the claimed prosthesis. It is also made of Vitallium, which is a Co-Cr-Mo alloy having the required properties. Document D6 explains that the subsidence (distal movement of the stem within the cement) can be considerably improved by a number of features such as the use of a collarless, smooth, polished and tapered stem. Although D11 is not a pre-published document, it can nevertheless be considered

as evidence (cf. page 978) that an Exeter polished stem according to Fowler (D6) had been known before the priority date and been polished up to a surface roughness of 0.03 micrometer, falling within the claimed range. The combination of documents D17 and D6 (D11), therefore, discloses all the features which are essential to the solution of the basic problem stated in the patent in suit. The remaining features represent a simple matter of design and serve to solve the different problem of providing resistance to the torsional movement of the stem, which is not even addressed in the patent. Besides the fact that these additional features are of minor importance and represent only an alternative design of the prosthesis, they are known *per se* e.g. from document D21, which discloses a shoulder portion including a lower straight portion and a line of demarcation between the lower and the upper portions of the shoulder, and from document D10 which discloses a stem with a circular distal end progressively merging into an oval configuration towards its proximal end. These features, therefore, fail to add any inventive step to the claimed subject-matter.

Reasons for the Decision

1. The appeal is admissible.
2. *Formal aspects*

The subject-matter of the claim in suit is based on the embodiment according to Figures 14 to 18 of the description of the original PCT application, in

particular from page 11, line 32 to page 12, line 8 and page 12, lines 20 to 24, which are also part of the patent as granted. The specification of the Co-Cr-Mo alloy is based on claim 2 and on page 5, lines 12 to 16 and page 8, lines 7 to 11, of the application as filed. The amendments, therefore, are not such as to extend the subject-matter beyond the content of the application as filed. With respect to the version as granted, the claim was redrafted in a one-part form and the amendments made by incorporating additional features so as to restrict the protection.

The amendments applied to the description were made to adapt the introductory part of the patent specification in conformity with the amended claim and to focus the invention on the specific embodiment of Figures 14 to 18.

It results therefrom that the provisions of Article 84 and 123(2) and (3) EPC are met.

3. *Novelty*

Novelty was not disputed by the parties. Also the Board sees no reason to challenge novelty, since none of the cited documents discloses all the claimed features in combination.

4. *Inventive step*

4.1 The closest prior art is represented by the report D6, one of the co-authors (R. S. M. Ling) of which is one of the inventors of the present patent. D6 explains the phenomenon of the distal movement of the stem within

the mantle of cement (subsidence) without disruption of the cement-bone interface, upon which the present invention is based (cf. pages 477, right column; page 480, last paragraph and page 485, point 3).

Following the same terminology as in the claim at issue, D6 discloses a collarless femoral hip joint prosthesis adapted to be cemented into an intramedullary canal, the prosthesis having an elongated stem with a proximal end and a distal end extending along a first axis, the proximal end extending to an area of juncture with a neck portion extending along a second axis disposed at an obtuse angle to the first axis. The stem is convergently tapered towards its distal end. The area of juncture forms a smooth arcuate contour in the included angle between the first and second axis and an enlarged shoulder on the opposite side, including a lower portion aligned with the stem and an upper portion following a smooth curved path merging with the neck portion (cf. Figure 3, page 481 and Figure 6, page 488).

The subject-matter of the claim differs from the disclosure of document D6 by specific features related to the shape of the prosthesis and by the use of a Co-Cr-Mo alloy for enabling a high degree of polishing, i.e. having a maximum surface roughness of 102 nm (4 microinches). The skilled person is also taught by D6 that the degree of polishing of the stem surface, which determines the coefficient of friction between the stem and the cement, plays a prominent part on the compressive forces acting on the cement (cf. Figure 5 and text referred to) and that the twisting component

is greatly responsible for loosening and breakage of the prosthesis (cf. page 487, first paragraph). Although document D6 also addresses the general problem of the present patent which consists in allowing for subsidence of the stem within the cement mantle by using a collarless, smooth, polished and tapered stem, it uses for this purpose stems made of 316L or Orthinox stainless steels (cf. pages 478, 488 and Table 1). Moreover, the stem is shaped to as to form a double-tapered wedge having a rectangular cross-section, in the same manner as illustrated in Figures 3 and 4 of the present patent, for achieving the requested stability with respect to torsional forces applied to the head of the prosthesis (cf. page 485, bottom of the right column).

- 4.2 In view of the teaching of document D6, the objective problem underlying the present patent is, therefore, to provide a prosthesis having all advantageous characteristics and effects recited in D6 with regard to subsidence and, additionally, having a prolonged lifetime in the patient.

This problem is solved, according to the claimed subject-matter, by a prosthesis made of Co-Cr-Mo alloy, having a polished surface with a roughness equal to or less than 102 nm, by a stem 51 having a circular cross-sectional distal end merging into an oval cross-sectional configuration towards its proximal end while approaching the arcuate contour 55 and the shoulder 56, and by the shoulder having a straight line lower portion 57 aligned with the stem and an upper portion 58 having a straight line between opposite edges 58A, 58B across its width and a line of demarcation 59 at

the juncture between the lower and the upper portions of the shoulder.

Thus, in the invention, the resistance with respect to torsional forces applied to the head of the prosthesis is achieved not only by the oval configuration of the stem (Figure 17) but also by the hexagonal or diamond shaped configuration of the shoulder 56 (Figure 16), which is more specifically defined in the claim by the edges 58A, 58B and by the line of demarcation 59 between the straight line lower portion and the upper portion of the shoulder. Said line of demarcation is represented by a straight line on the left side of Figure 16 while the edges are forming the apexes of the diamond shape between the flattened segments 61 and 62. It will be understood by the skilled reader that this configuration is self-tightening against rotation, although this effect is not specifically mentioned in the present patent.

- 4.3 Document D10 discloses a prosthesis with a stem having a circular cross-section at its distal end (Figure 3) merging into an elongated cross-section at its proximal end (Figure 4) and opposite surface portions 20, 20' converging or diverging with respect to each other according to the direction considered, and provided with grooves. The purpose of this structure is to achieve a proper distribution of stresses within the prosthesis, in particular in the proximal portion, and to provide a maximum resistance to the force F applied to the head (cf. column 4, lines 9 to 15). This is just the contrary of promoting subsidence of the stem within its cement mantle. This document, therefore, does not disclose any of the claimed structural features nor is

it concerned with subsidence or resistance to torsional forces.

Document 21 (cf. Figure 1) discloses a prosthesis having a shoulder with a lower portion following a straight line aligned with the stem and a sharp juncture between the lower and the upper portions. The stem is, however, formed with a longitudinal channel (Figure 2), the depth of which is variable between the proximal and the distal ends (Figure 5) in order to affect the movement of inertia along the length of the stem and thereby achieve optional stem flexibility. This document, therefore, does neither disclose the shape nor the structure of the prosthesis as claimed. In document D17 (page A-34) the schematic and shaded representation, in a side view, of the Exeter femoral prosthesis, does not allow to identify or deduce the structural features of the invention.

Documents D17 and D21 both disclose the use of Co-Cr-Mo alloy or Vitallium for making a femoral hip prosthesis. However D21 (cf. column 3, lines 22 to 26 and column 6, lines 11 to 18) prefers the use of a titanium alloy instead of a Co-Cr-Mo alloy because it exhibits a better elastic modulus, a property specifically requested in this document. The catalog D17 does not mention the reasons why Vitallium was selected. It is, however, known from document D12 (column 2, lines 35 to 49) originating from the same manufacturer (Howmedica) that Vitallium was used principally for its clinical inertness in relation to living tissues and its high degree of resistance to corrosion. Although it was generally known that Vitallium, when polished, was exceedingly smooth and permanently lustrous, this

knowledge was not condensed to a technical teaching. D12 is completely silent about the degree of polishing.

Only the not prepublished (November 1990) document D11 (cf. page 978, right column) reports a measured surface roughness CLA (Center-Line-Average) of 0.03 micrometer (30 nm) with reference to talysurf traces of the surface of a polished Exeter stem experienced by Fowler et al., in 1988. It is not clear from this document whether said CLA measurement was performed on used stems after explantation of the prosthesis from the patients (cf. case histories on pages 972 to 974) or on stems before their implantation and corresponding actually to those described by Fowler in D6. The reference to Fowler on page 978 may simply refer to the references listed on page 979. Therefore, in the Board's view, the roughness value mentioned on page 978 is not prior art and cannot be taken to interpret or complete the teaching of D6.

By specifying an upper limit for the surface roughness of the stem, the claim under consideration is defining the very high degree of polishing which is indispensable for achieving the required level of subsidence, having regard to the peculiar geometry of the prosthesis. Therefore, the Board is satisfied that the invention resides in the combination of all the claimed features, which is not disclosed nor suggested by the state of the art. Even a combination of all pre-cited documents would not allow to arrive at the claimed subject-matter. For these reasons, the subject-matter of the single claim involves an inventive step 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 first instance with the order to maintain the patent in amended form on the basis of the single claim according to the main request submitted at the oral proceedings, the description as submitted at the oral proceedings and the figures as granted.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß