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Datasheet for the decision of 15 June 2016

Case Number: T 0972/12 - 3.2.02

Application Number: 01920504.6

Publication Number: 1265559

IPC: A61B17/17, A61F2/30

Language of the proceedings: EN

Title of invention:
A METHOD OF MAKING A CUSTOM REPLACEMENT DEVICE FOR RESURFACING A FEMUR

Applicant:
Kinamed, Inc.

Headword:

Relevant legal provisions:
EPC Art. 123(2), 84, 54, 56

Keyword:
Added subject-matter (no)
Clarity (yes)
Novelty and inventive step (yes)

Decisions cited:

Catchword:

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Case Number: T 0972/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 June 2016

Appellant: (Applicant)	Kinamed, Inc. 2192-C Anchor Court Newbury Park, CA 91320-1603 (US)
Representative:	South, Nicholas Geoffrey A.A. Thornton & Co. 10 Old Bailey London EC4M 7NG (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 23 November 2011 refusing European patent application No. 01920504.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	M. Stern
	P. L. P. Weber

Summary of Facts and Submissions

I. The applicant lodged an appeal against the decision of the Examining Division posted on 23 November 2011 refusing European application No. 01 920 504.6. The Examining Division found that the then pending claims did not fulfil the requirements of Articles 123(2) and 84 EPC and that the claimed device lacked novelty in view of document

D2: US-A-5 755 803.

II. The following documents cited in the examination proceedings are also mentioned in the present decision:

D1: WO-A-00/13 616
D3: FR-A-2 440 185
D4: US-A-5 156 777.

III. Notice of appeal was filed on 23 January 2012 and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 3 April 2012.

IV. The Board presented its provisional opinion in a communication dated 16 March 2016.

V. With its letters dated 13 May 2016 and 3 June 2016, the appellant filed amended application documents. It requested that the decision under appeal be set aside and that a patent be granted on the basis of: claims 1 to 6 of the main request filed on 3 June 2016; description pages 7, 8 and 10 to 15 as originally filed, pages 1, 2, 2a, 3 to 6, 9 and 16 filed on 3 June 2016; and figure sheets 1/6 to 6/6 as originally filed. Failing that, the appellant requested the grant of a

patent on the basis of one of the first to third auxiliary requests filed on 13 May 2016.

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

"A method of making a customized replacement device (4) for resurfacing the distal end of a femur (2), the femur having a trochlear groove surface (3), said method comprising the steps of:

duplicating the surface of the distal anterior femur from an individual patient;

using the duplicate to form a bottom surface (6) of the customized replacement device (4), the bottom surface being custom formed to match and fit the natural contour of the trochlear groove surface of the patient's femur; and

forming a top surface (7) of the device to have a contour that replicates the trochlear groove tracking pattern of the patient’s femur."

Claims 2 to 6 are dependent claims.

VII. The appellant's arguments relevant for the decision are those on which the reasons set out below are based.

Reasons for the Decision

1. The appeal is admissible.

2. Main request - Articles 123(2) and 84 EPC

2.1 The claimed invention relates to a method for making a customised prosthesis ("replacement device") for the distal femur of an individual patient, in particular a prosthesis for the patella-femoral joint. One of the

advantages of custom-forming a prosthesis for an individual patient is to obtain a prosthesis which replicates as closely as possible the original articulating movement of the patella about the trochlear groove of the femur (page 5, lines 24 to 33; page 2, lines 17 to 23; Figures 1 and 2). Moreover, the fitting of the customised prosthesis requires less removal of bone from the femur than is the case with standardised prostheses (page 8, lines 26 to 30; page 9, lines 16 to 23).

2.2 A basis for the bottom and top surfaces of the replacement device formed according to the method of claim 1 is given by claim 1 and page 8, lines 12 to 14 and page 6, lines 31 to 34 of the original application. These passages of the description make it clear that the top (or front) surface of the device has a contour which replicates the trochlear groove tracking pattern of the patient’s femur. The tracking pattern refers to the tracking of the patella within the trochlear groove of the patient's femur during articulation (page 6, lines 31 to 34). The definition in claim 1 that the bottom (or bone-contacting) surface of the device is custom-formed to match and fit the natural contour of the trochlear groove surface of the patient's femur is disclosed in original claim 1 and page 6, lines 24 to 26.

A basis for the surface-forming steps of claim 1 is given on page 4, lines 21 to 24 of the original application.

As a consequence, claim 1 of the main request satisfies the requirements of Article 123(2) EPC.

2.3 The impugned decision concerned device claims which defined the replacement device in terms of the result to be achieved, in particular the replication of the trochlear tracking pattern of a patient. Such a tracking pattern certainly varies from patient to patient. Accordingly, the Examining Division held the claimed device to lack clarity (point 2.1.2).

Current claim 1 is no longer a device claim, but a method claim defining the manufacturing of a replacement device customised for a specific patient. As a consequence, the clarity objection raised now no longer applies.

Further clarity deficiencies, concerning dependent claims as well, which were raised by the Board in its communication, have also been remedied.

The Board is therefore satisfied that the claims of the main request comply with the requirements of Article 84 EPC.

3. Main request - novelty and inventive step

3.1 Document D2 discloses a femoral prosthesis having a bottom surface (inner area 24 in Figure 1) which (at least to some degree) matches and fits the trochlear groove of a femur (column 7, lines 1 to 3; column 5, lines 42 to 45) and a top surface (external to inner area 24) which replicates as close as possible the trochlear groove (column 5, lines 47 to 52; column 8, lines 33 to 35). Although D2 discloses that the geometry of the bottom surface can be varied as desired (column 7, lines 6 to 8), the prosthesis disclosed in D2 is a standardised prosthesis of a predetermined shape to which the patient's bone is fitted using a

milling bit (column 7, lines 17 to 32). The prosthesis of D2 is not, however, a *customised* prosthesis made by *duplicating the surface* of the femur from an individual patient (for example by creating a surface from CT image data as mentioned in the application on page 14, lines 11 to 15) and by *using the duplicate to form the bottom surface* to match and fit the natural contour of the trochlear groove surface of the patient's femur, as defined in claim 1.

Hence, the method of claim 1 of the main request is novel with respect to D2.

3.2 Given that D2 discloses *standardised* knee prostheses, the skilled person would not readily arrive at a method for *custom-forming* a replacement device to match and fit the natural contour of the trochlear groove surface of the patient's femur as defined in claim 1.

As explained under point 2.1 above, the method of the invention makes it possible to obtain a custom-fitted prosthesis which maintains as closely as possible the original articulating movement of the patella about the trochlear groove. Moreover, the fitting of the customised prosthesis requires less removal of bone from the femur than is the case with standardised prostheses.

Hence, the method of claim 1 of the main request does not result in an obvious way from D2.

3.3 Documents D1 and D3 also disclose *standardised* knee prostheses of a predetermined shape. Hence, for the same reason as for D2, the method of claim 1 of *custom-forming* a replacement device does not result in an obvious way from D1 or D3 either.

3.4 Document D4 was cited during the examination proceedings (communication dated 10 November 2008, points 3.1 and 4) as the closest prior art for original method claims 22 and 17. D4 is the only document on file in which a method for making a customised prosthetic implant is disclosed. It discloses producing a prosthetic implant at a predetermined organ site from 3D data including surface contour information of the organ site (column 1, lines 42 to 55). Figure 1 shows the physical model of a patient's skull (10) which is produced from 3D computed axial tomography data and onto which a wax implant model (14) is to be attached which is complementary to the external surface contour (13) of the attachment area (12) of the skull. The wax implant model (14) is subsequently replaced by the implant, which is typically made of a pliant, flexible and compressible material such as a silicone rubber (column 3, lines 1 to 9).

Although D4 explicitly mentions that "the present invention is applicable to reconstructive and aesthetic surgery of other organ sites" (column 3, lines 38 to 42), there is no disclosure or suggestion to apply it also to structural implants with important mechanical characteristics such as those in a patient's knee joint. In particular, the pliant, flexible and compressible materials of the implant of D4, e.g. silicone rubber, are entirely unsuitable for a knee prosthesis as claimed, which is subjected to intensive movement and large forces. Hence, without knowledge of the present invention it would not have been obvious for the skilled person to apply the detailed teaching of D4 concerning orthopaedic facial reconstructive and aesthetic surgery to the manufacture of a device for resurfacing the distal end of a femur.

The Board considers, therefore, that the method of claim 1 of the main request also involves an inventive step when starting from D4.

3.5 It is concluded that the method of claim 1 of the main request satisfies the requirements of novelty and inventive step of Article 52(1) EPC. This applies, a fortiori, for the preferred embodiments defined in dependent claims 2 to 6.

4. Since the Board considers the main request to be allowable, there is no need to consider the auxiliary requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of:

   - claims 1 to 6 of the main request filed on 3 June 2016;

   - description pages 7, 8 and 10 to 15 as originally filed, pages 1, 2, 2a, 3 to 6, 9 and 16 filed on 3 June 2016; and

   - figure sheets 1/6 to 6/6 as originally filed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated