

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 27 April 2022**

Case Number: T 1526/17 - 3.2.02

Application Number: 11725733.7

Publication Number: 2720634

IPC: A61B19/00

Language of the proceedings: EN

Title of invention:

METHOD AND DEVICE FOR DETERMINING THE MECHANICAL AXIS OF A BONE

Applicant:

Brainlab AG

Headword:

Relevant legal provisions:

EPC Art. 53(c)

RPBA Art. 11, 12(4)

Keyword:

Main request and auxiliary request 1 - exceptions to
patentability - method for treatment by surgery (yes)
Late-filed request - admitted (yes)
Remittal to the department of first instance
Remittal - (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1526/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 27 April 2022

Appellant:
(Applicant)

Brainlab AG
Olof-Palme-Straße 9
81829 München (DE)

Representative:

SSM Sandmair
Patentanwälte Rechtsanwalt
Partnerschaft mbB
Joseph-Wild-Straße 20
81829 München (DE)

Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted on 3 February 2017
refusing European patent application No.
11725733.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Böttcher
W. Sekretaruk

Summary of Facts and Submissions

- I. The applicant filed an appeal against the examining division's decision to refuse European patent application No. 11725733.7.
- II. The examining division held that claim 1 of the main request and of auxiliary requests 1 to 6 then on file did not meet the requirements of Article 53(c) EPC. The division did not admit auxiliary request 7 since claim 1 contravened Article 123(2) EPC.
- III. Oral proceedings took place on 27 April 2022.
- IV. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or either of auxiliary requests 1 and 2, all filed with the statement of grounds of appeal.
- V. Claim 1 of the main request reads as follows.

"A method for operating a medical navigation system comprising a stationary marker device (8) and an electronic device (1) which is rigidly attached to the bone (6) and comprises a video camera (4), for calculating a first point (P1) of the mechanical axis (A) of a bone (6), the mechanical axis (A) being a straight line running through the first point (P1) and a second point (P2), by:

- calculating the first (P1) of the two points as the centre of rotation when the bone (6) is pivoted in two rotational dimensions about the first point (P1), the centre of rotation being calculated from an output signal of the camera (4) which captures the stationary

marker device (8)."

Claim 1 of auxiliary request 1 corresponds to claim 1 of the main request but the feature "when the bone (6) is pivoted" has been replaced with "after the bone (6) is pivoted".

Claim 2 of the main request and auxiliary request 1 reads as follows.

"The method of claim 1, wherein the position of the second point (P2) is determined from the position of at least one point on the bone (6) which is sampled using a pointer (9) which comprises a marker device (10), said marker device (10) being detected using the camera (4)."

Claim 6 of the main request and auxiliary request 1 reads as follows.

"The method of any one of claims 1 to 5, wherein the electronic device (1) is attached to the bone (6) such that a defined direction of the electronic device (1) coincides with a defined direction (AP) of the bone (6)."

Claim 1 of auxiliary request 2, which does not include any method claims, reads as follows.

"An electronic device (1) comprising: a video camera (4); means (2) for rigidly attaching the device to a bone (6); and a control unit (12) which is configured to calculate a first point (P1) of the mechanical axis (A) of a bone (6), the mechanical axis (A) being a straight line running through the first point (P1) and a second point (P2), by carrying out the method steps

of:

- calculating the first (P1) of the two points as the centre of rotation when the electronic device (1) is rigidly attached to the bone and the bone (6) is pivoted in two rotational dimensions about the first point (P1), the centre of rotation being calculated from an output signal of the camera (4) which captures a stationary marker device (8)."

VI. The appellant's arguments, in so far as relevant to the present decision, can be summarised as follows.

Main request - Article 53(c) EPC

The method of claim 1 did not encompass the step of pivoting the bone. The claim in fact related to a method of operating a medical navigation system that encompassed only data processing or calculation steps. The last full paragraph on page 4 disclosed that the calculation involved some approximations so that it could be carried out after the movement had been completed and independently of that movement.

Furthermore, a step of pivoting a bone was not a surgical step.

With regard to claim 6, claim 1 did not comprise the step of attaching the electronic device to the bone - claim 6 referred to an electronic device which is already attached to the bone before the method is performed. Page 11, second paragraph, made it clear that the surgical step of attaching the device to the bone was carried out before the claimed method was applied.

Thus, claim 1 of the main request met the requirements

of Article 53(c) EPC.

Auxiliary request 1 - Articles 123(2) and 53(c) EPC

Support for the feature whereby the step of calculating the first point takes place after the bone is pivoted could be found on page 4, paragraphs 4 and 5, of the description of the application as originally filed.

It was clear from this passage that first the bone was pivoted, then images were captured at different positions of the camera, and lastly the centre of rotation was calculated. Hence, the surgical step of pivoting the bone was not part of the claimed method.

Claim 1 of auxiliary request 1 thus met the requirements of Articles 123(2) and 53(c) EPC.

Auxiliary request 2 - admittance

This request was based on auxiliary request 7 filed during the examination proceedings, with claim 1 further specifying that the electronic device is rigidly attached to the bone. Auxiliary request 2 should be admitted into the proceedings since this amendment overcame the examining division's objection (point 4 of the decision).

Reasons for the Decision

1. Subject-matter of the application

The application relates to a method and an electronic device for determining the mechanical axis of a bone. The mechanical axis is important for diagnostic purposes as well as for preparing surgical steps. It can, for example, be a reference for a cutting plane, prior to making a cut for implanting an artificial replacement. The positions of two points define the axis. The first point is typically the centre of a joint which allows for relative movement in two rotational dimensions, such as a ball joint or a saddle joint. The second point is the exit point of the mechanical axis on the outer surface at the opposite end of the bone to the first point. If the bone is a femur, then the first point is the centre of the femoral head and the second point is the deepest point in the intercondylar notch (fossa intercondylaris).

The method defined in claim 1 of the main request uses a medical navigation system (Figure 2) comprising a stationary marker device (8) and an electronic device (1) which comprises a camera. The electronic device is rigidly attached to the bone (6), e.g. via a cutting block (7).

The first point is calculated as the centre of rotation when the bone (i.e. the leg with the bone) is pivoted in two rotational dimensions about the first point. During this movement, as described in the application, the camera (4) of the electronic device (1) repeatedly captures images of a stationary marker device (8). The position of the camera (4), and therefore of the electronic device (1), relative to the marker device

(8) is calculated in the co-ordinate system of the electronic device (1) from the output image of the camera (4). The camera positions are located on a spherical surface. A plurality of positions on the spherical surface are calculated from the position of the camera (4) relative to the marker device (8). The centre of the spherical surface, and therefore the first point P1, is calculated from said plurality of positions.

2. Main request - Article 53(c) EPC

- 2.1 Claim 1 is directed to a method for operating a medical navigation system. The medical navigation system comprises a stationary marker device and an electronic device which is rigidly attached to the bone. Hence, its operation is not limited to mere data processing or calculation steps. The possibility that the bone is moved with the attached electronic device is not excluded from the claimed method by the wording of claim 1. The board agrees with the examining division (point 1.6 of the decision) that the output signal of the camera can only be analysed to calculate the first point if the camera assumes different positions during bone movement. Hence, the movement of the bone with the attached electronic device and the associated data acquisition are indispensable requirements for calculating the first point, even when the calculation involves some approximation (last full paragraph on page 4) and may be carried out after the movement is completed. Hence, said movement is to be considered an integral part of the claimed method.

As a consequence, the claimed method comprises the step of pivoting the bone with the electronic device attached to it to produce the data for calculating

point P1.

The examining division explained why it considered the step of pivoting the bone to be a surgical step (point 1.3 of the decision). The appellant stated that this was not the case but did not provide any reasons in this respect.

The board agrees with the examining division that pivoting the exposed bone involves substantial health risks for the patient and has to be considered a surgical step.

- 2.2 The examining division held that the step of sampling the position of at least one point on the bone as defined in claim 2 encompassed contacting the bone with a pointer, which constituted a surgical step (points 1.4 and 1.7 of the decision).

The appellant did not make any further arguments on this issue.

The board agrees with the examining division that determining the second point encompasses a surgical step.

- 2.3 According to claim 1 the electronic device "is rigidly attached to the bone". This wording can be understood either as describing the position of the electronic device before the claimed method begins, or as referring to an attaching step comprised in said method. In view of dependent claim 6, which can only be understood as defining the step of attaching the electronic device in a specific direction, claim 1 has to be interpreted in the second way, i.e. as comprising the step of attaching the electronic device to the

bone. In this respect it is immaterial that the description (page 11, second paragraph) states that the electronic device is to be attached to the bone "beforehand" and that the surgical steps "are carried out before the methods described above are applied". Not only does the same paragraph explicitly state further on that the surgical steps are "preferably" not part of the present invention, but most importantly the statements in the description relating to preferred embodiments cannot limit the scope of the claims.

The board considers attaching the electronic device to the bone to be a surgical step. This has not been disputed.

- 2.4 It follows that claim 1 relates to a method of treating the human body by surgery, which is excluded from patentability pursuant to Article 53(c) EPC.

3. Auxiliary request 1

The objections mentioned in points 2.2 and 2.3 above apply also to claim 1 of auxiliary request 1. Moreover, as explained above, the objection under point 2.1 applies likewise to the situation where the calculation is performed after the device has been moved. Hence, claim 1 of this request contravenes Article 53(c) EPC too.

4. Auxiliary request 2

This request is based on auxiliary request 7 filed during the examination proceedings, which the examining division did not admit as it included added subject-matter.

This objection has been overcome by adding the feature whereby "the electronic device is rigidly attached to the bone" to claim 1. Hence, the board exercised its discretion under Article 12(4) RPBA 2007 to admit the request.

The claims of auxiliary request 2 relate to an electronic device, to a navigation system and to a computer program. They are thus not objectionable under Article 53(c) EPC.

5. The contested decision was based only on the grounds of Articles 53(c) and 123(2) EPC. The issues of novelty and inventive step were not considered.

Were the board not to remit the case to the examining division, it would have to examine all the other legal requirements and effectively replace the examining division, instead of reviewing the contested decision in a judicial manner (Article 12(2) RPBA 2020). It follows that special reasons present themselves as per Article 11 RPBA 2020.

Hence, the board remits the case to the examining division for further prosecution.

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 for further prosecution.

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated