

Internal distribution code:

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

**Datasheet for the decision
of 9 August 2022**

Case Number: T 2136/19 - 3.2.02

Application Number: 14704776.5

Publication Number: 3107475

IPC: A61B34/20

Language of the proceedings: EN

Title of invention:

METHOD FOR ASSISTING THE POSITIONING OF A MEDICAL STRUCTURE ON
THE BASIS OF TWO-DIMENSIONAL IMAGE DATA

Applicant:

Brainlab AG

Relevant legal provisions:

EPC Art. 53(c), 83, 84, 111, 123(2)
RPBA 2020 Art. 11, 12(2)

Keyword:

Amendments - added subject-matter (no)
Claims - clarity (yes)
Sufficiency of disclosure - (yes)
Exceptions to patentability - (no)
Remittal - (yes)

Decisions cited:

G 0001/07



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 2136/19 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 9 August 2022

Appellant: Brainlab AG
(Applicant) 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 25 February
2019 refusing European patent application No.
14704776.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: S. Dennler
C. Schmidt

Summary of Facts and Submissions

I. The applicant has filed the appeal against the examining division's decision refusing European patent application No. 14704776.5.

In this decision, the examining division held that the main request and auxiliary requests I to VI then on file failed to meet at least some of the requirements of Articles 83, 84 and 123(2) EPC, and/or were directed to subject-matter excluded from patentability under Article 53(c) EPC.

II. With its statement of grounds of appeal, the appellant submitted a main request and auxiliary requests I to III for consideration by the Board.

III. In response to the Board's communication pursuant to Article 15(1) EPC, in which the Board had provided its preliminary opinion, with its submission dated 30 June 2022 the appellant filed a new main request and new auxiliary requests I to III. The former main request and auxiliary requests I to III filed with the statement of grounds of appeal were maintained as lower-ranking auxiliary requests.

IV. Oral proceedings before the Board were held on 9 August 2022.

V. During the oral proceedings, the appellant filed amended claims 1-11 which, in combination with the description of the main request filed on 30 June 2022, were to constitute the appellant's new main request. The previously filed requests were maintained as lower-ranking requests.

VI. At the end of the oral proceedings, the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed at the oral proceedings before the Board ("the main request"), or, as auxiliary measures, on the basis of the main request or auxiliary requests I to III filed with the submission dated 30 June 2022, or on the basis of the main request or auxiliary requests I to III filed with the statement of grounds of appeal.

VII. Independent claims 1 and 11 of the main request read as follows (amendments compared with claims 1 and 15 as originally filed have been highlighted by the Board):

"1. A medical data processing method for assisting the positioning of a first medical structure (1) relative to a second medical structure (2) in at least one of two directions, the method being constituted to be executed by a computer and comprising the following steps:

- ~~acquiring~~ receiving, at a digital processor of a computer, two-dimensional projection image data comprising two-dimensional projection image information describing a two-dimensional projection image of at least the first medical structure (1), and taken in a spatial direction that is perpendicular to said two directions;

- ~~acquiring~~ receiving, at the processor, registration data comprising registration information describing ~~the~~ a registration of the two-dimensional projection image with respect to the first medical structure (1), wherein the registration is based on the spatial direction the two-dimensional image is taken in;

- ~~acquiring~~ determining, by the processor and, on the basis of said two-dimensional projection image data, two-dimensional position data comprising position information describing, in the two-dimensional projection image, the position of at least one a base point (3) assigned to the first medical structure (1) in an invariant positional relationship, and at least one a reference point (4) in the two-dimensional projection image assigned to the second medical structure (2) in an invariant positional relationship;

- ~~acquiring~~ determining, by the processor and, on the basis of the two-dimensional position data, positional relationship data comprising positional relationship information describing the positional relationship the directional distance between the at least one base point (3) and the at least one reference point (4) in said at least one of two directions of the two-dimensional projection image;

- ~~acquiring~~ receiving, at the processor, three-dimensional position data comprising position information describing the position of the ~~at least one~~ base point (3) and the ~~at least one~~ reference point (4) in the three-dimensional anatomical space, ~~in particular relative to the first medical structure (1);~~

- determining, by the processor and, on the basis of the positional relationship data, the registration data and the three-dimensional position data, three-dimensional reference point correspondence data comprising correspondence information describing ~~whether or not the position of the at least one reference point (4) corresponds to the position of the at least one reference point (4) in the two-dimensional~~

projection image whether or not the directional distance between the base point (3) and the reference point (4) in said at least one of two directions within the three-dimensional anatomical space corresponds to the directional distance between the base point (3) and the reference point (4) in the two-dimensional projection image."

"~~1115~~. A program which, when running on a computer or when loaded onto a computer, causes the computer to perform the method steps of the method according to any one of the preceding claims and/or a program storage medium on which the program is stored and/or a computer on which the program is running or into the memory of which the program is loaded and/or a signal wave, in particular a digital signal wave, carrying information which represents the program."

Claims 2 to 10 are dependent claims.

VIII. The appellant's arguments that are relevant for the present decision can be summarised as follows.

The claims of the main request were based on those originally filed with further amendments to overcome the examining division's objections raised in the decision under appeal and the concerns expressed by the Board. The amendments were all supported by the application as originally filed, so the requirements of Article 123(2) EPC were met.

Claim 1 had been amended to reflect that the method in accordance with the invention did not aim to create three-dimensional coordinates out of two-dimensional coordinates, but rather to compare a directional distance measured in a two-dimensional projection image

of the patient's anatomy with the correlating directional distance, i.e. in the same direction, obtained directly on the actual patient's anatomy. In that context, the "depth information", i.e. the point coordinates in the spatial direction the two-dimensional projection image was taken in, clearly had to be excluded from the comparison as such information was not available from the two-dimensional projection image. The description contained detailed explanations as to how the directional distances were determined and then compared. Therefore, the invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and the requirements of Article 83 EPC were met.

Moreover, the claimed method was limited to a data processing method which was exclusively carried out within a computer processor, without encompassing any surgical step or having any therapeutic effect. Therefore, the claimed method did not constitute a method for treatment of the body by surgery or therapy as excluded from patentability under Article 53(c) EPC.

Reasons for the Decision

1. The subject-matter of the application

- 1.1 The application relates to a computer-implemented data processing method for assisting the positioning of a first medical structure relative to a second medical structure, for example the positioning of a medical implant or surgical instrument relative to a bony structure of a patient.

The method according to the invention takes advantage of the fact that a surgeon may better judge the

patient's individual anatomy, and may thus plan a surgical operation more easily, on the basis of two-dimensional projection images such as x-ray images rather than on the basis of image-free navigation techniques alone, directly on the patient's body (page 12 of the description as originally filed, second paragraph).

- 1.2 In practice, a two-dimensional projection image of at least the first medical structure is taken (for example, an x-ray image of the pelvis) and registered.

The respective positions, in this two-dimensional projection image, of two particular points respectively assigned to the first and second medical structures (called the base point and the reference point in the application) are determined and the directional distance between these two points in a predetermined direction within the plane of the two-dimensional projection image is calculated. For example, these points may be easily identifiable points of the acetabular rim and of a cup implant to be implanted, and this directional distance may be the desirable directional distance between these points in the medial-lateral direction that would ensure an optimal implantation as determined by the surgeon on the basis of an anterior-posterior x-ray image (see Figure 1 and the corresponding description on page 20).

The actual positions of these two particular points in the three-dimensional anatomical space are then received, for example following their acquisition by the surgeon palpating the patient's anatomy and the implant with a navigated pointer.

Finally, the directional distance between the two points within the three-dimensional anatomical space, in the same predetermined direction, is calculated and compared with the directional distance previously determined in the two-dimensional projection image. This provides the surgeon with correspondence information describing whether or not these two directional distances correspond.

- 1.3 With this information, it is possible to verify the correct positioning of the second medical structure with respect to the first medical structure along the predetermined position. In the example mentioned above, the surgeon can thus verify the correct insertion depth of the cup implant with respect to the acetabular rim in the medial-lateral direction in accordance with previous planning carried out on the basis of the x-ray image.

2. Added subject-matter

- 2.1 Claim 1 of the main request incorporates the features of claims 1 and 5 as originally filed, with further amendments which are all supported by the application as filed.
- 2.1.1 Compared with claim 1 as originally filed, claim 1 of the main request defines two directions and stipulates that the two-dimensional projection image is taken in a direction that is perpendicular to these directions. Therefore, these two directions, in one of which the directional distances are calculated and compared as further defined in claim 1 and discussed in point 2.1.3 below, are within the plane of the two-dimensional projection image. Support for these amendments is found, for example, in the last paragraph on page 3 of

the description as filed, which discloses that the method can be implemented on the basis of two-dimensional images taken from any oblique directions, thus allowing any oblique shifts within the plane of the image to be determined.

2.1.2 Claim 1 further includes the feature whereby the registration of the two-dimensional projection image with respect to the first medical structure is based on the spatial direction in which the two-dimensional image is taken. This amendment is supported by the second full paragraph on page 5 of the original description.

2.1.3 The final "whether or not" clause of claim 1 as originally filed has been replaced with the new clause "*whether or not the directional distance between the base point (3) and the reference point (4) in said at least one of two directions within the three-dimensional anatomical space corresponds to the directional distance between the base point (3) and the reference point (4) in the two-dimensional projection image*". As argued by the appellant, this amendment is supported by the application as filed, especially by the paragraph bridging pages 8 and 9 of the original description.

Contrary to the examining division's view in point 18.1 of the decision under appeal, the comparison of directional distances disclosed in this paragraph is actually a way of determining "*whether or not the position of the at least one reference point (4) corresponds to the position of the at least one reference point (4) in the two-dimensional projection image*" as defined in the original claim 1. Indeed, from the explanations given in the description with respect

to hip arthroplasty (page 7, first paragraph), with the base point and the reference point being, in that case, identifiable points of the patient's hip and of an implant, the person skilled in the art understands that the comparison of the directional distances described in the paragraph bridging pages 8 and 9 is a way to "*verify the proper placement of the implant in the three-dimensional anatomical space*", as disclosed two paragraphs earlier (page 8, second paragraph). This verification is nothing more than a verification of whether or not the position of the implant, and therefore that of the reference point, in the three-dimensional anatomical space corresponds to its position (for example, its planned position) in the two-dimensional projection image.

The replacement of the "whether or not" clause in claim 1 is therefore not in breach of Article 123(2) EPC.

- 2.1.4 The further objections under Article 123(2) EPC raised in the decision under appeal (points 15.1 and 17.1) concerned the particular wording "*determining (...) a directional distance (...) that corresponds to (...)*". The main request overcomes these objections as the last method step does not use this wording, but instead the new "whether or not" clause as discussed above.
- 2.1.5 Support for the limitation in claim 1 that the method steps are carried at or by a digital processor of a computer is found in the paragraph bridging pages 13 and 14 as well as in the paragraph bridging pages 18 and 19 of the description as originally filed.
- 2.2 The deletion of the terms "at least one" from the expressions "at least one base point" and "at least one

reference point" throughout the claims does not introduce added subject-matter.

2.3 Apart from the above-mentioned deletions, the remaining claims 2-11 are identical to claims 2-4, 6, 7, 10-13 and 15 as originally filed, which have merely been renumbered.

2.4 The description has been adapted to the claims of the main request. The alternative in which two-dimensional positional data may be transformed back into the three-dimensional anatomical space disclosed in the original description (page 9, first full paragraph: ", and vice versa") has been deleted.

2.5 The Board is therefore satisfied that the requirements of Article 123(2) EPC are met.

3. Clarity

3.1 The objections under Article 84 EPC set forth in points 12.2.1 to 12.2.4 of the decision under appeal either are not convincing or are overcome by the main request.

3.1.1 The wording "*that is consistent*" (point 12.2.1) that is objected to is not used in claim 1 of the main request. Instead, the last method step of claim 1 in essence foresees determining correspondence information describing "whether or not" a second directional distance "corresponds" to the first directional distance determined in a previous step.

The Board is satisfied that this last method step is clearly defined. In particular, there is no contradiction in the fact that claim 1 defines the first directional distance as "the directional distance

between the base point (3) and the reference point (4) in said at least one of the two directions *of the two-dimensional projection image*" (in the fourth method step) and the second directional distance as "the directional distance between the base point (3) and the reference point (4) in said at least one of two directions *within the three-dimensional anatomical space*" (in the last method step). As defined in the first method step of claim 1, the two-dimensional projection image is indeed taken in a spatial direction that is perpendicular to the two directions. Therefore, "said at least one direction" in which both directional distances are determined lies within the plane of the two-dimensional projection image.

- 3.1.2 The objection raised in point 12.2.2 actually appears to be an objection under Article 83 EPC, as demonstrated by the reference in the examining division's argument to point 12.1 of the decision; see point 4. below in this respect.

The meaning of the "*registration of the two-dimensional projection image with respect to the first medical structure*" in claim 1 does not deviate from its usual meaning in the context of the invention. This expression refers to establishing a relationship between the points of the real first medical structure in the three-dimensional anatomical space and their projections onto the image plane of the two-dimensional projection image, as actually interpreted by the examining division in the second paragraph on page 5 of the decision under appeal.

In this respect, the Board notes that "the spatial direction the two-dimensional image is taken in", on which the registration is based (second method step of

claim 1), simply designates the axis along which the projection takes place (first method step of claim 1), or, in other words, the axis perpendicular to the image plane. This direction is thus clearly defined in the three-dimensional anatomical space.

3.1.3 Claim 1 of the main request incorporates those features that the examining division objected to as missing in point 12.2.3, namely that the base point and reference points are respectively "assigned" to the first and second medical structures.

3.1.4 With the limitation introduced in claim 1 of the main request that the three-dimensional position data is "*receiv[ed], at the processor*", and not "*acquir[ed], by the computer*", it is clear that the claimed method does not encompass the use of a pointer to palpate the patient's anatomy. The contradiction pointed out by the examining division in point 12.2.4 has therefore been overcome.

3.2 More generally, the Board is convinced that the claims of the main request are clear and supported by the adapted description as required by Article 84 EPC.

4. Sufficiency of disclosure

4.1 Claim 1 of the main request stipulates that the correspondence information determined in the last method step describes "*whether or not the directional distance between the base point (3) and the reference point (4) in said at least one of two directions within the three-dimensional anatomical space corresponds to the directional distance between the base point (3) and the reference point (4) in the two-dimensional projection image*".

The person skilled in the art understands that this requires, in addition to the first directional distance previously determined in the fourth method step of claim 1, a second directional distance to be calculated and then requires it to be determined whether the two directional distances correspond.

Like the first directional distance, this second directional distance also represents the directional distance between the base point and the reference point; however, while the first directional distance is determined on the basis of the *two-dimensional position data* describing the positions of the base point and reference point *in the two-dimensional projection image*, the second directional distance is determined on the basis of the positions of these points *in the three-dimensional anatomical space*, i.e. on the basis of the *three-dimensional position data*. This is why the "reference point correspondence data" which comprises the correspondence information and which is referred to in the last method step of claim 1 is in fact three-dimensional.

This three-dimensional position data is received, at the processor, in the previous method step defined in claim 1. Hence, contrary to what the examining division had objected to in respect of the first-instance claim requests, in which the last method step of claim 1 had different wording (see point 12.1 of the decision under appeal and the *obiter dictum* in point 19), the method claimed in the main request does not require two-dimensional position data to be extrapolated into three-dimensional position data. In this respect, the original claim 14, which recites transforming two-dimensional position data into three-dimensional

position data, has been deleted from the claims of the main request and the corresponding passage of the description has been amended (see the last line on page 9 of the description of the main request).

- 4.2 The person skilled in the art also understands that the two directional distances are both determined in the same predetermined direction of the plane of the two-dimensional projection image (see point 3.1.1 above, second paragraph), namely "said at least one of two directions". Therefore, the two directional distances can be compared to enable a surgeon to verify whether or not the relative positioning of the base point and reference point in this predetermined direction in the three-dimensional anatomical space and in the two-dimensional projection image correspond, for example as explained in the first full paragraph on page 9 of the description as filed.

- 4.3 The Board further makes the following comments:

- 4.3.1 The Board does not share the examining division's concerns with respect to the "spatial direction the two-dimensional image is taken in" referred to in the second method step of claim 1 (see the last two paragraphs on page 5 of the decision under appeal).

As discussed in point 3.1.2 above, this direction simply designates the direction in which the projection from which the two-dimensional projection image results is carried out (see the first method step of claim 1), or, in other words, a direction perpendicular to the image plane.

When the two-dimensional projection image is an x-ray image, this direction is not the direction of the

actual x-ray imaging beam, strictly speaking, but rather a direction perpendicular to the image (for example, the reconstructed image). Hence, there is no need to rely on the assumption of "parallel x-ray imaging", as discussed in the decision, to carry out the method.

4.3.2 When determining the correspondence information describing whether the first and second directional distances correspond, it must be taken into account that these distances are respectively measured in two different spaces and thus may have to be converted before being compared. This is why the last method step of claim 1 also involves, in addition to the positional relationship data describing the positions of the base point and reference point in the two-dimensional projection image, on one side, and to the three-dimensional position data describing the positions of these points in the three-dimensional anatomical space, on the other side, registration data describing a registration of the two-dimensional projection image with respect to the actual first medical structure; however, contrary to the examining division's view, the method according to the invention does not seek to use this registration data to transform two-dimensional data into three-dimensional data.

4.4 The Board is therefore convinced that the invention as claimed in accordance with the main request is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The requirements of Article 83 EPC are thus met.

5. **Exception to patentability**

5.1 Claim 1 of the main request is directed to a data processing method "to be executed by a computer". All the method steps recited in claim 1 are explicitly defined as being carried out at or by a digital processor of a computer. These steps are limited to receiving some data at the processor (for example, receiving image data such as data defining an x-ray image) and to determining, by the processor, some data on the basis of other data (for example, calculating directional distances on the basis of position data).

5.2 In particular, the step of "*acquiring, by the computer, three-dimensional position data comprising position information describing the position of the base point (3) and the reference point (4) in three-dimensional anatomical space, in particular relative to the first medical structure (1)*", which the examining division had identified as encompassing the surgical step of using a navigated pointer to palpate the patient's anatomy (point 12.3 of the decision under appeal), has been replaced with the step of "*receiving, at the processor,*" this three-dimensional position data.

The Board acknowledges that the three-dimensional position data may well be acquired by palpating the patient's anatomy, thus by a step of a surgical nature; however, by virtue of the amendment above, the step of acquiring the position data itself is not part of the claimed method.

It is also true, as pointed out by the examining division, that the claimed method is for "assisting" the positioning of the first medical structure relative to the second medical structure; however, as explained in the description, this assistance is only achieved by ultimately providing the surgeon with the

correspondence information determined in the last method step (page 7 of the description of the main request, antepenultimate paragraph: "*Any or all of this information can also be indicated to a surgeon so as to assist the latter in positioning the first medical structure relative to the second medical structure.*"; page 9, third paragraph: "*Lastly (...) calculated and compared (...)*"; emphasis added by the Board). This correspondence information enables a surgeon to "*verify the correct position of the second medical structure with respect to the first medical structure*" and, if needed, to move them relative to each other (page 10, first three lines); however, positioning the first or second medical structures is not a step of the claimed data processing method.

5.3 More generally, claim 1 does not recite any method step defining or encompassing a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy (G 1/07, points 3.2.5 and 4.1 of the Reasons). The same applies to the dependent claims. The claimed method is strictly limited to a purely "passive" data processing method which is carried out entirely and exclusively within a computer without causing any effect on the patient's body as a result. It is irrelevant that the claimed method may be performed after or even iteratively during a surgical intervention on the body, as described in the description. In any event, there would be no functional link between the claimed method and any effects of a surgical or therapeutic nature that would occur during this intervention. Therefore, in the absence of such a functional link, the claimed method as such does not qualify as a method for treatment of the human or animal body within the meaning of Article 53(c) EPC (with regard to the requirement of a

"functional link", see G 1/07, point 4.3.2 of the Reasons).

- 5.4 It follows that the subject-matter of claims 1-10 of the main request does not fall under the exception to patentability of Article 53(c) EPC. The same applies to the subject-matter of independent claim 11, which relates to a computer program directed to the method of claim 1, to a program storage medium on which this program is stored and to a computer running or configured with this program.
6. It appears from the above considerations that the main request overcomes all the objections on which the decision under appeal was based.

7. Remittal to the examining division

The grounds on which the decision under appeal was based have been reviewed by the Board in view of the respective requirements of the EPC; however, the examining division did not deal with other requirements of the EPC, in particular those in relation to novelty and inventive step, since no search at all has been carried out yet.

For these reasons, and in view of the primary object of the appeal proceedings being to review the decision under appeal in a judicial manner (Article 12(2) RPBA 2020), the Board holds that special reasons within the meaning of Article 11 RPBA 2020 are present for remitting the case to the examining division for further prosecution, in accordance with Article 111(1) EPC.

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