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**Datasheet for the decision
of 10 September 2007**

Case Number: T 0542/06 - 3.2.02

Application Number: 04009835.2

Publication Number: 1591074

IPC: A61B 19/00

Language of the proceedings: EN

Title of invention:

Visualization of procedural guidelines for medical procedures

Applicant:

BrainLAB AG

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 54, 56, 52(4), 84

Keyword:

"Method of surgery - (no)"

"Novelty and inventive step (yes, after amendment)"

"Clarity - (yes)"

Decisions cited:

G 0001/04, T 0182/90, T 0383/03

Catchword:

-



Case Number: T 0542/06 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 10 September 2007

Appellant: BrainLAB AG
Ammerthalstrasse 8
DE-85551 Kirchheim/Heimstetten (DE)

Representative: Schwabe - Sandmair - Marx
Stuntzstrasse 16
DE-81677 München (DE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 1 December 2005
refusing European application No. 04009835.2
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 1 December 2005 to refuse European patent application No. 04 009 835.2.

The grounds of refusal were that the method claims 1-10 related to a method of surgical treatment excluded by Article 52(4) EPC, claims 14 and 15 related to computer programs, and claim 13 defined no technical features and did not meet the requirement of Article 84 EPC. Moreover, the subject-matter of claims 1 and 11 did not meet the novelty requirement of Article 52(1) EPC, having regard to each of the following documents:

D1: US-B-6 381 483

D2: EP-A-1 199 031

D3: EP-A-1 410 758

D4: EP-A-1 103 229

D5: US-A-5 638 819.

II. On 27 January 2006 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same day. On 31 March 2006 a statement of grounds of appeal was filed.

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:

Claim 1 filed by telefax dated 16 August 2007

Claims 2 to 8 (auxiliary request) filed by letter dated
20 June 2007

Description page 1 filed by telefax dated 16 August
2007

Description pages 2 to 9 (auxiliary request) filed by
letter dated 20 June 2007

Figures 1 to 3 as published.

IV. Independent claim 1 reads as follows:

"A method for visualizing procedural guidelines for positioning a catheter for administering substances to a body portion, in which a catheter is shown in an image representation of a body portion including an area in which the administration is to be carried out, wherein, in the vicinity of the delivering portion of the catheter, regions or locations are indicated which are of special relevance to the administration according to established guidelines for said administration, wherein the guidelines determine regions in which:

- the delivered substance is expected to spread;
- the delivering portion of the catheter is to be placed, in order to exhibit a sufficient distance from critical tissue portions;
- the delivering portion of the catheter is to be placed, in order to exhibit a sufficient distance from other delivering portions of other catheters;
- wherein one or more of the above regions may be displayed".

Claims 2 to 8 are dependent claims.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

Claim 1 has been amended to limit the claimed method to the use of a catheter for administering substances to a body portion, and is based on the combination of original claims 1, 6, and 7. Claims 2 to 8 are based on the original dependent claims 2 to 5, 8, and 9. The description has been amended for consistency with new claim 1.

The amendments are in accordance with Article 123(2) EPC.

3. *Clarity*

Original claim 13, against which an objection of lack of clarity was raised, has been cancelled and this objection no longer applies.

4. *Article 52(4) EPC*

Claim 1 of the application relates to a method for visualizing procedural guidelines in a medical procedure in which a medical instrument is shown in an image representation of a body portion including an area in which a medical procedure is to be carried out.

The purpose of the medical procedure itself is undoubtedly surgical. However, this does not inevitably mean that the method for visualizing procedural guidelines in such a surgical procedure also has a surgical character.

The question is whether the method according to claim 1 is a method which is suitable or potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of a human being or animal, or to prevent diseases (see T 383/03, OJ EPO 2005, 159, points 3.2 to 3.4).

In fact the method according to claim 1 represents a technical method for visualizing procedural guidelines for a medical procedure, and the claim does not include or inevitably require any surgical steps which may be necessary for placing a surgical instrument, etc. The method is not suitable or potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of a human being or animal, or to prevent diseases.

The examining division argued that the method of claim 1 inherently included a medical procedure, and that the then dependent claim 10 explicitly defined the surgical procedures involved, and therefore had a surgical nature.

G 1/04 (OJ 2006, 334) instructs that medical method claims must be narrowly interpreted. Therefore, in the present case claim 1 must be interpreted as only covering the method for visualizing procedural guidelines for a medical procedure and not any

preliminary steps necessary for facilitating the visualization, such as placement of a catheter.

According to the jurisprudence of the boards of appeal a single surgical step in a method for treatment of the human or animal body confers surgical character to the method (see T 182/90, OJ EPO 1994, 641). However, none of the claims defines such a step.

Claims 1 to 8, therefore, are not concerned with a method of treatment of the human or animal body within the meaning of Article 52(4) EPC.

5. *Novelty*

5.1 Claim 1 has been limited to a method for visualizing procedural guidelines for positioning a catheter for administering substances to a body portion, and the claim states that regions or locations are indicated which are of special relevance for the administration according to established guidelines. Guidelines are always predetermined, and in the present context it means that they are set out before an operation commences.

5.2 Figure 33 of D1 shows a tomogram of a patient's liver Hc, and a region 53 of coagulated tissue caused by the application of microwaves by an applicator 15. The region 53 appears to be the circle adjacent the end of the applicator 15, and shows the result after the application of microwaves, and not a region which is predetermined in any sense.

5.3 In D2 a monitor 14 displays a survey image 15 in which the current position of a magnetic field sensor 5 or the tip of a catheter 3 is superposed. Additionally the instantaneous image 16 of the vicinity of the catheter tip is displayed adjacent the image 15.

There is no indication of regions on a predetermined basis.

5.4 D3 describes magnetic resonance imaging (MRI) apparatus, which has a guide wire 105 (Figure 2) acting as an RF receiving antenna in a guide catheter 200 in a blood vessel 210. Figures 4 shows 8 slice images along the vessel 210, and Figure 5 shows one of the slice images in which the blood vessel 210 and its inner boundary 502 are shown. The sensitivity range 501 of the guide wire 105 is shown as a circle 501 in Figure 5.

The sensitivity range 501 cannot be considered to be related to a guideline; it merely depicts a property of the wire 105.

5.5 D4 relates to planning a surgical procedure using an MRI scan image 130 (Figure 3). A virtual surgical instrument 132 is positioned and oriented so as to define a virtual tool trajectory 140, and a virtual entry point 150 and a virtual target point 152 are selected. A computer system then interactively guides an actual instrument along the planning trajectory 140. An image of a virtual bulls-eye 160 (Figures 4a-4c) and a scale 170 are displayed and are sensitive to the position and orientation of a device 50 (Figure 1) for guiding the instrument, as tracked by an optical system. The size of the bulls-eye and the position of the scale

reflect the accuracy of the alignment of the instrument to the trajectory 140.

D4 does not relate to positioning a catheter for administering substances to a body portion.

- 5.6 D5 is similar to D4. In Figure 1 is shown a probe 12 with a tip 36 for performing an operation on a patient 14. Figure 2 shows a tomogram slice 42 of the patient on which are marked a target (tumour) 52, an entry point 82 for the probe, and a desired trajectory 54 for the probe. Figure 2 also shows a circular image 46 for helping to guide the probe 12 towards the target. Figure 7 shows the probe 12 misaligned to the trajectory 54 and the target 52, and this is shown as an asymmetric image in Figure 8.

D5 also does not relate to positioning a catheter for administering substances to a body portion.

- 5.7 Therefore, none of the documents D1 to D5 anticipates the claimed method.

6. *Inventive step*

The technical problem of the application is set out in paragraphs 0003 to 0005 of the application. What this means in the context of catheters is that the surgeon should have a clear visual indication of regions of the body where a catheter tip may or may not be placed.

The solution is to determine these regions by calculation (see original claim 9 and paragraph 0023), or using standard guidelines (original claim 8), and to

display these regions together with an image of the catheter and a body portion in which a substance is to be administered by the catheter. The surgeon then has a clear pictorial view of where the catheter is in relation to a body part and to the region.

Since none of the prior art documents discusses displaying such regions in the context of a catheter or any other surgical instrument, the claimed method cannot be considered to be obvious.

7. In view of the above findings, the application in its present form meets the requirements of the 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 grant a patent on the basis of the following documents:

Claim 1 filed by telefax dated 16 August 2007.

Claims 2 to 8 (auxiliary request) filed by letter dated 20 June 2007.

Description page 1 filed by telefax dated 16 August 2007.

Description pages 2 to 9 (auxiliary request) filed by letter dated 20 June 2007.

Figures 1 to 3 as published.

The Registrar

The Chairman

V. Commare

T. Kriner