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**Datasheet for the decision  
of 10 November 2016**

**Case Number:** T 1802/13 - 3.5.05

**Application Number:** 05794215.3

**Publication Number:** 1769418

**IPC:** G06F19/00

**Language of the proceedings:** EN

**Title of invention:**

Method and system for creating deep brain stimulation models

**Applicant:**

THE CLEVELAND CLINIC FOUNDATION

**Headword:**

Brain stimulation/CLEVELAND

**Relevant legal provisions:**

EPC Art. 52(2)(d)

EPC 1973 Art. 56

RPBA Art. 15(3)

**Keyword:**

Oral proceedings - non-attendance of appellant

Inventive step of "mixed invention" - (no): no technical effect derivable from the manner in which information is presented

**Decisions cited:**

T 0641/00, T 0928/03, T 1143/06, T 1749/06, T 1741/08,  
T 1539/09, T 1237/10, T 1375/11, T 1715/11, T 0651/12,  
T 0336/14

**Catchword:**

See point 2.1 of the Reasons.



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

European Patent Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89 2399-4465

Case Number: T 1802/13 - 3.5.05

**D E C I S I O N**  
**of Technical Board of Appeal 3.5.05**  
**of 10 November 2016**

**Appellant:** THE CLEVELAND CLINIC FOUNDATION  
(Applicant) 10265 Carnegie Avenue  
Cleveland, OH 44106 (US)

**Representative:** Granleese, Rhian Jane  
Marks & Clerk LLP  
90 Long Acre  
London WC2E 9RA (GB)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 9 January 2013  
refusing European patent application  
No. 05794215.3 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chair** A. Ritzka  
**Members:** K. Bengi-Akyuerek  
G. Weiss

## Summary of Facts and Submissions

I. The appeal is against the decision of the examining division to refuse the present European patent application on the grounds of lack of clarity, lack of patentable subject-matter under Article 53(c) EPC (regarding independent method claim 11) and lack of inventive step, having regard to the combined disclosures of

**D1:** E. Micheli-Tzanakou et al.: "Computational intelligence for target assessment in Parkinson's disease", Proceedings of SPIE, Vol. 4479, pp. 54-69, 2001

and

**D2:** C.C. McIntyre et al.: "Electric field and stimulating influence generated by deep brain stimulation of the subthalamic nucleus", Clinical Neurophysiology, Vol. 115, No. 3, pp. 589-595, 2004.

II. With the statement setting out the grounds of appeal, the appellant filed amended sets of claims according to a main request and four auxiliary requests. It requested that the decision of the examining division be set aside and that a patent be granted on the basis of the main request or one of the auxiliary requests. In addition, oral proceedings were requested as an auxiliary measure.

III. In a communication under Rule 100(2) EPC, the board gave its preliminary opinion on the appeal. In particular, it raised objections under Article 56 EPC

1973, having regard to D1 and D2.

- IV. In a letter of reply, the appellant submitted counter-arguments to the objections raised in the board's communication under Rule 100(2) EPC.
- V. In an annex to the summons to oral proceedings pursuant to Article 15(1) RPBA, the board indicated that it maintained its objections under Article 56 EPC 1973, mainly in view of D2.
- VI. With a letter of reply, the appellant informed the board that it would not be attending the scheduled oral proceedings and that it looked forward "to receiving a final decision on the written submissions that have been filed to date".
- VII. Oral proceedings were held on 10 November 2016 in the absence of the appellant. The board established from the file that the appellant's final requests were that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the main request or one of the first to fourth auxiliary requests, all submitted with the statement setting out the grounds of appeal.

After due deliberation on the basis of those final requests and the written submissions, the board's decision was announced at the end of the oral proceedings.

- VIII. Claim 1 of the **main request** reads as follows:

"A computerized system (400) comprising:  
an imaging data storage circuit (404) adapted to store imaging data corresponding to an image of an

anatomic volume of a patient (401);

a processor circuit (412), coupled to the imaging data storage circuit (404), the processor circuit (412) configured to:

generate a model of brain tissue that represents a non-uniform spatial distribution of tissue conductivity including inhomogeneous and anisotropic tissue conductivity, wherein the model includes a representation of an implanted electrode leadwire;

and

for each of at least one set of stimulation parameters and prior to use of an electrode leadwire (428) in accordance with the respective set of stimulation parameters, calculate a predicted volume of activation (420) by calculating a second difference of the electric potential distribution produced by the electrode leadwire using the model of brain tissue which represents the non-uniform spatial distribution of tissue conductivity;

the processor being further configured to register the image of the anatomic volume of the patient to an atlas of the brain to create a patient-specific atlas of the brain tissue; and

the system further comprises a computer display (424), coupled to the processor circuit (412), wherein the processor circuit (412) is adapted to display on the computer display a map in which the electrode leadwire (428) and the predicted volume of activation (420) are superimposed on the patient-specific atlas of the brain tissue."

Claim 1 of the **first auxiliary request** comprises all the features of claim 1 of the main request, with the only difference that the processor circuit is now defined by the following phrase (amendments to claim 1

of the main request underlined by the board):

"the processor being further configured to register the image of the anatomic volume of the patient to a pre-labeled canonical atlas of the brain to create a patient-specific atlas of the brain tissue;"

Claim 1 of the **second auxiliary request** comprises all the features of claim 1 of the main request, with the only difference that the "generate a model" clause now further includes the following phrase:

"wherein the spatial distribution of tissue conductivity is determined from diffusion tensor imaging data derived from magnetic resonance imaging of a human brain".

Claim 1 of the **third auxiliary request** corresponds to a combination of claim 1 of the second and third auxiliary requests.

Claim 1 of the **fourth auxiliary request** reads as follows (amendments to claim 1 of the main request underlined by the board):

"A computerized system (400) comprising:  
an imaging data storage circuit (404) adapted to store imaging data corresponding to an image of an anatomic volume of a first patient (401);  
a processor circuit (412), coupled to the imaging data storage circuit (404), the processor circuit (412) configured to:  
generate a model of brain tissue that represents a non-uniform spatial distribution of tissue conductivity including inhomogeneous and anisotropic tissue

conductivity, wherein the model includes a representation of an implanted electrode leadwire, wherein the spatial distribution of tissue conductivity is determined from diffusion tensor imaging data derived from magnetic resonance imaging of a human brain of at least one other patient than the first patient;

and

for each of at least one set of stimulation parameters and prior to use of an electrode leadwire (428) in accordance with the respective set of stimulation parameters, calculate a predicted volume of activation (420) by calculating a second difference of the electric potential distribution produced by the electrode leadwire using the model of brain tissue which represents the non-uniform spatial distribution of tissue conductivity;

the processor being further configured to register the image of the anatomic volume of the first patient to a pre-labeled canonical atlas of the brain to create a patient-specific atlas of the brain tissue; and

the system further comprises a computer display (424), coupled to the processor circuit (412), wherein the processor circuit (412) is adapted to display on the computer display a map in which the electrode leadwire (428) and the predicted volume of activation (420) are superimposed on the patient-specific atlas of the brain tissue."

## **Reasons for the Decision**

1. *Non-attendance of the appellant at oral proceedings*
- 1.1 The appellant decided not to attend the scheduled oral proceedings before the board (cf. point VI above). Pursuant to Article 15(3) RPBA, the board is not



"obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case."

1.2 In the present case, the appellant submitted arguments in support of the patentability of its application in response to the objections raised in the board's communication under Article 15(1) RPBA. The board considered those arguments but found that claim 1 of all claim requests on file still gave rise to objections under Article 56 EPC 1973 (cf. points 2.1 and 3.1 below). So, in the exercise of its discretion under Article 15(3) RPBA, the board took a decision at the end of the oral proceedings, in the absence of the appellant.

## 2. MAIN REQUEST

Claim 1 of the main request differs from claim 1 underlying the appealed decision essentially in that it further specifies that (emphasis added by the board)

- the generated model includes a representation of an implanted electrode leadwire;
- the predicted volume of activation is calculated using the model of brain tissue which represents the non-uniform spatial distribution of tissue conductivity;
- the image of the anatomic volume of the patient is registered to an atlas of the brain to create a patient-specific atlas of the brain tissue;
- the electrode leadwire and the predicted volume of activation are superimposed on the

patient-specific atlas of the brain tissue.

The board is satisfied that the above amendments comply with Article 123(2) EPC (supported e.g. by page 16, lines 6-9; page 17, lines 16-26; page 19, lines 20-22; page 32, lines 21-26, in conjunction with Fig. 3, steps 304 to 312) and also overcome the objections raised under Article 84 EPC 1973 in the decision under appeal (cf. Reasons 12).

2.1 *Novelty and inventive step*

In the board's judgment, present claim 1 does not meet the requirements of Article 56 EPC 1973, for the reasons set out below.

2.1.1 The board does not see any prejudicial errors in the assessment of inventive step as conducted in the decision under appeal, having regard to prior-art documents **D1** and **D2** (cf. Reasons 3 and 4).

2.1.2 Although the impugned decision relied on D1 as closest prior art, the board agrees with the appellant that document **D2** may likewise be regarded as a starting point for assessing inventive step. In particular, it discloses the following features of present claim 1:

A computerised system ("DBS system") comprising:

- a) an imaging data storage circuit adapted to store imaging data corresponding to an image of an anatomic volume of a patient (see e.g. Fig. 1);
- b) a processor circuit, coupled to the imaging data storage circuit, configured to
  - b1) generate a model of brain tissue ("diffusion tension imaging DTI") that represents a non-uniform spatial distribution of tissue

conductivity including inhomogeneous and anisotropic tissue conductivity, wherein the model includes a representation of an implanted electrode leadwire ("3-dimensional finite element models of the Medtronic 3387 DBS lead") (see abstract; page 590, left-hand column, second and third paragraphs);

b2) calculate, for each of the set of stimulation parameters (e.g. "stimulus amplitude") and prior to use of an electrode leadwire in accordance with the respective set of stimulation parameters, a predicted volume of activation by calculating a second difference ( $\Delta^2 V_e$ ) of the electric potential distribution ( $V_e$ ) produced by the electrode leadwire ("DBS electrode") using the model of brain tissue which represents the non-uniform spatial distribution of tissue conductivity (see e.g. page 590, right-hand column, last paragraph; page 592, right-hand column, second paragraph; Fig. 1B);

b3) register the image of the anatomic volume of the patient to an atlas of the brain to create a patient-specific atlas of the brain tissue (see e.g. page 590, right-hand column, lines 32-35; Fig. 1B);

c) a computer display, coupled to the processor circuit, configured to display on the computer display a map ("FEM VR Map") in which the electrode leadwire and the predicted volume of activation are displayed (see Fig. 1B).

2.1.3 As regards feature c), it is apparent to the board that the "FEM VR Map" shows the DBS electrode and the modelled volume of activation, while the screen relating to "Human DTI" displays the patient's brain

atlas (see e.g. caption of Fig. 1B: "... *The right panels of the top row shows[sic] the volume ratio ... for the entire axial slice (far right) and the ... region that was used in the finite element model (middle right)*"). Thus, those displays indeed do not directly and unambiguously disclose the superimposition of the electrode leadwire and the predicted volume of activation on the patient's brain atlas as called for by claim 1. Consequently, the sole difference between present claim 1 and the disclosure of D2 is that

- i) a map is displayed in which the electrode leadwire and the predicted volume of activation are superimposed on the patient-specific atlas of the brain tissue.

2.1.4 The focal question is now whether distinguishing feature i) has a *technical* effect or whether it relates merely to *presentations of information as such* within the meaning of Article 52(2)(d) and (3) EPC. In this context, the board notes that the superimposition of both the monitored data ("electrode leadwire") and the calculated data ("predicted volume of activation") on the patient's brain atlas is evidently concerned with "how" specific cognitive data is actually presented rather than "what" is presented.

2.1.5 The appellant submitted that the case law of the Boards of Appeal relating to presentation of information had "relied heavily on the understanding that it is important *how* the data is displayed not *what* is displayed" (cf. appellant's letter dated 7 April 2016, first page, last paragraph). The appellant seems to rely for authority on the conclusions drawn in T 1749/06-3.4.03 of 24 February 2010 (see Reasons 4.1.3), which are further elaborated by

reference to the corresponding PCT provisions in recent case T 651/12-3.4.03 of 14 April 2016 (see Reasons 3.2, page 15, last paragraph to page 16, second paragraph).

In that regard, the board recalls that e.g. T 1143/06-3.5.01 of 1 April 2009, relied on by several boards, states that "a feature which relates to the **manner** how cognitive content is conveyed to the user on a screen **normally** does not contribute to a technical solution to a technical problem. An **exception** would be if the manner of presentation can be shown to have a credible technical effect" (see Reasons 5.4, emphasis added by this board). This is also reflected (almost verbatim) in the Guidelines for Examination in the European Patent Office (see G-II, 3.7, second paragraph e.g. in the version of November 2016).

Similar to the issue of "what" is presented (see e.g. T 336/14-3.5.05 of 2 September 2015, Headnote), the board finds that - regarding the technicality of the manner in which (i.e. "how") information is presented - the main issue to be established is whether the underlying user interface together with the manner in which cognitive content is presented *credibly* assists the user in performing a *technical* task by means of a continued and guided human-machine interaction process (basically related to the question "for what purpose" the content is presented).

This was the case in T 928/03-3.5.01 of 2 June 2006, cited by the appellant in its letter dated 7 April 2016 (cf. second page, first paragraph), where it was held that displaying, in an interactive video soccer game, guide marks indicating the direction in which the football is to be passed by the active soccer player at predetermined locations of the screen solved the

objective technical problem of resolving conflicting technical requirements, namely that (1) a portion of an image is desired to be displayed on a relatively large scale and that (2) the display area of the screen is not too small to show a complete zone of interest (cf. Reasons 4.3). In the context of distinguishing the claimed subject-matter from the prior art by the *manner* in which information is presented, a technical effect and a contribution to inventive step were also acknowledged in recent cases T 1375/11-3.4.03 of 31 March 2016 (relying on the problem of improving ergonomics and user-friendliness in an online gambling system including physiological considerations; see Reasons 4.3) and T 1715/11-3.2.04 of 22 July 2015 (relying on the problem of facilitating man-machine interactions; see Reasons 3).

2.1.6 Coming back to the present case, in the appellant's opinion, distinguishing feature i) had the technical effect of "lowering the cognitive burden of a user", resulting in a more efficient man-machine interface (cf. statement setting out the grounds of appeal, fourth page, last paragraph), while the objective problem addressed by feature i) was the "provision of an improved system that provides a more efficient method of selecting the electrode parameters for DBS" (cf. appellant's letter dated 7 April 2016, first page, fourth paragraph).

2.1.7 However, it is established jurisprudence of the Boards of Appeal that "lowering the cognitive burden of a user" *per se* cannot in principle be considered to be a technical effect (see e.g. T 1741/08-3.5.06 of 2 August 2012, Reasons 2.1.6; T 1539/09-3.5.06 of 18 July 2013, Reasons 4; T 1237/10-3.5.07 of 16 October 2015, Reasons 5.4). Nor is it derivable from present claim 1

- beyond mere speculation - that it credibly brings about the technical effect of accurately predicting the electrodes' properties and providing that information to the surgeon in an *efficient* manner (contrary to the appellant's assertion in the statement setting out the grounds of appeal, page 5, eighth paragraph).

Rather, the board holds that feature i) corresponds to presenting cognitive content which addresses solely the user's mental process instead of credibly and causally assisting the user (surgeon) in performing the task of neurosurgical operations via a continued and/or guided human-machine interaction process. In particular, the board finds that the mere fact that two specific types of information (i.e. "electrode leadwire" and "predicted volume of activation") are presented in a *superimposed* manner with regard to another type of information ("patient-specific atlas") is not sufficient - contrary to the situation in case T 928/03-3.5.01 - to conclude that the underlying system is thereby indeed *improved* or that the corresponding method is *more efficient*. Rather, this remains mere speculation. For example, such a superimposition of different data may arguably - depending on the display resolution and/or the user's (surgeon's) cognitive capabilities or preferences - detrimentally affect the comprehensibility and usability of the data presented and thus might even deteriorate the efficiency of selecting the optimal DBS electrode parameters.

Accordingly, the board judges that feature i) relates to presentations of information as such, i.e. to a non-technical feature, which has to be disregarded in the assessment of inventive step according to the established jurisprudence of the Boards of Appeal (see

e.g. T 641/00-3.5.01, OJ EPO 2003, 352, first headnote).

2.2 In view of the above, the main request is not allowable under Article 56 EPC 1973.

### 3. AUXILIARY REQUESTS

The first to fourth auxiliary requests differ from the main request basically in that claim 1 as amended further specifies that (emphasis added by the board)

b3') the image of the patient's anatomic volume is registered to a pre-labeled canonical atlas of the brain (*first, third and fourth auxiliary requests*);

b4) the spatial distribution of tissue conductivity is determined from diffusion tensor imaging (DTI) data derived from magnetic resonance imaging of a human brain (*second to fourth auxiliary requests*);

b5) the DTI data is derived from a human brain of at least one other patient (*fourth auxiliary request*).

#### 3.1 *Novelty and inventive step*

3.1.1 The feature analysis and reasoning with respect to claim 1 of the main request outlined in point 2.1 above apply *mutatis mutandis* to claim 1 of the present auxiliary requests.

3.1.2 Furthermore, the board holds that feature b3'), which relates to the provision of a (not further defined) brain atlas generation scheme, and feature b4), concerned with applying a certain medical imaging



scheme for human brains to the underlying models, are also anticipated by D2 (see e.g. page 590, right-hand column, lines 32-35, in conjunction with Fig. 1B and page 590, left-hand column, line 20 to right-hand column, line 22).

3.1.3 As to feature b5), the board concedes that it is not directly and unambiguously derivable from D2. However, it finds that this feature has no effect other than providing an alternative way of retrieving DTI data of a human brain, e.g. in the event that DTI imaging of a certain patient is, for whatever reasons, not available, as corroborated by the present application itself ("for example, when a non-DTI imaging modality is used"; see e.g. page 15, line 29 to page 16, line 5 of the application as originally filed). Contrary to the appellant's view (cf. appellant's letter dated 7 April 2016, second page, penultimate paragraph), the board is therefore of the opinion that the alleged technical effect of "saving of data processing" and "minimizing of discomfort to the patient during the data gathering step" cannot be credibly established from the fact that DTI data is simply derived from another patient, especially when considering that "discomfort" is usually not measurable in a reliable and objective way.

3.2 In conclusion, the first to fourth auxiliary requests are likewise not allowable under Article 56 EPC 1973.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chair:



K. Götz-Wein

A. Ritzka

Decision electronically authenticated