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**Datasheet for the decision  
of 31 March 2011**

**Case Number:** T 1376/08 - 3.4.01  
**Application Number:** 05075990.1  
**Publication Number:** 1559369  
**IPC:** A61B 5/11, A61N 1/36  
**Language of the proceedings:** EN

**Title of invention:**  
Feedback mechanism for deep brain stimulation

**Applicant:**  
CORNELL RESEARCH FOUNDATION, INC.

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 123(2)

**Relevant legal provisions (EPC 1973):**  
EPC Art. 76, 83, 56

**Keyword:**  
"Added subject-matter (no)"  
"Sufficiency of disclosure (yes)"  
"Inventive step (yes)"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 1376/08 - 3.4.01

**D E C I S I O N**  
of the Technical Board of Appeal 3.4.01  
of 31 March 2011

**Appellant:** CORNELL RESEARCH FOUNDATION, INC.  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 24 January 2008  
refusing European patent application  
No. 05075990.1 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman:** B. Schachenmann  
**Members:** P. Fontenay  
F. Neumann

## Summary of Facts and Submissions

- I. European patent application No. 05 075 990.1 was refused by a decision of the examining division dispatched on 24 January 2008. The application is a divisional of earlier patent application No. 00 939 701.9 which was granted on 31 August 2005.

This earlier application had been originally filed under the PCT and published under No. WO-A-00/76580. It was originally directed to methods for treating conscious patients having impaired cognitive function. In particular, all the original claims related to methods including a step of applying electrical stimulation to subdivisions of the patient's subcortical structures involved in the generation and control of generalised efference copy signals.

- II. In contrast thereto, the original claims in the present divisional application were directed, *inter alia*, to a cognitive function improving apparatus, the use of an electric current in the manufacture of a therapeutic electrical stimulus for the treatment of a patient, and the use of one or more pharmacological agents in the manufacture of a medicament for use in improving cognitive function of a conscious patient.

In their decision to refuse the application, the examining division primarily held that claim 1 of each of the main request and auxiliary requests 1 to 5, then on file, contained subject-matter extending beyond the content of the parent application as filed contrary to Article 76 (1) EPC 1973. The requests on file were also considered to violate the requirements of Article 83

EPC 1973 as to the requirements concerning sufficiency of disclosure.

The examining division further judged that independent claim 33 of each of the main request and auxiliary requests 1, 3 and 4, which concerned the use of an electrical current in the manufacture of a therapeutic electrical stimulus for the treatment of a patient (main request and auxiliary request 3) or a therapeutic electrical stimulus for treatment of a patient (auxiliary requests 1 and 4), actually defined a method of treatment by therapy and surgery excluded, as such, from patentability under Article 53(c) EPC. In addition, independent claim 34 of each of the main request and auxiliary requests 1, 3 and 4, defining the use of one or more pharmacological agent in the manufacture of a medicament, was considered to contravene to the requirements of clarity under Article 84 EPC 1973.

III. By notice filed by facsimile on 7 March 2008, the appellant (applicant) lodged an appeal against this decision and paid the prescribed appeal fee. The statement setting out the grounds of appeal was filed on 3 June 2008. It contained various sets of claims according to a main request and auxiliary requests 1 to 5.

IV. At the appellant's request, summons to attend oral proceedings were issued.

On 29 November 2010, in preparation of the oral proceedings, the Board issued a communication pursuant to Article 15(1) Rules of Procedure of the Boards of

Appeal (RPBA), expressing its provisional opinion with regard to the requests then on file. Concerning the aspect of added subject-matter, the Board indicated that the passages referred to by the appellant in the statement of grounds did not appear to constitute a sufficient basis for the apparatus claims on file. The Board also indicated that it was not convinced by the appellant's argument with regard to the question of sufficiency of disclosure. It appeared, in particular, questionable whether, in the absence of disclosure concerning the means to detect efference copy signals, the skilled person would have been able to identify the locations within a patient's brain indicative of such generalised efference copy signals. In this respect, the Board was not convinced that the documents cited by the appellant constituted sufficient evidence of the general technical knowledge in the field of the invention. Doubts were also expressed as to the capacity of the skilled person to reproduce the claimed effect of improving the cognitive function of the patient in the absence of any indication in the description as to the relationship existing between the electrical stimulation to be applied and the generalised efference copy signals actually detected.

In the Board's view, the praetorian construction developed by the Enlarged Board of Appeal in decision G 5/83, concerning the possibility for applicants to draft claims according to the so-called "Swiss-type" format did not apply to a claim directed to the use of an electrical current. In this respect, the Board also shared the view of the examining division that the claims directed to the use of an electrical current actually defined a method of treatment of the human

body. Similar comments applied to the corresponding purpose-related claims according to Article 54(5) EPC relating to "a therapeutic electrical stimulus for treatment of a patient".

With regard to the claims relating to the use of pharmacological substances or to the corresponding purpose-related claims, the Board indicated that it intended to focus the debate on the question of their inventive merits.

- V. Under cover of a letter dated 28 February 2011, the appellant filed additional auxiliary requests 6 to 11 in which the claims directed to an electrical current or the use of an electrical current in the manufacture of an electrical stimulus had been deleted and in which further amendments had been made taking into account some of the comments made by the Board in relation to the issue of added subject-matter. In its letter, the appellant also commented on the relevance of document WO-A-97/45160, introduced by the Board in their previous communication.

An excerpt of a reference book, "The organisation of action: A new synthesis" by C. R. Gallistel (1980), pages 166-209, was filed as evidence of common general knowledge in the field of the invention. The document describes, in a comprehensive analysis, the principles of the theory underlying the present invention and includes a section corresponding to the article of E. von Holst and H. Mittelstaedt referred to in the original parent application on page 29, lines 5-10, with regard to the definition of efference copy signals.

VI. Both the appellant's representative and one of the co-inventors cited in the present application, Dr Nicholas D. Schiff, were present at the oral proceedings, which took place on 31 March 2011. A new main request, replacing all previous requests on file, was then filed.

The appellant, thus, requested that the decision under appeal be set aside and a patent be granted with claims 1 to 24 and description pages 1 to 30, filed as sole request at the oral proceedings, and the drawing sheets 1/11 to 11/11 as published.

Claim 1 reads:

*"1. A cognitive function improving apparatus comprising:*

*(i) means for applying electrical stimulation to at least a portion of a patient's subcortical structures involved in the control of generalised efference copy signals;*

*(ii) means for detecting generalised efference copy signals of the patient, comprising means for identifying regional or intrahemispheric changes in brain waves; and,*

*(iii) means for controlling the time on and time off of the applied electrical stimulation in response to detected generalised efference copy signals of the patient."*

Claims 2 to 24 depend on claim 1.

VII. This decision is issued after the entry into force of the EPC 2000 on 13 December 2007. Reference is thus

made to the relevant transitional provisions for the amended and new provisions of the EPC, from which it may be derived which Articles of the EPC 1973 are still applicable to the present application and which Articles of the EPC 2000 are to apply. When Articles or Rules of the former version of the EPC are cited, their citations are followed by the indication "1973".

## **Reasons for the Decision**

1. The notice of appeal and the corresponding statement of grounds comply with the requirements of Articles 106 to 108 EPC and Rule 99 EPC. The appeal is, thus, admissible.

2. *Added subject-matter*

References to the original parent application apply to the published PCT application WO-A-00/76580. The original description of the present application combines the original description with the original claims of the parent application, the latter being incorporated at the end of the description under the heading "*The present invention thus includes*". The original version of the present application, thus, differs from the original parent application essentially by the introduction of new claims.

- 2.1 *Independent claim 1*

Original claim 1 and the corresponding passage in the original parent description defines on page 2, lines 18-21, the step of applying electrical stimulation to



at least a portion of the patient's subcortical structures involved in the generation and control of generalised efference copy signals under conditions effective to improve the patient's cognitive function. In the Board's judgement, this evocation constitutes an implicit disclosure of the means required for completing this procedure as now recited in feature (i) of claim 1, specific embodiments thereof being set out on page 8 of the description.

Moreover, the appellant was able to provide convincing evidence that the terms "generalised efference copy signals", and "internally generated movement" used throughout the original parent application, are equivalent and all define the activity within the brain related to the intended movement of the body of the patient (cf. page 29, lines 7-13 in the original parent application). As plausibly put forward by the appellant during the oral proceedings, the saccadic eye movements constitute a special situation insofar as the observable movement directly reflects the actual efference activity taking place in the brain. In this context, the embodiment illustrated in relation with Figure 6A, with a camera recording saccadic eye movements, constitutes a particular illustration of means for detecting generalised efference copy signals of the patient and does not contradict the definition of generalised efference signals, as was initially assumed by the Board. However, the measurement of saccadic eye movement is not the only method by which generalised efference copy signals may be detected. Indeed, claim 29 of the original parent application and the corresponding passage in the description on page 21 lines 23-30, indicate that conventional techniques may

be used to monitor regional and intrahemispheric changes in brain waves. In the context of the electrical stimulation described on page 21, this must be taken to mean that the efference copy signals are detected using these methods, thus providing a valid basis for the definition of feature (ii) in claim 1. The evocation in this passage of three different alternatives, such as the use of electroencephalograms, magnetoencephalograms or the monitoring of changes in metabolic activity for monitoring changes in brain activity, is considered indeed to constitute sufficient evidence for the claimed generalisation.

Feature (iii) in claim 1 finds its basis in claim 38 of the original parent application and the corresponding passage of the description on page 24, lines 31, 32, with regard to the control of the applied electrical stimulation. As may be observed in Figure 5, in connection with the monitoring of saccadic eye movements, the sequence of stimulation is to be determined by reference to the registered efference signals and should take place within a period of about 200ms after occurrence of the efference signal, thus *de facto* excluding that the time on and time off of the stimulation be controlled by a human operator. For these reasons, the passages referred to above are considered to constitute an implicit disclosure of the means actually required to perform such stimulation.

In conclusion, the Board holds that, under the present circumstances, the original disclosure in the parent application of a method for improving cognitive function of a conscious patient necessarily requires, for its implementation, the provision of the

appropriate equipment. Consequently, the subject-matter of independent claim 1 may be considered to derive directly and unambiguously, from the original parent application (Article 76 EPC 1976).

- 2.2 Similarly, the parent application as filed is considered to provide a sufficient basis for the subject-matter of dependent claims 2 to 24.

The various functionalities regarding the means for controlling the applied electrical stimulation or the pulse generator (claims 2 to 4) are disclosed in the passage on page 11, lines 3-21, and page 22, lines 27-31. The use of an electrode (claim 5) is explicitly addressed on page 8, lines 8-11. The paragraph bridging pages 10 and 11 constitutes sufficient basis for the definition of the stimulating parameters as recited in claims 6 to 8. The ability of the means for applying electrical stimulation to stimulate specific cortical regions (claims 9, 21, 22) is disclosed e.g. on page 16, lines 15-23; page 20, line 18 - page 21, line 8. Synchronised and/or periodic stimulation of the selected brain areas (claims 10, 23, 24) are addressed on page 21, lines 12-15, and page 23, lines 18-20. The aspects concerning the electrode (claims 11 to 14) derive from the passage on page 8, line 8 to page 9, line 8. The features relating to a pharmacological agent (claims 15-19) are disclosed on page 9, lines 8-15. The possibility of auditory stimulation of the patient, disclosed on page 24, lines 7-11, implies the presence of the corresponding means (claim 20) since it is associated to a feedback loop.

2.3 Since the content of the present application as originally filed incorporates the original description and claims of the parent application, the identification of a suitable basis for current claims 1 to 24 under Article 76 EPC 1973 also implies that the conditions of Article 123(2) EPC are met.

3. *Sufficiency of disclosure*

3.1 The excerpt filed by the appellant in its reply to the Board's communication constitutes evidence of common general knowledge in the field of the invention. This article by C. R. Gallistel confirms the view put forward in the second statement filed by the co-inventor, Dr Schiff, with the statement of grounds according to which the terms "generalised efference copy signals", "internal efference copy signals" and "internally generated movements", used throughout the present application, are equivalent and all refer to the activity within the brain relating to the intended movement of the body of the patient. In this respect, the Board sees no reason to question the existence of such signals, at least insofar as it provides a credible basis for the disclosed method of treatment, particularly in view of the fact that such signals appear to be acknowledged by the community of neurologists.

The Board has also no doubts that the means referred to in the application and relating to the conventional techniques such as electroencephalography, magnetoencephalography or the monitoring of changes in metabolic activity are indeed adapted to detect various activities taking place within the brain. These means

would therefore be able to record, *inter alia*, generalised efference copy signals. These techniques do not require any precise identification of the areas within the brain actually responsible for generating these signals. Moreover, the inventor was able to convince the Board during the oral proceedings that the skilled person would indeed be able to identify on the basis of the present teaching the contribution in the recorded signals actually pertaining to efference activity. As a matter of fact, the principle underlying such identification in the case of the recording techniques mentioned above is similar to the one discussed in the present application in relation with saccadic eye movements, illustrated in Figures 6A to 6D. It was emphasised, in this respect, that generalised efference copy signals displayed specific characteristics well known to the skilled person in terms of spectrum, intensity or sequence which permitted their detection and isolation from other background signals and that conventional signal processing techniques well known in the art would be capable of detecting such signals.

It was further stressed that the purpose of the claimed invention was not to design a stimulation signal of a specific waveform depending on the kind of efference signal actually detected, but simply to adapt the timing of the electrical stimulation in response to efference copy signals being detected. As a matter of fact, the present invention is similar, in its principle, to a conventional cardiac pacemaker. The Board is satisfied that the wording of feature (iii) in claim 1 clarifies this aspect and that the skilled

person would have no particular difficulties in designing the corresponding hardware.

4. *Patentability*

4.1 The following documents are of importance for the present decision:

D1: US-A-5 716 377,

D3: WO-A-97/45160.

4.2 Document D1 discloses an apparatus for treating movement disorders. It comprises electrodes implanted into the brain which receive stimulating pulses from a signal generator. Although document D1 does not provide much information as to the portions of the brain actually stimulated, the means disclosed therein are adapted for being implanted into any subcortical structure, i.e. also in areas of the brain involved in the control of generalised efference copy signals.

Even if a sensor in the form of an electrode for implantation deep in the brain of the patient is disclosed in document D1 (cf. D1, column 4, lines 24-30), there is no indication to be found therein that such a sensor and the associated processing means would be adapted for detecting generalised efference copy signals. In this respect, Dr Schiff expressly confirmed, during the oral proceedings before the Board, that the recorded electrical activity referred to in column 4, lines 47-49, of D1 did not correspond to such efference signals but, instead, was indicative of the actual physical movement, i.e. the tremor

affecting the patient, since involuntary movement of this nature did not produce an efference copy signal.

Moreover, even if the pulse generator disclosed in D1 allows some control of the delivered pulse width, it does not suggest controlling the time on and time off of the applied pulses, as such.

Document D3 discloses a method and apparatus for treating a subject suffering from a symptom resulting from traumatic brain injury. Electrical stimulation is applied to a portion of the vagus nerve and, thus, also indirectly causes activation of several parts of the brain involved in cognitive processing. There is, however, no indication in D3 that vagus nerve stimulation would also permit stimulation of subcortical structures involved in the control of generalised efference copy signals.

Document D3 also does not disclose any means for detecting such signals and for controlling the applied stimulation in response thereto.

Neither D1 nor D3 appears to disclose an apparatus as recited in independent claim 1 which subject-matter is, therefore, new in the sense of Article 54 EPC 1973.

Document D1 is considered to illustrate the closest prior art because it has the most relevant technical features in common with the claimed apparatus. Broadly speaking, the apparatus of document D1 comprises similar components and functions in a similar manner to the claimed apparatus. Concretely, the apparatus of D1 comprises means for applying electrical stimulation to

a patient's brain, means for detecting electrical activity deep in the brain and feedback means for controlling the applied stimulation in response to said detected signals.

The claimed subject-matter differs from this known system, essentially, in that means are provided for controlling the time on and time off of the applied electrical stimulation in response to detected generalised efference copy signals.

These controlling means permit the creation of a physiological natural synchronising pulse. Using such a pulse to stimulate the intralaminar-nuclei enhances the efference copy signal and is thought to activate and synchronise several parallel thalamocortical basal ganglia loops. This in turn enables the signals to be rechannelled to other brain structures prepared to accept such activation (cf. published application, paragraph [0064]).

The problem solved by the present invention is thus to improve cognitive function by reintegrating impaired but potentially functional networks (cf. published application, paragraph [0064]).

While it is known, for example from document D3, to somehow stimulate brain areas to treat epilepsy or improve functions associated to memory, there is no indication to be found in the prior art according to which improved cognitive function could be achieved by detecting generalised efference copy signals and stimulating, in response thereto, the corresponding brain regions. There is, therefore, no incentive for



the skilled person to use the system of D1 to apply stimulation to subcortical structures involved in the control of generalised efference copy signals and, consequently, to adapt said system so as to allow control of the time on and time off of the stimulation pulses.

It follows that the claimed apparatus does not derive in a straightforward manner from the available prior art. The subject-matter of independent claim 1 fulfils, thus, the requirements of Article 56 EPC 1973 as to the presence of an inventive step.

## **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 with the order to grant a patent with claims 1 to 24 and description pages 1 to 30, all filed as sole request at the oral proceedings, and the drawings sheets 1/11 to 11/11 as published.

The Registrar:

The Chairman:

R. Schumacher

B. Schachenmann