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Datasheet for the decision of 30 March 2011

Case Number: T 0471/08 - 3.4.01

Application Number: 98953638.8

Publication Number: 1027099

IPC: A61N 1/36

Language of the proceedings: EN

Title of invention:
Deep Brain Stimulation

Applicant:
CORNELL RESEARCH FOUNDATION, INC.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
EPC Art. 54, 56

Keyword:
"Added subject-matter (no)"
"Novelty (yes)"
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0471/08 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 30 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 15 October 2007 refusing European application No. 98953638.8 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal against the decision of the examining division to refuse European patent application No. 98 953 638.8. The application had been originally filed within the framework of the PCT and published as WO-A-99/20342. It was directed to deep brain electrical stimulation methods and, more specifically, to methods for treating conscious patients having impaired cognitive function.

II. The original claims, which all referred to methods of treatment including a step of applying electrical stimulation to a patient's intralaminar nuclei, had been abandoned in the course of the examination proceedings. Instead, various requests had been filed including claims directed to a system for treating cognitive function in a patient, to the use of an electrical current in the manufacture of a therapeutic electrical stimulus for treatment of a conscious patient, or to the use of one or more pharmacological agents in the manufacture of a medicament for use in the treatment of a conscious patient.

In the decision under appeal, the examining division held that the subject-matter of claim 1 of the main request and auxiliary requests 1 to 8 contained added subject-matter contrary to Article 123(2) EPC 1973. It further considered that the requests then on file did not meet the requirements of novelty (main request), inventive step (auxiliary requests 1 and 2), or clarity (auxiliary requests 3 to 9).

The decision to refuse the application was dispatched on 15 October 2007.

III. The notice of appeal was received at the EPO by facsimile on 12 December 2007. The prescribed appeal fee was paid on the same day. With the statement setting out the grounds of appeal, filed on 22 February 2008, the appellant submitted various sets of claims according to a main request and auxiliary requests 1 to 12.

IV. Oral proceedings were appointed, as requested by the appellant in the case that the Board did not intend to grant the main request.

On 9 September 2010, in a communication pursuant to Article 15(1) Rules of Procedure of the Boards of Appeal (RPBA), the Board provided a preliminary assessment of the case. The attention of the appellant was drawn to the fact that various features of the claimed system had no basis in the original application (Article 123(2) EPC). Moreover, in the Board's view, the praetorian construction developed by the Enlarged Board of Appeal in decision G 5/83, as to the possibility for an applicant to adopt the so-called "Swiss-type" format for inventions directed to substances or compositions, did not apply to an electrical current; neither did the purpose-related format available since the entry into force of EPC 2000 under Article 54(5) EPC. It was further stressed that the Board intended to extend the debate to the question of the allowability of the claim concerning the use of pharmacological substances in the manufacture of a

medicament, although this claim had been considered allowable by the examining division.

V. In reaction to the communication of the Board, the appellant filed, with a letter dated 28 February 2011, additional auxiliary requests 13 to 25.

Oral proceedings before the Board took place on 30 March 2011 in the presence of both the appellant's representative and the inventor, Mr Nicholas D. Schiff. During these proceedings, a new main request was filed which replaced all previous requests on file.

The appellant, thus, requested that the decision under appeal be set aside and a patent be granted on the basis of claims 1 to 8 and description pages 1-36, all filed as sole request at the oral proceedings, and drawing sheets 1/6 - 6/6 as published under the PCT.

Claim 1 of the sole request reads:

"1. A system for treating cognitive function in a patient, said system comprising;

an implantable multipolar electrode allowing electrical stimulation to be applied to a selected subdivision of the patient's intralaminar nuclei, or allowing electrical stimulation to be applied to the selected subdivision and other subdivisions, and

a pulse generator for varying specific stimulation parameters such that a patient's intralaminar nuclei can be electrically stimulated periodically and at the same frequency and that the stimulation of the individual subdivisions can be completely in phase, partially in phase or completely out of phase."

Claims 2 to 8 are dependent on claim 1.

VI. 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 appeal is admissible.

2. Added subject-matter

In the following, references to the original disclosure apply to the application as published under the PCT as WO-A-99/20342.

Although focussing essentially on electrical stimulation methods in accordance with the original claims and primary teaching of the present application, the description also contains information as to the devices or systems being used in such methods. In accordance with established jurisprudence of the boards of appeal, in order to constitute a basis for possible amendments, such information must derive directly and unambiguously from the original disclosure. It may, however, result from explicit statements as well as

from implicit indications in the application as filed. Under the present circumstances, a large part of the available information as to the system used is of implicit nature; it finds its source in the disclosure of the stimulation methods, insofar as the disclosed method steps indeed necessarily imply the existence of the appropriate technical equipment.

2.1 Independent claim 1

2.1.1 The use of an implantable multipolar electrode is addressed on page 9, lines 1-21, of the original application. In this passage, electrodes of the type Medtronic DBS 3280, with four contacts, are presented as more particularly adapted for delivering stimulation to a patient's intralaminar nuclei. It is further referred, on page 9, lines 23-31, to a preferred embodiment in which the electrode is an implantable multipolar electrode used with either an implantable pulse generator or a radiofrequency controlled device. The passage on page 9, line 31 to page 10, line 4, is still more explicit as to the type of electrode to be used: It reads: "*More preferably, the multipolar electrode contacts allow for adjustment in a broader range than those recited above, particularly toward higher intensities. Such preferred electrodes include a Medtronic 3387 electrode (available from Medtronic, Minneapolis, Minnesota) and are described, for example, in Benabid et al., "Chronic Electrical Stimulation of the Ventralis Intermedius Nucleus of the Thalamus As a Treatment of Movement Disorders," J. Neurosurgery, 84:203-214 (1996), which is hereby incorporated by reference*".

These various passages in the description provide, thus, ample evidence that the feature of the implantable multipolar electrode, as recited in claim 1, is disclosed in the original application.

2.1.2 The combination of an electrode with a pulse generator is described with more details on page 12, lines 28-32, of the original description. This passage follows the indication on page 12, lines 15 and 16, that the electrical stimulation can be continuous, intermittent, or periodic. The passage on page 13, lines 1-6, further specifies that the signal pulse generator should preferably be capable of generating voltage wave trains of any desired form (sine, square wave, spike, rectangular, triangular, ramp, etc.) in a selectable voltage amplitude in the range from about 0.1 volts to about 10 volts and at selectable frequencies.

The statement on page 26, lines 1-5, according to which: "*Where two or more subdivisions of the patient's intralaminar nuclei are electrically stimulated periodically and at the same frequency, such stimulation can be completely in phase, partially in phase and partially out of phase, or completely out of phase*" is considered particularly relevant for the feature of the pulse generator as defined in current claim 1. The evocation of these stimulation schemes constitutes, in the Board's judgement, an implicit disclosure of means capable of controlling these parameters, i.e. of the presence of a pulse generator and of its ability to generate such stimulation signals.

Even if it cannot be excluded from the content of the application as filed that the control of the phases of the various stimulation signals is performed by a plurality of pulse signal generating units being somehow synchronised, it is nevertheless considered that the combination of such generating units with the synchronising means would, as a matter of fact, also constitute a pulse generator in the sense of the present application. Consequently, this interpretation of the original disclosure would still be in agreement with the definition in claim 1 according to which all signals are generated and controlled by a pulse generator.

Furthermore, the Board accepted the argument put forward by the inventor during the oral proceedings according to which the statements on page 26, lines 1-5, implicitly apply to multipolar electrodes. It was more specifically stressed that the implantation of electrodes in the brain required special skills in terms of accuracy and care, considering the sensitivity of the brain regions affected. In this respect, the determination of the path through which each electrode to be implanted has to be introduced while minimising risks to the patient adds to the complexity of such operations. Therefore, in the case that multiple subdivisions of the intralaminar nuclei were to be stimulated, the skilled person would have excluded implanting a plurality of monopolar electrodes in such a reduced volume but would have, instead, made use of the disclosed multipolar electrodes as the sole technically meaningful alternative capable of limiting any potential trauma imposed to the brain regions.

2.1.3 Consequently, the original disclosure provides a sufficient basis for a system for treating a cognitive function as recited in claim 1. Claim 1 meets, therefore, the requirements of Article 123(2) EPC.

2.2 Dependent claims 2 to 8

The electrical stimulation of all subdivisions of the patient's intralaminar nuclei except the centromedian-parafasicularis or central lateral or both parts is explicitly disclosed on page 19, lines 17-22, of the original disclosure. The evocation of this stimulation scheme is considered to constitute an implicit disclosure of the means, recited in dependent claim 2, actually required to carry out this kind of stimulation.

Similarly, the passages on page 19, lines 23-31, in combination with Table 2, page 16, lines 14-18, and page 21, lines 9-18, provide a valid basis for the ability of the claimed system to stimulate subdivisions of the patient's intralaminar nuclei as recited, respectively, in claims 3 to 5.

A basis for dependent claims 6 to 8 may be found in the original description on page 9, lines 27-31, according to which the multipolar electrode contacts should allow for adjustments of frequency, amplitude and pulse width within the ranges: about 2-200 Hz, about 0.1-10 Volts, and about 50-500 microseconds. Although referring to the multipolar electrodes, the corresponding functionalities also implicitly apply to the pulse generator. Moreover, in the absence of any functional relationship between these various parameters, the

Board is convinced that the intermediate generalisation resulting from the new claims' wording, according to which the ability to control these parameters is now dissociated, is indeed allowable.

3. Patentability

3.1 The following documents, cited during the course of the examining proceedings (D1, D2, D3) or cited in the original application (D3, D4), were considered more particularly relevant:

D1: US-A-5 269 303;
D2: EP-A-072 611;
D3: WO-A-95/05117;
D4: A. Benabid et al., "Chronic electrical stimulation of the ventralis intermedius nucleus of the thalamus as a treatment of movement disorders", J. Neurosurgery, Vol. 84, pages 203-214, February 1996;
D5: M. Velasco et al., "Electrocortical and behavioural responses produced by acute electrical stimulation of the human centromedian thalamic nucleus", Electroencephalography and clinical Neurophysiology, Vol. 102, pages 461-471, 1996.

3.2 Novelty

3.2.1 Document D1 discloses a method and associated system for treating dementia by selective stimulation of the vagus nerve. Since this nerve projects directly or indirectly to a number of brain structures (cf. D1, column 7, lines 32-35), its stimulation permits to modulate the activity of the brain structures including

cortex, reticular formation and hippocampus, thus, further allowing some control of the cognitive functions of a patient (cf. column 7, lines 56-61; column 5, lines 34-37).

According to the teaching provided in document D1, a bipolar electrode is implanted and secured on the vagus nerve in the patient's neck (cf. column 10, lines 53-60). There is no indication to be found in D1 that the stimulation of the vagus nerve would permit (indirect) activation of subdivisions within the patient's intralaminar nuclei. In a first statement dated 19 February 2008, Mr Schiff, the inventor of the invention underlying the present application, presented convincing arguments according to which the electrode disclosed in D1 is not adapted to the claimed function. As a matter of fact, the individual contacts and lead sizes disclosed in D1 are not appropriate to make contact with selected subdivisions of a patient's intralaminar nuclei. This view was further confirmed by Mr W. N. Borkan, the inventor named in relation with document D2, in a statement filed on 22 February 2008 with the statement of grounds of appeal.

Moreover, the bipolar electrode of D1 does not appear to allow separate control of the two electrode contacts to the nerve. There is accordingly no indication in D1 that the pulse generator coupled to the electrode would allow various areas to be stimulated in phase, out of phase or partially in phase, as recited in claim 1.

3.2.2 In Document D2, use is made of individual monopolar electrodes rather than a multipolar electrode (cf. D2, page 7, lines 12-17, page 9, lines 1-7, Figure 1). In

his statement, Mr Borkan, the inventor of the invention disclosed in this prior art, confirmed that this document did not disclose the design of an electrode and pulse generator as would be actually required to activate specific subregions of the human thalamus.

Moreover, although the pulse generator of D2 permits to define the polarity of the electrodes relative to one another (cf. page 9, lines 13-16), i.e. to provide in phase or out of phase stimulation of various areas, it does not provide the additional functionality recited in claim 1 as to the capability of the pulse generator to deliver signals being partially in phase.

3.2.3 An implantable multipolar electrode for use in the treatment of epilepsy is disclosed in document D3. The electrode is, however, primarily intended to detect electrical activity within the brain. It is made of a flexible plastic strip with a plurality of electrode plates disposed therein (cf. page 7, lines 6-15) and is to be implanted in the subdural cavity, i.e. between the brain and the skull (cf. page 2, lines 6-10; page 8, lines 9-19).

Consequently, the Board concurs with the appellant's view that the geometry of the contacts and design of the electrode disclosed in D3 preclude its implantation into deep brain structures.

Moreover, since the electrode of D3 is primarily intended for recording purposes, this prior art document does not contain any information as to a pulse generator.

3.2.4 Documents D4 and D5 have been explicitly acknowledged in the original application on page 9, lines 1-22, and page 9, line 23 to page 10, line 5, respectively, with regard to preferred electrodes adapted for delivering an electrical signal to the patient's intralaminar nuclei. In actual fact, D4 and D5 describe processes in which commercial electrodes available from "Medtronic", in particular model numbers 3387 or DBS 3280, are used for stimulation of the ventralis intermedius nucleus of the thalamus or the centromedian thalamic nucleus, respectively.

Both documents D4 and D5 disclose a multipolar electrode in association with a pulse generator (cf. D4, subsections "Surgical Procedures" and "Stimulation Parameters" pages 205 and 206; D5, section "Methods", page 462). It is suggested in the section "Stimulation Parameters" on page 206, in D4, that the pulse generator disclosed therein allows some control of the pulse width, frequency and applied voltage. The pulse generator used in D5, similarly, allows a control of the voltage and frequency.

Neither D4 nor D5, however, contain any information as to the ability of the pulse generator to permit the individual stimulation of each of the multiple contacts, i.e. to activate the poles of the multipolar electrode with signals being in phase, partially in phase or out of phase.

3.2.5 Since none of the available prior art discloses a system as recited in claim 1, its subject-matter is new in the sense of Article 54 EPC 1973.

3.3 Inventive step

3.3.1 Although the treatment of dementia disclosed in document D1 involves some control of the cognitive functions, there is no hint to be found in this document that this purpose could be achieved by stimulation of selected subdivisions of a patient's intralaminar nuclei. There is thus no incentive for the skilled person, starting from the teaching of D1, to adapt the bipolar electrode defined therein so as to permit direct stimulation of this specific brain region or subdivisions thereof.

Document D2 focuses on a system for controlling nervous or muscular disorders. The mere indication on page 33, lines 5-9, that the system can be used to stimulate, among other areas, the brain to elicit psychological responses is not sufficient to lead the skilled person to consider adapting the system to make it suitable for stimulation of subdivisions of the intralaminar nuclei.

Document D3 is even less relevant since the multipolar electrode disclosed therein is intended for recording electrical potentials within the brain. Its flexibility makes it unsuitable for being introduced into deep brain structures.

For these reasons, the closest prior art appears to be disclosed by document D4 (or possibly D5) which discloses a system well adapted and actually designed for stimulation of areas deep within the brain. As acknowledged by the applicant in the original disclosure, the electrodes disclosed therein would be adapted for stimulation of the intralaminar nuclei or

subdivisions thereof so as to treat cognitive functions of a patient.

3.3.2 The subject-matter of claim 1 differs from the system of D4 (or D5) in that the pulse generator is capable of controlling the stimulation so that individual subdivisions of the intralaminar nuclei can be stimulated completely in phase, partially in phase or completely out of phase.

As the appellant plausibly submitted, this added functionality permits a greater flexibility in the control of the stimulation parameters, thus allowing customisation of the stimulation patterns of the individual subdivisions of the intralaminar nuclei. This ultimately enables improved coordination of function across cortical regions. The possible mechanisms involved in this process include changes in global dynamics of a distributed network, changes in inhibition or excitation at one or more points in large loops of circuits activated by intralaminar nuclei inputs, and increases in metabolic rate that change the firing rates or other cellular processes. Increases in synchrony may, similarly, promote increased firing rate and increased metabolism or vice versa (cf. original description, page 29, lines 9-20).

The problem solved by the claimed invention may, thus, be defined as to apply electrical stimulation under conditions effective to relieve the patient's impaired cognitive function (cf. original description, page 2, lines 29-32; page 3, lines 26-29; page 8, lines 32-36). It is emphasised in this respect that the deep brain stimulation carried out in D4 and D5 was aimed at

alleviating Parkinsonian tremor and epileptic seizures, respectively; neither of these stimulation processes were directed to relieving impaired cognitive function.

In the absence of any clear teaching in the prior art to employ the system disclosed in D4 (or possibly D5) for stimulation of the intralaminar nuclei with the aim of restoring impaired cognitive function, the skilled person had no reason to adapt the pulse generator disclosed in these documents so as to provide appropriately synchronised stimulation trains. In particular, the provision of a pulse generator capable of stimulating individual subdivisions of the intralaminar nuclei independently of each other would not have been considered by the skilled person when starting from the deep brain stimulation arrangements described in D4 and D5. For these reasons, the claimed invention cannot be considered to derive in a straightforward manner from the available prior art.

The subject-matter of claim 1 meets, therefore, the requirements of the EPC as to the presence of an inventive step (article 56 EPC 1973).

4. Since announcing the decision, the Board has become aware of a clerical error in claim 4, which refers back to claim 8 instead of claim 3. The Board is, however, not entitled, in the absence of any request for correction, to modify *ex officio* the wording of claim 4. Should the appellant request correction of this error under Rule 139 EPC, it will be up to the examining division to decide on its allowability.

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 with claims 1 to 8 and description pages 1-36, all filed as sole request at the oral proceedings, and the drawings sheets 1/6 to 6/6 as published under the PCT.

The Registrar: The Chairman:

R. Schumacher B. Schachenmann