

ET0789.96 - 021130008

## **DECISIONS OF THE BOARDS OF APPEAL**

**Decision of Technical Board of Appeal 3.4.1 dated 23 August 2001**

**T 789/96 - 3.4.1**

(Translation)

Composition of the board:

Chairman: G. Davies

Members: U. G. O. Himmler

G. Assi

**Applicant: ELA MEDICAL**

**Headword: Therapeutic method/ELA MEDICAL**

**Article: 52(4) EPC**

**Keyword: "Method for treatment of the human or animal body by therapy - no"**

*Headnote*

*A method applied to the human or animal body involving the use of a pacemaker with a therapeutic effect is not a therapy within the meaning of Article 52(4) EPC if the invention consists in refining said method but the refinement does not have the effect of preventing or treating a pathological condition.*

## Summary of facts and submissions

I. The applicant's appeal was received on 14 June 1996. It is against the examining division's decision, posted on 12 April 1996, refusing patent application No. 92 918 047.9. The fee for appeal was paid on 17 June 1996. The statement setting out the grounds of appeal was received on 7 August 1996.

II. In its decision, the examining division had concluded that the application did not meet the requirements of Article 52(4) EPC, especially as regards claims 1 to 37 directed to a method for controlling stimulation energy in a pacemaker.

III. The appellant asked that the contested decision be set aside, and a patent granted on the basis of the following documents:

Main request:

- claims:

No. 1 filed by letter of 5 August 1996

Nos. 2 to 5, 6 (page 20), 37 (page 28), 38 and 39 (page 28) filed by letter of 7 February 1996

Nos. 6 (page 21), 7 to 36, 37 (page 27), 41 (page 30), 42 to 50 as published

Nos. 39 (page 29), 40, 41 (page 29) filed by letter of 17 July 1995

- description:

pages 1, 4, 5, 7-11, 13-18 as published, pages 2, 2a, 6a filed by letter of 17 July 1995

pages 3, 6, 12, 19 filed by letter of 7 February 1996

- drawings:

sheets 1/6-6/6 as published

Auxiliary request:

- claims:

Nos. 38 to 50 as per the main request

- description and drawings as per the main request.

IV. Claim 1 as per the main request reads as follows:

"1. Method for controlling stimulation energy in a pacemaker, using a computer program to measure a capture parameter and characterised in that:

- a capture parameter is defined which varies according to the stimulation energy;

- the characteristics representative of the capture parameter according to the stimulation energy are determined during a calibration phase;

- a reference value for determining stimulation effectiveness is defined on the basis of these characteristics;

- the threshold capture value is determined from this reference value during a threshold determination phase;
- and the stimulation energy is determined according to the threshold capture value."

Claim 25 as per the main request reads as follows:

"25. Method for controlling the stimulation energy of a pulse having a pacemaker-delivered amplitude and breadth, comprising the following steps:

- analysing the endocavitary response to a pacemaker-delivered pulse;
- defining a capture parameter varying according to the stimulation energy;
- providing a calibration phase to determine the characteristics representative of the capture parameter, according to the cardiac response analysed in response to one or more stimulating pulses;
- defining a reference value to determine pulse effectiveness on the basis of the representative characteristics determined for the capture parameter;
- providing a threshold determination phase to determine the threshold capture value from this reference value;
- and determining the stimulation energy of the pulses delivered according to the value determined for the threshold capture."

Claim 26 as per the main request reads as follows:

"26. Method for controlling the stimulation energy of a pacemaker-delivered stimulating pulse having a stimulating amplitude and breadth, characterised by the following steps:

- monitoring the endocavitary signals in response to a pacemaker-delivered stimulating pulse and supplying a response value representative of the cardiac response;
- defining a capture threshold corresponding to a minimal stimulating pulse energy producing a desired cardiac response value;
- controlling the stimulating pulse energy corresponding to the value defined for the threshold capture;
- determining that a stimulating pulse is effective if the cardiac response value is above the defined capture threshold, and ineffective if the cardiac response value is below the defined capture threshold, and
- producing a certain number of high-energy stimulating pulses in response to a stimulating pulse defined as ineffective."

Claim 38 as per the main request is directed to a device for controlling stimulation energy in a pacemaker.

Claims 2 to 24, 27 to 37 and 39 to 50 as per the main request are dependent claims.

V. The appellant argues as follows:

Although a pacemaker is by its nature a method for treatment of the human body, the claimed method for controlling stimulation energy has, in itself, no therapeutic function. The method is intended to solve the technical problem of reducing the energy of each stimulating pulse without losing efficiency, thereby prolonging the life or reducing the size of the pacemaker battery. This problem is unconnected with any therapeutic effect. In particular, measuring a capture parameter, ie an electric signal with no stimulation significance, selecting the capture parameter's representative characteristics, calculating a reference value and determining a capture threshold and the stimulation energy are steps controlled by software, without a doctor having to be present. The method in no way gives rise to cardiac stimulation for a therapeutic purpose.

### **Reasons for the decision**

1. The appeal is admissible.

#### *2. Main request*

##### 2.1 Article 123(2) EPC

The main request corresponds to the request underlying the impugned decision, only claim 1 having been amended. Leaving aside the fact that the method steps are now described in the passive voice, the only difference between the original claim 1 and claim 1 as per the main request is the addition of a feature indicating that control occurs "using a computer program". This feature is disclosed in the original description (page 17, lines 12 to 19). Claim 1 as per the main request therefore meets the requirements of Article 123(2) EPC.

##### 2.2 Article 52(4) EPC

2.2.1 Under Article 52(4) EPC, methods for treatment of the human or animal body by surgery or therapy are not considered inventions which are susceptible of industrial application, and are therefore excluded from patentability. Such exclusions are normally construed narrowly, and therefore not applied to methods having no therapeutic effect (see T 144/83, OJ EPO 1986, 301, Reasons point 3).

In this connection, the Enlarged Board of Appeal has expressly stated in decision G 5/83 (OJ EPO 1985, 64, Reasons point 22) that "The intention of Article 52(4) EPC ... is only to free from restraint non-commercial and non-industrial medical and veterinary activities".

2.2.2 The examining division took the view that because the claimed method produced cardiac stimulations it was a method for treatment of the human or animal body by therapy. It argued that the method was intended to determine the stimulation energy to enable the stimulating pulse to play its role of stimulating the heart effectively. Such cardiac stimulation required medical knowledge, so the method was of a therapeutic nature.

The board cannot follow this argumentation for the following reasons.

2.2.2.1 True, a method involving the use of a device having an effect on the heart is in principle a method of treatment by therapy. But in the present case the method as per claim 1 is directed not to cardiac stimulation but to "controlling stimulation energy in a pacemaker". In other words, it is designed to optimise a pacemaker's energy consumption. This gives special relevance to the point made in T 245/87 (OJ EPO 1989, 171, Reasons point 3.2.3) that "A method ... does not fall within the scope of the first sentence of Article 52(4) EPC if there is no functional link and hence no physical causality between its constituent steps carried out in relation to a therapy device and the therapeutic effect produced on the body by that device".



2.2.2.2 The fact that the method as per claim 1 defines a capture parameter, a reference value and a capture threshold does not make it a therapeutic method. These parameters are actually determined by a program contained in the pacemaker. In this connection, T 426/89 (OJ EPO 1992, 172, Reasons point 3.2) held that "The programming of a pacemaker is no more than an act performed **on an apparatus**. And although that act can be performed by a doctor in the exercise of his professional skills, it does not constitute direct treatment by therapy of the human ... body" (original board's emphasis).

2.2.2.3 It should also be pointed out that in the method as per claim 1 the parameters defined by the pacemaker are not used to regulate the amplitude, the stimulation frequency or any other value acting **directly** on the heart; there is therefore no corresponding functional link. On the contrary, in the method claimed, the capture parameter is used exclusively to minimise the energy needed for cardiac stimulation; it influences the therapeutic effect of that stimulation neither positively nor negatively. The present case thus differs completely from the facts underlying T 82/93 (OJ EPO 1996, 274, Reasons point 1.5) which found that the "activities or actions which are set out in the claim consist of the use of a sensed pressure value derived from a particular part of the human body for quantitatively controlling the output of the pacer which is applied to the human body in order to obtain a therapeutic effect. ...., in the present case there is therefore **a functional link between the value which is measured and the therapeutic treatment which is applied**" (present board's emphasis).

2.2.2.4 The view that the method claimed is not a therapeutic treatment is borne out by the fact that a patient fitted with a pacemaker functioning only as per the said method could die because the method is activated only periodically (eg every 6 or 24 hours) when he might need uninterrupted cardiac stimulation. Also, it operates entirely automatically, "using a computer program", without a doctor being involved.

2.2.3 To conclude: a method applied to the human or animal body involving the use of a pacemaker with a therapeutic effect is not a therapy within the meaning of Article 52(4) EPC if the invention consists in refining said method but the refinement does not have the effect of preventing or treating a pathological condition. The present invention is a method whose technical steps have been refined with a view to reducing the energy consumption of a pacemaker whose therapeutic effect **does not depend** on the presence of the steps claimed. It is clear from the above that the method as per the present invention has no therapeutic effect on the body and is thus not excluded by Article 52(4) EPC.

2.2.4 For all these reasons, the method as per claim 1 of the main request meets the requirements of Article 52(4) EPC, as do method claims 25 and 26 as per the main request.

### 3. Auxiliary request

The main request is granted, so there is no need to consider the auxiliary request.

4. In the impugned decision, the examining division concluded only that the method claims did not comply with Article 52(4) EPC. The board is unwilling in such circumstances to deprive the appellant of a two-instance appraisal of the outstanding issues, and will therefore exercise its discretion under Article 111(1), second sentence (second possibility), EPC and remit the case to the department of first instance for further prosecution.

### **Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.