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D E C I S I O N
of 24 January 2002

Case Number: T 0654/99 - 3.2.2

Application Number: 93630004.5

Publication Number: 0554208

IPC: A61B 5/0452

Language of the proceedings: EN

Title of invention:
Implantable cardiac patient monitor

Applicant:
Cardiac pacemakers, Inc.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54, 56

Keyword:
"Novelty (yes)"
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0654/99 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 24 January 2002

Appellant: Cardiac Pacemakers, Inc.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 19 January 1999 refusing European patent application No. 93 630 004.5 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
R. T. Menapace

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 19 January 1999 to refuse European patent application No. 93 630 004.5

The ground of refusal was that, having regard to document D3 (FR-A-2 559 671), the subject-matter of independent claim 1 lacked novelty. The decison was based on the meaning given to the word "within" in claim 1, but the decision went on to say, by way of an obiter, that if instead the meaning of this word was that given by the applicant then the claimed subject-matter would lack an inventive step.

The examining division argued that document D3 disclosed the element 5 to be **in** the header (**dans** la pièce moulée en matière plastique), which was to say it was within the header, and the device of claim 1 was, therefore, not novel. If, however, "within" did not imply complete containment, then this difference would not have involved an inventive step since it simply amounted to an obvious simplification of the device of D3 by eliminating the auxiliary sensing function of the element 5.

II. On 17 March 1999 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee at the same time. On 19 May 1999 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:

- Claims 1 to 6 filed with the letter dated 26 January 1998.

- Description pages 1 to 51 as originally filed.

- Drawing sheets 1/24 to 24/24 as originally filed.

IV. Independent claim 1 of this request reads as follows:

1. "A device which monitors activity of the human heart, the device being fully implantable beneath the skin of a patient and including a hermetically sealed enclosure (32), the enclosure (32) including a perimeter (612), and an electrically insulating header (610) sealingly engaging the perimeter, at least one electrode (604) for sensing activity of the heart, and an electronic circuit within the enclosure and coupled to the at least one electrode for monitoring the activity of the heart sensed by the at least one electrode and for generating data indicative of the monitored activity of the heart, the device characterised by telemetry means (116) disposed within the header for transmitting the data to a non-implanted external receiver."

Claims 2 to 6 are dependent on claim 1.

V. The appellant argues as follows:

In the present context the word "within" could only mean "completely inside". Claim 1 was based on original claim 49 where this word was used two times, once for a circuit means and once for the telemetry means, and it must have the same meaning at each occurrence. The circuit means was clearly completely inside the

enclosure where it was protected from body fluids, and for consistency it must be admitted that the telemetry means was also completely inside the header.

The problem to be solved was not that of simplifying the device of document D3, as argued by the examining division, but of improving data transmission. This document did not suggest the use of telemetry means completely inside the header since this would imply the use of a further electrically conducting element completely inside the header, which would render the prior art device more complicated instead.

Reasons for the Decision

1. The appeal is admissible.

2. *Novelty*

The Board agrees with the examining division in that document D3 discloses all the features of the preamble of claim 1. That the appellant also agrees with this analysis is signalled by the fourth complete paragraph on page 3 of the grounds of appeal. Accordingly, the point at dispute is whether or not the claimed device is indeed characterised by telemetry means disposed within the header for transmitting the data to a non-implanted external receiver, or whether this feature is also disclosed in document D3.

The question of novelty turns on the exact meaning of the word "within". The appellant argues that whereas the telemetry means (116) of the application is contained entirely within the header, that of document

D3 is exposed to the outside and, therefore, is not "within" the header.

The support for this feature of claim 1 is to be found only on Figure 27 of the application, which shows a plan view of the device, and column 36, line 54 to column 37, line 27 of the A2 publication, but these do not indicate the exact the meaning of this word.

The appellant has filed a page from the Longman Dictionary of contemporary English, which defines this word as "not beyond or not more than", or "enclosed or contained by", and other dictionaries provide similar definitions, all of which indicate that an object need not be completely enclosed by its container in order for it to be within the container, contrary to the argument of the appellant.

Nevertheless, as the appellant argues, the context must be taken into consideration in order to establish the true meaning of this word, and this favours the opposite view, that the telemetry means (116) of the application is indeed contained entirely within the header.

The claimed device contains sensitive metallic parts such as circuits, electrodes, and fine wires, and is a fully implantable cardiac monitor, which is to say it is intended for long term implantation. For implantation in the body special non-corrosive materials for containers have been developed to counter the hostile environment within the body. Similarly, in the case of electrodes for such devices special bio compatible or inert materials have been developed for use in those parts that must be exposed to the outside

of the container. All other parts that need not be exposed must be fully encapsulated to protect them from the harmful effects of body fluids.

The telemetry means 116 of the application is a coil and there is no statement that it is made of such a special material. There is also no explicit statement that the telemetry means is exposed, so it must be assumed that it is completely enveloped by a protective housing or encapsulation, and claim 1 must be interpreted accordingly. In contrast thereto, in document D3 there is an explicit statement that the electrode 5 is exposed for contact with the body tissue, see, for example, page 3, lines 32 and 33.

This difference between the device of claim 1 of the application and that of document D3, that the electrode 5 is exposed to body tissue whereas the telemetry means (116) is not, renders the claimed device novel.

3. *Inventive step*

For the same reason that the device of claim 1 is considered to be novel, it is also considered not to involve an inventive step. That is, unless there are compelling reasons for exposing an electrode or other metal parts of an implantable device to body tissue, the person skilled in the art would, as a routine matter, encapsulate it in a protective housing. In other words to completely enclose the part within the housing would be a compulsory measure and not one born of inventive considerations.

That such parts would automatically be encapsulated is

supported by the appellant's own statement in the grounds of appeal, in the first complete paragraph on page 2, which implies that the circuit means is (obviously) completely in the inside of the housing since it requires protection from body fluids which would be harmful to the circuit means.

Thus, it is the context that decides the configuration of the electrodes in an implanted device, ie whether or not is to be fully encapsulated or partly exposed. This is what the examining division meant in the impugned decision by stating that the feature that the electrode is completely within the header amounts to a simplification of the device of D3 by eliminating its auxiliary sensing function.

In the case of document D3, there is a specified reason for exposing the electrode 5, ie it performs an auxiliary function other than sensing or stimulating (page 2, lines 5 to 11 and page 4, lines 4 to 9). One given auxiliary function is telemetry, and in the case of this document the mechanism of telemetry is by transmission of data directly through body tissue, as stated in the ground of appeal, page 4. Therefore, the electode 5 must be exposed in the device of document D3.

The present application, in keeping with modern practice, employs telemetry via an induction coil, for which the coil does not have to be exposed. It would then have to be completely enveloped by the encapsulation provided by the header, on account of the chemically aggressive nature of body fluids, which is well known to the person skilled in the art. No inventive step is involved in realising this.

The appellant's argument that the problem to be solved by the application was not that of simplifying the device of document D3, but of improving data transmission, is not accepted by the Board, since the application sets out no such problem, and moreover, completely enclosing an electrode within a dielectric would hardly affect the data transmission outside the body since induction telemetry is employed, which is not impaired by passing through small amounts of dielectric material.

The device of claim 1 does not involve an inventive step, accordingly.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare W. D. Weiß