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D E C I S I O N
of 21 December 2004

Case Number: T 0185/03 - 3.4.1

Application Number: 93116884.3

Publication Number: 0596319

IPC: A61N 1/368

Language of the proceedings: EN

Title of invention:
Heart stimulator

Patentee:
St. Jude Medical AB

Opponent:
Biotronik GmbH & Co. KG

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Admissibility of late-filed document (yes)"
"Novelty and inventive step (yes - main request)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0185/03 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 21 December 2004

Appellant: (Opponent)
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Respondent: (Proprietor of the patent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 27 November 2002 rejecting the opposition filed against European patent No. 0596319 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
H. K. Wolfrum

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 27 January 2003, against the decision of the opposition division, despatched on 27 November 2002 rejecting the opposition against European patent No. 0 596 319. The fee for the appeal was paid on 27 January 2003 and the statement setting out the grounds of appeal was received on 28 March 2003.

II. The opposition had been filed against the patent as a whole based on Article 100(a) EPC, in particular on the grounds that the subject-matter of claim 1 of the patent as granted was not novel within the meaning of Article 54 EPC and did not involve an inventive step within the meaning of Article 56 EPC.

III. In the decision under appeal, the opposition division held that the grounds for opposition did not prejudice the maintenance of the patent as granted, having regard, *inter alia*, to the following documents:

E4: DE-C-27 01 104

E8: CH-A-547 644

E9: EP-B-0 114 679

IV. With the statement of grounds of appeal, the appellant filed the following new documents:

E10: US-A-4 585 004

E11: *Henry G. Freeman:* "Wörterbuch technischer Begriffe mit 6500 Definitionen nach DIN", 4. Auflage, Deutsches Institut für Normung e. V., 1992

V. In response to a communication from the Board accompanying the summons to oral proceedings, the respondent (patentee) filed, by letter dated the 22 November 2004, two sets of claims 1 to 5 by way of First and Second Auxiliary Requests.

VI. Oral proceedings were held on 21 December 2004.

VII. The appellant requested that the decision under appeal be set aside and the patent be revoked.

VIII. The respondent requested that the appeal be dismissed and the patent be maintained as granted (Main Request) or that the patent be maintained on the basis of the claims according to either the First or Second Auxiliary Requests.

IX. Claim 1 according to the Main Request reads as follows:

"1. A heart stimulator, comprising a pulse generator in a stimulator housing (14) and an electrode system which contains at least one bipolar electrode with one pole (4, 34) arranged in the atrium and one pole (6, 36) in the ventricle, or at least two unipolar electrodes (24, 26) arranged in the atrium and ventricle respectively, for detecting atrial and ventricular electrical activity signals, wherein an atrial measurement unit (16) is arranged to measure the signal between the two poles (4, 6, 34, 36) of the bipolar electrode, or between the two unipolar electrodes (24, 26), and a

ventricular measurement unit (18) is arranged to measure the signal between the ventricular pole (6, 36), or the unipolar electrode (26) arranged in the ventricle, and the stimulator housing (14)."

Claims 2 to 6 are dependent on claim 1.

Claim 1 according to the First Auxiliary Request differs from claim 1 according to the Main Request in that it further comprises the following feature:

"and wherein a logic unit (20, 22) is connected to the measurement units (16, 18) to approve signals from the atrial measurement unit (16) as atrial events only if the ventricular measurement (18) unit fails to detect any signal for a defined period of time around the time an atrial signal is measured."

Claim 1 according to the Second Auxiliary Request differs from claim 1 according to the First Auxiliary Request in that the connection between the atrial measurement unit and the two poles of the bipolar electrode or the two unipolar electrodes is specified as follows:

"wherein each of said two poles (4, 6, 34, 36) are connected directly to said atrial measurement unit (16)"

"wherein each of said two unipolar electrodes (24, 26) is connected directly to said atrial measurement unit (16)".

X. The appellant argued essentially as follows:

The subject-matter of claim 1 of the granted patent lacked novelty because the wording of the claim did not specify that the atrial measurement unit directly measured signals across the atrial and ventricular electrodes or poles, and thus it covered heart stimulators as disclosed in documents E8 and E10.

Even if it were assumed that the claimed invention was distinguishable from the prior art, it lacked an inventive step with respect to the combination of E8 and E9 or of E4 and E9.

XI. The respondent's arguments may be summarised as follows:

Claim 1 of the patent as granted clearly defined an atrial measurement unit for measuring cardiac activity in the atrium by means of two unipolar electrodes or of two poles of a bipolar electrode, whereby the electrodes or the poles were arranged in the atrium and ventricle, respectively. As none of the cited documents disclosed the combination of features recited in claim 1, the subject-matter of this claim satisfied the requirements of Article 54 EPC.

Furthermore, in the light of the teaching of E9, it would not have been obvious to a skilled person starting from a heart stimulator according to E8 or E4 to arrive at a heart stimulator falling within the terms of claim 1. Hence, the subject-matter of this claim also involved an inventive step within the meaning of Article 56 EPC.

Reasons for the Decision

1. The appeal is admissible.

2.1 Of the two new documents cited by the appellant with the statement of grounds of appeal, E11 is an excerpt from a technical dictionary relating, *inter alia,* to the meaning of the term "measuring", whereas E10 is a US patent which, in the appellant's view, should further substantiate the lack of novelty of the claimed invention.

The respondent objected to the introduction of E10 into the proceedings on the ground that it was late-filed, it was mentioned for the first time in the statement of grounds of appeal without any reason as to why it had not been cited within the time limit under Article 99(1) EPC, and furthermore its disclosure was *prima facie* not relevant to the proceedings.

2.2 Before summoning the parties to the oral proceedings and relying essentially on the appellant's submissions concerning the disclosure in E10, in particular on the fact that this document showed an electrode configuration for detecting atrial and ventricular signals similar to the one claimed in the contested patent (see E10, Figures 1 and 4), the Board arrived at the conclusion that E10 indeed appeared, *prima facie*, relevant to the issue of novelty, though its actual import could only be established after carefully assessing its content and discussing it with the parties. By referring to E10 in some detail in its preliminary opinion and thus inviting the parties to

make submissions relating to the content of this document, the Board effectively admitted E10 into the appeal proceedings.

3.1 The gist of the present invention consists essentially in detecting electrical activity in the atrium by means of an electrode configuration comprising two unipolar electrodes located in the atrium and ventricle, respectively, or one bipolar electrode with one pole in the atrium and one pole in the ventricle, and in detecting ventricular signals between the ventricular electrode (or pole) and the stimulator's housing. In other words, the contested patent teaches to combine bipolar detection of atrial signals with unipolar detection of ventricular electrical activity by means of two intracardial electrodes (or poles) and one extracardial electrode, *ie* an electrode arrangement usually directed to unipolar detection.

3.2 According to the appellant, however, claim 1 of the main request would also cover heart stimulators comprising a measurement unit which detected atrial electrical activity on the basis of signals occurring between the atrial and indifferent electrodes and between the ventricular and indifferent electrodes. As E8 showed such a heart stimulator, the subject-matter of claim 1 of the patent in suit was not new within the meaning of Article 54 EPC.

4.1 It is not contested that E8 shows a heart stimulator comprising the following features recited in claim 1 of the main request:

– a pulse generator in a stimulator housing and

– an electrode system which contains at least two unipolar electrodes arranged in the atrium and ventricle respectively, for detecting atrial and ventricular electrical activity signals.

Figure 1 of E8 shows a heart stimulator comprising a first bipolar electrode with two poles 7 arranged in the atrium and a second bipolar electrode with two poles 5, 6 located in the ventricle. According to an alternative embodiment specified in column 3, lines 41 to 45, however, the bipolar electrode arrangement of Figure 1 could be replaced by two unipolar electrodes (one in the atrium and one in the ventricle) and by an indifferent electrode implanted in the patient's body. As pointed out by the appellant, it is customary in the technical field of the invention to use the stimulator's housing as indifferent electrode.

Thus, as far as the lack of novelty objection is concerned, the essential question to be decided is whether the heart stimulator according to E8 also discloses atrial and ventricular measurement units as specified in claim 1 as granted.

4.2 The Board agrees with the appellant that both the claimed invention and the heart stimulator shown in E8 comprise measurement units for "detecting" cardiac activity signals of a predetermined minimum level at their inputs, in the sense that they output a certain logic level when the signals "measured" at their inputs are above a preset threshold. In effect, it seems that the terms "measure" and "detect" in the field of the present invention are, to a certain extent,

interchangeable. In the opinion of the Board, however, claim 1 of the contested patent clearly specifies a heart stimulator comprising two separate measurement units (an *"atrial measurement unit"* and *"a ventricular measurement unit")*, and there is no reason to assume that the wording of the claim could be understood as covering embodiments with a single measurement unit which performs the functions of both the atrial and ventricular measurement units, or which includes the ventricular measurement unit as one of its component parts. It is in the light of this straightforward interpretation of the wording of claim 1 that the issue of novelty should be addressed.

4.3 In the heart stimulator shown in Figure 1 of E8, whereby the atrial and ventricular bipolar electrodes are replaced by unipolar electrodes according to the alternative embodiment disclosed in column 3, lines 41 to 45, it is possible to identify an atrial measurement unit, consisting of pre-amplifier 8 and amplifier 9, and a separate ventricular measurement unit, consisting of pre-amplifier 10 and amplifier 11. The latter unit clearly matches the definition of the ventricular measurement unit given in claim 1 of the contested patent. The atrial measurement unit identifiable in E8, however, differs from the corresponding unit specified in claim 1 in that its inputs are connected to the atrial electrode and to the indifferent electrode and not to the atrial and ventricular electrodes. This difference is sufficient to establish the novelty of the claimed heart stimulator with respect to E8.

4.4 According to the appellant, however, the combination of the two pre-amplifiers 8, 10, of the amplifiers 9, 11

and of the logic block 12 should be regarded as an atrial measurement unit corresponding to the one specified in claim 1 of the contested patent, since it was connected to the atrial and the ventricular electrodes and generated a logic level in response to the signal between said electrodes, as was the case for the atrial measurement unit 16 shown in Figure 1 of the patent in suit. As to the ventricular measurement unit, it would correspond to the combination of pre-amplifier 10 and amplifier 11.

4.5 The appellant's interpretation of E8 thus assumes that the ventricular measurement unit is an integral part of the atrial measurement unit. However, as pointed out above, claim 1 of the patent in suit leaves no doubt that the heart stimulator of the present invention has two different measurement units. Hence, even if it were assumed that the combination of pre-amplifiers 8, 10, amplifiers 9, 11 and (part of) circuit block 12 corresponded effectively to the atrial measurement unit according to claim 1, the subject-matter of this claim would still be distinguishable from the heart stimulator known from E8, because in the latter the circuits identified as the ventricular measurement unit would also constitute an essential component part of the atrial measurement unit. This difference is sufficient to establish the novelty of the subject-matter of claim 1 with respect to E8.

For the sake of completeness, it should also be pointed out that the atrial measurement unit identified by the appellant in the heart stimulator of E8 generates logic levels in response to signals between the atrial and indifferent electrodes or between the ventricular and

indifferent electrodes, thus by means of a unipolar electrode configuration involving an extracardial electrode. However, the logic level fed by the atrial measurement unit 16 specified in claim 1 of the contested patent to the logic circuit 20 (see Figure 1) is a function of the signals occurring between the atrial and ventricular electrodes and is therefore determined on the basis of a bipolar electrode configuration. Thus, as stressed by the respondent, the myopotentials which are excluded by the structure of the claimed stimulator as a result of the bipolar electrode configuration would not be avoided by the unipolar system of E8 which uses an extracardial electrode implanted in the patient's body.

4.6 Document E10 (Figures 1 and 4) shows a catheter with three electrodes: one ring electrode 30A located in the atrium, one ring electrode 30V and one tip electrode 26 in the ventricle. A first lead 28 connecting the ring electrodes is specified as being a data wire. A second lead 24 is connected to the tip electrode which is used for both pacing and sensing. As specified in the description (column 5, lines 40 to 45) electrodes 30V and 30A are unipolar and the pacemaker case 14 is the indifferent electrode. As pointed out by the respondent, the amplifier unit is not designed to detect signals between the atrial and ventricular electrodes, as specified in claim 1 of the patent in suit, but only signals between the atrial electrode and the housing.

5. In the result, none of the cited documents shows a heart stimulator comprising all the features recited in claim 1 as granted. The subject-matter of this claim is therefore new within the meaning of Article 54 EPC.

6.1 According to the appellant, the subject-matter of claim 1 of the patent in suit resulted from an obvious combination of the teachings of documents E8 and E9 or of documents E4 and E9. Though E8 disclosed a heart stimulator with two unipolar electrodes, it pointed out that bipolar detection of atrial and ventricular signals was preferable. On the other hand, E9 reported the advantages and drawbacks of both electrode configurations with respect to sensitivity, noise rejection and immunity against undesired muscle stimulation. In the light of the teaching of E9, a person skilled in the art, starting from a heart stimulator with unipolar detection, as known from E8 or E4, and wishing to improve the detection of atrial signals without increasing the number of leads, would inevitably consider the possibility of using the electrodes located in the atrium and in the ventricle to effect bipolar detection of atrial electrical activity.

6.2 All the documents cited by the appellant show either bipolar or unipolar detection of atrial and ventricular signals. As pointed out in document E9 (page 1, lines 7 to 19), cardiac pacers use leads which (emphasis added) *"may be either of unipolar (UNIP) construction …, or of bipolar (BIP) construction,….. Depending on the particular application, the use of one or the other of the two lead types may be advantageous. Unipolar leads have the advantage of being physically smaller and of providing less energy loss and greater sensitivity than bipolar leads. Bipolar leads have the advantage of providing improved noise rejection, improved immunity against undesired muscle stimulation and reduced*

susceptibility to artifacts resulting from patient movement.
The choice of the lead type is made by the physician at the time of implant, depending on the particular pacing requirements of the patient and any problems encountered with either the sensing or pacing functions."

Though the advantages and drawbacks of both configurations are well known in the art, there is no hint in the prior art that unipolar electrodes located in the atrium and ventricle could be connected to an atrial measurement unit for achieving bipolar detection of atrial activity and thus improving the recognition of low-level atrial signals without increasing the number of leads. In order to arrive at the claimed invention, the skilled person had to realise that it was possible to combine the advantages offered by bipolar detection and by the unipolar lead configuration merely by replacing the connection of the atrial measurement unit to an external electrode, as used for unipolar detection, with a connection to the ventricular electrode. For all the apparent simplicity of this measure, there is no suggestion in the cited prior art that it would have been obvious to the skilled person.

6.3 For the above reasons, the Board concludes that the subject-matter of claim 1 as granted involves an inventive step within the meaning of Article 56 EPC.

7. In the result, the Board finds that the grounds of opposition do not prejudice the maintenance of the

patent as granted and, consequently, there is no need to consider the respondent's auxiliary requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher G. Davies