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D E C I S I O N
of 7 April 2005

Case Number: T 0372/03 - 3.4.1

Application Number: 93250278.4

Publication Number: 0594274

IPC: A61N 1/39

Language of the proceedings: EN

Title of invention:
Atrial defibrillator and means for providing precardio-version pacing

Patentee:
Cardiac Pacemakers, Inc.

Opponent:
Biotronik GmbH & Co. KG

Headword:
-

Relevant legal provisions:
EPC Art. 56, 84

Keyword:
"Inventive step - no (main request and first to fourth auxiliary requests)"
"Lack of clarity (fifth auxiliary request)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0372/03 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 7 April 2005

Appellant: (Opponent)
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Representative:
-

Respondent: (Proprietor of the patent)
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Representative:
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 27 January 2003 rejecting the opposition filed against European patent No. 0594274 pursuant to Article 102(2) EPC.

Composition of the Board:

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

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 19 March 2003, against the decision of the opposition division, despatched on 27 January 2003, rejecting the opposition against the European patent No. 0 594 274. The fee for the appeal was paid on 19 March 2003 and the statement setting out the grounds of appeal was received on 5 June 2003.

II. The opposition had been filed against the patent as a whole based on Article 100(a) EPC and concerned, in particular, objections under Articles 52(1) and 56 EPC.

III. In the decision under appeal, the opposition division held, *inter alia*, that the subject-matter of independent claim 1 of the patent as granted involved an inventive step, having regard, in particular, to the following prior art documents:

E3: WO-A-82/ 02 836
E5: US-A-4 944 298
E6: US-A-4 722 341
E7: US-A-3 952 750

IV. In response to a communication by the Board summoning the parties to oral proceedings, the respondent (patentee) withdrew the request for oral proceedings by a letter dated 7 March 2005 and requested a decision based on the merits of the case. Furthermore, the Board was informed that neither the respondent nor the respondent's representative would attend the oral proceedings.

V. Oral proceedings were held on 7 April 2003 in the absence of the respondent.

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

VII. 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 following claims:

-- first auxiliary request -- claim 1 filed with the letter dated 7 March 2005 and based on a combination of claims 1 and 2 as granted;

-- second auxiliary request -- claim 1 filed with the letter dated 7 March 2005 and based on a combination of claims 1, 2 and 3 as granted;

-- third auxiliary request -- filed with the letter dated 7 March 2005 and based on a combination of claims 1, 2 and 4 as granted;

-- fourth auxiliary request -- filed with the letter dated 7 March 2005 and based on a combination of claims 1 to 4 as granted;

-- fifth auxiliary request -- filed with the letter dated 7 March 2005 and based on a combination of claims 1 to 5 as granted.

VIII. The wording of claim 1 according to the respondent's main request reads as follows:

"1. An implantable atrial defibrillator (30) including a first detector (50) for detecting atrial activity of a human heart (10), an atrial fibrillation detector (70) responsive to the first detector (50) for determining when atria (16,18) of the heart are in need of cardioversion, a cardiac rate stabilizer (63), and a cardioverter (76) for applying cardioverting electrical energy to the atria when in need of cardioversion, characterized in that:

the cardiac rate stabilizer (63) is responsive to the atrial fibrillation detector (30) for stabilizing the cardiac rate of the heart when the atria of the heart are in need of cardioversion; and that the cardioverter (76) applies the cardioverting electrical energy to the atria of the heart after the stabilizer (63) has stabilized the cardiac rate for a predetermined number of cardiac cycles."

Claims 2 to 11 are dependent on claim 1.

Claim 1 according to the respondent's first auxiliary request further comprises the following feature recited in claim 2 of the patent as granted:

"and that the stabilizer (63) includes a pacer (78) for pacing the ventricles of the heart."

Claim 1 according to the respondent's second auxiliary request differs from claim 1 of the patent in suit in

that it further comprises the following features recited in claims 2 to 3 of the patent as granted:

"and that the stabilizer (63) includes a pacer (78) for pacing the ventricles of the heart; and that the cardioverter applies the cardioverting electrical energy to the atria of the heart after the pacer (78) has paced the ventricles for a predetermined number of cardiac cycles."

Claim 1 according to the respondent's third auxiliary request differs from the claim 1 of the contested patent in that it comprises the following features recited in claims 2 and 4 of the patent as granted:

"that the stabilizer (63) includes a pacer (78) for pacing the ventricles of the heart; and that the pacer (78) paces the ventricles of the heart at a pacing rate and in a demand mode. "

Claim 1 according to the fourth auxiliary request differs from claim 1 of the patent as granted in that it comprises the following features recited in claims 2 to 4 of the patent as granted:

"that the stabilizer (63) includes a pacer (78) for pacing the ventricles of the heart; that the cardioverter applies the cardioverting electrical energy to the atria of the heart after the pacer (78) has paced the ventricles for a predetermined number of cardiac cycles; and that the pacer (78) paces the ventricles of the heart at a pacing rate and in a demand mode."

Claim 1 according to the respondent's fifth auxiliary request differs from claim 1 of the main request in that it comprises the following features recited in claims 2 to 5 of the patent as granted:

"that the stabilizer (63) includes a pacer (78) for pacing the ventricles of the heart; that the cardioverter applies the cardioverting electrical energy to the atria of the heart after the pacer (78) has paced the ventricles for a predetermined number of cardiac cycles; that the pacer (78) paces the ventricles of the heart at a pacing rate and in a demand mode; and further characterized by a pacing rate control (62) for increasing the pacing rate responsive to an unpaced cardiac cycle."

IX. The appellant's arguments may be summarised as follows:

Document E3 related, *inter alia*, to an implantable atrial defibrillator comprising the features recited in the preamble of claim 1 of the main request. The claimed device was characterised by the fact that it stabilised (*ie* paced) the heart before delivering a cardioverting pulse. It was known for instance from E5 or E6 to switch an atrial rate based pacemaker into the VVI mode at the onset of atrial tachycardia. In the light of the teaching of E5 or E6, it would have been obvious to a person skilled in the art to modify the implantable atrial defibrillator known from E3 in such a way that it automatically switched into the VVI mode upon detection of atrial tachycardia and prior to delivering the cardioversion treatment. In doing so, the skilled person would have arrived at a device

falling within the terms of claim 1 of the main request.

Claim 1 according to the first auxiliary request differed from the corresponding claim of the main request only in that it specified that the stabiliser included a pacer for pacing the ventricles of the heart. As it was already implicit in claim 1 of the main request that the stabiliser was in fact a cardiac pacer, the auxiliary request was essentially equivalent to the main request.

Claim 1 according to the second auxiliary request further specified that the cardioverter applied the cardioverting electrical energy after the pacer had paced the ventricles for a predetermined number of cardiac cycles. As it was common in the art not to apply the cardioverting shock immediately after detection of atrial or ventricular fibrillation but to wait for a confirmation of this diagnosis, (see for instance E7), it would have been obvious to a person skilled in the art to include also this feature in an implantable atrial defibrillator.

Claim 1 according to the third auxiliary request differed from claim 1 according to the first auxiliary request in that it further specified that the pacer paced the ventricles of the heart at a pacing rate and in a demand mode. Since this feature simply described the standard VVI pacing mode of a pacemaker, also the subject-matter of this claim did not involve an inventive step.

Claim 1 according to the fourth auxiliary request was based on a combination of the features recited in claim 1 of the second auxiliary request and in claim 1 of the third auxiliary request. For the same reasons given for the previous requests, also the subject-matter of the fourth auxiliary request did not involve an inventive step.

The implantable atrial defibrillator according to claim 1 of the fifth auxiliary request further comprised a pacing rate control for increasing the pacing rate responsive to an unpaced cardiac cycle. This feature could be interpreted as implying the provision of a standard override function and therefore it could not contribute to the inventive step of the claimed subject-matter. Moreover, the subject-matter defined by dependent claim 2 contained some features which were not compatible with the wording of the independent claim. Thus, claims 1 and 2 of the fifth auxiliary request lacked clarity within the meaning of Article 84 EPC.

X. The respondent argued in writing that the appellant's objections were not based on a correct interpretation of the language of claim 1 of the contested patent, and that, if properly interpreted, the subject-matter of this claim involved an inventive step in the light of the cited documents. As to the auxiliary requests, the respondent did not submit any arguments in support of their patentability.

Reasons for the Decision

1. The appeal is admissible.

Respondent's main request

2.1 Claim 1 according to the main request relates to an implantable atrial defibrillator comprising the following structural features:

(a) a first detector for detecting atrial activity of the human heart,

(b) an atrial fibrillation detector responsive to the first detector for determining when atria of the heart are in need of cardioversion,

(c) a cardiac rate stabiliser,

(d) a cardioverter for applying cardioverting electrical energy to the atria when in need of cardioversion.

The characterising portion of the claim describes the operation of the atrial defibrillator as follows:

(i) the cardiac rate stabiliser is responsive to the atrial fibrillation detector for stabilising the cardiac rate of the heart when the atria of the heart are in need of cardioversion,

(ii) the cardioverter applies the cardioverting electrical energy to the atria of the heart after

the stabiliser has stabilised the cardiac rate for a predetermined number of cardiac cycles.

2.2 As to the meaning of the term "*cardiac rate stabilizer*" (see feature (c)), it is noted that it merely implies a cardiac pacer for pacing the heart, in particular the ventricle, at a pacing rate suitable for preventing undesirable heart activity, such as ventricular arrhythmias. This interpretation is confirmed by the description of the contested patent (see column 8, lines 43 to 46 and 50 to 54) and by dependent claims 2 and 4. Thus it can be assumed that, in the context of the patent suit, the terms "*stabilizer*" and "*stabilizing*" are synonymous with "pacer" and "pacing".

As to feature (ii), it indicates that the cardioverting electrical energy is not delivered immediately after detection of atrial fibrillation but after a certain time interval corresponding to a certain number of pacing cycles.

2.3 In other words, claim 1 covers an implantable device comprising an atrial cardioverter and a cardiac pacer, whereby the pacer is switched into a pacing mode suitable for stabilising the heart rate upon detection of atrial fibrillation, and the atrial cardioverter applies the cardioverting energy to the atria a certain time interval (specified in terms of a predetermined number of pacing cycles) after detection of the atrial fibrillation.

3.1 Document E3 is essentially concerned with an implantable ventricular defibrillator capable of applying cardioverting electrical energy to the

ventricles and of pacing the heart according to different pacing modes (see page 6, line 26 to page 8, line 24). This document, however, points out that combined pacing and cardioverting electrode systems for delivering defibrillating energy to either the atria or the ventricles and pacing pulses are known in the art (page 4, lines 7 to 15). As acknowledged in the patent in suit (patent specification, column 3, lines 9 to 16), an implantable device, as referred to in E3, capable of performing cardiac pacing and atrial defibrillation necessarily comprises all the features recited in the preamble of claim 1 (see features (a) to (d)). E3, however, does not specify how such a device operates.

3.2 Thus, an essential question to be considered in the present appeal is whether it would be obvious to a person skilled in the art, wishing to develop an implantable device for cardiac pacing and atrial defibrillation, to make provision for allowing such a device to operate as indicated in claim 1 of the contested patent.

4.1 Several passages of E3 highlight the advantages of combining a defibrillator with a cardiac pacer capable of operating in different pacing modes. Thus, it is specified on page 2, lines 3 to 13, that "*it is considered highly desirable to develop a single implantable heart stimulator having the capability of selectively performing any one of the various techniques for responding medically to recognizable heart disorders or arrhythmias, that is to say, the development of a single implanted heart stimulator capable of performing defibrillating, cardioverting, and pacing functions on a selective basis and*

automatically in response to detection of the occurrence of the corresponding heart disorder or arrhythmia". In particular (see page 4, lines 7 to 24), such *"combined pacing and defibrillating functions are quite effective in an implanted device because some symptoms, such as the absence R-waves, could indicate an asystole or life-threatening ventricular fibrillation. It therefore would be desirable to have a combined pacer-defibrillator that first could attempt pacing in the presence of such symptoms, and then, if the symptoms persist, attempt defibrillation."*

Hence, in the light of the whole teaching of document E3, the Board considers that it would be implicit to a person skilled in the art to provide an implantable device for atrial fibrillation and cardiac pacing with all the functionalities of a standard programmable DDD pacemaker, as this arrangement would offer the widest range of options for treating patients with heart problems.

4.2 This choice of the kind of pacemaker to be combined with an implantable atrial defibrillator would also be suggested, for instance, by document E6, which relates to an atrium-controlled heart pacemaker operable in the DDD mode or in the VVI mode. In particular, when an atrial signal appears within a certain interval between two ventricular stimulation pulses, as it could be the case at the onset of atrial tachyarrhythmias, the pacemaker according to E6 is switched for generating either a low pulse rate or a high pulse rate in the VVI mode whereby a predetermined number of ventricular stimulation pulses will be emitted in any event (see E6, column 1, lines 41 to 51). The purpose of this

operation is to provide an atrium-controlled heart pacemaker which guarantees reliable operation independently of the chronological appearance of an atrial signal with respect to a ventricular stimulation pulse (column 1, lines 18 to 22).

The same teaching is divulged by E5 which relates to a dual chamber pacemaker programmed to operate in an atrial rate based mode and which switches automatically to a non-atrial rate based mode for a fixed number of stimulation pulses if the sensed atrial activity indicates that an atrial arrhythmia may be developing (see E5, column 4, lines 36 to 49; column 15, lines 1 to 34).

4.3 In other words, there is ample evidence in the prior art that, at least in the case of patients which are generally treated with an atrial rate based pacemaker, the first provision to be made when an atrial arrhythmia, such as fibrillation, is detected is to switch from the atrial rate based mode to the VVI mode so as to guarantee proper pacing of the ventricle and thus stabilise the cardiac rate. Thus, in the opinion of the Board, it would be a straightforward measure for the person skilled in the art to provide an implantable device for atrial defibrillation and cardiac pacing with the functionality set out in feature (i) of claim 1 according to the main request.

4.4 As to the question of whether the cardioverting electrical energy would be delivered immediately after detection or after a predetermined time interval corresponding to a predetermined number of paced heart cycles, the Board considers that there are several

reasons why the skilled person would prefer the latter. It is generally known that as soon as the need of cardioversion is determined, a capacitor for storing the required cardioverting energy has to be charged and that this requires a certain amount of time. Furthermore, it is also known to apply a routine for confirming the detection of fibrillation before applying cardioverting electrical energy which can cause considerable discomforts to the patient. Finally, it is also known to generate some warning of impending cardioversion by pacing the heart in a distinctive way in order not to shock the patient with an unexpected treatment. Thus, it would be an obvious choice for the skilled person to make provision for operating a combined atrial pacer and defibrillator as indicated by feature (ii) of claim 1.

4.5 In summary, the Board considers that, in the light of E5 (or E6) and of the general knowledge common in the art of cardiac pacing, it would be obvious to a person skilled in the art, wishing to develop an implantable device for atrial defibrillation and cardiac pacing, as referred to in E3, to arrive at a device falling within the terms of claim 1 according to the respondent's main request. Thus, the subject-matter of this claim does not involve an inventive step within the meaning of Article 56 EPC.

Respondent's auxiliary requests

5.1 The independent claims of the auxiliary requests 1 to 4 differ from claim 1 of the main request in that they contain additional features which are known from the prior art (see for instance document E5) and which

represent a straightforward implementation of an obvious teaching consisting in switching a pacer to a non-atrial based pacing mode when atrial tachycardia is detected.

5.2 In particular, claim 1 according to the first auxiliary request specifies that the stabiliser includes a pacer for pacing the ventricles of the heart. As pointed out above, E5 and E6 show a pacer for pacing the ventricles of the heart at the onset of atrial tachycardia.

5.3 As to the second auxiliary request, it would be obvious in the light of the cited prior art for a person skilled in the art to make provision for the pacemaker to apply cardioverting electrical energy to the atria after the ventricles have been paced for a predetermined number of cardiac cycles.

5.4. As pointed out above, the pacer shown in E5 or E6 paces the ventricles in demand mode, as specified in the last feature of claim 1 of the third auxiliary request.

5.5. As to the fourth auxiliary request, it is based on a combination of the features recited in the independent claims according to the first and third auxiliary requests, and therefore it differs from the main request only by features which do not contribute to the inventive step of the claimed subject-matter.

6.1. Claim 1 according to the fifth auxiliary request is based on all the features recited in claims 1 to 5 of the patent as granted and relates, in particular to an implantable atrial defibrillator with a cardioverter which "*applies the cardioverting electrical energy to*

the atria of the heart after the pacer (78) has paced the ventricles for a predetermined number of cardiac cycles", and with *"a pacing rate control (62) for increasing the pacing rate responsive to an unpaced cardiac cycle".* A flow chart of the embodiment of the invention which combines these two features is shown in Figure 3 of the patent specification.

6.2 According to dependent claim 2 of the fifth auxiliary request (cf Figure 4), the atrial defibrillator of claim 1 is "further characterized by a timer (64) for timing of the intervals of the cardiac cycles of the heart and wherein the predetermined number of cardiac cycles is the sum of paced cardiac cycles plus unpaced cardiac cycles having intervals substantially equal to a base interval corresponding to the pacing rate".

In other words, all consecutive (paced or unpaced) cardiac cycles are considered in order to count the predetermined of cardiac cycles, provided that their intervals are substantially equal to a base interval corresponding to the pacing rate.

6.3 This feature of dependent claim 2, however, is in contradiction with the wording of the independent claim which specifies that "the cardioverter applies the cardioverting electrical energy to the atria of the heart after the pacer (78) has paced the ventricles for a predetermined number of cardiac cycles" (emphasis added). As shown in the embodiment of Figure 3, the counter which counts the predetermined number of heart cycles is reset if an unpaced heart cycle (ie an R-wave) is detected. Thus, there is no doubt that, in the context of the claimed invention, pacing the ventricles

actually means delivering a pacing pulse to the ventricles.

Furthermore, in the only embodiment of the invention (see Figure 4) which shows that the predetermined number of cardiac cycles is the sum of paced and unpaced intervals, as set out in claim 2, the pacing rate is not always increased upon detection of an unpaced cycle, as set out in claim 1, but only when the unpaced heart cycle has an interval below a minimum interval T_{MIN} and above the base interval T_B.

6.4 As claim 1 and claim 2 of the fifth auxiliary request comprise some incompatible features, they do not satify the requirement of clarity according to Article 84 EPC.

7. As none of the respondent's requests is allowable, the patent has to be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

R. Schumacher H. Wolfrum