BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

Datasheet for the decision of 22 February 2007

Case Number: T 0544/04 - 3.4.01

Application Number: 93250276.8

Publication Number: 0594273

IPC: A61N 1/39

Language of the proceedings: EN

Title of invention:
Atrial defibrillator for providing improved atrial sensing

Patentee:
CARDIAC PACEMAKERS, INC.

Opponent:
BIOTRONIK GmbH & Co. KG

Headword:
-

Relevant legal provisions:
EPC Art. 100(a), 52(1), 54, 56, 111(1)

Keyword:
-

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0544/04 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 22 February 2007

Appellant: (Opponent)
BIOTRONIK GmbH & Co. KG
Woermannkehre 1
D-12359 Berlin (DE)

Representative:
Eisenführ, Speiser & Partner
Patentanwälte Rechtsanwälte
Spreepalais am Dom
Anna-Louisa-Karsch-Strasse 2
D-10178 Berlin (DE)

Respondent: (Patent proprietor)
CARDIAC PACEMAKERS, INC.
4100 Hamline Avenue North
St. Paul
Minnesota 55112 (US)

Representative:
UEXKÜLL & STOLBERG
Patentanwälte
Beselerstrasse 4
D-22607 Hamburg (DE)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 25 February 2004 rejecting the opposition filed against European patent No. 0594273 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: B. Schachenmann
Members: G. Assi
R. Bekkering

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 23 April 2004, against the decision of the opposition division, dispatched on 25 February 2004, rejecting an opposition against the European patent No. 0 594 273 (application number 93250276.8). The appeal fee was paid on 23 April 2004. The statement setting out the grounds of appeal was received on 1 July 2004.

II. The opposition had been filed against the patent as a whole and was based on the grounds pursuant to Article 100(a) EPC that the subject-matter of the patent was not patentable within the terms of Articles 52(1), 54 and 56 EPC having regard to the following documents among others:

(E1) EP-B-0 533 917;

(E3) EP-A-0 469 817.

After expiry of the time limit for opposition, with a letter of 6 January 2004, the opponent filed the further document:

(E8) US-A-4,974,589.

In the decision under appeal, the opposition division, pursuant to Article 114(2) EPC, disregarded document E8 and, moreover, held that the grounds for opposition did not prejudice the maintenance of the patent as granted.

III. In the appeal proceedings, with the statement setting out the grounds of appeal, the appellant filed the following further documents:

(E9) US-A-5,085,215;

(E10) N.V. Thakor et al., "*Ventricular Tachycardia and Fibrillation Detection by a Sequential Hypothesis Testing Algorithm*", IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, Vol. 37, No. 9, September 1990, pages 837-843;

(E11) J. Jenkins et al., "*Diagnosis of Atrial Fibrillation Using Electrograms from Chronic Leads: Evaluation of Computer Algorithms*", PACE, Vol. 11, May 1988, pages 622-631.

With a letter dated 19 January 2007 in reply to a communication of the Board of Appeal of 20 October 2006 the appellant filed the following further document:

(E12) US-A-4,624,260.

IV. Oral proceedings before the Board were held on 22 February 2007.

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

The respondent (proprietor of the patent) requested that documents E8 to E12 be disregarded and the appeal be rejected.

VI. The wording of the sole claim according to the patent reads as follows:

"*An implantable atrial defibrillator (30) for applying cardioverting electrical energy to the atria (16, 18) of a human heart (10) in need of cardioversion, the atrial defibrillator including a first detector (50) adapted for sensing activity of the heart in at least one of the atria of the heart, an atrial fibrillation detector (70) responsive to the activity of the heart sensed by the first detector for determining when the atria of the heart are in need of cardioversion, a second detector (52) for detecting ventricular activations of the heart, and a cardioverter (76) for applying cardioverting electrical energy to the atria of the heart when the atria of the heart are in need of cardioversion and being responsive to the second detector for applying the cardioverting electrical energy to the atria of the heart in predetermined time relation to a detected ventricular activation, the atrial defibrillator characterized by the atrial fibrillation detector being responsive to recorded activity of the heart sensed by the first detector for determining when the atria of the heart are in need of cardioversion, a recording stage (64) for recording the heart activity sensed by the first detector and data relating to the times in which the second detector detects ventricular activations of the heart, and a stage (66) responsive to the data relating to the times in which the second detector detects ventricular activations of the heart for causing the atrial fibrillation detector to ignore, in determining when the atria are in need of cardioversion, the recorded activity of the heart sensed by the first detector*

during the times of detection by said second detector of ventricular activations of the heart."

Reasons for the Decision

1. The appeal is admissible.

2. *Opposition grounds with regard to the prior art cited in the notice of opposition*

2.1 The Board has no reason to disagree with the reasons given by the opposition division in the decision under appeal for its conclusion that the claimed subject-matter was new and involved an inventive step having regard to documents E1 and E3 considered to be the most relevant among those cited with the notice of opposition.

2.2 An issue in dispute concerned the meaning to be given to the claimed terms "*record*" and "*ignore*" in the context of the patent disclosure.

In the appellant's view, according to the invention (see Figures 1 and 2; paragraph [0035]) the microprocessor, at stage 116, recorded a detected R-wave in the recording stage 64 and the blanking stage 66 precluded the recording stage 64 from recording the atrial activity sensed by the atrial channel. According to the modification described in paragraph [0038], the atrial fibrillation detector 70 was implemented to process stored data of atrial and ventricular activity, which were time stamped. This indicated that the terms "*record*" and "*store*" had different meanings, the former

term referring to atrial activity being sensed by the atrial detector. With this understanding, the claimed feature of "*ignoring*" the recorded activity sensed by the atrial detector corresponded to "*blanking*" the atrial channel.

The respondent disagreed. In its view, all necessary heart activity data was recorded but a portion of the recorded atrial activity related to the times of detection of ventricular activity was ignored in determining whether the atria were in need of cardioversion. This approach differed from the provision of an atrial blanking period preventing atrial activity from being detected.

According to the present invention as claimed, the atrial fibrillation detector 70 detects fibrillation by processing digital data provided by the atrial detector ("*first detector*") 50 and the analog to digital converter 60. In order to avoid the problem of far field R-wave detection, the fibrillation detector "*ignores*", i.e. does not process, some atrial data. A criterion is established for defining the atrial data to be ignored, which is implemented by the claimed recording stage 64 and stage 66. The criterion essentially relies on the determination of simultaneous occurrence of atrial and ventricular activity. Thus, atrial and ventricular information must be available in some form for selection of the atrial data to be processed by the atrial fibrillation detector. In the Board's view, the availability of the data is ensured according to the invention either by recording or storing the data. This reasonably means that the data are retained in the recording stage 64 at least for the

time needed for carrying out the criterion or for a longer time, in which case they are rendered identifiable by means of time stamps. The stage 66 has access to data in the recording stage 64 for selecting atrial data to be sent to the atrial fibrillation detector 70, i.e. for causing the atrial fibrillation detector to ignore some of the recorded atrial activity. Therefore, there is no contradiction between the terms "*record*" and "*store*", both terms referring to atrial and ventricular data being retained in order to be used for determining whether atria are in need of cardioversion. In this respect, it is noted that the ventricular channel continuously detects ventricular activity whereas the atrial channel is enabled if there is a reason to suspect the occurrence of an episode of atrial fibrillation (see paragraphs [0026], [0027] and [0033]). In conclusion, the Board does not find convincing the appellant's interpretation, for which the whole disclosure of the invention does not provide a support.

2.3 The parties and the opposition division agreed that an implantable atrial defibrillator according to the preamble of the claim was known from document E1 (see patent in suit, paragraph [0011], the Canadian application mentioned there corresponding to document E1). The Board has no reason to take a different view.

With regard to the characterising portion, the appellant considered that the known defibrillator also comprised the first two features, namely "*the atrial fibrillation detector being responsive to recorded activity of the heart sensed by the first detector for determining when the atria of the heart are in need of*

cardioversion" and "*a recording stage (64) for recording the heart activity sensed by the first detector*". The respondent disagreed with this view.

In this respect, the Board concurs with the opposition division that E1 does not disclose a unit for recording atrial activity comparable to the recording stage 64 of the invention, which is functionally distinguished from the atrial fibrillation detector 70 (see paragraph [0028]; Figure 1). The memory 92 of the defibrillator known from E1 (see column 6, line 52 to column 7, line 9), in particular, cannot be regarded as a recording stage in the sense of the present invention but rather corresponds to the memory mentioned in paragraph [0029] of the patent in suit. As a consequence of this finding, E1 (see Figure 1) does not disclose the feature that the atrial activity sensed by the amplifier 54 and digitally converted by the converter 60 is "*recorded*" prior to being sent to the atrial fibrillation detector 82.

Hence, the claimed subject-matter is novel with regard to E1 which only discloses the features of the preamble of the claim. As a matter of fact, novelty as such was acknowledged by the appellant in the grounds of appeal.

2.4 The implantable atrial defibrillator according to E1 has the drawback that atrial events due to far field R-wave detection are processed by the atrial fibrillation detector when determining whether the atria are in need of cardioversion (see paragraph [0011] of the patent in suit).

The appellant agreed with this definition of the problem and correctly stated that it was known to the skilled person. In its view, the claimed solution relying on the provision of the recording stage 64 and the blanking stage 66 might be understood as a measure, known from document E3, for blanking the atrial channel (see above). Thus, the claimed subject-matter did not involve an inventive step having regard to the combination of E1 and E3.

This argumentation, disputed by the respondent, is not convincing. Document E3 (see claim 1; abstract; page 3, lines 1-4; Figure 1) discloses an arrhythmia control system which monitors the cardiac state of a patient, utilizes an arrhythmia recognition algorithm to detect inter alia supraventricular tachycardia, and delivers therapy in the form of electrical energy to cardiac tissue for reverting selected arrhythmias and restoring normal sinus rhythm. It is known that atrial fibrillation is a type of supraventricular tachycardia. In a preferred form, the known system comprises an implantable combined dual chamber pacing and cardioverting device including means for sensing the atrial and ventricular signals, means for storing data corresponding to said signals, and means for delivering cardioversion shock therapy to the heart as required. In operation (see page 5, lines 8-34; Figure 1), the sensed signals are led to a sensing circuitry 16. In addition, the sensing circuitry 16, via a bus 28, receives input atrial and ventricular sense control signals from a microprocessor 19, which determine the sensitivity of the sensing circuitry. A change in the sensitivity affects the voltage deviation required at the sensing electrode for a sense to be registered.

The invention according to E3 aims at reducing or eliminating the "*false*" triggering of electrical discharges due to the occurrence of benign supraventricular tachycardia in a patient (see page 3, lines 39-41). This formulation implies the idea that the arrhythmia reversion should be triggered on the basis of reliable atrial data only. In this respect, the far field R-wave detection problem is addressed (see page 8, line 44 to page 9, line 1) in relation to the description of the arrhythmia recognition algorithm for an implantable dual chamber arrhythmia control device. In particular, upon the occurrence of an R-wave, a far field R-wave flag is set and a far field R-wave timer is reset to zero, which cause a blanking period to occur in the atrial channel to prevent any events from being detected in that channel during the blanking period. This is done in order to prevent an atrial event from being logged during the time period when a ventricular R-wave signal is occurring, since this event might be erroneously sensed in the atrial channel as a P-wave. The far-field R-wave timer is regularly incremented and the algorithm checks to determine whether the far-field R-wave timer has completed its timing period.

It thus results that the solution proposed by E3 for the problem of far field R-wave detection consists in blanking the atrial channel for a given period, i.e. in rendering the atrial channel insensitive to all signals by controlling its sensitivity. This solution is different from the claimed one in the Board's interpretation of the claim, according to which the problem of far field R-wave detection is solved by

selecting, on the basis of a time coincidence criterion, atrial data to be sent to the atrial fibrillation detector out of data provided by the atrial and ventricular channels. In view of the basically different approach, the atrial blanking period known from E3, on which the appellant based its argumentation, does not render obvious the claimed solution relying on the provision of the recording stage 64 and the stage 66.

2.5 Hence, the Board concludes that, with regard to the combination of documents E1 and E3, the grounds for opposition pursuant to Article 100(a) EPC in relation with Articles 52(1), 54 and 56 EPC do not prejudice the maintenance of the patent unamended. The same conclusion applies with regard to the other documents cited with the notice of opposition, which are considered to be less relevant that E1 and E3 and on which the appellant did not rely in appeal proceedings.

3. *Document E8 filed in the opposition proceedings*

3.1 Document E8 was filed by the appellant in the opposition proceedings after expiry of the time limit for opposition as evidence for the knowledge of the skilled person at the priority date of the present invention with regard to blanking. The opposition division decided to disregard this document with the argument that a patent application could not be considered as evidence for the common general knowledge.

3.2 In the appeal proceedings, the appellant did not contest the opposition division's conclusion; moreover, it did not produce any argument relying on E8 alone or in combination with other documents.

Thus, the Board has no reason to depart from the decision of the opposition division in this respect.

4. *Documents E9 to E12 filed in the appeal proceedings*

4.1 In the oral proceedings before the Board, the appellant stated that document E12 was the most relevant among the documents filed in the appeal proceedings. Indeed, E12, together with E3, played a main role in the appellant’s argumentation in the letter of 19 January 2007. In its view, E12 dealt with the problem of sensing atrial activity while "*ignoring*" atrial spurious signals from the ventricle (see column 1, first paragraph; column 5, lines 8-11, term "*ignore*"). Thus, the problem to be solved as well as the terminology used, which was similar to that of the patent in suit, rendered the document highly relevant for the present invention, in particular having regard to the issue concerning the interpretation of the claim.

The respondent considered inadmissible the late filing of a document disclosing general knowledge.

The Board agrees with the respondent that E12 is late filed. However, it is equitable to consider a document, which might be relevant, in the interest of the EPO to maintain valid patents and, owing to the new factual situation, to give the respondent the possibility to present its case in two instances. The Board thus

refrains from commenting the appellant's submissions concerning the relevance of E12 (see letter of 19 January 2007) and deliberately leaves open the question whether E12 is likely to prejudice the maintenance of the patent, since this might risk prejudicing the first instance consideration which is ordered below.

4.2 As regards the remaining documents E9 to E11, E9 may be disregarded since, as the appellant itself admitted in the oral proceedings, it is less relevant than E12. On the other hand, documents E10 and E11 are acknowledged as state of the art in document E1 (see column 11, lines 6-21) and, therefore, should not be disregarded.

5. *Remittal*

In conclusion, the Board remits the case to the opposition division for further prosecution having regard to documents E10, E11 and E12.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

R. Schumacher B. Schachenmann