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D E C I S I O N
of 30 November 2004

Case Number: T 0926/01 - 3.4.1

Application Number: 91300085.7

Publication Number: 0436517

IPC: A61N 1/368

Language of the proceedings: EN

Title of invention:
Apparatus for antitachycardia pacing in dual chamber arrhythmia control system

Patentee:
Pacesetter, Inc.

Opponent:
Biotronik GmbH & Co. KG

Headword:
-

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

Keyword:
"Novelty, inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0926/01 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 30 November 2004

Appellant: (Opponent)	Biotronik GmbH & Co KG Woermannkehre 1 D-12359 Berlin (DE)
Representative:	Eisenführ, Speiser & Partner Patentanwälte Rechtsanwälte Postfach 310260 D-80102 München (DE)
Respondent: (Proprietor of the patent)	Pacesetter, Inc. 15900 Valley View Court Sylmar, CA 91342 (US)
Representative:	Hackett, Sean James Marks & Clerk Alpha Tower Suffolk Street Queensway Birmingham B1 1TT (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 11 June 2001 rejecting the opposition filed against European patent No. 0436517 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: G. Davies
Members: R. Q. Bekkering
M. G. L. Rognoni

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 11 June 2001, rejecting the opposition against European patent No. 0 436 517. The notice of appeal was received on 9 August 2001, the appeal fee being paid on the same day, and the statement setting out the grounds of appeal was received on 11 October 2001.

II. Opposition had been filed against the patent as a whole based on Article 100(a) EPC, in particular on the ground of lack of inventive step (Articles 52(1), 56 EPC).

III. In the appeal proceedings reference was made to the following documents:

E1: EP-A-0 087 756

E2: S.M. Maas and J. Wickham, "Tachyarrhythmia therapy utilizing electrical stimulation: A review", Journal of Medical Engineering and Technology, Vol. 12, No. 6, November/December 1988, pages 255 to 259

E3: S. Levy, "Treatment of tachycardias by dual demand A-V sequential pacing", Cardiac pacing, 1982, pages 347 to 350

IV. Oral proceedings, requested by both parties, were held on 30 November 2004.

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

VI. The respondent (patentee) requested that the appeal be dismissed.

VII. Claim 1 of the patent as granted, using the feature numbering adopted in the opposition procedure, is directed to:

(1) a dual chamber antitachycardia pacing device (1) for the reversion of tachycardias in a heart (11) comprising:
(2) means (19) for detecting tachycardia,
(3) means (53) for measuring cycle length of said tachycardia,
(4) means (39) for determining an initial value of an AV delay interval,
(5) pulse generating means (17) for generating heart stimulating pulses for the atrium and for the ventricle,
(5a) responsive to said tachycardia detecting means,

characterised in that

(6) the dual chamber antitachycardia pacing device comprises means (56) for determining a value of a VA delay interval less than or equal to the tachycardia cycle length,

and in that

(5b) said pulse generating means includes means (39) for delivering a predetermined series of M pulse trains with each train consisting of a total of 2N,

where M and N are integers greater than 1, pacing pulses,

(5c) delivered in an alternating sequence to respective atrial and ventricular cardiac leads (21 and 31),

(5c1) so that timing of said delivered pulses is in accordance with the values of the VA delay interval and the AV delay interval, whereby each train comprises the delivery of a pacing pulse to atrial cardiac lead at the expiration of each of N VA delay intervals and a pacing pulse to the ventricular cardiac lead at the expiration of each of N AV delay intervals, and

(7) means (28 and 38) for varying said AV delay interval from said programmed initial value at least once prior to completion of said series of M pulse trains.

VIII. The appellant argued that the subject-matter of claim 1 lacked novelty with respect to document E1. In particular, the appellant considered a number of features of claim 1 to be at least implicit to a skilled reader from the rather concise description of the document. Furthermore, the subject-matter was at any rate considered to follow in an obvious manner from the general background knowledge of the skilled person as documented by document E2 in conjunction with the teaching of document E1.

IX. The respondent submitted that the teaching of document E1 was insufficient as far as the delivery of stimulation pulses to both the atrium and the ventricle for the purposes of terminating a tachycardia was concerned. The skilled reader of document E1 would have, if at all, only arrived at the claimed device of the

patent in suit with the benefit of hindsight. Also a combination of E1 with the teaching of document E2 would not have led to the claimed device in an obvious manner.

Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 and Rule 64 EPC and is therefore admissible.

2. *Novelty*

2.1 Document E1

From document E1 a dual chamber AV sequential demand pacemaker is known. The device is equipped with pacing means (10, 20) and sensing means (13, 23) for both the atrium and the ventricle (see the figure and corresponding description). On demand, that is to say in the absence of the detection of a natural contraction in the atrium or ventricle, the device will deliver a respective stimulation pulse. The time interval between an atrial event, either natural or stimulated, and the delivery of a stimulation pulse to the ventricle, the AV delay, is controlled by a time delay element (3). The reverse case is also possible whereby the delay element controls the time interval between a ventricular event and the delivery of a stimulation pulse to the atrium, the VA delay (see page 5, line 12 to page 6, line 2).

Furthermore, the pacemaker is equipped with additional means (5), which can be connected to the atrium or the ventricle, for detecting the presence of a tachycardia.

Following detection of the presence of a tachycardia, an antitachycardia pulse therapy is delivered in an attempt to terminate the tachycardia.

In a first case the antitachycardia pulse therapy consists of stimulating in the ventricle with a modified AV delay after an event in the atrium (see page 3, lines 3 to 8). Upon detection of a tachycardia the AV delay controlled by delay element (3) is modified from its normal value for a predetermined amount of time (see page 3, last paragraph). Should, after expiry, the tachycardia still exist, the AV delay is again modified. Alternatively, the AV delay returns to its normal value upon termination of the tachycardia as sensed by the tachycardia detector (5) (see page 4, first paragraph).

The modification of the AV delay may consist of a change to a reduced preset value and subsequent return to the initial value at termination of the tachycardia, or it may consist of a change according to a preset pattern, whereby for instance at each heart cycle the AV delay is increased or decreased (see page 3, line 22 to page 4, line 25).

In document E1 (see paragraph bridging pages 7 and 8) it is recognised that the tachycardia is prevented or terminated due to the delivery of an early stimulation pulse to the ventricle, anticipating the arrival of an activation signal from the atrium, placing the

ventricle in a refractory phase and thus making it unreceptive for the activation signal arriving from the atrium. Further activation is thus blocked.

Accordingly, in this case, in order to terminate the tachycardia, the device provides ventricular pacing triggered by atrial events.

The reverse case is also possible in order to terminate a tachycardia. In this case it is foreseen to derive the control signals from the ventricle and stimulate in the atrium (see page 3, lines 8 to 10). No further information is however provided in E1 concerning this reverse case, in particular as far as the VA delay to be used or the underlying physiological principle is concerned.

At any rate, in neither case it is explicitly foreseen to deliver, in an alternating sequence, stimulation pulses to the atrium and the ventricle.

However, as pointed out by the appellant, if the demand pacemaker of E1 in normal operation were to deliver stimulation pulses to the atrium due to a complete lack of natural atrial contractions, it has to be fairly assumed that, after onset of a ventricular tachycardia the pacemaker would continue to deliver stimulation pulses to the atrium during the delivery of the antitachycardia therapy. This therapy may, as discussed above, consist of ventricular stimulations following an atrial event, which under these circumstances would consist of an atrial stimulation.

Accordingly, in principle, the pacemaker of E1 can deliver a series of alternating atrial and ventricular stimulation pulses following the detection of a tachycardia.

However, the number of pulses delivered to the atrium in the antitachycardia sequence would depend on the presence or absence of natural contractions in the atrium and thus not necessarily result in a predetermined series of at least eight pulses delivered in an alternating sequence to the atrium and the ventricle, as *inter alia* required by feature (5b) of claim 1 of the patent in suit.

Moreover, there is no indication in document E1 that the VA delay between the delivery of a stimulation pulse to the atrium and to the ventricle should be taken to be less or equal to the tachycardia cycle length, as required by feature (6) of claim 1 in suit.

As such, there is no indication in Document E1 that the tachycardia cycle length (TCL) should be determined either. The appellant argued in this respect that the detection of the presence of a tachycardia as foreseen in E1 inevitably required a measurement of the TCL. It is however clear that a number of alternative ways for detecting tachycardias are available which do not rely on the measurement of the TCL, such as counting the number of events in a given time interval and comparing the count with a predetermined threshold value. Feature (3) of claim 1 as granted, therefore, cannot be held to be implicit from document E1.

Accordingly, the subject-matter of claim 1 as granted is novel with respect to document E1 (Articles 100(a), 52(1), 54(1) and (2) EPC).

2.2 Document E2

In document E2 various pulse sequences are discussed for pacemaker treatment of tachycardias. The aim is to deliver a premature pulse in a particular time zone prior to a natural contraction which will terminate the tachycardia (see page 256, left-hand column, second paragraph). The underlying principle of all sequences is to deliver stimulation pulses with intervals slightly below or above the TCL so that eventually a pulse will hit the tachycardia termination zone and stop the tachycardia (see "tachycardia termination algorithms", pages 257 and 258). Burst pacing and auto-incremental pacing (see page 258) are examples of such sequences in which a fixed number of pacing pulses is delivered. The interval between the pulses in the train is determined by the TCL and altered throughout the train.

There is, however, no indication in document E2 of a sequence of alternating pulses to the atrium and the ventricle.

Accordingly, the subject-matter of claim 1 as granted is also novel with respect to document E2.

2.3 Document E3

Document E3 discloses an AV sequential pacemaker for terminating tachycardias (see page 347, right-hand

column, last paragraph, page 348, left-hand column, first and second paragraphs and table III). Under normal conditions the pacemaker operates in the DVI mode. When however a tachycardia is detected, defined as five beats with a TCL shorter than 395 ms which corresponds to a rate higher than 150 bpm, the pacemaker switches to the DVO mode, that is to say with pacing in both the atrium and ventricle without inhibition, at a fixed rate of 77 bpm and with the AV delay reduced from 150 ms to 65 ms. Accordingly, the VA delay (about 715 ms) is substantially longer than the TCL in this case. Furthermore, there is no concrete indication in E3 of the (minimum) number of pulses used for terminating the tachycardia.

The subject-matter of claim 1 as granted is therefore also novel with respect to document E3.

3. *Inventive step*

3.1 Taking document E1 as the closest prior art, in view of the above identified distinguishing features of claim 1 the objective problem-to-be-solved could be seen as improving the antitachycardia therapy of document E1.

The appellant argued that as far as the number of consecutive pulses to be delivered as part of the antitachycardia therapy was concerned, the claimed sequence according to feature (5b) of claim 1 did not provide any recognisable unexpected effect and hence had to be seen as an arbitrary selection. Furthermore, a sequence of eight stimulation pulses was explicitly mentioned in document E2 (see page 258, "burst pacing")

as a suitable number of pulses forming a short burst for tachycardia termination.

Furthermore, it was submitted that based on the teaching of document E2, providing an overview of general principles of tachycardia therapies forming part of the general background knowledge of the skilled person, the skilled person would have been aware that the ventricular stimulations delivered as antitachycardia therapy in document E1 should have an intervening interval close to the TCL. As a consequence, the VA delay would have to be shorter then the TCL. Accordingly, both the requirement of determining the TCL according to feature (3) of the claim in suit, as well as feature (6) would have been readily apparent to the skilled person.

In the board's view, however, documents E1 and E2 rather provide two alternative solutions for tachycardia termination. In both cases the delivered pulse therapy aims at delivering a stimulation pulse to the ventricle at the right time, anticipating the arrival of the activation signal from the atrium, thereby placing the ventricle in a refractory phase and thus making it unreceptive for the arriving activation signal. Document E1 seeks to achieve this by delivering ventricular stimulations timed with respect to natural atrial contractions, document E2 in contrast by predetermined variations in the interval between the ventricular stimulations. There is nothing to suggest the skilled person that these two alternatives should be combined.

Neither can a setting of the VA delay in E1 equal to or less than the TCL be considered obvious. As discussed above, there is no explicit teaching in document E1 to stimulate the atrium in addition to the ventricle as part of the antitachycardia therapy. The stimulation of the atrium can nonetheless arise from the demand character of the pacemaker in the absence of natural atrial activity. However, under these circumstances there would be no obvious reason to stimulate the atrium at a very high rate, equal to or above the rate of the tachycardia.

In the patent in suit, on the other hand, it is recognised that the delivery of stimulation pulses to the atrium as part of the antitachycardia therapy, irrespective of the presence of any natural activity in the atrium, providing synchrony between the atrium and the ventricle, *inter alia* aids in maintaining the arterial pressure during the therapy and increases the chances of successful termination of the tachycardia.

3.2 In view of the above, in the board's opinion the cited prior art cannot be held to render the claimed solution obvious. Therefore, an inventive step has to be recognised for the subject-matter of claim 1 (Articles 100(a), 52(1) and 56 EPC).

3.3 The remaining claims 2 to 24 are dependent on claim 1 and provide further preferred features of the pacing device. The subject-matter of these claims, therefore, also involves an inventive step.

4. In view of the above, the grounds of opposition invoked by the appellant do not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher G. Davies