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D E C I S I O N
of 27 June 2003

Case Number: T 0146/99 - 3.4.1

Application Number: 90303812.3

Publication Number: 0401962

IPC: A61N 1/368

Language of the proceedings: EN

Title of invention:
Device for combined cardiac pacing and defibrillation

Patentee:
VENTRITEX, INC.

Opponent:
Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro Berlin

Headword:
Device for combined cardiac pacing and defibrillation/Ventritex, Inc.

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

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
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Case Number: T 0146/99 **-** 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 27 June 2003

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 7 December 1998 rejecting the opposition filed against European patent No. 0401962 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: G. Davies
Members: H. K. Wolfrum
R. Q. Bekkering

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 7 December 1998 rejecting the opposition. The notice of appeal was received on 3 February 1999 and the prescribed fee was paid on 11 February 1999. The statement setting out the grounds of appeal was received on 9 April 1999.

II. The opposition had been filed against the patent as a whole and based *inter alia* on the ground of Article 100(a) together with Articles 52(1) and 56 EPC by making reference *inter alia* to document :

E3: WO-A-89/01 802.

III. In a communication dated 2 September 2002 annexed to a summons to attend oral proceedings the Board expressed doubts as to the patentability of the subject-matter of claim 1 of the patent as granted.

IV. In reaction to said summons, the respondent (patent proprietor) announced in a letter dated 30 January 2003 that it would not be represented at the oral proceedings scheduled for 25 March 2003 and withdrew its request for oral proceedings.

The respondent has requested that the appeal be dismissed and the patent be maintained as granted.

V. The appellant has requested that the contested decision be set aside and the European patent be revoked in its entirety.

By a letter dated 17 February 2003, the appellant informed the Board that it would not insist on its auxiliary request for oral proceedings in case the appeal could be allowed and asked whether the oral proceedings would be cancelled.

VI. By a notification of 13 March 2003, the Board cancelled the oral proceedings.

VII. Independent claim 1 of the granted patent reads as follows:

"1. A device for combined cardiac pacing and defibrillating comprising:

an implantable pacer/defibrillator having sensing and pacing leads (42,44)
for connection to the atrium and the ventricle;
means (71) for sensing P-waves and R-waves;
means (90) for determining the presence of an arrhythmia; and
means (90) for providing arrhythmia therapy;
characterized by:
said pacer/defibrillator having a V-V timer for timing a V-V time interval and
a V-A timer for timing a V-A time interval, and
said device further including:
means (79) for resetting the V-V timer and the V-A timer if an R-wave is
sensed;
means (38) for providing a pacing stimulus to the ventricle if no R-wave is
sensed during the V-V time interval;
means (79) for inhibiting the pacing stimulus to the ventricle if an R-wave is

sensed during the V-V time interval;

means (79) for inhibiting a pacing stimulus to the atrium if a P-wave is

sensed during the V-A time interval; and

wherein said means (90) for determining the presence of an arrhythmia

determines the presence of said arrhythmia if an R-wave is sensed during the V-V time period; and

wherein said means (90) for providing arrhythmia therapy provides said

arrhythmia therapy if an R-wave is sensed during the V-V time period and an arrhythmia is determined to be present."

VIII. The appellant sees the subject-matter of claim 1 rendered obvious for a skilled person by the teaching of document E3 which related to an implantable device combining a dual chamber pacer with a defibrillator. Although a DDI pacing mode of operation was not explicitly mentioned in E3, this mode constituted the dual chamber analogue to the VVI pacing mode specifically referred to in E3. Moreover, as far as the determination of an arrhythmia by means of a sensing of R-waves was concerned, a DDI mode of operation did not require different measures than a VVI mode of operation. In this context, the tachycardia detection window according to E3 was to be considered to correspond to the claimed V-V and V-A time intervals.

IX. The respondent disputed the appellant's view, relying essentially on the following arguments:

Document E3 did not teach the dual chamber DDI pacing mode according to claim 1, but merely made a passing reference to dual chamber pacing. Moreover, it did not

teach the claimed means for determining the presence of an arrhythmia which determines the presence of an arrhythmia specifically if an R-wave is sensed during the V-V time period, and means for providing arrhythmia therapy which provides the arrhythmia therapy if an R-wave is sensed during the V-V time period and an arrhythmia is determined to be present. Whilst a similarity might be seen between a tachycardia detection window established according to E3 and the V-V time interval of the present invention, the former was significantly different from the V-A time interval. The known device did not have a V-A timer nor means for resetting the V-A timer if an R-wave is sensed, and the known detection window would not lead one to the use of the V-A time interval.

These distinguishing features were neither known from nor rendered obvious by any other document of the prior art cited in opposition.

X. According to the opposition division, the patent addressed the problem to provide dual chamber bradycardia support pacing for patients who needed an implantable defibrillator, with a minimum of adverse device mode interaction, and to reduce the incidence of atrial fibrillation induced by shocks for ventricular tachyarrhythmias. The solution was seen in the provision of a DDI-pacer having means determining the presence of an arrhythmia if an R-wave is sensed during the V-V time period and means for providing arrhythmia therapy if an R-wave is sensed during the V-V time period and an arrhythmia is determined to be present.

Document E3 referred only in a generalised manner to dual chamber pacing with which the skilled reader

associated rather DDD than DDI mode pacing. Moreover, the means for determining tachycardia and providing arrhythmia therapy were different in that, according to E3, events falling within a detection window were counted and therapy was delivered after reconfirmation of a certain condition to be met for the counted events. Therefore, the skilled man would not be inspired to derive the claimed V-A timer from the commonly known V-V and A-V intervals.

Reasons for the Decision

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

2. For the following discussion of the matter of inventive step, the Board will rely on a more convenient arrangement of the features of claim 1 as follows:

A device for combined cardiac pacing and defibrillating which comprises:

(a) an implantable pacer/defibrillator having

(b1) a **V-V timer** for timing a V-V time interval and

(b2) a **V-A timer** for timing a V-A time interval, and having

(c) **sensing and pacing leads** for connection to the atrium and the ventricle;

(d) **means for sensing P-waves and R-waves**;

(e) **means for resetting the V-V timer and the V-A timer** if an R-wave is sensed;

(f) **means for providing a pacing stimulus to the ventricle** if no R-wave is sensed during the V-V time interval;

(g) **means for inhibiting the pacing stimulus to the ventricle** if an R-wave is sensed during the V-V time interval;

(h) **means for inhibiting a pacing stimulus to the atrium** if a P-wave is sensed during the V-A time interval;

(j) **means for determining the presence of an arrhythmia** which determines the presence of an arrhythmia if an R-wave is sensed during the V-V time period; and

(k) **means for providing arrhythmia therapy** which provides the arrhythmia therapy if an R-wave is sensed during the V-V time period and an arrhythmia is determined to be present.

3. From document **E3** (see in particular Figure 1 with the corresponding description on pages 9 to 11) a device for combined cardiac pacing and defibrillating is known which comprises an implantable pacer/defibrillator having pacing leads, means for determining the presence of an arrhythmia, and means for providing arrhythmia therapy. According to page 11, lines 10 to 13, the "*pacemaker ... functions as a programmable bradycardia support pacemaker which preferably provides VVI pacing. However dual chamber pacing may also be provided.*" Thus, although in the preferred embodiment shown by

Figure 1 of E3 the pacer operates in the VVI mode (for which sensing and pacing occurs via a single bipolar lead in the ventricle only and a pacing stimulus to the ventricle is inhibited if a natural ventricular activity (ie an R-wave) is sensed during the V-V time period), the teaching of E3 nevertheless envisages as an alternative dual chamber pacing implying the provision of pacing and sensing leads connected to the atrium as well. In this context it can be directly inferred from the indicated function as a bradycardia support pacemaker that the dual chamber pacing should also be a pacing on demand and hence a pacing stimulus to the atrium would be inhibited if a natural atrial activity (ie a P-wave) is sensed. Moreover, it is apparent from Figures 3 and 5 and page 18, lines 3 to 1, and 26 to 35, of E3 that the beginning and duration of various time intervals, including a time interval within which the presence of a tachycardia is determined, is set by means of timers with the last detected ventricular activity (R-wave) acting as a point of reference.

4. There is no dispute between the parties that the device according to E3 shows aforementioned features (a), (c), (d), (f), (g) and (h), the latter except for the reference to specifically the V-A time interval.

However, the respondent sees the claimed subject-matter to be distinguished from the known device by the provision of timers as specified by features (b1), (b2) (and in particular by the use of a V-A timer), means for resetting these timers according to feature (e) and means for determining the presence of an arrhythmia as well as for providing arrhythmia therapy if an R-wave is sensed during the V-V time period according to

features (j) and (k). Moreover, E3 did not teach a DDI mode of pacing.

5. As regards the alleged difference concerning the pacer mode of operation (DDI versus DDD), the Board notes that claim 1 under consideration defines in this respect means for pacing and sensing in both the atrium and the ventricle and means for inhibiting stimulation in the presence of a natural P- or R-wave. As a matter of fact, a pacer having such means can be both a DDD mode pacer or a DDI mode pacer. There is nothing in claim 1 as granted from which it could be inferred that the pacer would necessarily and exclusively be operated in the DDI mode.

As indicated in item 3 above, means having exactly the functions of dual chamber operation specified in claim 1 are implied in the dual chamber alternative of the pacer/defibrillator indicated in E3.

6. With respect to the provision of a V-V and a V-A timer according to features (b1), (b2) and the means of their resetting according to feature (e) of claim 1, it is evident from column 5, lines 27 to 52, and column 8, line 53, to column 9, line 5, of the patent description that the role of the respective time intervals is to establish whether natural atrial and ventricular events occur at a desired rate so as to either inhibit the delivery of respective stimulating pulses to the atrium or ventricle if an event is sensed before the end of the respective time intervals or to provide stimulating pulses if no natural event is sensed within the time intervals. In particular the V-A interval, which is the longest time interval allowed for a natural atrial activity to follow a preceding ventricular activity,

does not have any other recognizable function than the implementation of a "waiting time" for the atrial activity (P-wave) to occur before the atrium would have to be paced. This, however, is a basic function performed by a dual chamber pacer operating in the DDI or DDD mode and not functionally related to defibrillation.

As regards the respective technical teaching given by E3, it predominantly concentrates on the means and measures taken for arrhythmia detection and treatment and does not discuss in detail circumstances of the indicated bradycardia support on demand. Nevertheless, the reference in E3 to a dual chamber pacing on demand implies the provision of appropriate timers and the setting of respective time intervals for the sensing of P- and R-waves. In this context, the Board is of the opinion that, for the skilled person having to complete the information missing from E3 so as to establish a dual chamber bradycardia support pacing by the known pacer/defibrillator, the last occurrence of a ventricular activity, ie a sensed R-wave, would appear a logical point of reference for the choice of suitable time intervals. Hence, the setting of a V-V time interval for sensing of natural ventricular events and of a V-A time interval for the sensing of natural atrial events together with the provision of the corresponding timers and means for resetting constitutes an obvious selection from among a very limited number of alternatives.

7. Finally, as regards features (j) and (k), the Board considers it a triviality that, for detecting for instance the occurrence of a ventricular arrhythmia, eg a ventricular tachycardia, the ventricular activity has

to be observed. Thus, the sensing of R-waves (which inevitably takes place in the V-V time interval) is an indispensable prerequisite for determining a (ventricular) arrhythmia and the corresponding provision of an arrhythmia therapy. Moreover, this is exactly what is apparent from E3 (cf. for instance Figures 3 and 5), when, subsequent to the sensing of an R-wave as a point of reference, further ventricular events are eventually observed to occur in close succession during subsequent time intervals, and, after confirmation of a tachycardia or arrhythmia in general, therapy is commenced.

8. For the above reasons, a device according to claim 1 of the patent as granted is rendered obvious to the skilled person by the teaching of E3.

Consequently, the ground of opposition under Article 100(a) EPC together with Article 56 EPC prejudices the maintenance of the patent.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar: The Chairman:

R. Schumacher G. Davies