DECISION of 17 January 2006

Case Number: T 0261/04 - 3.4.01
Application Number: 93250265.1
Publication Number: 0594271
IPC: A61N 1/39
Language of the proceedings: EN

Title of invention:
Atrial defibrillator for providing synchronized delayed cardioversion

Patentee: CARDIAC PACEMAKERS, INC.

Opponent: BIOTRONIK GmbH & Co. KG

Headword: -

Relevant legal provisions:
EPC Art. 52(1), 54(1),(2)

Keyword: "Novelty (no)"

Decisions cited: -

Catchword: -
Case Number: T 0261/04 - 3.4.01

DECISION
of the Technical Board of Appeal 3.4.01
of 17 January 2006

Appellant: BIOTRONIK GmbH & Co. KG
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Representative: Eisenführ, Speiser & Partner
Patentanwälte Rechtsanwälte
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Respondent: CARDIAC PACEMAKERS, INC.
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Representative: UEXKÜLL & STOLBERG
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
10 December 2003 concerning maintenance of
European patent No. 0594271 in amended form.

Composition of the Board:
Chairman: B. Schachenmann
Members: R. Bekkering
          H. Wolfrum
Summary of Facts and Submissions

I. The appeal was lodged by the opponent (appellant) against the interlocutory decision of the opposition division, dispatched on 10 December 2003, to maintain European patent No. 0 594 271 in amended form. The notice of appeal was received on 10 February 2004 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 19 April 2004.

II. In the interlocutory decision of the opposition division the patent was maintained in amended form on the basis of the following documents:

Claims: Nos. 1 and 5 filed during the oral proceedings before the opposition division on 11 November 2003; Nos. 2 to 4 and 6 of the patent specification;

Description: Columns 1 to 7 of the patent specification; Column 8 filed during the oral proceedings before the opposition division on 11 November 2003;

Drawings: Sheet 1/1 of the patent specification.

III. The appellant requested that the decision under appeal be set aside and the patent revoked in its entirety.

IV. The patentee (respondent) requested that the appeal be rejected and the patent maintained as granted.
V. Oral proceedings, requested by both parties as an auxiliary measure, were held on 17 January 2006. The respondent did not attend the oral proceedings, as announced by letter dated 21 December 2005.

VI. Reference was made inter alia to the following prior art document:

E1: CA-A-2 083 678

VII. Claim 1 in suit reads as follows:

"1. An implantable atrial defibrillator (30) for providing cardioverting electrical energy to the atria (16, 18) of a human heart (10), the atrial defibrillator including a first detector (52) for detecting ventricular activations of the heart and a cardioverter (78) for applying the cardioverting electrical energy to the atria of the heart, the atrial defibrillator characterized by a delay stage (82) responsive to the first detector for causing the cardioverter to apply the cardioverting electrical energy to the atria of the heart after completion of a ventricular activation and before the T wave of the heart immediately following the completed ventricular activation."

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. **Respondent's request**

The respondent requested that the appeal be rejected and the patent maintained as granted (see letter dated 22 November 2004, pages 1, 8). However, this request would put the opponent and sole appellant in a worse position than it was under the contested decision, ie constitute a reformatio in peius, and has, therefore, to be rejected as inadmissible (see G 9/92, OJ 1994, 875, headnote 2). In the present appeal proceedings the respondent is primarily restricted to defending the patent in the form in which it was maintained by the opposition division in its interlocutory decision. Accordingly, the respondent's request in the present appeal proceedings is deemed, in favour of the respondent, to be the maintenance of the patent in amended form as per the interlocutory decision.

3. **Novelty**

3.1 An implantable atrial defibrillator according to the preamble of claim 1 in suit is known from document E1 (cf. figure 1 and corresponding description). This is, as a matter of fact, uncontested between the parties.

In particular, document E1 (see figure 1) discloses, using the terminology of claim 1, an implantable atrial defibrillator (30) for providing cardioverting electrical energy to the atria (16, 18) of a human heart (10), the atrial defibrillator including a first detector (56) for detecting ventricular activations (ie R waves) of the heart and a cardioverter (112) for
applying the cardioverting electrical energy to the atria of the heart.

3.2 According to the characterising part of claim 1, the atrial defibrillator is characterised by:
- a delay stage
- responsive to the first detector
- for causing the cardioverter to apply the cardioverting electrical energy to the atria of the heart after completion of a ventricular activation and before the T wave of the heart immediately following the completed ventricular activation.

The defibrillator of document E1 has a microprocessor (62), the implementation of which results in a plurality of functional stages including a timer (68) (see figure 1 and page 14, lines 6 to 14). As shown in figure 6, following the detection of an R wave in the right ventricle by means of the electrodes (38, 40) arranged in the right ventricle, the microprocessor starts the timer and proceeds to the detection of an R wave in the left ventricle by means of the electrodes (42, 44) arranged near the left ventricle (see page 27, line 32 to page 28, line 6). If an R wave is detected in the left ventricle within a delay after detection of the R-wave in the right ventricle of between 5 and 30 ms, a counter (88) is incremented (see figure 6 and page 28, lines 6 to 24). Otherwise, this counter is reset. If the counter reaches a count of eg five, a cardioverting discharge is delivered to the atria.

In document E1, the delay stage including the timer is, thus, responsive to the detector for right ventricular activations. The cardioverting electrical energy
discharge, if delivered, is applied following the detection of an R wave in the left ventricle marking the completion of the ventricular activation and has a delay between 5 and 30 ms with respect to the detection of an R wave in the right ventricle. This discharge is, thus, applied to the atria of the heart after completion of the ventricular activation as per claim 1. Furthermore, since typically the T wave follows the R wave in about 250 ms (see also patent specification, column 3, lines 52-54) the discharge to the atria will occur well before the T wave of the heart immediately following the completed ventricular activation. As a matter of fact, document E1 notes in this respect that as a rule the delivery of electrical energy to the heart during the T wave is to be avoided (see paragraph bridging pages 2 and 3).

Accordingly, the defibrillator of document E1 falls under the definition given in claim 1 in suit.

3.3 In the decision under appeal (see page 5, last paragraph) it was held that there was "no direct causal relationship between detection of ventricular activation in the right ventricle and application of cardioverting electrical energy to the heart", since in the absence of a left ventricular R wave within the prescribed delay, the cardioverting energy would not be applied.

Indeed, according to document E1 no delivery of a discharge takes place if the delay between right- and left-ventricular detection is less than 5 ms or more than 30 ms, or if less than 5 consecutive R waves are
detected with the delay being between 5 and 30 ms (see figure 6 and page 27, line 22 to page 28, line 24).

In the board's opinion, however, claim 1 in suit does not define a direct causal relationship between detection of ventricular activation in the right ventricle and application of cardioverting electrical energy. In fact, claim 1 in suit merely requires the delay stage to be responsive to the detector for detecting ventricular activations for causing the cardioverter to apply the cardioverting electrical energy to the atria of the heart within a specified time window, if such energy is indeed applied. As such, claim 1 does not exclude that the application of cardioverting electrical energy to the atria may be subject to other conditions being met in addition to the detection of a right ventricular activation.

In this respect it is, furthermore, noted that according to the description in suit (see column 7, lines 8 to 43) the delay stage (82) comprises a synchronisation detector (64) (defined in dependent claim 5 in suit) which provides a pulse to a delay timer (66) in response to the pulse from the R wave detector (52) upon the detection of a ventricular activation. Prior to starting the delay timer, however, synchronization pulse counting may be employed wherein the synchronization detector first counts a predetermined number, such as five, consecutive R wave detect pulses from the R wave detector to assure that there is still reliable detection of the ventricular activations. Only upon the sixth consecutive detection of a ventricular activation, after the timed delay,
cardioverting electrical energy is delivered to the atria of the heart.

Accordingly, a direct causal relationship between detection of ventricular activation in the right ventricle and application of cardioverting electrical energy is in fact not required in the patent in suit.

Furthermore, it is noted that at any rate it suffices for lack of novelty that under certain conditions, ie in case of a confirmed detection of an R wave, the defibrillator of document E1 operates like the claimed defibrillator.

3.4 The respondent argued that the timer described in document E1 was not a delay stage for timing a delay period in response to a ventricular activation which caused (eg at the expiration thereof) a cardioverting electrical energy to be delivered to the atria of the heart. Rather, the timer was used to measure the time between the detection of an activation at two points in the heart, eg between the right and left ventricles to verify whether or not a true ventricular activation had taken place. Once a true ventricular activation was confirmed, eg after five consecutive ventricular activations having a time between detection of the activation in the right and left ventricles within the predetermined time window, defibrillating or cardioverting electrical energy was applied to the atria of the heart in synchronism with the ventricular activation. Although this could occur near the end of the ventricular activation, E1 did not describe or suggest specifically employing a delay stage for guaranteeing that the electrical energy would be
delivered to the atria of the heart after completion of a ventricular activation (and before the T wave of the heart immediately following the completed ventricular activation) as featured in Claim 1.

As noted above, however, the timer in document E1 inevitably causes the discharge to take place after completion of the ventricular activation (denoting the R wave according to the patent in suit (see column 3, lines 44 to 47)). As argued by the appellant, it is immaterial whether this particular function of the timer is explicitly indicated in document E1, as long as it meets this function.

3.5 For the reasons given above, the subject-matter of claim 1, thus, is not novel having regard to the disclosure of document E1 (Articles 52(1), 54(1) and (2) EPC).

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    B. Schachenmann