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# D E C I S I O N
# of 28 April 2004

**Case Number:** T 1078/00 - 3.4.1

**Application Number:** 91116709.6

**Publication Number:** 0479215

**IPC:** A61N 1/365

**Language of the proceedings**: EN

**Title of invention:**
Verification of capture using an indifferent electrode mounted on the pacemaker connector top

**Patentee:**
PACESETTER, INC.

**Opponent:**
Biotronik GmbH & Co. KG

**Headword:**
-

**Relevant legal provisions:**
EPC Art. 52(1), 54(1)(2), 56, 100(a)

**Keyword:**
"Novelty (yes)"
"Inventive step (no)"

**Decisions cited:**
-

**Catchword:**
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Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 1078/00 - 3.4.1

# D E C I S I O N
**of the Technical Board of Appeal 3.4.1**
**of 28 April 2004**

| | |
|---|---|
| **Appellant:** (Opponent) | Biotronik GmbH & Co. KG<br>Woermannkehre 1<br>D-12359 Berlin (DE) |
| **Representative:** | Eisenführ, Speiser & Partner<br>Patentanwälte Rechtsanwälte<br>Anna-Louisa-Karsch-Strasse 2<br>D-10178 Berlin (DE) |
| **Respondent:** (Proprietor of the patent) | PACESETTER, INC.<br>15900 Valley View Court<br>Sylmar<br>CA 91392-9221 (US) |
| **Representative:** | Rees, David Christopher<br>Kilburn & strode<br>20 Red Lion Street<br>London WC1R 4PJ (GB) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted 24 August 2000 rejecting the opposition filed against European patent No. 0479215 pursuant to Article 102(2) EPC.** |

**Composition of the Board:**

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

## Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 24 August 2000, rejecting the opposition against European patent No. 0 479 215. The notice of appeal was received on 20 October 2000, the appeal fee being paid on the same day, and the statement setting out the grounds of appeal was received on 29 December 2000.

II. Opposition had been filed against the patent as a whole, based on Article 100(a) EPC on the grounds of lack of novelty and inventive step (Articles 52(1), 54(1), (2) and 56 EPC).

III. Reference was *inter alia* made to the following documents:

E1: US-A-4 686 988

E2: US-A-4 817 605

E3: EP-A-0 308 536

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

V. The respondent requested that the appeal be dismissed.

VI. Summons to attend oral proceedings were issued on 23 January 2004 together with a communication of the board pursuant to Article 11(1) RPBA, *inter alia* drawing attention to the fact that in a provisional appreciation the subject-matter of claim 1 as granted

appeared to be rendered obvious by the teachings of documents E3 and E1.

VII. With a letter dated 6 April 2004 the respondent informed the board that the patentees did not intend to be represented at the oral proceedings.

VIII. Oral proceedings were held on 28 April 2004 with only the appellant being represented.

IX. Claim 1 of the patent as granted reads as follows:

*" A system for determining cardiac capture, comprising:*
*first pulse generating means (54, 56, 56U) for generating stimulation pulses;*
*a first electrical lead (32, 38, 32U, 38U) having a first electrically conductive electrode (34, 40, 34U, 40U) thereon, the first electrode (34, 40, 34U, 40U) for connection to the first pulse generating means ((54, 56, 56U) for delivery of stimulation pulses from first pulse generating means (54, 56, 56U) to the first electrode (34, 40, 34U, 40U);*
*first electrically conductive means (36, 42, 46) spaced away from the first electrode (34, 40, 34U, 40U) for providing a return path for stimulation (54, 56, 56U); and*
*means (76, 80, 158, 162) for verifying cardiac capture as a result of the stimulation pulses from the first pulse generating means (54, 56, 56U), the verifying means (76, 80, 158, 162) comprise an indifferent electrode (80) spaced away from the first electrode (34, 40, 34U, 40U) and the first electrically conductive means (34, 42, 46), the indifferent electrode (80) defining a first capture sense path;*

*characterised in that the first capture sense path is between the first electrode (34, 40, 34U, 40U) and the indifferent electrode (80).".*

X. The appellant argued that the subject-matter of claim 1 was not novel with respect to both documents E1 and E3. In particular, document E1 disclosed a system for determining cardiac capture having an intracardiac lead with a tip and a ring electrode, and a case electrode, pacing pulses being delivered between the tip electrode and the case electrode and capture sensing taking place between the ring electrode constituting an indifferent electrode and the case electrode. Document E3 provided a clear and unambiguous teaching regarding the combination of a bipolar stimulation and a unipolar capture sensing. Since the measurement in the atrium in E3 took place immediately after stimulation, the measurement could only relate to capture verification. Furthermore, the subject-matter of claim 1 lacked an inventive step with respect to document E1 or E2 in combination with document E3. The objective problem to be solved having regard to the teaching of document E1 or E2 consisted in increasing the life time of the pacemaker and improving the capture sense. The solution, consisting of providing for bipolar stimulation, was clearly suggested in document E3.

XI. The respondent submitted that claim 1 in the patent in suit showed novelty over E3. In particular, document E3 did not disclose an indifferent electrode, since all of the electrodes could be brought to a defined potential other than zero. Moreover, the claimed subject-matter also involved an inventive step over a combination of documents E1 and E2 with document E3. The fact that a

particular electrode in E3 could be configured under certain circumstances to have a zero potential for the purpose of capture sensing did not make it an indifferent electrode for all time.

## 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 From document E1 a system is known for determining cardiac capture, in particular atrial (P-wave) cardiac capture (cf Figures 1, 3 and 8 and corresponding text). The system comprises a bipolar atrial lead (22) provided in the atrium, the tip electrode (24) of the lead and the pacemaker case (64) being used for atrial stimulation, as well as for sensing naturally occurring atrial activity in the absence of atrial stimulation (cf P-wave sense/pace amplifier 48), and the ring electrode (26) of the lead and the pacemaker case being used for sensing atrial capture in response to atrial stimulation (cf P-wave sensing EGM amplifier 54).

The appellant argued that in this known arrangement the conductive case (64) of the pacemaker would correspond to the first electrically conductive electrode defined in claim 1 in suit, the tip of the lead (24) would correspond to the first electrically conductive means in claim 1 and the ring electrode (26) would correspond to the indifferent electrode defined in claim 1.

In the board's opinion, however, to the skilled reader the system known from E1 cannot reasonably be said to provide the pacemaker case on a first electrical lead or to provide a return path for stimulation through the tip electrode as defined in claim 1 of the patent as granted.

The same applies to document E2 which is in substance identical to document E1.

Accordingly, the subject-matter of claim 1 as granted is novel over documents E1 and E2.

2.2 From document E3 (cf Figures 1, 3 and 4 and corresponding description) a pacemaker system is known having a programmable configuration.

In one of the disclosed configurations the system comprises, using the terminology of claim 1 of the patent in suit:
first pulse generating means (12) for generating stimulation pulses;
a first electrical lead having a first electrically conductive electrode (16) (tip) thereon, the first electrode for connection to the first pulse generating means for delivery of stimulation pulses from first pulse generating means to the first electrode;
first electrically conductive means (18) (case) spaced away from the first electrode for providing a return path for stimulation;
sensing means comprising a further electrode (20) (ring) spaced away from the first electrode and the first electrically conductive means; wherein

a sense path is provided between the first electrode (tip) and the further electrode (ring).

In this configuration the further electrode (20) (ring) is not used for pacing or otherwise "active" and thus constitutes an "indifferent electrode" as defined in claim 1 of the patent in suit.

In an alternative configuration of E3 the tip electrode and ring electrode are used for bipolar pacing and thus constitute the first electrode and the first electrically conductive means, respectively, within the meaning of claim 1. A sense path is provided between the tip electrode and the case. The pacemaker case constitutes an indifferent electrode, not used for pacing, in this configuration, irrespective of the fact that during sensing the case may be connected by means of a switch (P21) to a reference potential of between -0.2 and -2.0 Volts (cf Figure 1 and page 8, lines 8 to 14).

It is noted that this configuration corresponds to the embodiment of the patent in suit shown in Figure 11 (cf column 12, lines 39 to 52) in which the pacemaker case forms the indifferent electrode.
The respondent's argument that document E3 did not disclose an indifferent electrode, since all of the electrodes could be brought to a defined potential other than zero, is not found convincing. An indifferent electrode, in the context of the claimed system, is an electrode which is not used for pacing. The contention that only electrodes which have a zero potential under all circumstances, and all configurations in case of a configurable system, are

indifferent electrodes is unfounded. As discussed above, depending on the chosen configuration in the system of E3 the case or the ring electrode is not used for pacing and thus constitutes an indifferent electrode.

Document E3 is concerned with the charge remaining on the coupling capacitor (capacitor C2, cf Figures 1, 2A, 3) after delivery of a stimulation pulse (eg to the atrium), rendering the connection to the sense circuit problematic (cf page 3, lines 13 to 30), as well as adversely affecting the magnitude of the pacing pulse that is delivered (cf page 5, lines 19 to 23). In order to remove the residual charges from the coupling capacitor, immediately following the delivery of a stimulation pulse (in unipolar operation), a switch (P3) creates a discharge path from the proximal side (24) of the coupling capacitor C2 to the case electrode (18) and a further switch (P8) connects the proximal side (24) of the coupling capacitor C2 to the negative battery potential Vss for a short period of time termed the "fast discharge period" (cf page 5, lines 19 to 25 and Figures 1 and 3). After the fast discharge period, in order to ensure that essentially all the charge is removed from side 24 of capacitor C2, a slow discharge path is provided through a resistor (R1) and a further switch (P5) (unipolar operation).
Sensing may for instance be realized by connecting the positive terminal of a sensing circuit (26) to the tip electrode 16 by closing a switch (P22), and connecting the ring electrode 20 to the negative terminal of the sensing circuit 26 through another switch (P24) (cf page 5, lines 35 to 38 and Figures 1 and 4). During the delivery of a pacing pulse and the fast discharge time all switches to the sensing circuit (P22 to P25) (cf

Figure 4) are switched off to avoid saturating the sensing circuit (cf page 8, lines 6 to 8). Furthermore, it is possible that some voltage will remain on coupling capacitor C2 after fast discharge, and this voltage could be misinterpreted by the sensing circuit 26 as cardiac activity. Accordingly, a further capacitor (C5) is provided preventing such misinterpretation from occurring. To ensure that any charge on capacitor C5 is removed, a short auto zero pulse of approximately 100 microseconds is used to discharge the capacitor through a switch (P30), just after the end of the fast discharge period (cf page 8, lines 15 to 22). Sensing in the atrium takes place in E3 in the remaining (slow discharge) time (cf Figure 2) after the fast discharge time and the short auto zero pulse, following the delivery of the atrial pacing pulse.

The fast discharge time for discharging the coupling capacitor C2, as well as the discharge time for capacitor C5, are short compared to the typical few tens of milliseconds between the delivery of the stimulation pulse and the occurrence of a corresponding heart action (cf document E1, column 1, lines 40 to 46 and Figure 4A; patent in suit, eg Figure 4). According to E3 the sensed signals comprise intracardiac ECG signals, which optionally may be fed to an ECG amplifier and telemetered to an external receiver (cf page 8, lines 26 to 28).

Accordingly, in E3 heart activity, both atrial and ventricular, closely following the delivery of the respective pulses is sensed.

It is, however, not unambiguously disclosed in E3 that this sensing is for verifying capture and that means for verifying cardiac capture are provided as defined in claim 1 of the patent in suit.

Accordingly, the subject-matter of claim 1 is considered to be novel with respect to document E3.

3. *Inventive step*

The problem of capture verification is specifically addressed in document E1. As such, document E1 is already referred to in document E3 as prior art allowing capture determination immediately after pacing (cf E3, page 2, lines 40 to 45). Capture sensing on the one hand guarantees that the stimulation pulse is sufficient to actually cause the heart, ie the atrium or ventricle, to respond to the stimulation pulse provided and on the other hand allows achieving capture at the lowest possible energy setting to conserve battery power (cf E1, column 1, lines 14 to 25). Thus, the skilled person working in the field of pacemakers was already aware at the filing date of the patent in suit of the desirability of capture sensing. Capture sensing, eg in the atrium, requires sensing in the atrium shortly after the delivery of the stimulation pulse to the atrium. Since the pacemaker of document E3 provides a configuration for sensing in the atrium closely following the delivery of a stimulation pulse, it would have been obvious to the skilled person, in view of the teaching of E1, to use the sensing capabilities of the pacemaker known from E3 for capture verification and complement the known pacemaker with means suitable to this end.

Accordingly, the subject-matter of claim 1 of the patent in suit does not involve an inventive step (Articles 52(1), 56 and 100(a) 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 G. Davies