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D E C I S I O N
of 9 November 2004

Case Number: T 0856/01 - 3.4.1

Application Number: 91116269.1

Publication Number: 0477878

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
System for recognizing and terminating pacemaker-mediated tachycardia

Patentee:
PACESETTER, INC.

Opponent:
Biotronik GmbH & Co. KG

Headword:
-

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

Keyword:
"Opposition grounds - lack of patentability"
"Inventive step - no"

Decisions cited:
-

Catchword:
-

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Case Number: T 0856/01 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 9 November 2004

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: (Proprietor of the patent)	PACESETTER, INC. 15900 Valley View Court Sylmar, CA 91392-9221 (US)
Representative:	Rees, David Christopher Kilburn & Strode 20 Red Lion Street London WC1R 4PJ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 4 May 2001 rejecting the opposition filed against European patent No. 0477878 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: M. G. L. Rognoni
Members: G. Assi
E. J. Dufrasne

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 2 July 2001, against the decision of the opposition division, dispatched on 4 May 2001, rejecting the opposition against the European patent No. 0 477 878 (application number 91116269.1). The appeal fee was paid on 2 July 2001. The statement setting out the grounds of appeal was received on 3 September 2001.

II. The opposition had been filed against the patent as a whole and was based on the ground 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.

In the decision under appeal, the opposition division held that the grounds for opposition did not prejudice the maintenance of the patent unamended, having regard to, *inter alia*, the following document:

(E2) US-A-4 569 350.

III. In response to the summons to oral proceedings, the respondent (patent proprietor) announced, by a letter dated 13 October 2004, that it would not attend the oral proceedings. The oral proceedings were held on 9 November 2004.

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

The respondent requested that the appeal be dismissed.

V. The wording of claim 1 of the patent as granted reads as follows:

"*A system for detecting the occurrence of a pacemaker mediated tachycardia, PMT, in a patient having an implantable pacemaker (10; 160), said system comprising: first detection means (12, 18; 166, 170, 174, 176, 180) within said implantable pacemaker for detecting a prescribed sequence of cardiac cycles, each cardiac cycle of said prescribed sequence comprising a P-wave followed by a V-pulse at a rate faster than a reference rate, the time interval between said P-wave and said V-pulse of each cardiac cycle comprising a P-V delay; means (12; 170) for momentarily changing said P-V delay in at least one selected cardiac cycle; and second detection means (12, 30; 170, 174, 176, 178, 180, 182) for detecting if a V-P interval associated with said selected cardiac cycle remains substantially unchanged from a V-P interval associated with at least one cardiac cycle immediately preceding said selected cardiac cycle, said V-P interval comprising the time interval between a V-pulse and a P-wave within a cardiac cycle;*

a substantially unchanged V-P interval within said changed cardiac cycle providing an indication that said prescribed sequence of cardiac cycles comprises a PMT."

Reasons for the Decision

1. The appeal is admissible.

2. As announced in writing, the duly summoned respondent did not attend the oral proceedings. Pursuant to

Rule 71(2) EPC, the oral proceedings on 9 November 2004 were held in its absence.

3. According to the appellant, the maintenance of the patent unamended was prejudiced by the ground for opposition pursuant to Article 100(a) EPC that the subject-matter of claim 1 of the patent as granted was not patentable within the terms of Articles 52(1) and 56 EPC, having regard, *inter alia*, to document E2 taken alone. The respondent objected to this view.

4. Document E2 discloses a system for detecting the occurrence of a pacemaker mediated tachycardia (PMT) in a patient having an implantable pacemaker (column 1, lines 6 to 12). The system comprises the following features:

- first detection means for detecting a prescribed sequence of cardiac cycles, each cardiac cycle comprising a P-wave followed by a V-pulse at a rate faster than a reference rate, the time interval between a P-wave and a V-pulse of a cardiac cycle representing the P-V delay (column 2, line 59 to column 3, line 13; Figures 5 and 6; claim 1);

- means for momentarily increasing the P-V delay by a predetermined amount in at least one selected cardiac cycle (column 3, line 13 to 18; claim 1); and

- second detection means for detecting if the P-P interval associated with the selected cardiac cycle increases by the same amount with regard to

the P-P interval immediately preceding the selected cardiac cycle, this providing an indication that PMT has occurred (column 3, lines 19 to 23; claim 1).

Therefore, the subject-matter of claim 1 of the patent as granted differs from the system according to document E2 by the provision of second detection means "*for detecting if a V-P interval associated with said selected cardiac cycle remains substantially unchanged from a V-P interval associated with at least one cardiac cycle immediately preceding said selected cardiac cycle, said V-P interval comprising the time interval between a V-pulse and a P-wave within a cardiac cycle; a substantially unchanged V-P interval within said changed cardiac cycle providing an indication that said prescribed sequence of cardiac cycles comprises a PMT.*"

5. Both the patent in suit and document E2 concern systems for detecting the occurrence of PMT if certain conditions are met. The condition specified in claim 1 consists in detecting whether the V-P interval remains unchanged when the preceding P-V delay is changed, rather than in detecting whether the corresponding P-P interval increases by the same amount as the P-V delay, as suggested by document E2. Thus, the essential question to be considered is whether the skilled person would regard the condition proposed by document E2 as an obvious alternative to the claimed one, as stressed by the appellant.

At first, it is noted that the claimed definitions of the P-V and V-P intervals are usual in the technical

field of pacemakers. As regards the P-P interval, it is generally known in the field that it is the sum of the P-V and V-P intervals.

Moreover, the skilled person is aware that, during PMT, the V-P interval is substantially constant since it is largely determined by "*retrograde conduction*", *i.e.* by a condition where the depolarization of the ventricles propagates backwards into the atria, causing the atria to depolarize prematurely. On the other hand, in a rapid sinus tachycardia, the V-P interval varies from cycle to cycle by a noticeable amount (patent in suit, column 6, lines 50 to 55). In view of the definition of the P-P interval, it is implicit that if the P-V delay is changed by a predetermined amount ä and the P-P interval varies by the same amount ä, the V-P interval remains unchanged. Thus, it is evident to the skilled person that the condition set out in E2 also detects the stability of the V-P interval.

6. The respondent objected (letter of 25 January 2002, page 5; letter of 18 July 1997, pages 2 and 3) that the system according to document E2 suffered from the drawbacks of lack of accuracy and reliability "*because of the potential of jitter in the signals detected*". Thus, in its view, there was no evidence that a person skilled in the art would consider the disclosure of E2 to be equivalent to the claimed subject-matter.
These findings are by no means conclusive. Indeed, an interpretation of the claimed feature concerning the second detection means in the light of the description (column 6, lines 44 to 50) involves a direct or an indirect measure of the V-P interval, an example of the latter being provided by the embodiment relating to the

method shown in Figure 8 and described in column 22, lines 4 to 36, where the difference between the V-V interval and the P-P interval is determined. In any case, both the direct and the indirect measurements of the V-P interval necessarily imply that the P-waves are sensed. Therefore, since the system of the present invention is supposed to provide an accurate detection of PMT (patent in suit, column 28, lines 28 to 31), the jitter of the P-waves cannot justify an objection of lack of accuracy and reliability with regard to the system of document E2.

More generally, the respondent did not deny the fact that the various cardiac signals were related, this being "*the nature of electrophysiology*". In its view, however, this fact did not mean that there could be no inventive step in the "*selection of one combination of cardiac signals over another*".
This argument is not relevant in view of the fact that the claimed feature concerning the second detection means cannot be regarded as representing the selection of a particularly advantageous interval. Indeed, as already stated, the claim does not specify that the V-P interval should be directly detected. The second detection means is rather defined in terms of the condition to be verified, namely the stability of the V-P interval permitting to determine the occurrence of PMT.

7. In conclusion, the Board finds that the claimed system represents an obvious alternative to the one according to document E2. Hence, the ground for opposition pursuant to Article 100(a) EPC in connection with

Articles 52(1) and 56 EPC prejudices the maintenance of the patent unamended.

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 M. Rognoni