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D E C I S I O N
of 21 September 2005

Case Number: T 0901/03 - 3.4.01

Application Number: 92305904.2

Publication Number: 0575674

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
Pacemaker employing tachycardia prevention based on ventricular gradient

Patentee:
Pacesetter, Inc.

Opponent:
Biotronik GmbH & Co. KG

Headword:
-

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

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0901/03 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 21 September 2005

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 91342 (US)

Representative:
Hackett, Sean James
Marks & Clerk
Alpha Tower
Suffolk Street Queensway
Birmingham B1 1TT (GB)

Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 6 August 2003 concerning maintenance of European patent No. 0575674 in amended form.

Composition of the Board:

Chairman: B. Schachenmann
Members: R. Bekkering
G. Assi

Summary of Facts and Submissions

I. The appeal was lodged by the opponent (appellant) against the interlocutory decision of the opposition division, dispatched on 6 August 2003, to maintain European patent No. 0 575 674 in amended form. The notice of appeal was received on 9 August 2003, the appeal fee being paid on the same day, and the statement setting out the grounds of appeal was received on 8 December 2003.

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

III. The patentee (respondent) requested that the appeal be dismissed and the patent maintained in amended form in accordance with the interlocutory decision of the opposition division on the basis of the following documents:

Claims:	No. 1 to 10 filed during the oral proceedings before the opposition division on 15 July 2003;
Description:	Columns 1, 2, 5 to 7 of the patent specification; Columns 3 and 4 filed during the oral proceedings before the opposition division on 15 July 2003;
Drawings:	Figures 1 to 4 of the patent specification.

As an auxiliary request, the maintenance of the patent on the basis of the following documents was requested:

Claims: 1 to 9 filed with the letter of 22 April 2004;

Description and drawings as for the main request.

IV. Oral proceedings, requested by both parties as an auxiliary measure, were held on 21 September 2005. Neither the appellant, nor the respondent attended the oral proceedings, as announced by the two parties by letters of 2 August 2005 and 22 August 2005, respectively.

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

E1: P.E. Puddu et al, "The QT-Sensitive Cybernetic Pacemaker: A New Role for an Old Parameter?", Pace, vol. 9, January-February 1986, part I, pages 108-123

E15: F.N. Wilson et al, "The determination and the significance of the areas of the ventricular deflections of the electrocardiogram", American Heart Journal, vol. 10, 1934, pages 46-61

E16: R. Plonsey, "A Contemporary View of the Ventricular Gradient of Wilson", Journal of Electrocardiology, vol. 12, no. 4, 1979, pages 337-341.

VI. Claim 1 according to the main request reads as follows:

"*1. A cardiac pacing system (100) for preventing tachyarrhythmia of a heart (214) comprising:*

means (206) for integrating at least a portion of an electrocardiac response from the heart (214) to obtain a ventricular gradient indicative of dispersion in the heart;
means (304, 305) responsive to said integrating means (206) for determining that an arrhythmia is impending if said gradient is above a predetermined value; and
means (303) responsive to said determining means (304, 305) for generating pacing pulses at a predetermined elevated rate when said determining means (304, 305) indicates that arrhythmia is impending such that said arrhythmia is prevented."

VII. Claim 1 according to the auxiliary request reads as follows:

"*1. A cardiac pacing system (100) for preventing tachyarrhythmia of a heart (214) comprising:*
means (206) for integrating an entire QT waveform associated with an electrocardiac response to obtain a ventricular gradient indicative of dispersion in the heart;
means (304, 305) responsive to said integrating means (206) for determining that an arrhythmia is impending if said gradient is above a predetermined value; and
means (303) responsive to said determining means (304, 305) for generating pacing pulses at a predetermined elevated rate when said determining means (304, 305) indicates that arrhythmia is impending such that said arrhythmia is prevented."

VIII. The appellant argued in substance that the skilled person already knew from document E1, and the therein cited document E15, that the ventricular gradient

reflected the cardiac dispersion and could be obtained by integrating the ECG signal between Q and T. Moreover, document E16 indicated that the ventricular gradient corresponded to the integral of the QRST interval and that it was characteristic for an unequal recovery of the ventricle and thus characteristic for the dispersion. Therefore, the subject-matter of claim 1 of both the main and the auxiliary request lacked an inventive step.

IX. The respondent submitted in substance that neither document E15 nor E16 would have enabled the skilled person to establish a link between the ventricular gradient and dispersion. Document E16 taught that the ventricular gradient was a measure of the recovery properties of the cardiac tissue and was essentially independent of activation. Document E16 did not suggest that the ventricular gradient was an indicator of impending arrhythmia and this parameter could not be considered to be the same as, or a measure of, inhomogeneity in ventricular activation-recovery properties.

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. *Main request*

Inventive step

2.1 In document E1, providing the closest prior art, a pacemaker is proposed for detecting the onset of a tachyarrhythmia of the heart and for overdrive pacing in response (see abstract and page 118, left-hand column, second paragraph). As also indicated in the description of the patent in suit (see patent specification, column 1, line 51 to column 2, line 37), document E1 acknowledges that it is established that the spatial dispersion in the ventricular recovery time is associated with an imminent tachyarrhythmia of the heart (see document E1, page 108, last paragraph). Furthermore, it is indicated in document E1 that "*dispersion of refractoriness might be instrumental in determining QT interval prolongation and increased propensity to arrhythmias*" (see page 115, left-hand column, last paragraph). However, according to document E1, "*direct measurement of dispersion of refractoriness is difficult, thus one needs to rely on accurate measurements of QT interval, with all the limitations inherent in these calculations*".

2.2 Claim 1 of the main request requires means for integrating at least a portion of an electrocardiac response from the heart to obtain a ventricular gradient indicative of dispersion in the heart, and means responsive thereto for determining that an arrhythmia is impending when the ventricular gradient exceeds a predetermined value.

The objective problem to be solved with respect to the disclosure of document E1 may accordingly be seen in conceiving a viable way of measuring dispersion of

refractoriness, or of recovery in general, of the heart and providing corresponding means in the pacemaker.

2.3 The formulation of the problem as such is considered obvious, as document E1 already indicates that such a direct measurement would be desirable.

Moreover, also the claimed solution would have been obvious to a skilled person working in the technical field at issue of cardiac pacing systems.

From document E16 it is known that the ventricular gradient, defined as the area of QRST, ie the time integral of the ECG signal over the QT interval, reflects local recovery properties and is, therefore, of particular value in the study of arrhythmias (see page 337, "Summary" and first three paragraphs; pages 340-341, "Discussion").

Accordingly, the skilled person would have considered providing means in the pacing system of document E1 for determining the time integral of the electrocardiac response over the QT interval, ie the ventricular gradient, in order to obtain a measure of the (spatial) dispersion of the recovery in the heart, and thereby an indication of an impending arrhythmia, as suggested in document E16. The specific provision to this end of corresponding integrating means for calculating the ventricular gradient and means responsive thereto for determining that an arrhythmia is impending when the ventricular gradient exceeds a predetermined value, in the pacemaker known from document E1, merely corresponds to the straightforward, practical implementation in a pacing system of the teaching of

document E16 and must be considered to lie within the competence of the skilled person.

2.4 The respondent argued that document E16 did not teach that the ventricular gradient was indicative of dispersion. According to document E16 the ventricular gradient was a measure of the recovery properties of the cardiac tissue, whereas according to the patent in suit the ventricular gradient was indicative of dispersion in the sense of inhomogeneity in ventricular activation-recovery properties (see letter of 24 January 2005).

It is, however, noted that in both the patent in suit and document E16 the same integral of the electrocardiac response over the QT interval, commonly termed the "ventricular gradient" in the technical field at issue, is determined. As such, a specification in the claim of the parameter characterised by this integral cannot provide a distinction over this prior art. Furthermore, it is noted that the entity of which the dispersion is considered is actually not specified in claim 1 of the patent in suit.

Moreover, is noted that according to the patent in suit "by detecting increased dispersion from the ventricular gradient, tachyarrhythmia can be prevented with readily available technology, and the problem of accurately measuring the QT time interval is overcome. Also, the QT interval is non-specific in that it is influenced by activation, e.g. QRS complex, whereas ventricular gradient is not so influenced" (see column 3, lines 13 to 19). Therefore, also according to the patent in suit the dispersion determined by the ventricular gradient

is not related to activation but only to the recovery properties of the cardiac tissue, as in document E16 (see page 337, right-hand column, lines 1 to 6).

2.5 For the reasons given above, the subject-matter of claim 1 of the main request does not involve an inventive step (Articles 52(1) and 56 EPC).

3. *Auxiliary request*

Claim 1 according to the auxiliary request in addition comprises means for integrating **an entire QT waveform** (emphasis added) associated with an electrocardiac response from the heart to obtain a ventricular gradient indicative of dispersion in the heart.

This amendment, however, does not alter the finding above. As such, it is a prerequisite to integrate over the (entire) QT interval for obtaining the ventricular gradient, as the latter is so defined (see document E16 and the patent in suit, column 3, lines 4 to 7). Moreover, it is noted that, as discussed above, integration over the (entire) QT interval is what is suggested in document E16 for obtaining a ventricular gradient indicative of dispersion of recovery properties in the heart.

Accordingly, the subject-matter of claim 1 according to the auxiliary request also lacks an inventive step (Articles 52(1) and 56 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