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D E C I S I O N
of 4 November 2003

Case Number: T 0351/99 - 3.4.1

Application Number: 92100427.1

Publication Number: 0495424

IPC: A61N 1/362

Language of the proceedings: EN

Title of invention:

System and method for post-processing intracardiac signals

Patentee:

PACESETTER, INC.

Opponent:

Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro
Berlin

Headword:

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Relevant legal provisions:

EPC Art. 52(1), 54(1), (2), 56

Keyword:

"Inventive step (no) - after amendment"

Decisions cited:

-

Catchword:

-



Case Number: T 0351/99 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 4 November 2003

Appellant: PACESETTER, INC.
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Representative: Rees, David Christopher
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Respondent: Biotronik Mess- und Therapiegeräte GmbH & Co
(Opponent) Ingenieurbüro Berlin
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Representative: Eisenführ, Speiser & Partner
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 1 February 1999
revoking European patent No. 0495424 pursuant
to Article 102(1) EPC.

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appellant (patentee) lodged an appeal against the decision of the opposition division, dispatched on 1 February 1999, revoking the European patent No. 0 495 424. The notice of appeal was received on 31 March 1999 and the appeal fee paid on the same day. The statement of grounds of appeal was received on 10 June 1999.
- 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).

Reference was in particular made to the following documents:

E1: US-A-4 809 697

E6: EP-A-0 398 660

The opposition division found that the subject-matter of claims 1 and 8 of the patent as granted lacked an inventive step with respect to documents E1 and E6, and revoked the patent accordingly.

- III. The appellant (patentee) requested that the decision under appeal be set aside and the patent maintained in amended form based on the following documents:

Claims 1 to 8 filed with a letter dated 10 June 1999;
Description columns 1 to 19 as granted;
Figures 1 to 8 as granted.

Oral proceedings were requested in the event that the board of appeal was inclined to refuse the appeal.

- IV. The respondent (opponent) requested that the appeal be dismissed.

An auxiliary request for oral proceedings was made.

- V. With a summons dated 25 March 2003 the parties were summoned to oral proceedings to be held on 26 June 2003. In an attached preliminary assessment the board held that the subject-matter of all claims according to the appellant's request lacked an inventive step (Articles 52(1) and 56 EPC).

With a letter dated 13 May 2003 the appellant stated that he would not be attending the scheduled oral proceedings.

With a notification dated 26 May 2003 the parties were informed that the oral proceedings had been cancelled and that the decision would follow.

- VI. Independent claims 1 and 8 according to the appellant's request read as follows:

"1. A system for enhancing the detection of particular physiologic phenomena manifested within intracardiac signals, said system comprising:

an implantable pacemaker (20), said implantable pacemaker (20) including means for sensing intracardiac signals, such as P-waves or R-waves, and means for telemetering said intracardiac signals to a

non-implanted location remote from said implantable pacemaker (20);

diagnostic means (29) in telecommunicative contact with said implantable pacemaker (20) for receiving and storing said intracardiac signals;

retrieval means for selectively retrieving said intracardiac signals stored by said diagnostic means; and

processing means (30) for selectively processing said intracardiac signals retrieved by said retrieval means in accordance with at least one of a plurality of signal processing strategies;

characterised in that said at least one of said plurality of signal processing strategies is applied repetitively and/or recursively to the same acquired data in order to enhance the detection of a [sic] particular physiologic phenomena manifested within said intracardiac signals."

"8. A method for enhancing the analysis of intracardiac signals, said method comprising the steps of:

(a) receiving and amplifying said intracardiac signals from a heart (20);

(b) converting said received and amplified cardiac signals to digital signals;

(c) storing said digital signals; and

(d) subjecting said stored digital signals, at a time subsequent to when the intracardiac signals are first received, amplified, converted to digital form, and stored, to at least one signal processing strategy,

characterised in that said at least one signal processing strategy is applied repetitively and/or recursively to the same acquired data in order to

enhance said intracardiac signals so as to reveal characteristics therein which are masked out when analyzing said signals prior to being subjected to said at least one signal processing strategy."

Claims 2 to 7 are dependent on claim 1.

VII. The appellant argued essentially as follows:

The invention in the patent in suit concerned enhancing ECG data by removing noise. It allowed for example for sequential processing of the data, not feasible in real time, whereby the stored ECG data was enhanced by repeated processing and for multi-aspect enhancement of the data, in which different enhancement operations were applied to separate aspects of the total data set. The spectrum of the stored data was thereby altered and the altered data was presented to the operator.

It was conceded that in the system known from document E6, ECG data was stored in a memory and retrieved for subsequent processing and display. However, merely shifting the QRS groups leftwards or rightwards did not constitute processing the data set repeatedly to enhance the detection of particular physiological phenomena. In particular, in E6 the spectrum of the stored data set was not altered and the stored data itself not enhanced.

VIII. The respondent's arguments may be summarised as follows:

Document E6 disclosed the shifting of data for the purpose of signal analysis as a data processing strategy. According to E6, this strategy was applied

repeatedly. Therefore, the subject-matter of claim 1 as amended was rendered obvious by documents E1 and E6 in the same manner as the subject-matter of claim 1 of the patent as granted.

Apparently, the objective problem to be solved by the patent in suit was to remove noise from the acquired ECG, as in substance also argued by the appellant. In order to solve this problem, however, it was textbook knowledge of the skilled person to use for the signal processing the recursive processes claimed by the patentee.

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, inventive step (Articles 52(1), 54(1), (2) and 56 EPC)*
 - 2.1 A system according to the preamble of claim 1 under consideration is known from document E1 which provides the closest available prior art.

In particular, using the terminology of claim 1, from document E1 (cf Figure 1 and corresponding description) a system for enhancing the detection of particular physiologic phenomena manifested within intracardiac signals is known, comprising:
an implantable pacemaker (20), the implantable pacemaker including means for sensing intracardiac

signals, such as P-waves or R-waves, and means for telemetering said intracardiac signals to a non-implanted location remote from said implantable pacemaker;
diagnostic means (28, 30, 31) in telecommunicative contact (26) with said implantable pacemaker for receiving and storing said intracardiac signals;
retrieval means for selectively retrieving said intracardiac signals stored by said diagnostic means;
and processing means (30, 34) for selectively processing said intracardiac signals retrieved by said retrieval means in accordance with at least one of a plurality of signal processing strategies (cf. column 3, line 67 to column 4, line 16; column 5, lines 58 to 66).

In particular, concerning the above last feature, in the system known from document E1 the measured intracardiac ECG data are optionally stored within the memory elements of the diagnostic means (in particular of the "APS-II" circuits) for subsequent retrieval, display and analysis, whereby displaying and analysing implies processing "in accordance with at least one of a plurality of signal processing strategies".

The system according to claim 1 differs from the system known from document E1 in that the at least one of said plurality of signal processing strategies is applied repetitively and/or recursively to the same acquired data in order to enhance the detection of particular physiologic phenomena manifested within said intracardiac signals.

The same applies in substance for the method according to independent claim 8.

Accordingly, the subject-matter of claims 1 and 8 is novel over document E1. Novelty has, in fact, not been disputed.

- 2.2 The objective problem-to-be-solved by the patent in suit as derivable from the above difference of the claimed subject-matter over the prior art provided by E1 may accordingly be seen as to enhance the detection of particular physiologic phenomena manifested within the acquired intracardiac signals.

No inventive merit can be attributed to formulating this problem which represents a general concern for the skilled person working in the technical field at issue.

As far as the claimed solution is concerned, from document E6 a system is known for enhancing the detection of particular physiologic phenomena manifested within a recorded electrocardiogram (ECG). In this system (surface) ECG data acquired over a predetermined amount of time are stored in a memory and subsequently retrieved, processed and displayed (cf column 4, lines 7 to 45; Figures 1, 2, 5 and 6), whereby three consecutive QRS groups are displayed on a screen of the system. A particular signal processing strategy applied to the stored ECG data, activated by pressing corresponding leftward or rightward screen shift keys on the system, results in the displayed three QRS groups being shifted to the left or right by one QRS group, thereby displaying the succeeding or preceding QRS group, respectively. The signal

processing strategy of shifting the QRS groups leftward or rightward by one position may also be applied repetitively by pressing the corresponding keys in succession (cf column 5, lines 46 to 50). By this shifting of the QRS groups by one or more positions, for instance the changes in the R-R intervals become visible, thereby enhancing the detection of R-R interval variations (change of heartbeat rate) from the cardiac signals.

It would have been readily apparent to the skilled person that, although the teaching of document E6 relates to surface cardiac signals, the disclosed signal processing would have been equally applicable to intracardiac signals as available in the system according to document E1. Accordingly, in order to enhance the detection of particular physiologic phenomena in the intracardiac signals, the skilled person would have provided the corresponding signal processing means suggested in document E6 in the system as known from document E1, thereby arriving at a system falling under the terms of claim 1 under consideration without the exercise of inventive skills.

The same applies in substance for the method according to independent claim 8.

- 2.3 The appellant argued that the invention in the patent in suit rather concerned enhancing ECG data by removing noise. In particular, previously stored data was enhanced by repeated processing, thereby altering the spectrum of the stored data, and the altered data was presented to the operator thereby enhancing the detection of particular physiological phenomena.

Neither claim 1, nor claim 8 are, however, limited to a system or method for removing noise from the intracardiac signals. The corresponding arguments of the appellant can, therefore, not support the presence of an inventive step in the claimed subject-matter. Furthermore, it is noted that in the description of the contested patent (cf column 16, line 44 to column 17, line 48) it is already acknowledged, with specific reference to textbooks and a scientific article, that the use of digital filtering as such, and in particular for processing ECG signals so as to enhance the diagnosis capabilities, was already known to the skilled person at the priority date of the patent in suit.

- 2.4 In view of the above, the subject-matter of claims 1 and 8 does not involve an inventive step (Articles 52(1) and 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

R. Schumacher

G. Davies