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D E C I S I O N
of 22 June 2006

Case Number: T 1241/04 - 3.4.01

Application Number: 93117898.2

Publication Number: 0613655

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
Device for analyzing the function of a heart

Patentee:
ST. JUDE MEDICAL AB

Opponent:
BIOTRONIK GmbH & Co. KG

Headword:
-

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

Keyword:
"Inventive step - yes (after amendment)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1241/04 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 22 June 2006

Appellant: St. Jude Medical AB
S-175 84 Järfälla (SE)

Representative: Bergstrand, Mikael Gudmundsson
Albihns GmbH
Bayerstrassse 83
D-80335 München (DE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 23 August 2004 refusing European application No. 93117898.2 pursuant to Article 97(1) EPC.**

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 23 August 2004, to maintain European patent No. 0 613 655 in amended form. The notice of appeal was received on 21 October 2004, the appeal fee being paid on the same day, and the statement setting out the grounds of appeal was received on 17 December 2004.

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 9 filed with the letter of 18 May 2000;
Description: Columns 1 to 7 of the patent specification;
Drawings: Figures 1 to 6 of the patent specification.

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

Claims: No. 1 to 7 filed in the oral proceedings on 22 June 2006;
Description: Columns 1 to 7 filed in the oral proceedings on 22 June 2006;

Drawings: Figure 4 filed in the oral proceedings on 22 June 2006;
Figures 1 to 3, 5 and 6 of the patent specification.

IV. Oral proceedings, requested by both parties as an auxiliary measure, were held on 22 June 2006. The appellant did not attend the oral proceedings, as announced by letter of 31 May 2006.

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

E1': US-A-3 616 791

E2: WO-A-91 19452

E6: US-A-4 812 976

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

"1. An implantable device for analyzing the function of a heart (2), said
device comprising a measurement unit (8) for generating a measurement signal related to an electrical or mechanical heart variable (2) and an evaluation unit (9,16,17) for evaluating the measurement signal, wherein the evaluation unit (9,16,17) comprises means (9) for generating at least one parameter signal on the basis of the measurement signal and analyzes related values for the measurement signal and the parameter signal by determining whether they satisfy a predetermined number of conditions, the related values corresponding to coordinates forming a curve (30,31) in

a coordinate system, with the measurement signal and the parameter signal as coordinate axes, the predetermined number of conditions corresponds to a predetermined number of areas in the coordinate system, whereby the evaluation unit (9,16,17) determines the sequence in which the curve passes the predetermined number of areas."

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

"1. A device for analyzing the function of a heart (2), said device comprising a measurement unit (8) for generating a measurement signal related to an electrical or mechanical heart variable (2) and an evaluation unit (9, 16, 17) for evaluating the measurement signal, wherein the evaluation unit (9, 16, 17) comprises means (9) for generating at least one parameter signal on the basis of the measurement signal and analyses related values for the measurement signal and the parameter signal by determining whether they satisfy a predetermined number of conditions, the related values corresponding to coordinates forming a curve (30, 31) in a coordinate system, with the measurement signal and the parameter signal as coordinate axes, the predetermined number of conditions corresponding to a predetermined number of areas in the coordinate system, wherein the evaluation unit (9, 16, 17) comprises a plurality of comparators (32, 33, 34, 35) each of which employing at least one of the measurement signal or the parameter signal as an input signal, each comparator (32, 33, 34, 35) representing a line (45, 46, 47, 48) in the coordinate system, which lines (45, 46, 47, 48) delineate the predetermined

number of areas, the corresponding comparator generating an output signal when the curve is on one side of a specific line, characterised in that the device is implantable and the evaluation unit comprises a sequence analyzer (17) for determining the sequence with which the comparators generate output signals, whereby the evaluation unit determines the sequence in which the curve passes the predetermined number of areas, wherein the means (9) for generating at least one parameter signal from the measurement signal comprises an integrator (13) which integrates the measurement signal."

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*

2.1 Inventive step

2.1.1 Document E1', providing the closest prior art as agreed by both parties, discloses (using the terminology of claim 1 in suit) a device for analyzing the function of a heart, comprising:
- a measurement unit (15) (see figure 14) for generating a measurement signal related to an electrical heart variable (ECG signal e), and
- an evaluation unit for evaluating the measurement signal, wherein the evaluation unit comprises means for generating at least one parameter signal on the basis

of the measurement signal (eg the time derivative of e, de/dt), and analyzes related values for the measurement signal and the parameter signal by determining whether they satisfy a predetermined number of conditions (see figure 14, comparators C1 to C4),
the related values corresponding to coordinates forming a curve in a coordinate system, with the measurement signal (e) and the parameter signal (de/dt) as coordinate axes, the predetermined number of conditions corresponds to a predetermined number of areas in the coordinate system.

In particular, the device of document E1' includes a plurality of comparators (C1 to C4) which compare the positive and negative portions of the measurement signal (+e, -e) and its time derivative (+de/dt, -de/dt) with a threshold signal which is proportional to the amount of noise detected on the measurement signal (see column 29, lines 9 to 39 and figure 14). The comparators, in an abstract graphic representation, thus, represent lines (+e=threshold, -e=threshold, -de/dt=threshold, +de/dt=threshold) in the e versus de/dt coordinate system delineating a number of areas, the comparators generating an output when the related value of the curve is on one side of a respective line (eg comparator C1 produces an output when +e>threshold etc.).

2.1.2 Furthermore, the board agrees with the appellant that in document E1' (see column 2, lines 26 to 71) the evaluation unit determines the sequence in which the curve passes the predetermined number of areas as required by claim 1.

In particular, in document E1' the evaluation unit determines a final system state which is a representation of the sequence of the predetermined number of conditions being satisfied (ie the outputs of flip-flops F/F-A to F/F-D in figure 14), which sequence is in turn a function of the shape of the QRS complex of the electrocardiogram (ECG)(see column 2, lines 35 to 38).

Clearly, the measurement signal and derived parameter signal satisfying the predetermined number of conditions in a given sequence corresponds, in an abstract graphic representation, to the measurement signal and derived parameter signal as coordinate points in a coordinate system forming a curve passing a predetermined number of areas of the coordinate system in a given sequence. Accordingly, the determination in document E1' of the sequence in which the predetermined number of conditions are satisfied corresponds to determining the sequence in which the curve passes a predetermined number of areas in the coordinate system.

In fact, according to the patent in suit (see column 3, lines 16 to 26; column 4, line 51 to column 5, line 5; figure 4) the evaluation unit actually comprises a number of comparators (each representing a line delineating areas in a coordinate system) and a sequence analyser which determines the sequence in which the comparators emit an output. This, however, is no different from the evaluation unit of document E1', where the sequence is determined in which flip-flops F/F-1 to F/F-4, associated with comparators C1 to C4, emit an output.

2.1.3 In the decision under appeal it was held that document E1' did not disclose an evaluation unit which determined the sequence in which the curve passed the predetermined number of areas, but only an evaluation unit which determined final states. Document E1' was only concerned with distinguishing between normal and abnormal states.

Document E1' provides a recognition logic circuit (see figures 11A, 11B) which operates to examine the four flip-flops F/F-1 to F/F-4 of the input and output circuit, and depending on the sequence of their energizations during the appearance of any ECG waveform to cause one of the eight outputs (51-9 to 51-16) to go low, indicating that one of the final system states (9 to 16, see figure 3) has been reached (see column 8, lines 52 to 60). It should be noted that although the recognition logic circuit is explained based on the input and output circuit shown in figure 7, it would operate in an analogous manner with the input and output circuit of figure 14 considered above. Hence, contrary to what is held in the decision under appeal, in document E1' the sequence in which the flip-flops F/F-1 to F/F-4 change state, and thus the sequence in which the curve passes the predetermined number of areas, is determined.

Indeed, in document E1' the eight outputs of the recognition logic circuit (51-9 to 51-16) reflect the determination of different sequences. In a subsequent morphology detection circuit the final system state is compared with stored state numbers and if a new state occurs which is not one of those stored earlier, indicating the occurrence of an abnormal waveform,

action is taken to the extent that a 3-second ECG trace is produced. As such the outputs of the recognition logic circuit (51-9 to 51-16) are comparable to the sequence signal lines Y1 to Ym of the patent in suit, reflecting in some manner the outcome of the sequence analysis of sequence analyzer 17, on which basis the microprocessor of the device decides whether any further action should be taken (see figure 1 and column 4, line 51 to column 5, line 5 of the patent specification).

Accordingly, not only does the fact that in document E1' final states are determined not alter the fact that the sequence in which the curve passes the predetermined number of areas is actually determined in document E1', but in effect also in the patent in suit the sequence in which the curve passes the predetermined number of areas is subsequently used to produce some final criterion, on which the decision whether further action should be taken is based.

2.1.4 The respondent, furthermore, argued that since in document E1' only a number of sequences would lead to a final system state, all other sequences remaining undetermined and, moreover, a number of sequences would lead to the same final state, document E1' did not unambiguously determine the sequence in which the curve passes the predetermined number of areas.

The argument however, is not convincing, since claim 1 in suit does not require that in each and every case the entire sequence is determined. In fact, it is noted that according to the patent in suit *"since every heart condition is unique, the sensing of every condition*

transition is not always necessary, only a few of which needing to be executed in a specific way (eg come from a specific state or take a specific amount of time to pass between two specific states)" (see column 7, lines 53 to 57), so that the sequence in which the curve passes the predetermined number of areas is not necessarily fully and unambiguously determined.

2.1.5 Accordingly, the only difference between the subject-matter of claim 1 and document E1' is the fact that the device is implantable. In document E1' the device is not for being implanted in a patient but for external monitoring. In view, however, of the general trend towards implantable devices providing ECG evaluation capabilities, as documented for instance by document E2 disclosing an implantable cardiac defibrillator with an ECG evaluation based on the analysis of the ECG signal plotted against its time derivative (see page 5, lines 1 to 28 and page 11, lines 3 to 6), it would be obvious for a skilled person working in the technical field at issue to provide the ECG monitoring system of document E1' as an implantable device.

2.1.6 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).

The main request of the respondent is, therefore, not allowable.

3. *Auxiliary request*

3.1 Amendments

Claim 1 according to the auxiliary request is based on claims 1, 2, 4 and 5 as originally filed. Dependent claims 2 to 7 correspond to originally filed claims 2 (the optional feature thereof), 3 and 6 to 9, respectively. The amendments, therefore, comply with the requirement of Article 123(2) EPC. Furthermore, having regard to claim 1 as granted, the amendments further limit the protection conferred, so that the requirement of Article 123(3) EPC is met as well.

3.2 Inventive step

3.2.1 Claim 1 according to the auxiliary request, with respect to claim 1 of the main request, in substance contains the following additional features:

- the evaluation unit comprises a plurality of comparators each of which employing at least one of the measurement signal or the parameter signal as an input signal, each comparator representing a line in the coordinate system, which lines delineate the predetermined number of areas, the corresponding comparator generating an output signal when the curve is on one side of a specific line,
- the evaluation unit comprises a sequence analyzer for determining the sequence with which the comparators generate output signals, whereby the evaluation unit determines the sequence in which the curve passes the predetermined number of areas, and

- the means for generating at least one parameter signal from the measurement signal comprises an integrator which integrates the measurement signal.

3.2.2 The above first feature is known from document E1' as well, as discussed above having regard to claim 1 of the main request.

3.2.3 The above second feature, despite the fact that it is in the characterising portion of the claim, is disclosed in document E1' as well, the circuitry shown in figures 11A and 11B constituting a sequence analyzer for determining the sequence with which the comparators C1 to C4 generate output signals, thereby determining the sequence in which the curve passes the predetermined number of areas, as discussed above with respect to the main request.

3.2.4 Regarding the above third feature, the appellant argued that document E1' included such an integrator.

According to document E1' (see figure 14 and column 29, lines 9 to 39) the rectified ECG signal is fed to a comparator 26 which triggers a one-shot multi-vibrator which in turn charges a capacitor 28 each time the rectified ECG signal exceeds a preset threshold 25 (see also column 6, line 60 to column 7, line 8). The voltage across the capacitor, which is proportional to the amount of noise in the ECG signal, is connected to the threshold input of the comparators. This circuit, however, acts on the rectified measurement signal and, moreover, only on those part of the signal exceeding a threshold, so that it cannot be held to integrate the measurement signal. In document E1' only the

measurement signal and its first time derivative are used.

The above third feature, thus, is not disclosed in document E1'. It is, furthermore, also not considered to be obvious to a skilled person from document E1', as the document only considers the measurement signal itself and, as only parameter signal, its first time derivative, there being nothing to suggest the use, as parameter signal, of any other derived signal or the integrated signal in particular.

3.2.5 The remaining available prior art documents do not include any hint in this respect either. Document E2 merely suggests that the second or higher order time derivative may be used for plotting.

The appellant also argued that document E6 disclosed an integrator (see figures 10A and 30) and that a skilled person would provide such an integrator in the device of document E1'.

Document E6 is, however, remote from the claimed subject-matter as it is not concerned with analysing the sequence in which a number of conditions are satisfied and, thus, a curve passes a number of predetermined areas in a coordinate system. Furthermore, the integrated signal itself is not used as coordinate axis (see figures 3 to 7). Accordingly, document E6 is not considered to provide any hint as to the use of an integrator in the device known from document E1'.

3.2.6 In view of the above, the subject-matter of claim 1 according to the auxiliary request is considered to involve an inventive step (Articles 52(1) and 56 EPC).

3.3 The dependent claims 2 to 7 define further preferred features of the device. The subject-matter of these claims, therefore, also involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of the following documents:

Claims:	No. 1 to 7 filed in the oral proceedings on 22 June 2006;
Description:	Columns 1 to 7 filed in the oral proceedings on 22 June 2006;
Drawings:	Figure 4 filed in the oral proceedings on 22 June 2006; Figures 1 to 3, 5 and 6 of the patent specification.

The Registrar: The Chairman:

U. Bultmann B. Schachenmann