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Datasheet for the decision of 15 November 2007

Case Number: T 0039/06 - 3.4.01

Application Number: 98110104.1

Publication Number: 0882469

IPC: A61N 1/37, A61N 1/368

Language of the proceedings: EN

Title of invention:
Implantable heart stimulator

Patentee:
St. Jude Medical AB

Opponent:
BIOTRONIK

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 123(2), 123(3), 56

Keyword:
"Added subject-matter"
"Extension of protection"
"Combination of documents does not lead to claimed subject-matter"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0039/06 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 15 November 2007

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 23 December 2005 rejecting the opposition filed against European patent No. 0882469 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: B. Schachenmann
Members: P. Fontenay
F. Neumann

Summary of Facts and Submissions

I. By a decision dated 23 December 2005, the Opposition Division rejected the opposition against the European patent EP-B-882469.

II. The appellant (opponent) lodged an appeal against the above decision by a notice of appeal filed on 11 January 2006 and paid the prescribed appeal fee on the same day.

The appellant requests that the impugned decision be set aside and the European patent be revoked in its entirety on the grounds of added subject-matter (Article 100(c) EPC) and lack of an inventive step (Article 100(a) EPC). The written statement setting out the grounds of appeal was received on 28 April 2006.

The following documents were of particular interest in the appeal procedure:

D3: US-A-5 607 457;
D5: US-A-4 905 708;
D7: EP-B-506 230;
D16: David Wyn Davies et al. "Detection of Pathological Tachycardia by Analysis of Electrogram Morphology", PACE 9, pages 200-208, March-April 1986;
D17: Gerald C. Timmis et al. "Discrimination of Anterograde From Retrograde Atrial Electrograms for Physiologic Pacing", PACE 11, Pages 130-140, February 1988.

III. The respondent (patentee) requests that the appeal be dismissed and the patent be maintained as granted or, alternatively, on the basis of claims 1 to 3 according to a first auxiliary request.

According to corresponding requests of the parties, oral proceedings were held before the Board of Appeal on 15 November 2007, in the absence of the appellant who had announced in a letter received on 15 October 2007 that it would not participate.

During the oral proceedings, the patentee filed a modified version of claim 1 according to the first auxiliary request and a new second auxiliary request.

IV. Claim 1 according to the main request corresponds to claim 1 as granted and reads as follows:

"A heart stimulator comprising:
a metallic housing (7) implantable in a subject; pulse generator means (8,9) contained in said housing for emitting stimulation pulses;
a first unipolar electrical lead (2) electrically connected to said pulse generator means for receiving said stimulation pulses therefrom and terminating in an atrial electrode (3) placeable in an atrium of a heart of said subject;
a second unipolar electrical lead (5) electrically connected to said pulse generator means for receiving said stimulation pulses therefrom, and terminating in a ventricular electrode (6) placeable in a ventricular electrode placeable in a ventricle of said heart (sic!);

control means (10) in said housing for controlling said pulse generator means for setting an amplitude and a rate of said stimulation pulses and for causing said stimulation pulses to be delivered to at least one of the atrium and the ventricle;
differential detector means (11) in said housing connected to said first and second electrical leads for differentially detecting cardiac activity between said atrial electrode and said ventricular electrode and for generating a differential electrical activity signal corresponding to said cardiac activity; and
a decision logic (14) employing a morphology analysis means, being supplied with said differential signal for analyzing said differential signal for classifying said cardiac activity among a plurality of different types of cardiac activity and for supplying a signal to said control means for causing said control means to alter said stimulation pulses, if necessary;
characterised in that said morphology analysis means comprises means for one or more of the following criteria; determining an energy content in said differential signal or; determining a slew rate in said differential signal for identifying an origin of said cardiac activity and;
if necessary alternatively evaluate the signal by a morphology method or algorithm by means of said decision logic (14)."

The first auxiliary request differs from the main request in that the terms: "if necessary alternatively" in claim 1 have been replaced by the statement: "if said criteria do not provide a definitive classification of the differential signal".

The second auxiliary request differs from the main request in that the characterising portion of claim 1 has been amended so as to more precisely define the morphology analysis means and in particular the way the various means constituting said morphology analysis means are coordinated. More specifically, the amendments carried out in claim 1 identify the condition under which the differential signal is to be evaluated by a morphology method or algorithm and the condition under which the other alternatives are to be performed.

The characterising portion of claim 1 according to the second auxiliary requests recites: "said morphology analysis means comprises means for one or more of the following criteria; determining an energy content in said differential signal or; determining a slew rate in said differential signal for identifying an origin of said cardiac activity **when the difference between signals on said first and second unipolar electrical leads exceeds a predetermined value** and;
when the difference between signals on said first and second unipolar electrical leads is below said predetermined value alternatively evaluate the signal by a morphology method or algorithm by means of said decision logic (14)." with the emphasis added by the Board.

Reasons for the Decision

1. The appeal complies with the requirements of Article 106 to 108 and Rule 64 EPC and is therefore admissible.

2. *Main request - Added subject-matter (Article 123(2) EPC)*

2.1 Original claim 1 was amended during the examination phase by replacing the former concept of a differential signal analysis means by the concept of a decision logic employing a morphology analysis means and by defining, in the characterising portion of claim 1, said morphology analysis means.

2.2 According to the patentee, the skilled person would derive from the wording of claim 1 as granted that the function of evaluating the signal by a morphology method constitutes a possibility which is to be applied, instead of the simpler methods relying on the energy content or slew rate, in situations where the latter methods would fail in identifying the origin of cardiac activity. In particular the structure of the claim would make clear to the skilled person that the alternative would not reside in the mere performing of the function but in the results obtainable by a morphology method or algorithm, compared to those obtainable from methods relying on energy content or slew rate. The wording of claim 1 would, thus, suggest that a first preevaluation is performed within the morphology analysis means in order to decide on the kind of means the differential signal is to be supplied to: on one hand, the means for determining an energy

content or a slew rate and, on the other hand, the means relying on a morphology method or algorithm.

It is acknowledged that the presence of the conjunction "and" before the terms "if necessary alternatively" does not contradict this interpretation since this conjunction is a direct consequence of the fact that the claim refers to a device i.e. a physical entity. As stressed by the patentee, the means for deciding on the criteria such as energy or slew rate and the means performing the morphology method are indeed required by the device in order for it to perform these functions whenever needed. The presence of this conjunction is therefore the expression of the fact that the morphology analysis means must incorporate all the means required for performing said various analyses in the case that such analyses would be required. It is therefore excluded, for the Board, that the terms "and, if necessary" could imply that the means carrying out the morphology analysis method or algorithm could constitute an optional feature of the claim.

2.3 The patentee further defends the view that these amendments, as reproduced in the characterising portion of the claim, are sufficiently supported by the passage in column 8, lines 1-26 of the published application. The Board, however, does not share this view.

The passage referred to by the patentee supports the fact that the morphology analysis method or algorithm is indeed performed if simpler techniques would fail to produce unambiguous results as to a possible classification of the differential signal. However, the cited passage also specifies that this alternative

analysis shall take place "only if more difficult waveforms occur" and that in "situations wherein the differential signal is relatively straightforward", or "in most "normal" situations", as illustrated in figure 6, simpler classification techniques can be employed. It is emphasized that the various situations outlined in this paragraph in which a morphology analysis will be employed all relate to the shape of the waveforms detected and more specifically to waveforms which would be difficult to analyse. In other words, this paragraph sets out that a morphology analysis will be employed for waveforms which cannot be directly recognised by simpler techniques.

In the opinion of the Board, the criterion referred to in this paragraph and selected in relation to the waveform, although defined in vague terms, is not sufficient to support the generalisation resulting from the use of the expression "if necessary". It is in particular considered that the necessity for the signals to be evaluated by a morphology method or algorithm may derive from completely different considerations than those actually referred to in the cited passage.

It is first stressed, in this respect, that morphology methods can distinguish signal patterns in a reliable manner (cf. column 3, line 56 - column 4, line 5). A medical doctor could therefore take advantage of these capabilities in order to evaluate the detected differential signal independently of the nature of the detected waveform. For example, the need to apply the morphology method may derive from the mere wish of a medical doctor to record data, in a programmable

stimulator, allowing a higher degree of classification; this type of analysis would then also apply to signals for which an origin of cardiac activity could well be determined by analysing the energy content or slew rate.

The need for this more complex type of analysis may also result from the necessity, for a particular patient, to provide a higher level of discrimination between possible dysfunctions of the heart such as arrhythmias, although some arrhythmias show signals which origin could be easily identified by simpler techniques.

The first paragraph in column 8 specifically makes the use of a morphology method conditional on the complexity of the differential signal, this complexity making it impossible for simpler techniques to define the origin of the cardiac activity. However, the introduction in claim 1 of the term "if necessary" means that claim 1 now defines that this type of morphology analysis is resorted to in the more general situations in which the differential signal, although straightforward in view of the origin of the associated cardiac activity, may require a higher degree of discrimination. The passage in column 8, lines 1-26 does not provide any further indication which could support such a generalisation.

Therefore, on the basis of just this single reason, the amended wording of claim 1 gives rise to an infringement of Article 123(2) EPC.

2.4 Moreover, the Board notes that the amendments which have been carried out in claim 1 and which relate to the decision logic and to the morphology analysis means, as defined in the characterising portion of the claim, are disclosed in relation with figure 5 in the original application. More specifically, the passage on column 8, line 27 to line 9, line 47 of the original application as published discloses a decision logic (14) incorporating means to analyze the slew rate of the stored signal or its energy content (see column 9, lines 1-4). As made clear by the introductory sentence in said paragraph: "Assuming that an output is emitted by the differential amplifier...", this kind of analysis is only carried out if the condition set in the previous paragraph has been met i.e. when the difference between the signals on the respective unipolar leads 2 and 5 exceeds a predetermined value.

By relying exclusively on the paragraph column 8, lines 1-26 of the original application, which constitutes a general introduction of the more specific embodiment disclosed in the following paragraphs in relation with figure 5, the patentee focuses on one single aspect of the amendments, namely the introduction of the expression "if necessary alternatively", whilst ignoring the fact that these amendments actually concern the means incorporated in the morphology analysis means and the manner in which they are coordinated. There is no mention in the paragraph referred to by the patentee, when considered in isolation, of slew rate and energy content analysing means as recited in claim 1. Such means are only disclosed in the following paragraphs referring to figure 5.

2.5 It must therefore be established whether this specific embodiment and in particular the paragraph on column 8, lines 40-46 referred to by the opponent and relied upon by the patentee during the examination phase could be sufficient to support claim 1 as granted. The issue hinges solely on the question whether the skilled person would have directly and unambiguously recognised from the embodiment disclosed in relation to figure 5 that the condition for a morphology analysis to be carried out, namely the amplitude of the differential signal must exceed a predetermined threshold, could have been generalised to all situations for which simpler techniques relying on energy content or slew rate would fail. The Board notes, in this respect, that the statements on column 8, lines 40-46 should be read in the light of the passage of the disclosure starting at column 7, line 37 and ending at column 9, line 47. This section establishes the need for preevaluation means in order to ascertain which of the various means present in the morphology analysis means should actually be employed. The differential amplifier 17 constitutes the only illustration of such preevaluation means. Moreover, the application does not define which characteristics of the signal are actually required in order for the energy content analysis means or the slew rate analysis means to be able to identify an origin of the cardiac activity. In the absence of such information, it is also not possible for the skilled person to determine the criteria on the basis of which a preevaluation means could possibly operate.
For these reasons, the Board considers that there is no teaching available in the present application which would lead the skilled person to generalize the

specific disclosure embodied by the differential amplifier 17.

2.6 The general statements concerning the invention in column 3, lines 41-46 and column 4, lines 6-29 of the published patent application are also not sufficient to support claim 1 as granted. In particular, the statement in column 4, lines 26-29 according to which "Only if this type of preliminary analysis fails to provide an unambiguous result would the microprocessor then resort to the use of morphology analysis" clearly establishes that morphology analysis is carried out if necessary and **additionally** to the previous analysis as to the slew rate or energy content and not **alternatively** to these analyses as defined by the wording of claim 1.

2.7 For all the reasons developed above, the Board concludes that claim 1 as granted contains subject-matter which extends beyond the content of the original application and therefore contravenes the requirements of Article 123(2) EPC.

3. *First auxiliary request*

3.1 Article 123(2) EPC

By reciting in amended claim 1 according to the first auxiliary request, that the signal is evaluated by a morphology method or algorithm by means of the decision logic if the criteria relying on the energy content or slew rate in the differential signal "do not provide a definitive classification of the differential signal", the claim relates to devices in which the morphology

method is applied after that the analyses based on energy content or slew rate have been carried out and failed. The amended wording implies therefore that the differential signal is first necessarily supplied to the energy content or slew rate determining means before being possibly analysed by the morphology method or algorithm.

This amended wording derives from the passage in the summary of the invention in column 4, lines 6-29 of the published application where it is stated that morphology analysis will only be undertaken if simpler techniques, consuming less power, fail to provide a definitive classification. The passage in column 4 further recites that: "this can be accomplished, for example, by analysing the energy content of the signal or by analysing the slew rate of various portions of the signal. Only if this type of preliminary analysis fails to provide an unambiguous result would the microprocessor then resort to the use of morphology analysis".

The Board concurs with the patentee that the above cited passage provides a basis for the sequence of analyses which are to be carried out in the morphology analysis means of claim 1, which thus, meets the requirements of Article 123(2) EPC.

3.2 Extension of protection - Article 123(3) EPC

The protection conferred by claim 1 as granted extends to heart stimulators comprising morphology analysis means which implicitly require some preevaluation means for selecting which analysis means to supply the

differential signal to: on the one hand, the energy content or slew rate analysis means or, on the other hand, the morphology method or algorithm.

Claim 1 as amended according to the first auxiliary request does not include such preevaluation means since the possibility of a morphology analysis being performed depends solely on the failure of the energy content or slew rate analysing means to deliver any results as to the origin of the cardiac activity.

It follows from the above that a stimulator, which does not include any means for selecting the type of analysis which should be performed, would as such not fall under the protection conferred by granted claim 1. Nevertheless, if, following a first analysis stage relying on the energy content or slew rate of the differential signal, said device would continue the analysing process by performing a morphology analysis, it would then fall under the protection conferred by claim 1 of the first auxiliary request. This example illustrates precisely the kind of situation that Article 123(3) EPC is supposed to prevent, since a device which does not infringe the granted claim would infringe the amended claim.

For these reasons, the subject-matter of claim 1 according to the first auxiliary request, extends the protection conferred by the patent contrary to the requirements of Article 123(3) EPC.

4. *Second auxiliary request*

4.1 Article 123(2) EPC

The passage of the description in column 8, lines 40-46 refers to the embodiment shown in figure 5 and recites: "If the difference between the respective signals on the unipolar leads 2 and 5 is below the aforementioned predetermined value, it is assumed that an unambiguous classification of the differential signal using simpler techniques would not be possible, in which case a morphology analysis will then be used to classify the incoming signal". Since this statement is to be read in the context of the embodiment disclosed in relation to figure 5, it is associated with the features recited in the following passage and referring to the two possibilities as to the simpler techniques: i.e. to analyze the slew rate or the energy content of the stored signal (cf. column 9, lines 1-4).

Even if the embodiment illustrated in relation to figure 5 associates these features with the specific configuration of a differential amplifier, the output of which is connected to an analog-to-digital converter, the Board is of the opinion that the skilled person would immediately recognize that the functionality referred to in the claimed device can be obtained by various hardware configurations which would be straightforward for the skilled person, so that the generalisation resulting from the functional definition is justified.

4.2 Inventive step - Article 100(a) EPC

4.2.1 Document D3 discloses, as acknowledged by the opponent, a heart stimulator comprising all the features recited in the preamble of claim 1 with the exception of the morphology analysis means. In particular, D3 relates to a heart stimulator comprising two unipolar electrodes to be placed respectively in the atrium or ventricle of a subject's heart and a differential detector means (see D3, column 1, lines 9-13; column 2, lines 19-34; figure 4).

Therefore, since the heart stimulator disclosed in D3 comprises a large number of the structural limitations of the claimed stimulator and since said stimulator shares a common aim with the present invention in that it also seeks to identify the source of the detected signal (see D3, column 2, lines 24-34, column 4, lines 51-60), the Board considers that it qualifies as the closest prior art.

4.2.2 The claimed heart stimulator differs from this known device in that:
a) the decision logic employs a morphology analysis means, being supplied with the differential signal for classifying said cardiac activity among a plurality of different types of cardiac activity and for supplying a signal to said control means for causing said control means to alter said stimulation pulses, if necessary; and in that:
b) said morphology analysis means comprises means for one or more of the following criteria; determining an energy content in said differential signal or; determining a slew rate in said differential signal for

identifying an origin of said cardiac activity when the difference between signals on said first and second electrical leads exceeds a predetermined value and; and, when this is not the case, alternatively evaluate the signal by a morphology method or algorithm by means of said decision logic.

4.2.3 The technical effects achieved by these distinguishing features are, insofar as feature (a) is concerned, to classify the cardiac activity according to the type it belongs to, and insofar as feature (b) is concerned, to select the process which, depending on the amplitude of the differential signal, will be the most appropriate in order to achieve the first effect while minimizing the amount of processing time required resulting in an elevated power drain (see column 8, lines 1-7).

4.2.4 The objective problems solved by both features may therefore be seen in providing an alternative to the correlation detector of D3 which guarantees a higher degree of discrimination of signals (cf. column 3, lines 48 - column 4, line 5 in the published application) and also minimizes the power requirements of the battery (cf. column 4, lines 11-18; column 8, lines 7-11).

Although the opponent is correct when stressing that the problem presented by the patentee, in the application, consists in identifying the origin of the cardiac activity (cf. D3, column 2, lines 24-29; column 3, lines 30-35), the Board cannot concur with its conclusion that this problem would also constitute the objective problem solved by the claimed invention. According to established jurisprudence of the Boards of

Appeal, the objective technical problem has to be defined in view of the technical effects that the invention provides over the closest prior art. In the present case, the heart stimulator of D3 also directly provides the effect of identifying the source of the evoked response (cf. D3, column 4, lines 53-58). This effect, therefore, cannot support the definition of the objective problem as submitted by the opponent.

4.2.5 The problem of providing a higher degree of discrimination is known and addressed in documents D5 or D16; both documents originate from the same inventors and provide essentially the same teaching. More specifically, the heart stimulator disclosed in both documents seeks to discriminate between pathological conditions which would require corrective action (cf. D16, page 205, left column, second paragraph). The solution proposed relies on morphology analysis and more specifically on the principle of gradient pattern detection (cf. D5, column 2, lines 46-60; D16, page 205, right column). Moreover, the problem resulting from the additional energy requirements resulting from GPD analysis is also addressed and solved by resorting to such a technique only in situations when trigger heart rate criteria are met.

4.2.6 However, as put forward by the patentee, the combination of the teachings of D3 with D5 (or D16) would not lead to the claimed subject-matter. Firstly the means in D3 which identify the origin of the detected signal are constituted by the correlation detector 12, which does not receive a differential signal but instead receives the signal detected by one of the unipolar leads 2 or 5 via the switching stage 13.

In order to improve the degree of discrimination between signals in D3 and taking into account the teaching of D5 (or D16), the skilled person would merely replace the correlation detector 12 of D3 by the morphology analysis means of D5 (or D16); the morphology analysis would then only be applied to the signals detected by one or other of the unipolar leads.

It is further emphasised that the slew rate or energy content analysis referred to in D3 (cf. column 6, lines 55-63) is carried out by the differential detector 11. Thus, the replacement of the correlation detector 12 by a gradient pattern detection (GPD) according to D5 would not lead to a device in which the energy content or slew rate would be carried out as an alternative to the morphology method, when predetermined conditions are met but, instead would be carried out in parallel and independently of the fact whether these signals meet certain criteria or not.

Moreover, even if the skilled person, in order to minimize the power requirements, would have considered, when adapting the stimulator of D3 in view of D5 (or D16), to incorporate the means required in order to limit morphology analysis to those situations which actually need it, he would have then relied on the trigger heart rate criteria referred to in D5. Neither D5, nor the other documents available, suggest that the amplitude of the differential signal could constitute an appropriate criterion on which to decide on the type of analysis which should be carried out.

Finally, contrary to the view expressed by the opponent, the Board cannot agree that the claimed subject-matter constitutes the mere juxtaposition of known features. It is emphasized, in this respect, that the morphology analysis means defined in the characterising portion is not limited to a mere collection of analysing means fulfilling various functionalities but also includes additional means, not explicitly recited in claim 1 but implicitly resulting from the functional definition provided therein, which are required in order to manage these analysing means in such a way that they act in a complementary manner, depending on the amplitude of the differential signal.

4.2.7 A second approach proposed by the opponent consisted in defining the objective problem solved by the invention when starting from document D3, as the need to distinguish anterograde atrial depolarisation from retrograde atrial depolarisation. The definition of this problem derives directly from document D16 referred to in column 3, lines 24-26 and column 6, lines 30-35 of the present published application as an example of a possible morphology analysis which could be carried out. According to the opponent, this problem would then directly lead to document D17.

The Board cannot follow this view. The problem identified by the opponent does not rely on the actual disclosure of the application but, instead relies on the prior art, namely D16, referred to in the application in order to define the morphology analysis relied upon in the embodiments of the invention. While it is acknowledged that the content of D16 indeed constitutes a part of the present disclosure insofar as

said morphology analysis is concerned, this does not apply to the other aspects addressed in said prior art and in particular to the problems which said prior art seeks to solve. Moreover, since in the prior art, morphology analysis is not limited to the purpose addressed in D16, nothing in the wording of claim 1 can objectively lead to the definition of the problem made by the opponent.

Furthermore, since D17 relates to a study and merely compares various analyses in order to identify those which are best adapted to a specific pathology, it does not as such disclose any specific structure able to adapt its analysis to the type of differential signal detected, as required by the claimed invention. It is also silent about the criteria which could be useful in order to decide on the best strategy to adopt in order to improve the degree of discrimination.

For these reasons, the Board cannot identify any reason which would have led the skilled person to amend the stimulator of D3 in view of D17.

4.2.8 The Board is also not convinced by the argumentation put forward by the opponent according to which the skilled person would also, starting from document D3 as closest prior art, amend it in view of D7 when seeking to identify the origin of the registered heart signals.

It is in particular stressed that the reference in document D7 to the method of document D5 (or D16) (cf. D7, page 2, lines 33-35 and footnote 6) concerns the prior art and does not as such constitute a feature of the invention disclosed in D7. Therefore, even if

document D7 addresses the need to discriminate between normal cardiac rhythms and arrhythmias (cf. D7, page 2, lines 10, 11), the solution disclosed therein relies on the analysis of amplitude, width and polarity of waveform peaks and does not disclose the solution recited in claim 1.

4.2.9 The subject-matter of claim 1 according to the second auxiliary request is therefore not rendered obvious by the prior art. The subject-matter of claim 1 is therefore inventive in the sense of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent in amended form with:
- Claims 1 to 3 filed at the oral proceedings as second auxiliary request;
- Description pages 2 and 4 to 7 as granted, page 3 as filed at the oral proceedings;
- Drawings as granted.

The Registrar: The Chairman:

R. Schumacher B. Schachenmann