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**D E C I S I O N**  
**of 30 March 2004**

**Case Number:** T 1077/00 - 3.4.1

**Application Number:** 89910959.9

**Publication Number:** 0490892

**IPC:** A61N 1/365

**Language of the proceedings:** EN

**Title of invention:**  
PMT Detecting pacemaker

**Patentee:**  
St. Jude Medical AB

**Opponent:**  
Biotronik GmbH & Co. KG

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art.

**Keyword:**  
"Novelty (yes) - main request"  
"Lack of inventive step - fresh ground of opposition (no)"  
"Remittal to the first instance (yes)"

**Decisions cited:**  
T 0131/01

**Catchword:**  
-



Case Number: T 1077/00 - 3.4.1

**D E C I S I O N**  
of the Technical Board of Appeal 3.4.1  
of 30 March 2004

**Appellant:** Biotronik GmbH & Co. KG  
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**Representative:** Eisenführ, Speiser & Partner  
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**Respondent:** St. Jude Medical AB  
(Proprietor of the patent) S-175 84 Järfälla (SE)

**Representative:** Harrison, Michael Charles  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 24 August 2000  
rejecting the opposition filed against European  
patent No. 0490892 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairman:** G. Davies  
**Members:** M. G. L. Rognoni  
R. Q. Bekkering

## Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal, received on 20 October 2000, against the decision of the opposition division, dispatched on 24 August 2000, rejecting the opposition filed against the European patent No. 0 490 892. The fee for the appeal was paid on 20 October 2000 and the statement of grounds of appeal was received on 29 December 2000.
- II. The opposition had been filed against the patent as a whole based on Article 100(a) EPC. In particular, the statement of grounds of opposition specified, *inter alia*, that the subject-matter of the contested patent was not new within the meaning of Article 54 EPC or, at least, it did not involve an inventive step within the meaning of Article 56 EPC.
- III. In the decision under appeal, however, the opposition division considered only the objection of lack of novelty under Article 54 EPC, since, in its opinion, the opponent had not substantiated the objection of lack of inventive step. Furthermore, the opposition division found that the requirement for starting an examination under Article 114(1) EPC was not fulfilled, as, *prima facie*, there was no reason to believe that this ground could prejudice the maintenance of the European patent. Thus, the opposition division considered that lack of inventive step under Article 56 EPC was not an admissible ground for opposition and concluded that the subject-matter of claim 1 was new with respect to the following documents:

E1: US-A-4 569 350

E2: US-A-4 515 161

E3: US-A-4 539 991.

Moreover, the opposition division decided to disregard the following late-filed document:

E4: *J. Daintith et al.*: "The Penguin Dictionary of Mathematics" Penguin Books Ltd. London (1989), page 76

IV. In the statement of grounds of appeal, the appellant referred also to the following documents:

E5: *I. N. Bronstejn et al.*: "Taschenbuch der Mathematik", Teubner Verlagsgesellschaft (1981), page 123

E6: "Meyers Lexikon der Technik und der exakten Naturwissenschaften", page 1530

V. Oral proceedings were held on 30 March 2004

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

VII. The respondent (patentee) requested that the appeal be dismissed and the patent be maintained as granted (main request); or that the patent be maintained on the basis of two sets of claims filed on 25 February 2004 by way of first and second auxiliary requests, respectively.

Furthermore the respondent requested that the ground of inventive step be considered as a late-filed ground of opposition and, as such, not be admitted into the appeal proceedings without the agreement of the patentee, or, if the Board considered that the ground of lack of inventive step was a valid ground of opposition, that the case be referred back to the first instance for further prosecution.

VIII. The wording of claim 1 according to the **main request** reads as follows:

*"1. A heart pacemaker (10) comprising at least sensing means (12) for detecting atrial events; stimulating means (14) for stimulating the ventricle; variable delay means (153) for generating a variable time delay between the detection of atrial events and the stimulation of the ventricle; time measuring means (16) for measuring the interval between consecutive signals of which at least one is generated by the heart; decision means (16) for at least deciding that a pacemaker mediated tachycardia is present, characterised by calculating means (16) for calculating the correlation between said time delay and said measured time interval; and that said decision means (16) decides that a pacemaker mediated tachycardia is present whenever the value of said correlation deviates from a first predetermined value."*

IX. The appellant's arguments may be summarised as follows:

In E1, against which claim 1 of the patent in suit was delimited, the determination of a pacer mediated tachycardia (PMT) was based on the verification of a

linear relationship between a variable AV time delay and the interval between two consecutive atrial events (P-waves). In particular, the pacemaker shown in E1 verified whether an increase of the AV time delay by a known amount caused the PP interval to increase by the same amount. The verification of the existence of a linear relationship between two intervals fell within the definition of "calculating a correlation" between such intervals, because a linear relationship merely expressed a special kind of correlation. In fact, two variables linked by a linear relationship were totally correlated. Thus, E1 disclosed the calculating means recited in claim 1 of the main request.

It was, furthermore, specified in E1 that, if the time interval between two P- waves remained **substantially** constant after the increase of the AV delay, then there was no PMT. The term "substantially" implied for the skilled person that the comparison between the AV and the PP intervals required the setting of a threshold, since a perfect match of their respective increases in case of PMT could, in practice, not be expected. In other words, it was evident to a person skilled in the art that E1 taught to determine that there was a PMT when the correlation between the AV and the PP intervals was close to 1, ie deviated from a predetermined threshold, as specified in the last feature of claim 1 of the contested patent. As E1 disclosed a pacemaker falling within the terms of claim 1, the subject-matter of this claim was not new within the meaning of Article 54 EPC.

In the statement of grounds of appeal, document D3 was cited against the novelty and the inventive step of the claimed subject-matter. As pointed out in decision T 131/01 (OJ EPO 2003, 115), a specific substantiation of the ground of lack of inventive step was neither necessary nor possible without contradicting the reasoning presented in support of lack of novelty. Thus, lack of inventive step was an admissible ground of opposition, even if a full argumentation in support of this objection had not been submitted with the statement of grounds of opposition.

As lack of inventive step was not a fresh ground of opposition, there was no reason to remit the case to the first instance for further prosecution.

X. The respondent argued essentially as follows:

Document E1 taught to detect a PMT when a predetermined increase of the AV delay resulted in the same increase of the PP interval. In other words, the pacemaker of E1 could only determine the occurrence of a PMT on the basis of a **direct** comparison between two time intervals. The pacemaker according to claim 1 of the contested patent, however, first calculated a correlation between the AV and the PP intervals and then compared the calculated correlation value with a predetermined value and decided that PMT occurred when the correlation value deviated from a predetermined value. In other words, the pacemaker of E1 reached its decision in one step, whereas the claimed pacemaker had a two-step approach and therefore was novel over the cited prior art.

As to the admissibility of the ground of lack of inventive step, the appellant failed to develop a lack of inventive step argument in the statement of grounds of opposition and merely stated that the claimed pacemaker was not novel or at least lacked an inventive step in view of E3. In the statement of grounds of appeal, however, the appellant relied on a combination of documents and not just on E3 to attack the inventive step of the claimed pacemaker. The circumstances of the present case were, therefore, substantially different from those considered in T 131/01, in which there was only one document relevant to novelty and inventive step. Hence, lack of inventive step had to be regarded as a fresh ground of opposition.

If lack of inventive step were to be considered an admissible ground of opposition, it was only equitable to refer the case back to the first instance, so as to give the patentee the opportunity to defend the contested patent before two instances.

## **Reasons for the Decision**

1. The appeal is admissible.
- 2.1 The contested patent relates to a pacemaker comprising means for detecting a pacemaker-mediated tachycardia (PMT). According to the description (column 1, lines 11 to 18), atrial synchronised pacing systems include an atrial (P-wave) sensing circuit, which, in connection with retrograde electrical conduction (ie conduction from the ventricle to the atrium), might cause a pacemaker-mediated tachycardia. PMT occurs when the

atrial sensing circuit detects a P-wave induced by ventricular activity outside the sensing circuit's refractory periods and the pacemaker subsequently initiates a paced ventricular beat.

The cycle time of a PMT comprises two delay intervals: one ( $D_1$ ) related to the retrograde heart tissue conduction (VA interval) and the other one ( $D_2$ ) depending on the interval or time delay introduced by the pacemaker between atrial activity and ventricular stimulation (AV interval). Though  $D_1$  can be stable or vary regularly or stochastically, it is assumed that, for short time periods,  $D_1$  is limited and substantially constant (cf description: column 3, lines 1 to 7).

2.2 The gist of the invention consists essentially in varying stochastically, or in accordance with a predetermined pattern, the AV interval  $D_2$ , and in calculating the correlation between this variable interval and the interval between two consecutive atrial events (P-waves).

If no PMT is present, the PP interval is the interval between two **spontaneous** atrial beats. Its correlation with the interval  $D_2$  is low, because variations of the PP-intervals are independent of the variations induced by the pacemaker. However, if a PMT is present, there is a high correlation between the PP interval and  $D_2$  because the former is the sum of the retrograde conduction VA interval  $D_1$  (supposed to be constant) and of the pacemaker-generated AV interval  $D_2$ .

*Respondent's main request*

- 3.1 Document E1, which represents the closest prior art, relates to a system for detecting a pacemaker-mediated tachycardia and teaches to determine whether there is a PMT by changing the AV -delay by a **selected amount (delta)**, for example 150 ms, and by measuring the interval between P-waves. If the interval between P-waves is greater by the **same amount (delta)** than the PP interval, this will indicate that the tachycardia is pacemaker-mediated. On the other hand, if the PP interval remains substantially the same as prior to the increase of the AV delay, this will indicate that there is no PMT (see E1 column 3, lines 8 to 27).
- 3.2 It is uncontested that the pacemaker shown in E1 comprises all the features recited in the preamble of claim 1 as granted.
- 4.1 The characterising portion of claim 1 specifies the following:
- that the pacemaker comprises:
    - (a) **calculating means** for calculating the **correlation** between the "*time delay*" (ie the time interval between the detection of an atrial event and the stimulation of the ventricle) and the "*measured time interval*" (ie the time interval between eg the detection of two successive atrial events);
  - and that:

(b) **decision means** decides that a pacemaker-mediated tachycardia is present whenever "*the value of said correlation deviates from a first predetermined value*".

4.2 Considering that a linear dependance was a particular form of correlation and that establishing whether two variables were linearly dependent would be the same as "*calculating the correlation*" between them, the appellant essentially argued that E1 implicitly disclosed to the skilled person "*calculating means*" as specified in feature (a) of claim 1 according to the main request. In fact, the skilled person understood that in practice the comparison between the two interval increases would be carried out by calculating means which calculated whether, to a certain (and inevitable) degree of approximation, the two intervals could be considered "equal".

Furthermore, in E1 a decision concerning the absence of PMT was taken if the interval between P waves remained "*substantially*" constant, ie when the AV and the PP intervals showed no correlation (cf. E1, column 3, lines 23 to 27). This implied that a decision concerning the absence of correlation was reached when the correlation of the two variables was close to zero or deviated from a threshold close to zero. To the skilled person, it was implicit that also a decision concerning a total correlation (ie a linear dependance) had to be taken when the two interval increases were not exactly the same, ie when the correlation of the corresponding intervals deviated from a value close to 1.

4.3 According to the respondent, however, there was a fundamental difference between **verifying** that two time intervals increased by the same amount, as taught in E1, and **calculating** their degree of correlation, as required by the claimed pacemaker.

5.1 The operation of the pacemaker of E1 can be summarized as follows:

- If the threshold rate is exceeded for a selected number of beats, for example, four beats, after the next P-wave is sensed a determination is made whether the ventricle has been stimulated at the end of the AV delay.
- If the ventricle has been stimulated, the AV delay is then changed by a selected amount (delta), for example 150 ms.
- If the interval between P-waves is now greater by 150 ms than the previous interval, this will indicate that the tachycardia is pacer-mediated.
- On the other hand, if the interval between P-waves remains essentially the same as the interval prior to the increase of the AV delay, this indicates that there is no pacer mediated tachycardia.

5.2 Thus, E1 teaches to **compare** the increase of the AV interval with the increase of the PP interval for the same cycle and to decide that there is a PMT if the two increases are equal or that there is no PTM when the PP interval is "*substantially*" constant. In other words, the "*decision means*" of E1 decides that a PMT is

present whenever the AV and PP intervals are **totally correlated**, and that there is no PMT when such intervals are **uncorrelated**. If it were assumed, as argued by the appellant, that the comparison between the two interval increases in E1 had to allow for measurement errors so that the decision means in reality never looked for a perfect match (ie a "correlation value" of 1) or for a constant PP interval (ie a "correlation value" of 0), as the term "substantially " indicated, then the criterion for determining the presence or absence of a PMT according to E1 could be expressed as verifying whether the correlation was **close to 1** or **close to 0**, and not whether "the value of such correlation" deviated "from a first predetermined value", as recited in claim 1 of the contested patent. Thus, the criterion according to claim 1 is different from the one disclosed in E1. As to the corresponding "decision means", it is true that, in some cases, they may arrive at the same decision. However, as the decisions result from the application of different criteria, it seems fair to assume that the corresponding decision means operate in two distinguishable ways. Consequently, the Board finds that E1 does not show feature (b) referred to above.

5.3 Since the subject-matter of claim 1 differs at least in feature (b) from the pacemaker known from E1 there is no need to consider feature (a) for the purpose of establishing that it is novel with respect to this prior art document.

6.1 As to the other documents cited by the appellant in the course of the appeal procedure, E2 teaches, *inter alia*, to minimize the probability of a PMT by setting the

atrial refractory period as a function of the patient's V-A conduction time and to determine the V-A conduction time according to the following procedure:

- A certain **atrial sense window** is defined and during such window, a sensed signal termed "early atrial signal" (EAS) does not cause resetting of the pacemaker and the starting on a new cycle but is simply recorded with respect to its time (column 4, lines 1 to 4).
- The pacing rate is set reasonably high so that there is little likelihood of sensing a natural P-wave within the atrial sense window. Thus, a P-wave sensed within the atrial sense window is deemed to be not natural and probably caused by retrograde conduction (column 4, lines 8 to 14).
- Thus, if the retrograde P-wave conduction is taking place and if the sense window is set at a time which excludes natural P-waves (because the frequency is very high), then the early atrial signal is going to occur at a substantially constant time at each pacing cycle, since the V-A conduction time remains substantially constant over the short duration of the test (column 4, lines 21 to 27).
- On the other hand, if this interval varies over successive cycles of fixed ventricular stimulation, then it is apparent that the sensed atrial signals are not retrograde (column 4, lines 31 to 34).

6.2 Since a natural atrial rate may occur at the exact setting of the ventricular pacing rate, "*further certainty can be added by changing the pacing rate, and determining whether the time of the EAS remains the same. If a change in pacing rate does not affect  $t_{EAS}$ , then there is additional certainty that it represents retrograde P waves, such that the V-A conduction time can be determined accurately*" (column 4, lines 36 to 42).

6.3 Thus, in E2 the rate of ventricular stimulation is varied to distinguish atrial events due to retrograde conduction from "true events", ie from natural atrial pulses.

7.1 E3 relates to a pacemaker comprising means for monitoring the **time relationship** between delivered ventricular stimulus pulses and the following atrial heartbeats for determining the occurrence of pacemaker caused tachycardia.

The teaching of E3 can be summarized as follows (cf column 5, lines 42 to 65):

- whenever an atrial P- signal falls within a certain window W (see Fig. 2C), a counter is incremented, providing an indication of the successive number of P- signals sensed to have fallen within the window W;
  
- in the case of retrograde P-waves resulting from the pacemaker ventricular stimulus pulses, each retrograde P-wave occurs at substantially the same

interval following the delivery of the ventricular stimulus;

-- since time zero for the pacer cycle starts at the end of the window W and not at the time of the sensed P-signal, and since the retrograde conduction time from ventricle to atrium is substantially constant, each sensed retrograde P-signal will fall in the window which has been positioned to see such P-wave;

-- this is in contrast to the condition of physiological high atrial rates, whereby the sensed P signal shifts through the window after a number of cycles.

7.2 Furthermore, E3 teaches to set the window W when there has been an increase of a natural or physiological origin of the atrial rate toward a predetermined maximum rate. According to one embodiment (column 8, lines 55 to 66), *"the pacemaker may take the differential between the rate stored for the prior cycle and the most recent rate, or process the rate over a plurality of successive cycles, applying a predetermined algorithm to determine whether there has been an increase in rate which is deemed to be a physiological increase, whereby the criteria for setting the window are met. It is to be understood that the rate may thus be processed in any one of a number of different ways, the window being set or not in accordance with whether the processed rate meets predetermined logical criteria"*.

Thus, the evaluation of successive cycles in E3 is directed to deciding whether the window W should be established and not to determining the occurrence of a PMT (cf statement of grounds of appeal, page 7, first paragraph).

8. The appellant has referred to E4 and E5 to prove that the term "correlation" may be applied to two linearly dependant variables, and to E6 to show that a linear function is represented by a straight line.

Though late-filed, these documents reflect background knowledge and thus, their admission into the proceedings cannot be regarded as unfair to the respondent.

9. Summarizing, none of the cited prior art documents discloses a pacemaker comprising all the features recited in claim 1 of the respondent's main request. Thus, the subject-matter of this claim is new within the meaning of Article 54 EPC.

*Admissibility of "lack of inventive step" as a ground of opposition*

- 10.1 In the statement of grounds for opposition (page 1, second paragraph), it was specified that the **object** of the European patent lacked novelty within the meaning of Article 54 or lacked an inventive step within the meaning of Article 56 EPC.

Documents E1 and E2 were considered to anticipate the subject-matter of claim 1 of the patent as granted (cf *ibid.* page 3, third and fourth paragraphs).

As to E3, the opponent made the following submission (cf statement of grounds for opposition, page 4, second paragraph) :

*"Im übrigen ist die beanspruchte Lehre auch aus dem hiermit neu genannten Dokument US-A-4 539 991 (nachfolgend E3) vorweggenommen oder doch zumindest nahegelegt" (emphasis added).*

10.2 Thus, within the opposition period, the opponent (appellant) had filed a statement of grounds of opposition in which the subject-matter of claim 1 of the contested patent was attacked on the grounds of lack of novelty in view of document E3 and on the ground of lack of inventive step, having regard to the same prior art. As pointed out in decision T 131/01, *supra*, in such circumstances the objection of lack of inventive step should be regarded as having been substantiated pursuant to Rule 55(c) EPC, because (emphasis added) "*a specific substantiation of the ground of lack of inventive step is neither necessary - given that novelty is a prerequisite for determining whether an invention involves an inventive step and such prerequisite is allegedly not satisfied - nor generally possible without contradicting the reasoning presented in support of lack of novelty*" (cf Headnote).

10.3 It is true, as pointed out by the respondent, that the appellant later decided to base the lack of inventive step objection not only on E3 but, *inter alia*, on a combination of E1 and E3 (see statement of grounds of appeal, pages 6 and 7). However, in the opinion of the Board, the submission at a later stage of new arguments in support of a ground for opposition which, as in the

present case, is considered to have been validly raised within the opposition period cannot put into question the admissibility of such ground.

10.4 Thus, lack of inventive step is not a fresh ground for opposition which could be examined in the appeal proceedings only with the agreement of the patentee.

11.1 As the opposition division considered that lack of inventive step was not an admissible ground of opposition, it must be assumed that the parties were not able to argue their respective cases before the opposition division. Thus, the Board agrees with the respondent that, in the present case, the respondent should not be denied the opportunity of being heard twice on this matter.

11.2 Hence, the Board decides to make use of its powers under Article 111(1) EPC to refer the case back to the first instance for further prosecution on the basis of the respondent's main request.

12. Under these circumstances, there is no need for the Board to consider the respondent's first and second auxiliary requests.

**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 for further prosecution.

The Registrar:

The Chairman:

R. Schumacher

G. Davies