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D E C I S I O N
of 26 February 2003

Case Number: T 0271/00 - 3.4.1

Application Number: 92305248.4

Publication Number: 0518599

IPC: A61N 1/39

Language of the proceedings: EN

Title of invention:
Implantable pacemaker/cardioverter/defibrillator device for incorporating multiple bradycardia support pacing rates

Patentee:
Pacesetter, Inc.

Opponent:
BIOTRONIK Mess- und Therapiegeräte GmbH & Co
Ingenieurbüro Berlin

Headword:
-

Relevant legal provisions:
EPC Art. 123(2), 54, 56

Keyword:
"Added subject-matter (no)"
"Novelty and inventive step (yes, after amendment)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0271/00 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 26 February 2003

Appellant: (Opponent)
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Respondent: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 28 January 2000 rejecting the opposition filed against European patent No. 0 518 599 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: G. Assi
Members: M. G. L. Rognoni
P. Mühlens

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 7 March 2000, against the decision of the opposition division, despatched on 28 January 2000, rejecting the opposition filed against the European patent No. 0 518 599. The fee for the appeal was paid on 7 March 2000 and the statement setting out the grounds of appeal was received on 27 May 2000.

II. The opposition had been filed against the patent as a whole based on Article 100(a) EPC and concerned, in particular, objections under Articles 54 and 56 EPC.

III. The contested decision referred, *inter alia,* to the following documents:

E1: US-A-4 587 970

E3: US-A-4 998 974

E4: Silbernagel: "Taschenatlas der Physiologie", dtv, Stuttgart 1991, pages 46 to 49

E5: Schmidt, Thews (Hrsg.): "Physiologie des Menschen", Springer-Lehrbuch, Berlin 1990, pages 558, 559, 686, 687 and 692.

IV. Oral proceedings were held on 26 February 2003.

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

VI. The respondent (patentee) requested that the patent be maintained in amended form in the following version:

- claims 1 to 21 filed in the oral proceedings; description and drawings as granted (**main request**);

- claims 1 to 20 filed in the oral proceedings; description and drawings as granted (**auxiliary request**).

VII. The wording of claim 1 according to the respondent's **main request** reads as follows:

"*Apparatus (10) for treating arrhythmias of a patient's heart (14), comprising:*

bradycardia pulse therapy means (35, 36, 39) for delivering bradycardia pacing pulses to the heart (14) at a programmable standby rate;
detection means (37) for detecting the presence of a tachycardia of the heart (14);
antitachycardia therapy means responsive to said detection means for delivering antitachycardia therapy to the heart to revert said tachycardia; and
bradycardia pacing rate setting the means (16) for setting the rate of said bradycardia pacing pulses at a normal pacing rate value and setting said bradycardia pacing rate to one other standby rate value for bradycardia pacing after reversion of a tachycardia, wherein said one other post-reversion standby rate value is set for a predetermined post-reversion period of time and [in that] said one other standby rate value is set at a value higher then said normal pacing rate value, to compensate for hemodynamic compromise experienced during tachycardia and/or following

antitachycardia therapy".

Claims 2 to 21 are directly or indirectly dependent on claim 1.

The wording of claim 1 according to the respondent's **auxiliary request** reads as follows

"Apparatus (10) for treating arrhythmias of a patient's heart (14), comprising:

bradycardia pulse therapy means (35, 36, 39) for delivering bradycardia pacing pulses to the heart (14) at a programmable standby rate;
detection means (37) for detecting the presence of a tachycardia of the heart (14);
antitachycardia therapy means responsive to said detection means for delivering antitachycardia therapy to the heart to revert said tachycardia; and
bradycardia pacing rate setting the means (16) for setting the rate of said bradycardia pacing pulses at a normal pacing rate value and setting said bradycardia pacing rate to one other standby rate value for bradycardia pacing after reversion of a tachycardia, characterised in that said one other post-reversion standby rate value is set for a predetermined post-reversion period of time and in that said one other standby rate value is set at a value higher than said normal pacing rate value, to compensate for hemodynamic compromise experienced during tachycardia and/or following antitachycardia therapy, wherein said antitachycardia therapy comprises a selected therapy from the group of therapies including

antitachycardia pacing therapy, cardioversion therapy and defibrillation therapy, wherein said one other rate value is different depending on whether said one other rate value is set by said bradycardia pacing rate setting means following antitachycardia pacing therapy or set by said bradycardia pacing rate setting means following defibrillation or cardioversion therapy."

Claim 2 to 20 are directly or indirectly dependent on claim 1.

VIII. The appellant's arguments may be summarized as follows:

Document E1 related to an apparatus for treating arrhythmias and taught, *inter alia*, to pace the patient's heart at a decreasing rate which merged into the standby pacing rate. Since the wording of claim 1 of the respondent's main request covered the possibility that the *"post-reversion period of time"* could be the first pacing cycle following the antitachycardia pacing and the last clause of the claim merely related to an effect which necessarily accompanied a pacing rate higher than the normal standby rate, all the features of claim 1 could be read onto the apparatus known from E1.

Hence, the subject-matter of claim 1 of the respondent's main request was not new within the meaning of Article 54 EPC.

However, even if it were assumed that E1 did not take away the novelty of the subject-matter of claim 1 according to the respondent's main request, because the "*predetermined post-reversion period of time*" specified in the claim was assumed to be longer than a pacing

cycle, the subject-matter of claim 1 did not involve an inventive step within the meaning of Article 56 EPC. As shown by E3, the person skilled in the art was aware that hemodynamic compromise could occur after a tachyarrhythmia. Furthermore, it was commonly known that a healthy heart's natural response to a situation of stress was to increase the heart rate (see E4 and E5). Thus, it would have been obvious to a skilled person, wishing to enhance the compensation of the hemodynamic compromise effected by the post-reversion pacing taught in E1, to arrive at an apparatus falling within the terms of claim 1 of the respondent's main request.

IX. The respondent argued essentially as follows:

E1 taught to smooth the transition between the fast pulses used to terminate a tachycardia episode and the subsequent beating in sinus rhythm by generating pacing pulses at increasing pacing intervals until they merged into standby pacing. This document ignored the problem of compensating for the hemodynamic compromise resulting from the tachycardia and/or the antitachycardia therapy. Furthermore, the wording of claim 1 according to the main request could not be read onto the apparatus shown in E1 because it did not make any technical sense to assume that the post-reversion period of time referred to in the claim could be limited to a single pacing cycle. In fact, it was evident that the claimed effect (*ie* compensation for the patient's hemodynamic compromise) could not be achieved in such short period of time.

Though the problem of hemodynamic compromise after a cardioversion was mentioned in E3, there was no suggestion that it could be solved by increasing the

pacing rate for a predetermined post-reversion period of time. As to E4 and E5, these documents would not give the skilled person any useful information about a possible treatment of the heart after tachycardia therapy because they related to a healthy heart's behaviour.

Hence, the subject-matter of claim 1 according to the main request satisfied the requirements of Article 54 and 56 EPC.

Reasons for the Decision

1.1 The appeal is admissible.

2.1 The patent in suit addresses the problem of compensating patients dependent on bradycardia support pacing for the hemodynamic compromise resulting from tachycardia and/or antitachycardia therapy (see patent as published column 1, lines 54 to 59).

2.2 The proposed solution consists essentially in providing an apparatus which delivers antitachycardia pacing therapy and cardioversion/fibrillation therapy when needed. It includes maintaining bradycardia support pacing at a rate higher than the normal standby pacing rate for a predetermined period of time following the delivery of the antitachycardia therapy.

The respondent's main request

Admissibility of the amendments

3.1 In claim 1 according to main request the following expressions:

- "*one other standby rate value*" and

- "*one other post-reversion standby rate value*"

replace the wording:

- "*at least one other standby rate value*" and

- "*at least one other post-reversion standby rate value*"

used in claim 1 as granted. As acknowledged by the respondent, the deletion of "*at least*" is meant to avoid that the independent claim of the contested patent could be interpreted as covering the prior art apparatus known from E1.

3.2 The Board is satisfied that the wording of claim 1 reflects the embodiment of the invention specified in the description, whereby one particular post-reversion standby rate value is set for a predetermined post-reversion period of time. In other words, the claim now excludes the possibility that more than one post-reversion standby rate higher than the normal standby rate is set within the predetermined post-reversion period of time.

3.3 In the appellant's view, the wording of claim 5, dependent on claim 1, was not compatible with the subject-matter of the independent claim, because the latter specified that there was only one standby rate value for bradycardia pacing after reversion of a tachycardia. According to claim 5, however, the bradycardia pacing means set a first rate value for bradycardia pacing following an antitachycardia pacing therapy and a second rate value following a

defibrillation or cardioversion therapy.

3.4 The contested patent clearly specifies that the term "*tachycardia*" is supposed to cover any fast abnormal rhythm of the heart (patent specification, column 3, lines 12 to 19). Hence, the expression "*setting said bradycardia pacing rate to one other standby rate value for bradycardia pacing after reversion of a tachycardia*" used in claim 1 is to be understood as meaning that **one rate value** is set for **a particular kind** of tachycardia. This interpretation does not exclude the possibility that a different value may be chosen for a different kind of tachycardia, as specified in claim 5.

As to the amendments made to claim 5 of the patent as granted, they are merely directed to adapting the claim language to the new independent claim and do not involve any introduction of new subject-matter.

3.5 Since claim 1 now relates to an apparatus having bradycardia pacing means which sets the pacing rate to **one** other standby rate value for bradycardia pacing after reversion of a tachycardia, it limits the protection conferred by the patent as granted.

3.6 In the result, the Board is satisfied that all amendments made to the patent specification are admissible under Articles 123(2) and (3) EPC.

Novelty

4.1 It is undisputed that E1 represents the closest prior art and that this document relates to an apparatus for treating arrhythmias of a patient's heart, comprising the following features recited in claim 1 according to

the respondent's main request:

- bradycardia pulse therapy means for delivering bradycardia pacing pulses to the heart at a programmable standby rate;

- bradycardia pacing rate setting means for setting the rate of said bradycardia pacing pulses at a normal pacing rate value.

- detection means for detecting the presence of a tachycardia of the heart;

- antitachycardia therapy means responsive to said detection means for delivering antitachycardia therapy to the heart to revert said tachycardia;

4.2 As to the remaining features of the claim 1, the appellant essentially argued that they were also known from E1 since the "*predetermined post-reversion period of time*" referred to in the claim did not necessarily encompass more than one pacing period. Furthermore, it was customary to speak of a "*pacing rate value*" even for a single pacing pulse, since such rate value was the reciprocal of the escape interval preceding the pulse delivery. As shown in Figure 3, the apparatus of E1 started the post-reversion pacing phase B by generating a pacing pulse which was separated from the last pulse of the treatment phase A by a longer pacing interval. Hence, in the appellant's view, E1 implied also bradycardia pacing rate setting means for setting the rate to one standby rate value, defined as the reciprocal of the escape interval following the last pulse of the tachycardia treatment (phase A), for a predetermined time period, corresponding to time interval separating the last pacing pulse of phase A

from the first pacing pulse of phase B.

4.3 The Board agrees with the appellant that it is possible to associate a pacing rate to a pacing pulse even if the rate varies from pulse to pulse. In fact, E1 uses this terminology for expressing the fact that the pacing intervals are successively lengthened (E1, column 5, lines 6 and 7: "*we provide a second phase of pacing in which the pacing pulses are generated at slower and slower rates*").

However, claim 1 specifies that the bradycardia pacing rate setting means sets a **standby** rate value for **a predetermined** post-reversion period of time. This wording implies in the context of the present invention that the two parameters (rate and predetermined period of time) can be set independently. In E1, the rate value of the first pulse of phase B is a function of the preceding time interval, (ie of the time interval separating this pulse from the last pulse of phase A), so that the apparatus of E1 does not comprise any means for setting these two parameters independently.

Furthermore, the Board agrees with the respondent that it would not make much technical sense to limit the post-reversion high-rate bradycardia pacing to a single pulse, as this kind of heart stimulation could not contribute in any significant way to the claimed effect, ie to compensating for the hemodynamic compromise experienced by the patient after a cardioversion.

4.4 In conclusion, the Board finds that the apparatus of E1 does not fall within the terms of claim 1 and that therefore the subject-matter of this claim is new within the meaning of Article 54 EPC.

Inventive step

5.1 The subject-matter of claim 1 differs from the apparatus shown in E1 essentially in that:

- the bradycardia pacing rate setting means also sets the bradycardia pacing rate to **one other standby rate value** for bradycardia pacing after reversion of a tachycardia **for a predetermined post-reversion period of time**;

- said one other standby rate value is set at a value higher than the normal pacing rate value, to compensate for hemodynamic compromise experienced during tachycardia and/or following antitachycardia therapy.

5.2 According to the appellant, the skilled person starting from the teaching of E1 would realise that an increased pacing rate did not have only the effect of smoothing the transition from the antitachycardia pacing rate to the standby rate, but it contributed also to reducing the hemodynamic compromise suffered by a patient after a cardioversion. In fact, it was known that the patient's hemodynamic status was compromised after reversion of a tachycardia (cf. E3) and that and the hemodynamic compromise could be compensated for by increasing the heartbeat (cf. E4 and E5)

5.3 E3 relates to an apparatus and a method of antitachycardia pacing. The passage referred to by the appellant reads as follows (column 3, lines 58 to 68):

"*Especially in the case of ventricular antitachycardia pacing, although the pacing may revert an arrhythmia, at the same time however, it increases the risk of*

adversely affecting the patient by means of a decrease in arterial pressure due to the rapid pacing. As a result of the haemodynamic compromise or lowered haemodynamic status of the myocardium during the arrhythmia and pacing, there is a high risk of a ventricular tachycardia accelerating to a faster ventricular tachycardia and even to a ventricular fibrillation."

In other words, E3 not only points out that the patient's hemodynamic status may be lowered after reversion of a tachycardia, it also identifies the increased pacing used to treat tachyarrhythmias as one of the possible causes for the hemodynamic compromise and, consequently, for the acceleration of a ventricular tachycardia to a faster ventricular tachycardia or to a ventricular fibrillation.

5.4 Hence, in the opinion of the Board, E3 does not seem to support the appellant's argument that a pacing rate higher than the normal standby rate would be perceived as beneficial by the skilled person, since it necessarily improved the patient's hemodynamic status after reversion of a tachycardia. On the contrary, E3 appears to caution the skilled person against the risks involved in pacing at a high rate.

Similarly, the description of the contested patent specifies the following (column 7, lines 34 to 40):

"*It is also preferable that bradycardia support pacing be inhibited for programmable periods of time after reversion of a tachyarrhythmia by either antitachycardia pacing therapy or defibrillation shock therapy, so as to avoid any pro-arrhythmic effect. The use of such a delay is described in the aforementioned*

US patent No. 4,940,054."

5.5 As to E4 and E5, these documents relate to the behaviour of a healthy heart and show, *inter alia*, that for a certain time interval following a period of physical stress the heart keeps beating at a rate higher than the normal rate at rest. The Board agrees with the appellant that a pacemaker normally seeks to simulate the heart's natural behaviour. However, there is not suggestion in the cited prior art that bradycardia support pacing after antitachycardia therapy should be modelled on a normal heart's reaction to a situation of increased physical or emotional stress.

5.6 In the result, the Board considers that it would not be obvious to a person skilled in the art, starting from the teaching of E1, to arrive at an apparatus falling within the terms of claim 1 of the main request. Hence, the subject-matter of this claim involves an inventive step within the meaning of Article 56 EPC.

Claims 2 to 21 are dependent and, therefore, their subject-matters also involve an inventive step.

6.1 For the above reasons, the Board finds that the respondent's main request is allowable and that the patent can be maintained on the basis thereof. Consequently, there is no need to consider the respondent's auxiliary request.

6.2 Furthermore, the Board notes that, in order to correct a linguistic error due to an inconsistency in the amendments made by the respondent to claim 1 ("*wherein said ..... and in that*"), the words "*in that*" in claim 1 are to be deleted (Rule 89 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 in the following version:

   - claims 1 to 21 of the respondent's main request as filed in the oral proceedings;

   - description and drawings of the patent as granted.

The Registrar: The Chairman:

R. Schumacher G. Assi