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D E C I S I O N
of 12 December 2002

Case Number: T 1011/98 - 3.4.1

Application Number: 89300232.9

Publication Number: 0324604

IPC: A61N 1/39

Language of the proceedings: E

Title of invention:
Appartus for controlling pulse energy in antitachyarrythmia and bradycardia pacing device

Patentee:
Pacesetter, Inc.

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

Headword:
-

Relevant legal provisions:
EPC Art. 114, 52, 54, 56

Keyword:
"Admissibility of late-filed document (yes)"
"Novelty (yes) - main request"
"Inventive step (no) - main and auxiliary requests"

Decisions cited:
-

Catchword:
-

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Case Number: T 1011/98 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 12 December 2002

Appellant: (Opponent)
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Respondent: (Proprietor of the patent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 13 August 1998 concerning maintenance of European patent No. 0 324 604 in amended form.**

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
H. K. Wolfrum

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 13 October 1998, against the interlocutory decision of the opposition division despatched on 13 August 1998, maintaining the European patent No 0 324 604 in amended form. The fee for the appeal was paid on 13 October 1998 and the statement setting out the grounds of appeal was received on 10 November 1998.

II. The opposition had been filed against the patent as a whole based on Articles 100(a) and (b) EPC and concerned *inter alia* objections under Articles 52(1), 54 and 56 EPC.

III. In the statement of grounds of appeal, the appellant referred *inter alia* to the following documents:

E1: US-A-4 693 253

E3: US-A-4 321 928

E4: EP-A-0 094 341

E6: M. Slepian *et al*.:"Automatic Implantable Cardioverter Defibrillator/Permanent Pacemaker Interaction: Loss of Pacemaker Capture Following AICD Discharge", Pace, Vol. 10 (September-October 1987), p. 1194 to 1197.

IV. In response to a communication of the Board summoning the parties to oral proceedings, the respondent (patentee), by letter dated 12 November 2002, filed new claims 1 to 10 as an auxiliary request.

V. Oral proceedings were held on 12 December 2002.

VI. The appellant requested that the decision of the opposition division be set aside and the patent revoked.

VII. The respondent (patentee) made the following requests:

main request: dismissal of the appeal and maintenance of the patent on the basis of claims 1-10 as granted and maintained in the opposition proceedings; columns 1-10, to line 39 of the description as amended and maintained in the opposition proceedings; sheets 1/5-5/5 of the Figures as granted;

auxiliary request: maintenance of the patent on the basis of claims 1-10 and amended column 3 of the description filed on 12 November 2002; remainder of the description and Figures as for the main request.

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

"1. An apparatus (10) for treating cardiac arrhythmias comprising:

bradycardia pulse supplying means (36) for

supplying bradycardia pacing pulses (44) at an energy level;
detecting means (16, 37) for detecting a tachycardia;
antitachycardia therapy means (15, 16) responsive to said detecting means for supplying antitachycardia therapy to revert said tachycardia; and
energy level setting means (16, 21) responsive to said detecting means for setting said energy level of said bradycardia pacing pulses, characterised by said energy level setting means setting said energy level to a first discrete energy level (4v), and said energy level setting means setting said energy level to a second discrete energy level (6v) for bradycardia pacing after a reversion of a tachycardia, said second level being higher than said first level."

Claims 2 to 10 are dependent on claim 1.

Claim 1 according to the auxiliary request differs from claim 1 of the main request only in that the term "discrete" referred to the first and second energy levels is replaced by "constant".

IX. The arguments of the appellant may be summarised as follows:

Document E6 was highly relevant and should be admitted into the proceedings, since it disclosed that the threshold to capture the heart increased after an antitachycardia treatment.

Document E1 related to a defibrillator and pacer

comprising bradycardia pulse supplying means, detecting means and energy level setting means as specified in the preamble of claim 1 of the respondent's main request. The characterising part of this claim simply specified that bradycardia pacing pulses were supplied at two different discrete energy levels and that the higher energy pulses should be delivered after defibrillation. E1 (column 2, lines 62 to 67) explicitly taught to use high energy pacing pulses after defibrillation and showed that such pulses had discrete values (see Figure 4). Furthermore, since the apparatus disclosed in E1 was a pacer/defibrillator, it was implicit that it comprised means for generating bradycardia pacing pulses at a normal (*ie* lower) energy level. In fact, it was generally known to have different discrete levels for bradycardia support pacing and to select the energy levels of the pacing pulses according to the heart's response (see E3 and E4). Since E1 disclosed either explicitly or implicitly all the features recited in claim 1 of the respondent's main request, the subject-matter of this claim was not new within the meaning of Article 54 EPC.

Even if it were assumed that E1 did not anticipate the claimed apparatus, the subject-matter of claim 1 according to the main request did not involve an Inventive step within the meaning of Article 56 EPC. E1 was a technical document and merely described the functions of a defibrillator/pacer without explaining why the pacing pulses were defined as being at a high energy level. E6, however, explained that the pacing threshold increased after defibrillation and therefore provided the physiological background knowledge for understanding all the aspects of the teaching of E1. In other words, E6 made clear that E1 used high energy

pulses after defibrillation to allow for the increased pacing threshold and that, consequently, lower energy pulses should be used for normal bradycardia pacing. Hence, the person skilled in the art reading E1 in the light of E6 would understand that high energy pulses were required to ensure heart capture after a defibrillation treatment and that for normal bradycardia pacing a lower energy level sufficed.

As to the auxiliary request, the amendment to claim 1 could not make the subject-matter of the claim Inventive over the prior art because it was generally known that bradycardia support pacing pulses generally had a constant energy level (*ie* a predetermined amplitude and a predetermined width) which was selected to ensure capture of the heart and to minimize energy consumption. Hence, also the subject-matter of claim 1 according to the auxiliary request did not meet the requirements of Article 56 EPC.

X. The respondent argued essentially as follows:

Though E6 reported on the failure to capture the heart after a tachyarrhythmia treatment, it did not point to any solution. Hence, E6 was not sufficiently relevant to be admitted into the proceedings.

Since E1 disclosed an apparatus for treating defibrillation and was not concerned with the problem of pacing the heart of a patient suffering from persistent bradycardia, it did not show an apparatus comprising the bradycardia pulse supplying means recited in the preamble of claim 1 according to the main request. Hence, the subject-matter of this claim was new within the meaning of Article 54 EPC.

The present invention related to a device which combined the functions of bradycardia treatment and of tachycardia treatment and took into account the problem of failure to capture occurring after a tachycardia treatment. The solution consisted essentially in providing pacing pulses at a second energy level higher than the first energy level used for normal bradycardia pacing. Since E1 was not concerned with bradycardia pacing, it did not provide a suitable starting point for the present invention. Document E6 referred to the problem of heart capture after defibrillation and discussed some of its possible causes but did not contribute to any specific solution. Hence, the combined teaching of E1 and E6 would not have led the person skilled in the art to the claimed subject-matter.

Claim 1 of the auxiliary request clarified that the two energy levels of the bradycardia pulses were constant, as shown in Figures 5 and 6 of the contested patent. In E1 the pacing pulses delivered after defibrillation had different energy levels and should not be assimilated to bradycardia pacing pulses. In fact, E1 did not address the problem of treating bradycardia and merely taught to help the heart resume its normal sinus rhythm after defibrillation by utilizing the residual energy available from the cardioverting energy source. Since there was no suggestion in the cited prior art to use pulses at a constant higher energy level for heart pacing after cardioversion, the subject-matter of claim 1 according to the auxiliary request involved an Inventive step within the meaning of Article 56 EPC.

Reasons for the decision

1. The appeal is admissible.

Admissibility of document E6

2.1 In exercising its discretion conferred by Article 114(2) EPC, the opposition division decided to disregard E6, since it considered that this (late-filed) document, which had been filed outside the opposition period as laid down in Article 99(1) EPC, was not more relevant than the prior art already on file.

2.2 The Board, however, considers that E6 is highly relevant and should be admitted into the appeal procedure because it contains information which appears to be essential for the assessment of the patentability of the claimed invention.

Main request

Novelty

3.1 The patent in suit relates to an apparatus for treating cardiac arrhythmias and for providing bradycardia pacing. It addresses, in particular, the problem of preventing loss of capture of the heart after antitachycardia therapy.

3.2 The gist of the present invention consists essentially in providing pulses at a first energy level for normal bradycardia support pacing and at a second higher energy level for pacing after an antitachyarrhythmia therapy. As pointed out in the description (column 7,

lines 20 to 26), setting the pulse energy at a high level prevents a loss of capture caused by the traumatic state of the heart after an antitachyarrhythmia therapy.

4.1 Document E1 relates to an automatic implantable defibrillator which includes a pacing pulse generator for delivering high energy cardiac stimulating pulses to the heart after defibrillation (see column 1, lines 6 to 12). Its operation is described as follows:

- if the cardiac tissue does not return to a normal sinus rhythm after a time period indicated by the escape interval timing ET then some of the residual energy stored within the energy storage means 10 will be delivered to the heart in the form of a pacing stimulus (see column 2, lines 56 to 61);

- in this fashion, the automatic implantable defibrillator and pacer according to E1 permits the high energy stimulation of the cardiac tissue if the cardioverting pulse delivered to the heart has prevented the prompt re-establishment of the normal sinus rhythm (column 2, lines 61 to 66);

- additional pacing stimuli may be produced in response to an extended interruption of the cardiac cycle (column 2, lines 66 to 67).

4.2 According to a preferred embodiment, energy is taken directly from the energy storage capacitor 10 used to store the charge required to generate the defibrillating pulse, whereby the capacitor is directly coupled to the heart by means of a switch. However, E1

foresees also the possibility of using a voltage regulator connected between the energy storage capacitor 10 and a pacing storage capacitor 11 in order to lower the voltage available at the energy storage capacitor after discharge of a defibrillating pulse.

It is further pointed out in E1 (see column 3, lines 15 to 21) that after normal sinus rhythm is restored and there is no further need for pacing or defibrillating energy, it may be desirable to discharge the energy on the defibrillating storage capacitor 10 as well as the pacing capacitor 11.

4.3 In other words, E1 teaches to deliver high energy pacing pulses to the heart in order to overcome a temporary loss of normal sinus rhythm which may be experienced after defibrillation, but it does not appear to be concerned with the problem of treating a patient suffering from both tachyarrhythmias and persistent bradycardia.

4.4 The Board agrees with the appellant that the means used in E1 for detecting a loss of sinus rhythm (*ie* the escape interval ET) is essentially the same as the means for monitoring the occurrence of bradycardia. However, the choice of the source of energy in E 1 (*ie* the energy storage capacitor) clearly shows that pacing pulses are expected to be needed only for a limited time period and not for permanent bradycardia support.

4.5 In summary, the Board finds that E1 does not disclose the bradycardia pulse supplying means specified in claim 1 of the contested patent and, consequently, it does not anticipate the subject-matter of this claim

(Article 54 EPC).

Inventive step

5.1 The subject-matter of claim 1 differs from the apparatus known from E1 essentially in that the former further comprises:

(a) bradycardia pulse supplying means for supplying bradycardia pulses at an energy level,

(b) energy level setting means for setting said energy level to a first discrete level and to a second discrete level for bradycardia pacing after reversion of a tachycardia,

(c) said second level being higher than said first level.

5.2 Starting from the apparatus known from E1, the problem addressed in the contested patent could be seen in developing an apparatus for treating both tachyarrhythmias and persistent bradycardia.

5.3 As acknowledged in the introductory part of the patent in suit (see column 2, lines 2 to 18), it is known to combine the pacemaker and defibrillation functions in a single implantable device. Hence, it cannot be regarded as Inventive to modify the apparatus of E1 so that it can deliver pacing pulses for the treatment of persistent bradycardia.

Though E1 consistently refers to high energy pulses to be delivered after an antitachycardia therapy, it does not specify whether their energy level should indeed be

higher than the one required by standard antibradycardia pacing.

Hence, the essential question to be considered is whether it would be obvious to a person skilled in the art, wishing to add to the apparatus of E1 the function of a pacemaker to consider the possibility of choosing an energy level for the treatment of bradycardia lower than the energy level of the pacing pulses delivered after the antitachycardia treatment.

5.4 E6 is concerned with the loss of pacemaker capture following an AICD [Automatic Implantable Cardioverter Defibrillator] discharge. According to E6, "post-AICD [Automatic Implantable Cardioverter Defibrillator] discharge bradycardia has been reported and might be expected to be seen more frequently", so that "the combination of an AICD with a pacemaker may become more frequent" (page 1194, left-hand column, first paragraph). Having established a clear link between the pacemaker failure to capture and an increase in the pacing threshold, E6 draws the following conclusions:

> "Pacemaker failure to capture following internal defibrillation from an AICD, may become a more prominent problem. Also, the design of devices which will pace and defibrillate need to consider this problem. Further work will need to guarantee that back-up pacemaker systems per se will be able to pace effectively post-discharge" (page 1196, last paragraph).

5.5 In summary, the person skilled in the art derives from E6, *inter alia*, the following teaching:

- post-discharge bradycardia is a common occurrence which can be dealt with by pacing the heart after cardioversion;

- a failure to capture the heart after an antitachycardia treatment, which implies, *inter alia*, an AICD discharge, is due to an alteration of the pacing threshold;

- in designing devices which combine pacemaker and defibrillator functions, care should be taken that the pacemaker system is able to pace effectively after a defibrillator treatment.

5.6 On the other hand, it is also well established in the art that the energy of a pacing pulse should be set to a level which both ensures heart capture and avoids any energy waste. The desire to fulfil these requirements has led to the development of pacemakers with selectable pulses of different amplitudes and lengths (*ie* different energies) (see E3 and E4).

5.7 Against the background of the teaching of E6 and of the general knowledge in the art, the skilled person would realise that the high energy pulses generated in E1 would not be required for normal antibradycardia pacing and that it would be advantageous to have two energy levels to cope with two different situations: *ie* with a normal pacing threshold in the case of persistent bradycardia and with an altered pacing threshold in the case of post-AICD bradycardia.
For the skilled person, the obvious consequence would be to provide a pacemaker/defibrillator with means for selecting between two energy levels in accordance with the varying pacing threshold.

5.8 Claim 1 of the contested patent further specifies that the energy level is "discrete". This wording has been interpreted by the appellant as covering also pacemakers having more than one distinct energy level for post-defibrillation pacing. According to this interpretation, this feature is known from E1 which shows pulses with several distinct energy levels. According to the respondent, however, the wordings "a first discrete energy level" and "a second discrete energy level" limit the claim to an apparatus having only two constant energy levels: one for post-tachycardia pacing and one for normal antibradycardia pacing.

In any case, the Board sees no Inventive contribution in modifying the apparatus of E1 so that the post-discharge pulses are all delivered at the same energy level. On the contrary, it would be an obvious modification to an apparatus which seeks to effect a simple conversion of the residual energy of the energy storage capacitor into pacing pulses and does not appear to be concerned with the problem of minimizing energy consumption.

5.9 In summary, the Board considers that, in the light of the prior art, it would be obvious to a person skilled in the art starting from the teaching of E1 and wishing to develop a device combining the pacemaker function with the defibrillator function to arrive at the following conclusions:

- post-defibrillation bradycardia was associated with a higher pacing threshold and thus required higher pacing energy;

- energy saving considerations implied the selection of the minimum energy required for heart stimulation; in the case of bradycardia with two different pacing thresholds, two distinct energy levels should be provided.

5.10 Since the above considerations would necessarily direct the person skilled in the art to an apparatus falling within the terms of claim 1 of the respondent's main request, the subject-matter of this claim does not involve an Inventive step within the meaning of Article 56 EPC.

Auxiliary request

6.1 Claim 1 of the respondent's auxiliary request differs from claim 1 of the main request only in that the first and second energy levels are defined as being "constant" instead of "discrete".

6.2 Since it is generally known to pace the heart at constant energy levels, the above amendment cannot make the subject-matter of claim 1 Inventive within the meaning of Article 56 EPC.

7. In the result, the Board finds that, since none of the respondent's requests is allowable, there is no basis for the maintenance of the patent.

Order

For these reasons it is decided that:

1. The decision of the opposition division is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

R. Schumacher G. Davies