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D E C I S I O N
of 24 June 2003

Case Number: T 0451/98 - 3.4.1

Application Number: 89303019.7

Publication Number: 0334681

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
Pacemaker with improved automatic output regulation

Patentee:
Pacesetter, Inc.

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

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty - main request (no)"
"Inventive step - first auxiliary request (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0451/98 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 24 June 2003

Appellant: (Proprietor of the patent)	Pacesetter, Inc. 15900 Valley View Court Sylmar, CA 91342 (US)
Representative:	Hackett, Sean James Marks & Clerk Alpha Tower Suffolk Street Queensway Birmingham B1 1TT (US)
Respondent: (Opponent)	Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro Berlin Woermannkehre 1 D-12359 Berlin (DE)
Representative:	Eisenführ, Speiser & Partner Anna-Louisa-Karsch-Strasse 2 D-10178 Berlin (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 3 March 1998 revoking European patent No. 0334681 pursuant to Article 102(1) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal, received on 1 May 1998, against the decision of the opposition division, despatched on 3 March 1998, revoking the European patent No. 0 334 681. The fee for the appeal was paid on 1 May 1998 and the statement setting out the grounds of appeal was received on the same day.

II. The opposition had been filed against the patent as a whole based on Articles 100(a) and (b) EPC. In the course of the appeal, the objections raised by the respondent (opponent) were essentially based on Articles 52(1), 54 and 56 EPC (see last paragraphs of the respondent's letters dated 23 and 26 May 2003).

III. In the contested decision, the opposition division held that the following document represented the undisputed closest prior art:

E2: EP-A-0 017 848.

IV. In response to a communication of the Board summoning the parties to oral proceedings, the representative of the respondent (opponent), by letter dated 23 May 2003, informed the Board that the respondent would not be represented in the oral proceedings.

V. Oral proceedings were held on 24 June 2003 in the absence of the respondent.

VI. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of:

Main request:
Claims 1 to 6 as granted;
columns 1, 2, 5, 6, 9 and 10 of the description filed in the oral proceedings;
columns 3, 4, 7, 8, 11 to 47 of the description as granted;
Figures 1 to 30 as granted.

First auxiliary request:
Claims 1 to 6 filed in the oral proceedings;
description and Figures as for the main request

Second auxiliary request:
Claims 1 to 6 filed in the oral proceedings;
description and Figures as for the main request;

Third auxiliary request:
Claims 1 to 6 filed in the oral proceedings;
description and Figures as for the main request.

VII. The respondent requested in writing that the appeal be dismissed and that possible requests of the appellant filed in the oral proceedings be refused as late filed.

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

"A rate-responsive pacemaker comprising means (54, 57) for periodically ascertaining the value of a measured rate control parameter ["MRCP"] which is based upon the sensing of an evoked potential; and means (48) for generating pacing pulses at a pacing rate which is a function of said MRCP; characterised by means (50)

responsive to the failure to sense an evoked potential following the generation of a pacing pulse for increasing the pacing rate so that if said failure was due to a fusion beat, then the next pacing pulse is more likely to result in a heart capture."

Claims 2 to 6 are dependent on claim 1.

Claim 1 according to the **first auxiliary request** differs from claim 1 of the main request in that the wording "*without increasing the pulse energy*" is inserted after "*for increasing the pacing rate".*

Claim 1 according to the **second auxiliary request** differs from claim 1 of the main request in that the wording "*without increasing the pulse energy for a predetermined number of cycles* " is inserted after "*for increasing the pacing rate".*

Claim 1 according to the **third auxiliary request** differs from claim 1 of the main request in that the wording "*without increasing the pulse energy for the first, second and third cycles*" is inserted after "*for increasing the pacing rate".*

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

Claim 1 according to the **main request** specified that the pacing rate was increased in response to the failure to sense an evoked potential. The pacemaker disclosed in E2, however, responded to such a failure by generating a backup pulse. While an increase in the pacing rate was ultimately achieved by reducing the escape interval, the delivery of a backup pulse

corresponded to the imposition of one extra stimulus and did not modify the sequence of timing intervals, such as the escape interval, which determined the pacing rate. Thus, E2 did not take away the novelty of the subject-matter of claim 1 of the main request.

Claim 1 according to the **first auxiliary request** specified that the pacing rate was increased without increasing the pulse energy. The pacemaker known from E2 responded to the failure to sense an evoked potential by generating a backup pulse which had an energy higher than the preceding stimulating pulse. Hence, the subject-matter of claim 1 was clearly distinguishable from the prior art teaching.

X. The respondent's arguments may be summarised as follows:

Since claim 1 according to the main request could be read on to the pacemaker disclosed in E2, which generated a backup pulse in response to the failure to sense an evoked potential, its subject-matter lacked novelty.

Only if it were made clear beyond doubt that the pacing pulse following the failure to detect an evoked potential had the same energy as the previous pacing pulse, would the claimed subject-matter be distinguishable from the pacemaker known from E2.

Reasons for the decision

1. The appeal is admissible.

2.1 The patent in suit relates to a rate-responsive pacemaker which determines the pacing rate as a function of a rate control parameter derived from an "evoked potential" , ie from the heart's electrical response to a pacing pulse, and which is provided with an automatic output control in order to ensure heart capture for the lowest possible pulse output energy. As pointed out in the description (patent specification: column 1, lines 6 to 13), the automatic output regulation may be confounded by a "fusion beat" which is defined as a combined intrinsic and paced event occurring when the pacemaker does not have enough time between start of the intrinsic beat and timeout of the escape interval to inhibit generation of a stimulus. A failure to sense an evoked potential as a result of a fusion beat results in the erroneous conclusion that the heart has failed to respond to the pacing pulse and that there is a need to increase the pulse energy.

2.2 In order to avoid an unnecessary increase of the pulse output energy, the pacemaker of the contested patent seeks to distinguish between a fusion beat and a loss of heart capture due to insufficient pulse output energy by increasing the pacing rate in response to a failure to sense an evoked potential.

Appellant's main request

3.1 An essential question to be considered in the present appeal is whether E2 discloses a pacemaker falling within the terms of claim 1 of the appellant's main request.

3.2 It is not in dispute that E2 relates to a pacemaker which comprises not only the features recited in the preamble of claim 1 of the contested patent but also means for delivering a **backup pulse** in response to a failure to sense an evoked potential following the generation of a pacing pulse.

3.3 As submitted by the respondent, the total number of pulses delivered in a given time interval increases when a backup pulse is generated in response to a failure to sense an evoked potential. Since the pacing rate can be defined as the ratio between the number of pulses and the corresponding time interval, the means for delivering backup pulses shown in E2 could be considered to correspond to "*means responsive to the failure to sense an evoked potential following the generation of a pacing pulse for increasing the pacing rate*" as recited in the characterising part claim 1.

As to the last clause of claim 1, it merely specifies that increasing the pacing rate when loss of heart capture is sensed would make it "more likely" for the next pacing pulse to result in a heart capture, if the failure to sense an evoked potential following the previous pacing pulse was due to a fusion beat. In other words, the claimed pacemaker does not seek to determine the cause of a loss of capture but, in the wake of a failure to detect an evoked potential, it takes a certain measure (pacing rate increase) which may or may not contribute to achieving a desired result (sensing of a heart capture), though it would make it "more likely", if the cause was a fusion beat.

In the pacemaker of E2 the pacing rate (ie the number of stimulating pulses in a given time interval) is also increased independently of the cause of a failure to detect an evoked potential, and the pacing pulse following a sensed loss of capture due to a fusion beat is also more likely to succeed in stimulating the heart because the pulse level is raised (see E2, page 14, lines 28 to 32).

Since the last clause of claim 1 does not establish a clear functional link between fusion beats (as the cause of a failure to sense an evoked potential) and a pacing rate increase (as a measure to avoid fusion beats), it does not suffice to distinguish the claimed subject-matter from the pacemaker shown in E2.

3.4 Summarizing, the Board finds that the wording of claim 1 of the main request covers the pacemaker according to E2, and that, therefore, the claimed subject-matter is not new within the meaning of Article 54 EPC.

Appellant's first auxiliary request

4.1 Claim 1 according to the first auxiliary request differs from claim 1 of the main request in that in the former the pacing rate is increased "*without increasing the pulse energy".* This amendment filed by the appellant in the oral proceedings seeks to overcome an objection raised by the respondent in writing a month before the date of the oral proceedings (see letter dated 23 May 2003: page 2, second paragraph), and relates to a feature which, as suggested by the

respondent, would establish the novelty of the claimed subject-matter.

4.2 Since the amendment, albeit filed at a very late stage, is "clearly allowable", in the sense that it can quickly be seen to introduce no new objections under the EPC and to meet the outstanding objection of novelty, and it cannot be supposed to take the respondent by surprise, the Board sees no reason to refuse its admission in the appeal procedure.

5.1 As pointed out by the appellant, the amendment is supported by Figure 16 of the patent specification which shows that for a number of pacing cycles following a failure to sense the evoked potential only the pulse frequency is changed, and by the description (cf patent specification: column 28 , lines 1 to 14, and column 36, line 58 to column 37, line 6) which specifies that before increasing the output pulse energy in an attempt to regain capture, the system tries to avoid fusion beats by increasing the pacing rate without increasing the output energy.
Thus, the Board is satisfied that this amendment is admissible under Article 123(2) EPC.

5.2 Furthermore, since the amendment constitutes a limitation of the protection conferred by claim 1 of the patent as granted, it complies with Article 123(3) EPC.

6.1 Claim 1 according to the first auxiliary request specifies that only the pacing rate is modified in response to a failure to sense an evoked potential while the pulse energy (*ie* amplitude and/or length) is

not changed. This clarifies that a pacing rate increase cannot be achieved by generating additional backup pulses, as in the pacemaker of E2, because such pulses have a higher energy (see E2, page 15, line 25 to page 16, line 13).

6.2 Thus, the subject-matter of claim 1 according to the first auxiliary request is new within the meaning of Article 54 EPC.

7.1 Since none of the documents cited by the respondent deals with the problem of eliminating fusion beats as a possible cause of the failure to detect an evoked potential, or suggests increasing the pacing rate without increasing the pulse energy in response to a loss of heart capture, the person skilled in the art, starting from the teaching of E2, would not have had any incentive to arrive at a pacemaker falling within the terms of claim 1 of the first auxiliary request.

7.2 Hence, the subject-matter of claim 1 according to the appellant's first auxiliary request involves an inventive step within the meaning of Article 56 EPC.

Claims 2 to 6 are directly or indirectly dependent on claim 1 and, thus, their subject-matters also involve an inventive step.

8. In summary, the Board finds that the appellant's first auxiliary request is allowable, and that the patent can be maintained on the basis thereof. Consequently, there is no need to consider the appellant's second and third 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 department of first instance with the order to maintain the patent on the basis of the appellant's first auxiliary request, as follows:

   Claims 1 to 6 filed in the oral proceedings;

   columns 1, 2, 5, 6, 9 and 10 of the description filed in the oral proceedings;
   columns 3, 4, 7, 8, 11 to 47 of the description as granted;

   Figures 1 to 30 as granted.

The Registrar: The Chairman:

R. Schumacher G. Davies