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D E C I S I O N
of 23 August 2005

Case Number: T 0055/02 - 3.4.01

Application Number: 92112460.8

Publication Number: 0526798

IPC: A61N 1/368

Language of the proceedings: EN

Title of invention:
Rate-responsive dual-chamber pacemaker

Patentee:
Pacesetter, Inc.

Opponent:
Biotronik GmbH & Co. KG

Headword:
-

Relevant legal provisions:
EPC Art. 100(a), 54, 123(2)

Keyword:
"Novelty - main request, first auxiliary request (no)"
"Amendments - added subject-matter - second auxiliary request (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 0055/02 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 23 August 2005

Appellant: Biotronik GmbH & Co. KG
(Opponent) Woermannkehre 1
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Representative: Eisenführ, Speiser & Partner
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Respondent: Pacesetter, Inc.
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Representative: Rees, David Christopher
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 16 November 2001
rejecting the opposition filed against European
patent No. 0526798 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: B. Schachenmann
Members: G. Assi
M. Rognoni

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 10 January 2002, against the decision of the opposition division, dispatched on 16 November 2001, rejecting the opposition against the European patent No. 0 526 798 (application number 92112460.8). The appeal fee was paid on 10 January 2002. The statement setting out the grounds of appeal was received on 15 March 2002.

II. The opposition had been filed against the patent as a whole and was based on the grounds pursuant to Article 100(a) EPC that the subject-matter of the patent was not patentable within the terms of Articles 52(1), 54 and 56 EPC.

In the decision under appeal, the opposition division held that the grounds for opposition did not prejudice the maintenance of the patent as granted with regard to the following document among others:

(E1) US-A-4 890 617.

III. Oral proceedings were held on 23 August 2005. As provisionally announced in writing by a letter dated 22 July 2005, the respondent was not present.

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

V. The respondent (proprietor of the patent) requested, as a main request, that the patent be maintained as granted or, alternatively, that the patent be maintained as amended with the following documents:

First auxiliary request:

Claims 1-22 filed with a letter of 22 July 2005,
Description page 5 filed with the letter of 22 July
2005,
Description pages 2-4 and 6-15 of the patent as granted,
Figures 1-7 of the patent as granted.

Second auxiliary request:

Claims 1-22 filed with the letter of 22 July 2005,
Description page 5 filed with the letter of 22 July
2005,
Description pages 2-4 and 6-15 of the patent as granted,
Figures 1-7 of the patent as granted.

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

"A rate-responsive, dual-chamber pacemaker configured to operate in a DDDR mode of operation and having a system for preventing atrial competition comprising: means (52) for defining a physiological pacing rate; control means (26) for generating timing signals indicative of when an atrial and/or ventricular stimulation pulse should be generated by the pacemaker in order to maintain the physiological pacing rate; sensing means (14, 15, 22; 16, 17, 24) coupled to the control means for sensing atrial and ventricular activity, such as P-waves, indicating natural atrial activity, and R-waves, indicating natural ventricular activity, the control means generating the timing signals needed to generate atrial and/or ventricular stimulation pulses on demand as needed in the absence of intrinsic P-waves and/or R-waves; and stimulation

pulse generating means (18, 20) coupled to the control means for generating the atrial and/or ventricular stimulation pulses in response to the timing signals; the control means including PVARP generating means (76) for generating a post ventricular atrial refractory period, PVARP, subsequent to the generation of each ventricular stimulation pulse or the sensing of an R-wave, the PVARP defining a time interval during which sensed atrial activity is not considered as a valid P-wave, and atrial pulse prevention means (78, 70, 54) for preventing an atrial stimulation pulse from being generated that is in competition with atrial activity sensed during the PVARP; characterised in that the atrial pulse prevention means (78, 70, 54) comprises: means for generating an atrial competition prevention, ACP, interval in response to atrial activity sensed during the PVARP; and means for preventing any atrial stimulation pulse from being generated during the ACP interval, whereby an atrial pacing pulse is not generated in competition with sensed atrial activity that occurs during the PVARP for at least the duration of the ACP interval."

Claims 2-23 according to the respondent's main request are dependent on claim 1.

VII. The wording of claim 1 according to the respondent's first auxiliary request differs from that of claim 1 of the main request in that the following expression has been inserted in the characterising part after the first mentioning of "PVARP":

", the ACP interval having a prescribed duration".

Claims 2-22 according to the respondent's first request are dependent on claim 1.

VIII. The wording of claim 1 according to the respondent's second auxiliary request differs from that of claim 1 of the main request in that the following expression has been inserted at the end of the claim:

"; and in which the atrial pulse prevention means comprises: rate determining means (70) for determining an intrinsic atrial rate; first comparison means (54) for determining whether the sensed intrinsic atrial rate is approaching a reference rate; and means responsive to the first comparison means for changing the first PVARP to a second PVARP which is different from the first PVARP"

Claims 2-22 according to the respondent's second auxiliary request are dependent on claim 1.

Reasons for the Decision

1. The appeal is admissible.
2. *Novelty of claim 1 of the respondent's main request*
 - 2.1 Document E1 (see column 3, lines 27-32) discloses a rate-responsive dual-chamber pacemaker operating in a DDDR mode. In particular, the pacemaker known from E1 (see column 3, line 65 to column 4, line 14) comprises three timers, two of which are devoted to timing out the pacer's V-A interval. A first V-A LRT timer sets an escape interval corresponding to a programmed lower

rate. A second V-A ACT timer sets a variable escape interval depending on the patient' activity level. Both of these timers are started at the same time. Whichever one of them times out first provokes an atrial pace event. A third physiologic timer is located in the S-A node of the heart. If the natural timer causes a natural atrial contraction at approximately the same time as the second ACT timer, atrial competition arises, i.e. a conflict between natural and artificial activity based stimulation. This situation is avoided by operating the pacemaker according to the diagram of Figure 9 (see column 8, lines 17-34). After a VP ventricular pace, an ACT-AP atrial pace is provoked by the ACT timer, which times out first. After an A-V delay, a VP ventricular pace occurs, which starts the LRT and ACT timers as well as an AREF atrial refractory period, i.e. a PVARP period using the terminology of the present patent. An ARS atrial sense event occurs during the AREF period and is ignored by the pacemaker, which paces the atrium with a LRT-AP pulse at LRTVATO time out. Thus, any P-wave detected in the AREF (PVARP) period disables the activity based rate for that one pacing cycle and forces the programmed lower rate. In other words, atrial sensing early in the V-A period inhibits the activity based timer; the pacemaker defers to the LRT timer (see column 4, lines 15-32).

- 2.2 The parties agree that the pacemaker known from E1 comprises the features of the preamble of claim 1 of the patent in suit, in particular the PVARP generating means and the atrial pulse prevention means for preventing generation of an atrial stimulation pulse in competition with atrial activity sensed during a PVARP period (see grounds of appeal, page 2, point I, first

sentence; respondent's letter of 22 July 2005, page 1, "Main Request", second paragraph).

2.3 The question arises whether the atrial pulse prevention means of the known pacemaker can be considered as including the features according to the characterising portion of claim 1, i.e.:

(i) means for generating an ACP interval in response to atrial activity sensed during the PVARP period and

(ii) means for preventing any atrial stimulation pulse from being generated during the ACP interval.

By these means, atrial competition is avoided for at least the duration of the ACP interval.

2.4 A controversial issue in this respect concerns the meaning of feature (i), in particular the interpretation of the expression "*in response to*". The appellant took the view that the subject-matter of a clearly formulated claim should not be interpreted in an undue restrictive way by referring to the description. Thus, in disagreement with the respondent, the appellant submitted that the claimed expression "*in response to*" did not necessarily imply that the sensing of a P-wave during the PVARP period immediately initiated the ACP interval.

The Board is aware of the fact that an interpretation of the claim in the context of the whole disclosure of the patent (see page 11, lines 35, 36, Figure 3(D);

page 11, line 40, Figure 3(E); page 11, line 46, Figure 3(F); page 12, lines 47-56, Figure 4) would lead to the understanding that the sensing of a P-wave during the PVARP period immediately initiates the ACP interval. Such an interpretation made in the context would indeed be possible. However, in the present case, a literal interpretation of the claim taken *per se* is also possible because the claim does not suffer from a lack of clarity. This literal interpretation would lead to the understanding that the term "*in response to*" implies a functional but not any particular temporal relationship. Considering that both interpretations make sense from a technical point of view, the Board has no reason to privilege the former over the latter so that it comes to the conclusion that claim 1 covers both situations of a P-wave sensed during the PVARP period initiating the ACP interval either immediately or after some delay. Therefore, the time point when the ACP interval starts with respect to the sensed P-wave is not relevant for assessing novelty.

- 2.5 Another issue concerns the meaning of the term "*means*" in features (i) and (ii) which are not defined *per se* by their structure but by their function. For example, feature (i) does not define a counter counting a predetermined number of clock impulses corresponding to the ACP interval. Rather, the function of generating the ACP interval is claimed in terms of a functional feature. Thus, when assessing novelty of the subject-matter of claim 1 over E1, identity between the functionality of the claimed and the known pacemaker would result in identity between the "*means*" supporting this functionality.

2.6 In the light of the above interpretations, the appellant took the view that both features (i) and (ii) should also be considered to be known from document E1. At the oral proceedings, the appellant, with regard to Figure 9 of E1, identified an interval, corresponding to the claimed ACP interval, between the ARS atrial sense event occurring during the AREF period and the immediately following LRT-AP pulse emitted at LRTVATO time out, in analogy to Figure 3(E) of the patent in suit. Alternatively, the interval might also be considered between the end of the AREF period, during which the ARS atrial event is sensed, and the said LRT-AP pulse.

This view is convincing. The Board notes that, in terms of functionality, any atrial stimulation pulse is prevented from being generated during both the claimed ACP interval and the corresponding intervals identified in Figure 9. As a result, the claimed pacemaker and that known from E1 avoid atrial competition for at least the duration of the ACP interval or the corresponding ones in Figure 9. Moreover, in view of the foregoing, the functional identity entails that claimed "means" (i) and (ii) are not novel. These "means", which reflect a functionality of the microprocessor-based control system 26 of the claimed pacemaker (see patent in suit, Figures 1 and 2; page 7, lines 27-31), are namely anticipated by the V-A LRT timer and the V-A ACT timer as well as the means generating the AREF atrial refractory period.

2.7 Due to its absence at the oral proceedings, the respondent did not submit any comment on this issue discussed at the oral proceedings.

2.8 In conclusion, the ground of opposition of lack of novelty over document E1 prejudices the maintenance of the patent as granted. The respondent's main request is not allowable.

3. *Novelty of claim 1 of the respondent's first auxiliary request*

3.1 At the oral proceedings, the appellant submitted that the amendment to claim 1 of the patent as granted consisting in the provision of an ACP interval having a prescribed duration could not render the subject-matter of the amended claim 1 novel over document E1.

This view is convincing with regard to the above identified interval between the end of the AREF period, during which the ARS atrial event is sensed, and the said LRT-AP pulse (see Figure 9). Indeed, the start and end points of this interval are fixed in the sense that they do not change with the heart cycles.

3.2 Due to its absence at the oral proceedings, the respondent did not submit any comment on this issue discussed at the oral proceedings.

3.3 Hence, the subject-matter of the amended claim 1 lacks novelty over document E1. The respondent's first auxiliary request is not allowable.

4. *Admissibility of amended claim 1 of the respondent's second auxiliary request*

4.1 At the oral proceedings, the appellant submitted that the amendment to claim 1 of the patent as granted resulted from the combination of the ACP embodiment and the ARV embodiment of the invention. This combination was not originally disclosed so that the provisions of Article 123(2) EPC were not met.

4.2 The application as filed discloses two embodiments of the rate-responsive dual-chamber pacemaker operating in a DDDR mode.

According to an ACP embodiment, an atrial stimulation pulse is prevented from being generated in competition with atrial activity sensed during the PVARP period by the provision of features (i) and (ii) mentioned above. This ACP embodiment is disclosed in the combination of original claims 1 and 4, the latter directly depending on the former.

According to an ARV embodiment, the effect of preventing atrial competition is achieved by the provision of rate determining means for determining an intrinsic atrial rate, first comparison means for determining if the sensed intrinsic atrial rate is approaching a reference rate, and means responsive to the first comparison means for changing the PVARP period to a second one, the second PVARP period being different from the first one. This ARV embodiment is disclosed in the combination of original claims 1 and 7, the latter directly depending on the former.

The structure of the original claims, in particular the direct dependence of claims 4 and 7 on claim 1, clearly indicates that the ACP and ARV embodiments are independent from each other. Moreover, the description of the application as filed does not give any hint at the possibility of combining features of both embodiments which are rather disclosed in a separate way.

4.3 Due to its absence at the oral proceedings, the respondent did not submit any comment on this issue discussed at the oral proceedings.

4.4 Therefore, the patent has been amended in such a way that it contains subject-matter extending beyond the content of the application as filed because the amended claim 1 results from the combination of two independent embodiments of the invention. The respondent's second auxiliary request is not allowable.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

R. Schumacher

B. Schachenmann