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# D E C I S I O N
# of 17 June 2005

**Case Number:** T 0934/04 - 3.4.1

**Application Number:** 97250170.4

**Publication Number:** 0811399

**IPC:** A61N 1/39

**Language of the proceedings:** EN

**Title of invention:**
Post atrial cardioversion high rate atrial pacing with gradual rate return

**Applicant:**
Cardiac Pacemakers, Inc.

**Opponent:**
-

**Headword:**
-

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

**Keyword:**
"Novelty - no (main request)"
"Added subject-matter - yes (auxiliary request)"

**Decisions cited:**
-

**Catchword:**
-

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**Case Number:** T 0934/04 - 3.4.1

# D E C I S I O N
**of the Technical Board of Appeal 3.4.1**
**of 17 June 2005**

**Appellant:** Cardiac Pacemakers, Inc.
4100 Hamline Avenue North
St. Paul, MN 55112 (US)

**Representative:** UEXKÜLL & STOLBERG
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**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted 20 February 2004 refusing European application No. 97250170.4 pursuant to Article 97(1) EPC.**

**Composition of the Board:**

**Chairman:** B. J. Schachenmann
**Members:** M. G. L. Rognoni
G. Assi

## Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal, received on 20 April 2004, against the decision of the examining division, posted on 20 February 2004, refusing the European Patent application No. 97 250 170.4. The appeal fee was paid on 20 April 2004 and the statement setting out the grounds of the appeal was received on 29 June 2004.

II. In the decision under appeal, the examining division held, *inter alia*, that the subject-matter of claims 1 according to the main and auxiliary requests then on file were not novel with respect to the following document:

D1: EP-A-0 518 599.

III. With the statement of grounds of appeal, the appellant filed two sets of claims 1 to 10 identified as "Main Request" and "Auxiliary Request", respectively.

IV. In a communication dated 7 April 2005, accompanying a summons to attend oral proceedings, the Board expressed, *inter alia*, the preliminary opinion that the independent claims 1 according to the main and auxiliary requests did not appear to be allowable.

V. By a letter dated 9 May 2005, the Board was informed that the appellant's representatives would not attend the oral proceedings on 17 June 2005.

VI. Oral proceedings were held on 17 June 2005 in the absence of the appellant.

VII. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 10 according to the main request or of claims 1 to 10 according to the auxiliary request.

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

*"An implantable atrial defibrillator (30) including a cardioverter (90) for applying cardioverting electrical energy to atria of a heart when the atria are experiencing an atrial fibrillation and are in need of cardioversion; the defibrillator characterized by a pacer (92), the pacer being immediately enabled in response to and after each application of cardioverting electrical energy to begin atrial pacing in a pacing mode to pace the atria of the heart, the pacing mode of the enabled pacer having at least one predetermined pacing rate to discourage reinitiation of the atrial fibrillation, the pacing of the atria being responsive to and after application of cardioverting electrical energy to the atria of the heart regardless of whether pacing was performed prior to the application of cardioverting electrical energy."*

Claims 2 to 10 are dependent on claim 1.

The wording of claim 1 according to the auxiliary request reads as follows:

*"An implantable atrial defibrillator (30) including a cardioverter (90) for applying cardioverting electrical*

*energy to atria of a heart when the atria are experiencing an atrial fibrillation and are in need of cardioversion; the defibrillator characterized by a pacer (92), the pacer being immediately enabled in response to and after each application of cardioverting electrical energy to pace the atria of the heart before a premature or disorganized ectopic beat to force all of the atrial tissue to activate and recover together, and pace the atria of the heart, in a pacing mode having at least one predetermined pacing rate that is sufficiently rapid to discourage reinitiation of the atrial fibrillation, the pacing of the atria being responsive to and after application of cardioverting electrical energy to the atria of the heart regardless of whether pacing was performed prior to the application of cardioverting electrical energy."*

Claims 2 to 10 are dependent on claim 1.

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

Document D1 related to an implantable defibrillator and to a method incorporating multiple bradycardia support pacing rates to compensate for haemodynamic compromise experienced during tachycardia and/or following antitachycardia therapy. D1, however, did not disclose a pacer for pacing the atria of the heart immediately after application of cardioverting electrical energy to the atria. In particular, the defibrillator of D1 did not describe a pacer which was immediately enabled in response to and after each application of cardioverting electrical energy to begin atrial pacing, as specified in claim 1 according to the main request. Additionally, the problem stated in D1 and the proposed solution did

not correspond to the problem and the solution specified in the present application.
Hence, the subject-matter of claim 1 according to the main request was both new with respect to the prior art document D1 and involved an inventive step.

Claim 1 of the auxiliary request was amended to specify some aspects of the present invention relating to atrial pacing for the prevention of atrial fibrillation after the application of cardioverting electrical energy to the atria. Support for these amendments could be found in the application as originally filed (see *e.g. c*olumn 2, lines 15 to 37), where three mechanisms causing induction of atrial fibrillation and their solutions in terms of atrial stimulation were identified. As the cited prior art documents neither showed nor suggested the additional features of claim 1 according to the auxiliary request, the subject-matter of this claim satisfied the requirements of Articles 54 and 56 EPC.

## Reasons for the Decision

The appeal is admissible.

2.1 The present application is directed to *"an improved atrial cardioverter/defibrillator wherein after an application of atrial cardioversion therapy, the atria are paced from a relatively high rate to a gradually derived normal or bradycardia rate to prevent spontaneous reversion from normal sinus rhythm back to atrial fibrillation"* (application as published, column 1, lines 13 to 19).

The application identifies the following three mechanisms which may explain why, in some cases, the heart spontaneously reverts from normal sinus rhythm back to atrial fibrillation after the application of cardioverting therapy to the atria (see *ibid.* column 2, lines 22 to 33)

(i) *"after a cardioverting shock, there may be localized foci of atrial tissue which activate at different times thereby eliminating the possibility of a well organized activation wavefront";*

(ii) *"after the cardioverting shock, the heart may experience a bradycardia episode and have no intrinsic rhythm";*

(iii) *"after a cardioverting shock, the atria may experience dispersion of refractoriness so that not all of the atrial cells will be repolarized at any one time".*

2.2 According to the description (column 2, lines 39 to 45), a solution to the problem of reinitiation of atrial fibrillation *"regardless of its cause"* consists in pacing the atria after each application of a therapy shock to force all of the atrial tissue to activate and recover together.

*Main Request*

3.1 Claim 1 according to the main request relates to an "*implantable atrial defibrillator*" comprising the following structural features (emphasis added):

– *"a **cardioverter** (90) for applying cardioverting electrical energy to atria of a heart when the atria are experiencing an atrial fibrillation and are in need of cardioversion";*

– *"a **pacer** (92)".*

The independent claim further comprises the following features relating to the **activation of the pacer** and to the corresponding **pacing mode** (emphasis added):

(a) *"the pacer being **immediately** enabled **in response to** and after each application of cardioverting electrical energy to begin atrial pacing in a pacing mode to pace the atria of the heart";*

(b) *"**the pacing mode** of the enabled pacer having at least one **predetermined pacing rate** to discourage reinitiation of the atrial fibrillation";*

(c) *"the **pacing of the atria** being responsive to and after application of cardioverting electrical energy to the atria of the heart **regardless of** whether pacing was performed prior to the application of cardioverting electrical energy".*

3.2 As to feature (a), it is noted that the wording "***immediately*** *enabled* ***in response to*** *…. each application of cardioverting electrical energy*" does not occur in the application as originally filed (emphasis added). The relevant passages in the published application read as follows (emphasis added):

> "***After applying*** *the cardioverting electrical energy to the atria, the microprocessor 60, through the disable stage 63,* ***enables the pacer*** *92 which has been preprogrammed into preferably the AAI modality.*" (column 7, lines 23 to 26)
>
> "*…****immediately after*** *application of cardioverting electrical energy…*" (claim 1).

In the light of the disclosure, the expression "*in response to each application of cardioverting electrical energy*" appears to be merely a repetition of "*after each application of cardioverting electrical energy*", and thus does not constitute a further limitation of the claimed subject-matter. The same is true for the attribute "*immediately*" which does not define a specific time interval.

3.3 As to feature (b), the application as originally filed identifies only the following rates (cf. column 7, lines 30 to 34):

- "*a relatively high first rate, well above a bradycardia rate*"
- "*a lower second rate, such as a bradycardia rate*".

As pointed out in the description (see item 2.1 above), reinitiation of atrial fibrillation after a cardioverting shock may have three different causes. One of these causes is the **absence of an intrinsic rhythm**. In this particular case, the bradycardia rate would suffice to discourage reinitiation of the atrial fibrillation. Another known cause of atrial fibrillation, requiring a higher pacing rate as a preventive measure, could be "*a premature or disorganized ectopic beat*" (cf. column 2, lines 44 to 45). The present application seeks to provide a solution to the problem of reinitiation of atrial fibrillation "*regardless of its cause*", and teaches to start pacing "*at a relatively high rate, well above a bradycardia rate*" (cf. column 7, lines 31 to 34). Hence, the "*predetermined pacing rate*" specified in feature (b) has to be interpreted as a "*high rate*" above the normal pacing rate used for the treatment of bradycardia.

3.4 As to feature (c), it appears to be a mere repetition of feature (a). In fact, if atrial pacing is started after each application of cardioverting electrical energy (feature a), it is implicit that it occurs regardless of what may have happened prior to the application of the cardioverting shock.

3.5 In summary, claim 1 according to the main request is essentially concerned with an implantable atrial defibrillator comprising a cardioverter and a pacer for pacing the heart at a relatively high pacing rate above the bradycardia rate immediately after each application of cardioverting electrical energy.

4. In the contested decision, the examining division held, *inter alia*, that the subject-matter of claim 1 according to the main request then on file (essentially corresponding to claim 1 of the present main request) was not new in the light of document D1.

5.1 D1 relates to "*implantable medical devices which deliver energy to cardiac tissue in an attempt to revert tachycardia and restore a normal sinus rhythm to a patient*" (column 1, lines 3 to 8). In particular, it is specified in D1 (column 4, lines 8 to 15; emphasis added) that the "*invention applies to devices which deliver cardioverting shocks alone, as well as to devices which deliver antitachycardia pacing pulses alone or in a combination with cardioverting shocks. The invention will usually apply to ventricular implantable cardioverters, but is* ***equally applicable to atrial cardioverters*** *or multiple chamber cardioverters or* ***defibrillators****.*"

As pointed out in column 7, lines 5 to 1, reversion of tachyarrhythmia starts a post-pacing timer. As long as the time elapsed following reversion does not exceed a predetermined time interval, the pacing rate is set to a **predetermined programmed high value** and will remain at that high value until the expiration of the "*post-pacing time-out period*". Similarly, a post-defibrillation timer is started when a defibrillation shock therapy is applied and the pacing rate is set to the programmed high value.

5.2 Hence, D1 relates, *inter alia*, to an implantable atrial defibrillator comprising the following structural features recited in claim 1 according to the main request (see point 3.1, *supra*):

– a cardioverter for applying cardioverting electrical energy to the atria of a heart when the atria are experiencing an atrial fibrillation and are in need of cardioversion;

– a pacer.

5.3 As shown in Figure 4, a high pacing rate is set after each application of cardioverting electrical energy for a predetermined period of time.
Thus, the operation of the device known from D1 and summarised in Figure 4 implies that the pacer is immediately enabled in response to each application of cardioverting electrical energy to begin atrial pacing in a pacing mode to pace the atria of the heart, as specified in claim 1 of the main request. Since the pacing takes place at a rate higher than the normal bradycardia rate and, as pointed out in the present application, an unspecified high rate is sufficient to discourage reinitiation of atrial fibrillation, it is implicit that also the high pacing rate used in D1 must have the same effect using the same means.

In other words, even if the declared purpose of the post-defibrillation pacing disclosed in D1 (compensation for haemodynamic compromise experienced during tachycardia and/or following antitachycardia therapy) may be different from the object of the present application, the means (high rate pacing) and

the way such means is applied are the same. It must, therefore, be assumed that the claimed device and the one known from the prior art produce the same effects.

Though the applicant may indeed have found out that pacing at a high rate after a cardioverting shock not only compensates for the haemodynamic compromise but also discourages reinitiation of atrial fibrillation, the discovery of a novel effect produced by a known device operating in a known manner cannot make the device distinguishable from the prior art.

5.4 Hence, the subject-matter of claim 1 according to the main request is not new with respect to D1 (Article 54 EPC).

*Auxiliary request*

6.1 Claim 1 according to the auxiliary request differs from the corresponding claim of the main request essentially in that it further specifies the following:

(j) the pacer being immediately enabled *"to pace the atria of the heart before a premature or disorganized ectopic beat to force all of the atrial tissue to activate and recover together";*

(*jj*) one predetermined pacing rate "*that is sufficiently rapid*" to discourage reinitiation of the atrial fibrillation.

6.2 According to the appellant, support for the amendment could be found in the application as filed. The passages of the description cited by the appellant,

however, relate essentially to the three mechanisms which may explain the reinitiation of atrial fibrillation after the application of a cardioverting shock, and to rapid atrial pacing as a means for preventing a premature atrial contraction. In fact, the present application, apart from specifying that the rate should be higher than the bradycardia rate (*e.g.* 150 beats per minute), does not teach how it can be ensured that the first stimulation pulse actually occurs "*before a premature or disorganized ectopic beat*", or how the pacing rate should be selected so that it is "*sufficiently rapid*" to discourage reinitiation of the atrial fibrillation.

6.3 In conclusion, as far as features (*j*) and (*jj*) imply some means or functionality that would distinguish the claimed device from a defibrillator/cardioverter for pacing the atria at a high rate immediately after the application of a cardioverting shock, as known from D1, they involve subject-matter which was not originally disclosed (Article 123(2) EPC).

7. For the above reasons, it must be concluded that none of the appellant's requests is allowable.

## Order

**For the above reasons it is decided that:**

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher B. Schachenmann