

Internal distribution code:

- (A) Publication in OJ
(B) To Chairmen and Members
(C) To Chairmen
(D) No distribution

D E C I S I O N
of 30 November 2005

Case Number: T 0679/02 - 3.4.01

Application Number: 93850176.4

Publication Number: 0589860

IPC: A61N 1/368

Language of the proceedings: EN

Title of invention:
Pacemaker

Applicant:
Schüller, Hans

Opponent:
BIOTRONIK GmbH & Co. KG

Headword:
-

Relevant legal provisions:
EPC Art. 100(a), 54, 56

Keyword:
-

Decisions cited:
-

Catchword:
-



Case Number: T 0679/02 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 30 November 2005

Appellant:
(Opponent)

BIOTRONIK GmbH & Co. KG
Woermannkehre 1
D-12359 Berlin (DE)

Representative:

von Oppen, Joachim F.M.
Eisenführ, Speiser & Partner
Anna-Louisa-Karsch-Strasse 2
D-10178 Berlin (DE)

Respondent:
(Proprietor of the patent)

Schüller, Hans
Jullovsvägen 25
S-224 67 Lund (SE)

Representative:

Harrison, Michael Charles
Albihns GmbH
Bayerstrasse 83
D-80335 München (DE)

Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 12 June 2002
rejecting the opposition filed against European
patent No. 0589860 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: B. Schachenmann
Members: G. Assi
H. Wolfrum

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 25 June 2002, against the decision of the opposition division, dispatched on 12 June 2002, rejecting an opposition against the European patent No. 0 589 860 (application number 93850176.4). The appeal fee was paid on 25 June 2002. The statement setting out the grounds of appeal was received on 9 October 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.

III. In the appeal procedure, the following documents were considered:

(E1) EP-A-0 574 127;

(E2) EP-A-0 087 756;

(E6) E. Alt, "*Schrittmachertherapie des Herzens, Grundlagen und Anwendung*", 3rd Edition, perimed Fachbuch-Verlagsgesellschaft mbH, Erlangen (DE), 1990, pages 78 to 80;

(E10) Recent Progress in Cardiac Pacing, H.D. Friedberg, M.D., Editor, "*Pacing Techniques in the Management*

of Supraventricular Tachycardias", Part 2, "An Implanted Atrial Synchronous Pacemaker with a Short Atrioventricular Delay for the Prevention of Paroxysmal Supraventricular Tachycardias" by R.A.J. Spurrel et al., Journal of Electrocardiology, 1976, Vol. 9, No. 1, pages 89 to 96.

- IV. Oral proceedings before the Board of Appeal were held on 30 November 2005.
- V. The appellant requested that the decision under appeal be set aside and the patent be revoked in its entirety.
- VI. The respondent (patent proprietor) requested that the appeal be rejected and the patent be maintained as granted.
- VII. The wording of claim 1 of the patent as granted reads as follows:

"A pacemaker (1) comprising a first electrode lead (3) disposed in one atrium of a heart (5) for stimulating atrial reactions, a second electrode lead (6) disposed in one chamber of the heart (5) for stimulating and sensing chamber reactions, a stimulating pulse generator (2) for generating and emitting stimulating pulses to the atrium and the chamber via said first and said second electrode lead (3, 6), respectively, and a control device (8) for controlling the emission of stimulating pulses and the sensing of reactions, said control device (8), after each emitted atrial stimulating pulse, starting an AV interval having a first duration (AV1), after the expiry of which a chamber stimulating pulse is emitted if no chamber

reaction has been sensed during said AV interval, wherein the control device (8), when a chamber stimulating pulse is emitted, replaces said first duration (AV1) of said AV interval with a second duration (AV2) which is shorter than the first duration (AV1), and wherein the control device (8) after a predetermined number of pulses, or a predetermined time, replaces said second duration (AV2) of the AV interval with said first duration (AV1)."

Claims 2 and 3 of the patent as granted are dependent claims.

Reasons for the Decision

1. The appeal is admissible.
2. *Ground for opposition of lack of novelty*
 - 2.1 The appellant submitted that the subject-matter of claim 1 lacked novelty with regard to document E1.
 - 2.2 Document E1 is a state of the art pursuant to Article 54(3) EPC for all the Contracting States designated in respect of the present patent (Article 54(4) EPC).
 - 2.3 Document E1 (see Figure 1 and the corresponding description) discloses a DDD pacemaker including the following features:
 - atrial sensing means,
 - ventricular sensing means,
 - atrial stimulating means,

- ventricular stimulating means and
- programmable microcontroller means coupled to the atrial and ventricular sensing means as well as the atrial and ventricular stimulating means for causing the ventricular stimulating means to issue a pacing pulse after a predetermined AV delay, if a natural ventricular depolarization signal is not sensed within the AV delay.

2.4 According to the embodiment of Figure 2 (see the corresponding description), the microcontroller means is programmed to execute an algorithm providing for two AV delays, namely a long AV delay (LAV) and a short AV delay (SAV). The pacemaker is operated with the LAV delay to enhance the probability of detecting intrinsic activity in the ventricle. On the other hand, operation with the SAV delay is optimal from a haemodynamic standpoint when natural beats are not occurring during the AV delay and the pacemaker is providing ventricular stimulating signals to the heart. The pacemaker starts pacing with the LAV delay. Sequentially occurring natural (n_s) and paced (n_p) ventricular depolarization signals are counted until the total number of sensed and paced signals exceeds a predetermined value n_v . In this case, after saving n_s and n_p , the ratio n_s/n_p is computed and converted to a percentage value. If the percentage ratio n_s/n_p is smaller than a pre-programmed value X (see block 64, output "NO"), i.e. if paced ventricular beats are occurring relatively frequently, the LAV delay is automatically switched to the SAV delay in an effort to optimize cardiac output. Ventricular paced beats are then counted. If a programmed number of such beats is accumulated without detecting intrinsic activity, the algorithm switches

the AV delay back to the LAV delay. On the other hand, if the percentage ratio n_s/n_p is greater than the value X (see block 64, output "YES"), i.e. if intrinsic ventricular beats are occurring at an adequate rate, the LAV delay is maintained for as long as the mentioned ratio remains above the threshold. In this way, the algorithm maximizes the probability of sensing intrinsic activity by setting a long AV delay while switching to a shorter AV delay when a low level of intrinsic activity is present.

- 2.5 In summary, according to the embodiment of Figure 2 of E1, the pacemaker begins pacing with the LAV delay, and *"if a predetermined level of intrinsic activity is not sensed in a pre-programmed interval"*, the LAV delay is automatically switched to the SAV delay (see column 3, lines 38 to 42). This teaching is confirmed throughout the application, although in different words (see column 6, lines 23 to 34; column 7, lines 18 to 26; claim 1, feature (c)).

It results that document E1 does not disclose the claimed feature that a long AV delay is replaced by a short AV delay *"when a chamber stimulating pulse is emitted"*, i.e. in immediate response to the occurrence of each paced ventricular beat.

- 2.6 The appellant argued in the grounds of appeal that the claimed condition should be regarded as a particular case of the general teaching of E1. Reference was made, in particular, to the case $n_s=0$ and $n_p=1$.

This view is not convincing. As a matter of fact, the particular case referred to does not form part of the

explicit disclosure of document E1 that does not mention any example defining the numbers n_s , n_p and their sum n_v . Nor does it form part of the implicit disclosure because it would not be technically meaningful in the context of the whole teaching that relies on the counting of a plurality of intrinsic and paced ventricular events occurring during a time interval.

2.7 In conclusion, the ground of lack of novelty is unfounded.

3. *Ground for opposition of lack of inventive step*

3.1 The appellant submitted at the oral proceedings that Figure 1 of the patent in suit showed a DVI pacemaker lacking atrial sensing means. In the light of this disclosure, claim 1 might be understood as relating to a DVI pacemaker. Its wording, however, was not limited to this embodiment but also covered a pacemaker operating in a DDD mode.

The Board disagrees with this broad interpretation of claim 1 understood as covering DDD pacemakers too. With regard to the claim *per se*, it clearly states that a first electrode lead is disposed in one atrium "*for stimulating atrial reactions*" whereas a second electrode lead is disposed in one chamber (ventricle) "*for stimulating and sensing chamber reactions*". Moreover, the functionality of the pacemaker as defined in claim 1 presupposes the emission of atrial stimulating pulses for starting the AV intervals. This only makes technical sense in view of the well-known dual-chamber pacing DVI mode, referred to by the

appellant, which consists in pacing both the atrium and ventricle but only sensing the ventricle. As the respondent correctly pointed out, atrial tracking, rather than sensing, characterized the response of the claimed pacemaker, according to which each atrial stimulating pulse led to a ventricular pulse (see claim 1, feature "*said control device (8), after each emitted atrial stimulating pulse, starting an AV interval having a first duration (AV1), after the expiry of which a chamber stimulating pulse is emitted if no chamber reaction has been sensed during said AV interval*").

The same conclusion as drawn above is reached if the claim is read in the light of the description. In column 1, paragraph 0001, the pacemaker of the present invention is described as lacking atrial sensing means. Such a pacemaker is intended for treating patients suffering from a sick sinus node syndrome characterized by the fact that the sinus node does not function properly so that the atrium has to be stimulated regularly by the pacemaker (see column 2, paragraph 0005). In such a case, there is no need for atrial sensing, which is confirmed by the embodiment of Figure 1 as well as the diagrams of Figures 2 to 4 showing a regular atrial stimulation (see column 4, paragraph 0020; column 5, paragraph 0023; column 6, lines 18 and 19).

- 3.2 The appellant submitted that the problem addressed by the present invention regarded retrograde conduction, which would cause the operation in the loop mentioned in paragraph 0007 of the patent in suit in a pacemaker operating with a long AV delay. Document E2 disclosed a

pacemaker operating with a programmable AV delay. This document taught that, if an atrial ectopic beat was detected, which announced the onset of a tachycardia, the AV delay had to be reduced so as to suppress the tachycardia, the initial AV delay being then restored after a predetermined time. In the appellant's view, an ectopic beat might result from retrograde conduction of a ventricular stimulation pulse. For this reason, a skilled person, to suppress the tachycardia, would consider the possibility of anticipating the occurrence of the ectopic signal by immediately reducing the AV delay if a ventricular stimulating pulse was emitted. Therefore, the subject-matter of claim 1 lacked inventive step.

This argumentation is not convincing. In fact, the pacemaker according to claim 1 essentially differs from that according to document E2. As stated above, claim 1 does not require atrial sensing means, which is indeed unnecessary for the claimed atrial tracking owing to the regular atrial stimulation. By maintaining a regular atrial stimulation, the shortened AV interval of the invention makes sure that the atrium is not paced in a depolarized state which might result from a retrograde conduction of a ventricular stimulation at the end of the AV interval. The pacemaker of E2 (see the Figure; claims 1 and 2), however, is provided with a detector 5, which senses an occurring tachycardia or its onset as announced by an ectopic beat. The detector then sends a signal to a unit 3 controlling the AV delay. It thus results that atrial sensing is essential for the operation of the pacemaker of E2 since it reacts to a sensed atrial event, contrary to the claimed pacemaker which reacts to a ventricular

stimulation following an atrial pacing. Therefore, the claimed pacemaker and that of E2 are different not only from a structural point of view but also with regard to their operation. Only with hindsight, the skilled person would consider to change the teaching of E2 according to claim 1 of the patent in suit.

In view of the essential character of the identified difference, there is no need to go into the controversial issue regarding the nature of an ectopic beat, namely whether it was technically correct to consider such a beat as resulting from retrograde conduction of a ventricular stimulation pulse, as the appellant submitted. In this respect, it is sufficient to note that the appellant itself admitted that a ventricular stimulation would not necessarily cause an ectopic beat. This implies that the claimed criterion for reducing the AV delay, i.e. the emission of a ventricular stimulating pulse, does not correspond to the known criterion of sensing an ectopic beat. As a matter of fact, the claimed invention reacts to a ventricular stimulating pulse following an atrial stimulating pulse. By maintaining a constant rate for atrial stimulation, the shortened AV interval according to claim 1 avoids any risk related to retrograde conduction by immediately reacting each time a ventricular stimulating pulse is emitted. In distinction thereto, the pacemaker of E2 reacts to a sensed natural atrial event and, by reducing the AV interval, aims at avoiding or stopping a tachycardia.

- 3.3 The appellant also relied on documents E6 and E10 for substantiating the ground of lack of inventive step.

Document E6, a text book, addresses the issue of retrograde conduction, which may cause a re-entry-tachycardia in patients with an implanted pacemaker operating in VDD or DDD modes. This tachycardia may, for example, be started by a ventricular extrasystole reaching the atrium along a retrograde path. E6 discloses that a reduction of the AV delay can avoid the risk of retrograde conduction. However, it does not mention any criterion for deciding when the said reduction should be carried out.

Document E10 (see Summary; page 90, left-hand column, first full paragraph) concerns an atrial synchronous pacemaker with an AV delay of 30 ms implanted in a patient with a paroxysmal supraventricular tachycardia. Thus, during sinus rhythm each left atrial potential is followed 30 ms later by a ventricular stimulus. Atrial premature beats occurring with a coupling time of 300 ms or greater are sensed and ventricular stimulations occur 30 ms later. Atrial premature beats with coupling times less than 300 ms are also sensed but no ventricular stimulation occurs. This document thus describes a pacemaker with a constant AV delay and does not teach a reduction of the AV delay.

Hence, documents E6 and E10 are not relevant, either taken alone or in combination with E2.

3.4 In conclusion, the ground of lack of inventive step is unfounded.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

R. Schumacher

B. Schachenmann