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D E C I S I O N
of 3 November 2005

Case Number: T 0488/03 - 3.4.01

Application Number: 95118517.2

Publication Number: 0718009

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
Atrial tachycardia-detecting heart stimulator

Applicant:
St. Jude Medical AB

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 54(1), (2), 111(1)

Keyword:
"Novelty - yes"
"Remittal for further prosecution - ordered"

Decisions cited:
-

Catchword:
-

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Case Number: T 0488/03 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 3 November 2005

Appellant: St. Jude Medical AB
S-175 84 Järfälla (SE)

Representative: Kramer - Barske - Schmidtchen
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 13 December 2002 refusing European application No. 95118517.2 pursuant to Article 97(1) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal, received on 12 February 2003, against the decision of the examining division, dispatched on 13 December 2002, refusing European patent application No. 95 118 517.2 (publication number 0 718 009). The fee for the appeal was paid on 12 February 2003. The statement setting out the grounds of appeal was received on 4 April 2003.

II. In the contested decision, the examining division held that the subject-matter of claim 1 then on file did not meet requirements of Article 54(1),(2) EPC with regard to the following document:
(D1) US-A-5,247,929.

III. Oral proceedings were held on 3 November 2005.

IV. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

Claims:
Nos. 1 to 3 as filed at the oral proceedings on 3 November 2005;

Description:
Pages 1 to 3, 6 to 8 as originally filed,
Pages 4, 4a, 4b, 5, 9 as filed with the grounds of appeal;

Drawings:
Figures 1 to 3 as originally filed.

V. The wording of claim 1 reads as follows:

"*A heart stimulator (2) adapted for detecting atrial tachycardia, containing*
a control device (6) to which are connected
an atrial detector (8), having a blanking period, adapted for detecting atrial events,
a ventricular stimulation unit (14) adapted for delivering stimulation pulses in a ventricle,
a counter (16) adapted for generating a variable PV interval between a detected atrial event and a stimulation pulse delivered by said ventricular stimulation unit (14), and
a time measurement unit (18) adapted for measuring the PP intervals between two consecutive, detected atrial events,
wherein the heart stimulator (2) also contains
a calculation unit (20), provided with a tachycardia test interval (24), which can either be preset or made dependent on the PV interval such that the tachycardia test interval (24) consists of about twice the sum of the existing PV interval and the blanking period,
an atrial tachycardia test being performed when the PP interval is shorter than the tachycardia test interval (24) in one or a plurality of measurement intervals,
said calculation unit (20) in said atrial tachycardia tests being arranged to cause the counter (16) to shorten the PV interval so that the sum of the shortened PV interval and the atrial detector's (8) blanking period is equal to half or less than half of an adjustable threshold value PP tachycardia (22),
the time measurement unit (18) then sending a tachycardia detection signal (30) to the control device (6) when, after a defined number of measured

consecutive PP intervals, the PP interval is shorter than the threshold value PP tachycardia (22) as an indication that atrial tachycardia exists."

Claims 2 and 3 are dependent claims.

Reasons for the Decision

1. The appeal is admissible.

2. During the appeal procedure, the appellant amended the claims. The Board addressed the issues of clarity of the claimed subject-matter (Article 84 EPC) and admissibility of the amendments (Article 123(2) EPC). In this respect, the Board did not have any objection with regard to the present wording of the claims.

3. *Novelty of claim 1 with regard to D1*

3.1 Claim 1 relates to a heart stimulator adapted for detecting atrial tachycardia. The heart stimulator includes structural features, i.e. a control device, an atrial detector having a blanking period, a ventricular stimulation unit, a counter generating a variable PV interval, a time measurement unit measuring PP intervals, and a calculation unit.
Moreover, the heart stimulator includes functional features relating to a condition to be met for an atrial tachycardia test to be carried out, the step of shortening the PV interval and a further condition to be met for tachycardia to be detected. The functional features rely on the provision of a tachycardia test

interval and an adjustable threshold value PP tachycardia.

3.2 Document D1 discloses a dual chamber pacemaker operating in a synchronous tracking mode (column 1, lines 7 to 12). Such a pacemaker includes an atrial generator 61, an atrial sense amplifier 65, a ventricular generator 63, a ventricular sense amplifier 66, a microprocessor system 60 with internal memory, and hardware logic and/or timing circuits 68 (Figure 2). The following correspondence may be established between the structural features of the claimed heart stimulator and those of the known pacemaker:

claim 1	**D1 (Figures 1 and 2)**
control device 6	microprocessor system 60
atrial detector 8	atrial sense amplifier 65
ventricular stimulation unit 14	ventricular generator 63
counter 16	timing circuits 68
time measurement unit 18	timing circuits 68
calculation unit 20	logic circuits 68 and/or microprocessor system 60

The dual chamber pacemaker known from D1 provides for an atrial blanking period which is set as small as possible, so that substantially all spontaneous atrial events are sensed (column 8, lines 28 to 37; column 14, lines 12 to 15; column 18, line 64 to column 19, line 2). Moreover, the timing circuits 68 of the known pacemaker are considered responsible for generating a variable PV interval (column 17, lines 31 to 34; column 19, lines 17 to 22; claims 1, 14, 15 and 25) and for measuring PP intervals as well (column 8, lines 37 to 42). It is noted that the acronym "*AV*" in the terminology of D1 (column 5, definitions of the

acronyms "*AS*" and "*VS*"; column 15, lines 59 to 61) may encompass the acronym "*PV*" as used in the present application.

Thus, the structural features of the claimed heart stimulator are known from document D1.

3.3 Figure 3 of D1 illustrates a procedure for dynamic AV tracking in DDD or VDD modes (column 4, lines 10 to 12), in particular when an atrial event is determined to be physiological (column 8, lines 20 to 23). The procedure is based on the assumption that any occurring atrial event is recognized by the pacemaker. As already stated above, this implies a very small atrial blanking time providing for a substantially continuous sensing of the atrial channel (column 8, lines 28 to 37).

At block 70, the atrial rate (or the corresponding atrial interval) is determined and compared to a given "*phys_range*" for checking whether it is physiologic. The phys_range extends between a lower limit setting the pacing interval and an upper limit determining how high an atrial rate can be tracked. The change of the atrial rate is also checked to see whether it is physiologic (column 8, lines 37 to 49). If a situation is detected, in which a pathologic atrial tachycardia is excluded, dynamic AV tracking takes place according to the branch given by blocks 71, 72 and 73.

Moreover, at block 70, if the atrial rate is not within the phys_range and rate change limits, it is controlled whether the atrial rate is such that ventricular tracking is still possible (block 75). If yes, AV tracking is achieved by Wenckebach pacing (block 79).

If Wenckebach pacing is not possible, it is determined whether an Atrial Sync Pulse ASP can be delivered (block 76). Then, either an ASP is delivered (block 77) and the ventricle is paced (block 78) or, if an ASP cannot be delivered, the ventricle is paced at once (block 78) (column 9, lines 4 to 20). The ASP is intended for providing safe atrial pacing and for re-synchronising the atrium and the ventricle after certain events like, for instance, Brady Atrial Sense (BAS), Premature Atrial Contraction (PAC) or Retrograde Conduction (RC). Details of the ASP feature are shown in Figures 16a and 16b.

3.4 The disclosure of D1 does not anticipate the combination of the functional features (No. 3.1 above) of the heart stimulator according to claim 1 for various reasons.

3.4.1 As stated above, according to D1, tachycardia is detected by the test provided at block 70 (Figure 3). The test would only correspond to the claimed condition for entering into a tachycardia test mode, i.e. the condition that at least a PP interval is shorter than a tachycardia test interval. This condition, however, does not amount to the detection of a tachycardia as claimed, which rather requires two steps. First, the PV interval is shortened so that the sum of the shortened PV interval and the atrial detector's blanking period is equal to half or less than half of an adjustable threshold value PP tachycardia. Second, it is determined whether, after a defined number of measured consecutive PP intervals, the PP interval is shorter than the threshold value PP tachycardia.

3.4.2 The present invention (Figure 3) is based on the findings that a P wave may not be detected during tachycardia if it occurs during the atrial detector's blanking period. Thus, the claimed functional feature of shortening the PV interval is intended to exclude the risk of overlooking P waves while detecting whether or not tachycardia is present. This feature is not disclosed by document D1 which, in this respect, teaches the different solution of setting the atrial blanking time so small that a substantially continuous sensing of the atrial channel is provided.

The Board thus disagrees with the view of the examining division in the decision under appeal that the feature of shortening the PV interval was known from D1. The document discloses the feature of shortening an AV interval, which, however, is not presented in the context of a tachycardia test mode, as in claim 1, but in relation to a procedure for determining whether and when an Atrial Sync Pulse ASP could be delivered for the purpose of re-synchronizing following detection of a non-physiological state (column 4, lines 55 to 59; column 17, lines 9 to 21; Figures 16a and 16b), i.e. following the detection stage at block 70. In other words, the known AV shortening feature should not be extracted from its context, i.e. ASP delivery, and then compared with the PV shortening feature of claim 1, which, although similar, has a meaning in a different context, i.e. a test for detecting atrial tachycardia. In fact, the known AV shortening feature concerns the shortening of the interval between a paced atrial event and a subsequent ventricular stimulation, whereas the subject-matter of claim 1 refers to the shortening

between a detected natural atrial event and the subsequent ventricular stimulation.

3.4.3 A further issue concerns the claimed atrial tachycardia detection signal. Document D1 may be understood as implying that, after tachycardia is detected at block 70, a detection signal is sent to the microprocessor system of the known heart stimulator in order to activate the steps following block 70. However, the document does not disclose the claimed feature that such a detection signal should be sent when, after a defined number of measured consecutive PP intervals, the PP interval is shorter than the threshold value PP tachycardia.

3.5 In conclusion, document D1 does not disclose a heart stimulator comprising all the features of claim 1. Thus, the subject-matter of claim 1 is novel with regard to D1.

4. *Further prosecution*

4.1 During the first instance procedure, in the communications of 8 February 2002 and 16 August 2002 as well as in the decision under appeal, the examining division only addressed the issue of lack of novelty with regard to document D1.

4.2 During the appeal procedure, the appellant amended the claims. The Board held that the amended claims are clear, that the amendments to the claims are admissible and that their subject-matter is novel with regard to document D1.

4.3 In these circumstances, the Board considers it appropriate to remit the case to the first instance for further prosecution (Article 111(1) EPC, second sentence, second alternative).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution on the basis of the following documents:

Claims:
Nos. 1 to 3 as filed at the oral proceedings on 3 November 2005;

Description:
Pages 1 to 3, 6 to 8 as originally filed,
Pages 4, 4a, 4b, 5, 9 as filed with the grounds of appeal;

Drawings:
Figures 1 to 3 as originally filed.

The Registrar: The Chairman:

R. Schumacher B. Schachenmann