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D E C I S I O N
of 30 March 2006

Case Number: T 0945/03 - 3.4.01

Application Number: 91300109.5

Publication Number: 0448193

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:

A metabolic demand driven rate-responsive pacemaker

Patentee:

TELECTRONICS N.V.

Opponent:

BIOTRONIK GmbH & Co. KG

Headword:

-

Relevant legal provisions:

EPC Art. 56, 84

Keyword:

"Inventive step (no; main request)"

"Clarity (no; first and second auxiliary request)"

Decisions cited:

-

Catchword:

-



Case Number: T 0945/03 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 30 March 2006

Appellant:
(Opponent)

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(Patent Proprietor)

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Decision under appeal:

Interlocutory decision of the Opposition
Division of the European Patent Office posted
3 July 2003 concerning maintenance of European
patent No. 0448193 in amended form.

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 19 August 2003, against the interlocutory decision of the opposition division, dispatched on 3 July 2003, concerning the maintenance of European patent No. 0 448 193 (application number 91300109.5) in amended form. The appeal fee was paid on 19 August 2003. The statement setting out the grounds of appeal was received on 13 November 2003.

II. The opposition had been filed against the patent as a whole and was based on Article 100(a) EPC, in particular on the grounds that the claimed subject-matter lacked novelty (Article 54 EPC) and did not involve an inventive step (Article 56 EPC), and on Article 100(c) EPC.

In the decision under appeal, the opposition division held that the grounds for opposition did not prejudice the maintenance of the patent in amended form, having regard *inter alia* to the following document:

(E2) EP-A-0 313 881.

III. In the appeal procedure, the appellant filed the following further document:

(E7) Roche Lexikon Medizin, 4th edition, Urban & Fischer Verlag, Munich, 1999, definition of the term "*Pathologie*".

IV. In response to summons to oral proceedings, the respondent (proprietor of the patent) informed the Board, with a letter of 24 February 2006, that it would not attend the oral proceedings.

V. Oral proceedings were held on 30 March 2006 in the absence of the respondent.

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

VII. The respondent requested in writing, with the letter of 24 February 2006, that a decision be issued "*based on the papers as they stand*", i.e. that the appeal be dismissed, as a main request, or the patent be maintained on the basis of amended claims 1 filed by a letter of 26 April 2004, as first and second auxiliary requests.

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

*"A dual-chamber rate-responsive pacemaker, comprising:
means (130) for generating atrial and ventricular
pacing pulses;
means (115) for sensing atrial and ventricular
heartbeats;
sensor means for determining a metabolic indicator rate;
means for ascertaining whether sensed atrial heartbeats
are occurring at a rate which is pathological for the
current metabolic indicator rate; and
means (150) for controlling said generating and sensing
means to operate normally in a DDDR mode but to switch*

to a VVIR mode when the rate of atrial heartbeats is pathological."

- IX. The wording of claim 1 according to the respondent's first auxiliary request reads as follows:

*"A dual-chamber rate responsive pacemaker, comprising:
means (130) for generating atrial and ventricular
pacing pulses;
means (115) for sensing atrial and ventricular
heartbeats;
sensor means for determining a metabolic indicator rate;
means for determining a maximum atrial tracking rate as
a function of the current metabolic indicator rate;
means responsive to said atrial heartbeat sensing means
for deriving an indication of intrinsic atrial rate;
means for ascertaining whether sensed atrial heartbeats
are occurring at a rate which is pathological for the
current metabolic indicator rate when intrinsic atrial
rate exceeds the maximum atrial tracking rate for a
plurality of cardiac cycles; and
means for controlling said generating and sensing means
to operate normally in a DDDR mode but to switch to a
VVIR mode when the rate of atrial heartbeats is
pathological."*

- X. The wording of claim 1 according to the respondent's second auxiliary request reads as follows:

*"A dual-chamber rate responsive pacemaker, comprising:
means (130) for generating atrial and ventricular
pacing pulses;
means (115) for sensing atrial and ventricular
heartbeats;*

sensor means for determining a metabolic indicator rate;
means for determining a maximum atrial tracking rate as
a function of the current metabolic indicator rate;
means for determining an atrial refractory period as a
function of the current metabolic indicator rate;
means for ascertaining whether sensed atrial heartbeats
are occurring at a rate which is pathological for the
current metabolic indicator rate; and
means for controlling said generating and sensing means
to operate normally in a DDDR mode but to switch to a
VVIR mode when the rate of atrial heartbeats is
pathological; and
means for controlling said generating and sensing means
to switch from the VVIR mode back to the DDDR mode when
a predetermined number of intervals between sensed
atrial beats exceeds the atrial refractory period."

Reasons for the Decision

1. The appeal is admissible.
2. Respondent's main request
 - 2.1 The prior art document E2 concerns an implantable, programmable, rate-responsive pacemaker having the capability of automatically switching the mode of operation and/or varying the hysteresis rate in response to sensed patient conditions (see column 1, lines 2-8). Whereas the first feature conserves the limited energy of the pacemaker's battery, the second one allows the physiological sensor of the rate-responsive pacemaker to vary the pacing interval as a function of sensed physiological need and, moreover,

the heart's SA node to take over should a heart block condition cease (see column 6, lines 37-56). The two features are independent of each other (see column 9, lines 42-47). Thus, on the one hand, the teaching of E2 relates to a rate-responsive pacemaker including hysteresis means (see claim 1) and, on the other hand, to a rate-responsive pacemaker with the automatic mode switching feature (see independent claim 15 together with dependent claim 16).

Only the automatic mode switching feature is relevant for the present case. This feature is based on the recognition that dual-chamber rate-responsive pacing, which is an optimum mode of operation from a haemodynamic point of view, results in high battery current drain at fast pacing rates. Since it has been recognized that such a pacing mode may be unnecessary at high "exercise" heart rates, the invention of E2 provides a dual-chamber rate-responsive pacemaker at low rates that automatically switches to a single-chamber mode of operation whenever the heart rate exceeds a predetermined fixed threshold (see column 9, line 56 to column 10, line 19; column 12, lines 20-37).

This disclosure is schematically represented in Figure 1C showing the operation of the rate-responsive pacemaker (see column 11, line 36 to column 12, line 19). In particular, a DDD mode is programmed at block 94. At block 102, it is then determined whether the heart rate is greater than a selected threshold. If so, the single-chamber mode VVI is enabled.

2.2 The subject-matter of claim 1, therefore, differs from the dual-chamber rate-responsive pacemaker with automatic mode switching according to E2 in that it includes "*means for ascertaining whether sensed atrial heartbeats are occurring at a rate which is pathological for the current metabolic indicator rate*" and, moreover, means for switching to the VVIR mode "*when the rate of atrial heartbeats is pathological*".

The parties concur with this novelty assessment.

2.3 As regards inventive step, the appellant took the view that the claimed term "*pathological*" should be broadly understood as referring to any abnormal and diseased heart rate differing from the rate that would be physiological for a given physical activity level. Evidence for this interpretation was provided by document E7. The claimed feature of switching from a DDDR mode to a VVIR mode when the atrial rate was pathological comprised the known switching when a prescribed threshold value was exceeded. The claimed pacemaker simply relied on a variable rather than fixed threshold.

According to the respondent, E2 disclosed that physical exercise caused the pacemaker to switch to the single-chamber mode in order to save energy. Since a high atrial rate due to exercise would be physiological, E2 did not teach switching in relation to detection of a pathological condition. Thus, the definition of the term "*pathological*" was irrelevant.

2.4 The disclosure of E2 relating to the automatic mode switching feature is based on a study conducted on patients, each having a programmable dual-chamber pacemaker implanted, and each exhibiting heart block in sinus rhythm (see column 12, lines 20-37). The study consisted in subjecting these patients to physical exercise, the pacemakers operating in three modes, i.e. DDD, VVTR and a combination of DDD at low rates with VVTR at rates greater than 89 beats/minute. The results indicated that ventricular rate-responsive pacing at high rates produced similar benefits as did dual-chamber rate-responsive DDD pacing. In other words, the study suggested that the dual-chamber rate-responsive DDD pacing may be unnecessary at high rates.

On this basis, E2 teaches that energy consumption of a dual-chamber rate-responsive pacemaker implanted in a patient with normal atrial activity and antegrade conduction block may be reduced by switching from the DDDR mode to the VVIR mode when the atrial rate physiologically increasing during physical exercise reaches a given value. Hence, the respondent correctly stated that the high heart rate switching in E2 occurred as a result of exercise.

Starting from this teaching, the distinguishing features of the present invention, as identified above, represent the solution of the problem of modifying the known pacemaker with the aim to cope with the occurrence of a pathological situation characterised by an atrial rate abnormally high as compared to the physiological rate corresponding to the level of exercise. Here, the broad definition of E7 is relied upon, according to which the term "pathological" does

not necessarily pertain to a disease ("*krankhaft*"), for instance a tachycardia, but also covers an event deviating from what should be considered normal ("*abnorm*"), for instance a high rate that is not yet classified as a tachycardia.

When such a situation occurs, the known pacemaker would switch to the VVIR mode if the pathological atrial rate is higher than the prescribed threshold. Thus, there would not be any functional difference between the operations of the claimed pacemaker and the known one. The appellant indeed submitted in this respect that the claimed feature of the switching from a DDDR mode to a VVIR mode at a pathological atrial rate included the known switching at a rate exceeding the threshold value. Should, however, the pathological rate, for example, be close to but not higher than the threshold, the known pacemaker would still operate in the DDDR mode, although the skilled person would know that, according to the teaching of E2, this energy consuming mode is not necessary from a haemodynamic point of view. In order to avoid undue energy consumption, the skilled person would then consider modifying the known switching condition by replacing the prescribed fixed rate threshold by a rate which suitable means of the pacemaker identifies as being pathologically high. Thereby, the skilled person would arrive at a pacemaker falling within the terms of claim 1.

2.5 For these reasons, the subject-matter of claim 1 lacks inventive step.

2.6 The respondent's main request is not allowable.

3. Respondent's first auxiliary request

3.1 The appellant objected that the clarity requirement of Article 84 EPC was not met because of an inconsistency between the amended claim 1 and claim 6 of the patent as granted.

3.2 As compared with claim 1 of the main request, claim 1 of the first auxiliary request further includes "*means for determining a maximum atrial tracking rate as a function of the current metabolic indicator rate*" and "*means responsive to said atrial heartbeat sensing means for deriving an indication of intrinsic atrial rate*". On the basis of the determined maximum atrial tracking rate and the derived intrinsic atrial rate, the rate of the sensed atrial heartbeats is considered to be "*pathological for the current metabolic indicator rate when intrinsic atrial rate exceeds the maximum atrial tracking rate for a plurality of cardiac cycles*". Thus, amended claim 1 includes a definition of the term "*pathological*" based on two previously defined features concerning the maximum atrial tracking rate and the intrinsic atrial rate.

Since the claimed pacemaker is switched from the DDDR mode to the VVIR mode "*when the rate of atrial heartbeats is pathological*", the amendments to claim 1 have the effect that the mode switching occurs "*when intrinsic atrial rate exceeds the maximum atrial tracking rate for a plurality of cardiac cycles*" (underline added). On the other hand, claim 6 of the patent as granted, which depends on claim 1, prescribes that the controlling means decides to switch from the DDDR mode to the VVIR mode "*when the intrinsic atrial*

rate exceeds the maximum atrial tracking rate by a predetermined percentage of the most recent cardiac cycles" (underline added). The two conditions in claims 1 and 6 have different meanings which are not necessarily compatible with each other. In particular, differing from "*a plurality of cardiac cycles*" concerning any cycles, the expression "*the most recent cardiac cycles*" implies a sequence of the last sensed consecutive cycles.

3.3 For these reasons, the amendments to the subject-matter of claim 1 cause a lack of clarity in view of claim 6.

3.4 The respondent's first auxiliary request is not allowable.

4. Respondent's second auxiliary request

4.1 As for the first auxiliary request, the appellant objected that the clarity requirement of Article 84 EPC was not met because of an inconsistency between amended claim 1 and claim 6 of the patent as granted.

4.2 As compared with claim 1 of the first auxiliary request, claim 1 of the auxiliary request II further includes "*means for controlling said generating and sensing means to switch from the VVIR mode back to the DDDR mode when a predetermined number of intervals between sensed atrial beats exceeds the atrial refractory period*".

For reasons similar to those mentioned in relation to the first auxiliary request, there is indeed an inconsistency between the amended claim 1 and claim 6

of the patent as granted. In particular, having regard to the feature of switching from the VVIR mode back to the DDDR mode, the expressions "*a predetermined number of intervals between sensed atrial beats*" (claim 1) and "*the most recent cardiac cycles*" (claim 6) have different meanings which are not necessarily compatible with each other.

4.3 Therefore, the amendments to the subject-matter of claim 1 cause a lack of clarity in view of claim 6.

4.4 The respondent's second auxiliary request is not allowable.

5. Owing to the respondent's absence at the oral proceedings, the claims of the first and second auxiliary requests could not be clarified. However, a continuation of the procedure in writing so as to give the respondent an opportunity to further amend the claims was not equitable considering that the respondent carries the responsibility for its absence (see Article 11(3) of the Rules of Procedure of the Boards of Appeal and decision T 522/02 of 20 July 2004).

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