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D E C I S I O N
of 19 November 2002

Case Number: T 0774/99 - 3.4.1

Application Number: 88116407.3

Publication Number: 0313881

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
Rate-responsive pacemaker with variable hysterisis rate

Patentee:
Pacesetter AB

Opponent:
BIOTRONIK Mess- und Therapiegeräte GmbH & Co Ingenieurbüro Berlin

Headword:
-

Relevant legal provisions:
EPC Art. 52, 56, 84, 123(2)

Keyword:
"Lack of clarity (yes) - main request"
"Inventive step (yes) - auxiliary request"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0774/99 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 19 November 2002

Appellant: (Opponent)
BIOTRONIK
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Respondent: (Proprietor of the patent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 26 May 1999 concerning maintenance of European patent No. 0 313 881 in amended form.**

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
G. Assi

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 27 July 1999, against the interlocutory decision of the opposition division, despatched on 26 May 1999, maintaining the European patent No 0 313 881 in amended form. The fee for the appeal was paid on 22 July 1999 and the statement setting out the grounds of appeal was received on 25 September 1999.

II. The opposition had been filed against the patent as a whole based on Article 100(a) EPC and concerned, in particular, an objection under Articles 52(1) and 56 EPC.

III. In the statement of grounds of appeal, the appellant referred, *inter alia,* to the following documents:

E1: WO-A-86/05698

E3: EP-B-0 000 987

E8: DE-A-35 06 789

IV. Oral proceedings were held on 19 November 2002.

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

The respondent (patentee) requested that the patent be maintained on the basis of:

Main request

Claims: 1 filed in the oral proceedings on 19 November 2002, and,
2 to 9 according to the main request filed by letter dated 16 October 2002;

Description: columns 1 to 6 and 9 to 15 of the patent specification with column 6, lines 14, 15 as amended and maintained by the opposition division, and
columns 7 and 8 filed in the oral proceedings on 19 November 2002;

Figures: sheets 1/5 to 5/5 of the patent specification

Auxiliary request

Claims: 1 to 4 filed in the oral proceedings on 19 November 2002;

Description: columns 1 to 15 of the patent specification with column 6, lines 14, 15 and column 7, line 34 as amended and maintained by the opposition division;

Figures: sheets 1/5 to 5/5 of the patent specification.

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

"1. A rate-responsive pacemaker (70, 10) for selectively stimulating the heart of a patient comprising: pulse generating means (52) for generating pulses to stimulate heart chamber contractions; sensing means (50) for detecting ventricular heart signals; means (72, 76; 12) coupling the pulse generating means (52) and sensing means (50) to the ventricular region of the patient's heart; physiological sensor means (24) for sensing physiological need and providing a corresponding signal to control stimulating pulse rate; and control means (58, 56) responsive to the physiological sensor means for varying the stimulating pulse escape interval to vary the stimulating pulse rate in accordance with physiological need; characterised by hysteresis means (56) for selectively causing the control means (58, 56) to extend the stimulating pulse escape interval by adding a prescribed hysteresis interval upon detection of a ventricular heart signal by the sensing means, and for varying the escape interval by different amounts within a range between a minimum and a maximum hysteresis rate, the prescribed hysteresis rate being higher when the controlled stimulating pulse rate is high and lower when the controlled stimulating pulse rate is low."

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

"1. A rate-responsive pacemaker (70, 10) for selectively stimulating the heart of a patient comprising: pulsegenerating means (52) for generating pulses to stimulate heart chamber contractions; sensing

means (50) for detecting ventricular heart signals; means (72, 76; 12) coupling the pulse generating means (52) and sensing means (50) to the ventricular region of the patient's heart; physiological sensor means (24) for sensing physiological need and providing a corresponding signal to control stimulating pulse rate; and control means (58, 56) responsive to the physiological sensor means for varying stimulating pulse escape interval to vary the stimulating pulse rate in accordance with physiological need; hysteresis means (56) for selectively causing the control means (58, 56) to extend a stimulating pulse escape interval by adding a prescribed hysteresis value upon detection of a ventricular heart signal by the sensing means, and inhibiting means (56, 60) responsive to the sensing means (50) for inhibiting the generation of a stimulating pulse upon the detection of selected ventricular heart signals, the inhibiting means (56, 60) comprising resetting means for resetting the stimulating pulse escape interval varied by the control means (58, 56), wherein the control means (56) comprises a variable escape interval delay stage for introducing a predetermined delay in the stimulating pulse escape interval corresponding to the stimulating pulse rate determined by the physiological sensor means (24), and the control means further comprises means (56) for varying the variable escape interval delay stage in accordance with physiological need as sensed by the physiological sensor means (24); and wherein the means (56) for varying the variable escape interval delay stage extends the stimulating pulse escape interval by varying degrees between minimum and maximum values over corresponding minimum and maximum

stimulating pulse rates as determined by the physiological sensor means (24)."

Claims 2 to 4 of the auxiliary reqest are dependent on claim 1.

VII. The appellant's arguments may be summarised as follows:

Claim 1 of the respondent's **main request** related to a particular aspect of the invention as shown in the embodiments according to Figures 3B and 4, namely to the fact that the hysteresis rate increased with increasing pacing rates. However, since no corresponding teaching was specifically disclosed in the application as originally filed, the subject-matter of claim 1 constituted a generalization of some preferred embodiments, and, as such, it was not admissible under Article 123(2) EPC.

Claim 1 according to the respondent's **auxiliary request** recited some standard features of a rate-responsive pacemaker, as known from document E1, together with some features concerning the fact that the escape interval determined by the physiological sensor output was extended by adding a variable hysteresis escape interval.

E3 related to a programmable demand pacemaker with hysteresis and taught to select the appropriate combination of pacing rates and hysteresis rates. It would have been obvious to a person skilled in the art to add the hysteresis function taught in E3 to a rate-responsive pacemaker according to E1. In fact, it was already known from E8 to provide a rate-responsive pacemaker with means which extended the escape interval

determined by the physiological sensor upon detection of spontaneous cardiac activity.

As to the particular relationship between hysteresis escape intervals and pacing rates specified in claim 1 of the auxiliary request, it would have been obvious to a person skilled in the art, wishing to develop a rate-responsive pacemaker with hysteresis, to consider the possibility of extending the hysteresis escape interval at higher pacing rates.
Hence, the subject-matter of this claim did not involve an inventive step within the meaning of Article 56 EPC.

IX. The respondent argued essentially as follows:

The present invention was based on the realisation that a faulty heart could start operating normally at higher rates, *ie* when the physiological need increased. In order to give the heart the opportunity to beat on its own when stimulation pulses were not required, the claimed rate-responsive pacemaker comprised hysteresis means which increased the hysteresis rate as a function of the sensor output, *ie* with increasing pacing rates. This particular aspect of the invention, which was clearly specified in claim 1 of the **main request**, constituted the underlying teaching of the whole disclosure and was illustrated in Figures 3B and 4. Hence, claim 1 according to the main request was admissible under Article 123(2) EPC.

Claim 1 according to the **first auxiliary request** comprised further features which defined a particular relationship between the hysteresis escape interval and the pacing rate determined by the physiological sensor. Since such relationship was neither shown nor suggested

in any of the cited prior art documents, the subject-matter of this claim involved an inventive step within the meaning of Article 56 EPC.

Reasons for the decision

1. The appeal is admissible.

Main request

2.1 Claim 1 according to the main request relates to a rate-responsive pacemaker comprising, *inter alia*, **hysteresis means**:

(a) for selectively causing the **control means** to extend the **stimulating pulse escape interval** by adding **a prescribed hysteresis interval** upon detection of a ventricular heart signal by the sensing means, and

(b) for **varying** the **escape interval** by different amounts within a range between a minimum and a maximum **hysteresis rate, the prescribed hysteresis rate** being higher when the controlled stimulating pulse rate is high and lower when the controlled stimulating pulse rate is low.

2.2 Hence, claim 1 defines how the hysteresis means acts upon the **stimulating pulse escape interval** in terms of **hysteresis interval**, **hysteresis rate** and **prescribed hysteresis rate.** In particular, feature (a) stipulates that the escape interval is extended "by adding a prescribed hysteresis interval", while, according to

feature (b), the escape interval is varied by **different amounts** with the result that:

- the hysteresis rate ranges between a minimum and a maximum hysteresis rate,

- a prescribed hysteresis rate is higher when the controlled stimulating pulse rate is high and lower when the controlled stimulating pulse rate is low.

2.3 According to the respondent, the combination of features (a) and (b) relates to an essential aspect of the present invention which consists in **varying** the **hysteresis interval** (*ie* the time interval by which the **escape interval** is extended after detection of spontaneous cardiac activity) as a function of the sensor output in such a way that the **hysteresis rate** (*ie* the difference between the **paced rate** determined as a function of the patient's physiological need and the minimum intrinsic heart rate allowed by the pacer) increases as the paced rate increases.

2.4 The Board notes, however, that a **constant** (*ie* independent of the pulse rate) "prescribed hysteresis interval" added to a stimulating pulse escape interval that varies as a function of the physiological sensor output may result in "a prescribed hysteresis rate" which is higher when the stimulating pulse rate is high and lower when the control stimulating pulse rate is low. On the other hand, hysteresis means which can vary **by different amounts** the constant "prescribed hysteresis interval" added to the escape interval by the control means may produce a hysteresis rate ranging between a maximum and a minimum.

In other words, the different parameters used in the claim allow interpretations of the operation of the hysteresis means which appear not to be consistent with some of the essential aspects of the invention, in particular with the fact that hysteresis is controlled by varying the **hysteresis escape interval** to be added to the **regular escape interval** as a function of the physiological sensor output (see patent specification, column 11, lines 53 to 58). Furthermore, some of the intrinsic ambiguities of the claimed subject-matter make it difficult to establish wether the requirements of Article 123(2) EPC are met.

2.5 Since claim 1 does not clearly define what is considered be an essential aspect of the invention as presented by the respondent, it does not meet the requirements of Article 84 EPC.

Auxiliary request

3.1 Claim 1 according to the respondent's auxiliary request is essentially based on a combination of claims 1 to 6 of the patent specification, whereas claims 2 to 4 reflect essentially claims 7 to 9 of the granted patent.

3.2 The appellant has not raised any objections concerning the admissibility under Article 123(2) and (3) EPC of the claims of the auxiliary request and the Board sees no reason to consider this matter further.

4.1 It is not in dispute that claim 1 differs from the rate-responsive pacemaker known from E1 essentially in that it comprises:

(i) hysteresis means for selectively causing the control means to extend the stimulating pulse escape interval by adding a prescribed hysteresis value upon detection of a ventricular heart signal by the sensor means;

and in that its control means comprises:

(ii) a variable escape interval delay stage for introducing a predetermined delay in the stimulating pulse escape interval corresponding to the stimulating pulse rate determined by the physiological sensor means;

(iii) means for varying the variable escape interval delay stage in accordance with physiological need as sensed by the physiological sensing means, such means extending the stimulating pulse escape interval by varying degrees between minimum and maximum values over corresponding minimum and maximum stimulating pulse rates as determined by the physiological sensor means.

4.2 The combination of features (i), (ii) and (iii) relates to an essential aspect of the present invention which consists in adding a variable hysteresis escape interval to the escape interval determined as a function of the sensor output (*ie* determined by the physiological sensing means), whereby such hysteresis escape interval varies between minimum and maximum values over corresponding minimum and maximum values for the stimulating pulse rate as determined by the physiological sensing means.

As pointed out by the respondent, the claimed invention

is based on the realisation that many patients who exhibit partial, intermittent, or complete heart block at normal rates, will exhibit normal anterograde conduction at higher rates, and that natural AV synchrony can be restored if competition between the rate-responsive pacemaker and the heart's SA node is prevented. By increasing the escape interval upon detection of spontaneous cardiac activity at higher pacing rates, the heart has a better chance to beat on its own before the pacer can "step in" and override the heart's activity by providing stimulation pulses.

4.4 E3 relates to a demand pacemaker with a programmable hysteresis function. According to the description (column 1, lines 44 to 54) "it is desirable with a demand pacemaker that the stimulating pulses are issued only when really needed by the heart, and that the latter is given the opportunity of functioning as naturally as possible. One approach to providing this desirable property has been to provide the implanted pacemaker with a fixed hysteresis function for the pacing rate, so that, after each natural heart beat detected which inhibits a stimulating pulse, a slight delay occurs before the next stimulating pulse is generated". However, E3 proposes a pacemaker which "enables a plurality of different hysteresis functions to be built into the pacemaker whereby any of these may be programmed and selected after implant, according to the patients condition" (column 2, lines 48 to 52). According to the embodiment of Figure 3, the outputs of a counter provide for normal/slow pulse rate combinations (*ie* without hysteresis or with hysteresis) which can be individually selected by a rate decoder.

In other words, E3 teaches to select the appropriate

combination of pacing and hysteresis rates, but it does not suggest that in a rate-responsive pacemaker the hysteresis function should be implemented by adding a variable hysteresis escape interval to the escape interval determined by the physiological sensor output in such a way that the hysteresis escape interval is varied between a minimum and a maximum corresponding to minimum and maximum pacing rates, as recited in claim 1 according to the first auxiliary request.

In fact, the Board agrees with the respondent that the teaching of E3 applied to the rate-responsive pacemaker as known from E1 would result in a rate-responsive pacemaker with different programmable hysteresis rates.

4.5 Document E8 relates to a rate-responsive pacemaker and deals, *inter alia*, with the problem of compensating for a possible difference in the physiological parameter's response to natural or artificial contractions of the heart. In particular, this document proposes to use a separate set of values for the escape interval following spontaneous or stimulated heart activity. However, this appears to serve the purpose of providing a pacing rate which is closer to the heart's natural rate. Furthermore, there is no suggestion in E8 that the hysteresis escape interval should be varied as a function of the patient's physiological need.

4.6 Though the fact of increasing the hysteresis rate at higher pacing rates in response to spontaneous cardiac activity may be regarded as a straightforward improvement of a rate-responsive pacemaker with hysteresis once it is realised that a faulty heart is more likely to function normally at higher rates *(ie* when physiological need increases), the cited prior art

fails to prove that this behaviour of the heart was known before the priority date of the contested patent.

4.7 In the absence of any indication in the cited prior art that some patients may suffer from heart block only at the lower normal heart rates and that spontaneous cardiac activity may resume at higher heart rates, the Board considers that it would not have been obvious to a person skilled in the art to develop a rate-responsive pacer with the hysteresis characteristics specified in claim 1 according to the auxiliary request. Hence, the subject-matter of this claim involves an inventive step within the meaning of Article 56 EPC.

Claims 2 to 4 are dependent on claim 1 and, thus, their subject-matters also involve an inventive step.

5. In the result, the Board finds that the subject-matter of claim 1 according to the respondent's auxiliary request satisfies the requirements of the EPC and that the patent can be maintained on the basis thereof.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the following documents according to the respondent's **auxiliary request:**

Claims: 1 to 4 filed in the oral proceedings on 19 November 2002;

Description: columns 1 to 15 of the patent specification with column 6, lines 14, 15 and column 7, line 34 as amended and maintained by the opposition division;

Figures: sheets 1/5 to 5/5 of the patent specification

The Registrar: The Chairman:

R. Schumacher G. Davies