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D E C I S I O N
of 12 May 2004

Case Number: T 0987/99 - 3.4.1

Application Number: 91304485.5

Publication Number: 0481583

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:

Method and apparatus for cardioverter/pacer utilizing
neurosensing

Patentee:

CARDIAC PACEMAKERS, INC.

Opponent:

Biotronik GmbH & Co. KG

Headword:

-

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step - no"

Decisions cited:

-

Catchword:

-



Case Number: T 0987/99 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 12 May 2004

Appellant: Biotronik GmbH & Co. KG
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
12 August 1999 concerning maintenance of
European patent No. 0481583 in amended form.

Composition of the Board:

Chairman: M. G. L. Rognoni
Members: G. Assi
H. Preglau

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 2 October 1999, against the interlocutory decision of the opposition division, dispatched on 12 August 1999, concerning the maintenance of European patent No. 0 481 583 (application number 91304485.5) in amended form. The appeal fee was paid on 2 October 1999. The statement setting out the grounds of appeal was received on 10 December 1999.

II. The opposition had been filed against the patent as a whole and was based on Article 100(a) and (b) EPC, *inter alia* on the ground that the claimed subject-matter did not involve an inventive step (Article 56 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 documents:

(E1) US-A-4 201 219 and

(E4) EP-A-0 317 065.

III. In the appeal proceedings, the following further documents were considered:

(E7) EP-A-0 307 093 and

(E9) EP-A-0 310 216.

IV. In response to the summons to oral proceedings, the respondent (proprietor of the patent) informed the Board, with a letter of 6 April 2004, that it would not attend the oral proceedings and withdrew its request therefor.

Oral proceedings were held on 12 May 2004 in the absence of the respondent.

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

The respondent requested in writing that the appeal be dismissed.

VI. The wording of claim 1 reads as follows:

"1. A programmable pacemaker apparatus comprising:

(a) a neurosense electrode (12) having a neurosignal output, the neurosense electrode being contactable with a sensed nerve to provide a neurosignal thereon;

(b) a neurosense amplifier (16) having a band pass filter including an input connected to the neurosignal output wherein the neurosense amplifier further has an output and provides an amplified neurosignal thereon;

(c) a frequency-to-voltage converter (20) having a first input connected to the neurosense amplifier output wherein the frequency-to-voltage converter has an output and provides a voltage converted signal thereon proportional to the frequency of the amplified neurosignal; and

(d) a microprocessor (28) having an input/output port;

characterised by an analog-to-digital converter (24) including an input connected to the frequency-to-voltage converter output wherein the analog-to-digital converter has an output for providing thereon a digital signal which is representative of the voltage converted signal and a function of a baroreceptor nerve neurosignal sensed by said neurosense electrode (12), the microprocessor (28) including an input connected to the analog-to-digital converter output and being operable to execute a pressure responsive control algorithm in response to said representative digital signal to provide said pacing signals according to the pressure responsive control algorithm and having a second output for providing defibrillation or cardioverting signals according to the control algorithm, said amplifier (16) having an automatic gain control, the pressure responsive control algorithm adapted to provide an increase in pacing stimulus rate in response to a decrease in pressure indicated by said baroreceptor nerve neurosignal and adapted to provide said defibrillation or cardioversion signals in response to a rapid fall in blood pressure indicated by said baroreceptor nerve neurosignal."

VII. The appellant essentially argued that the subject-matter of claim 1 was obvious having regard to the combined teachings of documents E1 and E4 considered in the light of the knowledge of the skilled person.

Document E1 described a physiologically responsive pacemaker, in which the pacing rate was adjusted in response to baroreceptor neurosignals which reflected arterial blood pressure. The graph of Figure 12 showed the behaviour of the neuroregulated pacemaker, which

followed the response of a normal heart during physical exercise. This behaviour was consistent with the well-known baroreceptor reflex (see E7) implying an inverse relationship between blood pressure and heart rate.

Document E4 related to a system for delivering defibrillating or cardioverting energy to the heart based on haemodynamic or both haemodynamic and rate criteria. In this document, the mean arterial pressure was considered to be an excellent parameter for detecting the heart condition. In this respect, a rapid fall in blood pressure was a known indicator for fibrillation.

Hence, the combined teachings of documents E1 and E4 would lead the skilled person to the pacemaker of claim 1, except for the features concerning the automatic gain control amplifier with a band pass filter and the analog-to-digital converter. These features, however, concerned the electronic circuitry and were not related to the problem of controlling the pacemaker by the blood pressure. They had to be considered separately. Since they represented common measures for processing physiological signals in the field of pacemakers, they could not contribute to the presence of an inventive step.

VIII. The respondent submitted that the appellant's arguments, based on a somewhat vague piecing together of bits of information from multiple documents, strongly suggested the use of hindsight.

In contrast to the present invention, the pacemaker known from document E1 did not include defibrillation

or cardioversion means. Moreover, E1 taught away from the subject-matter of claim 1 because the pacing rate was increased in response to an increase in arterial pressure.

Starting from the disclosure of document E1, in order to provide defibrillation or cardioversion in addition to the pacing function, it was doubtful whether the skilled person would turn to document E4, which described a system combining a pacemaker with a defibrillator and using the mean arterial pressure as well as the heart rate for deciding which action should be taken.

Indeed, document E4 taught away from the solution of the present invention for different reasons.

Although the mean arterial pressure was described as an excellent parameter for controlling the system, the document admitted that indwelling arterial catheters and transducers were needed, which over time were prone to infection and thrombus formation. Despite these deficiencies, the authors of E4 did not recognise the significance of neurodetectors for sensing arterial pressure.

Document E4, moreover, failed to teach how to distinguish, based on blood pressure only, between the need for pacing and the need for defibrillation or cardioversion. In contrast to the invention, pressure measurements were subordinate to heart rate measurements.

Lastly, although document E1 had been published about eight years before the priority dates of document E4, the significance of the teaching of E1 remained completely unrecognised by the authors of E4 despite the broad range of their intentions.

Reasons for the Decision

1. The appeal is admissible.
2. *Inventive step*
 - 2.1 It is not in dispute that document E1 can be regarded as representing the closest prior art.
 - 2.2 Document E1 discloses a physiological responsive cardiac pacemaker based on neurosensing (see column 1, first paragraph). Baroreceptors in the carotid sinus are sensitive to arterial blood pressure and generate trains of impulses transmitted along the glossopharyngeal nerve. Chemoreceptors in the carotid glomus are sensitive to the partial pressures pO_2 and pCO_2 in the blood and also generate trains of impulses transmitted along the glossopharyngeal nerve. A neurodetector senses these nerve impulses which have frequencies (I_s and I_g) depending on the arterial pressure (see Figure 7) and the partial pressures pO_2 and pCO_2 (see Figure 8). The output of the neurodetector is amplified and then sent to a separating filter which separates the impulses of the carotid sinus and the carotid glomus. Signals representing the average frequencies are lead to a voltage proportioning circuit which controls the pacing rate as a function of the frequency of the sensed impulses (see Figures 12 and 13), *ie* as a function of the sensed physiological parameters represented by the arterial pressure and the partial pressures pO_2 and pCO_2 .

Figures 9 to 11 of document E1 show the normal behaviour of the body during physical exercise. An increase in physical work results in a higher cardiac frequency (see Figure 9), a higher arterial pressure (see Figure 10) and a greater demand for oxygen (see Figure 11, lower pO_2 and higher pCO_2 values). Based on these physiological parameters, the control algorithm according to Figure 12 adjusts the pacing rate so as to reproduce the physiological behaviour of the healthy heart during exercise.

The known control algorithm is not in contrast to the claimed feature that the pacing rate is increased in response to a decrease in blood pressure. As already stated, the algorithm controls the heart rate depending on both the arterial pressure, represented by I_s , and the partial pressures pO_2 and pCO_2 , represented by I_g and related to breathing. With increasing exercise, the pO_2 value decreases so that the frequency I_g and the heart rate increase. A similar behaviour is observed with regard to the arterial pressure. For a given level of exercise, the combined effects of I_s and I_g keep the heart rate at a constant value depending on the level of exercise. Thus, it is implicit that in a situation, in which the blood pressure (see I_s) decreases without a reduction of the level of exercise, the algorithm must be adapted to provide an increase of the heart rate so as to restore the arterial pressure appropriate for that level of exercise. Indeed, different behaviours in such a situation would worsen the condition of the person and be contrary to the aim of a pacemaker. Moreover, in contrast to the decision of the opposition division, the Board considers that it is not possible to draw any conclusion concerning the heart rate merely

on the basis of the value of I_s alone (see Figure 12) because this would ignore the effect of I_g .

The interpretation of the behaviour of the pacemaker according to E1 takes account of the fact that the pacemaker's algorithm is supposed to reproduce the physiological reactions of the normal heart and is, in particular, consistent with the known "*baroreceptor reflex*", which provides a short term blood pressure control on the basis of an inverse relationship between blood pressure and heart rate (see document E7, column 7, lines 6 to 12).

2.3 Therefore, the subject-matter of claim 1 essentially differs from the pacemaker known from document E1 in that

- (a) the electronic circuitry includes an automatic gain control amplifier with a band pass filter and an analog-to-digital converter,
- (b) the microprocessor has an output for providing defibrillation or cardioverting signals, and
- (c) the pressure responsive control algorithm is adapted to provide defibrillation or cardioversion signals in response to a rapid fall in blood pressure.

2.4 The main technical problem as defined in the patent in suit (see column 1, lines 41 to 44) consists in providing a physiological responsive cardioverter-pacemaker based on baroreceptor neurosignals. In other words, it consists in extending the operation of the

pacemaker according to document E1 by adding a defibrillating or cardioverting function.

It should be clear that only features (b) and (c) solve this problem, while features (a) address different problems. In particular, according to the patent specification (see column 5, lines 4 to 22), the automatic gain control avoids long term drift in the amplitude of the signal from the nerve, whereas the band pass filter rejects noise which may be present in the nerve signal. As regards the analog-to-digital converter, it improves the signal processing.

- 2.5 Document E4 concerns a system for delivering cardioverting or defibrillating energy to the heart based on haemodynamic or both haemodynamic and rate criteria. According to the haemodynamic algorithm, the cardioverter-defibrillator is controlled by a change of a predetermined magnitude in a pressure parameter, for example the mean arterial pressure, from a baseline pressure value (see column 5, lines 4 to 27 and column 3, lines 2 to 15). The mean arterial pressure, in particular, is acknowledged as an excellent haemodynamic parameter for controlling the cardioverter-defibrillator (see column 4, lines 14 to 18) and can be measured by means of an arterial catheter or an automated mechanical blood pressure cuff or doppler technology (see column 3, line 48 to column 4, line 1). The haemodynamic and rate algorithms are also suitable for controlling a cardioverter-defibrillator integrated with an antitachycardia pacemaker, in which case the haemodynamic function determines which of these devices has to be engaged

(see column 4, lines 28 to 32 and column 1, lines 9 to 14).

2.6 Starting from the disclosure of document E1, the skilled person, wishing to solve the main problem, would consider combining the teaching of document E4 with that of E1. This combination leads to a pacemaker responsive to physiological need and combining the function of a defibrillator or cardioverter. It would be obvious to the skilled person to consider adapting the control algorithm according to document E1, *ie* the haemodynamic function based, *inter alia*, on arterial pressure, so as to provide defibrillation or cardioversion signals in response to the known "rapid" fall in blood pressure caused by a fibrillating heart (see E9, Figure 4D). Moreover, as regards the haemodynamic function, it is clear that the disadvantages mentioned in E4 with respect to the use of an indwelling arterial catheter, which over time is prone to infection and thrombus formation, would be overcome by sensing a baroreceptor nerve according to the teaching of E1.

2.7 For the above reasons, the Board finds that the combined teachings of documents E1 and E4 would lead the skilled person to a pacemaker apparatus having all the features of claim 1, except for the automatic gain control amplifier with the band pass filter and the analog-to-digital converter.

Automatic gain control amplifiers with band pass filters as well as analog-to-digital converters, however, were commonly used, at the priority date of the invention, in pacemakers with the same function

mentioned above. These features do not interact with the remaining features of claim 1 so as to produce an unexpected result and, therefore, do not contribute to the presence of an inventive step.

- 2.8 As to the respondent's argument that, contrary to the present invention, in document E4 pressure measurements were subordinate to rate measurements, it is observed that this document describes embodiments in which a decision for cardioversion or defibrillation is based on the haemodynamic criterion alone as represented by the sensed arterial pressure. However, the wording of claim 1 does not exclude that additional sensed parameters other than the blood pressure may also be taken into consideration by the microprocessor for deciding between pacing and cardioverting or defibrillating.

Furthermore, in the Board's view, the respondent's objection that the potential significance of the earlier document D1 had not been recognised by the authors of E4, does not prove that the skilled person would have been prejudiced against combining these documents.

- 2.9 For the above reasons, the subject-matter of claim 1 does not involve an inventive step having regard to the combination of documents E1 and E4 read in the light of the skilled person's knowledge.

3. Accordingly, the respondent's request is not allowable.

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:

D. Sauter

M. Rognoni