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

Case Number: T 0164/02 - 3.4.1

Application Number: 91105271.0

Publication Number: 0452733

IPC: A61N 1/37

Language of the proceedings: EN

Title of invention:

Rate-responsive pacemaker with circuitry for processing multiple sensor inputs

Patentee:

PACESETTER, INC.

Opponent:

Biotronik GmbH & Co. KG

Headword:

-

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (no)"

Decisions cited:

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Catchword:

-



Case Number: T 0164/02 - 3.4.1

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

Appellant:
(Opponent)

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

Representative:

Eisenführ, Speiser & Partner
Patentanwälte Rechtsanwälte
Arnulfstrasse 25
D-80335 München (DE)

Respondent:
(Proprietor of the patent)

PACESETTER, INC.
15900 Valley View Court
Sylmar, CA 91392-9221 (US)

Representative:

Rees, David Christopher
Kilburn & Strode
20 Red Lion Street
London WC1R 4PJ (GB)

Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 21 December 2001
rejecting the opposition filed against European
patent No. 0452733 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
R. Q. Bekkering

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal, received on 7 February 2002, against the decision of the opposition division, dispatched on 21 December 2001, revoking European patent No. 0 452 733 (application number 91 105 271.0). The appeal fee was paid on 7 February 2002 and the statement setting out the grounds of appeal was received on 19 April 2002.
- II. Opposition had been filed against the patent as a whole and was based on Article 100(a) EPC on the grounds of lack of novelty and lack of inventive step.
- III. In the decision under appeal, the opposition division held that the ground for opposition did not prejudice maintenance of the patent as granted, having regard *inter alia* to the following documents:
- E1: EP-A-0 225 839
- E1': US-A-4 867 163 (US patent family member of E1)
- E3: E. Alt et al., "A New Rate-Modulated Pacemaker System Optimized by Combination of Two Sensors", PACE, Vol. 11, August 1988, pp. 1119-1129
- IV. Oral proceedings before the Board were held on 12 October 2004. The respondent (patent proprietor) had informed the Board in due time, by letter dated 10 September 2004, that it would not attend the oral proceedings.

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 rejected and the patent maintained as granted.

VI. Claim 1 as granted reads as follows:

"A rate-responsive pacemaker (20) for stimulating the heart (44) of a patient, said pacemaker (20) comprising:

pulse generating means (34) for generating and delivering stimulation pulses to the patient's heart (44) in response to a selected rate signal;

a first sensor means (22) for sensing a first physiological parameter of a patient and producing a first signal in response thereto;

a second sensor means (24) for sensing a second physiological parameter of a patient and producing a second signal in response thereto;

a first conversion means (50 - 54) for converting said first signal into a first address signal;

a second conversion means (56 - 60) for converting said second signal into a second address signal; and

an addressable rate matrix (62, 30, RM) having as inputs said first and second address signals and having as an output a unique selected rate signal corresponding to the values of said first and second

address signals, said selected rate signal being supplied to said pulse generating means (34)."

VII. The appellant essentially argued as follows:

The rate-responsive pacemaker shown in Figure 5 of E1 was substantially more complex than that of claim 1 of the patent in suit because it included several other functions beyond the pure control of the pacing rate, such as regulation, calibration and error control. However, this should not detract from the fact that the basic principle of the rate-responsive pacemaker shown in Figure 5, which consisted in linking the outputs of physiological sensors with parameters indicative of the desired pacing rate by means of matrixes, was identical to that of claim 1.

Furthermore, it was taught in E3 that a pacing rate signal could be obtained on the basis of two measured parameters, such as blood temperature and body activity.

Thus, in the light of the cited prior art, it would have been obvious to a person skilled in the art, wishing to develop a simple rate-responsive pacemaker, to arrive at the claimed subject-matter.

VIII. The respondent's arguments may be summarised as follows:

The pacemaker according to claim 1 of the contested patent comprised an addressable rate matrix which contained a set of pre-programmed responses activated by signals from two physiological sensors. Thus, the values of the rate matrix were not **derived** from the output signals from the sensors in response to

monitored physiological input quantities but rather were **pre-programmed** values which were chosen dependent on the signals from the sensors. In the pacemaker according to Figure 5 of document E1, however, the pre-programmed values or stimulation parameters stored in the address matrix block 520 were combined with physiological sensor outputs which were then combined with an activity signal in block 524. The combined signals produced an output signal, or rate signal, from block 524. As such, while the matrix block 520 influenced the rate signal which was eventually supplied to the pulse generator, it did not define the specific rate as did the rate matrix of the patent in suit. Block 524 was an essential feature of the invention of E1 and there was no obvious reason for the skilled person to omit it.

The combination of the teaching of E1 and E3 did not assist the person skilled in the art to arrive at the invention of the contested patent. E3 related to a rate-modulated pacemaker system optimised by a combination of two sensors. The pacing rate in E3 was continuously **calculated** directly from the signals from both the sensors by means of a special algorithm and not a pre-programmed rate matrix as in the patent in suit. Therefore, given the teaching of E3, the person skilled in the art had no reason to modify the arrangements disclosed in E1 to include a rate matrix according to the present invention.

Reasons for the Decision

1. The appeal is admissible.

2. The contested patent relates to a rate-responsive pacemaker comprising two sensors for sensing corresponding physiological parameters in order to determine the pacing rate suitable for meeting the patient's physiological demands. The gist of the present invention consists essentially in providing an addressable matrix which stores the "*selected rate signal*" to be supplied to the pacemaker's pulse generating means, and in converting the output signals of the two sensors into corresponding address signals which are used to address the matrix cells and select the appropriate rate signal.

In other words, the rate-responsiveness of the pacemaker according to the present invention is achieved by establishing a functional relationship between the sensors' output signals and the rate signal by means of an addressable matrix which outputs a predetermined rate signal when the sensors' output signals fall within predetermined ranges corresponding to the matrix addresses (see Figures 2 and 3 of the contested patent).

Inventive step

- 3.1 It is not disputed that document E1 - and its US patent family member E1' - represents the closest prior art. Since both documents have substantially identical disclosures, in the following only document E1 will be referred to.

3.2 E1 relates to a rate-responsive pacemaker, ie to a pacemaker which automatically adapts the pacing rate to the physiological demand of the patient's body (see page 1c, lines 10 to 17).

In the detailed embodiments shown in Figure 5 of E1, sensors 506 and 507 sense two physiological parameters: the respiration rate (or the partial pressure of oxygen in the right ventricle) and the blood temperature (see page 39, lines 15 to 18). These sensed parameters are converted into digital addresses for accessing a two-dimensional matrix 520, wherein each digital signal addresses one coordinate axis of the matrix (see page 39, line 24 to page 40, line 7). The thus selected cell of the matrix contains a unique value which is fed to a further matrix 524 where it is combined with another measured signal indicative of the actual physical activity of the patient, in order to output a signal indicating the cardiac output requirement (see page 41, lines 6 to 18). The output of matrix 524 is fed to a further matrix 527 which controls the pacing rate on the basis of the instantaneous stroke volume (see page 42, line 30 to page 44, line 4).

3.3 According to the appellant (see letter dated 10 September 2004, page 3, first paragraph), E1 clearly hinted at the possibility that the heart rate control could be performed without taking into account the instantaneous stroke volume. In such a case, matrix block 524 in the embodiment of Figure 5 would output a signal which directly determined the stimulation rate and essentially corresponded to the "*selected rate signal*" specified in claim 1.

Thus, if the appellant's assessment of document E1 is taken into account, the subject-matter of claim 1 differs from the rate responsive pacemaker shown in Figure 5 of E1 in that the selected rate signal is obtained from two physiological parameters and one addressable rate matrix, as opposed to more than two sensed parameters and two addressable matrixes in E1.

4.1 According to the respondent, there was no reason why the skilled person would omit block 524 from the embodiment shown in Figure 5 of E1 in order to allow the rate signal to be generated by the output signal of block 520 alone. In fact, block 524 and all its corresponding inputs were an essential feature of the rate-responsive pacemaker of E1 and, therefore, this document taught away from the present invention.

4.2 In the appellant's view, however, E1 should not be interpreted as a unitary disclosure directed exclusively to a particular (complex) embodiment, but rather as a document covering different embodiments which should be considered independently. In particular, the teaching given in E1 that pure control functions were formed by linking input measured variables with stored pacing parameters should be considered as the starting point of the invention.

5.1 Indeed, as argued by the appellant, E1 contains the general teaching that "*Reine Steuerfunktionen*" (pure control functions) are formed by simple linkage of input measured variables (as address variables) and pacing parameters (as stored values) (see E1, page 34, lines 16 to 19). This teaching is reiterated in claim 8

(lines 16 to 18) which, *inter alia*, specifies that data stored in a memory as an output signal form a characteristic data field for at least indirectly influencing the pacing parameters. One way of effecting a combination of two physiological parameters suggested in E1 for the embodiment of Figure 5 would be by means of a "characteristic field", ("*mittels eines Kennfeldes*") (see page 40, lines 4 to 7). In the case of a two-dimensional "characteristic field" ("*bei einem zweidimensionalen Kennfeld*") each input parameter addresses one of the two coordinate axes. It is implicit that an addressable matrix represents the digital implementation of a "characteristic field".

- 5.2 Furthermore, E1 contains several hints that parts of the rate-responsive pacemaker of Figure 5 may be optional and, thus, suggests to the skilled person that a simplified version of the detailed embodiment could indeed be developed. In particular, it is pointed out on page 41, lines 13 to 22, that the block 520 combines exertion variables ascertained in the circulatory system (blood temperature and partial pressure of oxygen), whereas block 524 serves to link the output of block 520 with a signal designating the actual physical activity. The physical activity parameter and the output of the matrix block 520 are to some extent redundant and can be put in relation to one another in the following matrix block 524 in order to increase the system's reliability (E1, page 41, lines 18 to 22). On the other hand, the two physiological parameters used for addressing the first matrix 520 are complementary: the first one (the respiration rate or the partial pressure of oxygen) indicates the **instantaneous** oxygen deficit, due e.g. to the onset of physical activity,

whereas the second one (blood temperature) has an **integrating character** and rises or falls only after a certain time delay (see E1, page 39, lines 15 to 24).

The advantages of combining a body activity parameter, which yields a fast reaction following the onset of physical activity, with blood temperature, which better corresponds to body metabolism, in order to determine the stimulation rate suitable to meet the patient's demands are clearly pointed out in document E3 (see abstract).

5.3 In summary, the Board finds that the skilled person would immediately derive from the cited prior art the general teaching that a viable control parameter for the pacing rate required to meet the patient's physiological demands could be based on a functional relationship between two physiological parameters, both indicative of exertion but with different responses to the onset and the level of physical activity (such as partial pressure of oxygen and blood temperature), and the desired stimulation rate, and that such relationship could be easily implemented by means of an addressable matrix. The straightforward application of such teaching to a rate-responsive pacemaker would lead the skilled person to the subject-matter of claim 1 according to the respondent's request.

6. For the above reasons, the Board considers that the subject-matter of claim 1 does not involve an inventive step within the meaning of Article 56 EPC.

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

G. Davies