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D E C I S I O N
of 7 July 1999

Case Number: T 0383/95 - 3.4.1

Application Number: 87108111.3

Publication Number: 0249820

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
A cardiac pacer for pacing a human heart

Patentee:
Pacesetter AB

Opponent:
Biotronik Mess- und Therapiegeräte GmbH & Co. Ingenieurbüro Berlin

Headword:
Cardiac Pacer/PACESETTER AB

Relevant legal provisions:
EPC Art. 54(1), (3), (4), 52(4)

Keyword:
"Novelty (yes)"
"Therapeutic treatment (no)"

Decisions cited:
T 0312/94

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0383/95 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 7 July 1999

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 7 March 1995 concerning maintenance of European patent No. 0 249 820 in amended form.**

Composition of the Board:

Chairman: G. Davies
Members: H. K. Wolfrum
U. G. O. Himmler

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the interlocutory decision of the opposition division, dispatched on 7 March 1995, maintaining European patent No. 0 249 820 in amended form. The notice of appeal was received on 27 April 1995, the prescribed fee being paid on the same day. The statement setting out the grounds of appeal was received on 5 July 1995.

The appeal, as well as the opposition, was based on Articles 52(1) and 54(1) and (3) EPC relying on document D1: EP-A-0 222 681 as state of the art with earlier priority for all the designated Contracting States.

Moreover, an objection under Article 52(4) EPC was raised on appeal.

II. Oral proceedings were held on 7 July 1999.

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

The respondent (proprietor of the patent) requested as a main request that the appeal be dismissed and the patent be maintained on the basis of:

claims 1 to 11 as maintained by the Opposition Division, with pages 1, 1a, and 1b of the description filed on 7 June 1994 and column 2, paragraph 2 to column 5, paragraph 3 of the patent specification and the figures as granted.

Alternatively, maintenance of the patent was requested on the basis of three sets of claims and an amended page 1b of the description filed on 7 June 1999 as a first to third auxiliary request, respectively.

III. Independent claim 1 of the main request, which is the only relevant request for the purpose of this decision, reads (without reference numerals) as follows:

"1. A cardiac pacer for pacing a heart dependent on body activity, which pacer comprises means for generating pacing pulses at a predetermined basic pacing rate, means for transmitting the pacing pulses to the heart for pacing, a plurality of body activity sensor means for sensing body activity dependent on different physiological variables and for respectively generating a corresponding body activity output signal dependent thereon, means for varying the predetermined basic pacing rate dependent on the body activity output signals, and means for selecting single activity output signals and/or combinations thereof to determine different exercise stages dependent on different physiological variables, said means for selecting comprise means for successively selecting single activity output signals and/or combinations thereof in predetermined time steps after the start of an exercise cycle, whereby the means for varying the predetermined basic pacing rate varies said rate dependent on the selected body activity output signals or combination of signals."

IV. The appellant essentially relied on the following submissions:

The cardiac pacer disclosed by D1 operated on the use of look-up tables ("Kenn-felder") for processing input signals of sensors for various physiological variables in order to determine therefrom an output signal on which the variation of the pacing rate was dependent. In processing the sensor signals, time was used as a parameter in several respects. The pacer included a CPU and digital circuitry which operated under the control of clock signals, i.e. according to predetermined time steps. The sensor signals themselves were also time dependent. Furthermore, as was evident from Figure 4 and the corresponding description of D1, the processing of the input signals took preprogrammed time constants and/or delay times into account. Such time constants or delay times, however, were nothing else than predetermined time steps. Moreover, as was evident from the specific embodiments of Figures 6a - 6e, time was an essential parameter for the operation of the pacer according to preprogrammed response curves for the sensed physiological parameters. Furthermore, claim 11 of D1 had to be taken into consideration, which in one alternative specified that a switching element for the selection of different sensors for a physiological variable was controlled in a time dependent manner. Therefore, although D1 disclosed the use of predetermined time steps in a more complex manner than was shown by Figure 2 of the patent, its teaching nevertheless met the general definition provided by claim 1 of the main request in that it disclosed for the skilled reader a pacer in which the means for selecting activity output signals comprised means for successively selecting these signals in predetermined time steps after the start of an exercise cycle.

V. The respondent disputed the appellant's view, relying on the following arguments:

The expression "predetermined time steps" used in claim 1 of the main request meant time steps which were "preselected" or "prechosen" time steps, after the lapse of which the selecting means switched from the signal of one physiological variable to that of a different variable on which the variation of the pacing rate was to depend. Examples of such time steps were explicitly given in column 4, lines 10 to 12. Thus, predetermined time steps within the meaning of the patent were not to be confused with clock cycles of a CPU nor with "time constants" or "delay times" disclosed in D1 as being taken into consideration when processing signals from different sensors observing the **same** physiological variable. As regards the selection of signals of different physiological variables on which the pacing rate would depend during an exercise cycle, D1 constantly referred throughout the description to a switching based on the detection of specific values for the heart rate but nowhere indicated that the lapse of time intervals could be used as a suitable parameter for this purpose. As regards the ambiguous teaching given by claim 11 of D1, the indication of a time dependent control had to be interpreted in the light of the content of the description. When properly interpreted, claim 11 referred to the selection of sensors for a single physiological variable, as was described on page 2, second paragraph, and page 5, last paragraph, to page 6, first paragraph, of D1. Therefore the skilled reader had inferred from the reference in claim 11 to a time dependent control that it actually meant the

consideration of time constants or delay times but had never considered it to refer to the control of the switching between **different** physiological variables according to predetermined time steps.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is therefore admissible.

2. *Allowability*

Claim 1 of the main request is a combination of claims 1 and 3 as granted. Thus, the main request does not offend against Articles 123(2) and (3) EPC.

3. The Board is satisfied that the subject-matter of the claims under consideration enjoys the claimed priority of 16 June 1986.

As regards the state of the art, the only document referred to in the appeal procedure is document D1. D1, published on 20 May 1987, refers to a European patent application which enjoys an earlier priority than the patent under consideration and is thus comprised in the state of the art within the meaning of Article 54(3) EPC. Moreover, it designates the same Contracting States as the present patent.

Therefore, the issue to be decided is that of novelty of the claimed subject-matter with respect to the content of D1.

4. As regards claim 1 of the main request, the feature for which novelty is in dispute is the specification of the means for selecting to "comprise means for successively selecting single activity output signals and/or combinations thereof in predetermined time steps after the start of an exercise cycle".

5. This feature is claimed in the context of means for selecting which select activity output signals for the purpose of determining different exercise stages dependent on different physiological variables. The variation of the pacing rate is dependent on the thus selected activity output signal. It is evident from this context that the claimed pacer is equipped with a means which bases the control of the pacing rate successively on different physiological variables, the switching to another variable being made in preselected time intervals. From this it follows that the predetermined time steps at which such switching occurs during an exercise cycle have nothing in common with periodically recurring clock cycles which control the intrinsic operation of the pacer's processor circuitry.

6. In the teaching given by document D1, time is used as a parameter in the operation of the pacer. In the description and figures the use of time constants and delay times is discussed in processing sensor signals. Claim 11 specifies *inter alia* a switching or logical treatment element for the selection of different sensors for a physiological variable, the control of said element being in one alternative dependent on time.

6.1 Time constants and delay times are introduced in the

processing of the sensor signals in order to compensate for effects caused by the fact that for some physiological variables the signals are time dependent (cf. Figures 3 and 4; page 3, line 21 - page 5, line 5 of the description; page 35, lines 3 to 11) or to compensate for malfunctions (cf. page 4, line 27 - page 5, line 8). Reference is specifically made to two sensors for the blood temperature, arranged at different locations of a patient's body (cf. page 5, line 31 - page 6, line 17). The use of time constants and/or delay times is either disclosed in the context of processing signals of sensors measuring the **same** physiological parameter (cf. page 2, lines 12 to 19; page 7, lines 1 to 17) or in the context of processing signals of different time dependency to derive therefrom a combined signal on which the pacing rate is to depend (cf. claim 2; page 32, line 21 - page 33, line 9; page 39, line 15 - page 40, line 23). However, there is no indication given in D1 as to means for selecting which, in the course of physical exercise, would switch under the **control** of time constants or delay times from one processed signal on which the pacing rate is to depend to another (based on a **different** physiological variable or combination of variables).

6.2 As regards the selection of sensor signals relating to **different** physiological variables, it is recognized in D1 that some variables are suitable for short-term control of the pacing rate, whereas others are preferable for long-term control (cf. claim 4; page 1c, lines 14 to 30). However, the switching between these signals is exclusively controlled by a sensed physiological variable (cf. page 1c, lines 5 to 9;

Figures 6a to 6d and the corresponding description). In one specific example, the measured heart rate is used for controlling the selection of which of the physiological variables is to be used for determining the pacing rate (cf. page 1c, lines 14 to 30; Figure 6e with the corresponding description).

6.3 As regards the teaching given by claim 11, it defines as one alternative the control of means for selecting a physiological variable in a time dependent manner ("wobei die Ansteuerung des Schalt- oder Verknüpfungselements ... zeitabhängig erfolgt") . The wording of claim 11 allows for several interpretations. When read in isolation, it could be hypothetically interpreted as relating to a control of selection means in response to predetermined time steps.

However, in order to assess the true meaning of an ambiguous definition, such as the one given by claim 11, its definition has to be construed in the context of the contents of document D1 as a whole (cf. T 56/87 OJ 1990, 188, point 3.1 of the reasons; T 312/94 Case Law of the Boards of Appeal, third edition 1999, page 82).

Claim 11 defines the selection of a plurality of sensors ("Auswahl unterschiedlicher ... Meßwertaufnehmer") for a single physiological variable ("für die ... Meßgröße"). The skilled reader would thus understand claim 11 as referring to the processing of signals measured by a plurality of sensors for the same physiological variable as explained in the description. Therefore he would interpret the indication as to the

possibility of a time dependent control as relating to the time constants and delay times within the meaning as discussed in paragraph 6.1 above, i.e. as to a time dependent control of the processing of signals but not as a time dependent control of the selection between processed signals. In the absence of any indication in the remainder of D1 as to a means for selecting which would switch from one processed signal to another (based on a different physiological variable or combination of variables) in response to the lapse of a predetermined time step, the claim specification has to be construed as not including the aforementioned hypothetical interpretation.

6.4 For these reasons D1 does not disclose a cardiac pacer comprising a means for selecting activity output signals responsive to predetermined time steps as defined in claim 1 of the main request.

7. Having thus identified in claim 1 a device element which is novel over the teaching given by D1 and taking into consideration that claim 1 is directed to a device, the Board does not share the appellant's view that, if at all, the claimed subject-matter would be distinguished from D1 by a specific mode of operating the pacer and thus define a medical treatment excluded from patentability according to Article 52(4) EPC.

8. In summary, the Board is satisfied that the main request complies with the requirements of the EPC and is thus allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Beer G. Davies