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D E C I S I O N
of 24 February 2005

Case Number: T 0530/02 - 3.4.1

Application Number: 89300210.5

Publication Number: 0324598

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
Rate-responsive pacemaker

Patentee:
Webb, Stuart Charles, et al

Opponent:
Biotronik GmbH & Co. KG

Headword:

-

Relevant legal provisions:
EPC Art. 52(1), 56, 100(a)

Keyword:
"Inventive step - no"

Decisions cited:

-

Catchword:

-



Case Number: T 0530/02 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 24 February 2005

Appellant:
(Opponent)

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Representative:

Eisenführ, Speiser & Partner
Patentanwälte Rechtsanwälte
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Respondent:
(Proprietor of the patent)

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Representative:

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Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 27 March 2002
rejecting the opposition filed against European
patent No. 0324598 pursuant to Article 102(2)
EPC.

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appeal was lodged by the opponent (appellant) against the decision of the opposition division, dispatched on 27 March 2002, rejecting the opposition against European patent no 0 324 598. The notice of appeal was received on 17 May 2002, the appeal fee being paid on the same day, and the statement setting out the grounds of appeal was received on 29 July 2002.
- II. Opposition had been filed against the patent as a whole, *inter alia* based on Article 100(a) EPC on the grounds of lack of inventive step.
- III. Oral proceedings were held on 24 February 2005.
- IV. The appellant requested that the decision under appeal be set aside and the patent revoked.
- V. The respondent (patentee) requested that the appeal be dismissed.
- VI. Reference was made *inter alia* to the following document:

E1: EP-A-0 080 348
- VII. Claim 1 of the patent as granted reads as follows:

*"A pacemaker comprising means (3,4) for producing a first signal dependent upon a sensed bodily variable indicative of the level of activity of a user;
means (5) which controls pacing rate in response to a second signal which is related to said first signal by a function;*

means (17) for storing a value indicative of a value of said second signal which represents a target heart rate appropriate to a predetermined level of exercise; and means (16) operable in a programming mode of said pacemaker for automatically varying said function in response to a predetermined exercise routine until the function is such that in response to the predetermined level of exercise it will cause said second signal to assume said target heart rate, and for then setting the value of the function so that in normal operation of the pacemaker said second signal controls the pacing rate to reach the target heart rate in response to said predetermined level of exercise".

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

The subject-matter of claim 1 merely constituted a straightforward automation of the prior art as disclosed in the patent in suit and as provided by document E1 and, therefore, lacked an inventive step. In the prior art programming of the rate responsive pacemaker involved determining a predetermined level of exertion to be performed by the patient and a corresponding target stimulation rate, having the patient performing the predetermined level of exertion and varying the slope of the response function of the pacemaker which relates the sensor signal for body activity to the stimulation rate until the target stimulation rate was obtained. In the prior art establishing the target rate and varying the slope based on a comparison between the actual stimulation rate and the target rate was carried out by the physician. Claim 1 of the patent in suit merely provided for automation thereof by providing means for

storing the target rate in the pacemaker and means for automatically varying the function, including implicitly means for comparing the actual rate with the target rate. This, however, was nothing more than a straightforward automation of the functions otherwise carried out by the physician. As such, the patent merely added an automatic control loop to the known pacemaker control system, which, however, had to be seen as a standard procedure for an engineer.

IX. The respondent argued essentially as follows:

The subject-matter of claim 1 of the patent in suit provided a simple, elegant manner of solving the problems encountered in the programming of the prior art rate-adaptive pacemakers. In document E1 the slope had to be varied in an iterative manner, resulting in a time-consuming and complex procedure. With the claimed pacemaker, programming could take place in a single exercise being advantageous for both the patient and the medical staff. The claimed subject-matter was not a simple automation but could only be arrived at with the benefit of hindsight. Also the successful sales of the pacemaker according to the patent in suit had to be seen as indicative of its inventive merits.

Reasons for the Decision

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

2. *Inventive step*

2.1 The closest prior art is provided by document E1. From this document a rate adaptive pacemaker is known which comprises a force sensor located within the pacer, detecting the forces applied to the pacer by the interaction of the pacer and the patient's body and producing a (first) signal dependent upon a sensed bodily variable indicative of the level of activity of the patient, and means which control the pacing rate in response to a second signal which is related to said first signal by a linear function with a given slope (see figures 3, 4 and corresponding text). The programmable slope circuitry receives the slope parameter through non-invasive programming. This parameter permits the physician to control the interaction of the pacemaker with the patient (see page 7, lines 21 to 36).

There is no indication in document E1 of an automatic variation of the slope parameter or of means for storing a target heart rate, so that novelty of the subject-matter of claim 1 of the patent in suit over document E1 is given. Novelty, as a matter of fact, has not been in dispute.

2.2 As disclosed in the patent in suit (see column 2, lines 20 to 39), the programming procedure of rate adaptive pacemakers such as the one known from document E1 consists of establishing a predetermined level of exertion to be performed by the patient and a corresponding target stimulation rate, requiring the patient to exercise at a predetermined level of exertion and varying the slope of the response function

of the pacemaker until the target stimulation rate is obtained. Establishing the target rate and varying the slope based on a comparison between the actual stimulation rate and the target rate is carried out by the physician.

Claim 1 of the patent in suit provides for means for storing the target rate in the pacemaker, means for automatically varying the response function (eg its slope in case of a linear function) and, implicitly, means for comparing the actual rate with the target rate.

Hence, the functions performed manually by the physician in the prior art are taken over by the pacemaker in the patent in suit and thereby automated. Accordingly, the problem-to-be-solved by the patent in suit may be seen as automating the programming procedure in the prior art pacemaker.

As such, the automation of procedures so far carried out manually must be seen as following a general trend in engineering and, thus, being obvious. This is all the more true where the procedure involves iterative steps, rendering it time consuming, cumbersome and prone to errors when carried out manually, as is the case here.

Furthermore, also the concrete realisation of this automation in the pacemaker as defined in claim 1 is obvious. It is evident, when seeking automation of the above prior art programming sequence, that the target rate must be available in the pacemaker. The provision of suitable storing means in the pacemaker to this end

would constitute a trivial measure. Similarly, the provision of means for automatically varying the function or slope in the pacemaker until the target rate is assumed (including eg a comparator (see patent specification, paragraph [0023]) comparing the actual stimulation rate with the target rate so as to determine when the target rate is assumed), would be obvious, as this is nothing more than the provision of technical means carrying out exactly the same functions performed by the physician in the manual programming sequence.

The respondent sees the commercial success of the pacemaker of the patent in suit as indicative of the inventive merit involved. However, in the board's view, commercial success as the result of meeting a long-felt need in the art for automation of the programming procedure can only support inventiveness if the claimed pacemaker indeed overcomes specific technical difficulties that hindered the prior art from providing such automation. This is, however, not the case in the pacemaker as claimed.

- 2.3 For the reasons above, the subject-matter of claim 1 of the patent as granted does not involve an inventive step (Articles 100(a), 52(1) and 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