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D E C I S I O N
of 16 December 2003

Case Number: T 0483/00 - 3.4.1

Application Number: 89301474.6

Publication Number: 0331309

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
Rate-responsive pacemaker

Patentee:
Webb, Stuart Charles, et al

Opponent:
St. Jude Medical AB

Headword:
-

Relevant legal provisions:
EPC Art. 123(2)(3), 56

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
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Case Number: T 0483/00 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 16 December 2003

Appellants: (Proprietors of the patent)
Webb, Stuart Charles et al
5 Lingholm Way
Barnet
Hertfordshire (GB)

Representative:
Beresford, Keith Denis Lewis
BERESFORD & CO
16 High Holborn
London WC1V 6BX (GB)

Respondent: (Opponent)
St. Jude Medical AB
S-175 84 Järfälla (SE)

Representative:
Harrison, Michael Charles
Albihns GmbH
Grasserstrasse 10
D-80339 München (DE)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 7 March 2000 revoking European patent No. 0331309 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: M. G. L. Rognoni
Members: H. K. Wolfrum
V. Di Cerbo

Summary of Facts and Submissions

I. The appellants (patent proprietors) lodged an appeal against the decision of the opposition division, dispatched on 7 March 2000, revoking European patent No. 0 331 309. The notice of appeal was received on 8 May 2000 and the prescribed fee was paid on the same day. On 17 July 2000 the appellants filed the statement setting out the grounds of appeal.

II. Pursuant to Article 100(a) EPC, the opposition was based *inter alia* on the ground of lack of inventive step (Articles 52(1) and 56 EPC).

III. In a communication of 20 August 2003 annexed to summons to oral proceedings, the Board, *inter alia*, informed the parties that the question of inventive step of the claimed subject-matter, raised by the respondent (opponent) in the course of the appeal proceedings with respect to the combined teachings of documents :

D14: EP-A-0 191 404 and

D1: US-A-4 719 920,

would become one of the issues of debate in the oral proceedings.

IV. Oral proceedings were held on 16 December 2003 at the request of both parties.

In the oral proceedings, the appellants filed a new claim 1 replacing the former version of this claim.

V. The appellants requested that the decision under appeal be set aside and the patent maintained in amended form on the basis of claim 1 filed in the oral proceedings and claims 2 to 16 filed on 17 July 2000.

VI. The respondent requested that the appeal be dismissed.

VII. Independent claim 1 of the main request reads as follows:

"*1. A pacemaker comprising:*

a first sensor means (3) for providing a first signal which changes relatively rapidly in response to changes in a patient's exercise level but may inaccurately represent the pacing rate appropriate to said exercise level and a second sensor (9) for providing a second signal which changes relatively slowly in response to changes in exercise level but, after having changed, relatively accurately represents the required pacing rate; and

control means (5,6) for controlling pacing rate in response to said sensing means, said control means being operative to effect progressive changes in pacing rates so as:

(A) to provide a relatively low pacing rate when said first signal has a value less than a threshold;

(B) to provide a predetermined pacing rate higher than said relatively low rate when the first signal exceeds said threshold and the second signal has a value indicative of a pacing rate less than said predetermined rate; and

(C) to provide a pacing rate substantially equal to that indicated by the value of said second signal when the first signal exceeds said threshold and the second

signal indicates a rate higher than said predetermined rate, regardless of the amount by which said first signal may exceed said threshold."

VIII. The appellants essentially relied on the following submissions:

In the field of pacemakers, a wide range of technical solutions existed to the problem of pacing a patient according to his physiological needs. On this background, the patent provided a particularly simple and elegant solution to a complex problem which, only with hindsight, could be considered as obvious. As regards in particular the prior art according to documents D1 and D14, the skilled person had no incentive to combine the teachings thereof and, even if he did, would not have been led to the claimed invention. D14 concerned a pacemaker comprising an activity sensor which was only used as a switch to turn on control of the pacing rate by a physiological sensor. Since the sole purpose of providing the activity sensor was to save energy in the operation of the pacemaker, the teaching of D14 was directed to the solution of a problem which was different from that addressed by the present patent. Document D1 on the other hand related to a different type of pacemaker using only a single sensor for the control of the pacing rate. In order to devise advantageous control means for a two sensor system, the skilled person would not have considered pacemakers operating with only a single sensor. Moreover, the control means in the pacemaker known from D1 relied on the expiry of time-out intervals for switching to a different mode of operation of the control means. Thus, even if the

skilled person had applied the concept of D1 to the pacemaker known from D14, he would have devised timer driven control means but would not have arrived at control means operating according to features (B) and (C) of claim 1. Thus, the subject-matter of claim 1 involved an inventive step within the meaning of Article 56 EPC.

IX. The respondent's submissions may be summarized as follows:

Document D14 disclosed a pacemaker having two independent sensors, an activity sensor and a sensor of physiological variable. A signal from the activity sensor exceeding a given threshold was considered to be indicative of the onset of physical activity and used to turn on the power supply for the physiological sensor. The signal from the activated physiological sensor was then used for controlling the pacing rate. The skilled person, aware of the fact that there was a delay between the onset of physical exercise and the response of most physiological sensors, would have realised that the known pacemaker could not meet the metabolic needs of the patient immediately after the activation of the physiological sensor. This problem as well as its solution, which consisted in providing a predetermined elevated pacing rate until the physiological signal was truly indicative of the metabolic need of an exercising patient, were known from document D1. Thus, a straightforward combination of the teachings of D14 and D1 would have led the skilled person to the subject-matter of claim 1 on file.

Reasons for the Decision

1. *Amendments*

Present claim 1 has been amended by incorporating the additional features of dependent claim 5 of the patent as granted. Dependent claims 2 to 16 correspond to patent claims 2 to 4, 6, 7, and 11 to 20, respectively.

No objections under Articles 123(2) and 123(3) EPC have been raised by the respondent against the present version of the claims and the Board sees no reason to judge the matter differently.

2. *Inventive step*

2.1 Document D14 (see in particular Figures 4 and 5 with the corresponding description) shows a rate-responsive cardiac pacemaker which comprises sensing means and control means for controlling the pacing rate in response to a first signal provided by an activity sensor and to a second signal generated by a second sensor responsive to a physiological parameter (eg core temperature or respiration rate). When the first signal is below a predetermined threshold, the control means provides a relatively low pacing rate, provided that the heart does not show natural beats at this low rate, and thus operates according to mode (A) defined in claim 1 under consideration. At the same time, the second sensor is inoperative. Using a passive element, such as a piezoelectric element, to detect physical activity, no energy is consumed by the sensors when the patient is at rest. When the patient starts physical

exercise, the first signal eventually exceeds the predetermined threshold. In response, the power supply of the second sensor is turned on and the second sensor becomes operational. The control means then effects progressive changes in the pacing rate as a function of the value of the second signal. Since the pacing rate is independent of the value of the first signal, and consequently of the amount by which the first signal exceeds the threshold, the control means operates as specified under (C) in claim 1 on file.

2.2 Thus, the subject-matter of claim 1 differs from the pacemaker known from D14 in that, following the onset of physical exercise, the control means provides a predetermined pacing rate higher than the relatively low base rate at rest (cf (B) in claim 1).

The introduction of control mode (B) compensates for the delay in the response of a physiological variable to a change in the level of activity and overcomes the problem that the output of a physiological sensor does not reflect the true metabolic need of the patient immediately after the onset of physical exercise.

2.3 However, this problem as well as the claimed solution are known from document D1.

D1 (see in particular Figures 3 and 4 with the corresponding description) discloses a rate-responsive pacemaker comprising control means which rapidly detects the onset of physical exercise and produces a short-term elevation of the pacing rate closely paralleling that of a healthy person. When the patient starts exercising, the central venous blood

temperature T, monitored by the pacemaker's physiological sensor, begins to drop, owing to rapid circulation of initially cooler blood from the extremities to the heart, before a subsequent rise truly reflects the patient's increased metabolic need. If the absolute drop ΔT exceeds a certain minimum and the rate of change of the temperature drop $\Delta T/t$ exceeds a predetermined threshold slope, the control means detects the beginning of exercise and delivers a predetermined higher pacing rate either for a predetermined period of time (Figure 3) or until the sensed temperature corresponds to a rate higher than said predetermined rate (Figure 4). Subsequently, the pacing rate is controlled by the output of the blood temperature sensor. The control means shown in D1 is thus covered by modes (B) and (C) specified in claim 1 on file, although the claimed pacemaker uses a separate sensor for establishing the occurrence of physical activity.

2.4 Setting out from a pacemaker as known from D14, the skilled person would have immediately realised that there was a delay between the onset of physical activity and the delivery of a physiological signal suitable for controlling the pacing rate. Applying the solution offered by D1 to the pacemaker control means of D14 would not have posed any technical problem as no modification to the former would have been required and the teaching of D14 even foresaw the use of core blood temperature as the physiological variable. Therefore, no exercise of inventive skill would have been required for the skilled person to devise for the pacemaker of D14 control means which progressively changed the pacing rate according to modes (A), (B) and (C). In

doing so, the skilled person would have arrived at the subject-matter of claim 1 on file.

2.5 The appellants' argument that the skilled person would not have combined the teachings of D1 and D14 because these documents related to different types of pacemakers, D1 relying on the signal of a single sensor and D14 using signals of two independent sensors for the control of the pacing rate, is not convincing. Firstly, both documents relate to the same narrow technical field of rate-adaptive pacemakers and, secondly, the manner of operating the control means in the modes (A), (B) and (C) is independent of the physical nature of the sensor signals. The latter fact is even acknowledged in the patent specification which states in column 5, lines 52-57: "*It must be emphasised that Sensor 1 can in practice be any sensor that provides an immediate response to a change in the level of physical exertion being performed by the user whereas Sensor 2 can be any sensor that accurately determines the magnitude of this change.*"

The further submission that, even when combining the teachings of D1 and D14, the skilled person would not have devised the particularly simple control means defined in claim 1 but would have arrived at a more complex solution based on timers, can also not be accepted. Though based on the embodiment of Figure 3 of D1, the argument fails to acknowledge that the operation of the control means according to the embodiment of Figure 4 of D1 falls under the definitions of modes (B) and (C) (see point 2.3 above).

3. For these reasons, the claim 1 on file does not comply with the requirements of Articles 52(1) and 56 EPC.

4. In summary, having regard to the patent documents according to the appellants' sole request, the ground of lack of inventive step set out in Article 100(a) EPC prejudices the maintenance of the European patent.

Order

For these reasons it is decided that :

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher M. Rognoni