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D E C I S I O N
of 18 May 1994

Case Number: T 0448/92 - 3.4.1

Application Number: 83302535.6

Publication Number: 0096464

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Language of the proceedings: EN

Title of invention:
Exercise responsive cardiac pacemaker

Patentee:
PURDUE RESEARCH FOUNDATION

Opponent:
BIOTRONIK Mess- und Therapiegeräte GmbH & Co Ingenieurbüro Berlin

Headword:
-

Relevant legal norms:
EPC Art. 56

Keyword:
"Inventive step (no)"

Decisions cited:
-

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Case Number: T 0448/92 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 18 May 1994

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office dated 18 March 1992 concerning maintenance of European patent No. 0 096 464 in amended form.**

Composition of the Board:

Chairman: G.D. Paterson
Members: Y.J.F. van Henden
R.K. Shukla

Summary of Facts and Submissions

I. European patent No. 0 096 464 as granted contains five claims.

Independent Claim 1 of this patent reads:

"1. A cardiac pacemaker including means for variably controlling the stimulation rate of the heart according to the level of muscular exertion in the body, comprising:

a sensor means for sensing a blood temperature;

a stimulus means for applying an electrical stimulus to a heart;

a control circuit means for calculating dT/dt of said sensed blood temperature, said control circuit means including means for generating a rate control signal according to a predetermined algorithm relating heart rate to dT/dt; and

a pulse generator connected to said stimulus means and responsive to said rate control signal to variably control the stimulation rate of the heart."

II. The European patent was opposed by Biotronik and by Intermedics Inc. (Freeport, Texas, 7751 US) on the grounds mentioned in Article 100(a) EPC, referring, in particular, to the state of the art that can be derived from documents

D1: DE-A-2 609 365, and

D3: G. Csapo et al.: "Autoregulation of pacemaker rate by blood temperature", VIII World Congress of Cardiology in Tokyo, 17-23 September 1978.

The Opponent Intermedics Inc. withdrew its opposition during the proceedings before the Opposition Division.

III. At the end of oral proceedings held on 24 June 1991, the Opposition Division announced its decision that the European patent was maintained in amended form on the basis of Claims 1 to 3 and 5 as granted, and a new Claim 4 submitted by telecopy of 13 June 1991.

IV. The Opponent Biotronik and the Proprietor of the patent lodged separate appeals against the decision.

V. In a communication pursuant to Article 11(2) RPBA, the Board expressed the provisional opinion that none of the independent claims submitted by the Proprietor to form the basis of its requests seemed to involve an inventive step.

VI. Oral proceedings were held on 18 May 1994.

VII. The patent Proprietor requested that the European patent be maintained as granted and, subsidiarily, that it be maintained in the form accepted by the Opposition Division.

In support of its requests, the Proprietor argued in substance as follows:

In the field of regulation, the term "sign (dT/dt)" is not interpreted as a "plus" or a "minus" for, in most cases, this would lead to destabilisations. In fact, said term is interpreted in a binary context, i.e. as meaning one or zero according as the derivative (dT/dt) is positive or negative. The formula mentioned in column 6 of the European patent thus provides two different values of the heart's rate for each value of the blood's temperature in the right ventricle. Contrary thereto, document (D3) teaches varying the heart's rate in direct and fixed dependence upon blood temperature. A pacemaker embodying such teaching thus does not

distinguish between variations in temperature caused by exercise - in which case an initial temperature decrease is observed - and other causes. Therefore, such a pacemaker does not use an algorithm which represents the mathematical function relating blood temperature and rate of a normally functioning heart. Likewise, the paragraph bridging pages 5 and 6 of document (D1) does not suggest that (dT/dt) should be taken into account. The skilled person can indeed infer therefrom that, if the blood temperature rises from 37°C to 39°C, the pacing frequency has to increase from 70 to at most 110 beats/min, and that the change in heart rate per °C is smaller at higher temperatures, as actually illustrated by the S-curve of (D3). Claim 1, therefore, involves an inventive step.

Besides, Claim 4 too involves an inventive step. It states indeed that means are provided for "variably controlling the stimulation rate according to muscular exertion in the body" and for "implementing the output signal of the temperature sensing means by an algorithm which represents the mathematical function between blood temperature and the rate of a normally functioning heart".

VIII. The Opponent requested the revocation of the patent in suit. Its argumentation may be summarised as follows:

The mention of an algorithm in Claim 1 does not reveal more than the existence of some mathematical relationship between the derivative (dT/dt) and the heart's rate. Such a relationship, however, might be defined by any function, including such in which (dT/dt) is not the only parameter playing a part, as actually exemplified by the formula given in the European patent. As a matter of fact, the latter formula does not differentiate between exercise, fever and other causes

altering the blood's temperature, for instance taking a hot or a cold bath. Therefore, nothing can be inferred with certitude as regards eventual advantages provided by the claimed pacemaker. Besides, when a patient starts taking exercise, the heart has to react immediately, as revealed by (D3), without waiting until any increase of the blood's temperature is detected in the right ventricle. Finally, previously determined values of the temperature might get lost in case of interruption of the detection.

Claim 1 thus fails to set the conditions to be met in order to achieve with sufficient probability the desired effect. Furthermore, with regard to the disclosure in (D3), no inventive step can be perceived there. It is indeed obvious that, when a subject starts or ceases exerting physical effort, the temperature (T) of his blood varies more slowly than his heart beat's frequency or the rate at which his heart should be stimulated if it does not work normally. Consequently, it is equally obvious that, in order to correctly determine the stimulation rate to be achieved, the derivative (dT/dt) too should be taken into consideration.

IX. At the end of the oral proceedings, the decision was announced that the decision under appeal is set aside and that European patent No. 0 096 464 is revoked.

Reasons for the Decision

1. *State of the art*

1.1 Document (D1) pertains to a cardiac pacemaker and addresses the problem of variably controlling the stimulation rate of the heart according to the level of muscular exertion in the body - see the third page of

the description, first four lines of the last paragraph. In order to achieve this purpose, a cardiac pacemaker embodying the invention disclosed in (D1) comprises:

(a) a sensor means (6) for sensing the blood temperature in one of the heart's chambers - see the fifth page of the description, lines 10 to 12;

(b) a stimulus means, namely the stimulation electrodes (3a) and (3b), for applying an electrical stimulus to the heart - see the fifth page of the description, lines 5 to 10;

(c) a control circuit means including means (11,12) for generating a rate control signal according to a predetermined relation between heart rate and blood temperature - see the seventh page of the description, third paragraph, and note that the electrical characteristics of the components (6, 11, 12, ...) determine the relationship between blood temperature and pacing frequency - and

(d) a pulse generator (2) connected to said stimulus means and responsive to said rate control signal to variably control the stimulation rate of the heart - see the fifth page of the description, lines 5 to 10.

1.2 In the field of electronic data processing, an algorithm is a set of steps to be taken in an operation to effect a desired calculation. In mathematics, it is usually understood as a mathematical rule which, when applied repeatedly, will produce a result whose degree of accuracy will accord with the number of applications. It is nonetheless clear that any iterative calculation includes steps to be successively taken.

No calculation step being taken according to the teachings of document (D1), the subject-matter of Claim 1 of the European patent is distinguished over the prior art pacemaker described there in that

- the control circuit means calculates the time derivative (dT/dt) of the sensed blood's temperature;

- the rate control signal is generated according to a predetermined algorithm relating the heart's rate to (dT/dt), and in that

- the means for generating the rate control signal is included in the control circuit means.

The parties did not raise any objection concerning these findings.

1.3 Document (D3) addresses the regulation of pacemakers rate during exercise. It reveals that, in addition to changes in blood pH or in breathing, a further biological parameter for adapting the ventricular pacemaker's rate to the actual hemodynamic needs can be elaborated on the basis of changes of the central blood's temperature.

2. *Inventive step*

2.1 Taking the steps of an algorithm requires the provision of computational means, for instance a microprocessor. This appears to be actually the cases in the embodiment of the claimed invention described in the European patent. It is indeed stated there that the algorithm implementing means (15) can be programmed - see the sentence bridging columns 6 and 7. It is, however, widely known that, since the end of the seventies,

microprocessors have been increasingly used in all technical fields. Furthermore, pacemakers can no longer dispense with them because of the increasing complexity of the programs to be carried out in order to determine whether and when stimulation pulses will be delivered. Providing a microprocessor chip in a cardiac pacemaker, whereby the rate control signal is necessarily generated by means integral with the control circuit means, can thus not be credited with an inventive step.

2.2 When a cardiac patient carrying a pacemaker is taking physical exercise, a correction of said pacemaker's stimulation rate based on the measure of at least one physiological parameter cannot have any influence on the patient's performance. Therefore, no feedback is possible, so that the regulation loop is necessarily open.

In servo systems working with an open regulation loop, however, it is generally known to improve the correction of a variable to be regulated by anticipating the variations of the measurable parameter(s) to which said variable is related. To this purpose, the time derivative(s) of the measurable parameter(s) is(are) determined and taken into account to refine the correction. An example of this procedure is the well known "proportional-differential regulation" and, since he is a qualified electronics engineer, a person skilled in the design of cardiac pacers may not ignore its principle.

Furthermore, during the development of medical devices, it is common practice to submit them to extensive testing. Therefore, it is beyond doubt that, while testing pacemakers working only on the basis of the variation in the blood's temperature, the stimulation rate's adaptation would lag behind the variation in

blood temperature, and this would not escape the attention of the skilled person. As a matter of fact, this is confirmed by the test results reported on pages 2 and 3 of document (D3).

In view of the above, to the designer of pacemakers starting from the state of the art disclosed in document (D1) and envisaging to modify the cardiac pacer described there so as to base the regulation of the stimulation rate on a measure of the blood's temperature, it was evident to take into account not only the difference between the actual and reference values of this temperature, but also the time derivative of said difference, i.e. the time derivative (dT/dt) of the blood's temperature. This, however, leads him quite naturally to provide control circuit means adapted to calculate the derivative (dT/dt) of the sensed blood's temperature, as well as to generate the rate control signal of the pacemaker according to a suitable predetermined algorithm relating the heart's rate to said derivative (dT/dt). Thereby, no exercise of inventive ingenuity is required, and two values of the stimulation rate are related to each value of the blood's temperature.

2.3 To invalidate the above argumentation, the Proprietor argued that, when a patient starts taking physical exercise, his central blood's temperature initially decreases and afterwards increases. No such evolution of the blood's temperature being observed in other cases, the claimed pacemaker would thus be able to distinguish between increases of said temperature respectively caused by exercise and other causes, for instance fever. Likewise, as pointed out during the oral proceedings of 18 May 1994, it would also be able to distinguish between initial decreases of the blood's temperature respectively caused by physical exercise and by a cold

bath. In the latter case, no subsequent increase of the temperature takes indeed place. Nevertheless, the Proprietor did not claim the merit of having discovered the initial decrease of the blood's temperature of a patient taking physical exercise.

It is, however, known that a patient taking a cold bath shivers, that shivering is a muscular activity entailing a considerable consumption of energy, and that it is the more intense as the water is colder. An acceleration of the blood's circulations is consequently required in order to deliver more sugar to the muscles, and to maintain the temperature of the body's superficial regions at an acceptable level. Furthermore, it is also known and obvious that the colder the water is, the steeper the blood's central temperature decreases. Therefore, under the same circumstances, the cardiac reaction must also be the more marked. It is thus clear to the designer of pacemakers that, anytime a decrease of the blood's temperature **beneath its normal value** is detected, the pacing rate has to be increased, and the more so as the temperature's decrease is the more rapid. This, however, hints at taking the time derivative (dT/dt) into account.

2.4 In various submissions, the Proprietor also referred to the rate of a normally functioning heart. Cardiac pacers being provided to deliver stimulation pulses at a rate approaching that of a normally functioning heart, such a feature could not be considered as evidence of an inventive step and, anyway, is not mentioned in Claim 1. Finally, the formula given at the top of column 6 in the European patent specification may not be considered as entailing any limitation of the claimed protection. Moreover, in the wording of the claim, the algorithm relating heart rate to (dT/dt) is not specified, so that, in the Board's view, it is not clear that the

pacemaker will in fact distinguish between the temperature variations caused by exercise and other causes, respectively.

2.5 For these reasons, in the Board's judgment, Claim 1 as granted lacks an inventive step and is consequently not allowable - Article 52(1) EPC in conjunction with Article 56.

3. A condition for the maintenance of a European patent in opposition being that at least one request of the Proprietor be based on a set of claims which are all allowable, none of the second Appellant's requests, therefore, is allowable.

Under this circumstance, it is not necessary for the Board to examine whether Claim 4 according to any of said requests is allowable.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. European patent No. 0 096 464 is revoked.

The Registrar: The Chairman:

M. Beer G.D. Paterson