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D E C I S I O N
of 29 November 1996

Case Number: T 0967/93 - 3.4.1

Application Number: 86906215.8

Publication Number: 0244446

IPC: A61N1/36

Language of the proceedings: EN

Title of invention:
Myocardial contractility-sensitive pacer

Patentee:
THOMAS JEFFERSON UNIVERSITY

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

Headword:
Rate-adaptive pacer/THOMAS JEFFERSON UNIVERSITY

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step - affirmed"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0967/93 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 29 November 1996

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office dated 1 September 1993 rejecting the opposition filed against European patent No. 0 244 446 pursuant to Article 102(2) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. European patent No. 0 244 446 was opposed on the grounds under Article 100(a) EPC, that the subject-matter of the patent was not new and did not involve an inventive step having regard to the prior art documents:

D1: EP-A-0 178 528 and
D2: US-A-4 052 991,

document D1 being comprised in the state of the art according to Article 54(3) and (4) EPC and therefore only relevant to novelty.

The Opposition Division rejected the opposition in accordance with Article 102(2) EPC.

II. The only independent claim of the patent has the following wording:

"1. A rate adaptive pacemaker system including pulse means for generating pacing pulses, timing means (56, 60, 62) for generating timing signals controlling the time and rate of said pacing pulses, and connected to deliver said timing signals to said pulse means so as to control the rate of generated pacing pulses,

a lead (25) for delivering said pacing pulses to the heart of said patient, said lead (25) being connected to said pulse means and having

electrode means (32, 33) for delivering said pacing pulses to said patient heart,

said lead means also having a sensor (26) for sensing patient heart beats and for generating heart signals representative thereof,

a pressure sensor positioned on the lead (25) for implantation in the myocardium to sense myocardial pressure and generate a signal representative thereof, and

signal processing means (51) connected to said lead to receive said intramyocardial pressure signals and for processing same,

and a controller (56) connected to said signal processing means (51) to receive the processed intra-myocardial pressure signal and having

an output connected to said timing means for controlling the rate of generation of pacing pulses in accordance with sensed intramyocardial pressure, characterized in that the controller is constructed to respond to control the pulsing rate in proportion to a combination of the peak value of intramyocardial pressure and the peak rate of change of intramyocardial pressure during contraction such that it derives from the measured intramyocardial pressure an indication of myocardial contractility and controls the rate of generation of pulses in accordance therewith."

III. The Opponent lodged an appeal against the above decision and requested that the patent be revoked in its entirety, since the claimed subject-matter did not involve an inventive step with regard to document D2 and the following document cited in the grounds of appeal:

D3: US-A-4 543 954

The Respondent (Patent Proprietor) requested the dismissal of the appeal.

IV. In a letter dated 4 November 1996, the patent Proprietor informed the Office that the patent Proprietor will not be represented at the oral proceedings scheduled on 29 November 1996 and that the request for the dismissal of the appeal was maintained on the basis of the written submissions made in the appeal proceedings. Consequently, the oral proceedings took place in the absence of the patent Proprietor.

V. The Appellant presented essentially the following arguments in support of its request.

Claim 1 of the patent under dispute does not specify any precise relationship between the pacing rate on the one hand and a combination of peak value of the intramyocardial pressure (IMP) and peak rate of change of the intramyocardial pressure on the other hand. Also, it is not clear from the description of the invention how the peak value and the peak rate of change of the IMP are used to determine the pacing rate.

Document D2 discloses a rate adaptive pacemaker system with an intramyocardial pressure sensor (see figures 19 to 21). The subject-matter of claim 1 of the patent differs from the pacemaker system disclosed in document D2 only by some vague relationship between the pacing rate and a combination of the peak value and the peak rate of change of IMP. A skilled person however knows that the peak value and the peak rate of change are the most important parameters to use in any control system. Also, in a rate adaptive pacemaker, physiological considerations require that the pacing rate is adapted to peak value, and not the minimum value, of the myocardial pressure.

In the circuit shown in Figure 2 in document D2, it is evident that the sensed cardiac signals including intramyocardial pressure are applied to a circuit part B having a filter 5 and a trigger 6. Since the trigger 6 responds to a threshold value of the sensed signal, it follows that the circuit B provides an output in response to a peak value of the IMP. Similarly, the filter 5 which allows a certain band of frequencies to pass through can be regarded as providing IMP output signals which vary with time at rates exceeding a certain value. It would be thus evident to the skilled person that the circuit of Figure 2 senses the peak value and the peak rate of change of IMP. Since the claimed subject-matter does not specify any precise relationship between the pacing rate and IMP, its subject-matter must be seen as obvious to the skilled person.

Moreover, document D3 discloses a rate adaptive pacemaker where the rate is determined in relation to the blood temperature. The algorithm used (see column 6) takes the temperature and the rate of change of temperature into consideration. It would therefore be obvious to use a similar algorithm for determining the pacing rate in response to pressure in the rate adaptive pacemaker system of document D2. Furthermore, since the intramyocardial pressure (IMP) changes during a heart cycle, it is evident that this pressure should be detected at some fixed reference point in each cycle. The most obvious choice - and probably the easiest one - would be to measure the peak value and the peak rate of change. Thus having regard to the disclosure in documents D2 and D3, the claimed subject-matter was obvious for the skilled person.

VI. The patent Proprietor presented essentially the following arguments.

The invention is based on the idea that the myocardial contractility can be used as an indication of the needed pacing rate. Myocardial contractility is not the same as intramyocardial pressure. However, the inventor has found that by using the peak of the intramyocardial pressure and the peak rate of change of the intramyocardial pressure a relevant indication of myocardial contractility and thereby of the desired pacing rate can be obtained.

Document D2 is concerned only with long term change in pressure (column 28, lines 1-8) which may be detected only after several hours, and does not therefore give any hint towards the claimed invention. Document D3 is concerned with controlling pacing rate in relation to the blood temperature. The use of blood temperature to control pacing rate is vastly different from utilizing the intramyocardial pressure, in particular since the blood temperature is known to be practically constant during a heart cycle. Therefore, there is no reason to utilise an algorithm based on blood temperature in a pacer responsive to intramyocardial pressure. Furthermore, even if the algorithm of document D3 were to be used in connection with the pacemaker described in document D2, the skilled person would not be led to the invention as claimed, because none of the documents use the peak value of the rate of change.

VII. At the conclusion of the oral proceedings, it was announced that the appeal is dismissed.

Reasons for the Decision

1. *Inventive step*

1.1 The only issue to be decided in the present appeal is that of inventive step.

The patent in suit relates to a rate-adaptive pacemaker system for controlling cardiac pacing rate in response to exercise or emotional occurrences (see the patent, column 1, lines 42 to 45), and is based on the recognition that an indication of myocardial contractility can be obtained by measuring the stress in the cardiac muscle (IMP) and the rate of change of IMP, and that the sensed IMP characteristics can be used to vary the pacing rate. In the rate-adaptive pacer as claimed in claim 1 of the patent in suit, therefore, a controller is provided which is constructed to respond to control the pulsing rate in proportion to a combination of the peak value of IMP and the peak rate of change of IMP during contraction.

1.2 Document D2 relates to a demand pacemaker, i.e. a pacemaker system which supplies a stimulation pulse in the absence of a spontaneous heart beat signal, which takes into account whether the spontaneous signals are dangerous or not by having a variable waiting period before the pacer signals are delivered and by temporarily increasing the stimulation frequency (see the abstract and column 1, lines 33 to 50 and column 2, lines 33 to 50).

In the pacing system described in document D2, the stimulation frequency can thus be temporarily changed depending on the detection of certain spontaneous signals. However, there is no indication in this document that the frequency is changed in response to exercise or perceived stress.

Figures 19 to 21 and the corresponding description in document D2 disclose a sensor for sensing the intramyocardial pressure, and it is explained that the waiting period can be modified in response to the sensed intramyocardial pressure (column 27, lines 62 to 68). However, there is no clear explanation of how the waiting period is changed in response to the measured pressure. More importantly, it is explained in column 28, lines 1 to 8, that by intramyocardial pressure is meant **not the abrupt variations resulting from cardiac systole**, but on the contrary, the variation of the **average base pressure, measured** for example **during the rest of the cardiac muscle**. This variation, when it occurs, is very slow, and may be detected only after several hours in certain cases. It is evident from the cited text that the pacemaker of document D2 does not measure intramyocardial pressure during the cardiac systole as in the present invention, but measures it when the cardiac muscle is at rest. The pacemaker of document D2 cannot therefore be regarded as a rate adaptive pacemaker which responds to exercise or perceived stress and it also does not adapt the pacing rate by taking into consideration intramyocardial pressure characteristics as in the present invention.

1.3 Document D3 describes a rate-adaptive pacemaker responsive to exercise (see the abstract), wherein the venous blood temperature in the right ventricle is used to control the pacing rate of the pacemaker. In the

document the heart rate is expressed as a function of venous blood temperature and rate of variation of blood temperature for test dogs (column 6, lines 13 to 35). Document D3 also describes in column 3 to 4 that several parameters, such as ambient body temperature, respiratory rate, blood pressure and oxygen saturation of the blood, have been used in the prior art to control the pacing rate of an exercise responsive pacemaker. However, there is no indication in the cited prior art that the intramyocardial pressure can be used to control the pacing rate in an exercise responsive pacing system.

1.4 According to the Appellant, having regard to the relationship between the heart rate and blood temperature disclosed in D3, it is obvious to use a similar relationship between the heart rate and intramyocardial pressure in the pacemaker of document D2.

The Board does not accept this submission. Firstly, as explained above, document D2 does not concern a pacemaker in which the pacing rate is controlled in response to exercise taking into consideration intramyocardial pressure during the contraction of the heart. Secondly, whereas blood temperature increases gradually and linearly over the period of exercise (see Figures 2 and 3 in document D3), there is no evidence before the Board showing a similar behaviour of the intramyocardial pressure during the loading of the heart, so that there was no reason for the skilled person to utilise the relationship of document D3 in case of intramyocardial pressure.

Thus, document D2 or D3 taken alone or in combination do not render obvious the provision of a controller in the pacemaker system of document D2, which is constructed to control the pacing rate as set out in claim 1 under consideration.

1.5 For the above reasons, in the Board's judgment, the subject-matter of claim 1 of the patent would not be obvious to the skilled person in view of the cited prior art. Claim 1 therefore involves an inventive step as required by Article 52(1) EPC. The remaining claims being dependent claims also fulfil the requirement of inventive step.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar: The Chairman:

M. Beer G. D. Paterson