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D E C I S I O N
of 20 February 2003

Case Number: T 0392/99 - 3.4.1

Application Number: 93110579.5

Publication Number: 0582087

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:

Minute volume rate-responsive pacemaker

Patentee:

Pacesetter, Inc.

Opponent:

Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro
Berlin

Headword:

Minute volume rate-responsive pacemaker/PACESETTER, INC.

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 0392/99 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 20 February 2003

Appellant: Biotronik Mess- und Therapiegeräte GmbH &
(Opponent) Co Ingenieurbüro Berlin
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D-12359 Berlin (DE)

Representative: Eisenführ, Speiser & Partner
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Respondent: Pacesetter, Inc.
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 9 February 1999
rejecting the opposition filed against European
patent No. 0 582 087 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: G. Assi
Members: H. K. Wolfrum
C. Holtz

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 9 February 1999, rejecting the opposition against European patent No. 0 582 087. The notice of appeal was received on 13 April 1999 and the appeal fee was paid on the same day. On 18 June 1999, a statement of grounds of appeal was filed.
- II. The opposition was based, *inter alia*, on the ground of lack of inventive step (Articles 56 and 100(a) EPC).
- III. The appellant requested that the contested decision be set aside and that the European patent be revoked.

In the appeal proceedings, reference was made to the following documents:

E1: US-A-4 702 253,

E5: US-A-4 708 144, and

E6: US-A-4 223 681.

Documents E5 and E6 were cited for the first time in the statement of grounds of appeal. The respondent (patentee) did not object to their introduction into the proceedings.

- IV. The respondent requested that the appeal be dismissed.
- V. Oral proceedings were held on 20 February 2003.

VI. Independent claim 1 of the granted patent reads as follows:

"1. A rate-responsive pacemaker comprising pulse generating means (19); means (10,12) for coupling said pulse generating means to a patient's heart; means (28) for monitoring a rate control parameter ["RCP"]; means (50,52) for deriving short-term and long-term values of said RCP; and means (54) for deriving the difference between said short-term and long-term RCP values and for adjusting the rate of said pulse generating means in accordance therewith; characterised by means (60) responsive to said difference exceeding a threshold value for inhibiting changes in said long-term RCP value."

Claims 2 to 7 of the patent as granted are dependent claims.

VII. The appellant essentially relied on the following submissions:

The subject-matter of claim 1 was rendered obvious by the combined teachings of documents E1 and E5 or E1 and E6.

A pacemaker according to the preamble of claim 1 was known from E1. In the known pacemaker as well as in the patent in suit, the long-term RCP value, which was formed as an average of a considerable number of measured short-term RCP values, served to establish a correspondence to the minimum pacing rate and was used as a reference against which instantaneous short-term RCP values were compared when changing the pacing rate according to metabolic demands. The long-term RCP value

was constantly updated so as to accommodate the system to long-term variations in the measurement system of the RCP on the assumption that these variations were not due to changes in metabolic demand. From this assumption it would have been immediately clear that changes of the long-term RCP value should not be influenced by measured short-term RCP values which were determined by changes of the metabolic demand. Hence, the skilled person, wishing to safeguard that the long-term RCP value remained a suitable reference for changes of the pacing rate according to metabolic demands even during extended periods of exercise, was led by E1 towards the claimed solution, in that it would have been immediately apparent to him that short-term RCP values which were due to changes in the metabolic demand had to be suppressed from the averaging when forming the long-term RCP value, as otherwise the assumption on which the teaching of E1 was based would no longer be valid. The only task remaining was to find a suitable criterion to distinguish short-term RCP values which were due to changes in the metabolic demand from those which reflected permanent or semi-permanent changes in the measurement system.

In this respect, the skilled person would have found a suitable example in the teaching of document E5 or that of E6. E5 related to the same technical field of pacemakers and addressed a similar aspect of deriving from sample measurements a long-term value of a parameter which was to be used for reference purposes in the context of controlling the operation of the pacemaker. In this respect, E5 taught the general principle to use a threshold condition for discriminating unsuitable measurement values in the

determination of the long-term average value. A similar teaching was given by document E6.

This general principle was readily applicable to the situation faced in a pacemaker according to document E1, where the effects of variations in the measurement system on the short-term RCP value were much smaller than those of changes in the metabolic demand, and would have led the skilled person to discard short-term RCP values differing significantly from the long-term RCP value by implementing the threshold condition defined in the characterising clause of claim 1. Even if other solutions would have been theoretically conceivable, the claimed solution was the most obvious alternative to safeguard that the long-term RCP value remained a suitable reference for determining the pacing rate required by the metabolic demand.

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

The prior art cited by the appellant did not render the present invention obvious. Neither E1 nor E5 addressed the problem of a decreasing pacing rate during lengthy periods of physical exercise occurring in rate-responsive pacemakers using a continually updated long-term RCP reference value. Nor did any of these documents hint at the claimed solution.

The appellant's interpretation of the teaching of E1 was based on hindsight since E1 did not disclose to discard short-term RCP values when determining the long-term RCP reference and thus to freeze the latter during extended periods of stress or exercise.

Moreover, the teaching of document E5 was not pertinent for the present invention since it related to a completely different situation. E5 was not concerned with the control of a pacing rate but with the effects of noise when controlling the sensitivity of measurements of the activity of the heart. Instead of addressing changes of a long-term reference value during extended periods of physical exercise, it taught that the time for averaging in order to obtain the long-term reference value could be shortened by suppressing noisy signals. Even the threshold condition used for establishing the presence of noise was different from the claimed condition in that it was based on an absolute measurement value, whereas, according to the patent, the threshold condition concerned a relative value, ie the difference between the short-term and long-term RCP values. Document E6 was even less relevant as it did not relate to a pacemaker.

Far from being obvious, the claimed solution was based on the recognition, resulting from extensive clinical testing, of the fact that extraneous factors caused much smaller changes of the short-term RCP value than metabolic demand. Instead of arriving at the invention, the skilled person would have had various alternatives to overcome the problem of an unsuitable long-term RCP value during lengthy periods of exercise. For instance, he could have resorted to a further parameter value obtained by an independent measurement, such as the use of an accelerometer, in order to establish a condition of long-term exercise and determine a suitable reference for the adjustment of the pacing rate in such circumstances.

Reasons for the Decision

1. The sole issue discussed in the appeal proceedings concerns the matter of inventive step.
2. *Subject-matter of independent claim 1 of the patent as granted*
 - 2.1 The invention as defined in claim 1 refers to a rate-responsive pacemaker which comprises means for adjusting the pacing rate to the metabolic needs of a patient, which needs are different for periods of rest and periods of exercise or stress. In order to determine the required pacing rate, a physical or physiological parameter (the rate control parameter RCP) is measured, which is indicative of the metabolic demand. Since extraneous factors may influence the measurement system of the pacemaker so that measured RCP values would change even when there is no change in the metabolic demand, a long-term RCP value is determined by averaging so as to reflect any such factors and act as reference against which instantaneously measured values (the short-term RCP values) are compared. By using the difference between the short-term and long-term RCP values for adjusting the rate of pacing pulses, undesired influences on the measurement system are eliminated.
 - 2.2 However, in periods of sustained exercise, the long-term RCP value, being a continuously updated average over a number of short-term RCP values, eventually keeps up with the increased short-term RCP value so that the difference between the two values drops and so does the pacing rate, although metabolic demand would still require a higher rate (see column 2, lines 4 to

17 of the patent description).

In order to overcome this problem, the patent in suit foresees means to inhibit changes in the long-term RCP value so that when the difference between the short-term and long-term RCP values exceeds a certain threshold value the long-term RCP value is frozen, ie will not change. This solution is based on the recognition that the extraneous factors on the measurement system lead to difference values which are smaller than those due to changes in the metabolic demand (see column 4, lines 13 to 19 of the patent description).

3. *Closest prior art*

There is agreement between the parties that document E1 (see Figures 1, 2, 4 and 5 with the corresponding description) constitutes the closest prior art. It discloses a pacemaker showing the features comprised in the preamble of claim 1 under consideration. Measured short-term and long-term RCP values serve the same purposes as indicated in point 2.1 above for the patent in suit (see column 3, lines 3 to 52; column 9, lines 9 to 16; and column 10, lines 16 to 30). Moreover, as in the specific embodiment of the patent in suit, the parameter chosen in the pacemaker according to E1 is the so-called "minute volume", which is a measure of the amount of air breathed in by a patient as a function of time. The long-term value of the minute volume is obtained by averaging over a large number of measured short-term values. From the observation "*It should be borne in mind that the reason for deriving a long-term average value is in order to accommodate the system to long-term variations which may arise due to*

changes in body chemistry, re-positioning of electrodes, etc., that is, factors which would otherwise cause a permanent change in the standby rate even when there is no cause for it. Consider for example a long-term minute volume average value measurement which slowly increases not because of changes in metabolic demand, but rather because of electrode re-positioning." given in column 9, line 66, to column 10, line 8, it is evident that the long-term value is determined and used on the assumption that its variations essentially reflect extraneous factors on the measurement of the minute volume.

4. The subject-matter of claim 1 under consideration differs from the pacemaker known from E1 by the additional provision of the aforementioned means to inhibit changes in the long-term RCP value when the difference between the short-term and long-term RCP values exceeds a certain threshold value. Thus, in the operation of the pacemaker according to the invention, a reduction of the pacing rate during lengthy periods of stress or exercise is prevented.

5. As regards the problem as such, although not addressed by the teaching of E1, it can be assumed, by controlling the operation of the known pacemaker, that the skilled person would eventually detect an undesired drop of the pacing rate during periods of sustained exercise. Moreover, it would appear that straightforward contemplations would even have allowed the skilled person to identify the cause of the problem, ie that the undesirable drop of the pacing rate was due to a decreasing difference between the short-term and long-term RCP values.

However, for the following reasons, the claimed solution would not have been rendered obvious by the cited prior art.

- 6. Document E1 does not teach or hint at the claimed solution.
- 6.1 As a matter of fact, its teaching is silent as to what would or should happen if over an extended period of strong physical exercise with a correspondingly long succession of relatively high short-term RCP values, the long-term RCP value would significantly increase as well, resulting in an undesired decrease of the pacing rate.
- 6.2 According to the specific embodiment shown in E1 (see Figure 5), the long-term value of the minute volume is formed in a two-stage averaging process from short-term values, each corresponding to a sample of the minute volume measured in a 20-second interval. In the first stage, a running average over the 32 most recent 20-second samples is determined as an intermediate average value, and in the second stage, a running average is formed over 32 consecutive intermediate average values obtained in the first stage so that the long-term RCP value is an average over 1024 (ie 32 x 32) 20-second short-term samples and is only periodically updated in intervals of 32 x 20 seconds. It follows that, in case of an increase in the short-term minute volume due to metabolic demand, the long-term value remains unchanged for the first 10 minutes and 40 seconds. Even after 40 minutes of exercise, the long-term value would have increased by only 10%.
- 6.3 The Board does not find convincing the appellant's

allegation that E1 taught to discard short-term sample values of the minute volume which showed an increase due to metabolic demand. Indeed, the teaching of E1 does not foresee to suppress or discard any short-term sample values when forming the long-term average. In fact, no doubt is left that all short-term sample values measured in the normal operation of the pacemaker are to be used for forming the long-term average. Apparently, in the pacemaker according to E1 the slow update of the long-term RCP value by stepwise averaging over a large number of samples suppresses short-term effects to a considerable extent.

Nevertheless, had the skilled person been confronted with the task to cope with an undesirable change of the long-term reference value during very long periods of physical exercise and thus with the problem addressed by the patent in suit, he would have immediately realised that such an undesirable increase in the long-term average value could effectively be further delayed or reduced by simply delaying the update, ie by increasing the number of samples averaged in the first stage of averaging, and/or by further increasing the number of intermediate average values averaged in the second stage.

- 6.4 It follows that the skilled person would have rather considered a solution which was different from that of the patent in suit and which did not require additional means in order to be put into practice, whereas the appellant's interpretation of the teaching of E1 introduces an essential element of the claimed solution, which has no basis in the teaching of that document. Hence, this interpretation relies on hindsight, having knowledge of the patent in suit.

7. In view of the fact that the skilled person could already have devised a solution on the basis of the teaching of E1, he would not have had any incentive to search the prior art for alternative solutions. But even so, the available prior art, would not have hinted at the subject-matter of claim 1 under consideration, in particular E5 and E6.

Document E5 (see the abstract and Figure 2 with the corresponding description) refers to a pacemaker in which the sensitivity for detecting cardiac events is automatically controlled. This is achieved by measuring the peak value of the strongest electrical signals from the heart (ie the R-waves) and deriving a long-term average thereof. The gain of the sense channel is then adjusted automatically in accordance with the average of the measured peak values. The period of time over which the average value has to be determined can be reduced if the peak values which occur in the presence of noise (ie for noise exceeding a predetermined level) are excluded from forming the average (see column 4, lines 1 to 25).

It follows that if the skilled person had learned from E5 anything of relevance at all for a pacemaker according to document E1, it was the fact that the time for averaging in determining a long-term average value of a measured parameter could be shortened by suppressing noisy signals. Thus, a straightforward application of the teaching given by E5 would have led the skilled person to establish, by means of a threshold condition, whether noise of an undesirable degree was present and to discard all those samples from forming the long-term average of the RCP values which were taken in the presence of strong noise.

In view of the foregoing, the Board disagrees with the appellant's allegation that E5 disclosed a general principle concerning a threshold condition for discriminating unsuitable measurement values in the determination of a long-term average value, because this view is based on an excessive abstraction of the concrete teaching of the document. Moreover, without the benefit of hindsight, the skilled person would a *priori* not have had any reason to disregard short-term RCP sample values just because they reflect metabolic demand.

The same considerations apply to the teaching of document E6, which is even less relevant since it does not relate to the control of the operation of a pacemaker but to the measurement of blood pressure.

8. On the basis of the above considerations, the Board concludes that the subject-matter of claim 1 of the patent in suit is not rendered obvious by the teaching of the prior art referred to by the appellant in the appeal proceedings.

As regards the teachings of the further prior art documents discussed in the decision under appeal, the Board has no reason to doubt the respective findings of the Opposition Division as to their lack of relevance.

9. For these reasons, the ground for opposition under Article 100(a) EPC together with Article 56 EPC does not prejudice the maintenance of the patent unamended.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

R. Schumacher

G. Assi