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D E C I S I O N
of 15 July 1999

Case Number: T 0270/95 - 3.4.1

Application Number: 87108112.1

Publication Number: 0249821

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
A cardiac pacer for pacing a heart

Patentee:
Pacesetter AB

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

Headword:
Cardiac pacer/PACESETTER AB

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

Keyword:
"Inventive step (yes, after amendment; main request)"
"Extension of protection conferred (no; main request)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0270/95 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 15 July 1999

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 18 January 1995 rejecting the opposition filed against European patent No. 0 249 821 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: G. Davies
Members: H. K. Wolfrum
U. G. O. Himmler

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 18 January 1995, rejecting the opposition against European patent No. 0 249 821. The notice of appeal was received on 14 March 1995, the prescribed fee being paid on the same day. The statement setting out the grounds of appeal was received on 24 May 1995.

The appeal, as well as the opposition, was based on Articles 52(1) and 56 EPC relying *inter alia* on documents:

D5: US-A-4 298 007 and

D6: DE-A-31 50 524.

II. Oral proceedings were held on 15 July 1999.

The respondent (proprietor of the patent) requested as a main request that the appeal be dismissed and the patent be maintained on the basis of:

claims 1 to 9, page 1a and columns 1 to 6, line 11, of the description filed in the oral proceedings with the Figures as granted.

In the alternative, maintenance of the patent was requested on the basis of two sets of claims 1 to 7, page 1a and columns 1 to 6, line 11, of the description filed in the oral proceedings with the Figures as granted as a first and second auxiliary request, respectively.

The appellant requested that the decision under appeal be set aside and that the European patent be revoked. In addition to an objection of lack of inventive step, an objection under Article 123(3) EPC was raised against the amended claims filed by the patent proprietor.

III. Independent claim 1 of the main request, which is the only relevant request for the purpose of this decision, reads (without reference numerals) as follows:

"1. A cardiac pacer for pacing a heart comprising means for generating pacing pulses at a predetermined basic pacing rate, means for transmitting the pacing pulses to the heart for pacing, means for sensing physical activity and for generating a control signal dependent thereon and means for altering the rate from the predetermined basic pacing rate to a rate dependent on the control signal, characterized by means for monitoring when the pacing rate runs at or above a predetermined high rate for a predetermined time period, and for generating an output signal if said high rate is reached and by means dependent on said output signal when said predetermined time period has elapsed for forcing said pacing rate back to a rate lower than said predetermined high rate."

IV. The appellant essentially relied on the following submissions:

A. Amendments

The amendments made to the claims changed the scope of protection and thus infringed the requirement of

Article 123(3) EPC. In particular the replacement in claim 1 of the requirement "when said predetermined time period is reached" by "when said predetermined time period has elapsed", i.e. the change from a requirement relating to the beginning of a time period to one which related to the end of a time period, constituted a shift in the scope of protection. Moreover, the replacement in claim 4 of the phrase "until the control signal falls below the predetermined high rate" by "until the control signal is indicative of a rate below the predetermined high rate" widened the definition of the control signal to an extent which was not encompassed in the claims as granted.

B. Inventive step

A cardiac pacer as specified in claim 1 of the main request was rendered obvious by a combination of the teachings given by documents D5 and D6.

Document D5 referred to a rate responsive pacer and addressed the same problem as the patent in suit in that any rise in the heart rate should be sufficiently long to sustain physical activity but not allow that activity to continue past the point of serious fatigue, as was evident from column 2, lines 48 to 52 in D5. In order to solve this problem, the pacer according to D5 operated in a continuous, dynamic manner by varying the pacing rate with one time constant in response to a sensed control signal for the physical activity and at the same time permanently reduced the rate with a longer time constant to its lowest allowable value, wherein capacitor 122 in the circuit according to Figure 2b acted as a means for monitoring the pacing

rate. An upper limit for the pacing rate was not exceeded.

The subject-matter of claim 1 of the main request differed therefrom at best in that the rise and fall of the heart rate occurred in a rather static manner. Claim 1 defined in principle that a hysteresis was involved in rising and lowering the pacing rate of the claimed pacer. The use of a hysteresis characteristic for stabilizing a system was, however, a common measure in any field of technology. Moreover, the operation of the pacer according to D5 produced a hysteresis characteristic as well, as was indicated in column 15, lines 11 to 16.

Document D6 disclosed a pacer with a rate limiting system. As regards the operation at or above the predetermined high rate, it was apparent from Figure 1 and curves C and D in Figure 2 that the rate as determined from a control signal derived from the patient's heart had to be monitored for at least one period, since otherwise it could not be established whether it was above the high rate or not. A rate being too high was limited to the predetermined high rate. Furthermore, as indicated on page 9, second paragraph, it was envisaged that the pacer would be operated above the predetermined high rate for diagnostic purposes. For this purpose, any manufacturer would have provided means for operating the pacer in an automated manner in order to render it "doctor-proof".

By adopting the technical concept of forcing a high pacing rate back to a safe range, as known from D5, in a pacer according to D6 which could be operated for

some time above a predetermined high rate, the skilled person would have arrived at the subject-matter of claim 1 of the main request without having to exercise inventive skill.

As regards claim 1 of the auxiliary requests, the added features did not involve an inventive step either because it was obvious for the skilled person that, without the capability of returning back to an operation under the control of the control signal, a pacer having the pacing rate forced below the high rate could never work as a rate responsive pacer for the rest of its operating life.

V. The respondent disputed the appellant's view, relying on the following arguments:

A. Amendments

The amendments made to the claims defined in a more precise manner what was comprised in and meant by the definitions of the claims as granted. Therefore, they did not shift or extend the scope of protection and complied with Article 123(3) EPC.

B. Inventive step

The pacer known from D5 operated with different means than those of the claimed pacer. In particular, it did not have means which monitored the pacing rate and generated an output signal if a predetermined high rate was reached. Nor did it have means responsive to said output signal for forcing the pacing rate back to a rate lower than the predetermined high rate after a

predetermined time had elapsed.

The pacer according to document D6 had means for limiting the pacing rate to a predetermined high value. In normal operation, the pacing rate output to the heart was not allowed to run above said high rate. Although these limiting means could be overridden for diagnostic purposes, there was never a need to monitor the actual pacing rate nor was there any indication as to an automated operation above the high rate for a predetermined time period.

Reasons for the Decision

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

2. *Amendments (Articles 123(2) and (3) EPC)*

The amendments made to the claims of the main request serve to avoid possible misinterpretations and specify that the pacing rate when being forced back is forced to a rate below the predetermined high rate. The Board is satisfied that the context of the amendments is disclosed in the description. In particular, as regards the lowering of the rate, the respective amendment is based on column 5, lines 40 to 45 in combination with column 6, lines 10 to 12 of the published application documents.

The Board does not share the appellant's view that some of the amendments would extend the protection conferred. As regards claim 1, the appellant objected

to the replacement of "is reached" by "has elapsed" in the definition of the predetermined time period. In the Board's opinion, the phrase "is reached" is not specific as to when exactly within said period the means for forcing the pacing rate back become operative and covers in principle the whole of the predetermined time period, whereas the phrase "has elapsed" implies that this happens at the end of said time period. The amendment made to claim 1 thus selects one alternative from various alternatives comprised in claim 1 as granted. As regards claim 4, the amendment that the control signal "is indicative of a rate" is implicit in the definition of the control signal given in the preamble of claim 1 and merely removes an ambiguity in the wording of claim 4 as granted.

For these reasons, the amendments made to the claims according to the main request comply with the requirements of Articles 123(2) and (3) EPC.

3. Inventive step (Articles 52(1) and 56 EPC)

3.1 Document D5 (cf. in particular the abstract; and Figures 1 to 3 with the corresponding description) discloses a rate adaptive cardiac pacer in which the control signal for rate adaptation is derived by monitoring and determining changes in the period of the atrial cycle. In determining this control signal, a predetermined time period (in the order of 30 seconds to 1.5 minutes) elapses before a change in the control signal becomes effective for a change in the ventricular rate, i.e. the pacing rate (cf. column 2, lines 37 to 63). Moreover, the pacer includes a circuit which using a much longer time scale (in the order of

30 minutes) continuously tends to reduce the pacing rate down to the predetermined basic rate (cf. column 3, lines 5 to 14). Furthermore, the circuit of the pacer includes means for setting an upper limit to the pacing rate (cf. column 13, lines 58 to 63 showing resistor 168, which limits the maximum current delivered to the heart and thereby the maximum pacing rate to e.g. 130 beats per minute).

The subject-matter of claim 1 under consideration is distinguished from the pacer according to D5 in that it comprises means which allow operation of the pacer for a predetermined time period above a predetermined high rate and, after this time period has elapsed, to force the pacing rate back to a rate below said high rate. It is evident from the context of claim 1 that the pacer, when having the pacing rate forced back to a rate below the high rate, operates outside the control of the control signal. No such operation, which is not comparable to a hysteresis characteristic for the pacing rate, is foreseen in the pacer according to D5, nor is the known pacer equipped with the required means. In particular, the Board is unable to identify in the known pacer means which would be capable of monitoring the pacing rate and of generating an output signal if the predetermined high rate is reached. The capacitor "122" in Figure 2b of D5, identified by the appellant as a monitoring means, is merely a passive circuit element which cannot perform the functions of monitoring a pacing rate and, responsive thereto, of generating an output signal.

3.2 Document D6 (cf. in particular claim 1; and Figures 1 to 3 with the corresponding description) discloses a

cardiac pacer generating pulses ("Eingangsrate" on line 24) at a pacing rate which is *inter alia* determined by a control signal derived from the patient's heart. These pacing pulses are input to a rate limiting system (logic circuit 12). As long as the pacing rate lies between predetermined lower and upper limits, the system lets the pulses pass to be amplified and output to the heart. If, however, the pacing rate determined by the control signal exceeds a predetermined upper limit, the rate of the pacing pulses output to the heart is set at this upper limit (cf. waveforms C and D of Figure 2). In addition thereto, D6 contains the information (cf. page 9, second paragraph) that it might be desirable (for diagnostic purposes) to extend the pacing rate beyond the predetermined, physiologically safe limits. In this mode of operation, the rate limiting system can be "turned off", allowing for the pacing pulses to pass as if their rate were lying within the allowed range.

However, in contrast to the subject-matter of claim 1 under consideration, the pacer known from document D6 does not comprise means which would **force** the pacing rate back to a rate **below** the predetermined high rate. In the normal mode of operation of the known pacer, the pacing rate which is output to the heart is held at the predetermined high rate as long as the control signal is indicative of a rate above the high rate. The respective means are purely that of a rate limiting system. There is no means which would force the rate back to a rate lower than the high rate after a predetermined time period has elapsed. As regards the special mode of operating outside the physiologically safe limits for diagnostic purposes, no technical

details are disclosed concerning the respective means. It would, however, be evident for a skilled person that suitable means for this mode of operation would have to override the normal mode and allow the pacer to run above the predetermined high rate outside the control of the control signal. Moreover, regardless of which technical means is chosen to end the diagnostic testing, it would have to bring the pacer back to its normal operation under the control of the control signal. Thus, whichever means the skilled person would choose for the pacer according to D6, their function would be opposite to that of the means defined in claim 1 under consideration, which allow for running the pacer at a rate above the high rate under the control of the control signal and, after a predetermined time has elapsed, force the pacing rate back to a rate below the high rate and thus operate the pacer at the lowered rate outside the control of the control signal. Thus, the means to be devised for the pacer according to D6 would be quite different from those defined in claim 1.

3.3 In the absence of any indication in the prior art as to a pacer having means which allow the pacer to run for a predetermined period of time at or above a predetermined high rate as determined by the control signal and, thereafter, force the pacing rate back to a rate below the high rate which is no longer under the control of the control signal, a skilled person would not have arrived at the subject-matter of claim 1 of the main request, even when combining the teachings given by documents D5 and D6. For this reason, claim 1 of the main request defines novel and inventive subject-matter.

4. In summary, the Board is satisfied that the main request complies with the requirements of the EPC and is thus allowable.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the first instance with the order to maintain the patent on the basis of the main request.

The Registrar: The Chairman:

M. Beer G. Davies