BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

A		B		C	X

File No.: T 0235/91 - 3.4.1

Application No.: 83 302 485.4

Publication No.: 0 094 758

Classification: A61N 1/362

Title of invention: Tachyarrythmia pacer

D E C I S I O N
of 10 August 1993

Applicant:

Proprietor of the patent: MEDTRONIC, INC.

Opponent: BIOTRONIK Mess- und Therapiegeräte GmbH & Co

Headword:

EPC: Art. 56, 84

Keyword: "Inventive step (yes, after amendments)" - "Clarity (yes)"

Headnote
Catchwords

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0235/91 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 10 August 1993

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office dated 6 February 1991 concerning maintenance of European patent No. 0 094 758 in amended form.**

Composition of the Board:

Chairman: G.D. Paterson
Members: Y. van Henden
U.G.O.M. Himmler

Summary of Facts and Submissions

I. The Respondent is proprietor of European patent No. 0 094 758, disclosing a tachyarrhythmia pacer in which tachy beats detection is achieved by comparing beat periods to a programmed threshold period (PTP) and to a running average threshold (RAT) calculated from a running average (RAP) of the preceding beat periods.

II. The Appellant filed an opposition against that patent on the grounds laid down in Article 100(a) EPC, referring to the prior art which can be derived from documents:

D1: EP-A-0 005 170
D2: EP-A-0 016 574.

III. The Opposition Division maintained the European patent in amended form on the basis of new Claims 1 to 6 filed on 4 September 1990 with a letter dated 30 August 1990.

IV. The Opponent lodged an appeal against the decision of the Opposition Division, setting forth that the new claims did not disclose how the desired results, i.e. detection of tachyarrhythmia and initiation of the relevant treatment, should be achieved.

The Respondent commented on the grounds of appeal in a telefax received on 13 January 1992.

V. In a communication pursuant to Article 11(2) RPBA, the Board took the provisory view that the running average period (RAP) is not calculated from heart beat periods which are greater than both the PTP and the RAT, as nevertheless stated in Claim 1 as filed on 4 September 1990, but from beat periods which are longer than at least one of the PTP and the RAT.

VI. In response, the Respondent submitted on 13 July 1993 four amended versions (A, B, C, D) of Claim 1 to be examined during oral proceedings.

Claim 1 according to the Respondent's main request - i.e. version (A) - reads:

"a pacer of the type having at least one sense amplifier for detecting depolarization of cardiac tissue and at least one output amplifier for providing electrical stimulation to the cardiac tissue and comprising:

timing means for determining time periods between successive cardiac polarizations;

averaging means for calculating a running average period;

means for calculating a running average threshold period from said running average period;

means for comparing each said determined time period with said running average threshold period producing a first criterion detection signal if the time period is less than or equal to said running average threshold period;

means for comparing the time period with a preselected programmed threshold period and for producing a second criterion detection signal if said time period is less than or equal to the programmed threshold period;

means responsive to the production of both said first and second criteria detection signals for incrementing a tachy beat counter; and

means responsive to said tachy beat counter for initiating a tachyarrhythmia treatment regime, said averaging means being arranged to calculate the running average period over a preselected number of periods which excludes periods which satisfy both said criteria."

Version (B) of Claim 1 differs from the preceding in that the statement "said running average threshold being a fraction of said running average period" has been inserted after the mention of "means for calculating a running average threshold period from said running average period".

Version (C) differs from version (A) in that the statement "and wherein said averaging means is not responsive to time periods terminated by an artificially stimulated depolarization" has been inserted at the end of the last clause.

Version (D) of Claim 1 is distinguished over version (A) in that "immediately preceding" has been inserted before "periods which excludes periods which satisfy both said criteria" in the final clause.

VII. In a letter dated 1 July 1993, the Appellant commented on the Respondent's submissions of 13 January 1992 and on the Board's communication. In said letter, the Appellant referred to documents:

D3: US-A-3 857 398 and
D4: EP-A-0 011 934,

already cited in the European Search Report, as well as to new documents:

D5: US-A-3 524 442 and
D6: WO-A-81/00806,

of which, copies were annexed to the Appellant's letter.

VIII. Oral proceedings were held on 10 August 1993.

IX. The Appellant requested that the decision under appeal be set aside and that the patent in suit be revoked.

In support of these requests, the Appellant argued in substance as follows:

Though not with certitude, it could be inferred from the patent in suit that the invention aims at providing a pacer which detects tachyarrhythmia not only on the basis of a predetermined threshold, but also on the basis of patient's data. Nevertheless, neither from the file documents nor from the Patentee's explanations is it possible to infer how a heart beat should be classified as a tachy one: it is stated in Claim 1 as originally filed that both criteria mentioned there should be satisfied, whereas the Patentee asserted in its submission of 13 January 1992 that tachy beats are those having a period shorter than the programmed threshold period (PTP). It is also difficult to understand how the result of a discriminating test could also be used as criterium for discriminating. This, however, is what Claim 1 teaches. A consequence thereof is that, in case of tachyarrhythmia, beat periods slightly slower than the preceding ones and being nonetheless tachy periods would not be considered as such.

From (D3), it is known to detect tachycardia by comparing a mean value of the heart's beat periods with a predetermined threshold. Furthermore, it was known from (D5) and (D6) to determine a threshold on the basis of beat periods measured during a given time interval and to compare the following beat intervals to this threshold in order to detect tachyarrhythmia. Such teachings are also derivable from (D1), for the PLL frequency mentioned there follows the actual frequency with a certain delay, and a beat is classified as a

tachy one if its duration is inferior to a variable threshold. As a matter of fact, the circuit described in (D1) is suitable for achieving the purpose of the invention. The subject-matter of Claim 1 is therefore not inventive.

X. The Respondent requested that the appeal be dismissed and that the patent be maintained in accordance either with the main request (A) or in accordance with one of the auxiliary requests (B) to (D) filed on 13 July 1993.

The Respondent's argumentation may be summarised as follows:

Document (D5) discloses a system for detecting abnormally premature beats, i.e. PVCs, with the purpose of providing indications of the serious nature of a patient's heart activity in time. Document (D6) discloses an automatic high speed Holter scanning system which receives and processes pre-recorded electrocardiograms. There is no relationship whatsoever between such devices and a pacer incorporating a tachycardia detection system according to the invention. Therefore, documents (D5) and (D6) are not relevant to the case and should be disregarded under Article 114(2) EPC.

The Appellant's argumentation is based on a misinterpretation of the European patent and of the Patentee's submissions. For instance, in the Patentee's comments dated 11 January 1992, the statement that all genuine tachycardia beats falling below the PTP will be detected does not mean that said beats could not fall below the RAT. This latter condition was not mentioned because the argument was made in response to the Appellant's assertion that the PTP may decrease, whereby not all tachy beats would be detected.

The invention is concerned with detecting tachycardias which can be treated by pacing, only. It identifies a treatable tachycardia by detecting not only abnormally high heart rate but also the sudden onset of tachycardia. To achieve that purpose, two criteria are needed according to whether the patient is at rest or taking exercise. In the first case, the RAT is higher than the PTP and, in the second case, it is lower than the PTP. Although the paragraphs of (D2) and (D3) cited by the Appellant disclose comparing a beat with a rhythm established by previous beats, these disclosures have been taken out of context, for the purpose there is identifying and logging individual PVCs, and not testing the rate of a continuing tachycardia. Nevertheless, PVCs cannot be treated by pacing, so that it is only with the benefit of hindsight that the possibility of combining the teachings of (D2) and (D3) can be perceived.

XI. After deliberation by the Board, the decision was announced that the decision of the Opposition Division is set aside and that the case is remitted to the first instance with the order to maintain the patent on the basis of Claim 1 set out in main request (A) filed on 13 July 1993.

Reasons for the Decision

1. *Requirements of Article 123(2) and (3) EPC*

From the European patent application underlying the grant of the patent in suit, it can be inferred that it is only when a measured heart beat period has previously been found to be inferior to the PTP that it is tested whether said period is also inferior to the RAT - see page 10 of the published patent application, lines 17 to

35. Furthermore, it is stated there that, if the measured time interval fails this test - i.e. if it is superior to the RAT - then the process updates the RAP - see page 10, lines 32 to 37. Therefore, the application as filed does not exclude that, among the preselected number of periods over which the RAP is calculated, there might be periods shorter than the PTP and longer than the RAT. Now, when a patient is at rest, the RAT shall obviously be superior to the PTP, as actually suggested by Figure 3 of the application as filed. Consequently, neither did the latter exclude that, among said preselected number of periods, there might also be periods inferior to the RAT.

It may thus not be denied that the averaging means disclosed in the application as filed are arranged to calculate the RAP over a preselected number of periods which excludes periods which satisfy both criteria mentioned in version (A) of Claim 1. The preceding part of the claim being identical to Claim 1 of the European patent, the Board has no objection to raise under Article 123(2) and (3) EPC against version (A) of Claim 1.

2. The reasons explained in section 1 of the present decision furthermore show that, contrary to the Appellant's analysis of the file documents, it can be inferred from the latter how a heart beat shall be classified as a tachy one and how the RAP and RAT shall be determined.

3. *State of the art*

3.1 Document (D1) pertains to a portable system for detecting arrhythmia in electrocardiogram signals during a comparatively long period, e.g. a few days, which system is to be used externally from the human body - see: page 1, first and second paragraph; page 3, third paragraph; page 4, second paragraph. This system comprises: an output amplifier (2); a Schmitt trigger (3) transmitting the detected signals having an amplitude superior to a predetermined threshold - i.e. the QRS complex; a multivibrator (4) receiving the signals forming the QRS complex and outputting in response pulses of definite duration; a second multivibrator (5) for masking signals initiated by T waves; a phase locked loop (9) whose time constant is continuously adapted to the prevailing heart frequency and oscillating at a frequency which is a fixed multiple of the heart frequency; and a counter (8) which, by counting a predetermined number of pulses at the PLL (phase locked loop) frequency, defines a time window - see: from page 6, line 23 to page 7, line 4; page 7, lines 22 to 25; from page 8, line 32 to page 9, line 7; page 9, lines 14 to 29; page 11, lines 4 to 14; Figures. QRS complexes occurring during said time window are detected as tachy beats, whereby signals are transmitted by a gate circuit (6) and recorded by a counter (7) - see page 12, lines 16 to 23.

A tachyarrhythmia detection threshold analogous to the RAT defined in the European patent is thus determined. Nevertheless, this threshold is determined on the basis of all QRS complexes, including those which belong to a tachycardia condition. Furthermore, the pulses from the second multivibrator having a constant duration, the time window for tachycardia detection becomes narrower

during periods of rapid heart beats, whereby genuine tachy beats can eventually not be detected.

3.2 Document (D2) describes a pacer comprising a QRS detector (6), a ramp generator (8) which is reset by the pulses outputted by the detector (6), and an AND gate (10) receiving the outputs from said detector (6) and ramp generator (8). If the output of the ramp generator (8) has not reached a predetermined threshold value when a QRS is detected, the gate (10) provides an output pulse to a counter (12). If this condition prevails for three successive QRS beats, then the counter (12) outputs a signal fed to a monostable (14) which generates a stimulus pulse for terminating tachycardia - see Figure 2 and page 6, lines 9 to 23.

3.3 Document (D3) relates to a demand pacer comprising an analyser-control (12) which generates a pulse to energise a defibrillator (10) if, over a given time interval, the average rate of occurrence of the QRS complexes exceeds a predetermined value and if, in that interval, the duration of each of the Q to S periods exceeds a given period - see column 2, lines 28 to 30, and column 3, lines 13 to 23. Despite the statement that the waveforms of Figure 4 also represent the typical response of analyser control (12) to a heart undergoing ventricular tachycardia - see column 3, lines 8 to 11 - only defibrillation is contemplated in (D3).

3.4 Document (D4) relates to a pacer with a circuit limiting the rate of the stimulation signals - see page 5, lines 17 to 22.

3.5 As regards documents (D5) and (D6), the Board concurs with the Respondent that no relationship exists between the devices disclosed there and a pacer embodying the claimed invention. The Board, therefore, discards this late-filed evidence by the exercise of its discretionary power under Article 114(2) EPC.

3.6 Though not pertaining to a pacer, document (D1) thus discloses, in the Board's judgment, the most relevant prior art for assessing inventiveness of the claimed subject-matter. The latter, as defined by version (A) of Claim 1, is distinguished over said prior art in that:

(a) the RAT is updated taking into consideration only those heart beats which are not recorded as tachycardia events, and in that

(b) a beat period must fall below a further threshold for it to be recorded as a tachy one, said further threshold being predetermined.

4. *Inventive step*

4.1 Compared to the system known from (D1), the subject-matter of Claim 1 according to the Respondent's main request provides the following advantages:

(a) since they are not taken into consideration for updating the RAT, tachycardia beats do not lower it. Thereby it is precluded that tachycardia beats be eventually missed and that, in extreme cases, tachycardia be no longer recognised as such.

(B) the risk of missing tachy beats because of the time window is eliminated.

No incentive to go beyond the teachings of (D1) being given there to the skilled person, the achievement of these advantageous effects is evidence that, with respect to the prior art disclosed in (D1), providing the novel features of the claimed pacer involves an inventive step.

4.2 According to document (D2), for a QRS to be taken into consideration while controlling tachycardia, the output of ramp generator (8) must not have reached a predetermined value when said QRS is detected. The ramp generator being reset by the occurrence of QRSs, this condition is equivalent to the selection of a predetermined threshold period for discriminating whether a heart beat will - or will not - be considered as possible evidence of tachycardia. Nevertheless, because of the condition that three successive beat periods must fall below the threshold period for tachycardia to be diagnosed, a combination of the teachings respectively disclosed in (D1) and (D2) does not lead to the claimed invention and, moreover, does not achieve the same results. For instance, upon detection of isolated tachy beats or of couples of tachy beats, no stimulation pulse would be applied to the heart.

Since document (D2) does not envisage the possibility of diagnosing tachycardia when less than three successive beat periods are inferior to a predetermined threshold, the subject-matter of Claim 1 according to the Respondent's main request is also inventive over a combination of the teachings given in (D1) and (D2).

4.3 Because of the additional condition that the duration of Q to S periods should exceed a given value, document (D3) does not come closer to the claimed subject-matter than does (D2) and, therefore, does not hint at the invention. Finally, the remaining document (D4) is not relevant to the case in suit, as can be inferred from section 3.4 of the present decision.

4.4 In the Board's judgment, therefore, the subject-matter of Claim 1 according to Respondent's main request involves an inventive step.

5. Claim 1 according to the Respondent's main request is thus allowable - Article 52(1) EPC in conjunction with Article 56 EPC - and the grounds mentioned in Article 100(a) EPC do not represent a bar to the maintenance of the European patent on this basis.

6. The Respondent's main request being accepted, there is no reason for the Board to examine the Respondent's subsidiary requests.

7. In pursuance of Article 111(1) EPC, the Board remits the case to the first instance with the order to care for the adaptation of the description to Claim 1 according to the Respondent's main request, and to maintain the European patent in amended form on the basis of the following documents:

Description: as filed on 4 September 1990, with adaptation of the text to be inserted in place of lines 9 to 38 of column 2;

Claims: Claim 1, version A, filed on 13 July 1993;
Claims 2 to 6 as filed on 4 September 1990;

Drawings: sheets 1 to 4 of the patent as granted.

Order

For these reasons, it is decided that:

1. The decision of the Opposition Division is set aside.

2. The case is remitted to the first instance with the order to maintain the patent in amended form as indicated in section 7 above.

The Registrar: The Chairman:

M. Beer G.D. Paterson