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D E C I S I O N
of 3 August 1999

Case Number: T 0524/95 - 3.4.1

Application Number: 86306490.3

Publication Number: 0219943

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
Cardiac pacemaker adaptive to physiological requirements

Patentee:
Chirife, Raul

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

Headword:
-

Relevant legal provisions:
EPC Art. 54(3), 100(a)

Keyword:
"Novelty (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0524/95 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 3 August 1999

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 20 April 1995 rejecting the opposition filed against European patent No. 0 219 943 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
G. Assi

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 21 June 1995, against the decision of the Opposition Division, dispatched on 20 April 1995, rejecting the opposition against the European patent No. 0 219 943. The fee for the appeal was paid on 21 June 1995 and the statement setting out the grounds of appeal was received on 25 August 1995.

II. The appellant based the appeal essentially on Articles 100(a) and 54 EPC and referred to the following document:

D1: EP-A-0 194 224 (prior art according to Article 54(3) EPC)

III. Oral proceedings were held on 3 August 1999.

IV. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed and the patent maintained as granted.

V. Claim 1 reads as follows:

"1. A cardiac pacemaker adapted to respond to current physiological requirements of a patient being paced, comprising:

stimulus pulse generator (1) means having output means (E, 14) for coupling pacing pulses to the heart, said generator means changing its output pacing pulse rate in response to a varying control signal,

first sensing means for sensing in each heart cycle the occurrence of the onset of a QRS signal in an intrinsic QRS waveform or an artificial pacing pulse signal, whichever is first to occur in the cycle, sensing of one of said signals marking the start of a ventricular pre-ejection period (PEP) whose length varies with said current physiological requirements and during which pressure increases in the ventricles but blood is not ejected therefrom,

second sensing means (5) for sensing the abrupt increase in a selected one of blood pressure or blood flow in the arterial system resulting from ventricular ejection, which increase marks the end point of the PEP and determination of the length of the PEP, and

means (9, 10) for producing a control signal which is a function of the length of the PEP for said signal to control the rate of said pulse generator.

Claim 2 is dependent on claim 1.

VI. The appellant's arguments can be summarised as follows:

D1 related to a cardiac pacemaker controlled by a systolic interval such as the **Pre-Ejection Period** (PEP) or the **Left Ventricular Ejection Time** (LVET). The pacemaker described in detail in this document comprised a control circuit connected to the heart by two lines A and V, and an acoustic sensor (i.e. a microphone) to determine the length of a systolic interval (LVET) by means of heart sounds. The start of the PEP coincided with the beginning of the heart cycle, as defined by the onset of the QRS complex. Since the pacemaker described in D1 required the detection of the QRS complex to perform its normal

pacing functions, it comprised also the **first sensing means** specified in claim 1 of the contested patent. As to the **second sensing means** according to claim 1, it was immediately apparent to the skilled person that the same function could be performed by the microphone referred to in D1 because an acoustic sensor was suitable to detect the abrupt increase in blood pressure or blood flow which marked the end of the PEP.

Since D1 showed or necessarily implied all the features required by a PEP-controlled pacemaker as specified in claim 1 of the patent in suit, the subject-matter of this claim was not new within the meaning of Article 54 EPC.

VII. The respondent's arguments can be summarised as follows:

D1 taught to use a microphone to determine the length of the LVET. An acoustic transducer could not be used to measure the length of the PEP because both the beginning and the end of this systolic interval were silent events. As D1 showed a sensor which was only suitable for an LVET-controlled cardiac pacer, it taught away from the claimed invention. Hence, the passing reference in D1 to the PEP could not be regarded as a disclosure anticipating a pacemaker according to the contested patent.

Reasons for the Decision

1. The appeal is admissible.

2.1 The only issue to be examined by the Board in the present case is whether the subject-matter of claim 1 is new over the disclosure in D1 which constitutes prior art within the meaning of Article 54(3) EPC.

2.2 D1 shows a cardiac pacemaker adapted to respond to the physiological requirements of a patient being paced, comprising the following features recited in claim 1 of the patent in suit:

- stimulus pulse generator means 1 (cf. Figure 1) having output means A,V for coupling pulses to the heart, said generator means changing its output pacing pulse rate in response to a varying control signal; and

- means for producing a control signal.

According to D1, the control signal may be a function of the length of a systolic interval, such as the Pre-Ejection Period (PEP), the Left Ventricular Ejection Time (LVET) or their ratio (cf. D1, page 3, line 29 to page 4, line 2 and claim 3). However, the embodiment described in detail in D1 relates only to an LVET-controlled pacemaker comprising an acoustic transducer (i.e. a microphone) to detect the heart sounds which define the boundaries of the LVET (cf. D1, page 19, lines 16 to 17)

2.3 Hence, the subject-matter of claim 1 differs from the cardiac pacemaker **explicitly** disclosed in D1 essentially in that it further comprises the following features:

- **first sensing means** for sensing in each heart cycle the occurrence of the onset of a QRS signal in an intrinsic QRS waveform or an artificial pacing pulse signal, whichever is first to occur in the cycle, and

- **second sensing means** for sensing the abrupt increase in a selected one of blood pressure or blood flow in the arterial system resulting from ventricular ejection.

2.4 The Board agrees with the appellant that, since the start of the PEP is defined as the onset of the QRS complex, the first detecting means specified in claim 1 corresponds essentially to the means required in the pacer shown in D1 to monitor the heart's electrical activity.

2.5 As to the question of whether a person skilled in the art would use the microphone shown in D1 to detect the beginning of ventricular ejection (i.e. the end of the PEP) in a PEP-controlled pacemaker, the respondent has convincingly argued that the first heart sound, referred to as S1, is generated shortly after contraction of the heart starts, and well ahead of the onset of ejection, by the sudden tension of the ventricular wall and the closure of the mitral valve due to the increased ventricular pressure, which at that time exceeds atrial pressure. When the pressure within the ventricle reaches the level of the pressure existing in the aorta, the one-way aortic valve opens and ejection begins. Closure of the aortic valve, which marks the end of ventricular ejection, generates a second heart sound known as S2. As pointed out by the

respondent, the opening of the aortic valve is noiseless and can be detected only by a pressure, flow or pulse transducer placed within or in the vicinity of the aorta, or by means of a ventricular volume sensor (cf. contested patent, column 6, lines 27 to 42). Though there appears to be some correlation between the end of the heart sound S1 and the beginning of the blood outflow (i.e. the end of PEP), the Board agrees with the respondent that the skilled person would not consider this event suitable to mark the end of the PEP because of its "fuzziness", i.e. because of the difficulty involved in detecting with an acceptable degree of precision the end of a highly variable acoustic signal, such as a heart sound. Consequently, the skilled person would not read into D1 that a microphone might also be used to determine the PEP. In the Board's opinion, this argument is further strengthened by the fact that the circuit 5 shown in Figure 1a of D1 is supposed to measure the time interval between the **leading edges** of the S1 and S2 heart sounds, and that there is no suggestion in D1 that the same circuit might be used to detect the end of S1 (cf. D1, page 21, lines 5 to 16).

2.6 In summary, the Board finds that the detailed embodiment of an LVET-controlled pacemaker and the general reference in D1 to the possibility of using the PEP as a control signal in a pacemaker adapted to respond to a patient's physiological requirements do not necessarily imply a pacemaker falling within the terms of claim 1 of the contested patent. Hence, the claimed subject-matter is new within the meaning of Article 54 EPC.

2.7 In these circumstances, the patent can be maintained as granted.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. The patent is maintained as granted.

The Registrar: The Chairman:

M. Beer G. Davies