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D E C I S I O N
of 8 March 2005

Case Number: T 0648/01 - 3.4.1

Application Number: 92310071.3

Publication Number: 0541338

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:

Implantable cardiac function monitor and stimulator for
diagnosis and therapy delivery

Patentee:

CARDIAC PACEMAKERS, INC.

Opponent:

Biotronik GmbH & Co. KG

Headword:

-

Relevant legal provisions:

EPC Art. 52(1), 56, 100(a)

Keyword:

"Inventive step - no"

Decisions cited:

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Catchword:

-



Case Number: T 0648/01 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 8 March 2005

Appellant: Biotronik GmbH & Co. KG
(Opponent) Woermannkehre 1
D-12359 Berlin (DE)

Representative: Eisenführ, Speiser & Partner
Patentanwälte Rechtsanwälte
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Respondent: CARDIAC PACEMAKERS, INC.
(Proprietor of the patent) 4100 Hamline Avenue North
St. Paul, MN 55112-5798 (US)

Representative: Charig, Raymond Julian
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 15 February 2001
rejecting the opposition filed against European
patent No. 0541338 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: G. Assi
Members: R. Q. Bekkering
E. J. Dufrasne

Summary of Facts and Submissions

- I. The appeal was lodged by the opponent (appellant) against the decision of the opposition division, dispatched on 15 February 2001, rejecting the opposition against European patent No. 0 541 338. The notice of appeal was received on 10 April 2001, the appeal fee being paid on the same day, and the statement setting out the grounds of appeal was received on 21 June 2001.
- II. Opposition had been filed against the patent as a whole, based on Article 100(a) EPC, on the grounds of lack of novelty and inventive step, and on Article 100(c) EPC.
- III. Reference was made *inter alia* to the following documents:
- E10: DE-A-35 33 597
- E13: R. F. Schmidt, G. Thews, "Physiologie des Menschen", Springer Verlag, 1990, pages 492 to 498
- IV. The appellant requested that the decision under appeal be set aside and the patent revoked. Oral proceedings were requested as an auxiliary measure.
- V. The respondent (patentee) requested that the appeal be dismissed. An auxiliary request for oral proceedings was made.
- VI. Oral proceedings were held on 8 March 2005. The respondent having been duly summoned did not attend, as announced by letter of 13 January 2005.

VII. Claim 1 of the patent as granted reads as follows:

"1. Apparatus for applying therapy to a patient for treatment of chronic heart failure affecting wall stiffness to improve wall contraction or relaxation, the therapy being based upon the contractile state, as indicated by the levels of ventricular end-diastolic volume and pressure of said patient's heart, characterised in that the apparatus comprises :-

- (a) intracardiac sensing means (10) for sensing hemodynamic indicators of contractile state in at least one ventricular chamber of the heart, said hemodynamic indicators including (76) a measurement of the cardiac output of the heart;*
- (b) signal means (20,60) coupled to said sensing means (10) for developing a control signal in response to said hemodynamic indicators;*
- (c) patient therapy means (120,130,140), including electrical therapy means having at least one stimulating electrode (11) for applying stimulating pulses to the heart tissue in response to said control signal, within predetermined therapy options selected by a physician, to increase the strength of contraction of the patient's heart so that during contraction the cardiac output is increased; and*
- (d) application means (60) coupled to the patient therapy means (120,130,140) and to the signal means (20,60) for applying said control signal to said patient therapy means (120,130,140), for changing said contractile state by increasing the strength of contraction of the heart."*

VIII. The appellant argued in substance as follows:

The subject-matter of claim 1 as granted only differed from the apparatus known from document E10 in that a further hemodynamic indicator, in addition to the cardiac output, was considered. Since no specific effect on the operation of the apparatus of the further hemodynamic indicator was disclosed, the alleged invention was limited to the mere consideration of a further hemodynamic indicator for the contractile state of the heart. Since such further relevant indicators were generally known to the skilled person, as shown by the textbook E13, the subject-matter of claim 1 as granted lacked an inventive step.

IX. The respondent's written submissions may be summarised as follows:

According to claim 1 as granted at least three hemodynamic indicators, namely cardiac output, ventricular end-diastolic volume and pressure, were considered. None of the prior art suggested a device using a control signal generated in response to the three indicators for delivering therapy to increase the strength of contraction of the heart. Document E13 merely provided insight in the workings of the human heart, but did not suggest any concrete modification to existing pacemakers.

Reasons for the Decision

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

2. *Inventive step*

From document E10 (see column 2, line 8 to column 3, line 50) a rate responsive pacemaker is known for applying stimulation pulses to the heart, which is controlled so as to obtain a desired cardiac output. Intracardiac sensing means for measuring the stroke volume in the ventricle by means of electroplethysmography are provided (see column 3, lines 60 to 63). The pacemaker senses variations in stroke volume caused by changes in physiologic demand (eg during exercise) and increases the pulse rate according to a patient specific control curve (see figure 3 (curves K1-R1 to K3-R3) and column 3, line 55 to column 4, line 34).

The patient specific control curve is determined in an automatic calibration procedure (see column 4, line 35 to column 6, line 63). In particular, during calibration, at a high level of exertion confirmed by an activity sensor for blood temperature or respiration rate, the pacing frequency is swept through a predetermined frequency range and the cardiac output, given by the product of the stroke volume as measured and the pacing frequency, is calculated (see column 4, line 35 to column 5, line 65) and its maximum value is determined. The control curve with the maximal value of cardiac output as its endpoint is selected.

Accordingly, having regard to claim 1 of the patent in suit, document E10 (see figure 2 and corresponding description) discloses an apparatus for applying therapy to a patient having intracardiac sensing means (3) for sensing a hemodynamic indicator of contractile state in at least one ventricular chamber of the heart, signal means (4, 5) coupled to said sensing means for developing a control signal in response to the hemodynamic indicator, patient therapy means (1) including electrical therapy means having at least one stimulating electrode for applying stimulating pulses to the heart tissue in response to said control signal within predetermined therapy options selected by a physician, and application means (6, 1) coupled to the patient therapy means and to the signal means for applying said control signal to said patient therapy means.

According to claim 1 of the patent as granted, the apparatus, in response to a control signal, increases the strength of the contraction of the patient's heart so that during contraction the cardiac output is increased. As such, also the pacemaker known from document E10, like any ordinary pacemaker, when delivering stimulation pulses to a heart showing no natural contractions, increases the strength of contraction of the heart compared to when no pulses are delivered, and increases the cardiac output accordingly. The general wording of claim 1, thus, encompasses the therapeutical effects obtained with conventional pacemakers such as the one known from document E10.

Furthermore, according to claim 1 as granted, more than one hemodynamic indicator of contractile state is sensed and used for developing the control signal. One hemodynamic indicator is specified to be the cardiac output. The other hemodynamic indicators could be the ventricular end-diastolic volume and pressure, although it is doubtful whether claim 1 actually defines that these indicators are sensed and used in developing the control signal.

In the device known from document E10, in normal operation the stroke volume is measured and used for controlling, through the characteristic control curve, the pacing rate. Only in the calibration phase the cardiac output is measured. In this phase, however, the pacing rate is swept through a predetermined frequency range and, thus, not controlled by the measured cardiac output. Moreover, there is no indication in document E10 of the sensing of a further hemodynamic indicator of contractile state and of its use for developing the control signal. The activity sensor only used in the calibration procedure senses blood temperature or respiration rate, which are even not hemodynamic parameters.

The only difference between the subject-matter of claim 1 as granted and the prior art teaching given by document E10, thus, lies in the nature and number of the hemodynamic indicators of contractile state sensed and used for developing the control signal of the pacemaker.

Hemodynamic indicators of contractile state of the heart such as the cardiac output, end-diastolic volume

and pressure, as well as stroke volume or, for instance, ejection fraction, time-varying ventricular pressure dP/dt , stroke work, and the extent to which these indicators may be useful for controlling the contractile state of the heart, however, belong to the common textbook knowledge of the average practitioner (see eg document E13, pages 497 to 498). The mere selection as such of further, alternative *per se* well-known hemodynamic indicators to the stroke volume used in the pacemaker of document E10 did not require inventive skills from the skilled person. If anything, the specification of apparatus features, for instance providing a particular handling of specific sensed hemodynamic indicators resulting in improvements in the manner the therapy means are controlled or providing improvements in the characteristics of the therapy delivered by the therapy means, could involve an inventive step. Claim 1 in suit, however, is drafted in very broad terms and it is not apparent how the further, alternative hemodynamic indicators affect the operation of the apparatus. Accordingly, no inventive step can be recognised for this difference.

For the reasons given above the subject-matter of claim 1 as granted does not involve an inventive step (Articles 100(a), 52(1) and 56 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

R. Schumacher

G. Assi