BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen

D E C I S I O N
of 28 July 1999

Case Number: T 0227/96 - 3.4.1

Application Number: 87108102.2

Publication Number: 0249819

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
Cardiac pacer for pacing a human 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(2)

Keyword:
"Inventive step (yes, after amendment; first auxiliary request)"
"Subject-matter extending beyond the content of the application as filed (no)"

Decisions cited:
-

Catchword:

-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0227/96 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 28 July 1999

Appellant: (Opponent)
Biotronik
Mess- und Therapiegeräte GmbH & Co
Ingenieurbüro Berlin
Woermannkehre 1
12359 Berlin (DE)

Representative:
Christiansen, Henning, Dipl.-Ing.
Patentanwalt
Pacelliallee 43/45
14195 Berlin (DE)

Respondent: (Proprietor of the patent)
Pacesetter AB
175 84 Järfälla (SE)

Representative:
Harrison, Michael Charles
Albihns GmbH
Grasserstrasse 10
80339 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 28 December 1995 concerning maintenance of European patent No. 0 249 819 in amended form.**

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 interlocutory decision of the opposition division, dispatched on 28 December 1995, maintaining European patent No. 0 249 819 in amended form. The notice of appeal was received on 4 March 1996, the prescribed fee being paid on the same day. The statement setting out the grounds of appeal was received on 25 April 1996.

The appeal, as well as the opposition, was based on Articles 52(1) to 57 EPC relying *inter alia* on documents:

D1: US-A-4 303 075,

D2: EP-A-0 151 689, and

D4: EP-A-0 089 014.

II. In a communication accompanying a summons to oral proceedings, the Board drew the parties' attention to document

D5: US-A-4 030 509,

referred to in document D1 as disclosing a suitable structure of certain pacer leads and electrodes.

III. Oral proceedings were held on 28 July 1999.

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

The respondent (proprietor of the patent) requested that the appeal be dismissed and the patent be maintained on the basis of the following requests filed in the oral proceedings:

claims 1 to 12 and columns 1 to 4 with an amended page to be inserted in column 2 of the description and the Figures as granted (main request); and

claims 1 to 9 and columns 1 to 4 with an amended page to be inserted in column 2 of the description and the Figures as granted (named "first" auxiliary request).

IV. Independent claim 1 of the main request reads (without reference numerals) as follows:

"1. A cardiac pacer for pacing a human heart comprising
a) means for generating pacing pulses at a predetermined pacing rate;
b) means for generating an alternating signal which is unable to pace the heart;
c) a single lead connected with a single electrode for transmitting the pacing pulses together with the alternating signal to the heart;
d) means connected through leads to said lead for measuring and processing the alternating signal after transmittal to the heart for obtaining a respiratory signal and
e) means for varying the predetermined pacing rate dependent on the respiratory signal, the cardiac pacer having a conductive housing which defines both the indifferent electrode for pacing and the second electrode for the alternating signal generating means."

Claim 1 of the auxiliary request additionally specifies that the alternating signal is a "continuous alternating current signal".

V. The appellant essentially relied on the following submissions:

In both requests, the replacement in feature (c) of **means** for transmitting the pacing pulses together with the alternating signal to the heart as specified in the claims as granted by a "single lead connected with a single electrode" constituted an infringement of Article 123(2) EPC because the formerly-claimed means implied some source of energy, whereas a lead was merely a means for interconnection.

Moreover, the subject-matter of claim 1 of both requests was not inventive in view of the cited prior art and general technical principles observed by a person skilled in the art. The idea of using an electric lead or electrode for carrying more than one signal was a general and widely-employed principle in the field of electric technology known as the superposition or multiplexing principle. Its application to a pacer known from document D2 did not involve any inventive activity, the more so as it was known from documents D1 and D5 to use an electrode for pacing as well as for sensing or monitoring. As regards the main request, it was known from D2 to use the conductive housing as the indifferent electrode for pacing as well as the second electrode for the impedance measurement from which the respiratory signal was obtained. As regards the auxiliary request, the use of a continuous alternating current signal for

measuring a (complex) impedance was common practice in the art.

VI. The respondent disputed the appellant's view, relying on the following submissions:

The only correspondence between a pacer known from D1 in combination with D5 and the claimed subject-matter was feature (a).

The claimed subject-matter was distinguished from a pacer as known from D2 in particular by feature (c). The skilled reader had learned from D2 (cf. in particular the description of Figures 2 and 3 on page 6, lines 12 to 28,) that the electrodes measuring the impedance had to be subcutaneously positioned. The phrase "wherein an electrode (B) could correspond to the heart stimulation lead", given on page 6, lines 16 and 17, of D2 was ambiguous since it was not apparent what was meant by the term "correspond". Said phrase was part of the description of Figure 2 and thus could only be interpreted as meaning what was actually shown in this Figure. Confirmation of such an interpretation was to be seen in the fact that the subsequent description of Figures 2a and 3 exactly described what was shown in these Figures. A further difference was to be seen in claim feature (b), requiring an **alternating** signal in the meaning of alternating from one direction into another. In contrast thereto, in the pacer according to D2 a **pulsed** signal was generated for measuring the impedance. This finding was confirmed by a reference in D2 to document D4, which also disclosed a measurement of the impedance by **pulsed** signals transmitted to subcutaneous leads and electrodes

separate from the pacing electrode. Pulsed signals had the disadvantage that, even if they did not cause pacing, they would polarize the contacted tissue so that a skilled person would not have wanted pulsed signals other than pacing pulses to be applied to a pacing electrode. This difference was emphasized in claim 1 of the auxiliary request in specifying that the alternating signal was a continuous alternating current signal, i.e. a continuous alternating current which periodically reversed its direction.

Reasons for the Decision

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

2. *Amendments*

The amendments to claim 1 of both requests are based on technical information disclosed in column 3, lines 15 to 27 and 40 to 44 of the published application documents. As regards in particular the amendment to feature (c), the Board notes that claim 1 as granted as well as claim 1 of both requests under consideration specify the sources of energy for the pacing pulses and the alternating signal in features (a) and (b). It follows therefrom that the means for transmitting the pacing pulses and alternating signal according to feature (c) of claim 1 as granted relate to the electrical connection between the pacer and the heart. Therefore, specifying this means in the requests on file to be a "single lead connected with a single electrode", as disclosed in the description, does not

introduce subject-matter extending beyond the content of the application as filed.

Moreover, the amendments limit the scope of the claims as granted.

The Board is thus satisfied that the requests on file do not offend against Articles 123(2) and (3) EPC.

3. *Inventive step*

3.1 Main request

3.1.1 The Board considers document D2 to represent the closest prior art.

D2 (cf. in particular claims 3 and 7; and Figures 2, 2a, 3 and 5 with the corresponding description) discloses a rate responsive pacer varying a predetermined pacing rate dependent on a respiratory signal obtained from a measurement of the thoracic impedance. In the embodiment of Figure 2, the impedance is measured between two electrodes (A and B) which are subcutaneously positioned. According to the corresponding description on page 6, lines 15 to 17, one of these electrodes "could correspond to the heart stimulation lead". In alternative embodiments shown by Figures 2a and 3, one or even both of the impedance sensing electrodes are formed by conductive parts of the pacer housing.

The Board disagrees with the respondent as regards the extent of the technical information disclosed by D2. Notwithstanding the fact that Figure 2 shows a pacer

with two subcutaneously located electrodes A and B separated from the pacing lead HR for obtaining a respiratory signal, the corresponding description on page 6, lines 16 and 17, nevertheless points to the alternative that one of these electrodes "could correspond to the heart stimulation lead". The Board has no doubt that the word "correspond" is used in the meaning of "is" or "could be", as is evident from page 6, lines 17 to 19, where the same word is used to specify that the electrode B is formed by the conductive case of the pacer, as is indeed shown by Figure 3. Moreover, there is in fact no inconsistency between the technical information given by the description and that given by the drawings because, when describing said alternative to the arrangement of leads shown in Figure 2, the subjunctive mood is used, whereas for describing the arrangement actually shown in the Figures the indicative mood is consistently used. The Board also cannot accept the respondent's submission that the pacer according to D2 or D4 would not generate an alternating signal for measuring a respiratory signal because an alternating signal is any signal with a temporal change in its amplitude so that the pulse signals used in the pacers according to D2 and D4 have to be regarded as alternating signals as well. In consequence, the idea of using a single electrode for the dual purpose of transmitting to the heart pacing pulses as well as an alternating signal for obtaining a respiratory signal is already known from D2. The subject-matter of claim 1 under consideration thus differs from the teaching given by D2 only in

(i) that the alternating signal is expressly unable

to pace the heart; and

(ii) that the second electrode for the alternating signal generating means is formed by the conductive housing in combination with the first electrode being formed by a single lead connected with a single electrode for transmitting the pacing pulses together with the alternating signal to the heart.

3.1.2 The objective problem associated with these differences lies in the desire to avoid disturbance of the pacing function by the measurement of the respiratory signal and to simplify the arrangement of the electrodes.

3.1.3 Neither this problem nor its solution would have required the exercise of inventive skill.

As regards difference (i), D2 indicates on page 7, lines 5 to 12, that the means for generating the alternating signal are designed to consume a minimum quantity of energy and explicitly refers to document D4 for further technical details. From D4 (cf. page 10, lines 6 to 19) it is known that the alternating signals for measuring the thoracic impedance do not provoke contraction of the underlying muscles. Thus it is apparent that the pulse signals used in D2 for measuring the respiration signal are unable to pace the heart.

As regards difference (ii), the desire to simplify the structure of a device is a general incentive for any skilled person in any technical field and as such

cannot contribute to inventive step. The skilled person, when taking up the indication in D2 as to the use of the heart electrode HR for pacing as well as for transmitting and measuring the alternating signal, has to determine a suitable location for the necessary second electrode. Knowing from D2 that this electrode should be subcutaneously located and that it "can be placed in any suitable and non-critical position vis-à-vis electrode B keeping in mind that such position has to allow the detection of geometric variations of a part of the chest barely affected by the movements of the upper limbs of the patient" (cf. D2, page 6, lines 22 to 28), knowing further that the pacer housing could form one of the electrodes for measurement (cf. D2, page 6, lines 18 to 19), and being aware of the fact that the position of the pacer is as good a subcutaneous location as any other location in the patient's chest, the skilled person would have readily taken into consideration a replacement of the second electrode by the conductive housing.

3.1.4 For these reasons, the subject-matter of claim 1 does not involve an inventive step.
The main request is therefore not allowable.

3.2 (First) auxiliary request

3.2.1 The Board agrees with the respondent that a skilled reader of claim 1 would interpret the term "continuous alternating current signal" as referring to a continuous alternating current (e.g. of sinusoidal type) which periodically reverses its direction.

3.2.2 An alternating signal of this type is clearly

distinguished from the train of unipolar pulses constituting the alternating signal for measuring the respiration signal in the pacers according to D2 and D4. The objective problem associated with this additional difference over the prior art is to be seen in the desire to suppress polarization effects in the heart tissue as a result of the measurement of the respiration signal.

3.2.3 None of the available prior art documents provides any indication as to this specific problem.

Document D1 (cf. in particular Figure 1 with the corresponding description), although relating to a pacer having heart electrodes for measuring an impedance, is silent about any technical details concerning the signal to be used for measuring the impedance.

Document D5 (cf. in particular Figures 3 to 7 with the corresponding description), referred to in D1, discloses a specific structure of electrodes extending to the heart and being capable of defibrillation as well as sensing and monitoring, but does not mention impedance measurements at all.

The pacers disclosed by documents D2 and D4 comprise means for generating unipolar pulses to be transmitted to the electrodes for measuring the respiratory signal. There is no indication that these signals may not be optimal when one of the electrodes is formed by the pacing electrode going to the heart.

3.2.4 Thus, although the skilled person in the technical

field at issue, having the qualification of an electrical engineer, would have known about the theoretical possibility of measuring an impedance by means of a continuous alternating current signal, he would not have obtained from the available prior art documents any indication as to any advantageous effect this theoretical option could have for the solution of the aforementioned specific problem, which arises only if the pacing electrode is also used as one of the measuring electrodes.

In consequence, although the claimed solution might appear to be a straightforward choice between alternatives which are known as such, the Board does not see how the skilled person would have arrived at the claimed subject-matter without the benefit of hindsight.

3.2.5 For these reasons, the subject-matter of claim 1 is considered to meet the requirements of Articles 52(1) and 56 EPC.

Moreover, the Board is satisfied that the (first) auxiliary request as a whole complies with the requirements of the EPC and is thus allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

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

The Registrar: The Chairman:

M. Beer G. Davies