

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [X] To Chairmen
(D) [] No distribution

D E C I S I O N
of 23 April 2001

Case Number: T 0131/97 - 3.4.1

Application Number: 89300895.3

Publication Number: 0327292

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:

Minute volume rate-responsive pacemaker

Patentee:

TELECTRONICS N.V.

Opponent:

Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro
Berlin

Headword:

-

Relevant legal provisions:

EPC Art. 123(2), 54, 56

Keyword:

"Added subject-matter (no)"

"Novelty and inventive step - (yes) after amendment"

Decisions cited:

-

Catchword:

-



Case Number: T 0131/97 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 23 April 2001

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

Representative: Eisenführ, Speiser & Partner
Pacelliallee 43/45
D-14195 Berlin (DE)

Respondent: TELECTRONICS N.V.
(Proprietor of the patent) De Ruyterkade 58A
P.O. Box 837
NL-Curaçao (NL)

Representative: Hackett, Sean James
Marks & Clerk
Patent Attorneys
Alpha Tower
Suffolk Street Queensway
Birmingham B1 1TT (GB)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 25 November 1996
rejecting the opposition filed against European
patent No. 0 327 292 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
U. G. O. Himmler

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal, received on 30 January 1997, against the decision of the opposition division, despatched on 25 November 1996, rejecting the opposition against European patent No. 0 327 292. The appeal fee was paid on 30 January 1997. The statement setting out the grounds of appeal was received on 6 March 1997.
- II. The opposition had been filed against the patent as a whole on the basis of Article 100(a) EPC, in particular on the grounds that the subject-matter of claim 1 was not patentable within the meaning of Articles 52(1), 54 and 56 EPC.
- III. The opposition division held that the grounds of the opposition did not prejudice the maintenance of the patent as granted, having regard to the following documents:
- 01: US-A-4 702 253
- 02: EP-A-0 151 689
- 03: EP-A-0 249 824
- IV. Oral proceedings were held on 23 April 2001.
- V. The appellant requested that the decision under appeal be set aside, and that the patent be revoked in its entirety.

The respondent (patentee) requested that the decision under appeal be set aside and that the patent be

maintained on the basis of the following documents:

Claims: Nos. 1 to 6 as filed at the oral proceedings on 23 April 2001,

Description: columns 1 to 6 as filed at the oral proceedings on 23 April 2001, columns 7 to 13 of the patent as granted,

Drawings: Figures 1 to 3 and 4A to 4E of the patent as granted.

VI. The wording of claim 1 reads as follows:

"1. A rate-responsive pacemaker comprising a housing, means (18) for pulsing a patient's heart at a controlled rate, a two-electrode bipolar lead having a tip (10) electrode and a ring (12) electrode, the tip electrode for coupling said pulsing means to the patient's heart, means (14) for deriving a blood impedance signal, and means (28) for adjusting said controlled rate in dependence on the blood impedance signal, wherein said means (28) for adjusting said controlled rate is operative to control derivation of the blood impedance signal by periodically causing current pulses to flow between said ring electrode and a reference point (30) and causing the corresponding voltage across said tip electrode and said reference point to be determined, wherein the reference point is the housing."

Claims 2 to 6 are dependent on claim 1.

VII. The appellant's arguments may be summarised as follows:

Claim 1 as amended at the oral proceedings constituted an intermediate generalisation of the invention as originally disclosed, since it did not comprise all the features of the embodiment of Figure 1, and since, apart from some general statements on the functions of the pacemaker, the application as originally filed contained only this particular embodiment.

Furthermore, the subject-matter of claim 1 resulted from an obvious combination of the teachings of documents O1 and O3. If document O1 were taken as the closest prior art, it would be obvious to the skilled person wishing to adapt the pacemaker of O1 for use with a two-electrode lead to choose the tip electrode for sensing the voltage generated by the current pulses applied to the ring electrode for the determination of the blood impedance signal, since it was known from O3 to use the tip electrode for impedance measurement. On the other hand, if the skilled person were supposed to start from document O3 to develop a pacemaker for a two-electrode lead, the obvious choice for current sourcing would be the ring electrode, since it was known, for instance, from document O1 that the signal/noise ratio of the blood impedance signal improved when the current was sourced in the blood, and that application of a current to the tip electrode could induce arrhythmia in the patient. Hence, the claimed subject-matter did not involve an inventive step within the meaning of Article 56 EPC.

VIII. The respondent's arguments may be summarised as follows:

Documents O1 and O3 relied on different principles for determining the blood impedance signal. Only with

hindsight could elements of these two teachings be combined. Furthermore, the skilled person wishing to develop a rate-responsive pacemaker for a conventional two-electrode lead would be more likely to rely on technologies, such as shown in O2 and O3, which were already suited to be used with a two-electrode lead. Hence, the claimed subject-matter was patentable.

Reasons for the Decision

1. The appeal is admissible.

Admissibility of the amendments

- 2.1 Claim 1 differs from the independent claim as granted in that:

(a) it is now specified that the bipolar lead is "a two-electrode bipolar lead";

and in that:

(b) the following wording of the granted claim:

"characterised by measuring the voltage across said tip electrode and said reference point, wherein the reference point is the housing" (emphasis added)

is replaced by:

"and causing the corresponding voltage across said tip electrode and said reference point to be determined, wherein the reference point is the housing" (emphasis added).

- 2.2 The first amendment (a) aims at clarifying that the expression "bipolar lead" used in the claim as granted is meant to define a lead with only two electrodes and not just a lead comprising two electrodes which can be used in the bipolar pacing mode. It is not contested that this amendment finds support in the application as originally filed.
- 2.3 The second amendment (b) specifies that the voltage across the tip electrode and the reference point is related to the current pulses applied to the ring electrode for the purpose of determining the blood impedance signal, and that the determination of such signal, i.e. the application of current pulses and the detection of a corresponding voltage, is controlled by the "means 28".
- 2.4 According to the appellant, the application as originally filed contains only a general reference to means for deriving a blood impedance signal (cf. claim 1 of the application as originally filed) and a more specific embodiment (cf. Figure 1) comprising a controller 28 linked to different circuit blocks. However, since the originally filed documents do not explicitly disclose means 28 "causing the corresponding voltage across the tip electrode and the reference point to be determined", the above amendment (b) constitutes, in the appellant's opinion, an intermediate generalisation which offends against Article 123 (2) EPC.
- 2.5 The application as originally filed contains the following references to the "means 28" and to its functions relating to the determination of a blood

impedance signal:

- "All pacemaker logic is under control of controller 28 (which may include a microprocessor, although discrete blocks are shown in figure 3) " (page 8, lines 33 to 35);
- "The impedance measurement is made when controller 28 pulses conductor 20 and informs block 14 that a measurement is required" (page 9, lines 16 to 18);
- "The blood impedance is measured by block 14 determining the potential between tip electrode 10 and the case. Samples are derived at the rate of 20 per second, and digital samples are extended over conductor 22 to controller 28" (page 9, lines 23 to 27).

In other words, it is made unmistakably clear in the application as originally filed that all operations of the pacemaker, and, in particular, the determination of the blood impedance signal, are controlled by the controller 28, and that, therefore, such "means" is ultimately responsible for causing current pulses to flow between the ring electrode and the housing and for causing the voltage across the tip electrode and the housing to be determined.

- 2.6 Hence, the Board has no doubt that both amendments (a) and (b) are fully supported by the application as originally filed and, thus, admissible under Article 123 (2) EPC. Furthermore, since these amendments limit the scope of the granted independent claim, they comply with the requirements of Article 123 (3) EPC.

Novelty

3. None of the cited documents discloses a rate-responsive pacemaker comprising all the features recited in claim 1 and, therefore, the subject-matter of this claim is new within the meaning of Article 54 EPC.

Inventive step

- 4.1 The contested patent relates to a rate-responsive pacemaker which uses the "minute volume" (i.e. a measure of the amount of air breathed in as a function of time) as stress-related parameter for controlling the pacing rate of a patient's heart, whereby such minute volume is derived from a blood impedance signal.

The gist of the present invention consists essentially in using a conventional two-electrode lead, having a tip electrode and a ring electrode, and in determining a blood impedance signal indicative of the minute volume by passing current pulses between the ring electrode and the pacemaker's housing, and by measuring the corresponding voltage between the tip electrode and the housing.

- 4.2 The cited prior art documents O1, O2 and O3 show three different kinds of rate-responsive pacemakers which rely on the minute volume as control parameter.

The pacemaker according to O1 determines the minute volume from a blood impedance signal obtained by causing a current to flow from a first ring electrode to the housing, and by measuring the corresponding voltage between a second ring electrode and the housing. Hence, this pacemaker requires a special lead

having at least two ring electrodes for blood impedance measurement and a tip electrode for heart pacing and sensing.

In the pacemaker according to O2, the minute volume is determined by detecting variations in time of the electrical impedance of a part of the chest by means of two electrodes positioned subcutaneously.

The pacemaker shown in O3 requires only one electrode located within the heart (i.e. a tip electrode) both for pacing and for impedance measurement, with the housing as indifferent electrode for both functions. According to a first embodiment, an alternating current (AC) is supplied to the tip electrode together with the pacing pulses. The AC signal sensed at the tip electrode is sent to a demodulator which provides an output indicative of the blood impedance. According to a second embodiment, a respiratory signal is obtained by evaluating the decay of the pacing pulses.

4.3 As far as its structure and functions are concerned, the pacemaker shown in O1 comes closest to the present invention. In particular, the subject-matter of claim 1 differs from the pacemaker according to O1 essentially in that it comprises a two-electrode lead, and in that the voltage drop generated by the current pulses sourced at the ring electrode is measured across the tip electrode and the pacemaker's housing.

4.4 It could be argued, as pointed out by the appellant, that the skilled person, starting from O1 and wishing to adapt the pacemaker disclosed in this document to a conventional two-electrode lead, would have only to decide which of the two available electrodes should be

used for current sourcing and which for voltage sensing. According to the appellant, the skilled person's obvious choice would be to keep the current sourcing at the ring electrode, as suggested in O1 (column 4, lines 37 to 39: "the sensitivity and the signal/noise ratio are compromised if the current sourcing is done in the endocardium rather than in the blood") and to use the tip electrode both for pacing and voltage measurement, as shown in O3.

5.1 In the opinion of the Board, however, an essential question to be considered in the present case is whether the skilled person, confronted with the problem of developing a minute volume controlled pacemaker for use with a conventional two-electrode lead, would consider at all the possibility of adopting the technology disclosed in O1 for a lead with at least three electrodes, i.e. two ring electrodes and a tip electrode.

5.2 As to the determination of the minute volume on the basis of a blood impedance signal, document O1 teaches, *inter alia*, the following:

- "The volume of air in the lungs is related to a corresponding pressure called pleural pressure. The pleural pressure, in the pleural cavity, manifests itself in a change in the diameter of blood vessels in the immediate vicinity of the cavity. The blood in the vessels comprises a volume conductor, and its impedance is measured by establishing a known current field and measuring the voltage which develops in the field" (column 2, lines 21 to 29);

- "The impedance change which is due to respiration depends on the particular placement of the current source electrodes as well as the voltage sense electrodes" (col.2, lines 29 to 32);
- "Preferably, the current source is established between the blood in the right ventricle and the pacemaker case, and the voltage is measured between either the high atrium or the superior vena cava ("SVC") and the pacemaker case" (column 2, lines 32 to 36);
- "in general, the electrode used for the impedance measurement may range in position from the vicinity of the high atrium to 3-4 cm above the margin" (column 4, lines 28 to 31).

5.3 Hence, there is no suggestion in O1 that the impedance measurement may be carried out successfully if the voltage measurement takes place in the endocardium rather than in the blood flowing in, or in the vicinity of, the superior vena cava, as this is the case if the voltage generated by the current pulses is sensed by the tip electrode. On the contrary, O1 clearly indicates that the voltage measuring electrode should be located "above" the current sourcing electrode.

5.4 Even if O1 discloses most of the features of the present invention and, therefore, may be considered as the closest prior art, only with hindsight could it be assumed that a person skilled in the art would use this document as a starting point for a solution to the problem of determining the minute volume for a rate-responsive pacemaker with a conventional two-electrode lead. In the opinion of the Board, the skilled person

would be more likely to consider a prior art, such as O3, which requires only one electrode, or a technology (cf. D2) which does not involve the heart stimulation lead.

- 6.1 According to the appellant, document O3 would also enable the skilled person to arrive at the claimed subject-matter without the exercise of any inventive activity. Although this document teaches to use the same electrode for current sourcing and voltage determination, it would be obvious, in the appellant's view, to use both electrodes made available by a two-electrode lead, whereby the ring electrode would be the natural choice for current sourcing, since it is known, for instance, from O1 that a current applied to the tip electrode might induce arrhythmia in the patient, and that a more accurate measurement of the blood impedance signal can be obtained when the current is sourced in the blood.
- 6.2 However, the appellant's argument disregards the fact that the differences between the subject-matter of claim 1 and the disclosure of O3 go beyond the mere use of a bipolar lead instead of a unipolar lead. As pointed out above (see item 4.2), the pacemaker according to O3 determines a blood impedance signal on the basis of a substantially different technique consisting in feeding a continuous alternating current to an electrode and demodulating the signal picked up by the same electrode. Hence, in order to arrive at the claimed subject-matter, the skilled person starting from O3 would have to decide not only to use two electrodes instead of one but also to replace the impedance measurement of O3 with the one shown in O1. There is no suggestion in the prior art that such

modifications of the pacemaker shown in O3 should be regarded as obvious.

7. In summary, the Boards finds that the claimed pacemaker is not the result of a combination of the teachings disclosed in documents O1 and O3, and that, therefore, the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC.
- 8.1 For these reasons, claim 1 is considered to define patentable subject-matter. The dependent claims 2 to 6 relate to specific embodiments of the rate-responsive pacemaker of the invention and, therefore, their subject-matters also involve an inventive step.
- 8.2 The description on file is in accordance with the wording of the allowable claims.
9. Hence, the Board is satisfied that the respondent's request meets the requirements of the EPC.

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 department of the first instance with the order to maintain the patent on the basis of the following documents:

Claims: Nos. 1 to 6 as filed at the oral proceedings on 23 April 2001,

Description: columns 1 to 6 as filed at the oral proceedings on 23 April 2001, columns 7 to 13 of the patent as granted,

Drawings: Figures 1 to 3 and 4A to 4E of the patent as granted.

The Registrar:

The Chairman:

R. Schumacher

G. Davies