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D E C I S I O N
of 3 July 1996

Case Number: T 0769/93 - 3.4.1

Application Number: 84100570.5

Publication Number: 0114679

IPC: A61N 1/362

Language of the proceedings: EN

Title of invention:

Cardiac pacemaker having input/output circuit programmable for use with unipolar and bipolar pacemaker leads

Patentee:

TELECTRONICS N.V.

Opponent:

BIOTRONIK Mess- und Therapiegeräte GmbH & Co Ingenieurbüro Berlin

Headword:

Cardiac Pacemaker/TELECTRONICS N.V.

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step - yes"

"Allegation of lack of inventive step based on hindsight analysis"

Decisions cited:

-

Catchword:

-



Case Number: T 0769/93 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 3 July 1996

Appellant:
(Opponent)

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Respondent:
(Proprietor of the patent)

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Decision under appeal:

Interlocutory decision of the Opposition Division
of the European Patent Office dated 15 June 1993
concerning maintenance of European patent No.
0 114 679 in amended form.

Composition of the Board:

Chairman: G. D. Paterson
Members: R. K. Shukla
H. J. Reich

Summary of Facts and Submissions

- I. European patent No. 0 114 679 relating to a cardiac pacer was opposed on the ground that the subject-matter of the patent was not patentable under Articles 52 to 57 EPC (Article 100(a) EPC). The following prior art documents were cited in the notice of opposition:

D1= EP-A-0 030 897

D2= DE-A-2 944 631.

- II. By an interlocutory decision the Opposition Division maintained the patent in amended form in accordance with Article 102(3) EPC.

According to the above decision, the amended independent claim 1 as filed on 2 February 1993 fulfils the requirement of an inventive step for essentially the following reasons:

In the pacer according to the closest prior art disclosed in Document D1, the different operating modes are selected by a switchboard comprising a battery of twelve switches between the pacer leads and the input/output circuit of the pacer. In order to select a given mode of operation, a train of twelve bits is applied to the switchboard. According to the amended claim of the patent in suit, in which the switches connect the respective electrodes to ground, a considerably simpler operation is obtained by only three switches operated by three signals stemming from two mode control signals. This construction cannot be considered as equivalent to the switching arrangement of document D1, so that the pacer according to claim 1 includes an inventive step.

III The Opponent lodged an appeal against the above decision and requested that the patent be revoked in its entirety, because the claimed subject matter did not involve an inventive step with respect to document D1.

The Respondent (Patent Proprietor) requested that the appeal be dismissed.

IV. In an annex to summons to oral proceedings, the Board informed the parties that, as contended by the Appellant, the wording of claim 1 did not appear to exclude the use of more than three switches, and that the term "ground" in the claim appeared to be unclear having regard to the description according to which the "ground" referred to both i.e. to signal ground (+VB) and to system ground.

V. In its response, dated 31 May 1996, the Respondent submitted an amended set of 9 claims. Claim 1 of this set was subsequently replaced by Claim 1 filed with the letter dated 11 June 1996.

VI. During the Oral proceedings held on 3 July 1996, the Appellant reiterated its submissions concerning inventive step and additionally contended that the amended claim 1 did not fulfil the requirement of Article 123(3) EPC, since according to the text of claim 1 as granted the second switching means connects an electrode to ground in response to a second mode control signal, whereas according to the text of claim 1 which is now under consideration, a non-inverting input is connected to the ground in response to such a control signal.

The Respondent filed amended claims 1 to 8 during the oral proceedings, so as to overcome the objection under Article 123(3) EPC, and requested that the patent be maintained in amended form, on the basis of the following documents:

Description:

pages 2 and 2a, replacing page 2, lines 18 to 36 (until "sensing of") as granted;

pages 8 to 10, replacing page 3, line 42 to page 4, line 29 (until "connec...") as granted;

page 12, replacing page 4, lines 45 (from "signals") to line 61 (until "deve...") as granted;

page 14, replacing page 5, line 23 (from "bipolar") to line 41 (until "disconnect the") as granted;

all replacement pages filed on 4 November 1991.

The remainder of the description is in accordance with pages 2 to 6 as granted;

Drawings: Figures 1 to 7 as granted;

Claims: 1 to 8 as filed during the oral proceedings on 3 July 1996.

VII Independent claim 1 of this set of claims has the following wording:

"1. A cardiac pacer (10) being selectively operable in unipolar or bipolar pacing or sensing mode, comprising:

[a] a power source;

[b] a reference electrode means (27) adapted for electrical contact with the patient's body; and

[c] a first and a second pacer lead terminal means (20,21) for delivering pacing pulses to and obtaining sensing pulses from a heart to be stimulated, each of said pacer lead terminal means (20,21) including a cathode electrode (22,24) and an anode electrode (23,25);

[d] an input/output circuitry (26) coupling each of said pacer lead terminal means (20,21) to a control circuitry;

[e] a first and a second differential amplifier (37,48) being respectively provided for said first and second pacer lead terminal means (20,21), each of said amplifiers (37,48) having an inverting input (-) and a non-inverting input (+);

[f] a coupling means for connecting the respective cathode electrode (22,24) to said inverting input (-) and the respective anode electrode (23,25) to said non-inverting input (+);

[g] a switching means, consisting of

[g.1] a first switch (46) which, in response to an applied first mode control signal, is connecting the first anode electrode (23) to ground,

[g.2] a second switch (56) which, in response to an applied second mode control signal, is connecting the second anode electrode (25) to ground, and

[g.3] a third switch (63) which, in response to an applied third mode control signal, is connecting said reference electrode means (27) to ground; and

[h] mode control means being responsive to an applied mode designation signal for generating said first, second and third mode control signals so as to selectively condition the respective switch or switches between a conductive and a non-conductive state in order to provide unipolar or bipolar pacing or sensing at said terminal means (20,21)."

Claims 2 to 8 are dependent on Claim 1.

VIII. The Appellant did not maintain its objection under Article 123(3), to the above text of Claim 1.

The Appellant's submissions in respect of inventive step can be summarised as follows:

- (i) The technical aspects of the invention are not clear from claim 1 and the description in the following respects, so that any technical contribution by the invention over the state of the art is not clear:
 - (a) In the art of cardiac pacers, the system ground is normally not the same as the supply voltage as has been contended by the Respondent. Also, the use of the terms, "system ground" and "signal ground" in the description renders the use of the term, "ground" in the claim unclear.
 - (b) The operation of the operational amplifier in UNIP sensing mode shown in Figure 6 is not clear when the non-inverting input of the amplifier is grounded.

- (c) The wording in item (g) of the claim is not specific about the switches which are to be selectively operated to achieve different modes of operation.
- (d) Contrary to the submissions of the Respondent, the wording of claim 1 does not exclude the use of more than three switches for performing switching functions specified in the claim.
- (ii) Document D1 discloses a pacemaker with switching means shown in Figure 7, which enables the use of the pacemaker in, inter alia, the UNIP and BIP modes as shown in Figures 1 and 4. There is thus no real functional difference between the claimed subject matter and the pacemaker disclosed in document D1. The concept "ground" does not refer to a specific potential, so that an electrode at some fixed potential can be regarded as being connected to the ground potential. The only difference between the claimed subject matter and the pacemaker disclosed in document D1 is that in the former the reference electrode can be selectively connected to ground. However, in the field of electro-cardiography, connection of an unused electrode to ground is a commonly employed measure. Therefore, the claimed subject matter, in so far as it can be understood, does not involve an inventive step.

IX. The Respondent presented essentially the following arguments in support of its request.

In pacemaker circuits it is a normal practice to maintain both the system and signal ground at a positive potential. The skilled person therefore understands that the signals $+V_b$ and the "ground symbol" in the description refer to one and the same potential.

In the pacemaker of document D1, a matrix of twelve switches connects two pacer leads and the housing of the pacemaker to four input/output terminals of amplifiers. In the pacemaker of the present invention, on the other hand, only three switches are required to connect selectively the pacer electrodes and the reference electrode to **ground**. Also the reference electrode in document D1 is permanently connected to ground, whereas in the pacemaker according to the invention the reference electrode is only selectively connected to ground depending upon the mode of operation. Thus, the switch matrix of document D1 performs a function different from that of the switching means in the present invention, is complicated in its construction and is likely to suffer from cross-talk between the signals operating the switches. There is no hint in the prior art which would lead the skilled person to the claimed invention, and the allegation of lack of inventive step by the Opponent is based on an unacceptable hindsight analysis.

- X. At the conclusion of the oral proceedings it was announced that the decision of the Opposition Division is set aside and the case is remitted to the first instance with an order to maintain the patent with text and drawings as specified in paragraph VI above.

Reasons for the Decision

1. As mentioned in paragraph VIII above, the Appellant did not maintain its objection under Article 123(3) EPC to the text of claim 1 under consideration. In the Board's view the text of the claim does not violate Article 123(3) EPC.

In the present appeal, therefore, the only other issue to be decided is that of inventive step.

2. *Inventive step*

2.1 Interpretation of the wording of claim 1

2.1.1 In the description of the cardiac pacer in the patent in suit, reference is made to two ground terminals, i.e. signal ground (which is connected to pacer battery voltage $+V_B$) and system ground (represented in the drawings by the usual ground symbol; see, e.g. page 3, lines 53 to 56). The wording of the claim in feature (g), however, does not make any distinction between these two ground connections and simply refers to a "ground" to which first anode electrode, second anode electrode and a reference electrode means are selectively connected.

Moreover, in the description and drawings, the terms "signal ground" and "system ground" are not used consistently. Thus, for example, according to the UNIP pacing mode as described on page 4, lines 36 to 43 and as shown in Figure 7, and the BIP sensing mode as shown in Figure 4, the reference electrode 27 (pacer casing) is connected to the system ground. In contrast, in the pacer circuit as shown in Figure 3, this reference electrode 27 is connected to signal ground ($+V_B$) through a transistor 63.

The Board finds that the Respondent's submissions in this respect that in the art it is commonly known that the specific potential at which these two terminals are maintained is not crucial so that the two terminals may be at the same "ground" potential, is plausible. Also, in the Board's opinion, this interpretation explains the apparent inconsistencies in the description and the drawings, mentioned above.

2.1.2 In feature [g.1] of claim 1 under consideration, it is stated "a first switch (46), which in response to an applied first mode control signal, is connecting the first anode electrode (23) to ground". Similarly, second and third switches according to features [g.2] and [g.3] respectively, connect the second anode electrode and the reference electrode means, respectively, to ground.

In the Board's view, contrary to the submissions by the Appellant (see paragraph VIII(i)(d) above), the above wording makes it clear that between a respective electrode and the ground, there is only one switch which connects them in response to a mode signal. In all, there are only three switches which provide selective connections between the respective electrodes and the ground in response to respective mode signals. The wording of the claim "a switching means, **consisting of**" excludes that further switches are involved in the switching means as claimed.

2.2 Document D1 constitutes the closest prior art, and describes an implantable cardiac pacer (1) which is selectively operable in unipolar or bipolar pacing or sensing modes (see Figures 1 and 4 and the description on page 4, line 33 to page 6, line 26 and page 7, lines 13 to 16). The cardiac pacer is provided with a source of electricity (4), an electrically conducting casing (3), an electronic circuit (5) including input and output amplifiers (11,12; Figure 6), and pacer electrodes (8a,8b). A switching means (15) comprising a matrix of twelve switches (K1 to K12) is provided between the pacer electrodes (connected to terminals (Tea, Teb) of the switching means (15)) and the casing terminal (Tb) on one hand and input/output terminals (13a,13b,14a,14b) of the input and output amplifiers

(11,12) on the other (see Figures 6 and 7 and the description on page 5, lines 22 to 27; page 7, line 33 to page 8, line 11). A control means (16) supplying a train of bits (16) selectively operates switches (K1 to K12) to obtain various modes of operations as described with reference to Figures 1 to 4.

2.3 From the statement on page 5, lines 22 to 27 in document D1, in the Board's view, it is evident that the function of the switching means (15) is to provide connection of the pacemaker electrodes with the input/output terminals of the amplifiers, and not with the casing terminal (3). Moreover, the casing terminal is floating, since it is not derivable from document D1 that it is connected to any reference potential, i.e. to "ground" in the sense of the present invention. Consequently, in the pacemaker disclosed in document D1 there is no switch provided for a selective connection between the casing terminal, corresponding to the reference electrode means mentioned in claim 1 under consideration, and the ground. Nevertheless a connection between a first pacemaker electrode (9a or 9b) and the casing terminal (3) would be possible using the switching means (15). However, as can be seen from Figure 7 of document D1 such a connection can only be obtained through the simultaneous operation of **two switches**, (e.g. K4 and K8 for a connection between the electrode 9a and the casing terminal (3)). In contrast, as mentioned in paragraph 2.1.2 above, in the present invention, only **one** switch is provided for connecting a pacemaker electrode (i.e. anode) to ground.

Moreover, in the pacemaker disclosed in document D1, a matrix of 12 switches is needed for a single pair of electrodes provided for ventricular pacing and sensing.

This means that for a second pair of electrodes as in the present invention, a further matrix of 12 switches would be needed.

2.4 In view of the above differences in relation to the closest prior art, the objective problem underlying the present invention can be regarded as simplifying the switching means in the cardiac pacemaker of document D1.

2.5 The Board agrees with the Appellant that the pacemaker disclosed in document D1 requires a large number of switches since it provides additionally several modes of operation which are not possible in the cardiac pacer of the present invention, so that it would be obvious to the skilled person to dispense with some of the switches in document D1 for the limited number of modes of operation according to the present invention. Also, the Appellant's submission that in electro-cardiography it is a common practice to connect to ground an unused pacer electrode might well be true. Nevertheless, in the Board's opinion, even when using such a measure to simplify the switching arrangement of the closest prior art, the switching arrangement as claimed in the present invention consisting of only three switches and enabling the claimed modes of operations does not follow plainly and logically from the complex arrangement of switches in document D1. The allegation of lack of inventive step by the Appellant, is thus regarded to be based on a hindsight analysis, and is therefore not convincing.

2.6 It is evident from the above comparison of the claimed subject-matter with the disclosure in document D1 (see paragraphs 2.2 and 2.3 above) that the Board's positive assessment of inventive step does not rely on any details of the selective operation of the first, second and third switches for realising various modes of

operation. Therefore, the Appellant's submission (see paragraph VIII (i)(c)) that the wording in item (g) of the claim is not specific about the switches which are to be selectively operated to achieve different modes of operation is considered not to be relevant to the question of inventive step.

- 2.7 For the foregoing reasons, in the Board's judgement, the subject matter of claim 1 fulfils the requirement of inventive step according to Article 52(1) EPC within the meaning of Article 56 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 first instance with an order to maintain the European patent with the documents specified in section VI above.

The Registrar:

The Chairman:

M. Beer

G. D. Paterson