BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS | BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE | CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Publication in the Official Journal ~~Yes~~ / No

File Number: T 591/89

Application No.: 85 102 404.2

Publication No.: 0 160 801

Title of invention: Implantable medical device power source depletion indicators

Classification: A61N 1/368

D E C I S I O N
of 7 February 1991

Applicant: Medtronic, Inc.

Proprietor of the patent:

Opponent:

Headword:

EPC Art. 123(2) and 56

Keyword: "Inventive step (yes - after amendment)"

Headnote

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 591/89

D E C I S I O N
of the Technical Board of Appeal
of 7 February 1991

Appellant : Medtronic, Inc.
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Minneapolis Minnesota (US)

Representative : Polus, Camille
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Decision under appeal : **Decision of Examining Division 040 of the European Patent Office dated 5 April 1989 refusing European patent application No. 85 102 404.2 pursuant to Article 97(1) EPC**

Composition of the Board :

Chairman : G.D. Paterson
Members : H. Reich
U. Himmler

Summary of Facts and Submissions

I. European patent application 85 102 404.2 (publication number 0 160 801) is a divisional application in accordance with Article 75 EPC from the parent application 82 400 225.7 (publication number 0 058 603) and was refused by decision of the Examining Division.

II. In a communication, the Examining Division took the view that the subject-matter of Claim 1, received 4 March 1985, did not satisfy the requirements of Articles 52 and 56 EPC having regard to document

D1: US-A-3 661 158

and those of Article 123(2) EPC. The reason for the refusal was, however, based on Article 123(2) EPC only. The Examining Division was of the opinion that Claim 1 included the following features which were not disclosed in the application as filed:

(a) "a variable desired lower rate interval which controls the interval between a detected ventricular depolarization and the production of a subsequent atrial stimulation pulse", in part i;

(b) "means for providing a triggering signal for discharging the atrial capacitor at the end of said variable desired interval", in part ii, and

(c) "means ... to disable this detecting means (for detecting ventricular depolarizations) for a predetermined period of time extending from the time

when said atrial capacitor is discharged by said triggering signal", in part iii.

III. The Appellant lodged an appeal against this decision. With the grounds of Appeal, the Appellant filed an amended Claim 1 and argued inter alia that this new claim is adequately supported by the original disclosure and implies an inventive step in view of document D1, because in contradiction to the claimed invention in the prior art device

(a) there will nevertheless be produced atrial stimulation pulses even if naturally occurring P waves are sensed, and

(b) there is no programmable interval between an atrial stimulation and the production of a subsequent ventricular stimulation pulse. Thus, the prior art device does not store information representing the desired programmable interval between a detected P wave and the production of a subsequent ventricular stimulation pulse.

IV. In response to a communication of the Board of Appeal, inviting the Appellant to further amend Claim 1, in particular in order to satisfy Article 123(2) EPC with regard to the stored data "corresponding to a lower rate" and the fast recharge control signal being generated "to control the recharge cycle", the Appellant now requests that the contested decision be set aside and that a patent be granted on the basis of the following documents:

Claim 1 received 2 October 1990 with letter dated 28 September 1990;

Description: pages 1 to 3 and 6 to 26, line 18, according to EP-A-0 160 801; and
pages 4, 5, 5a received 2 October 1990 with letter dated 28 September 1990;

Drawings: pages 1/5 to 4/5 according to EP-A-0 160 801.

V. Claim 1 reads as follows:

"1. A programmable medical device including:

(a) an atrial output stage (14) for providing atrial stimulating pulses at a recurring rate interval, said output stage (14) including an atrial capacitor (134);

(b) means for detecting ventricular depolarizations (12);

(c) means for applying external programming signals to the programmable device for programming variable operational parameters and variable modes (32, 124, 126);

(d) programmable digital control means (18) including

(i) means for storing (Figure 2 - 212, 214) variable digital data derived from said externally applied programming signals corresponding to a lower rate at which the pulse generator will pace if neither P (atrial) waves nor R (ventricular) waves are sensed within the escape intervals established by said lower rate data and for storing the desired programmable interval between the production of

an atrial and a subsequent ventricular stimulation pulse (A-V interval);

(ii) means for providing (Figure 2 - 216, 218, 222, 224, APT, P-pace) an atrial pace initiate signal (PWA) to said atrial output stage (14) to initiate an atrial stimulating pulse if no naturally occurring P wave is sensed within the escape interval established by the lower rate data, the atrial stimulating pulse being the discharge of said atrial capacitor (134);

(iii) means for providing and applying a control signal (SVI, SV2), Figure 2b - 218, 220, 222, 86, 88) to the means for detecting ventricular depolarizations (12) to disable this detecting means for a predetermined period of time starting in timed relation to the generation of an atrial pace initiate pulse (PWA), so that the means for detecting ventricular depolarizations (12) cannot sense said atrial stimulation pulse and mistake it for a ventricular depolarization, and

(iv) means (Figure 2b - 224) for generating a fast recharge control signal (Figures 1b and 2b - FRV, 156) to control the recharge cycle."

Reasons for the Decision

1. The appeal is admissible.

2. **Article 123(2) EPC**

The three objections of the Examining Division mentioned in point II above have been removed by appropriate amendments:

2.1 Having regard to objection (a): In the current wording of part (i) of Claim 1 the causal interdependency between the lower pace rate and VA-interval is eliminated. Part (i) deals now with the storing of the lower rate data and of a different operating parameter, the AV-interval, both storages being independent from each other. The original description in the parent application discloses the storage of the lower pace rate on page 9, line 27, and that of the AV- (not VA as before) interval on page 9, lines 27-30.

2.2 Objection (b) is completely removed by the new wording of Claim 1. The initiation of the atrial stimulating pulse by the PWA-signal is disclosed on page 8, line 36 to page 9, line 11. The atrial demand pacing - i.e. if no natural P wave is sensed - is described on page 8, lines 11 to 16. The formation of the atrial stimulating pulse by discharge of the atrial capacitor (134) can be derived from page 15, line 32 to page 16, line 10; all text passages referring to the description of the parent application.

2.3 Having regard to objection (c): The explicit timed relation between the atrial pace initiate pulse (PWA) on the one hand and the disabling signals for the detector of ventricular depolarisations (SV1 and SV2) on the other hand has been replaced by the effect to be produced; see the new formulation in part (iii): "timed relation ... so that ...". The subject-matter of amended part (iii) is disclosed on page 13, lines 12 to 15 and 25 to 29 of the description of the parent application. The indication on page 24, lines 7-10, that after an atrial event the ventricular amplifier is blanked does - contrary to the opinion of the

Examining Division - not exclude that the disabling of the ventricular amplifier has already started a short time before the atrial event as derivable, in particular from page 13, lines 25-29 of the parent application.

2.4 Moreover, the amended wording of Claim 1 now clearly states that only one quantitative value of the lower pace rate is stored and that the fast recharge control signal (FRV 156) quite generally "initiates the recharge of the atrial capacitor" without specifying further details, which are not derivable from the original disclosure.

2.5 For the reasons stated above in points 2.1 to 2.4, the Board is convinced that Claim 1 - as well as the further application documents - in their present form satisfy Article 123(2) EPC.

3. **Novelty**

3.1 Document D1, the only document cited in the European Search Report, describes a programmable medical device including

(a) an atrial output stage (65', T9', T8', T7' in Figure of D1) for providing atrial stimulating pulses at a recurring interval (column 4, lines 35 to 37 of D1), said output stage including an atrial capacitor (65');

(b) means for detecting ventricular depolarisations (E1, E2, T1-T6 in Figure 1); and

(iii) means for providing and applying a control signal to the means for detecting ventricular polarisations to disable this detecting means for a predetermined period of time starting in timed relation to the generation of an atrial pace initiate pulse, so that the means for detecting ventricular depolarisations

cannot sense said atrial stimulation pulse and mistak it for a ventricular depolarisation (see column 11, lines 11-57 of D1).

3.2 Features (c), (d), (i), (ii) and (iv) of Claim 1 - see point V above - are not known from document D1.

3.3 Thus, the subject-matter of Claim 1 is considered novel in the sense of Article 54 EPC.

4. **Inventive Step**

4.1 Starting from document D1 the objective problem underlying Claim 1 is to further develop this known device, so that the A-V-interval can be programmed independently from the pace rate, the atrial stimulation can be suppressed when a naturally occurring P-wave is sensed, and the recharge of the capacitors producing the pulse energy can be separately controlled.

4.2 This problem is solved by features (i), (ii) and (iv) of Claim 1.

4.3 In the device known from document D1 there is no possibility to program the AV-interval independently from the pace rate (AA or VV-interval). In this known device a detected R-wave is transmitted via capacitor 53 (in Figure 1) simultaneously to the base of transistors T6 and T6'. Therefore, the time of atrial and ventricular stimulation is always related to the same preceding ventricular event; see also Figure 3 of D1 with the corresponding description.

4.4 In the known device the atrial stimulation cannot be suppressed when a natural P-wave occurs. Though document D1 mentions in column 6, lines 45-50 that a suppression of atrial stimulation might theoretically be possible, it also

states explicitly that it is "exceedingly difficult to detect the P-wave due to its small magnitude". However, above all, there is no hint in document D1 to shift the reference point for timing the ventricular stimulation from the last preceding **ventricular** event as in D1 to the last preceding **atrial** event as in Claim 1.

4.5 It follows from document D1, column 3, lines 64-67, column 4, lines 3-10 and Figure 1 that in the prior art device capacitors 65, 65' are always connected to batteries 3, 5 and 7 and are charged continuously. There is no possibility of a separate control.

4.6 In deciding the item of inventive step in addition to the possibility of externally programming the working parameters of the claimed device and the use of digital techniques (features (c) and (d) of Claim 1) taken into account by the Examining Division, additionally the differences over the device known from document D1 as indicated in points 4.3 to 4.5 above have to be taken into account. In the Board's view, these additional differences are not obvious to a skilled person. In particular, the Board is convinced that it cannot be expected from a skilled person to suppress atrial stimulation if a natural P-wave occurs and to use an atrial event for controlling ventricular stimulation (i.e. the combined use of the features mentioned in points 4.3 and 4.4) without being inventive.

4.7 Thus, the subject-matter of Claim 1 is considered to involve an inventive step in the sense of Article 56 EPC.

5. Hence, it follows that Claim 1 is 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 grant a European patent on the basis of the following documents:

Claim:	1, received 2 October 1990
Description:	pages 1 to 3 and 6 to 26, line 18 according to EP-A-0 160 801; and pages 4, 5, 5a, received 2 October 1990
Drawings:	pages 1/5 to 4/5 according to EP-A-0 160 801.

The Registrar: The Chairman:

P. Martorana G.D. Paterson