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D E C I S I O N
of 9 December 2004

Case Number: T 1038/01 - 3.4.1
Application Number: 91104263.8
Publication Number: 0453761
IPC: A61N 1/368
Language of the proceedings: EN

Title of invention:

Implantable intravenous cardiac stimulation system with pulse generator housing serving as optional additional electrode

Patentee:

CARDIAC PACEMAKERS, INC.

Opponent:

Biotronik GmbH & Co. KG

Headword:

-

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

"Added subject-matter (yes - all requests)"

Decisions cited:

T 0187/91

Catchword:

-



Case Number: T 1038/01 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 9 December 2004

Appellant I:
(Opponent)

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Appellant II:
(Proprietor of the patent)

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Decision under appeal:

Interlocutory decision of the Opposition
Division of the European Patent Office posted
26 July 2001 concerning maintenance of European
patent No. 0453761 in amended form.

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
H. K. Wolfrum

Summary of Facts and Submissions

I. The appellant I (opponent) and the appellant II (patentee) lodged appeals against the interlocutory decision of the opposition division, despatched on 26 July 2001, maintaining the European patent No. 0 453 761 in amended form.

The opponent filed the notice of appeal on 17 September 2001 and paid the prescribed fee on the same day. The corresponding statement of grounds of appeal was received on 30 November 2001.

The patentee's notice of appeal was received on 4 October 2001 and the prescribed fee was paid on the same day. The corresponding statement of grounds of appeal was received on 5 December 2001.

II. The opposition had been filed against the patent as a whole and based on the grounds of Articles 100(a) and (c) EPC.

III. In the contested decision, the opposition division held, *inter alia*, that the subject-matter of claim 1 of the patentee's main request was admissible under Article 123(2) EPC but it did not involve an inventive step within the meaning of Article 56 EPC.

IV. At the request of both parties, oral proceedings were held on 9 December 2004.

V. The opponent requested that the decision under appeal be set aside and the patent be revoked.

VI. The patentee requested that the decision under appeal be set aside and that the patent be maintained on the basis of the following:

Main Request: Claims 1 - 10 filed on 5 December 2001;

First Auxiliary Request: Claims 1 - 10 filed on 5 December 2001;

Second Auxiliary Request: Claims 1 - 6 filed on 5 December 2001;

Third Auxiliary Request: Claims 1 - 10 filed on 5 December 2001 and corresponding to the claims as allowed by the opposition division.

VII. Claim 1 according to the patentee's Main Request reads as follows:

"An implantable heart treatment system having anti-arrhythmia pacemaking, cardioversion, and defibrillation capabilities for maintaining proper function of the heart, said system comprising:

an implantable pulse generator means (18) for producing an anti-arrhythmia waveform;

a pulse generator housing (10,10') enclosing and containing said pulse generator means (18), said generator housing (10,10') including a conductive surface (14,14') electrically connected to said pulse generator means (18) for delivering electrical energy to the heart, said housing (10,10') being implantable proximate the heart with said conductive surface facing the heart;

a first electrode (28) being implantable in or about the heart and being electrically connected to said pulse generator (18);

a second electrode (29) being implantable in or about the heart and being electrically connected to said pulse generator (18);

characterised in that programmable switching means (16) are provided for directing said anti-arrhythmia waveform:

(i) upon a first condition of said heart, to at least one of said first (28) and second (29) electrodes and to said conductive surface (14,14') of said pulse generator housing (10,10');

(ii) upon a second condition of the heart directing said anti-arrhythmia waveform to said first (28) and second (29) electrodes and to said conductive surface (14,14') of said pulse generator housing (10,10'), said second condition being indicative of rapid ventricular tachycardia or fibrillation; and

(iii) upon a third condition of the heart to said first and second electrodes."

Claim 1 according to the First Auxiliary Request differs from claim 1 of the Main Request in that it further comprises the following features:

" and further characterised in that upon said second condition the pulse generator means (18) and the programmable switching means (16) are operable to apply a lower energy cardioverting waveform between the first and second electrodes (28,29) and said conductive surface (14,14') of said pulse generator housing (10,10') and, if the heart does not revert back to normal sinus rhythm, subsequently to apply a higher

energy defibrillation waveform between the first and second electrodes (28,29) and the conductive surface (14,14') of said pulse generator housing (10,10')."

Independent claim 7 according to the First Auxiliary Request differs from claim 1 of the Main Request in that the portion of the preamble relating to the first and second electrodes reads as follows:

"a transvenous lead (30) which is implantable in the heart and having first and second electrodes (28, 29), said first and second electrodes (28,29) being electrically connected to said pulse generator (18), wherein the first and second electrodes (28, 29) are arranged on the transvenous lead (30) such that the first electrode (28) is located at a distal position so as to be located in the right ventricle of the heart and the second electrode (29) is located at a proximal position so as to be located in the atrium or vena cava region of the heart,"

Claim 1 according to the Second Auxiliary Request corresponds to claim 7 of the First Auxiliary Request.

Claim 1 according to the Third Auxiliary Request corresponds to claim 1 of the First Auxiliary Request.

VIII. The arguments of the opponent may be summarised as follows:

The independent claims of all the patentee's requests related to an implantable heart treatment system comprising switching means for switching three different electrode configurations upon the occurrence

of three different heart conditions. The application as originally filed, however, neither disclosed nor suggested a three-stage switching operation. In fact, both claims 1 and 18 and the embodiments specified in the description (column 4, lines 7 to 42 of the published application) identified two possible heart conditions and explicitly referred to the selection of the appropriate electrode configurations on the basis of a first or a second heart condition.

As the independent claims of all requests were based on subject-matter which extended beyond the content of the originally filed application, they violated Article 123(2) EPC.

IX. The patentee argued essentially as follows:

The switching means specified in the independent claims of all requests were programmed to select one of the electrode configurations explicitly disclosed in claim 1 and claim 18 of the application as originally filed. The opposition division found that these claims did not relate to different embodiments and that it was permissible to combine their features.

In any case, the description from line 28 of column 3 to line 24 of column 4 disclosed to a skilled person the three electrode configurations specified in the claims. As to the disclosure of corresponding conditions of the heart, there was ample evidence in the originally disclosed application documents that the gist of the invention was to provide a programmable system which selected an appropriate electrode configuration in response to the detection of heart

signals indicative of a certain heart condition. The fact that the switching means could select one of three electrode configurations necessarily implied the detection of one of three heart conditions.

Furthermore, the "Summary of the Invention" at lines 48 to 52 of column 1 indicated that the present invention involved switching between different electrode configurations for different conditions of the heart. It did not indicate that only two different electrode configurations were possible. The skilled person reading the whole disclosure would "seriously contemplate" utilising three or more electrode configurations upon the occurrence of corresponding heart conditions. According to Decision T 187/91 a specific example which the skilled reader would seriously contemplate as a possible practical embodiment of the described invention was part of the content of the application as filed. In summary, the switching means recited in the independent claims of all requests did not constitute added subject-matter and therefore did not violate Article 123(2) EPC.

Reasons for the decision

1. The appeal is admissible.

- 2.1 The independent claims of all requests are directed to an "*implantable heart treatment system*" comprising, *inter alia*, programmable switching means for directing an anti-arrhythmia waveform as follows:

- (i) upon a first condition of the heart, to at least one of a first (28) and a second (29) electrode and to a conductive surface of the pulse generator housing;
- (ii) upon a second condition of the heart, to said first (28) and second (29) electrodes and to said conductive surface of said pulse generator housing, said second condition being indicative of rapid ventricular tachycardia or fibrillation; and
- (iii) upon a third condition of the heart, to said first and second electrodes.

2.2 It is uncontested that the application as originally filed does not explicitly disclose switching means for selecting one of three electrode configurations in response to one of three conditions of the heart. Thus, the essential question to be considered in the present appeal is whether this subject-matter finds implicit support in the originally filed documents.

3.1 Claim 1 as originally filed recites the second (ii) and third (iii) electrode configurations specified in the independent claims of all requests, whereas independent claim 18 of the original application covers the first (i) and the second (ii) electrode configurations.

As pointed out by the patentee, the opposition division found that the two embodiments identified in the specification of the original application differed only in features relating to the pulse generator housing electrodes (see Figures 2 and 4), and that, since

original claims 1 and 18 did not specify these distinguishing features, they had to relate to both embodiments. A combination of the features of these claims was therefore permissible.

Regarding the three conditions of the heart referred to in the independent claims of all requests, in the patentee's view, it was implicit from the whole disclosure that a certain electrode configuration had to be switched when a predetermined condition of the heart was detected. Even if there was no direct reference to a particular heart condition triggering the selection of a particular electrode configuration, it was implicit to the person skilled in the art that the whole point of having different electrode configurations was the possibility of treating different heart conditions. Thus, it was immediately clear to the skilled person that the disclosure of three electrode configurations in the original application documents implied the determination of three conditions of the heart.

- 3.2 The features at issue are specified as follows in claim 1 of the application as originally filed (emphasis added);

"switching means for directing said anti-arrhythmia waveform on the one hand, to said first and second electrodes upon a first condition of said heart, and on the other hand directing said anti-arrhythmia waveform to said first and second electrodes and to said conductive surface of said pulse generator housing upon a second condition of the heart."

Thus, the claim identifies "a first condition of said heart" and "a second condition of said heart" and two possible electrode configurations, whereby both configurations involve the first and second electrodes 28 and 29, but only one additionally includes the conductive surface of the pulse generator housing. As shown in Figures 2 and 4, an electrode configuration comprising or excluding the conductive surface of the pulse generator requires selective activation of the switch 16 which connects this surface to the pulse generator circuitry 18 (see column 3, lines 2 to 4 and lines 37 to 39).

Claim 18 as originally filed specifies the switching means as follows (emphasis added):

"switching means for directing said anti-arrhythmia waveform on the one hand, to at least one of said first and second electrodes and to said conductive surface of said pulse generator housing upon a first condition of said heart, and on the other hand directing said anti-arrhythmia waveform to said first and second electrodes and to said conductive surface of said pulse generator housing upon a second condition of the heart."

Thus, this claim identifies also two heart conditions and specifies two corresponding electrode configurations, both involving the conductive surface of the pulse generator housing. In other words, the switching means of the embodiment covered by claim 18 has only to switch between the first and second electrodes located in or about the heart. It does not have to selectively activate a switch for connecting the pulse generator circuitry 18 to the conductive

surface of the pulse generator, since this surface is always included in the two selected electrode configurations. Though the claim does not make use of reference signs, it is apparent that the only switching means disclosed in the application which can perform the function of selecting one of the two claimed electrode configurations is the "*programmable switch 18*" (see column 4, lines 33 to 37 of the application as originally filed).

3.3 In other words, an essential difference between the two embodiments covered by claims 1 and 18 is that the former requires only a programmable switch 16 for selectively connecting the conductive surface of the pulse generator housing to the pulse generator circuitry 18, whereas in the latter the programmable switch 18 is programmed to select one of the electrodes 28 and 29. In this embodiment, the switch 16 is not required for delivering the anti-tachycardia waveform to the selected electrode configuration because it is always active and, in effect, it could be replaced by a direct connection.

3.4 Thus, in the opinion of the Board, claim 1 and claim 18 of the originally filed application are indeed directed to different embodiments and thus do not recite different features of the same embodiments which, in principle, it would be permissible to combine into a single claim, as argued by the patentee and the opposition division.

4.1 As the originally filed claims do not provide sufficient support for the subject-matter under consideration, the question must be addressed whether a

person skilled in the art could derive this subject-matter directly and unambiguously from the description and drawings of the application as originally filed.

- 4.2 Figure 6 of the application as published shows a system comprising a lead implanted transvenously in the heart with a first electrode 28 in the right ventricle and second electrode 29 proximate the right atrium. When an arrhythmia is sensed and it is appropriate for an electrical shock to be delivered to the heart, the programmable switch 18 determines which electrodes are energised under control of circuitry 18. If the heart activity is slower or faster (bradycardia or tachycardia) than normal, "*the switch 16 is triggered so that the pulse generator circuitry 18 selects only electrode 28*" (see application as published: column 4, line 6 to line 14). As pointed out by the patentee, this electrode configuration, which relates to unipolar pacing, would necessarily involve the conductive surface of the pulse generator housing.

On the other hand, if the sensed activity is indicative of rapid ventricular tachycardia or fibrillation requiring higher energy stimulation, switch 16 is triggered so that the pulse generator circuitry selects both distal and proximate electrodes 28 and 29 as well as the electrode discharge surface 14 to discharge energy from the conductive walls of the housing 10 or 10' for generating a defibrillating electric field across the heart (*ibid*: column 4, lines 14 to 24).

In another alternative form, the programmable switch 18 may be programmed to select one of the electrodes 28 and 29 and the electric discharge surface 14 of the

pulse generator housing 10, whereby the choice between the electrodes 28 and 29 may be based on certain cardiac conditions (*ibid*: column 4, lines 33 to 42).

- 4.3 In other words, when describing in detail an embodiments, the application as originally filed distinguishes between a first condition of slow or faster heart activity (bradycardia or tachycardia), which is treated by pulses applied to one electrode located in the heart, and a second condition of rapid ventricular tachycardia or fibrillation, which requires delivery of electrical energy across the heart and thus the application of an electrical discharge between the cardiac electrodes 28 and 29 and the conductive surface of the pulse generator housing.

As to the "*alternate form*" referred to in the description at lines 33 to 42 of column 4, which involves the selection of one of the electrodes 28 and 29 and the delivery of the charge between one of these two electrodes and the housing, it is open to question whether it is suggested as an alternative to a first electrode configurations ("*only electrode 28*" and the conductive wall of the pulse generator housing) or to the second electrode configuration ("*both distal and proximal electrodes 28 and 29*" and the conductive wall of the pulse generator housing). In any case, also this alternative embodiment involves the pulse generator housing as electrode and therefore does not identify the third electrode configuration specified in the claims under consideration.

4.4. According to the patentee, the third electrode configurations finds support not only in claim 1 of the application as originally filed but also in the passage of the description which specifies that the switch 16 "is selectively activated to include or exclude the conductive surface of side wall 12 from the discharge sequence" (application as published: column 3, lines 37 to 39). As argued by the patentee, the fact that the switch may exclude the conductive surface of the housing necessarily implies for the skilled person that the discharge sequence must be applied to the two electrodes located in the heart. The description, however, does not specify that this electrode configuration should be adopted when "a third condition of the heart" is detected. On the contrary, the wording of the originally filed claim 1 appears to suggest that the bipolar stimulation provided by this electrode configuration constitutes an alternative to the unipolar stimulation according to claim 18, which should also be selected upon detection of "a first condition of the heart".

4.5 In summary, though the application as originally filed may be interpreted as covering three possible electrode arrangements, it does not necessarily suggest to the skilled reader an implantable heart treatment system with a programmable switching means for selecting one of the three electrode configurations in response to the detection of one of three heart conditions.

5.1 The patentee referred to T 187/91 (OJ 1994, 572) and argued that the present case was similar and that the present Board should also arrive at the same conclusions.

According to T 187/91 (see headnote), "*A specific example within a generic disclosure forming part of the description of the invention in an application as filed is part of the content of the application as filed for the purpose of Article 123 (2) EPC if the skilled reader would seriously contemplate such specific example as a possible practical embodiment of the described invention, having regard to its context in the remainder of the application as filed, and subject to any understanding of the skilled reader to the contrary*".

Since the skilled reader of the present application would seriously contemplate, as a possible practical embodiment of the described invention, an embodiment having switching means for selecting three different electrode arrangements upon the occurrence of corresponding heart conditions, the independent claims on file did not infringe Article 123(2) EPC.

- 5.2 In the opinion of the Board, however, the case considered in T 187/91 is essentially different from the present one.

In T 187/91 the appellant requested the grant of a patent for a fibre optic amplifier. The claims in the application as filed referred to "*a plurality of pump light sources*", ie two or more light sources; the amended claims referred to "*a pump light source*" and, thus, sought protection for a fibre optic amplifier including one or more light sources. The invention and its preferred embodiment were described throughout the application as filed as having more than one light

source. However, in one occasion, it was stated in the description that "*Further, while the drawings show three such light sources 60 mounted on the cone-shaped rod 50, it will be understood that more or less sources 60 may be utilised*" (see item 3.3 of the decision). The board noted that, in the absence of such sentence, there would be nothing in such content to indicate expressly the possibility of using only one light source when getting out of the invention (see item 4.) However, this sentence was a generic statement that the preferred embodiment of the invention might include any number of light sources either more or less than three, including only one light source. In the board's view, this sentence indicated that the writer of the application as filed was aware of the fact that the invention could be carried out with only one light source.

- 5.3 In the present case, however, there is no generic statement to the effect that each one of the possible electrode configurations should be selected in response to a corresponding different condition of the heart and that an implantable heart treatment system could be provided with switching means which operates accordingly. On the contrary, there is a clear indication that the switching means are intended to respond only to two different heart conditions: *ie* to a first heart condition demanding unipolar or bipolar electric stimulation and to a second heart condition requiring the delivery of an electric shock across the heart. Furthermore, there is no indication that the switching means should be programmed to automatically select between unipolar and bipolar stimulations in response to different heart conditions. As far as the

disclosure is concerned, such unipolar or bipolar pacing could indeed be pre-selected in accordance to the general pathology of the patient's heart.

Summarising, the Board sees no reason to assume that a person skilled in the art would seriously contemplate, as a possible practical embodiment of the described invention, a heart treatment system comprising the switching means specified in the independent claims of all the patentee's requests.

- 6.1. In the result, the Board finds that all the independent claims of the patentee's requests comprise subject-matter extending beyond the content of the application as originally filed (Article 123(2) EPC).

- 6.2 As none of the patentee's requests is admissible under Article 123(2) EPC, the patent has to be revoked.

Order

For these reasons it is decided that:

1. The appeal of the patentee is dismissed.
2. The decision under appeal is set aside.
3. The patent is revoked.

The Registrar:

The Chairman:

R. Schumacher

G. Davies