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D E C I S I O N
of 7 August 2003

Case Number: T 0122/99 - 3.4.1

Application Number: 91307243.5

Publication Number: 0526671

IPC: A61N 1/05

Language of the proceedings: EN

Title of invention:
Unitary intravascular defibrillating catheter with separate bipolar sensing

Patentee:
CARDIAC PACEMAKERS, INC.

Opponent:
Biotronik Mess- und Therapiegeräte GmbH & Co. Ingenieurbüro Berlin

Headword:
-

Relevant legal provisions:
EPC Art. 100(a), 56

Keyword:
"Opposition grounds - lack of patentability"
"Inventive step - no"

Decisions cited:
-

Catchword:
-

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Case Number: T 0122/99 **-** 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 7 August 2003

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 21 December 1998 rejecting the opposition filed against European patent No. 0526671 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: G. Davies
Members: G. Assi
M. G. L. Rognoni

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 28 January 1999, against the decision of the opposition division, dispatched on 21 December 1998, rejecting the opposition against the European patent No. 0 526 671. The fee for appeal was paid on 28 January 1999. The statement setting out the grounds of appeal was received on 29 April 1999.

II. Opposition had been filed against the patent as a whole and was based on Article 100(a) EPC, on the ground that the claimed subject-matter did not involve an inventive step (Article 56 EPC). Moreover, the opposition division allowed a late-filed ground for opposition under Article 100(b) EPC.

In the decision under appeal, the opposition division held that the mentioned grounds for opposition did not prejudice the maintenance of the patent unamended, having regard *inter alia* to the following documents:

(D1) US-A-4 614 192,
(D2) JACC Vol. 11, No. 2, February 1988, pages 365-370, Roger A. Winkle *et al*, "*Comparison of Defibrillation Efficacy in Humans Using a New Catheter and Superior Vena Cava Spring-Left Ventricular Patch Electrodes*", and
(D4) US-A-4 603 705.

III. In the statement setting out the grounds of appeal, the appellant did not maintain the ground for opposition under Article 100(b) EPC.

IV. With a letter dated 8 April 2003, the parties were summoned to oral proceedings. A time limit was set for filing any comments, amended documents or requests.

By letter dated 4 July 2003, the respondent (patent proprietor) informed the Board that it had decided not to be represented at the forthcoming oral proceedings and that it did not intend to make any further written submissions within the set time limit.

Oral proceedings were held on 7 August 2003.

V. The appellant requested that the decision under appeal be set aside and the patent be revoked in its entirety.

VI. The respondent requested in writing that the appeal be dismissed.

VII. Claim 1 of the patent as granted reads as follows:

"An intravascular cardioversion apparatus comprising an elongate flexible, dielectric catheter body (18; 120; 191); first and second sensing electrodes (20, 22; 122, 124; 205, 207) mounted at a distal end region of the catheter body, said second sensing electrode being spaced apart proximally of the first sensing electrode by a predetermined first distance; first and second flexible conductors (56, 60; 128, 130) connected to the first and second sensing electrodes respectively, for transmitting electrical pulses between said first and second sensing electrodes respectively and a pulse-sensing means (80) near a proximal end region of the catheter body; a first stimulating electrode (24; 142, 195) mounted on the catheter body at said distal end

region; a second stimulating electrode (26; 144; 193) mounted on said catheter body proximally of said first stimulating electrode and spaced apart from the first stimulating electrode; a said sensing electrodes (20, 22; 122, 124; 205, 207), first and second conductors (56, 60; 128, 130) and sensing connector means (46, 52, 54, 62) forming part of a cardiac sensing circuit, a third (44; 152) flexible conductor connected to the first stimulating electrode for conducting electrical pulses between the stimulating electrodes and a cardioversion pulse generating means (72) proximate said proximal end of the catheter body;

characterised in that a fourth flexible conductor (50, 154) is connected to the second stimulating electrode for conducting electrical pulses between the stimulating electrodes and a cardioversion pulse generating means (72) proximate said proximal end of the catheter body and said stimulating electrodes (24, 26; 142, 144; 193, 195) third and fourth conductors (44, 50; 152, 154) and cardioversion pulse generating means (72) form part of a cardioversion circuit electrically isolated from said sensing circuit, and in which the first and second stimulating electrodes (24, 26; 142, 144; 193, 195) are utilized as a cardioversion electrode pair;

in that each of said first and second stimulating electrodes (24, 26; 142, 144; 193, 195) has a surface area at least three times the surface area of each of the first and second sensing electrodes (20, 22; 122, 124; 205, 207); and

in that each of the sensing electrodes is spaced apart from each of the stimulating electrodes by a selected second distance so as to isolate tissue

proximate and between the stimulating electrodes from tissue adjacent the sensing electrodes."

Claim 4 of the patent as granted reads as follows:

"*An intravascular cardioversion apparatus comprising an elongate, flexible and dielectric sensing catheter body (160); first and second sensing electrodes (168, 170) mounted at a distal end region of the sensing catheter body and the second sensing electrode spaced apart proximally from the first sensing electrode by a first predetermined distance; first and second flexible conductors connected to the first and second sensing electrodes respectively, for transmitting electrical pulses between the sensing electrodes and a pulse-sensing means electrically coupled by a sensing connector means near a proximal end region of the sensing catheter body, said sensing electrodes, first and second conductors, sensing connector means and pulse-sensing means forming part of a cardiac-sensing circuit; a first stimulating electrode (178); a second stimulating electrode (176) disposed proximally of and spaced apart from the first stimulating electrode; a flexible third conductor connected to the first stimulating electrode;*

characterised in that a fourth conductor is connected to the second stimulating electrode, the third and fourth conductors being for transmitting electrical pulses between the stimulating electrodes (178, 176) and a cardioversion pulse-generating means; said stimulating electrodes, said third and fourth conductors and cardioversion pulse generating means forming part of a cardioversion circuit utilizing the

first and second stimulating electrodes as a cardioversion electrode pair; and

in that the cardioversion apparatus further comprises an elongate, flexible and dielectric cardioversion catheter body (162) having a proximal end region and a distal end region, said first and second stimulating electrodes being mounted to said cardioversion catheter body with said first stimulating electrode being mounted near the distal end region; and

in that the cardioversion apparatus includes means for mounting said sensing catheter body and stimulating catheter body with their respective sensing electrodes (168, 170) and stimulating electrodes (178, 176) in spaced relationship to each other, with each of the sensing electrodes separated from each of the stimulating electrodes by a selected second distance so as to isolate tissue proximate and between the stimulating electrodes from tissue adjacent the sensing electrodes."

Claims 2, 3 and 5-26 are dependent.

VIII. The appellant essentially argued as follows:

Claim 4 of the patent as granted covered the embodiment of an intravascular cardioversion apparatus comprising a sensing catheter body and a separated cardioversion catheter body (see Figure 5).

Document D1 disclosed an intravascular cardioversion apparatus comprising a bipolar sensing catheter and a pair of stimulating electrodes, sensing and cardioversion taking place at separated locations. One

of the stimulating electrodes was a patch electrode to be implanted by means of surgery.

According to document D2, ventricular defibrillation could be achieved by means of a "*single*" transvenous catheter positioned with the distal electrode at the right ventricular apex and the proximal electrode at the right atrial junction of the superior vena cava. Starting from the arrangement known from D1, the replacement of the pair of stimulating electrodes by the defibrillating catheter mentioned in D2 would avoid the disadvantage of having to resort to surgery for implanting the patch electrode and would lead to the claimed subject-matter.

IX. The respondent essentially argued in writing as follows:

Document D1 taught to use two intravascular catheters, one having two sensing electrodes whereas the other one was provided with one electrode only, which in combination with an external patch electrode was used for stimulation. With regard to Figure 1, the stimulating electrode 20 was also used for PDF sensing. Thus, in document D1, the lack of a clear and consequent separation between sensing circuit and stimulation circuit lead away from claim 4 of the patent as granted.

Document D2 showed in Figure 1B a defibrillator arrangement with a single intravascular catheter having three electrodes, which in pairs were used for sensing and stimulating. According to Figure 1A, the arrangement comprised only one intravascular catheter, thus giving no hint at the solution that two of them

could be used with an electrode separation according to claim 4.

Reasons for the decision

1. The appeal is admissible.

2. *Claim 4 of the patent as granted*

2.1 Claim 4 relates to an intravascular cardioversion apparatus including a sensing catheter body and a cardioversion catheter body. The wording of the claim covers an embodiment (see Figure 5) in which the sensing catheter body and the cardioversion catheter body are separately implantable. Indeed, the claimed features are followed by reference signs relating to Figure 5 which concerns an alternative embodiment of the invention comprising two leads separately implanted in the heart (see the patent specification, column 5, lines 6 to 8).

2.2 Document D1 is considered to represent the closest prior art document.

This document (see Figures 1, 5) discloses an implantable cardiac defibrillator having sensing means for detecting the occurrence of abnormal cardiac rhythms and for automatically issuing defibrillation pulses in response thereto (see column 2, lines 30 to 35).

Different electrodes are connected to the patient's heart. Bipolar sensing is achieved by a catheter 18

including a distal tip electrode 303 and a proximal ring electrode 304, both placed in the right ventricle (see column 12, lines 6 to 44). Cardioversion is achieved by an electrode 20 located in the superior vena cava and a patch electrode 22 placed at the apex of the heart (see column 4, lines 15 to 28). Furthermore, the electrode 20 is connected to a PDF analysis circuit to monitor ventricular rate on the basis of a probability density function (PDF) (see column 1, lines 33 to 38, and Figure 1.

2.2.1 Having regard to the foregoing and using the wording of claim 4, document D1 (see Figures 1 and 5) relates to an intravascular cardioversion apparatus comprising the following features:

- an elongate, flexible and dielectric sensing catheter body 18,

- first and second sensing electrodes 303, 304 mounted at a distal end region of the sensing catheter body 18, the second sensing electrode 304 being spaced apart proximally from the first sensing electrode 303 by a first predetermined distance,

- first and second flexible conductors 308, 307 connected to the first and second sensing electrodes respectively, for transmitting electrical pulses between the sensing electrodes and a pulse-sensing means 30 electrically coupled by a sensing connector means 310 near a proximal end region of the sensing catheter body,

- the sensing electrodes, first and second conductors, sensing connector means and pulse-sensing means forming part of a cardiac-sensing circuit,

- first and second stimulating electrodes 22, 20,

- third and fourth flexible conductors connected to the first and second stimulating electrodes respectively,

- the third and fourth conductors transmitting electrical pulses between the stimulating electrodes and a cardioversion pulse-generating means 34,

- the stimulating electrodes, third and fourth conductors and cardioversion pulse-generating means forming part of a cardioversion circuit utilizing the first and second stimulating electrodes as a cardioversion electrode pair,

2.2.2 The skilled person reads the disclosure of D1 regarding the arrangement of the electrodes in the light of its technical knowledge. In particular, the skilled person knows that "*Following cardioversion, the tissue in the area immediately adjacent the discharge electrodes at least temporarily loses a substantial portion of its ability to conduct electrical impulses due to the high energy just applied to the area. Full recovery most often results, but there is a time when electrical conduction suffers. This phenomenon deleteriously impacts on the sensing capability of the prior art devices which sense and cardiovert from the same two*

electrodes, at least at a time when sensing is of utmost importance." (see document D4, column 3, lines 23-33, as well as the patent in suit, column 2, lines 21-32). Thus, considering that document D1 underlines the importance of R-wave detection since "*the ability to detect the R-wave with the utmost accuracy is vital to the proper and efficient operation of the implantable defibrillator device*" (see column 2, lines 1 to 4), the skilled person will understand that the electrode arrangement, as disclosed by D1 (see, in particular, Figure 1), provides separated locations, at which sensing and cardioversion take place.

It follows that document D1 relates to an intravascular cardioversion apparatus also comprising the following feature of claim 4 (using the wording of this claim):

- the cardioversion apparatus including means for mounting the sensing catheter body, *ie* the respective sensing electrodes, and the stimulating electrodes in spaced relationship to each other, each of the sensing electrodes being separated from each of the stimulating electrodes by a selected second distance so as to isolate tissue proximate and between the stimulating electrodes from tissue adjacent the sensing electrodes.

2.3 Thus, the subject-matter of claim 4 differs from the cardioversion apparatus according to document D1 in that:

- the cardioversion apparatus comprises an elongate, flexible and dielectric cardioversion catheter

body having a proximal end region and a distal end region,

- the first and second stimulating electrodes being mounted to the cardioversion catheter body, the first stimulating electrode being mounted near the distal end region and the second stimulating electrode being disposed proximally of and spaced apart from the first stimulating electrode.

In other words, in the claimed cardioversion apparatus the defibrillating electrodes are included in a cardioversion catheter body (just as the sensing electrodes are included in a sensing catheter body), whereas in the cardioversion apparatus known from document D1 the two defibrillating electrodes are separately implanted, one in the right ventricle and the other one, the patch electrode, externally at the apex of the heart.

2.3.1 According to the respondent, a difference between the claimed invention and the teaching of document D1 would consist in that there is no clear and consequent separation between sensing circuit and stimulation circuit in the known cardioversion apparatus because, with regard to Figure 1, the stimulating electrode 20 is also used for PDF sensing.

This argument is not convincing because claim 4 does not exclude the possibility that one of the stimulating electrodes may also be used for PDF sensing or any other additional function.

2.4 As already stated, the cardioversion electrode pair according to D1 consists of a spring electrode located in the superior vena cava and a patch electrode placed at the apex of the heart. It is known that such a system including a patch electrode is usually required in special situations in which high cardioverting energy is necessary (see document D4, column 7, lines 21 to 24). Moreover, the known system requires "*a greater degree of skill and effort for implantation*" (see the patent in suit, column 9, lines 18 to 24) because the patch electrode has to be connected to the myocardium by means of surgery.

Therefore, the novel features of claim 4 solve the problem of achieving an intravascular low-energy cardioversion apparatus in which the cardioversion electrode pair can be easily implanted. Indeed, according to the claimed invention, a low-energy cardioversion catheter body is used instead of two separated electrodes, one of which is a patch electrode.

2.5 Document D2 (see page 368, right-hand column, "*Previous catheter defibrillation investigations*", first paragraph) refers to articles in the relevant technical literature concerning implantable cardioversion systems. These articles demonstrate the feasibility and effectiveness of low-energy transvenous catheter defibrillation in humans. In particular, episodes of ventricular fibrillations were terminated by means of a "*single*" transvenous catheter positioned with the distal electrode at the right ventricular apex of the heart and the proximal electrode at the right atrial junction of the superior vena cava, *ie* the same

positions mentioned for the stimulating electrodes in document D1.

2.6 Thus, it would be obvious to the person skilled in the art to consider replacing the cardioversion electrode pair according to D1 with the transvenous cardioversion catheter known from document D2 in order to solve the stated problem.

In this respect, it is noted that, according to an embodiment of the invention disclosed in the application documents underlying the patent in suit (see column 10, lines 18 to 23), a patch electrode is secured to myocardial tissue and used "*in lieu of*" one of the stimulating spring electrodes, "*if desired*", *ie* when high cardioverting energy is needed. This arrangement, which corresponds to the pair of stimulating electrodes according to document D1, is thus presented as an alternative to the cardioversion catheter (see D2) to be used for low-energy cardioversion.

2.7 In view of the foregoing, the subject-matter of claim 4 of the patent as granted lacks inventive step having regard to the combination of documents D1 and D2.

3. It follows that the ground for opposition mentioned in Article 100(a) EPC together with Article 56 EPC prejudices the maintenance of the European patent.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The European patent is revoked.

The Registrar: The Chairman:

R. Schumacher G. Davies