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Datasheet for the decision of 17 March 2010

Case Number: T 1738/06 - 3.4.01

Application Number: 01968281.4

Publication Number: 1363697

IPC: A61N 1/05

Language of the proceedings: EN

Title of invention:
Coronary viens lead for pacing or sensing

Applicant:
CARDIAC PACEMAKERS, INC., et al

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
EPC Art. 56

Keyword:
"Amendments - added subject-matter (no)"
"Inventive step - (yes) after amendment"

Decisions cited:
-

Catchword:
-

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Case Number: T 1738/06 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 17 March 2010

Appellant: CARDIAC PACEMAKERS, INC.
4100 Hamline Avenue North
St. Paul, Minnesota 55112 (US)

Representative: Peterreins, Frank
Fish & Richardson P.C.
Highlight Business Towers
Miles-van-der-Rohe-Strasse 8
D-80807 München (DE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 18 May 2006 refusing European patent application No. 01968281.4 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: B. Schachenmann
Members: F. Neumann
H. Wolfrum

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division dated 18 May 2006 to refuse the European patent application number 01 968 281.4.

II. The appellant requests that the decision be set aside and that a patent be granted on the basis of claim 1 as filed during the oral proceedings of 29 May 2009, description pages filed with letter of 05 March 2010 and the figures as published.

III. Claim 1 of the sole request reads as follows:

"A lead (2000) for pacing and/or sensing a heart from within the coronary vasculature, the lead comprising:
a lead body (2006) having a proximal end (2034), a distal end (2002) and an intermediate portion extending therebetween;
a preformed biased portion (2030) located at the intermediate portion (2004) of the lead body, the preformed biased portion (2030) having a helical shape;
an unbiased portion (2010, 2032) extending between said preformed biased portion (2030) and said distal end (2002);
a connector (110) located at the proximal end of said lead body (2006);
at least one conductor (2020) disposed within said lead body (2006) and adapted to carry signals; and
electrodes (2036) disposed on said lead body (2006) along said biased portion (2030) so as to be urged towards said wall of said coronary vasculature and coupled with said at least one conductor (2020), the electrodes (2036) being disposed along the helical

shape, wherein the electrodes on the helical shape are spaced 120 degrees apart;
wherein said unbiased portion (2010, 2032) comprises an elongate flexible tapered tip portion (2012), said tapered tip portion being significantly more flexible than said preformed biased portion (2030) and having an outer diameter that tapers continually along its length to reduce the outer diameter towards said distal end (2002)."

IV. During the proceedings, the following documents pertinent to the structure of pacing leads were taken into account:

D1: US-A-5 871 531,
D2: US-A-6 021 354,
D3: EP-A-0 919 254,
D5: US-A-5 476 498.

V. The arguments of the appellant, insofar as they are relevant for the present decision, can be found below in the reasons for the decision.

Reasons for the Decision

1. Reference is made to the transitional provisions for the amended and new provisions of the EPC, from which it may be derived which Articles of the EPC 1973 are still applicable to the present application and which Articles of the EPC 2000 shall apply.

2. Amendments - Article 123(2) EPC

2.1 The subject matter of claim 1 of the main and only request may be derived from claims 20, 25 and 26 of the application as originally filed, supplemented by details derivable from originally filed page 1, lines 7-8; page 6, lines 12-16; page 10, lines 11-12; page 11, lines 3-8, page 12, lines 13-16; and page 23, lines 28-29.

The Board is satisfied that the requirements of Article 123(2) EPC are fulfilled.

3. *Inventive step - Article 56 EPC 1973*

3.1 In the present case, D3 is considered to represent the closest prior art.

3.1.1 D3 discloses a lead 100 for pacing and/or sensing a heart from within the coronary vasculature (Figures 1 and 9; column 3, lines 9-13; column 4, lines 54-57; column 5, lines 14-18) the lead comprising:
a lead body 100 having a proximal end 203, a distal end 911 and an intermediate portion extending therebetween (Fig. 2);
a preformed biased portion 202 located at the intermediate portion of the lead body (the portion 202 is "preformed" into a straight portion which includes a tine 102 and exhibits a certain bias since its stiffness means it will adopt its preferred form, as exemplified by the fact that the stiffness of this portion allows the lead to be wedged into position);
an unbiased portion (moulded nose 110: column 5, lines 30-33, 51-54) extending between said preformed

biased portion 202 and said distal end (Fig. 2; column 6, lines 12-17);
a connector located at the proximal end of said lead body (column 7, lines 7-10);
at least one conductor 112-115 disposed within said lead body and adapted to carry signals (Figs. 3 to 6; column 7, lines 19-52); and
electrodes 104 (erroneously appearing as 164 in Figs. 2 and 10), 103, 101 disposed on said lead body along said biased portion 202 so as to be urged towards said wall of said coronary vasculature (Figures 1, 7A, 7B, 9; column 7, line 55 to column 8, line 11) and coupled with said at least one conductor (column 7, lines 19-52);
wherein said unbiased portion comprises an elongate flexible tapered tip portion 110 (Fig. 2; column 5, lines 30-33, 51-54), said tapered tip portion being significantly more flexible than said preformed bias portion (column 6, lines 12-17, 53-58) and having an outer diameter that tapers continually along its length to reduce the outer diameter towards said distal end (Fig. 2; column 6, lines 17-20).

3.1.2 A first glance at Figures 1 and 2 of D5, which was cited in the search report, may suggest that the lead of D5 should perhaps be taken as the closest prior art. However, on closer inspection, a number of differences between the lead of D5 and that defined in current claim 1 become clear. The tip of D5 has the same internal structure as the preformed helical biased portion and thus exhibits the same flexibility and bias as the helical portion. Moreover, only one electrode is disposed on the helical portion of D5.

3.1.3 In accordance with established case law, the closest prior art for assessing inventive step is normally that prior art document which discloses subject-matter conceived for the same purpose as the claimed invention and having the most relevant technical features in common. In the present case, it is D3 which appears to contain the most common features.

3.2 The lead of claim 1 is distinguished from the lead disclosed in D3 in that the preformed biased portion has a helical shape and the electrodes are disposed along the helical shape and are spaced 120 degrees apart.

3.3 The technical effect of this difference is not only that the arrangement ensures that the electrodes are urged into contact with the wall of the vasculature, but also that the arrangement improves the chances of locating the electrodes in a position which enables sensing and stimulation of the appropriate coronary vessel.

3.4 The coronary vein into which the helical portion is to be implanted is bounded on one side by the myocardial wall and on the other side by a free wall. In order to pace and/or sense the heart using a lead positioned within the cardiac vasculature, the electrodes must contact the myocardial wall. The problem to be solved by the present invention may therefore be seen to be the modification of the lead of D3 to provide a secure fixation of the electrodes against the myocardial wall of the coronary vasculature.

3.5 This problem is solved by the combination of the helical fixing portion and the distribution of electrodes around the helix at 120°.

The helical lead form ensures continuous contact of the entire lead portion with the interior surface of the vasculature. Moreover, the separation by 120° means that during the implantation procedure, the surgeon may place the lead in an orientation in which two electrodes both face the myocardial wall. This increases the density of electrodes on the myocardial side of the vein once the helix is oriented in that direction, which in turn improves the chances that at least one of these electrodes will provide a good enough contact to ensure stimulation of the coronary vessel from within the coronary vasculature, even if the other electrode is prevented from intimate tissue contact due to the presence of plaques, for example. In other words, the distribution of electrodes at 120° along the helix make correct positioning and electrical contact easier and more reliable and the provision of a resilient helical structure ensures secure fixing of the electrodes to the inner wall of the vasculature.

3.6 The arrangement defined in claim 1 of the present application has not been suggested in the prior art and cannot be considered to be obvious to the skilled person.

3.6.1 The use of a helical lead form is discussed in D2, where it is used to provide fixation of the lead and the associated atrial pacing electrodes 16 and 18 within the superior vena cava. However, D2 does not contain any discussion of the manner in which the

electrodes are distributed along the lead, and in particular does not contain any suggestion to distribute the electrodes in the specific fashion around the helix defined in claim 1. In the implanted state, the electrodes of D2 are maintained adjacent the wall of the superior vena cava (column 6, lines 41-53). In this particular configuration, right atrial pacing will be achieved regardless of which portion of the vena cava is contacted by the electrodes and so a specific layout of the electrodes is not required. D2 goes on to discuss the use of a sigmoidal form to assist in fixing the lead within the coronary sinus (Fig. 6; col. 7, lines 9-27), but does not elaborate on the relative positions of the electrodes along the lead: reference is merely made to the defibrillation electrode which is positioned adjacent to the left atrium and the tip electrode which is positioned adjacent the left ventricle.

When the lead is inserted for pacing and/or sensing from within the cardiac vasculature, effective stimulation can only occur if the electrodes contact the myocardial wall. D2 neither indicates the need to locate the electrodes against the myocardium nor suggests a 120° spacing around a helix to improve the chances of such contact.

3.6.2 D5 discloses an intravenous lead for implantation in the coronary sinus. The lead includes a preformed biased portion of helical shape on which a single, elongated electrode is located. This arrangement guarantees electrical contact along the entire inner surface of the vein, including the myocardium. There is no suggestion in D5 that the form of the electrode

should be modified in any manner, and in particular, no suggestion to depart from the single elongated electrode of D5 to provide a plurality of discrete electrodes distributed at 120° along the helix.

3.6.3 D1 discloses an entirely different structure and is therefore considered to be further removed from the subject matter of claim 1 of the current application. In D1 the tip portion itself constitutes a self-propelling spiral electrode which may be rotated along the coronary sinus and which permits sensing and stimulation of the left atrium. This citation gives the skilled person no motivation to modify the lead of D3 in the manner set out in claim 1.

3.7 Thus, whilst it may conceivably be argued that in order to hold the lead in intimate contact with the inside wall of the vasculature, the fixation portion 202 of D3 (the stiff portion which is wedged into position in the coronary sinus) could be replaced by the helical fixation portion of D5 or D2, none of the available prior art suggests a distribution of electrodes at 120° around the helical surface. It is the combination of the helical structure with the 120° distribution which achieves a secure fixation of the electrodes against the wall of the coronary vasculature at positions which increase the probability that the myocardium will be contacted.

3.8 Even if D5 were to be used as the starting point in the assessment of inventive step and even if it were to be considered obvious to provide a tip with increased flexibility relative to the remainder of the lead, as may be seen from the above, the prior art contains no

suggestion that the single elongated electrode of D5 should be replaced by discrete electrodes arranged at 120° around the helix.

3.9 In conclusion, the specific arrangement defined in claim 1 of the current application cannot be considered to be obvious.

4. As the application in the version submitted by the applicant also meets the other requirements of the EPC, the Board remits the case to the examining division with the order to grant a patent.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division with the order to grant a patent on the basis of:

   Claim 1 as filed at the oral proceedings of 29 May 2009.

   Description pages 1-3, 3a, 5-26 as filed with letter of 05 March 2010.

   Figures pages 1/16 to 16/16 as published.

The Registrar: The Chairman:

R. Schumacher B. Schachenmann