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D E C I S I O N
of 10 February 2005

Case Number: T 0468/02 - 3.4.1

Application Number: 93118002.0

Publication Number: 0601338

IPC: A61N 1/05

Language of the proceedings: EN

Title of invention:
Electrode system for a defibrillator

Patentee:
St. Jude Medical AB

Opponent:
Biotronik GmbH & Co. KG

Headword:
Defibrillator and electrode system

Relevant legal provisions:
EPC Art. 123(2), 123(3), 84, 56

Keyword:
"Inventive step (yes; first auxiliary request)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0468/02 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 10 February 2005

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 25 February 2002 rejecting the opposition filed against European patent No. 0601338 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: G. Davies
Members: H. K. Wolfrum
R. Q. Bekkering

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 25 February 2002, rejecting the opposition against European patent No. 0 601 338. The notice of appeal was received on 23 April 2002 together with a statement of grounds of appeal and the payment of the prescribed fee.

II. Pursuant to Article 100(a) EPC, the opposition was based on the ground of lack of inventive step (Articles 52(1) and 56 EPC).

III. Oral proceedings were held at the request of the parties on 10 February 2005.

IV. The appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent (patent proprietor) requested as a **main request** that the appeal be dismissed and the patent maintained as granted. As an auxiliary measure the respondent requested the maintenance of the patent in amended form on the basis of the following documents :

first auxiliary request:
claims 1 to 3 and columns 1 and 2 of the description filed in the oral proceedings, with columns 3 and 4 of the description and Figure 1 of the patent as granted;

second auxiliary request:
claims 1 to 3 and columns 1 and 2 of the description filed on 10 January 2005, with columns 3 and 4 of the description and Figure 1 of the patent as granted.

V. During opposition and in the appeal the appellant based its objection as to lack of inventive step *inter alia* on the following documents:

D2: WO-A-92/11898; and

D3: D.N. Dunbar et al : "Intracavitary Electrode Catheter Cardioversion of Atrial Tachyarrhythmias in the Dog", in JOURNAL OF AM. COLL. CARDIOL.; vol. 7, No. 5, May 1986, pages 1015-1027.

By letter of 5 January 2005, the appellant made further reference to documents :
D4: EP-A-0 085 417; and

D5: US-A-4 708 145.

VI. Independent claim 1 of the respondent's **main request** reads as follows :

"*1. An electrode system for a defibrillator with three intravascular electrodes, one (12) of said electrodes being adapted to be placeable in the inferior vena cava (6), an additional intravascular electrode (14) being adapted to be placeable in the superior vena cava (2), the third (18) of said three electrodes (12,14,18) being arranged on an electrode cable (16) and being adapted to be placeable in the coronary sinus (8) including its prolongation along the base of the heart, the two electrodes (12,14) being adapted for placement in the inferior vena cava (6) and the superior vena cava (2) being arranged on a common electrode cable at a predetermined distance, the intravascular electrodes*

(12,14,18) in the electrode system having means for affixation to the inner wall of the vein in which they are sited, the fixation means being achieved when the electrodes (12,14,18) in the affixed position have the shape of hollow, resilient cylinder whose diameter exceeds the diameter of the vein enough for the electrode to press against and affix the electrode to the inner wall of the vein."

Claims 2 and 3 are dependent claims.

Claim 1 of the **first auxiliary request** reads:

"1. *An electrode system and a defibrillator, said defibrillator being connected to three intravascular electrodes, one (12) of said electrodes being adapted to be placeable in the inferior vena cava (6), an additional intravascular electrode (14) being adapted to be placeable in the superior vena cava (2), the third (18) of said three electrodes (12, 14, 18) being arranged on an electrode cable (16) and being adapted to be placeable in the coronary sinus (8) including its prolongation along the base of the heart, the two electrodes (12, 14) being adapted for placement in the inferior vena cava (6) and the superior vena cava (2) being arranged on a further and common electrode cable (10) at a predetermined distance, the intravascular electrodes (12, 14, 18) in the electrode system having means for affixation to the inner wall of the vein in which they are sited, the fixation means being achieved when the electrodes (12, 14, 18) in the affixed position each have the shape of a hollow, resilient cylinder whose diameter exceeds the diameter of the*

vein enough for the electrode to press against and affix the electrode to the inner wall of the vein."

Claim 1 of the **second auxiliary request** is based on claim 1 of the main request and additionally specifies details of the connection of the electrodes to the defibrillator.

VII. The appellant essentially relied on the following submissions:

The subject-matter of claim 1 of the main request was rendered obvious in view of the teachings of documents D2 and D3. Documents D4 and D5 provided additional confirmation that the structure of the claimed electrode system was conventional. Document D3 described a temporary setup for defibrillation experiments on dogs and showed an electrode system consisting of two electrode cables each having two electrodes separated by a predetermined distance. One cable was inserted into the vena cava with an electrode located in the superior vena cava and the other cable was inserted through the inferior vena cava into the right atrial appendage. In terms of structure, the claimed electrode system differed from the system known from D3 only in that the former had fixation means by providing the electrodes in the shape of a hollow resilient cylinder, the diameter of which exceeded the diameter of the vein into which the electrode was inserted. The problem of permanent fixation of defibrillation electrodes in blood vessels without impeding the flow of blood was addressed in document D2, which, moreover, showed the claimed solution. In fact, by explicitly referring to defibrillation

electrodes to be located in the vena cava as well as in the coronary sinus and by pointing to the possibility of providing more than one electrode on the same cable, D2 disclosed each of the two electrode cables of the claimed electrode system. Document D4 provided further evidence that fixation of stimulating electrodes by means of expandable resilient helical structures was a conventional measure in the technical field at issue. Furthermore, document D5 showed that a widespread distribution of the defibrillating current by means of a three-electrode configuration and the use of an electrode lead having electrodes separated by a distance so as to fit in the superior and inferior vena cava position constituted conventional measures.

Similar considerations applied to the subject-matter of the respective claims 1 of the auxiliary requests. In view of the fact that D2 taught the claimed structures of the individual electrode cables for placement within the vena cava and the coronary sinus, that each of D3 and D5 showed two electrode cables connected to the defibrillator, and that D5 explicitly disclosed a three electrode configuration for the purpose of improving the distribution of the defibrillating current in the heart, the claimed subject-matter had to be regarded as being rendered obvious to the skilled person. In this context, although D5 did not show electrodes having the shape of hollow, resilient cylinders and made use of an epicardial or subcutaneous patch electrode, the skilled person knew from D2 of such a suitable fixation structure and the alternative of replacing a patch electrode by an electrode located within the coronary sinus.

Moreover, the respective claims 1 of the auxiliary requests did not fully comply with the requirement of Article 84 EPC having regard to clarity in that the scope of protection conferred by these claims was not unambiguously clear.

VIII. The respondent's submissions may be summarised as follows :

As regards the main request, claim 1 thereof being directed to an electrode system had to be understood as a "kit of parts" type claim, in distinction to a coincidental assembly of electrode cables, the parts being properly selected according to the circumstances of each individual use. The claimed subject-matter, which required an electrode cable having two electrodes separated by a distance so as to allow for a simultaneous placement in the superior and inferior vena cava combined in a system with an electrode cable carrying an electrode to be placed into the coronary sinus, was thus distinguished from individual electrodes and cables as known from D2. By providing electrodes to be exclusively located within the veins of a heart, the invention allowed for a better current distribution compared to the use of an electrode located within the ventricle and at the same time avoided any blocking of the blood flow. Even a combination of the teachings of D2 and D3 would not have led the skilled person to the claimed electrode system. Notwithstanding the fact that D3 showed an electrode system consisting of two electrode cables each with two electrodes, neither of the two cables was positioned so that its electrodes were simultaneously at the location of the inferior vena cava and superior

vena cava, respectively. Furthermore, in all experiments one of the cables was located with one of its electrodes in the atrial appendage and there was no incentive for the skilled person to replace this electrode by a coronary sinus electrode nor was there any reason to provide that electrode with the claimed fixation means which were meaningful only for electrodes located in a vein (or other blood vessel). Document D5 did not lead the skilled person to the claimed subject-matter either because it did not teach to place the electrodes only in the veins of the heart but instead taught to use electrodes located in the ventricle and patch electrodes outside the heart.

As regards the auxiliary requests, the fact that the amended claims 1 claimed the electrode system in combination with the defibrillator, to which the electrodes were connected, removed any possibility of a coincidental selection of electrode cables which might be considered as falling within the terms of claim 1 of the main request. Since none of the cited documents of the prior art showed a defibrillator to which an electrode system was connected comprising electrodes to be located in the superior vena cava, the inferior vena cava and the coronary sinus, a skilled person could arrive at the claimed subject-matter only with the benefit of hindsight.

Reasons for the Decision

1. The appeal complies with the requirements of Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.

2. *Main request*

2.1 Construction of claim 1

The claim is directed to an "electrode system for a defibrillator with three intravascular electrodes". The electrodes, the number of which need not be limited to three (see column 4, lines 23 to 34, of the patent specification), are defined, on the one hand, by explicit structural features, namely the requirements for an arrangement of two electrodes on a common cable and of the third electrode on another cable as well as for the provision of fixation means and their shape. On the other hand, the electrodes are defined by features relating to their individual suitability for placement at intended locations within the heart of a patient, namely the vena cava and the coronary sinus. Hence the question arises which concrete structural features would be associated with the latter group of features.

Undisputedly, an electrode with the claimed fixation means consisting of a resilient cylinder, the diameter of which has to exceed to some extent the diameter of the vein within which the electrode is intended to be placed, has to possess a diameter adapted to the size of the vein, being either the comparatively large vena cava or the significantly narrower coronary sinus. Likewise, the intended placement of the two electrodes on the common lead at the position of the superior vena cava and the inferior vena cava, respectively, in principle entails a suitable distance between the two electrodes. However, all these considerations become meaningful structural requirements only when electrodes

are selected for a concrete application on the basis of the physiological conditions of a given patient. For an electrode system as such, the intended locations of placement do not constitute unambiguously recognizable structural features because, for instance, a vena cava electrode suitable for one individual (human being or animal) will not fit the corresponding sizes of another individual. This is all the more true as claim 1 under consideration only requires that the claimed electrode system is in principle suitable for use with a defibrillator but does not limit the system even to this specific use. Thus, in the absence of any limitation to a concrete use, the intended locations of placement of the various electrodes do not impose particular structural limitations to the claimed electrode system.

The respondent argued that the term "system" had to be understood as implying a specific selection and purposeful combination of two electrode cables having a certain relationship of sizes as regards their respective diameters and the distances in-between them so as to fit the specified electrode locations. Thus the claim definition implied structural features which rendered the claimed subject-matter distinguishable from a coincidental arrangement of two electrode cables.

The Board does not share this view, first of all for the reason that size relationships for placement in the vena cava and the coronary sinus vary from individual to individual (from child to adult; from human beings to animals; from one animal species to another species) so that a specific selection would be suitable for one

class of patients but not suitable for another class of patients. Thus, in fact a wide range of relative size ratios of pairs of electrode cables falls under the terms of claim 1 under consideration. Moreover, in the Board's opinion, the term "system" does not exclusively have the meaning given to it by the respondent but encompasses in general any pair of electrode cables wherein one cable carries at least two electrodes separated from each other along the length of the cable and the other cable carries at least one electrode. In the absence of any limitation in claim 1 as to the circumstances of a concrete use such a pair could form part of a set of cables without serving any particular technical purpose.

2.2 Electrode cables for use with a defibrillator being specifically adapted to be inserted into the coronary, venous and arterial systems and having electrodes with fixation means in the shape of hollow resilient cylinders as defined in claim 1 of the patent as granted are known from document D2 (see in particular Figures 1 to 4 and pages 2 to 4 of the description). Specific examples mentioned are electrodes adapted to be located in the superior vena cava or in the coronary sinus. Moreover, it is known from D2 that more than one electrode may be arranged on an electrode cable.

From document D3 (see in particular Figure 1 and pages 1016 to 1018) the skilled person knows about the possibility of using for defibrillation a pair of electrode cables each having two spaced-apart electrodes (with each electrode being in fact formed by a pair of closely spaced rings). Figure 1A of D3 shows an experimental setup which comprises a first electrode

cable inserted into the vena cava of a dog's heart with one electrode being positioned in the superior vena cava and the second being located further up in the vein. Although no use is made of this second electrode in the defibrillation experiments described, the spacing between the two electrodes (which, as shown in the example of Figure 1C, may be for instance 50 mm) nevertheless approximately fits the distance between the superior and inferior vena cava of a dog's heart. A second electrode cable of similar structure is inserted so that the electrode at the distal end is positioned within the right atrial appendage.

2.3 Knowing on the one hand from D2 that electrodes for defibrillation, which are intended to be located in the venous system of the heart, are, for the purpose of fixation in the blood vessel, advantageously given the shape of hollow, resilient cylinders and that more than one such electrode can be located on a cable and knowing on the other hand from D3 about the flexibility of defibrillation arrangements associated with an electrode system consisting of two cables which have electrodes arranged at a distance corresponding in principle to the distance between the superior vena cava and the inferior vena cava, a skilled person in exercising his normal skills would devise and prepare electrode cables with electrodes of varying sizes and distances which would happen to include pairs of cables falling under the terms of claim 1 under consideration.

Consequently, the subject-matter of claim 1 of the patent as granted does not involve an inventive step within the meaning of Article 56 EPC.

2.4 For these reasons, the respondent's main request is not allowable.

3. *First auxiliary request*

3.1 Allowability of the amendments

The appellant has not raised any objections under Articles 123(2) and (3) EPC against the amendments and the Board has no concerns either.

Whereas claim 1 as granted is directed to an electrode system as such, amended claim 1 is directed to the electrode system and a defibrillator, the defibrillator being connected to the three intravascular electrodes of the electrode system. The claim wording is further amended so as make it clear beyond any reasonable doubt that the three electrodes are arranged on two cables and that each electrode has the shape of a hollow resilient cylinder, the latter amendment concerning claim 2 as well.

As regards the requirement of Article 123(2) EPC, the electrode system consisting of two cables connected to the defibrillator is disclosed in column 2, lines 51 to 57, of the published application. The fact that each of the intravascular electrodes has the shape of a hollow resilient cylinder is disclosed for instance by Figure 1 and the corresponding description. Furthermore, by claiming the electrode system when connected to the defibrillator, the amendment limits the scope of protection compared to that conferred by the patent as granted and thus complies with the requirement of Article 123(3) EPC as well.

3.2 Clarity

The appellant has objected to a lack of clarity of amended claim 1 because its scope of protection was not unambiguously clear.

Apart from establishing whether the scope of protection of an amendment meets the requirement of Article 123(3) EPC, the determination of the scope of protection is not the task of the opposition appeal proceedings. Moreover, in the Board's view, the claim wording defines in unambiguous terms the structure of the electrode system connected to the defibrillator so that amended claim 1 meets the requirement of Article 84 EPC having regard to clarity. In fact, the appellant has not put forward any concrete argument to support its objection.

3.3 Novelty and inventive step

3.3.1 For an electrode system connected to a defibrillator, a specific selection of electrode cables has to be made in terms of suitable electrode sizes and distances according to the claimed intended locations and the respective physiological conditions of a certain patient. The intended placement of two electrodes on a common cable at the location of the superior vena cava and the inferior vena cava and of a third electrode on a separate cable in the coronary sinus of said patient in fact implies certain relationships between the diameter and separation of the vena cava electrodes as well as between the diameters of the electrodes on the two cables so as to be adapted to the patient's heart.

The claimed defibrillator and electrode system allow for a favourable distribution of defibrillating energy in the heart and at the same time avoid health risks which would be associated with prior art arrangements including an electrode cable inserted into the ventricle (see column 1, lines 41 to 57, of the patent specification).

3.3.2 As a matter of fact, none of the documents of the available prior art shows a defibrillator connected to a system of two electrode cables, with one cable carrying properly separated electrodes for placement in the superior and inferior vena cava, respectively, and the other cable being adapted for placement of an electrode in the coronary sinus.

Of the cited documents, D3 and D5 show a defibrillator connected to more than one electrode cable. Common to all embodiments shown in document D5 is the use of a ventricular electrode for defibrillation which is arranged on one cable together with an electrode located either in the superior vena cava or the inferior vena cava. A further feature common to the teaching of D5 is the use of a separate electrode cable carrying a patch electrode which is implanted subcutaneously or in the abdominal cavity (see Figures 3a, 4 and 5). The coronary sinus is mentioned as a further suitable location for placement of a defibrillating electrode (column 8, lines 66 to 68). However, there is no hint that a ventricular electrode should be avoided and be specifically replaced by a coronary sinus electrode.

As already indicated in paragraph 2.2 above, the defibrillator known from document D3 is connected to one cable which has a first electrode extending into the right atrial appendage and a second electrode being either placed in the mid right atrium or the inferior vena cava position (Figures 1A to 1C). As regards the other cable, use is made of only one of its electrodes which is placed in the superior vena cava, although the cable could in principle provide in combination a superior vena cava and an inferior vena cava electrode. The document is specifically concerned with atrial defibrillation and thus does not provide any incentive to replace the electrode in the right atrial appendage by an electrode placed in the coronary sinus. Moreover, none of the electrodes has the shape of an expandable hollow resilient cylinder as claimed in present claim 1.

Although such an electrode structure is known from D2 to be advantageous for intravascular placement and although D2 mentions in this context *expressis verbis* electrode cables suitable for implantation into the vena cava and the coronary sinus, respectively, the document does not teach to use these two types of cables in combination together with one defibrillator.

Document D4, finally, relates to an implantable electrode, a part of which is given the shape of an expandable helix as a fixation means. However, since the electrode is to be implanted in the epidural space (spinal canal) its teaching falls behind that of document D2.

3.3.3 The appellant has argued in essence that the claimed subject-matter was rendered obvious to the skilled person because all of the claimed features were in principle known from the cited prior so that, in particular when setting out from the teaching of document D3, the coronary sinus as a suitable alternative location for defibrillation to an electrode located in the right atrial appendage would have readily come to the skilled person's mind in view of the teachings of documents D2 and D5. Moreover, D2 would have incited the skilled person to give all intravascular electrodes the shape of hollow resilient cylinders.

The Board concurs with this argumentation in so far as D2 provides a clear incentive for the skilled person to form intravascular electrodes as hollow resilient cylinders. However, the appellant's further argumentation overlooks the fact that none of the documents of the available prior art teaches that for defibrillation purposes the coronary sinus would be a suitable alternative location to the right atrial appendage, or that a defibrillator with a coronary sinus electrode and two vena cava electrodes should be provided. As a matter of fact, the prior art does not contain any hint which could have incited the skilled person to the purposeful compilation of an electrode system having a superior vena cava electrode and an inferior vena cava electrode on one cable in combination with a coronary sinus electrode on another cable connected to a defibrillator. Nor can such an arrangement be regarded as a conventional or straightforward design option for the skilled practitioner. Therefore, the appellant's assessment of

lack of inventive step has to be judged as a hindsight analysis.

3.3.4 For the above reasons, the subject-matter of claim 1 under consideration is to be considered novel and inventive and thus complies with the requirements of Articles 52(1), 54 and 56 EPC.

3.3.5 Dependent claims 2 and 3 define advantageous embodiments of the subject-matter of claim 1.

The description has been adapted to the subject-matter of the amended claims.

3.3.6 In summary, the Board has come to the conclusion that, taking into consideration the amendments made to the patent documents according to the respondent's first auxiliary request, the patent and the invention to which it relates meet the requirements of the EPC.

4. Having found the first auxiliary request allowable, there was no reason to deal with the second auxiliary request.

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 maintain the patent on the basis of the respondent's first auxiliary request filed in the oral proceedings of 10 February 2005.

The Registrar: The Chairman:

R. Schumacher G. Davies