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D E C I S I O N
of 15 March 2005

Case Number: T 0409/02 - 3.4.1

Application Number: 92304540.5

Publication Number: 0522693

IPC: A61N 1/39

Language of the proceedings: EN

Title of invention:
Automatic cardioverter/defibrillator

Patentee:
Pacesetter, Inc.

Opponent:
Biotronik GmbH & Co. KG

Headword:
Automatic cardioverter/defibrillator with plurality of atrial
cardioversion electrode configurations/PACESETTER

Relevant legal provisions:
EPC Art. 54(1)(2), 56, 123(2)

Keyword:
"Novelty (yes; main request)"
"Inventive step (no; main request)"
"Added subject-matter (yes; auxiliary request)"

Decisions cited:
-

Catchword:
-



Case Number: T 0409/02 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 15 March 2005

Appellant: Biotronik GmbH & Co. KG
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Representative: Eisenführ, Speiser & Partner
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Respondent: Pacesetter, Inc.
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 20 March 2002
rejecting the opposition filed against European
patent No. 0522693 pursuant to Article 102(2)
EPC.

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 20 March 2003, rejecting the opposition against European patent No. 0 522 693. The notice of appeal was received on 16 April 2002 and the prescribed fee was paid on the same day. On 22 July 2002 a statement of grounds of appeal was filed.

- II. Pursuant to Article 100(a) EPC the opposition had been based on the grounds of lack of novelty and inventive step (Articles 52(1), 54(1) and (2) and 56 EPC). In the appeal, reference was made, inter alia, to the following document:

E1: US-A-5 005 587.

- III. In response to a communication of the Board of 26 October 2004 summoning the parties to oral proceedings, the respondent (patent proprietor), by letter of 11 February 2005, informed the Board that it would not be represented at the oral proceedings.

- IV. Oral proceedings were held on 15 March 2005 in the absence of the respondent.

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

- VI. The respondent requested in writing, as a main request, that the appeal be dismissed and the patent maintained as granted. As an auxiliary request, maintenance of the

patent in amended form was requested on the basis of the following documents:

claims: 1 and 14 filed on 11 February 2005;
2 to 13 and 15 to 30 of the patent as granted;

description: columns 1, 2 and 7 to 19 of the patent as granted;
columns 3 and 4 filed on 11 February 2005;
columns 5 and 6 filed on 14 February 2005;

drawings: Figures 1 to 11 of the patent as granted.

VII. Independent claims 1 and 14 of the **main request** read as follows (with an itemisation (a) to (g) added to claim 1 by the Board):

*"1. An implantable atrial cardioverting device (10) for the reversion of atrial tachycardias, comprising:
(a) means for storing electrical energy;
(b) means (17, 19) for detecting the presence of an atrial tachycardia;
(c) an electrode lead system including a plurality of electrode leads (150, 151, 152) therein, each of said leads including a cardioverting electrode (142, 142A, 90, 80) having a substantially larger surface area and lower electrode impedance than the surface area and impedance of a pacing lead electrode (114, 114A, 116, 116A);*

(d) a plurality of atrial cardioversion electrode configurations, each of said configurations including at least two of said electrode leads, one of said leads being an atrial endocardial electrode lead (150) adapted to be disposed in an atrium and the other being an electrode lead (151, 152) adapted to be disposed outside the atrium;

(e) switching means (16) responsive to the detection of an atrial tachycardia by said detecting means for selectively connecting said energy storage means to one of said atrial cardioversion electrode configurations;

(f) means (19) for setting the level of electrical energy stored in said electrical energy storing means to an appropriate level for an atrial cardioversion shock; and

(g) means (16) for discharging said stored electrical energy across said selected atrial cardioversion electrode configuration."

"14. An implantable cardioverting/defibrillating device (10) for the reversion of tachycardias, comprising:
means for storing electrical energy;
means (17,19) for detecting the presence of an atrial tachycardia;
means (17,19) for detecting the presence of a ventricular tachycardia;
an electrode lead system including a plurality of electrode leads (150, 151, 152) therein, each of said leads including a cardioverting electrode (142, 142A, 90, 80) having a substantially larger surface area and lower electrode impedance than the surface area and impedance of a pacing lead electrode (114, 114A, 116, 116A), at least a first one of said leads being an atrial endocardial electrode lead (150) adapted to be

disposed in an atrium and a second one of said leads being a ventricular endocardial electrode lead (151) adapted to be disposed in a ventricle;

a plurality of atrial cardioversion electrode configurations, each of said configurations including at least two of said electrode leads, one of said leads being said atrial endocardial electrode lead (150) and the other being an electrode lead (151, 152) adapted to be disposed outside the atrium;

a plurality of ventricular defibrillating electrode configurations, each of said configurations including at least two of said electrode leads, one of said leads being said ventricular endocardial electrode lead (151) and the other being an electrode lead (150, 152) adapted to be disposed outside the ventricle;

first switching means (16) responsive to the detection of an atrial tachycardia by said atrial tachycardia detecting means for selectively connecting said energy storage means to one of said atrial cardioversion electrode configurations;

second switching means (16) responsive to the detection of a ventricular tachycardia by said ventricular tachycardia detecting means for selectively connecting said energy storage means to one of said ventricular defibrillating electrode configurations;

means (19) for setting the level of electrical energy stored in said electrical energy storing means to an appropriate level for an atrial cardioversion shock;

means (19) for setting the level of electrical energy stored in said electrical energy storing means to an appropriate level for a ventricular defibrillation shock; and

means (16) for discharging said stored electrical energy across a selected one of said atrial and ventricular electrode configurations."

Claims 2 to 13 and 15 to 30 are dependent claims.

Claim 1 of the **auxiliary request** differs from claim 1 of the main request in that the definition of the switching means according to feature (e) is replaced by the following definition:

"switching means (16) responsive to continued detection of an atrial tachycardia by said detecting means for selectively switching connection of said energy storage means from one programmed electrode configuration to another programmed electrode configuration of said plurality of said atrial cardioversion electrode configurations according to programmed instructions."

A similar amendment is made to claim 14 of the auxiliary request as regards the definition of the first switching means, whereas the second switching means are amended to be responsive to "continued " detection of ventricular tachycardia (for) selectively "switching connection of" said energy storage means to "a programmed" one of said ventricular defibrillating electrode configurations "according to programmed instructions".

VIII. The appellant essentially relied on the following submissions:

An implantable atrial cardioverting device having all the features specified in claim 1 of the main request

was known from document E1, which referred to an electrode lead system comprising a plurality of electrode leads including large surface cardioversion electrodes to be placed in an atrium and ventricle, respectively, and used for an automatic implantable cardioverter defibrillator in combination with one or more subcutaneous electrodes. In this context, the term "plurality of electrode configurations" according to claim 1 under consideration should be interpreted as, for instance, referring to a single fixed electrode configuration consisting of leads/electrodes to which various potentials or polarities were applied, with the switching means merely serving for selecting said potentials or polarities, as was shown in the figures of the patent. Moreover, regarding the claimed switching means, a simple and straightforward switching in terms of "turning on" of an atrial cardioversion electrode configuration in response to the detection of an atrial tachycardia had to be regarded as falling under the terms of claim 1.

The subject-matter of claim 1 of the patent as granted was in any case rendered obvious to the average skilled person by the teaching of E1.

As regards the auxiliary request, it suffered from a variety of deficiencies with respect to the requirements of Articles 84, 123(2) and (3) EPC.

- IX. The respondent argued in writing that claims 1 and 14 of the patent as granted had to be interpreted as defining electrode configurations and switching means for switching from one atrial cardioversion electrode configuration to another in response to the detection

of a persisting atrial tachycardia, as argued in the decision of the opposition division. The amendments made to independent claims 1 and 14 according to the auxiliary request further clarified this functionality, which was not disclosed or hinted at in any one of the cited documents.

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 Novelty (Articles 52(1) and 54(1) and (2) EPC)
 - 2.1.1 Document E1 refers to catheters for use with an implantable defibrillator. It states that the electrical connections of a catheter for an automatic implantable cardioverter defibrillator generally utilize electrodes for pacing, fibrillation sensing and rate sensing, and electrodes for cardioverting and defibrillation (column 1, lines 42 to 46). The principal object addressed by E1 is to provide a catheter (or "electrode lead" in the terminology of the present patent) having an electrode of a large surface area for the delivery of a countershock, ie a cardioverting or defibrillating shock, to the heart (column 2, lines 3 to 6). Two versions of endocardial catheters are foreseen : one version being suitable for use in the right ventricle and the other being suitable for use in the right atrium (column 2, lines 51 to 53;

column 6, lines 44 to 47; column 7, line 59, to column 8, line 10). According to the specific embodiments of Figures 1 and 4, each catheter is tripolar, having a pair of electrodes for pacing and sensing as well as a braid electrode of large surface area for the application of an electrical shock (column 6, lines 27 to 30). Moreover, the catheters may be used in combination with either a large surface area patch counter-electrode, or an elongate tubular counter-electrode, adapted for subcutaneous implantation in proximity to the heart (column 2, lines 51 to 58; column 6, lines 47 to 49). As regards a preferred method of use, the two versions of the catheters are used together so as to allow cardioversion and defibrillation treatment of the atrium and the ventricle. According to a particularly preferred method, one or more subcutaneous electrodes placed outside the chest cavity but in proximity to the heart is also used. In that case, the two catheter braid electrodes and one or two subcutaneous electrodes are connected in a selected combination for the application of cardioverting or defibrillating countershock (column 8, lines 11 to 25). Furthermore, reference is made to the fact that various combinations of electrodes and countershocks have been described in the literature and that these include single current pathways, simultaneous dual current pathways, sequential shocks and biphasic shocks (column 8, lines 25 to 29).

2.1.2 With respect to the subject-matter of claims 1 and 14, document E1 implicitly discloses, by referring to the use of the known electrode lead system with an automatic implantable cardioverter defibrillator, features (a), (b), (f) and (g). Moreover, the known

electrode lead system includes a plurality of electrode leads, each of which comprises a large surface electrode of low impedance for cardioversion and defibrillation, within the meaning of feature (c), and provides, in principle, a plurality of atrial cardioversion electrode configurations within the meaning of feature (d).

Thus, the decisive point for assessing novelty of the claimed subject-matter with respect to the teaching of document E1 concerns the interpretation of feature (e) of claim 1 relating to the definition of the switching means and the corresponding feature relating to the first switching means in claim 14 and the respective teaching of E1.

In this respect, the Board does not share the respondent's view that the wording of claims 1 and 14 limited the function of the switching means or first switching means, respectively, to a switching from one atrial cardioversion electrode configuration to another in response to the detection of a persisting atrial tachycardia. In the Board's view, a straightforward meaning of "switching means ... for selectively connecting ...energy storing means to one of said atrial cardioversion electrode configurations" is a switching means which, in response to the detection of an atrial tachycardia, switches the device from an unspecified mode of operation and associated electrode configuration (which in fact could be an idle mode, a mode of pacing or sensing, a mode of ventricular cardioversion, or possibly also a preceding mode of atrial cardioversion) to one of the available atrial cardioversion electrode configurations. However, in

distinction to the appellant's interpretation, the Board understands the expression "for selectively connecting" in feature (e) as defining a switching means which is capable of selecting in situ, *ie* in response to the detection of an atrial tachycardia, according to unspecified criteria or programmed rules, any one of the available atrial cardioversion electrode configurations for connection to the energy storage means.

It is this specific functionality, which, in the Board's opinion, is not clearly and unambiguously derivable from the teaching provided by document E1. Although the implanted electrode lead system comprises in principle a plurality of atrial cardioversion electrode configurations as such, there is no indication in E1 as to the provision of switching means which would be capable of selecting any one of these configurations for connection to the energy storage means. It would for instance be conceivable that out of the plurality of theoretically possible atrial cardioversion electrode configurations only one configuration is intended to be used for the known device and thus preselected for connection at the time of implanting the electrode lead system.

Therefore, the subject-matter of claims 1 and 14 of the main request is considered to be novel over the teaching of document E1.

2.2 Inventive step (Articles 52(1) and 56 EPC)

The aforementioned difference of the claimed switching means with respect to the prior art according to E1, *ie*

the functionality of readily rendering operational any one of the plurality of existing atrial cardioversion electrode configurations, increases the number of options available to the physician to treat an atrial tachycardia with the cardioverting device.

In the Board's view, the desire to increase the operational flexibility and thus the flexibility of therapeutic treatment by implanted heart stimulating devices is a common incentive for the average skilled person in the technical field at issue, who develops implantable stimulating devices according to the directives of a physician and has the qualification of an electrical engineer. Moreover, since the atrial cardioverting device which is apparent from the teaching of document E1 is already provided with an electrode lead system comprising a plurality of atrial cardioversion electrode configurations, it would have been obvious for the skilled person to consider the possibility of rendering accessible any of these configurations for therapeutic treatment of a given patient. The Board has no doubt that it would have been self-evident for the skilled person that, in order to put this idea into practice, some kind of switching means was needed for a purposeful selection during operation of the implanted device of one of the available electrode configurations for connection to the energy storage means.

Since claims 1 and 14 under consideration merely define a straightforward implementation of an obvious idea in the device according to document E1, their subject-matter does not involve an inventive step within the meaning of Article 56 EPC.

2.3 Therefore, the respondent's main request is not allowable.

3. *Auxiliary request*

3.1 According to the respondent, independent claims 1 and 14 of the auxiliary request have been further clarified to define the novel and inventive concept of switching means for selectively switching connections from one programmed atrial cardioversion electrode configuration to another programmed atrial cardioversion electrode configuration in case of an established persistent atrial tachycardia.

Such a functionality of the cardioverting device and its switching means is disclosed by Figures 4C and 5 and the corresponding description (column 12, lines 24 to 50, and column 13, lines 23 to 56, of the published application), according to which, in response to the detection of an atrial tachycardia, atrial cardioversion treatment is commenced by connecting a first programmed atrial cardioversion electrode configuration to the energy storage means. After delivery of a cardioversion shock, the device verifies whether or not the shock delivered successfully stopped the atrial tachycardia. Only in case the shock is found unsuccessful, does the switching means connect the energy storage means to another programmed atrial cardioversion electrode configuration.

However, amended claims 1 and 14 do not define switching means the operation of which would be responsive to an established unsuccessful attempt of

cardioversion with one electrode configuration but instead specify that the selectively switching connection from one programmed electrode connection to another one is "responsive to continued detection of an atrial tachycardia".

The expression "responsive to continued detection" is vague and ambiguous. It does not say that the switching means become operative only when an unsuccessful cardioversion attempt by one electrode configuration has been established. It could for instance be understood as referring to a mere activity of continued detection of an atrial tachycardia, ie without any evaluation or verification of the success of a cardioversion treatment, constituting a prerequisite for the operation of the switching means. Still further, the expression "responsive to continued detection of an atrial tachycardia" could simply mean that an episode of atrial tachycardia has to be established for a certain period of time before a treatment regime including switching between atrial cardioversion electrode configurations is started. Switching means which possess the latter functionalities are however technically different from the switching means disclosed in the originally-filed application documents. Thus, the amendments made to the independent claims of the auxiliary request introduce subject-matter which extends beyond the content of the application as filed.

- 3.2 For these reasons, the auxiliary request does not comply with the provision of Article 123(2) EPC and is therefore not allowable.

Order

For these reasons it is decided that :

1. The decision of the opposition division is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

R. Schumacher

G. Davies