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D E C I S I O N
of 6 December 2005

Case Number: T 0894/03 - 3.4.01

Application Number: 93113741.8

Publication Number: 0588125

IPC: A61N 1/39

Language of the proceedings: EN

Title of invention:
Apparatus for producing heart defibrillation sequences from stimulation pulses and defibrillation shocks

Patentee:
St. Jude Medical AB

Opponent:
BIOTRONIK GmbH & Co. KG

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty and inventive step - yes after amendment"

Decisions cited:
-

Catchword:
-

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Case Number: T 0894/03 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 6 December 2005

Appellant: (Opponent)	BIOTRONIK GmbH & Co. KG Woermannkehre 1 D-12359 Berlin (DE)
Representative:	Eisenführ, Speiser & Partner Patentanwälte Rechtsanwälte Spreepalais am Dom Anna-Louisa-Karsch-Strasse 2 D-10178 Berlin (DE)
Respondent: (Proprietor of the patent)	St. Jude Medical AB S-175 84 Järfälla (SE)
Representative:	Harrison, Michael Charles Albihns GmbH Bayerstrasse 83 D-80335 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted 4 June 2003 concerning maintenance of the European patent No. 0588125 in amended form.**

Composition of the Board:

Chairman: B. Schachenmann
Members: M. Rognoni
H. Wolfrum

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the interlocutory decision of the opposition division, posted on 4 June 2003, concerning the maintenance of the European Patent No. 0 588 125 in amended form. The notice of appeal was received on 31 July 2003 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 10 October 2003.

II. The opposition, filed against the patent as a whole, was based on Article 100 (a) EPC and substantiated on the grounds of lack of novelty and lack of inventive step (Articles 52(1), 54 and 56 EPC).

III. In the decision under appeal, the opposition division held, *inter alia*, that the grounds of opposition did not prejudice the maintenance of the patent on the basis of an independent claim which, in addition to the subject-matter of claim 1 of the granted patent, specified the following feature:

"said pulse being of the order of one millijoule to assure creation of a refractory area around the stimulation electrode in order to achieve part of the heart's defibrillation".

In its decision, the opposition division considered in particular the following documents:

E1: EP-A-0 324 604
E3: DE-A-40 30 306
E5: US-A-5 074 301

IV. In response to the summons to oral proceedings, the representative of the appellant informed the Board by letter dated 2 August 2005 that neither the appellant nor its representative would attend the oral proceedings on 6 December 2005.

V. In the course of the oral proceedings, which were held as scheduled on 6 December 2005 in the absence of the appellant, the Board expressed some doubts over the admissibility under Article 123(2) EPC of the amendments made to claim 1 of the granted patent during the opposition proceedings. In particular, the application as originally filed consistently referred to a series of stimulation pulses as having the effect of the assuring creation of a refractory area around the stimulation electrode in order to achieve part of the heart's defibrillation, whereas in the amended claim 1 this effect was attributed also to a single pulse.

In response to the Board's objection, the respondent (patent proprietor) filed a new set of claims 1 to 10 and an amended description by way of its only request.

VI. Claim 1 of the respondent's request reads as follows:

"1. An apparatus for producing defibrillation sequences formed of stimulation pulses (6,10) and defibrillation shocks (8,12), comprising a unit (22) for delivering stimulation pulses (6,10) through an intracardiac or epicardiac electrode (4) for pacemaker stimulation, a defibrillator circuitry (18) for delivering defibrillation shocks (8,12) through defibrillation

electrodes (1, 2, 3), a control unit (20) connected to said unit (22) for delivering stimulation pulses (6,10) and to said defibrillator circuitry (18) for determining the times for delivering the stimulation pulses (6,10) and the defibrillation shocks (8, 12), wherein during a defibrillation sequence the control unit (20) controls the unit (22) for delivering stimulation pulses (6,10) to deliver at least one pulse and said defibrillator circuitry (18) to deliver at least one shock within an interval which has a duration of a fraction of the refractory period of a heart cell, wherein the control unit (20) controls said unit (22) for delivering stimulation pulses and the defibrillator circuitry (18) to deliver a series of stimulation pulses before each defibrillation shock to assure creation of a refractory area around the stimulation electrode in order to achieve part of the heart's defibrillation, wherein the interval between consecutive pulses is a fraction of the refractory period of a heart cell and wherein said pulses are of the order of one millijoule."

Dependent claims 2 to 7 and 8 to 10 corresponds to granted claims 2 to 7 and 10 to 12, respectively.

VII. The appellant requested in writing that a decision under appeal be set aside and that the patent be revoked.

The respondent requested that the decision under appeal be set aside and the patent be maintained on the basis of:

– claims 1 to 10, filed at the oral proceedings,

– description, columns 1 to 5, filed at the oral proceedings, and

– drawings, Figures 1 to 4, of the patent as granted.

VIII. In the statement of grounds of appeal the appellant relied essentially on documents E1, E3 and E5. However, the arguments submitted in writing against the patent as maintained by the opposition division no longer apply to claim 1 filed in the oral proceedings before the Board.

Reasons for the Decision

1. The appeal is admissible.

2.1 Claim 1 according to the respondent's only request differs from claim 1 of the patent as granted essentially in that it is drafted in the one - part form and further comprises the following features:

(i) *"wherein the control unit (20) controls said unit (22) for delivering stimulation pulses and the defibrillator circuitry (18) to deliver a series of stimulation pulses before each defibrillation shock to assure creation of a refectory area around the stimulation electrode in order to achieve part of the heart's defibrillation";*

(ii) *"wherein the interval between consecutive pulses is a fraction of the refractory period of a heart cell"; and*

(iii) *"wherein said pulses are of the order of one millijoule".*

2.2 Feature (i) finds support in claim 9, column 1, lines 28 to 32 and column 3, lines 27 to 33, of the published application, while feature (ii) is specified both in claim 8 and in the description (published application: column 3, lines 36 to 38). Feature (iii) is disclosed in column 2, lines 47 and 48, of the description.

The amendments made to the description aim at bringing it into conformity with the new set of claims.

Thus, the Board finds that the claims and the description according to the respondent's request are admissible under Article 123(2) EPC.

2.3 As the combination of features (i) to (iii) limits the protection conferred by claim 1 of the granted patent and of claim 1 of the patent as maintained by the opposition division, the independent claim of the respondent's only request complies both with Article 123(3) EPC and with the principle of "*reformatio in peius*".

The Board is also satisfied that the claims clearly define the matter for which protection is sought and are in conformity with the description (Article 84 EPC).

3.1 The contested patent relates to an apparatus for producing heart defibrillation sequences comprising

stimulation pulses and defibrillation shocks. As pointed out in the description (see column 1, lines 27 to 43 of the patent specification), the energy requirement of a heart defibrillator can by reduced by delivering a series of high-energy stimulation pulses followed by a defibrillation shock. The stimulation pulses, which are separated by an interval corresponding to a fraction of the refractory period for a heart cell, achieve part of the heart's defibrillation, *i.e.* primarily in the area around the stimulation electrode, whereas the subsequent defibrillation shock defibrillates other parts of the heart in the customary manner. It is an implicit and essential aspect of the teaching of the contested patent that also the time interval separating a defibrillation shock from the preceding stimulation pulse should be a fraction of the refractory time of a heart cell. In fact, the timing of the stimulation pulses and of the defibrillation shock specified in the claim is necessary for ensuring that both the refractory area created around the stimulation electrode and the state of partial defibrillation of the heart achieved by the stimulation pulses are maintained when the actual defibrillation shock is delivered to the heart (cf. *ibid.* column 3, lines 12 to 26).

3.2 The apparatus for producing defibrillation sequences formed of stimulation pulses and defibrillation shocks specified in claim 1 comprises the following features which are generally present in apparatuses of the same kind:

-- a unit for delivering stimulation pulses through an intracardiac or epicardiac electrode for pacemaker stimulation;

-- a defibrillator circuitry for delivering defibrillation shocks through defibrillation electrodes;

-- a control unit connected to said unit for delivering stimulation pulses and to said defibrillator circuitry for determining the times for delivering the stimulation pulses and the defibrillation shocks.

3.3 Claim 1 further comprises the following features which relate to the timing of the defibrillation sequence generated by the apparatus of the invention and the energy of the stimulation pulses:

(a) during a defibrillation sequence the control unit controls the unit for delivering stimulation pulses to deliver at least one pulse and said defibrillator circuitry to deliver at least one shock within an interval which has a duration of a fraction of the refractory period of a heart cell;

(b) the control unit controls said unit for delivering stimulation pulses and the defibrillator circuitry to deliver a series of stimulation pulses before each defibrillation shock to assure creation of a refractory area around the stimulation electrode in order to achieve part of the heart's defibrillation;

(c) the interval between consecutive pulses is a fraction of the refractory period of a heart cell; and

(d) said pulses are of the order of one millijoule.

3.4 The Board is satisfied that none of the cited prior art documents discloses an apparatus comprising the combination of features specified in claim 1 of the respondent's request. Thus, the subject-matter of this claim is new within the meaning of Article 54 EPC.

4.1 The remaining question to be considered is whether, in the light of the available prior art, it would have been obvious to a person skilled in the art to arrive at the claimed apparatus.

4.2 E5 (see Figures 1 and 2) relates to an apparatus for producing defibrillation sequences formed of one stimulation pulse followed by a defibrillation shock and comprises, *inter alia*, a unit 39 for delivering atrial stimulation pulses through an intercardiac electrode for pacemaker stimulation, a defibrillator circuitry 16 for delivering defibrillation shocks through defibrillation electrodes, a control unit 19 connected to the unit 39 and to the defibrillator circuitry 16 for determining the times for delivering the stimulation pulse and the defibrillation shock.

The stimulation pulse generated by the apparatus according to E5 before the defibrillation shock aims at producing an atrial refractory condition which minimizes the risk of post-shock arrhythmias induced by the delivery of a defibrillation shock during the atrial vulnerable zone (see column 2, lines 39 to 48).

In order to achieve this effect, the time interval separating the atrial stimulation pulse from the following defibrillation shock has to be shorter than the refractory period of a heart cell. Thus, the apparatus known from D5 further comprises feature (a) of claim 1 of the respondent's request.

Though E5 does not specify the energy of the atrial stimulation pulse, it could be assumed that it would be obvious to a person skilled in the art, wishing to implement the apparatus known from E5, to select an energy level approaching the one identified in the contested patent (see feature (d) above). It is in effect generally known that pulses of higher energy are required to stimulate a heart traumatized by a tachycardia or fibrillation episode.

E5, however, does not suggest generating a series of atrial stimulation pulses with a time interval between consecutive pulses as specified in features (b) and (c) of claim 1 of the respondent's request.

4.3 Document E1 relates to an apparatus for delivering a series of stimulation pulses at a level of 8 Volt, instead of the usual stimulation level of 4 Volt used for standard pacing, in order to revert ventricular tachycardia and restore a normal sinus rhythm (see column 8, lines 28 to 41). As shown in Figure 6 and specified in column 8, lines 41 to 44, these antitachyarrhythmia pacing pulses may be followed by a defibrillation shock, if they are not successful.

Thus, the apparatus known from D1 comprises feature (b) and implies feature (d).

However, since the purpose of antitachyarrythmia pacing is to capture the heart during an episode of tachycardia, it is necessary that the pulses are separated by a time interval greater than the refractory time interval of the heart cells which are to be stimulated. Thus, feature (c) of claim 1, which is directed to maintaining a refractory condition in the stimulated heart cells, does not appear to be compatible with the teaching of E1.

4.4 E3 relates to a defibrillation method which consists in delivering a plurality of bursts of electrical current to the heart. As pointed out in this document (page 4, first paragraph), the timing between the shocks is a crucial parameter based upon the patient's fibrillation cycle. A preferred interval range for administering successive shocks is from about 60% to 85% of the fibrillation cycle length (claim 5; page 5, second paragraph). Furthermore, it is specified in E3 that it is known to deliver to a fibrillating heart pulses of electrical current separated by a fixed time interval from 70 ms to 130 ms (page 2, lines 23 to 26). Though this range appears to be covered by the time intervals specified in claim 1 (see features (a) and (c)), it relates to successive defibrillation shocks which usually involve energies of several Joules and, thus, well above the energy of the stimulation pulses specified in the claim 1 of the respondent's request (see feature (d)).

4.5 Summarising, documents E1, E3 and E5 indeed appear to contain elements of the present invention. However, in each one of these documents, the features relevant to

the present case are disclosed in the context of different apparatuses directed to the solution of different problems, and there is no evidence that the person skilled might be led to combine them as taught in the contested patent.

The other prior art documents cited in the course of the opposition proceedings appear to be less relevant and, consequently, their respective teaching cannot affect the outcome of the present case.

4.6 As, in the light of the cited prior art documents, it would not have been obvious to a skilled person to arrive at an apparatus falling within the terms of claim 1 of the respondent's only request, the subject-matter of this claim involves an inventive step within the meaning of Article 56 EPC.

5. In the result, the Board finds that the documents of the respondent's request meet the requirements of the EPC and that the patent can be maintained on the basis thereof.

Order

For the following reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of:

   – claims 1 to 10, filed at the oral proceedings,

   – description, columns 1 to 5, filed at the oral proceedings, and

   – drawings, Figures 1 to 4 of the patent as granted.

The Registrar: The Chairman:

R. Schumacher B. J. Schachenmann