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D E C I S I O N
of 26 August 2005

Case Number: T 0756/03 - 3.4.01

Application Number: 92304020.8

Publication Number: 0568739

IPC: A61N 1/39

Language of the proceedings: EN

Title of invention:
Non-committed defibrillation/cardioversion system

Patentee:
Cardiac Pacemakers, Inc.

Opponent:
Biotronic GmbH & Co. KG

Headword:
-

Relevant legal provisions:
EPC Art. 100(c), 123(2),(3)

Keyword:
"Amendments - added subject-matter (main request - yes)"
"Amendments - broadening of claim (2nd auxiliary request -
yes)"

Decisions cited:
G 0001/93

Catchword:
-

Case Number: T 0756/03 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 26 August 2005

Appellant: (Proprietor of the patent)	Cardiac Pacemakers, Inc. 4100 Hamline Avenue North St-Paul Minnesota 55112-5798 (US)
Representative:	Lindner, Manfred Klaus Patentanwälte Walter-Eggers-Lindner Göllheimer Strasse 5 D-81241 München (DE)
Respondent: (Opponent)	Biotronic GmbH & Co. KG Woermannkehre 1 D-12359 Berlin (DE)
Representative:	Von Oppen, Joachim Eisenführ, Speiser & Partner Anna-Louisa-Karsch-Str. 2 D-10178 Berlin (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 5 May 2003 revoking European patent No. 0568739 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman:	B. Schachenmann
Members:	G. Assi
	R. Bekkering

Summary of Facts and Submissions

I.   The appellant (patent proprietor) lodged an appeal,
        received on 14 July 2003, against the decision of the
        opposition division, dispatched on 5 May 2003, revoking
        the European patent No. 0 568 739 (application number
        92304020.8). The appeal fee was paid on 14 July 2003.
        The statement setting out the grounds of appeal was
        received on 16 September 2003.

II.   An opposition had been filed against the patent as a
        whole and was based *inter alia* on the ground pursuant
        to Article 100(c) EPC.

        In the decision under appeal, the opposition division
        held that the ground for opposition pursuant to
        Article 100(c) EPC prejudiced the maintenance of the
        patent unamended.

III.   Oral proceedings before the Board of Appeal were held
        on 26 August 2005.

IV.   The appellant requested, as main request and first
        auxiliary request (only differing in respect of their
        supporting argumentation), that the decision under
        appeal be set aside and the patent be maintained as
        granted and, as second auxiliary request, that the
        patent be maintained on the basis of an amended claim 1
        filed during the oral proceedings.

V.   The respondent requested that the appeal be dismissed.

VI.   The wording of claim 1 according to the appellant's
        main and first auxiliary request is as follows:

        "*Apparatus (10) for defibrillating/cardioverting the
        heart, comprising sensing means (16) for sensing the
        electrical activity of the heart, including the
        interval between successive R-waves of the ECG;
        detector means for detecting an arrhythmia of the heart;
        storage means (23) for storing the interval between
        successive R-waves; a defibrillation capacitor (24);
        charging means (22) for charging the defibrillation
        capacitor to a predetermined voltage level upon
        detection of an arrhythmia of the heart by said
        detector means; and triggering means (26) for
        triggering the discharge of said defibrillation
        capacitor; characterised in that logic means (20) are
        provided, said logic means (20) including means for
        providing a first delay of a first predetermined period
        of time subsequent to said capacitor being charged to
        said predetermined voltage level; said logic means
        including means for providing a second delay of a
        second predetermined period of time subsequent to said
        first delay; said logic means including means for
        comparing a most recent of stored intervals between
        successive R-waves detected during charging of said
        defibrillation capacitor with a preset value (PCLL)
        during said first delay; said logic means including
        means for entering said second delay of said second
        predetermined period of time if said most recent of
        stored intervals between successive R-waves is greater
        than said preset value; and said logic means including
        means for causing discharge of said defibrillator
        capacitor to the heart if any of the stored intervals*

between successive R-waves is less than said preset value (PCLL) during said second delay."

The wording of claim 1 according to the appellant's second auxiliary request is as follows:

"*Apparatus (10) for defibrillation/cardioverting the heat (sic), comprising sensing means (16) for sensing the electrical activity of the heart, including the interval between successive R-waves of the ECG; detector means for detecting an arrhythmia of the heat (sic); storage means (23) for storing the interval between successive R-waves; a defibrillation capacitor (24); charging means (22) for charging the defibrillation capacitor to a predetermined voltage level upon detection of an arrhythmia of the heart by said detector means; and triggering means (26) for triggering the discharge of said defibrillation capacitor; characterized in that logic means (20) are provided, said logic means (20) including means for providing a first delay of a first predetermined period of time subsequent to said capacitor being charged to said predetermined voltage level; said logic means including means for providing a second delay of a second predetermined period of time subsequent to said first delay; said logic means including means for comparing a most recent of stored intervals between successive R-waves detected during charging of said defibrillation capacitor with a preset value (PCLL) during said first delay; said logic means including means for entering said second delay of said second predetermined period of time if said most recent of stored intervals between successive R-waves is greater than said preset value; and said logic means including*

means for causing discharge of said defibrillator
capacitor to the heart if any of the intervals between
successive R-waves is less than said preset value (PCLL)
during said second delay, in a manner that during the
second delay, if any R-R interval detected is less than
said preset value (PCLL), discharge of the
defibrillation capacitor is immediately effected on the
second R-wave of the first fast interval detected."

Reasons for the Decision

1.   The appeal is admissible.

2.   *Appellant's main and first auxiliary requests*

2.1   In the decision under appeal, the opposition division
        came to the conclusion that the ground for opposition
        mentioned in Article 100(c) EPC prejudiced the
        maintenance of the patent as granted. According to the
        last feature of claim 1, the logic means included means
        for causing discharge of the defibrillator capacitor to
        the heart if any of the stored intervals between
        successive R-waves was less than a preset tachycardia
        rate cycle length limit (PCLL) during the second delay.
        The feature that the said intervals were "*stored*"
        represented subject-matter extending beyond the content
        of the application as filed.

2.2   The application as filed discloses an apparatus for
        defibrillating/cardioverting the heart. According to
        Figure 1 and column 4, lines 31-35 (all citations refer
        to the A1 publication), the apparatus comprises *inter*
        alia a memory 23 "*for storing cardiac condition*

information such as R-R wave intervals and programmable data". The operation of the apparatus and, in particular, the function of the memory can be understood having regard to Figures 2 to 4 and the corresponding description. A so-called "*abort algorithm*", on the basis of which the apparatus operates, essentially consists of three steps.

According to a first step 34, after an arrhythmia is detected, a defibrillation capacitor is charged to a selected level to defibrillate the heart, if necessary. The abort algorithm operates with R-wave sensing during the charging of the capacitor and is accomplished by logic means (see column 2, lines 22-26). The detected R-R intervals are stored in the said memory (see column 5, lines 48-54 in combination with column 4, lines 31-35; claim 15, feature (c); claim 21, feature (d)).

Once the capacitor is fully charged, a first period is initiated. During this period (see claim 9, lines 27-31), alternatively at its end (see column 2, lines 44-49) or thereafter (see claim 1, feature (e)), a comparison is made, at step 42, between the "*last*" or "*most recent*" R-R interval detected while charging the capacitor and the value of PCLL (see Figure 2, step 42).

If the "*last*" or "*most recent*" R-R interval is greater than the value of PCLL, a second "*non-committing*" period is initiated, during which further monitoring of the heart activity is made (see column 6, lines 1-5) and a check is made, at step 46, whether "*any*" R-R interval detected during this period is less than PCLL (see Figure 2, step 46; column 2, line 58 to column 3,

line 9; column 6, lines 12-16; claim 1, features (f),
(g) and (h); claim 9, lines 35-38; claim 15, features
(e), (f) and (g)). If this is the case, the capacitor
charge is delivered to the heart immediately but
synchronously with the second R-wave of the first fast
interval detected during the non-committing period (see
column 6, line 56 to column 7, line 3).

It results from the foregoing that the comparisons made
at steps 42 and 46 substantially consist in comparing
R-R intervals with the value of PCLL. However, they are
different with regard to the number of times and the
moment of the comparison. Whereas the step 42 requires
a single comparison relying on the last R-R interval
detected earlier within the charging time of the
defibrillation capacitor, the step 46 repeats the
comparison for each R-R interval detected during the
second non-committing period until a fast interval is
found being shorter than the value of PCLL. As to the
R-R intervals detected while charging the
defibrillation capacitor, they are stored in memory 23
in order to render the "*last*" R-R interval detected
available for electronic treatment at a later time, i.e.
for the comparison step 42.

2.3   The appellant took the view that the claimed expression
        "*stored intervals*" was an explicit formulation of a
        feature unambiguously deriving from the content of the
        application as filed read by a skilled person. As a
        support for this statement, the appellant argued that
        the apparatus was controlled by a microprocessor having
        a memory in which the R-R intervals were stored.
        This view is not convincing. It is not denied that the
        application as filed discloses a microprocessor having

a memory (see column 4, lines 31-35; Figure 1). However, the function of this memory cannot be inferred from the description of the apparatus as such but only from the phases of the abort algorithm. In particular, whereas the original disclosure explicitly puts the execution of step 42 in direct relation to the microprocessor memory (see column 5, lines 48-54, in particular line 53), it does not permit to conclude beyond doubt that the memory also plays a role with regard to the execution of the further step 46. In the absence of any instruction in this respect, the skilled person would not understand that the teaching pertaining to the previous step 42 also applies to step 46. As a matter of fact, the feature of storing the R-R intervals detected during the second non-committing period is not absolutely necessary for carrying out the comparison step 46 (see point 2.5 below). In this respect, it does not matter that, as the appellant underlined, such a feature would make sense from a technical point of view. It is the requirement under Article 123(2) EPC that counts, according to which a feature representing an amendment has to derive in a direct and unambiguous way from the disclosure of the application as filed, as the respondent submitted. In the present case, this condition is not met.

2.4   The Board is also not convinced by the appellant's further argument that the skilled person, who had the instruction of sensing the R-waves and storing the R-R interval during the defibrillation capacitor charging phase in order to carry out the comparison step during the first period, would not interrupt the storing of R-R intervals during the second period because the original disclosure did not give any hint in this

respect. As a matter of fact, the application as filed is completely silent as to whether the storing step should be carried out or not during the second period too. It is not admissible to interpret this lack of information as an implicit instruction to extend the storing step to the second period. The original disclosure rather leaves to the skilled person the initiative as to how the comparison during the second period should be carried out. The skilled person may well consider whether to store the R-R intervals or not. This, however, does not mean that the feature of storing can be derived in a direct and unambiguous way from the disclosure of the application as filed.

2.5   According to the appellant, the comparison step during the second period implied the necessity of stored rather than volatile values. This was convincingly contested by the respondent which drew attention to the fact that the R-R intervals might well be determined by a counter without the need to store any value. As already stated, the original disclosure does not give any information concerning the way the R-waves should be processed in order to determine the R-R intervals to be compared with the value of PCLL. Thus, any conclusion as to the necessity of storing the R-R interval must be considered as being speculative. It is essential that, unlike the comparison during the first period, each R-R interval detected during the second period is immediately checked until an interval is found being shorter than the value PCLL. This would not render a storing step during the second period necessary or even desired. As the respondent convincingly submitted, the feature that the capacitor charge was delivered to the heart immediately but

synchronously with the second R-wave of the first fast
interval detected during the non-committing period
rather indicated that a storing step would not be
meaningful.

2.6   In conclusion, the appellant's main and first auxiliary
        requests are not allowable because the ground for
        opposition pursuant to Article 100(c) EPC prejudices
        the maintenance of the patent as granted.

3.   *Appellant's second auxiliary request*

3.1   Claim 1 of the second auxiliary request corresponds to
        claim 1 of the main request, in which the term "*stored*"
        is deleted and the last feature "*in a manner that ...*"
        is added (see point VI above).

3.2   In the appellant's view, the amendments avoided the
        problem of the conflicting requirements of Article 123
        EPC, paragraphs 2 and 3, addressed to in decision
        G 1/93 (OJ 1994, 541). In line with this decision (see
        Headnote, point 1, last sentence), in the application
        as filed there was a basis in column 6, line 12-23 for
        replacing the term "*stored*" with the last feature added
        without violating Article 123(3) EPC. Regarding both
        amendments together, claim 1 as amended should be
        interpreted as involving a comparison of the R-R
        intervals detected during the second period, which did
        not necessarily require a storing step as resulted from
        the immediate discharge of the defibrillation capacitor
        effected on the second R-wave of the first fast
        interval detected.

3.3   The added feature is disclosed in column 6, lines 12-16
       of the application as filed. As such it limits the
       protection conferred because the amended claim includes
       a further feature. However, the limiting effect cannot
       compensate for the extension caused by the deletion of
       the term "*stored*". Unlike claim 1 of the patent as
       granted which necessarily requires that the R-R
       intervals be stored during the second period, the
       amended claim 1 covers an embodiment in which the
       storing step is facultative. This interpretation is
       consistent with both the amendments made; with the
       first amendment by way of deletion because there is
       obviously no longer the obligation to store the said
       intervals, with the second amendment by way of addition
       because the term "*immediately*" may also be understood
       as implying that the discharge of the defibrillation
       capacitor is effected without any delay after the first
       fast R-R interval has been detected and stored, if
       desired only. Thus, the appellant's interpretation
       limits the scope of the claim in an undue way. It
       results that the added feature cannot constitute a
       basis for deleting the term "*stored*" without violating
       Article 123(3) EPC. In conclusion, the protection
       conferred is extended, as the respondent submitted.

3.4   Hence, the appellant's second auxiliary request is not
       allowable because of a violation of Article 123(3) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

R. Schumacher   B. Schachenmann

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