

Internal distribution code:

- (A) [] Publication in OJ
(B) [] To Chairmen and Members
(C) [x] To Chairmen
(D) [] No distribution

D E C I S I O N
of 18 December 2001

Case Number: T 0626/97 - 3.4.1

Application Number: 90903344.1

Publication Number: 0458850

IPC: A61N 1/37

Language of the proceedings: EN

Title of invention:

In a living body implantable electromedical device

Patentee:

St. Jude Medical AB

Opponent:

Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro
Berlin

Headword:

In a living body implantable electromedical device/
ST. JUDE MEDICAL AB

Relevant legal provisions:

EPC Art. 83

Keyword:

"Sufficiency of disclosure (no)"

Decisions cited:

T 0005/99

Catchword:

-



Case Number: T 0626/97 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 18 December 2001

Appellant: Biotronik Mess- und Therapiegeräte GmbH &
(Opponent) Co Ingenieurbüro Berlin
Woermannkehre 1
D-12359 Berlin (DE)

Representative: Eisenführ, Speiser & Partner
Pacelliallee 43/45
D-14195 Berlin (DE)

Respondent: St. Jude Medical AB
(Proprietor of the patent) S-175 84 Järfälla (SE)

Representative: Harrison, Michael Charles
Albihns GmbH
Grasserstrasse 10
D-80339 München (DE)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 2 April 1997
rejecting the opposition filed against European
patent No. 0 458 850 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: G. Assi
Members: H. K. Wolfrum
B. J. Schachenmann

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 2 April 1997 rejecting the opposition against European patent No. 0 458 850. The notice of appeal was received on 6 June 1997, the prescribed fee being paid on the same day. The statement setting out the grounds of appeal was received on 10 July 1997.
- II. Opposition had been filed against the patent as a whole and based on the grounds of Articles 100(a) and 100(b) EPC and substantiated on the grounds of lack of inventive step (Articles 52(1) and 56 EPC) and lack of sufficiency of disclosure (Article 83 EPC).
- III. Maintaining these grounds in the appeal, the appellant requested that the contested decision be set aside and that the European patent be revoked.
- IV. The respondent (patentee) requested that the appeal be dismissed and that the patent be maintained as granted (main request) or on the basis of the claims filed as auxiliary requests 1, 2 and 3, respectively, with a letter dated 16 November 2001.
- V. Oral proceedings were held on 18 December 2001.
- VI. Independent claim 1 of the granted patent reads as follows:

"1. Electromedical device, such as a pacemaker (2), implantable into a living body (1) and comprising stimulating means (11) for the stimulation of a

*physiological function in the living body (1),
stimulating mode selector means (12) connected to said
stimulating means (11) to enable modification of said
stimulation by selecting one or more out of a plurality
of available stimulating modes,
a power source in the form of a battery (10) for
powering said stimulating means (11) and stimulating
mode selector means (12),
sensing means (13) connected to said battery (10) to
enable sensing of the instantaneous battery capacity,
and evaluating means (14) connected to said sensing
means (13) to establish whether the battery capacity,
on a sensing event, is higher or lower than a
predetermined first threshold value (ERT-value) adapted
to guarantee, in an assumed standard operation of the
device, its function within a predetermined time
interval during which said battery capacity shall
exceed a lower second threshold value (EOL-value),
characterized in
that said sensing and evaluating means (13, 14) are
arranged to vary said first threshold value (ERT-value)
in dependence on the utilized stimulating mode and in
dependence on degree of utilization of previously
selected stimulating modes recorded in and available
from the stimulating mode selector means (12) in such a
way that a higher threshold value is selected for
stimulating modes with a higher energy consumption and
higher degree of utilization and a lower threshold
value is selected for stimulating modes with a lower
energy consumption and a lower degree of utilization."*

The independent claims 1 of the auxiliary requests are based on claim 1 as granted and define further features, concerning the limitation, by the evaluating

means, of the selection of the stimulating modes to those with a reduced energy consumption when the first threshold value is reached and/or the use of batteries having an internal resistance which increases with decreasing battery capacity.

VII. In the contested decision, the opposition division considered the invention as defined in claim 1 of the granted patent to be disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In particular, the term "*degree of utilization of previously selected stimulating modes*", although not defined in the patent specification, was held to be clear and meaningful to a skilled practitioner, indicating the mean energy consumption which was to be evaluated for the past when estimating a new ERT-value. Such an evaluation was considered as a routine work for the skilled person who could easily calculate the mean energy consumption from the actual lifetime of the battery, the initial capacity of the battery and the remaining capacity of the battery. In the view of the opposition division, the remaining capacity could easily be calculated from the measured actual voltage of the battery and its initial capacity.

VIII. The appellant essentially relied on the following submissions:

Apart from a variety of inconsistencies in the claim wording which could not be resolved on the basis of the patent specification, the crucial point concerned the requirement in claim 1 to vary the first threshold value in dependence on the degree of utilization of previously selected stimulating modes. As regards the term "degree of utilization", the patent did not

provide any definition, and in the written appeal procedure the respondent had relied on different, mutually excluding interpretations of this parameter. Moreover, the patent specification was silent as to how pertinent information regarding this parameter should be obtained. But even if such information could somehow be established, the skilled person would not learn from the patent how to determine therefrom a new value for the first threshold level. There was not a single example or embodiment in the patent specification in which the said threshold value would be varied according to circumstances of the previous use of the battery.

- IX. The respondent disputed the appellant's view, relying essentially on the following arguments:

The skilled person would understand from the patent as a whole that the degree of utilization of a stimulating mode could only mean an indication of the actual power consumed relative to the maximum power consumption in this mode. The maximum possible power consumption of any single mode would be known in advance and prestored in the stimulating mode selector means linked to a mode-specific ERT-value so that when the mode was changed a corresponding new first threshold value was set. It was furthermore possible to measure the time diagram for the voltage or internal resistance of the battery in analogy to the time diagrams shown in Figure 3 of the patent and to store this data in appropriate memory means such as the memory and control circuit 15 associated with the stimulating mode selector means. As was shown by Figure 4, on detection of the ERT-value representing the effective threshold for the beginning of the safety time interval for a maximum degree of

utilization of the respective mode, a signal was generated which activated a switching circuit shown in Figure 5 to cause the memory and control circuit 15 to generate a limitation signal for inhibiting the selection of stimulating modes with high power consumption. Depending on a second signal which was delivered to the switching circuit from the stimulating mode selector means and indicative of whether the degree of utilization of the previously selected stimulating modes had been high or low, said limitation signal was either immediately delivered when the degree of utilization of the previously selected mode had been 100%, or a time delay circuit was started to postpone delivery of said limitation signal when the degree of utilization of the previously selected mode had been lower than 100%. In the latter case, the "real" first threshold value for the start of the inhibition of the selection of high power stimulating modes and thus the beginning of any meaningful safety time interval was lower than the prestored ERT-value and could readily be determined from the stored time diagram data, the knowledge of the fixed second threshold value (EOL-value indicating the end of life of the battery) and the desired (constant) duration of the safety time interval. In summary, the provision of a time delay for the effective safety time to start depending on the degree of utilization of previously selected stimulating modes resulted in an associated lowering of the real first threshold value. Thus, the wording of claim 1 was perfectly supported by the disclosed embodiment and the skilled person would be capable of filling in minor technical details not explicitly addressed by the description.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is therefore admissible.
2. *Sufficiency of disclosure (Articles 100(b) and 83 EPC)*

Notwithstanding some ambiguities in the claim wording objected to by the opponent, the relevant question to be addressed for deciding this issue is whether the patent as a whole would provide sufficient information so as to enable a skilled person, i.e. an expert in the field of implantable electromedical devices, to vary the first threshold value (ERT-value) in dependence on the degree of utilization of previously selected stimulating modes recorded in and available from the stimulating mode selector means, as defined in claim 1 of the granted patent, so as to achieve the object of the invention set out in column 3, lines 9 to 12, of the patent description, i.e. a constant safety time between the appearance of the first and the second threshold value (EOL-value) for the capacity of the battery.

- 2.1 In order to put the claimed subject-matter into practice, the skilled reader of the patent would have to gain, first of all, an understanding of what is meant by the term "degree of utilization of previously selected stimulating modes".
 - 2.1.1 In the course of the appeal proceedings, the respondent has relied on various, mutually excluding interpretations of the term in question. Adopting the opinion of the opposition division, it was first held to refer to a mean energy consumption (cf. point 1 of

the letter dated 27 January 1998). Thereafter, it was interpreted as a measure of how often a mode is used (cf. page 2, line 2 of the letter dated 26 January 1999). The latter definition was finally replaced by an interpretation according to which the degree of utilization is a quantity indicating the ratio of the actually consumed power to the maximum power consumption possible for a selected stimulating mode.

- 2.1.2 As a matter of fact, the patent does not provide an explicit definition of the term referred to above.

The only reference to a degree of utilization as a percentage figure is given in column 7, lines 1 to 13, of the patent description, stating that *"It should be further noted that when the battery capacity is below the ERT-value, the terminal voltage must not be lower than the current voltage valid for the EOL-value of the selected stimulating mode. So, the safety time must be selected in consideration of the possibility that the degree of utilization of the selected stimulating mode could increase drastically. Therefore, for an expected maximum degree of utilization, an ERT-value higher than for a somewhat reduced degree has to be chosen, so that the pacemaker 2 is able to function with a 100% degree of utilization, or at least 80%, during the safety time."* However, quite apart from the fact that the cited passage (as well as the description as a whole) does not explain the exact nature of the "degree of utilization" and is silent as to how the ERT-value, i.e. the first threshold value, would have to be determined, the passage refers to a degree of utilization **after** the first threshold value has been reached and teaches to **preselect** a higher threshold

value when it is to be **expected** that the degree of utilization of the selected stimulating mode could strongly increase during the safety time. Thus, the passage referred to above does not contain any information on how to determine the degree of utilization of **previously** selected stimulating modes.

Moreover, the patent specification neither explicitly nor implicitly refers to quantities such as a "maximum power consumption possible for a selected stimulating mode" or an "actually consumed power for a selected mode", relied on by the respondent in its most recent interpretation of the degree of utilization.

Therefore, the patent specification does not support the respondent's most recent interpretation of the degree of utilization of a stimulating mode.

2.1.3 None of the other interpretations previously relied on by the respondent would be supported by the patent specification either. A "mean energy consumption" is not addressed in the patent nor is there any indication that in operation of the device a record would be kept as to how often a selected mode was used. The interpretation relied on in the contested decision appears to be particularly speculative in view of the fact that it would in general appear difficult, if not impossible, to determine a reliable information about a battery's **remaining** capacity from a measurement of its actual voltage or internal resistance.

2.1.4 In these circumstances, it is not possible for a person skilled in the art to determine the proper technical meaning of the term "degree of utilization of previously selected stimulating modes", which

constitutes an essential characteristic of the claimed subject-matter in that it influences the claimed variation of the first threshold value so as to achieve a constant safety time interval. In view of such a fundamental ambiguity concerning an important characteristic of a claim, which cannot be resolved on the basis of the patent as a whole, the disclosure has to be considered not to be sufficiently clear and complete to be carried out by a skilled person (cf. T 5/99).

- 2.2 The Board wishes to add that, depending on the exact meaning of the "degree of utilization", quite different technical means would be required in order to obtain a respective record for previously selected stimulating modes, such as means keeping a record of the number of the stimulating events and the energy delivered in each event, or a counter for recording of the number of times a selected mode was used, or means establishing and keeping a record of time diagram data for the voltage of the battery.

None of the means of the electromedical device disclosed in the patent is described to perform any of the above functions. In particular, according to column 7, lines 47 to 54, of the patent description, *"It is further possible to make corrections for certain stimulating parameters to increase the ERT-value when a high degree of utilization of the selected stimulating mode is established and vice versa"*. However, no explanation is given as to the nature of the parameters, the circumstances of the corrections or the specific means involved. As a matter of fact, the patent specification does not give a single example according to which, during operation of the device, the

first threshold value is indeed varied in dependence on the degree of utilization of previously selected stimulating modes. Thus, even if a record of a degree of utilization of previously selected stimulating modes was somehow available (as is indicated in the context of a possible introduction of a time delay for inhibiting the selection of stimulating modes with a high power consumption), the skilled reader of the patent specification would still not learn how to derive therefrom a new value of the first threshold level so as to achieve a constant safety time.

For these reasons, the skilled reader is not in a position to try and sort out without undue burden those technical means and functions which would guarantee a solution to the posed problem of achieving a constant safety time by a variation of the first threshold value.

- 2.3 As regards the respondent's explanation relating to a variation of a "real" first threshold value occurring in the disclosed device, it is based on a distinction between a preset ERT-value for a given stimulating mode (being determined for the maximum possible power consumption in the respective mode) and a "real" first threshold value (which would be lower than the ERT-value when the actual power consumption is lower than maximum).

However, according to column 2, lines 28 to 47, and column 5, lines 53 to 56, of the patent description, the "safety time" is defined as the time period from a certain point in time, called elective replacement time (ERT), when the battery capacity approaches a critical first threshold value (ERT-value) till the end of life

(EOL) of the battery, when the battery capacity approaches a lower second threshold value (EOL-value). In column 6, lines 54 to 58, it is further stated that *"during the safety time, it is therefore suitable to introduce a restriction in the selection of stimulating modes so that there is only a selection of stimulating modes having an energy consumption lower than a predetermined value"*. Throughout the description, the terms "first threshold value" and "ERT-value" are used as synonyms. The patent specification does not comprise any indication to a "real" first threshold value which would differ from the ERT-value. As becomes evident from column 7, lines 36 to 47, the ERT-value is used as an adjustable reference voltage for a voltage comparator and corresponds *"to the selected stimulating mode, whereby, for a stimulating mode with a high energy consumption, the ERT-value is higher than for a stimulating mode with a lower energy consumption"*. Moreover, it is stated in column 7, line 57, to column 8, line 2, that if the measured voltage of the battery *"agrees with or is lower than the reference voltage, the voltage comparator 47 changes its output state and starts the safety time"*.

Hence, the description does not leave any doubt that the safety time starts with the first observation of the battery voltage being at or below the first threshold value.

It follows that the respondent's submission relies on a misinterpretation of the patent specification and thus cannot be accepted.

2.4 For the above reasons, it is to be concluded that, in the absence of a clear technical disclosure of the term

"degree of utilization" of a stimulating mode as well as due to the lack of any indication as to how and by which means the degree of utilization of previously selected modes could be established and as to how a specific variation of the first threshold could be derived therefrom, the skilled person is not in a position to select, on the basis of common general knowledge and the information provided by the patent specification, the first threshold value in dependence on the degree of utilization of previously selected stimulating modes so as to achieve a constant safety time between the appearance of the first and the second threshold value for the capacity of the battery. Thus, the patent as a whole does not enable the skilled person to carry out the invention.

- 2.5 Since the requirement for a variation of the first threshold value in dependence on the degree of utilization of previously selected stimulating modes is included in claims 1 of all the respondent's requests on file, the objection referred to above applies to all the requests. Consequently, none of these requests complies with the requirement of Article 83 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

R. Schumacher

G. Assi