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**D E C I S I O N**  
**of 13 July 2004**

**Case Number:** T 0277/01 - 3.4.1

**Application Number:** 90122538.3

**Publication Number:** 0431437

**IPC:** A61N 1/378

**Language of the proceedings:** EN

**Title of invention:**

A system and method for maintaining stimulation pulse amplitude at battery depletion by self-regulating current drain usage

**Patentee:**

PACESETTER, INC.

**Opponent:**

Biotronik GmbH & Co. KG

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 100(c)

**Keyword:**

"Amendments - added subject-matter (yes)"

**Decisions cited:**

T 1018/02

**Catchword:**

-



Case Number: T 0277/01 - 3.4.1

**D E C I S I O N**  
of the Technical Board of Appeal 3.4.1  
of 13 July 2004

**Appellant:** Biotronik GmbH & Co. KG  
(Opponent) Woermannkehre 1  
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**Representative:** Eisenführ, Speiser & Partner  
Patentanwälte Rechtsanwälte  
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**Respondent:** PACESETTER, INC.  
(Proprietor of the patent) 15900 Valley View Court  
Sylmar, CA 91392-9221 (US)

**Representative:** Roberts, Gwilym Vaughan  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 18 December 2000  
rejecting the opposition filed against European  
patent No. 0431437 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairman:** H. K. Wolfrum  
**Members:** R. K. Bekkering  
A. Pignatelli

## Summary of Facts and Submissions

- I. The appeal was lodged by the opponent (appellant) against the decision of the opposition division, dispatched on 18 December 2000, rejecting the opposition against European patent No. 0 431 437. The notice of appeal was received on 27 February 2001, the appeal fee being paid on the same day, and the statement setting out the grounds of appeal was received on 27 April 2001.
- II. Opposition had been filed against the patent as a whole, *inter alia* based on Article 100(c) EPC.
- III. Oral proceedings were held on 13 July 2004. The patentee (respondent) did not attend, as announced by letter of 17 May 2004.
- IV. The appellant requested that the decision under appeal be set aside and the patent revoked.
- V. The respondent requested that the appeal be dismissed.
- VI. Independent claims 1 and 13 of the patent as granted read as follows:

*"1. An implantable pacemaker comprising:  
a battery (66) having a battery voltage which is dependent on current drain from the battery;  
a battery voltage threshold detector (64) for monitoring the battery voltage of the battery, the battery voltage threshold detector (64) detecting when the battery voltage drops at least to a first predetermined voltage;*

a pulse generator (14) for generating stimulation pulses to a patient's heart; the stimulation pulses having a constant amplitude when the battery voltage is above the first predetermined voltage;

a signal processor (42) coupled to the battery voltage threshold detector (64), the signal processor (42) being capable of operating in at least three modes of operation each having a different level of current drain; and

means for switching the signal processor (42) from a mode of operation having a higher level of current drain to a mode of operation having a lower level of current drain when the battery voltage threshold detector (64) detects that the battery voltage is below the first predetermined voltage, characterised in that the stimulation pulse amplitude is maintained at the constant value when the signal processor (42) is switched to a mode of operation having a lower level of current drain."

"13. A method of maintaining a constant stimulation pulse amplitude as the battery approaches depletion and preventing rapid depletion of a battery in an implantable stimulation device, comprising the steps of: generating stimulation pulses with the implantable stimulation device, the implantable stimulation device being capable of operating in a high current drain mode and at least two progressively lower current drain modes;

detecting when the voltage across the battery drops below a predetermined threshold; and

switching from the high current drain mode to a progressively lower current drain mode each time the

*battery voltage is detected below the predetermined threshold."*

VII. The appellant argued that claim 1 as granted contained subject-matter extending beyond the content of the application as originally filed, contrary to Article 100(c) EPC. Whereas the original disclosure related to a pacemaker system for maintaining a constant amplitude of the stimulation pulses for as long as possible, the subject-matter of claim 1 as granted encompassed also a pacemaker in which the stimulation pulse was not constant. According to the granted wording, the pulse amplitude could be maintained constant merely for the short period of time in which the switching between the modes of operation took place. The amended wording of the claim thus included numerous other embodiments and therefore constituted an inadmissible broadening.

VIII. The respondent submitted that the amendments in claim 1 as granted were no more than a rearrangement and clarification of claim 1 as originally filed. Furthermore, the assertion of the appellant that claim 1 as granted merely required that the pulse amplitude remained constant for the duration of the switching between modes of operation made no sense in the light of the remainder of the wording of the claim or the specification as a whole.

## 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. *Article 100(c) EPC*

2.1 Amendments

The wording of claim 1 as granted is based on that of claim 1 as originally filed with the replacement of the designation of the invention "*In an implantable stimulation device, a system for maintaining a constant stimulation pulse amplitude and for preventing rapid battery depletion*" by "*An implantable pacemaker*" and the addition of the characterising part "*characterised in that the stimulation pulse amplitude is maintained at the constant value when the signal processor is switched to a mode of operation having a lower level of current drain*".

2.2 Matter defined by claim 1

According to the respondent, claim 1 as granted defines an implantable pacemaker in which the stimulation pulse amplitude is maintained at the constant value in all modes of operation of the processor throughout the life of the battery until this is no longer possible at the end of the battery's life.

In the appellant's opinion, on the other hand, the wording of claim 1 as granted also encompasses an implantable pacemaker in which the stimulation pulse

amplitude is maintained at the constant value of the stimulation pulses generated when the battery voltage is above a first predetermined voltage, for the period of time in which the signal processor is switched to a mode of operation having a lower level of current drain, but in which the pulse amplitude is varied subsequently. Thus, according to the appellant, "when" in the characterising portion of claim 1 as granted not only has to be understood in the meaning of "in the event that" but definitely also in the meaning of "during the time that" having regard to the switching of the signal processor.

It is noted that, as such, alterations of the stimulation pulse amplitude in the time period after the signal processor is switched to a mode of operation having a lower level of current drain, which, as a matter of fact, still may extend over several months or even years, performed by the pacemaker eg to adapt to changing physiological conditions of the patient such as the capture threshold, undoubtedly make technical sense. Furthermore, it makes technical sense to concentrate in particular, in the design of the pacemaker, on the maintenance of the pulse amplitude at the time of switching between modes of operation, in order to warrant continuity in the delivery of pacing therapy to the patient.

In the board's view, therefore, the skilled person would understand claim 1 as indicated by the appellant.

Accordingly, the matter for which protection is sought defined by claim 1 of the patent in suit, as understood by the skilled person working in the technical field of

pacemaker systems at issue, includes an implantable pacemaker in which the stimulation pulse amplitude is maintained at a constant value for the period of time in which the signal processor is switched to a mode of operation having a lower level of current drain, but varied subsequently.

### 2.3 Original disclosure

Claim 1 as originally filed, which of all originally filed claims resembles most claim 1 of the patent as granted, is directed to "a system for maintaining a constant stimulation pulse amplitude". Independent claim 5 as originally filed, which is also directed to a system for maintaining a constant stimulation pulse amplitude, defines that the stimulation pulse amplitude is maintained constant "for as long as possible". Accordingly, these claims disclose a system maintaining a constant stimulation pulse amplitude throughout all modes of operation until this is no longer possible due to almost complete depletion of the battery.

According to the description and the drawings as originally filed (see in particular Figures 2B, 3, 4A, 4B and corresponding description), the stimulation pulse amplitude is maintained over the life of the battery up to when it approaches its end-of-life by decreasing the "allowable" maximum sensor rate of the pacemaker in successive steps until it reaches the programmed base rate. Furthermore, according to the description (cf application as published, column 10, line 40, to column 11, line 8), more in general the pacemaker may have high current drain modes including rate responsive pacing, automatic capture verification,



automatic amplitude adjustment, automatic sensitivity adjustment, telemetry transmission of ECG data or measurements, waveform analysis, tachycardia or arrhythmia recognition, or any other features which increase microprocessor processing time. In order to maintain stimulation pulse amplitude as the pacemaker approaches the battery's end-of-life, the pacemaker includes means for switching from a high drain current mode to successively lower current drain modes which are achieved by altering or limiting parameters such as reducing the sampling rate, pacing rate, or otherwise reducing the duty cycle of the microprocessor. In particular, the high current drain modes may be successively switched to lower current drain modes according to a predetermined priority based on basic life support and quality of life.

- 2.4 Accordingly, the application documents as originally filed disclose a pacemaker maintaining an at least substantially constant stimulation pulse amplitude throughout all modes of operation until this is no longer possible at the end of the battery's life.

Claim 1 as granted on the other hand encompasses a pacemaker allowing for intentional variations of the pulse amplitude thereby providing a broadening of the original disclosure.

- 2.5 The respondent, as well as the first instance in the decision under appeal, in substance argued in this respect that the above reading of the claim by the appellant made no sense in the light of the remainder of the claim, did not appear to make technical sense and lacked any support in the patent (cf letter of the

respondent dated 7 January 2002, page 2, second paragraph).

As expounded in paragraph 2.2, the claim in itself allows for the above understanding by a skilled reader which makes technical sense. It thus provides an additional reading of the claim to the more restricted reading relied upon by the respondent.

Regarding the argument above that the appellant's reading of the claim "lacked any support in the patent", as far as it implies that the claim should be read restrictively in the light of the description and drawings (cf Article 69(1) EPC), it is noted that as far as the requirements of Article 100(c) EPC are concerned, where amendments to a claim lead to different possible readings of a claim, as such all making technical sense to the skilled reader of the claim in itself, like in the present case, the description or drawings cannot be used, in the board's view, to rule out a reading of the claim which is not derivable from the description or drawings. Such amendments introduce subject-matter which extends beyond the content of the application as filed and are, therefore, inadmissible (Article 100(c) EPC). In the board's opinion, a different finding would lead to an erosion of the requirement of Article 100(c) EPC in respect of amendments to the claims, since in particular generalising amendments as a rule could be justified by only attributing the meaning to the amendments to the extent in which they had been disclosed in the description and drawings (see also decision T 1018/02, point 3.8 of the reasons). Moreover, to ignore the definitions provided by a claim, as

suggested by the respondent, would be at odds with the function of the claims of defining the matter for which protection is sought. In the board's view, an interpretation of the claim using the description and drawings as provided for by Article 69(1) EPC with the corresponding protocol on the interpretation would appear neither necessary nor appropriate having regard to amendments at a procedural stage at which claims can still be amended.

- 2.6 Accordingly, for the reasons given above, claim 1 as granted contains subject-matter which extends beyond the content of the application as originally filed, contrary to Article 100(c) 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:

D. Sauter

H. Wolfrum