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**D E C I S I O N**  
**of 14 May 2002**

**Case Number:** T 0881/97 - 3.4.1

**Application Number:** 91109118.9

**Publication Number:** 0463410

**IPC:** A61N 1/08

**Language of the proceedings:** EN

**Title of invention:**

Apparatus for stimulating living tissue

**Patentee:**

St. Jude Medical AB

**Opponent:**

Biotronik Mess- und Therapiegeräte GmbH & Co Ingenieurbüro  
Berlin

**Headword:**

Apparatus for stimulating living tissue/ST. JUDE MEDICAL AB

**Relevant legal provisions:**

EPC Art. 54(1) and (2), 84

**Keyword:**

"Novelty (no; main request, first and second auxiliary  
request)"

"Late-filed requests (not admitted; third to fifth auxiliary  
request)"

**Decisions cited:**

T 0409/00, T 0607/93, T 1002/92

**Catchword:**

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Case Number: T 0881/97 - 3.4.1

**D E C I S I O N**  
**of the Technical Board of Appeal 3.4.1**  
**of 14 May 2002**

**Appellant:** Biotronik Mess- und Therapiegeräte GmbH &  
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**Representative:** Christiansen, Henning  
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**Respondent:** St. Jude Medical AB  
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**Representative:** Harrison, Michael Charles  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 17 June 1997  
rejecting the opposition filed against European  
patent No. 0 463 410 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairman:** G. Davies  
**Members:** H. K. Wolfrum  
R. Q. Bekkering

## Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 17 June 1997 rejecting the opposition against European patent No. 0 463 410. The notice of appeal was received on 12 August 1997, the prescribed fee being paid on the same day. The statement setting out the grounds of appeal was received on 17 September 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 novelty and inventive step (Articles 52(1), 54(1) and (2) and 56 EPC) as well as lack of sufficiency of disclosure (Article 83 EPC).
- III. In the appeal, the appellant pursued the ground of Article 100(a) EPC by relying *inter alia* on document:  
  
D1: EP-B-0 071 965.
- IV. Oral proceedings were held on 14 May 2002.
- V. The appellant requested that the contested decision be set aside and that the European patent be revoked.
- VI. The respondent (patentee) requested that the appeal be dismissed and that the patent be maintained as granted (main request) or on the basis of one of auxiliary requests 1 to 5 filed in the oral proceedings.

VII. Independent claim 1 of the **main request** reads as follows:

"1. Apparatus for stimulating living tissue comprising a battery (11) with an internal resistance (12), which is dependent on the charge of the battery (11), a stimulating pulse generator (10), which is connected to the battery (11) and includes an output capacitor (6), which is slowly charged by the battery (11), and, in order to deliver a stimulating pulse, quickly discharged across the tissue, a measuring device (3), which measures the voltage across the output capacitor (6), and a control device (1), which controls the stimulating pulse generator (10) dependent on a predetermined stimulating pulse time interval and on the fact that the voltage across the output capacitor (6), which is measured by the measuring device (3), reaches a, by the control device (1) selected, predetermined value (1), for the stimulating pulse amplitude, characterized in that the control device (1) gives a minimum value of the stimulating pulse time interval  $T_m$  and in that the minimum value is increased if the time period, from the time when the voltage across the output capacitor (6) has reached the value of the stimulating pulse amplitude until the time when the stimulating pulse is delivered, is shorter than a predetermined safety time interval  $T_a$  selected by the control device (1)."

In claim 1 of the **first auxiliary request**, the definition of the control device in the preamble is changed to "a control device (1), which controls the stimulating pulse generator (10) to deliver a stimulating pulse when a predetermined stimulating

*pulse time interval has expired"*, and in the characterizing clause the minimum value of the stimulating pulse time interval  $T_m$  is defined by the phrase "*that the control device (1) limits the stimulating pulse time interval by a minimum value  $T_m$* ". Moreover, the patent specification has been amended inter alia by deleting from column 3, lines 15 to 19 the passage "*The value of the minimum stimulating pulse time interval may thereby be increased also during the stimulating pulse time interval, in which the time period is shorter than the safety time interval.*"

In distinction to claim 1 as granted, according to the **second auxiliary request** the phrase "*the minimum value is increased*" has been transferred to the end of claim 1 and is followed by the phrase "*after delivery of said stimulation pulse*". The same passage as for the first auxiliary request is deleted from the patent specification.

The **third auxiliary request** differs from the second auxiliary request by the deletion of dependent claim 4 and the corresponding description in column 2, line 51 to column 3, line 15.

In the **fourth auxiliary request**, dependent claims 2 to 4 of the patent as granted are formulated as independent claims 1 to 3, respectively, and the description was correspondingly amended.

According to the **fifth auxiliary request**, claim 1 differs from claim 1 as granted in that the phrase "*the minimum value is increased*" has been transferred to the end of the characterizing clause where it is preceded

by the phrase "*and if a stimulating pulse is delivered during said predetermined safety time interval  $T_a$* " and followed by the phrase "*by said control device before delivery of a subsequent stimulation pulse*". As in the first to third auxiliary requests the aforementioned passage from column 3, lines 15 to 19 of the patent specification has been deleted.

VIII. In the contested decision, the opposition division considered the subject-matter of claim 1 as granted to differ from the teaching of document D1 by the provision of a minimum value of the stimulating pulse time interval  $T_m$  and the measure that said value is increased if the time period, from the time when the voltage across the output capacitor has reached the value of the stimulating pulse amplitude until the time when the stimulating pulse is delivered, is shorter than a predetermined safety time interval  $T_a$ . Since D1 did not make obvious the provision of a safety time interval, a combination with documents referring to safety time intervals in different contexts did not render obvious the subject-matter of claim 1 as granted.

IX. The appellant essentially relied on the following submissions:

**Main request**

The subject-matter of claim 1 of the main request lacked novelty with respect to the prior art according to document D1. The known apparatus did not only show the structural features comprised in the preamble of claim 1 but also operated in the same manner as specified in the characterizing part of the claim. In

the specific circuit according to Figure 1 of D1, a minimum value of the stimulating pulse time interval was given by the switching time  $t_{m2}$  of the monostable flip-flop 11. Moreover, in the known apparatus, a slower charging of the output capacitor caused a delay in the delivery of the stimulating pulses, which had to be considered as an effective increase in the minimum value of the stimulating pulse time interval. The condition for increasing the minimum value even included the presence of a "safety time interval" because the delivery of a stimulating pulse was inevitably delayed due to inherent switching times of the NOR gate 12, a further flip-flop 10 and the transistor switch 3 as well as signal propagation delays in the electrical interconnections. Hence, in the operation of the circuit shown by Figure 1 of D1, there occurred always a time interval between the time when the voltage across the output capacitor had reached the value of the stimulating pulse amplitude until the time when the stimulating pulse was actually delivered, i.e. the output capacitor was discharged by the switching of transistor switch 3. In view of the continued charging of the output capacitor, this time interval guaranteed a safety margin for the desired stimulating pulse amplitude to be reached. In comparing the functions of the claimed and known apparatuses, the wording of claim 1 under consideration was not to be interpreted as defining an increase in the minimum value  $T_m$  only after the actual delivery of a stimulating pulse, because, in the light of the information given in column 3, lines 12ff of the patent specification, the phrase "*until the time when the stimulating pulse is delivered*" had to be interpreted as including a fictitious point in time when the stimulating pulse should have been delivered.



### **Auxiliary requests**

With the exception of the first auxiliary request, which corresponded in substance to a request filed in due time before the oral proceedings, the auxiliary requests were filed late and thus should not be admitted into the proceedings. Moreover, none of the claims of these requests defined in a clear and unambiguous manner that the minimum value of the stimulating pulse time interval was increased only after a stimulating pulse time had actually been delivered and thus was effective only for subsequent stimulating pulses and that in fact a comparison was made between the specified time period and the predetermined safety interval.

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

### **Main request**

The subject-matter of claim 1 of the main request differed from an apparatus for stimulating living tissue as known from document D1 by the features given in the characterizing clause.

The apparatus as shown in figure 1 of document D1 operated with a single frequency of the stimulating pulses ("Grundfrequenz") set by the switching time of a monostable flip-flop and thus with a fixed and unique stimulating pulse time interval which could not be considered to constitute a "minimum value of the stimulating pulse time interval" set by the control device according to the clear and well-defined meaning of the present patent.

Moreover, no increase was foreseen in the known apparatus of the unique stimulating pulse time interval if the charging time of the output capacitor exceeded the switching time of the flip-flop. Hence the charging of the capacitor determined the frequency with which stimulating pulses could be delivered. In distinction thereto, claim 1 as granted defined a condition for increasing the minimum value of the stimulating pulse time interval, namely if the time period between the time it took to charge the capacitor and the time when the stimulating pulse was delivered was shorter than a predetermined safety time interval  $T_a$  selected by the control device. In this context, it was apparent from the expression "*when the stimulating pulse is delivered*", which defined the end of the time period which was to be compared to the safety time interval, that the increase in the minimum value  $T_m$  was effected **after delivery** of the stimulating pulse for subsequent stimulating pulses. Due to the claimed use of the parameters  $T_m$  and  $T_a$ , a stimulating pulse was delivered after expiry of the predetermined stimulating pulse time interval, irrespective of subsequently effected adaptations thereof necessitated by variations in the stimulating pulse amplitude or duration. Thus, control of the stimulating pulse time interval by the control device could be retained.

Document D1 did not teach to introduce a predetermined safety time interval as a delay between the charging time of the capacitor and the time of delivery of the stimulating pulse nor did it hint at a comparison to be made between said time period and the safety time interval.

**Auxiliary requests**

The amendments made in the auxiliary requests further emphasized the distinctions between the active control of the stimulating pulse time interval according to the invention and the passive reaction of the pulse generator circuit in the apparatus according to D1 to increasing charging times of the output capacitor.

More specifically, the amendments to claim 1 of the first auxiliary request further clarified the fact that the control device independently determined the stimulating pulse time interval and limited the minimum value thereof. A piece of information which possibly could give rise to confusion in this respect was deleted from the description.

As regards the second auxiliary request, the amendments to claim 1 made it unambiguously clear that the minimum value  $T_m$  was increased after delivery of the stimulating pulse. In the third auxiliary request, the whole embodiment was deleted, in the context of which the aforementioned, possibly confusing information was given.

The independent claims of the fourth auxiliary request related to specific embodiments of the active control of the stimulating pulse time interval by the control device.

Claim 1 according to the fifth auxiliary request expressly defined that the minimum value  $T_m$  was only increased if a stimulating pulse was delivered during the predetermined safety time interval.

## **Reasons for the Decision**

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is therefore admissible.

2. *Novelty (Articles 52(1) and 54(1) and (2) EPC)*

2.1 Main request

2.1.1 Subject-matter of claim 1

Claim 1 as granted is directed to an apparatus for stimulating living tissue. In the preamble, the apparatus is defined by its basic structural elements, such as a stimulating pulse generator including an output capacitor connected to a battery, a measuring device for measuring the voltage across the output capacitor, and a control device controlling the delivery of stimulating pulses. The characterizing part consists of definitions of physical activities to be performed by the apparatus in that the control device is required to give a minimum value of the stimulating pulse time interval  $T_m$  and in that the minimum value is increased if a certain condition is met.

The condition is that the time period, from the time when the voltage across the output capacitor has reached the value of the stimulating pulse amplitude until the time when the stimulating pulse is delivered, is shorter than a predetermined safety time interval  $T_a$  selected by the control device.

The respondent interpreted this condition as implying that a stimulating pulse must have been actually delivered before an increase in the minimum value  $T_m$  could occur since it was the delivery of the stimulating pulse which defined the end of the time

period that was compared with the safety time interval.

The Board concedes that the respondent's interpretation of the claim wording is as such perfectly reasonable. However, it is not the only interpretation which is justified in the light of the patent specification. In this context, reference is made to column 3, lines 12 to 19 of the patent specification stating "*Further, the difference between the time period and the safety time interval may be determined already before the stimulating pulse is delivered. The value of the minimum stimulating pulse time interval may thereby be increased also during the stimulating pulse time interval, in which the time period is shorter than the safety time interval.*" It follows that the phrase "when the stimulating pulse is delivered" is also meant to define a point in time at which the stimulating pulse would only have been **intended** to be delivered. In this alternative interpretation, the end of the time period is given by the fictitious end of a predetermined stimulating pulse time interval, whereas the actual delivery of the stimulating pulse is delayed until the safety time interval has expired, as the consequence of an immediate increase in the minimum value  $T_m$  in a single step. Moreover, it is noted that the claim wording does not specify how and by which means a comparison between the specified time period and the safety time interval would be made.

#### 2.1.2 Prior art according to document D1

Undisputedly, document D1 shows an apparatus for stimulating living tissue which comprises the physical entities according to the preamble of claim 1 under consideration. According to the specific embodiment

given by the circuit shown in Figure 1, the known apparatus will deliver a stimulating pulse by discharging the output capacitor 5 when a transistor 3 is switched into its conducting state. The switching occurs only when two conditions are met at a NOR gate 12 : the voltage at the output capacitor has reached a selected predetermined value  $V_{\min}$  for the stimulating pulse amplitude (as is controlled by a comparator 8) **and** a pulse time interval  $t_{m2}$ , which corresponds to the switching time of a monostable flip-flop 11, has elapsed. In normal operation of the apparatus, the switching time of the monostable flip-flop 11 determines the basic operating frequency and thus a fixed (although in principle variable) stimulating pulse time interval. If the time required for charging the output capacitor to the desired pulse amplitude  $V_{\min}$  becomes longer than the switching time of the monostable flip-flop 11, the delivery of the stimulating pulse is delayed (and thus the stimulating pulse time interval is increased) until  $V_{\min}$  is reached.

### 2.1.3 Discussion

In the known apparatus, the basic operating frequency is set to a predetermined value (by monostable flip-flop 11) which can in principle be varied but, once set, will not be exceeded and hence constitutes an upper limit of the stimulating pulse rate. Consequently, the switching time of the monostable flip-flop 11 determines a stimulating pulse time interval which, notwithstanding the fact that it happens to coincide with the predetermined stimulating pulse time interval, cannot become shorter and thus, in any reasonable interpretation of the term, constitutes a "minimum value" of the stimulating pulse time

interval.

The respondent's argument brought forward in this context that the fixed and unique stimulating pulse time interval appearing in the apparatus known from D1 could not be considered to constitute a "minimum value of the stimulating pulse time interval" within the meaning of the present patent, as well as the corresponding judgement of the opposition division according to points (2a) and (3c) of the reasons, rely on the assumption that the predetermined stimulating pulse time interval and the minimum value thereof were different entities. However, claim 1 under consideration only specifies that the control device controls the stimulating pulse generator "*dependent on a predetermined stimulating pulse time interval*" and that "*the control device gives a minimum value of the stimulating pulse time interval*". In fact, the claim wording does not allow for an unambiguous distinction between the "predetermined" stimulating pulse time interval and its "minimum value" and, in view of the broad and unspecific meaning of the terms used, encompasses an operation at a given minimum value of the stimulating pulse time interval as described in document D1.

A further point to be considered is whether it can be said that the minimum value of the stimulating pulse time interval according to D1 would be "increased" according to circumstances. Although in the apparatus according to Figure 1 of D1, an increase in the pulse time interval of the stimulating pulses delivered (in response to an increase in the charging time  $T_L$  of the capacitor) is not strictly speaking the result of a corresponding increase in the setting of the switching

time  $t_{m2}$  of the monostable flip-flop 11, the overall effect of the operation of the circuit is nevertheless as if such a new setting had been performed. In other words, if the circuit of Figure 1 of D1 were considered a "black box", its function in reaction to an increase in the charging time of the output capacitor could legitimately be described as an increase in the minimum value of the stimulating pulse time interval. It is to be noted in this respect that claim 1 under consideration does not provide any information as to how and by what exactly the minimum value  $T_m$  would be determined and increased.

Having established that the effective operation of the known device can be described as an increase of the minimum value of the stimulating pulse time interval according to circumstances, it has finally to be considered whether the conditions for such an increase would correspond to those claimed. Claim 1 specifies that the minimum value is increased *"if the time period, from the time when the voltage across the output capacitor has reached the value of the stimulating pulse amplitude until the time when the stimulating pulse is delivered, is shorter than a predetermined safety time interval  $T_a$  selected by the control device"*. As follows from the observations given in point 2.1.1 above, this condition has to be interpreted as encompassing the possibility of an immediate, one-step increase of the minimum value  $T_m$  (and thereby a delay for the actual delivery of a stimulating pulse) if the initially intended time of delivery of the stimulating pulse time falls within the time interval given by the time it takes for charging the output capacitor plus a predetermined safety time interval. With the switching time  $t_{m2}$  of the monostable



flip-flop 11 in Figure 1 of D1 being the minimum value of the stimulating pulse time interval and determining at the same time the initially intended time of delivery of the stimulating pulse, the condition for an increase of the minimum value has to be considered as falling within the claimed terms. This is all the more true as the claim wording under consideration does not require a comparison between the specified time period and the safety time interval to be performed as an active step of operating the apparatus.

2.2.4 In summary, in the Board's judgement, the teaching of D1 falls within the general functional terms of claim 1 of the main request, so that the subject-matter of the latter lacks novelty, contrary to the requirement of Articles 52(1) and 54(1) and (2) EPC.

## 2.2 First auxiliary request

The amendments proposed to claim 1 concern the features that the control device controls the stimulating pulse generator to deliver a stimulating pulse when a predetermined stimulating pulse time interval has expired and that the control device limits the stimulating pulse time interval by a minimum value  $T_m$ .

Obviously, the amendments do not remove the crucial ambiguity in the interpretation of the claim wording referred to in point 2.1.1 above so that the subject-matter of claim 1 of the first auxiliary request also lacks novelty and thus does not comply with Articles 52(1) and 54(1) and (2) EPC.

In this context, it is added that the mere removal, as in the present case, of passages from the patent

specification which expressly support a wider interpretation of the claim wording does not limit the scope and interpretation of a broad claim definition with respect to the prior art (see decisions T 607/93 in "Case Law of the Boards of Appeal of the European Patent Office, 4th edition 2001, page 64; and T 409/00, not published).

## 2.3 Second auxiliary request

### 2.3.1 Admissibility

In the oral proceedings, the Board had deemed it appropriate to admit the late-filed second auxiliary request into the proceedings because it differed in substance from the main request merely by the addition of a short expression to claim 1 and appeared to be a suitable basis for discussion whether and possibly how the invention could be distinguished from the cited prior art.

### 2.3.2 Novelty

In the Board's opinion, the additional specification that the minimum value is increased "*after delivery of said stimulation pulse*" is too vague and thus insufficient to exclude an interpretation of the claim according to which the stimulating pulse was a fictitious pulse, which was only intended to be delivered. In fact, the amended claim wording does not unambiguously specify that the increase of the minimum value was made for stimulating pulses following the actual delivery of a stimulating pulse for which the claimed condition was observed by a comparison of the time period with a predetermined safety time interval

and continued until said time period exceeded the safety time interval. Moreover, in view of the fact that an apparatus for stimulating living tissue delivers stimulating pulses on a more or less regular basis (see for instance the specific embodiments according to Figures 2 to 4 of the present patent), there would always be a stimulating pulse preceding an increase of the minimum value.

Accordingly, the subject-matter of claim 1 of the second auxiliary request lacks novelty with respect to the teaching of document D1 (Articles 52(1) and 54(1) and (2) EPC).

3. *Admissibility of the third to fifth auxiliary requests*

3.1 These requests were filed at a very late stage of the appeal proceedings after the time limit set by the Board in its summons to the oral proceedings had expired.

3.2 In the Board's view, the subject-matter of these requests is not sufficiently limited so as to unambiguously define a novel teaching with respect to the prior art and/or introduces further deficiencies:

Since the claims of the third auxiliary request are identical to certain claims of the second auxiliary request, the judgement given for the latter applies with equal force.

The filing of a set of claims containing three independent claims of the same category and thus providing three independent definitions of the invention, as according to the fourth auxiliary

request, does not comply with the requirement of concise claim drafting according to Article 84 EPC.

As regards the fifth auxiliary request, the wording of claim 1 thereof also does not unambiguously define novel subject-matter in that it fails to define an operation in which the increase of the minimum value  $T_m$  would follow a stimulating pulse which was actually delivered within the safety time interval nor that the control device would carry out an active comparison between the defined time period and the safety time interval. On the contrary, the proposed amendment "*and if a stimulating pulse is delivered during said predetermined safety time interval  $T_a$* " gives rise to a further ambiguity, contrary to the requirements of Article 84 EPC, in that it remains unclear what should happen if this condition were not fulfilled.

- 3.3 In view of the facts that, for the above reasons, none of the third to fifth auxiliary requests was *prima facie* found allowable and that these requests had been late-filed, the Board decided not to admit them into the proceedings (see T 1002/92, OJ EPO 1995, 605).

**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