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D E C I S I O N
of 6 August 2002

Case Number: T 0723/98 - 3.4.1

Application Number: 92112935.9

Publication Number: 0528224

IPC: A61N 1/365

Language of the proceedings: EN

Title of invention:
Sensor-controlled implantable medical device

Patentee:
St. Jude Medical AB

Opponent:
Biotronik Mess- und Therapiegeräte GmbH & Co. Ingenieurbüro Berlin

Headword:
-

Relevant legal provisions:
EPC Art. 123(3), 56, 69

Keyword:
"Inventive step - no (main request)"
"Extended protection - no (auxiliary request)"
"Inventive step - yes (auxiliary request)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0723/98 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 6 August 2002

Appellant: (Opponent)
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Respondent: (Proprietor of the patent)
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Representative:
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 26 May 1998 rejecting the opposition filed against European patent No. 0 528 224 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: G. Davies
Members: M. G. L. Rognoni
H. K. Wolfrum

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 18 July 1998, against the decision of the opposition division, despatched on 26 May 1998, rejecting the opposition against the European patent No. 0 528 224. The appeal fee was paid on 18 July 1998 and the statement setting out the grounds of appeal was received on 25 September 1998.

II. The opposition had been filed against the patent as a whole, based on Articles 100(a) and (b) EPC and concerned, in particular, objections under Articles 52(1) and 56 EPC.

III. Of all the cited documents, the following remain relevant to the present decision:

E1: US-A-4 428 378

E3: US-A-4 966 146

E4: US-A-5 016 632

IV. Oral proceedings were held on 6 August 2002.

V. The appellant requested that the decision of the opposition division be set aside and the patent be revoked.

VI. The respondent (patentee) requested that the appeal be dismissed and the patent be maintained as granted (**main request**), or that the patent be maintained on the basis of claims 1 to 7 and pages 2, 2a and 3 to 5 of the description filed in the oral proceedings of 6 August

2002 with the Figures as granted (**auxiliary request**).

VII. The wording of claim 1 of the patent as granted (**main request**) reads as follows:

"1. An implantable medical device (1, 26) for stimulating a heart (2) in a living creature, including a stimulation pulse generator (3) which generates and delivers stimulating pulses to the heart (2), an activity sensor (7) which emits an activity signal in response to the living creature's physical activity and a control device (6) which, when the activity signal exceeds a preset threshold value, controls the rate at which the stimulation pulse generator (3) delivers stimulating pulses,

whereupon every activity signal value is transformed into a stimulation rate signal value by a preset response amplification in the control device (6), characterised in that the device (1,26) further comprises an evaluation device (14, 30), which registers the stimulation rate over a period of time and then compares this rate to a preset mean rate, and that the control device (6), on the basis of this comparison, then changes the response amplification so it increases when the mean stimulation rate registered during the period is slower than the preset mean rate and decreases when the registered stimulation rate is faster than the preset mean rate."

Claims 2 to 8 are dependent on claim 1.

The wording of independent claims 1 and 3 of the **auxiliary request** reads as follows:

"1. An implantable medical device (1, 26) for stimulating a heart (2) in a living creature, including a stimulation pulse generator (3) which generates and delivers stimulating pulses to the heart (2), an activity sensor (7) which emits an activity signal in response to the living creature's physical activity and a control device (6) which, when the activity signal exceeds a preset threshold value, controls the rate at which the stimulation pulse generator (3) delivers stimulating pulses,

whereupon every activity signal value is transformed into a stimulation rate signal value by a preset response amplification in the control device (6), characterised in that the device (1,26) further comprises an evaluation device (14, 30), which registers the stimulation rate over a period of time and then compares this rate to a preset mean rate, the evaluation device (14) comprising a first timer (20), which for the said period of time measures the time during which the stimulation rate is slower than the preset mean rate, a second timer (21), which for the said period of time measures the time during which the stimulation rate is faster than the preset mean rate, and a comparator (22), which compares the time measured by the first timer (20) to the time measured by the second timer (21), and that the control device (6), on the basis of this comparison, then changes the response amplification so it increases when the time measured by the first timer (20) is longer than the time measured by the second timer (21) and decreases if the reverse is the case."

"3. An implantable medical device (1, 26) for stimulating a heart (2) in a living creature, including

a stimulation pulse generator (3) which generates and delivers stimulating pulses to the heart (2), an activity sensor (7) which emits an activity signal in response to the living creature's physical activity and a control device (6) which, when the activity signal exceeds a preset threshold value, controls the rate at which the stimulation pulse generator (3) delivers stimulating pulses,

whereupon every activity signal value is transformed into a stimulation rate signal value by a preset response amplification in the control device (6), characterised in that the device (1,26) further comprises an evaluation device (14, 30), which registers the stimulation rate over a period of time, calculates the mean value of the registered stimulation rate and then compares this mean value to a preset mean rate, and that the control device (6), on the basis of this comparison, then changes the response amplification so it increases when the calculated mean value is less than the preset mean rate and decreases when the reverse is the case."

Claim 2 and claims 4 to 7 are dependent on claims 1 and 3, respectively.

VIII. The appellant's arguments can be summarised as follows;

According to the penultimate feature of claim 1 as granted, the stimulation rate" was compared to a "preset mean rate". However, if this was read in the light of the last feature, which specified that the response amplification was changed as a function of the difference between the "mean stimulation rate" and the "preset mean rate", it was clear that there was a

contradiction in the claim. This contradiction could be removed by assuming that the term "mean" was indicative of the average level of activity experienced by the patient during adjustment of the response amplification.

E3 taught to calibrate the response of a rate-responsive pacemaker by comparing the stimulation rate generated in response to a certain level of activity with a target rate appropriate for such level of activity. Hence, the only difference between the subject-matter of claim 1 as granted and the device known from E3 was that the latter did not recommend any particular level of activity for the pacemaker's calibration. However, a person skilled in the art wishing to implement the teaching of E3 would consider it obvious to select a level of activity for the calibration of the pacemaker which corresponded to the average of the varying levels of activity a patient was likely to be exposed to.

Another way of removing the ambiguity in claim 1 as granted would be to assume that it covered only the second embodiment of the invention and that therefore the stimulation rate compared with the preset mean rate was in fact the mean stimulation rate. According to this interpretation, the subject-matter of claim 1 differed from the device shown in E3 only in that the average stimulation rate, and not the instantaneous rate, was registered and compared with a preset mean rate. It was generally known that physiological parameters were affected by undesired fluctuations and that these could be removed by replacing instantaneous values with average values. Hence, it was implicit in the teaching of E3 that the calibration of the

pacemaker's response amplification could be advantageously performed on the basis of a comparison between a mean stimulation rate and a preset mean rate. Furthermore, there was a clear hint in E4 that the principle of averaging the stimulation rate could be applied to different situations involving the control or calibration of a pacemaker.
No matter how claim 1 as granted was interpreted, its subject-matter lacked an inventive step within the meaning of Article 56 EPC.

The respondent's auxiliary request comprised two independent claims. Claim 1 was directed to the first embodiment of the invention which, as pointed out above, was not covered by claim 1 as granted. Thus, this claim extended the protection conferred by the contested patent. Claim 3 was based on a combination of features originally specified in claims 1 and 4 with amendments consisting in deleting the last feature of claim 1 as granted and in replacing the term "rate" with "mean value" of the registered stimulation rate. Such amendments extended the protection conferred by the granted independent claim. Hence, the respondent's auxiliary request was not admissible under Article 123(3) EPC.

On the other hand, even if it were assumed that the claims were admissible, the subject-matter of claim 3 of the auxiliary request did not involve an inventive step within the meaning of Article 56 EPC. In fact, this claim related to the second embodiment of the invention which consisted essentially in carrying out a calibration of the pacemaker's response amplification by comparing the average of the stimulation rate over a period of time with the expected average for that

period of time. As pointed out above, this was an obvious measure for a person skilled in the art wishing to suppress fluctuations which were inherent in measurements of physiological parameters. Furthermore, it was generally known that the response of a control system could be stabilized by using average values of a fluctuating parameter as control variable. Merely in the light of such general principle and of the teaching of E3, it would have been obvious to a skilled person to arrive at the subject-matter of claim 3. However, there were also clear hints in E4 and E1 that it was advantageous to effect the control and calibration of a pacemaker on the basis of a mean value of a physiological parameter.
Hence, the respondent's auxiliary request was not allowable.

IX. The respondents argued essentially as follows;

Though the wording of claim 1 as granted contained some ambiguities, the person skilled in the art would interpret it in the light of the description and thus arrive at the conclusion that the term "stimulation rate" could not mean an instantaneous rate but only a rate registered over a period of time and compared with a preset mean rate. Consequently, the value of the stimulation rate compared with the preset mean was indicative of the variations of the stimulation rate during the whole period of time. In contrast, the arrangement of E3 taught to measure the stimulation rate after a period of sustained exertion. On the other hand, the patent in suit and E3 dealt with different problems: the former related to a pacemaker which could automatically and periodically perform a calibration of the response amplification on the basis of varying

levels of exertion, while the latter taught to calibrate a pacemaker by monitoring its response when the patient underwent a predetermined level of exertion. None of the cited prior art documents provided any teaching that could lead the skilled person from E3 to the claimed device. Hence, the subject-matter of claim 1 as granted involved an inventive step within the meaning of Article 56 EPC.

As to the auxiliary request, claims 1 and 3 were directed to the first and second embodiments of the patent, which were covered by claim 1 as granted, and thus these claims could not extend the protection conferred by the contested patent.
The device according to claim 3 differed from E3 in that the adjustment of the response amplification was based on a comparison between a mean value of the stimulation rate and a preset mean rate. Even if it were assumed that the person skilled in the art would consider the possibility of improving the device of E3 by removing response instabilities which might be caused by fluctuations in the values of the measured physiological parameter, such skilled person would integrate the output of the activity sensor rather than derive a mean value of the stimulation rate registered over a time period.
Since there was no suggestion that it would be obvious to a skilled person starting from E3 to arrive at the claimed devices, the subject-matter of claims 1 and 3 involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.

Main request

2.1 There is agreement between the parties that E3 represents the closest prior art and that the implantable medical device for stimulating the heart of a living creature shown in this document comprises the following features recited in claim 1 as granted:

- a stimulation pulse generator which generates and delivers stimulating pulses to the heart;

- an activity sensor which emits an activity signal in response to the living creature's physical activity;

- a control device which, when the activity signal exceeds the preset threshold value, controls the rate at which the stimulation pulse generator delivers stimulating pulses, whereupon every activity signal value is transformed into a stimulation rate signal value by a preset response amplification in the control device.

2.2 Claim 1 of the patent in suit further comprises the following features:

(a) an evaluation device, which registers the stimulation rate over a period of time and then compares this rate to a preset mean rate;

(b) the control device, on the basis of this comparison, then changes the response amplification so that it increases when the mean stimulation rate registered during the period is slower than the preset mean rate and decreases

when the registered stimulation rate is faster than the preset mean rate.

2.3 Both parties agree that features (a) and (b) in the context of claim 1 may be open to interpretation. According to the respondent, however, it was clear from the description that these features reflected an essential aspect of the invention which was not known from the prior art and consisted in carrying out the calibration of the pacemaker (*ie* an adjustment of the amplification used to convert the activity sensor output into a stimulation rate) on the basis of the deviation of the stimulation rate corresponding to varying levels of activity from a predetermined mean rate.

2.4 The Board acknowledges that it is, in principle, possible to refer to the description and figures to remove some ambiguities in the wording of a claim. In the present case, however, the description does not appear to suggest a straightforward interpretation of claim 1 as granted. On the contrary, the meaning of features (a) and (b) becomes particularly ambiguous and even contradictory when an attempt is made to read the first and second embodiments of the invention onto the wording of the independent claim.

2.5 According to the first embodiment (see patent as published column 5, lines 16 to 46), when activity starts, the control circuit compares the "current stimulation rate" with the mean rate programmed by the physician with a programming unit. If the current stimulation rate is slower than the mean rate, a first timer is activated and kept active as long as the stimulation rate is slower than the mean rate. If the

current stimulation rate is faster than the mean rate, a second timer is activated and kept active as long as the stimulation rate is above the mean rate. Whenever either of the two timers reaches a preset time value, the control circuit sends the first and second timers an order to transfer their respective measurement values to a subtraction circuit which subtracts the first timer's measurement value from the second timer's value. Hence, the subtractor's output indicates whether the current stimulation rate tends to be slower or faster than the preset rate within a certain time period.

According to the second embodiment (patent as published column 6, line 28 to column 7, line 12), an evaluation device compares a "calculated mean value for the stimulation rate" when activity is present with a preset mean rate, whereby the mean value is obtained by dividing the number of stimulating pulses counted over a certain time period of activity by said time period.

2.6 Hence, if claim 1 is read in the light of the first embodiment, the "stimulation rate" referred to in feature (a) should be interpreted as the current stimulation rate which is "registered" (ie determined) over a period of time so as to be compared with a preset mean rate. This interpretation of the claim implies that the "mean simulation rate" referred to in feature (b) should not be understood as an average rate obtained by dividing the number of stimulation pulses in a given period of time by said time period. In fact, the criterion applied according to the first embodiment to adjust the amplification factor could be summed up as follows: if, within a given period of activity, the current stimulation rate is above the preset rate

longer than it is below said preset rate, the amplification factor is decreased, and vice versa.

However, if claim 1 is read in the light of the second embodiment of the invention, then the stimulation rate according to feature (a) can only represent the mean stimulation rate calculated over the given time period of activity and it should be assumed that the stimulation rate is "registered"" (*ie* recorded) for the purpose of allowing a calculation of the mean value. According to this embodiment, the stimulation rate is registered by counting all the stimulation pulses generated within a given time period.

2.7 As shown above, a reference to the two embodiments of the invention specified in the description leads to a contradictory interpretation of the subject-matter defined by claim 1.

2.8 On the other hand, the Board notes that the actual wording of claim 1 as granted can be interpreted in a way which would remove all ambiguities and make technical sense in the context of the general problem (calibration of a rate-responsive pacemaker) addressed in the patent.

According to this interpretation, the wording "preset mean rate" could merely indicate a target rate appropriate for the average level of activity which the patient is expected to experience, while the "mean stimulation rate" could represent the actual rate generated by the pacemaker in response to such average level of activity. On the other hand, the reference to the stimulation rate being "registered over a period of time" could refer to the fact that calibration is an

iterative process to be carried out over several pacemaker cycles.

2.9 In the light of this interpretation, the matter defined in claim 1 (and for which protection is sought under Article 84 EPC) differs from the rate-responsive pacemaker disclosed in E3 only in that the adjustment of the response amplification is performed on the basis of a stimulation rate and a preset rate corresponding to a mean level of physical activity.

2.10 In the opinion of the Board, it would be obvious to a person skilled in the art, starting from the teaching of E3, to consider the possibility of selecting a level of activity for calibration which corresponded to the average activity experienced by the patient. In so doing, the skilled person would arrive at a device falling within the terms of claim 1. Hence, the subject-matter of claim 1 of the main request does not involve an inventive step within the meaning of Article 56 EPC.

Auxiliary request

Admissibility of the amendments

3.1 Claim 1 according to the auxiliary request is a combination of the features of claims 1 and 2 as granted, whereby the last feature of claim 1 (see feature (b), point 2.2 above) has been deleted.

Independent claim 3 is based on a combination of the features of claims 1 and 4 as granted, whereby the expression "compares this rate" in the characterising

part of claim 1 as granted (see feature (a) above) has been replaced by "compares this mean value" and the last feature of claim 1 (feature (b)) has been deleted.

3.2 According to the appellant, the substitution of the word "rate" in claim 3 and the deletion of a feature in claim 1 as granted would extend the protection conferred by the contested patent and, thus, the independent claims of the auxiliary request would not be admissible under Article 123(3) EPC.

3.3 There can be no doubt that dependent claim 2 of the patent as granted relates to the first embodiment of the invention. Though the subject-matter of this claim is formally defined by the combination of all the features recited in claims 1 and 2, it is evident that some features of claim 1 cannot be associated with the first embodiment of the invention. In particular, the Board considers that a person skilled in the art reading the claims as granted would immediately realize that feature (b) (see point 2.2 above) was not compatible with the embodiment covered by the features recited in claim 2 and thus could not contribute to the determination of the extent of protection conferred by such claim (see Article 69 EPC). Hence, the removal of this feature from an independent claim based on claims 1 and 2 and relating to the first embodiment cannot be objected to under Article 123 (3) EPC.

3.4 The same considerations apply to claim 3 of the auxiliary request which is directed to the second embodiment of the invention and is based on an amended combination of claims 1 and 4 of the patent as granted. The amendment consists essentially in removing a contradiction in the wording of claim 1 which becomes

immediately apparent when the claim is read in the light of the second embodiment, and in deleting a feature of claim 1 as granted (see feature (b) above) which merely anticipates a feature of claim 4. In particular, a person skilled in the art, reading dependent claim 4 as granted, would realize that, in a device according to the second embodiment, it was not the "stimulation rate" but a "mean value" of the stimulation rate generated over a predetermined time period which was compared with the "preset mean rate". Consequently, replacing "stimulation rate" with "mean rate" in a claim directed to the second embodiment would not affect the extent of protection which claim 4 was intended to confer.

3.6 In the result, the claims of the auxiliary request are admissible under Articles 123(2) and (3) EPC.

Inventive step

4.1 As pointed out above, claim 3 of the auxiliary request relates to the second embodiment of the invention, whereby the current stimulation rates registered over a period of time in response to varying levels of activity are used to calculate a mean stimulation rate for that period of activity which is then compared with a preset mean rate in order to adjust the pacemaker’s response amplification.

4.2 Hence, the subject-matter of claim 3 differs from the device shown in E3 essentially in that the adjustment of the response amplification is carried out on the basis of the comparison between a mean value of the stimulation rate and a preset mean rate.

4.3 According to the appellant, it was not only taught in E4 and E1 but it was also generally known that fluctuations in the measurement of a variable could produce instabilities in a control circuit, and that the reliability of a control loop could be increased by using mean values of the control parameter instead of instantaneous values. The obvious application of this principle to the device known from E3 would lead the skilled person to the claimed device.

4.4 In order to understand the real significance of the differences between the subject-matter of claim 3 and the device known from E3, it should be considered that they serve essentially different purposes. E3 is, in effect, concerned with the calibration of a pacemaker under the supervision of a physician who determines the appropriate level of physical activity at which the calibration should be performed, while the patent in suit relates to the automatic and periodic adjustments of a pacemaker in response to levels of physical activity which are expected to vary over a certain time period. Since in E3 the level of activity and, thus, the expected stimulation rate are known and selected by the physician, there would be no reason for adding the function of calculating the mean value of the registered stimulation rate to the control device responsible for adjusting the amplification response . Hence, even though the features recited in claim 3 are, to a large extent, known from E3, this document does not provide any incentive to the skilled person to effect all the modifications which would be required to arrive at a device falling within the terms of claim 3.

4.5 E4 shows a pacemaker comprising, *inter alia*, means for comparing the stimulation intensity (pacing rate) with

a threshold and for calculating the time interval during which the stimulation intensity remains below the threshold for the purpose of establishing a physical condition of rest.
It is furthermore specified in E4 that "in order to prevent small and brief-duration fluctuations of the heartbeat rate of the patient from causing modifications in the sensitivity E, the microprocessor 5 calculates the chronological average of the heartbeat rate over a plurality Z of device cycles" (E4 column 7, lines 56 to 60). However, E4 does not suggest that the adjustment of the response amplification in a rate-response pacemaker could be carried out as a function of a varying stimulation rate and be based on a comparison between the mean value of such stimulation rate over a certain time period and a preset mean rate for that time period.

4.6 E1 relates to a rate-responsive pacemaker with programmable response amplification. Though it teaches to determine the pacer’s escape interval on the basis of an activity signal integrated over a selectable time period, it does not suggest that a mean value of the stimulation rate might be used to adjust automatically the response amplification of the pacer.

4.7 In the light of the cited prior art, it would not be obvious to a person skilled in the art starting from the teaching of document E3, to arrive at a device falling within the terms of claim 3 according to the auxiliary request. Therefore, the subject-matter of this claim involves an inventive step within the meaning of Article 56 EPC.

4.8 As to claim 1 according to the auxiliary request, its

subject matter is even further removed from the teaching of E3 than the subject-matter of claim 3. In fact, the appellant has not provided any argument against the patentability of this claim and the Board has no reason to doubt that also its subject-matter meets the requirements of Article 56 EPC.

4.9 Claims 2 and 4 to 7 are dependent and, thus, their subject-matter also involves an inventive step.

5. In the result, the Board comes to the conclusion that the patent as amended according to the respondent's auxiliary request meets the requirements of the EPC.

Order

For the above reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the respondent's auxiliary request, as follows:

Claims: No. 1 to 7 filed in the oral proceedings of 6 August 2002,

Description: pages 2, 2a and 3 to 5 filed in the oral proceedings,

Drawings: Figures 1 to 4 as granted.

The Registrar: The Chairman:

R. Schumacher G. Davies