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**D E C I S I O N**  
of 16 May 2002

**Case Number:** T 0526/98 - 3.4.1

**Application Number:** 88101405.4

**Publication Number:** 0326629

**IPC:** A61N 1/365

**Language of the proceedings:** EN

**Title of invention:**  
Pacer with a hysteresis function

**Patentee:**  
St. Jude Medical AB

**Opponent:**  
BIOTRONIK Mess- und Therapiegeräte GmbH & Co Ingenieurbüro  
Berlin

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 54, 56, 84, 108, 114(2)  
EPC R. 64

**Keyword:**  
"Admissibility of the appeal (yes)"  
"Novelty (no - main request)"  
"Admissibility of late-filed documents (no)"  
"Inventive step (yes - first auxiliary request)"  
"Remittal for further prosecution (no)"

**Decisions cited:**  
T 0198/84, T 0026/85, T 0279/89, T 0666/89, T 0012/90,  
T 0247/91, T 1002/92

**Catchword:**  
-



Case Number: T 0526/98 - 3.4.1

**D E C I S I O N**  
of the Technical Board of Appeal 3.4.1  
of 16 May 2002

**Appellant:**  
(Opponent)

BIOTRONIK  
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**Representative:**

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**Respondent:**  
(Proprietor of the patent)

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**Representative:**

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**Decision under appeal:**

Interlocutory decision of the Opposition Division  
of the European Patent Office posted 9 March 1998  
concerning maintenance of European patent  
No. 0 326 629 in amended form.

**Composition of the Board:**

**Chairman:** G. Assi  
**Members:** M. G. L. Rognoni  
S. U. Hoffmann

## Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 18 May 1998, against the decision of the opposition division, despatched on 9 March 1998, maintaining the European patent No 0 326 629 in amended form. The fee for the appeal was paid on 18 May 1998 and the statement setting out the grounds appeal was received on 24 June 1998.

II. The opposition had been filed against the patent as a whole based on Article 100(a) EPC and concerned, in particular, objections under Articles 54 and 56 EPC.

III. The contested decision referred to the following documents:

D1: Siemens brochure A91003-M3372-L772-02-7600

D2: EP-B-0 000 987

D3: EP-B-0 077 800

D4: EP-A-0 140 472

D5: EP-A-0 313 881

D6: US-A-4 052 991 (this document having not been admitted into the proceedings).

IV. In response to a communication from the Board summoning the parties to oral proceedings and expressing, *inter alia*, the provisional opinion that D6 submitted after the opposition period was not considered to be admissible, the appellant filed the following document by letter dated 16 April 2002:

D7: US-A-4 503 857.

V. Oral proceedings were held on 16 May 2002.

VI. The appellant requested that the decision under appeal be set aside and the patent revoked (main request), or that the case be remitted to the first instance for further prosecution with respect to the respondent's first auxiliary request having regard to D5 (auxiliary request).

VII. The respondent (patentee) requested that:

**main request:** the appeal be dismissed and the patent be maintained in the form considered allowable by the opposition division, ie on the basis of the following documents:

Claims 1 and 2 filed with letter dated 9 July 1997;

Pages 3 to 6 of the patent specification,  
Pages 2, 2a filed on 21 January 1998 in the oral proceedings before the opposition division;

Sheet 1/1 of the patent specification;

or that the decision under appel be set aside and the patent be maintained on the basis of the following documents:

**first auxiliary request:** Claim 1 filed in the oral proceedings on 16 May 2002;

Page 2, 2a of the description filed in the oral proceedings on 16 May 2002,

Pages 3 to 6 of the patent specification;

Sheet 1/1 of the patent specification;

**second auxiliary request:** Claim 1 filed in the oral proceedings on 16 May 2002;

description and drawings as for the first auxiliary request;

**third auxiliary request:** Claims 1 and 2 as filed in the oral proceedings on 16 May 2002;

Pages 2, 2a, 3 and 5 filed in the oral proceedings on 16 May 2002,

Pages 4 and 6 of the patent specification;

Sheet 1/1 of the patent specification.

Furthermore, the appellant requested that the case be remitted to the first instance for further prosecution, if the late-filed document D7 were to be admitted into the proceedings.

VIII. The wording of claim 1 according to the main request reads as follows:

"A pacemaker (1) with a hysteresis function and comprising a pulse generator (5) controlled by a time base unit (6); said unit producing a variable basic escape

interval (P-P) between placing pulses so that the pulses are delivered at a basic rate in the absence of a sensed, pacemaker inhibiting heart event, said unit further including means (15, 19) for setting and adding a hysteresis interval to said basic escape interval to form an extended escape interval (S-P) in response to a sensed, pacemaker inhibiting, heart event, the hysteresis interval being varied automatically in direct relation to the basic escape interval length, which is in turn variable as a function of a body activity related sensor (9) signal, and said hysteresis interval being calculated as a fixed percentage of said basic escape interval length."

Claim 2 is dependent on claim 1.

The wording of the only claim according to the first auxiliary request reads as follows:

"A pacemaker (1) with a hysteresis function and comprising a pulse generator (5) controlled by a time base unit (6); said unit producing a variable basic escape interval (P-P) between placing pulses so that the pulses are delivered at a basic rate in the absence of a sensed, pacemaker inhibiting heart event, said unit further including means (15, 19) for setting and adding a hysteresis interval to said basic escape interval to form an extended escape interval (S-P) in response to a sensed, pacemaker inhibiting, heart event, the hysteresis interval being varied automatically in direct relation to the basic escape interval length, said hysteresis interval being a fixed percentage of said basic interval length which is in turn variable as a function of a body activity related sensor (9) signal, wherein said basic escape interval length is generated as a pulse count of pulses outputted from a Binary Rate Multiplier (13) in response to a control

data word (18), said hysteresis interval is calculated as said fixed percentage of said pulse count."

The claim according to the **second auxiliary request** differs from the claim according to the **first auxiliary request** in that the wording "said hysteresis interval is calculated as said fixed percentage of said pulse count" is replaced by "and said hysteresis interval being added by counting more pulses"

Claim 1 according to the **third auxiliary request** differs from claim 1 of the **main request** essentially in that it is specified that "said fixed percentage is 10%, 15% or 25%"

IX. The appellant argued essentially as follows:

As to the admissibility of the appeal, the appellant's motives for contesting the decision of the opposition division could be clearly inferred from pages 1 to 3, despite the fact that pages 4 to 6 of the statement of grounds of appeal did not relate to the case at hand. In particular, the objection against the patent as maintained by the first instance was *de facto* based on Articles 54(1) and (3) EPC because, as pointed out on pages 2 and 3, all the features of claim 1 could be derived from D5 which constituted prior art under Article 54(3) EPC. Thus, the appeal was admissible.

As to the respondent's main request, D5 defined hysteresis in a rate-responsive pacemaker as an extension of the basic escape interval length by a predetermined time period (*ie* by a hysteresis interval) which was related to the corresponding basic escape interval through the output of a physiological sensor. The most straightforward way to express such a variable hysteresis interval was in terms of a fixed percentage

of the variable basic escape interval. Furthermore, it was possible to show that, in some cases, the linear dependence of the paced rate and of the hysteresis rate on the sensor output shown in Figure 3b of D5 implied a hysteresis interval proportional to the basic escape interval. Hence, D5 anticipated all the features recited in claim 1 of the main request, and thus the subject-matter of this claim was not new within the meaning of Articles 54(1) and (3) EPC.

According to the opposition division, D6 was not relevant to the present case because it did not relate to a rate responsive pacer. However, D6 showed a pacemaker with a "waiting period" (ie an escape interval) which was varied, after the occurrence of a spontaneous heart signal, as a function of a parameter measured in the patient's body. As D6 disclosed or at least suggested the combination of features recited in claim 1 of the main request, its admission into the proceedings was justified.

The late filing of document D7 was a reaction to the unexpected negative opinion expressed by the Board on the admissibility of D6. As to its relevance, the rate responsive pacemaker shown in D7 comprised means for determining a hysteresis interval and adding it to the basic escape interval in response to a sensed pacer inhibiting heart event. The hysteresis interval was calculated as a fixed percentage of the length of the basic escape interval, while the latter was determined on the basis of the heart cycle, ie of a signal indicative of body activity. Hence, the pacemaker according to D7 fell within the terms of claim 1 according to the main request.

Anyhow, it was obvious to the person skilled in the art to apply the teaching of D7, relating to the use of a hysteresis calculated as a fixed percentage of the



basic escape interval, to pacemakers with different physiological sensors, since the basic problem of obtaining a variable hysteresis interval arose with any pacemaker with variable pacing rates. The subject-matter of claim 1 of the main request was therefore also made obvious by the teaching of D7 taken alone or in combination with the teaching of any one of documents D1 to D4 (Articles 54 and 56 EPC).

As to the respondent's first auxiliary request, the claim recited, *inter alia*, that the hysteresis interval was calculated as a fixed percentage of a pulse count representing the basic escape interval length. The description of the application as originally filed did not specify how the hysteresis values were calculated as a fixed percentage of the corresponding basic escape intervals and therefore it did not support the subject-matter of the claim (Article 84 EPC).

Moreover, D5 referred to a document (US-A-4 590 944) relating to technical details which had to be included within the design of a conventional pacemaker. If this document, which was incorporated by reference in D5, disclosed the feature relating to the basic escape interval length being generated as a pulse count of pulses outputted from a binary rate multiplier, then the subject-matter of the claim of the first auxiliary request would lack novelty over D5. In order to consider this question which had not been addressed in the opposition proceedings, the case should be remitted to the first instance for further prosecution.

The appellant did not argue against the inventive step of the subject matter of the claim according to the first auxiliary request on the basis of documents D1 to D4.

X. The respondent's submissions may be summarised as follows:

As to the admissibility of the appeal, the originally filed pages 4 to 7 of the statement of grounds of appeal were clearly erroneous. However, it was not apparent what the content of any missing page (or pages) actually had been before the final date (19 July 1998) for filing the statement of grounds of appeal, nor was it clear whether such a replacement page had existed at all on that date. For the matter of admissibility, only what had been filed by 19 July 1998 might be considered, since this set the legal time limit on which admissibility had to be judged. This was particularly important in the present case, since the only novelty argument submitted by the appellant appeared on replacement page 4. Similarly, the only inventive step argument based on a prior art document under Article 54(2) EPC related to document D6 which also only appeared on replacement page 4. Hence, the appellant had not filed a statement adequately setting out the grounds of appeal within the prescribed time limit and, therefore, the appeal should be rejected as inadmissible.

As to the main request, document D5 disclosed a pacemaker comprising a hysteresis interval which was calculated as a varying percentage of the basic escape interval length, whereas claim 1 according to the main request specified that the hysteresis interval was calculated as a fixed percentage of the basic escape interval length. Even if it were assumed that some of the possible linear relationships between hysteresis rate and sensor output or between paced rate and sensor output referred to in D5 might result in the claimed relationship between basic escape interval and hysteresis interval, the selection of this particular kind of linear relationships was novel under Article

54(3) EPC, because it was neither explicitly nor implicitly disclosed in D5.

D6 should not be admitted into the proceedings due to its late filing without justification and its lack of relevance.

The appellant sought to introduce document D7 to attack novelty and to combine this document with any one of D1, D2, D3 or D4 to argue against the inventive step of claim 1 according to the main request. The late submission of D7 was an evident abuse of procedure and altered the factual framework of the opposition. Even on this basis, D7 should not be admitted into the proceedings. Moreover, D7 did not relate to a rate responsive pacemaker and, thus, was of no relevance for the assessment of the patentability of the claimed invention.

As to the first auxiliary request, the claim, which was based on the combination of claims 1 and 2 of the main request, was evidently new over D5. Furthermore, there was no reason to believe that the combination of features of this claim could be regarded as implicitly disclosed by D5.

## **Reasons for the Decision**

### *Admissibility of the Appeal*

- 1.1 According to the respondent, the appeal is not admissible because the appellant did not file, within the prescribed time limit, a statement adequately setting out the grounds of appeal. In particular, the respondent has submitted that it is impossible to understand what particular aspects of the opposition

division's decision on inventive step are contested as being incorrect and what arguments or facts the appellant believes are relevant thereto.

Furthermore, the respondent (see letter dated 21 May 1999) contests the appellant's view (see letter dated 11 December 1998) that the statement of grounds of appeal implicitly refers to lack of novelty over D5.

1.2 In the last paragraph on page 3 of the statement of grounds of appeal, the appellant argued that the only formally new feature of claim 1 (see respondent's main request) was also suggested ("nahegelegt") by the closest prior art document D5. Hence, the wording used by the appellant appears to refer to an objection under Article 56 EPC. However, if it is considered that D5 constitutes prior art only under Article 54(3) EPC, it becomes apparent that only novelty can be contested and that, therefore, the statement of grounds is to be interpreted as meaning that D5 implicitly discloses also the last feature of claim 1. This means that, if the statement of grounds of appeal is read in the context of the decision of the opposition division, there can be no doubt that the appellant wished to contest the view expressed by the first instance that the last feature of claim 1 was not implied by D5.

1.3 On balance, the Board considers that the appeal is admissible since the statement of grounds contains the factual reason (features known explicitly or implicitly from D5) and implies the legal reason (lack of novelty over D5) in support of the appellant's request to set aside the decision of the opposition division.

*Respondent's main request*

2.1 Claim 1 according to the main request relates to a pacemaker with a variable basic escape rate interval and a

hysteresis function. The basic escape interval, which is defined as the time interval between pacing pulses and represents the reciprocal of the pacing rate, varies as a function of a sensor output related to body activity. In response to a sensed, pacer inhibiting, heart event the basic escape interval is extended by a hysteresis interval calculated as a fixed percentage of said basic escape interval.

2.2 As confirmed by the respondent in the oral proceedings, the wording "being calculated as a fixed percentage of said escape interval length" means that the hysteresis interval is a fixed percentage of the basic escape interval length and does not imply any means which may be involved in the actual "calculation" of the hysteresis interval as a function of the basic escape interval length.

2.3 As specified in the description of the patent as granted (see page 1, lines 12 to 16), by creating a difference between the programmed basic escape interval of the pacer (*ie* the interval following paced heartbeats) and the escape interval following a sensed spontaneous (natural) heartbeat, in the sense that the latter is extended, patients with periods of normal sinus rhythm are more likely to remain in their own rhythm and thus benefit from the advantages of AV-synchrony.

3.1 D5, which is an earlier document within the meaning of Article 54(3) EPC and thus forms part of the state of the art only as far as novelty is concerned, relates to a rate-responsive pacemaker with a variable hysteresis rate. As pointed out in the description (column 3, line 50 to column 4, line 13), rate-responsive pacemakers employ some type of physiological sensor for sensing a change in the metabolic needs of a patient. This change is used to adjust the rate at which

stimulation pulses are delivered. In a demand pacemaker, the physiological sensor adjusts the pacing rate by varying the escape interval.

According to D5 (column 5, lines 6 to 41), some patients who exhibit partial, intermittent or complete heart block at normal heart rates exhibit normal antegrade conduction at higher rates, so that the ventricle is stimulated from the SA node. If such patients are equipped with a rate-responsive pacemaker, ie with a pacemaker which adjusts the escape interval in accordance with the physiological needs, competition may occur between the patient's SA node and the pacemaker when the heart block is no longer present (see D5, column 5, line 57 to column 6, line 4).

D5 teaches to solve the above problem by extending the escape interval determined as a function of the physiological sensor output in response to the sensing of a natural heart contraction prior to the delivery of a stimulation pulse. This extension of the escape interval, known as hysteresis interval, results in a hysteresis rate, ie in an extension, below the sensor rates, of the range of (natural) rates at which inhibition of the pacer pulses will occur. In other words, hysteresis provides a longer escape interval than would be required according to the physiological sensor, thereby giving the heart more of an opportunity to beat on its own before the pacemaker steps in and provides stimulation pulses.

- 3.2 Summarising, in the absence of natural SA node signals, the heart is stimulated at the rate determined by the sensed physiological need. When a natural heart signal is detected within the escape interval, the hysteresis is activated to extend the escape interval by a predetermined amount related to the sensed

physiological need. The stimulating pulses are inhibited as long as normal heart activity is sensed. The extension of the escape interval under such conditions eliminates possible competition between the heart's normal activity and the paced stimulation. Thus, by varying the hysteresis rate as a function of the physiological sensor output, an extra margin of operating range for the SA node is obtained at higher heart rates.

3.3 According to D5 (column 13, lines 9 to 11), Figure 3A shows "the classical transfer curve or characteristics of a typical rate-responsive pacemaker". If the physiological sensor output indicates low-level physiological activity below a level P0, the paced rate is maintained at a constant minimum rate. If the physiological sensor output indicates high-level physiological activity above a level P2, the paced rate is maintained at a maximum rate. Between the points P0 and P2, the paced rate varies as a function of the sensor output. The typical relationship between the paced rate and the sensor output is shown in Figure 3A as being linear, though D5 specifies that "this relationship could, of course, be other than linear if needed" (see column 13, lines 32 to 35). Similarly, a linear relationship between the hysteresis rate and the sensor output within the intermediate range of sensor outputs P0 and P2 is depicted in Figure 3B (see column 14, lines 10 to 16).

4.1 According to T 565/90 (OJ 1994, 695), the definition of an invention which differs from the prior art only in its wording is insufficient to establish novelty. What is to be considered when addressing the question of novelty is whether the state of the art makes the subject-matter of the invention available to the skilled person in the form of a technical teaching.

4.2 Hence, the mere fact that the subject-matter of claim 1 is specified in terms of proportionality between basic escape interval and hysteresis interval, whilst D5 shows a linear relationship between paced rate and hysteresis rate, is not sufficient to establish the novelty of the claimed subject-matter over the prior art. What has to be decided is whether or not the definition of the linear relationship between paced rate and hysteresis rate given in D5 implies, *inter alia*, the disclosure of a relationship of proportionality between the corresponding escape and hysteresis intervals.

4.3 Expressed in the mathematical terms, the teaching of D5 (see point 3.3) could be summarised as follows:

- typically, the paced rate (or sensor rate)  $R_s$  of a rate responsive pacemaker is a linear function of the sensor output  $P$  of the kind:

$$R_s = a \times P + b \quad \text{where } a \text{ and } b \text{ are two constants}$$

- the hysteresis rate  $H_r$  is typically a linear function of the sensor output  $P$ , so that the curve expressing the minimum rate  $R_{min}$  to which the intrinsic rate may drop before the pacer provides stimulation pulses can be expressed as:

$$R_{min} = c \times P + d$$

whereby the only requirements for  $c$  and  $d$  are that  $c < a$  and  $d \leq b$ .

4.4 It is immediately apparent that if both  $c/a$  and  $d/b$  are equal to a constant  $k$ , then  $R_{min}$  can be expressed as  $R_s \times k$ . In fact:



$$\begin{aligned} R_{\min} &= c \times P + d = k \times a \times P + k \times b = \\ &k \times (a \times P + b) = k \times R_s. \end{aligned}$$

4.5 As the escape interval is the reciprocal of the paced rate, the hysteresis interval Hys can be expressed as follows:

$$\begin{aligned} \text{Hys} &= 1/ R_{\min} - 1/ R_s = 1/ (k \times R_s) - 1/ R_s = \\ &(1-k) / k \times 1/ R_s \end{aligned}$$

In the wording of the contested patent, the above relationship means that the hysteresis interval Hys is a "fixed percentage" of the basic escape interval  $1/R_s$ , as long as the linear function representing the relationship between the  $R_{\min}$  (paced rate with hysteresis) and the sensor output has coefficients  $c$  and  $d$  which are proportional to the coefficients  $a$  and  $b$  of the linear relationship between the paced rate  $R_s$  and the sensor output (ie  $c/a = d/b = k$ ).

4.6 In other words, the relationship of proportionality between the basic escape interval and the hysteresis interval specified in claim 1 identifies, *inter alia*, a certain class of linear relationships between the paced rate and the hysteresis rate among all the possible linear relationships referred to in D5.

5.1 The respondent has acknowledged that the link between values of basic escape interval and hysteresis interval covered by claim 1 of the contested patent could also be established in terms of linear relationships of the kind shown in D5. However, since, according to the respondent, only some of the linear functions expressing the paced rate and the hysteresis rate in terms of sensor output shown in D5 also imply the claimed proportionality between the corresponding basic and escape intervals, the subject-matter of claim 1

should be regarded as a novel selection within a generic disclosure.

5.2 In view of the respondent's submissions and of the fact that the relationships specified in D5 and in claim 1 of the contested patent overlap, in the sense that, to a certain extent, they provide different definitions of the same subject-matter, an essential question to be considered in the present appeal is whether the case law relating to selection inventions is relevant in the present case.

5.3 The principles applied by the boards of appeal as part of their established case law on the novelty of selection inventions expressed in terms of numerical ranges were developed in particular in T 198/84 (OJ 1985, 209). They are summarised briefly in T 279/89 (not published) as follows:

a selection of some range of numerical values from a broader range is new when each of the following criteria is satisfied:

- (a) the selected sub-range should be narrow;
- (b) the selected sub-range should be sufficiently far removed from the preferred part of the known range (as illustrated for instance in the examples given in the prior art);
- (c) the selected sub-range should not be an arbitrarily chosen specimen from the prior art, ie not merely one way of carrying out the prior teaching, but must provide a new invention (purposive selection).

The three postulates for the novelty of the selected sub-range are based on the premise that novelty is an

absolute concept. It is therefore not sufficient merely for the wording of the definition of an invention to be different. What has to be established in the examination of novelty is whether the state of the art is such as to make the subject-matter of the invention available to the skilled person in a technical teaching.

5.4 A straightforward application of the above criteria (in particular (a) and (b)) does not appear to be possible in the present case, since the claimed subject-matter and the relevant prior art do not relate to sets of elements with well-defined numerical boundaries such as ranges of numerical values. In fact, though it could be argued that the definition of claim 1 identifies a subset comprised within the set of linear relationships shown in D5, it is not possible to determine the "narrowness" of this subset with respect to the prior art set. Similarly, it cannot be established whether the subset of linear relationships covered by claim 1 should be considered "far removed" from the specific examples of linear relationships shown in Figure 3B of D5.

5.5 On the other hand, T 198/84 (supra) emphasised that novelty entailed more than just a formal delimitation vis-a-vis the state of the art. There would be delimitation only in respect of the wording of the definition of the invention, but not in respect of its contents, if the selection were arbitrary, ie if the selected range only had the same properties and capabilities as the whole range so that what had been selected was only an arbitrary specimen from the prior art (see criterion (c)).

5.6 The concept of "availability" referred to in T 198/84 (see criterion (c)) is also mentioned in other decisions which address the question of establishing

when a certain claimed subject-matter covered by a generic disclosure should be regarded as novel with respect to such disclosure.

Thus, T 247/91 pointed out that consideration had to be given not only to the examples but also to whether the disclosure of the prior art document as a whole was such as to make available to the skilled person as a technical teaching the subject-matter for which protection was sought.

According to T 666/89 (OJ 1993, 495), the term "available" in Article 54 EPC clearly went beyond literal or diagrammatical description, and implied the communication, expressed or implicit, of technical information by other means as well. Matter which was "hidden", in the sense of being reconditely submerged in a document, would not have been "made available" in the above sense. In the case of overlapping ranges of physical parameters between a claim and prior art disclosure, what would often help to determine what was "hidden" as opposed to what had been "made available", was whether or not a skilled person would find it difficult to carry out the prior art teaching in the range of overlap. A similar approach was to consider whether a person skilled in the art would, in the light of all the technical facts at the skilled person's disposal, "seriously contemplate" applying the technical teaching of the prior art document in the range of overlap.

The same conclusion was reached by T 26/85 (OJ 1990, 22).

5.7 The question of novelty in relation to overlapping generic domains was addressed in T 12/90 in the particular case of generically defined chemical compounds. The board pointed out that a distinction had

to be drawn between two situations:

- if the subject matter of the invention was a particular compound , whereas the prior art disclosed a family of compounds defined by a general structural formula including this particular compound but not describing it explicitly, the invention had to be considered novel
  
- if, with the same prior art, the subject matter of the invention was a second family of compounds partially covering the first, the invention was not new.

5.8 In the present case, for a given linear relationship between the paced rate and the sensor output, the relationship of proportionality specified in claim 1 between the hysteresis interval and the escape rate is, in principle, satisfied by an unlimited number of linear relationships between hysteresis rate and sensor output (see items 4.4 and 4.5 above), to the effect that the claimed subject-matter is effectively based on the definition of a generic domain overlapping the generic domain of linear functions referred to in D5.

Furthermore, since basic escape rates and hysteresis rates covered by claim 1 appear to have the same "properties and capabilities" as those explicitly disclosed in D5 or derivable from the linear relationships referred to in this document, the contested patent does not seem to entail more than a formal delimitation vis-a-vis the state of the art (see item 5.5 above). Consequently, the subject-matter of claim 1 does not constitute a "purposive selection".

Finally, the person skilled in the art reading document D5 had no reason to exclude from the set of all

possible linear relationships between paced rate and hysteresis rate referred to in D5 linear functions that would result in the hysteresis interval being proportional to the basic escape interval. In other words, the teaching of D5 is not restricted to the use of linear relationships resulting in the hysteresis interval not being proportional to the escape interval. The D5 as a whole is such as to make available to the skilled person as a technical teaching the claimed subject-matter.

- 5.9 Summarising, the Board finds that the claim 1 relates, *inter alia*, to subject-matter covered by the teaching of D5 and that, in the light of the general principles underlying the case law of the boards of appeal on selection inventions, it cannot be regarded as a novel "selection" with respect to the prior art generic disclosure.

For these reasons, the subject-matter of claim 1 of the respondent's main request lacks novelty within the meaning of Article 54 (3) EPC.

*Respondent's first auxiliary request*

- 6.1 Document D6 was filed during the opposition proceedings by letter dated 5 December 1997 and disregarded by the opposition division as not relevant (Article 114(2) EPC). By letters dated 24 June 1998 and 30 July 1998, the appellant contested the decision of the opposition not to admit D6 into the proceedings and argued that the pacemaker shown in D6 involved variable pacing rates.
- 6.2 D6 relates to a pacemaker in which the "waiting period", defined as the time period between two consecutive pacing pulses and thus corresponding to the basic escape interval, may be modified in response to

variations of the intramyocardial pressure, which is the average base pressure measured for example during the time of rest of the cardiac muscle. This variation, when it occurs, is very slow and may be detected only after several hours in certain cases (see D6, column 28, lines 1 to 7). Since there is no indication in D6 that this parameter might be indicative of the patient's physiological demands, this document does not relate to a rate responsive pacemaker. Furthermore, it is specified in D6 that following a spontaneous systole, "a waiting period is permitted to pass which is represented on the drawing by Y<sub>1</sub>" (see Figure 1 and column 2, line 68 to column 3, line 3), whereby said waiting period may be shorter or longer than the normal waiting period (see column 3, lines 24 to 34). According to the patent in suit, however, the basic escape interval is always extended by adding the hysteresis interval in response to a sensed, pacer inhibiting, heart event.

6.3 Hence, the Board finds that the opposition division was correct in disregarding D6 as late-filed and not sufficiently relevant to prejudice the maintenance of the patent in suit (see T 1002/92 (OJ 1995, 605)).

6.4 Though D6 was filed in opposition and therefore cannot be considered as late-filed as far as the appeal procedure is concerned, the Board decides that this document is to be disregarded under Article 114(2) EPC because it does not disclose matter likely to influence the outcome of the case. Furthermore, the admission into the appeal proceedings of a document, on whose relevance the opposition division already expressed a negative opinion shared by the Board, would imply the remittal of case to the first instance for further prosecution to safeguard the parties' right to have the contested patent examined by both instances in the

light of the new evidence. However, this would merely delay a final decision on which such document would anyway have no bearing.

7.1 D7 was filed by letter dated 16 April 2002 after the Board's communication dated 17 December 2001. The only justification for this late filing given by the appellant was that the Board's negative opinion on the admissibility of D6 had not been expected.

7.2 In this respect, the Board wishes to point out that according to the Rules of Procedure of the Boards of Appeal, a board has no obligation to communicate its preliminary opinion to the parties and, therefore, a preliminary negative opinion on the relevance of a document disregarded as late-filed and not relevant by the opposition division cannot provide a justification for the late filing of another document in the appeal. Furthermore, a preliminary opinion of the Board confirming a conclusion of the opposition division should not have come as a surprise to the appellant. Finally, it would be contradictory to accept as a reason for the admissibility of a document filed late in the appeal procedure the refusal by the first instance of another late-filed document.

7.3 As to the relevance of D7, the appellant has essentially submitted that this document discloses a pacemaker comprising all the features recited in claim 1 of the main request and, in particular, the addition of a hysteresis interval to a variable basic escape interval in response to a sensed, pacer inhibiting heart event, whereby the hysteresis interval is a fixed percentage of the basic escape interval. According to the appellant, the independent claims of all requests are not limited to a rate-responsive pacemaker but relate in general to pacemakers having a basic escape interval which varies as a function of a



body activity signal. Since D7 uses the heart cycle to determine the basic escape interval and this parameter can be regarded as a body activity signal, in the appellant's view, the wording of claim 1 covers also a pacemaker according to D7. Furthermore, the appellant has argued that it would have been obvious in the light of D1 to D4 to apply the teaching of D7, relating to the use of a hysteresis interval calculated as a fixed percentage of the basic escape interval, to a rate responsive pacemaker comprising other body activity sensors.

7.4 Though it is true that claim 1 of the patent as granted was meant to cover any kind of pacemaker with hysteresis, it is clear that the independent claims of the respondent's requests are limited to a pacer which uses a body activity sensor signal to set the basic escape interval. In fact, the description specifies that the sensor senses a variable such as "activity, temperature, blood oxygen saturation, PH-value and QT-interval" (page 3, lines 14 to 16). As generally known in the art, these are the typical parameters used to measure the metabolic needs of a patient.

7.5 D7 relates to "a pacer with means and a method to vary the pacing rate in response to sensed heartbeat signals in a manner dependent upon one of a plurality of programmed modes and the timing of the sensed heartbeat compared to the prior pacer cycle or cycles" (column 1, lines 6 to 12). As pointed out in the passage of the description cited by the appellant in support of the relevance of D7 (column 9, line 38 to column 10, line 17), in the "flywheel mode" the basic escape interval T is determined on the basis of the time interval between the occurrence of a spontaneous heartbeat and of the previous heartbeat, which could also be a paced heartbeat. If the measured value of T for the last heart cycle is within a certain range

determined by the previous pacing interval  $T_{pi}$ , then the escape interval is set to  $1.125 T$  and the pacing interval is set equal to  $T$ . "Thus, the 12.5% factor is established as a hysteresis differential, or factor, and if during the next cycle no natural pulse is received during time equal to  $1.125 T$  of the last interval, then a pacing pulse is delivered. Also by setting  $T_{pi}$  equal to  $T$ , the pacing interval and thus the pacing rate are caused to track the cycle-to-cycle changes in  $T$ " (see column 9, lines 58 to 65). In a rate responsive pacemaker, however, the pacing rate is essentially determined by the sensor output and is not supposed to track changes in the natural heart cycle.

- 7.6 In summary, the Board finds that the technical information provided by D7 is not so relevant as to justify its admission into the appeal proceedings according to the principles set out in T 1002/92 (*supra*). Hence, in the exercise of the discretion provided by Article 114(2) EPC, the Board decides to disregard the late-filed document D7.
8. The claim according to the respondent's first auxiliary request is based on the combination of all the features recited in claims 1 to 4 of the application as originally filed, corresponding to claims 1 to 4 of the patent specification. This claim is thus admissible under Articles 123(2) and (3) EPC.
- 9.1 As to the appellant's objection that the subject-matter of the claim does not find support in the description, it is implicit that the only embodiment of the invention specified in the description necessarily comprises the combination of features recited in claim 4 of the application as originally filed (corresponding to claim 2 of the patent as maintained by the opposition division), since, if the escape interval is extended by increasing a pulse count, the

number of pulses to be added to such pulse count must also be calculated.

9.2 Hence, in the opinion of the Board, the claim according to the respondent's first auxiliary request satisfies the requirements of Article 84 (second sentence) EPC.

10.1 The appellant's request to remit the case to the first instance for further examination is essentially based on the fact that D5 refers to a document (US-A-4 590 944) covering further technical features of a conventional pacemaker and that the features which render the subject-matter of the claim according to first auxiliary request new over D5 might be disclosed in such document.

However, having had the opportunity in the oral proceedings to examine the document US-A-4 590 944, the appellant was not able to provide any evidence that said features might indeed have been known in the field of pacemakers or that D5 implicitly referred to them. Furthermore, the technical details specified in D5 in connection with the acknowledged prior art concern "generating refractory periods, blanking intervals and the like" (D5, column 16, lines 8 to 11). Hence, there is no evidence that US-A-4 590 944 might contain information relating to the generation of the basic escape interval and the calculation of the hysteresis interval.

10.2 According to the established case law of the boards of appeal, a case should be remitted to the department of first instance when an entirely new situation has been created by the amendments made, so that the parties should be given the opportunity to defend their claims or submissions before two instances.

In the present case, the claim of the first auxiliary request is a straightforward combination of claims 1

and 2 of the patent as maintained by the opposition division. Thus, it cannot be said that the respondent's request has created a new, surprising situation for the appellant or that the factual framework of the contested decision has actually changed.

Furthermore, since the only claim of the first auxiliary request is a combination of claims 1 to 4 of the application as originally filed, it is assumed that its subject-matter has been duly searched by the EPO.

- 11.1 It is not in dispute that the subject-matter of the claim according to the respondent's first auxiliary request is new with respect to D5 or to any of the documents on file (Article 54 EPC).
- 11.2 None of the documents D1 to D4 shows a rate-responsive pacemaker with a hysteresis function or a pacemaker with a hysteresis interval which is a fixed percentage of different programmed escape intervals. Hence, in the light of the teachings of these documents, it would not have been obvious to a skilled person to arrive at the subject-matter of the claim of the first auxiliary request (Article 56 EPC).
12. In summary, the Board finds that the respondent's first auxiliary request is allowable and that the patent can be maintained on the basis thereof. Consequently, there is no need to consider the respondent's second and third auxiliary requests.

## Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The appellant's request for remittal to the first instance for further prosecution with respect to the respondent's first auxiliary request having regard to D5 is rejected.
3. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the respondent's first auxiliary request, as follows:

Claim 1 filed in the oral proceedings on 16 May 2002;

Page 2, 2a of the description filed in the oral proceedings on 16 May 2002,

Pages 3 to 6 of the patent specification;

Sheet 1/1 of the patent specification.

The Registrar:

The Chairman:

R. Schumacher

G. Assi

