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D E C I S I O N
of 9 May 2003

Case Number: T 0142/00 - 3.4.1

Application Number: 91302941.9

Publication Number: 0450943

IPC: A61N 1/36

Language of the proceedings: EN

Title of invention:
Apparatus and method for antitachycardia pacing in arrhythmia control systems

Patentee:
Pacesetter, Inc.

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

Headword:
-

Relevant legal provisions:
EPC Art. 83, 123, 84, 54, 56

Keyword:
"Lack of clarity and support (yes - main request)"
"Extension of protection (yes - first auxiliary request)"
"Lack of clarity (yes - second auxiliary request)"
"Extension of protection (yes - third auxiliary request)"
"Added subject-matter (no - fourth auxiliary request)"
"Novelty and inventive step (yes - fourth auxiliary request)"

Decisions cited:
T 0017/86, T 0284/94, G 0009/91

Catchword:
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Case Number: T 0142/00 **-** 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 9 May 2003

Appellant 01: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 22 December 1999 concerning maintenance of European patent No. 0450943 in amended form.

Composition of the Board:

Chairman: G. Assi
Members: M. G. L. Rognoni
R. Moufang

Summary of Facts and Submissions

I. The appellant 01 (opponent) lodged an appeal, received on 4 February 2000, against the decision of the opposition division, despatched on 22 December 1999, maintaining the European patent No 0 450 943 (application No 91302941.9) in amended form. The fee for the appeal was paid on 4 February 2000 and the statement setting out the grounds of appeal was received on 27 April 2000.

Against the same decision of the opposition division, the appellant 02 (proprietor) lodged an appeal, received on 23 February 2000. The fee for the appeal was paid on 22 February 2000 and the statement setting out the grounds of appeal was received on 28 April 2000.

II. The opposition had been filed against the patent as a whole based on Articles 100(a) and (b) EPC.

III. In the statement of grounds of appeal, the appellant opponent referred, *inter alia*, to the following document:

E3: US-A-4 830 006

IV. In response to the summons to oral proceedings, the representative of the appellant proprietor informed the Board that the proprietor would not be represented at the hearing and filed five requests by letter dated 9 April 2003, a main request and first, second, third and fourth auxiliary requests.

V. Oral proceedings were held on 9 May 2003 in the presence of the appellant opponent.

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

VII. The appellant proprietor requested in writing that the decision under appeal be set aside and that the patent be maintained on the basis of the following documents:

main request

claim 1 as filed with the letter dated 9 April 2003, claims 14 to 23 as granted to be renumbered to depend on claim 1;

Description and drawings of the patent as maintained by the first instance;

first auxiliary request

claim 1 as filed with the letter dated 9 April 2003, claims 14 to 23 as granted to be renumbered to depend on claim 1;

Description and drawings as for the main request;

second auxiliary request

claim 1 as filed with the letter dated 9 April 2003, claims 2 to 9 of the patent as maintained by the first instance;

Description of the patent as maintained by the first instance with the deletion of the words "*It is also preferable that*" in line 24 of column 4 of the printed specification

Drawings of the patent as maintained by the first instance;

third auxiliary request

claim 1 as filed with the letter dated 9 April 2003; claims 2 to 9 of the patent as maintained by the first instance;

Description and drawings as for the second auxiliary request;

fourth auxiliary request

any of the main or the first, second or third auxiliary requests with the addition of either one or both of the following:

(i) insertion of the words "*both upwards and downwards"* after "*.....for searching said plurality of storage locations.....*" in claim 1 of the first and third auxiliary requests or after the words *"....for searching said storage locations.....*" in claim 1 of the second and third auxiliary requests;

(ii) insertion of the word "*numerically*" before "*....closest....*" in the claim 1 of any of the requests.

VIII. The wording of claim 1 according to the appellant proprietor's **main request** reads as follows:

"Apparatus for treating tachycardias having cycle lengths within a predetermined range of tachycardia cycle lengths, comprising:

A) means for establishing a plurality of storage locations (fig 5A) each of which corresponds to a different sub-range of tachycardia cycle lengths within said range of tachycardia cycle lengths:
B) means for storing (fig 6), in corresponding ones of said storage locations, corresponding antitachycardia pacing parameters which have been successful in reverting previous tachycardias having cycle lengths that fall in said corresponding tachycardia cycle length sub-ranges; and
C) means for searching said storage locations to identify a storage location which corresponds to the tachycardia to be treated and for treating the tachycardia using the antitachycardia pacing parameter stored therein, and in the event there is no antitachycardia pacing parameter in the identified storage location, searching said storage locations to identify a storage location which contains a stored antitachycardia pacing parameter and which corresponds to a tachycardia cycle length which is closest to the newly confirmed tachycardia cycle length and for treating the tachycardia using the antitachycardia pacing parameter stored therein."

The wording of claim 1 according to the appellant proprietor's **first auxiliary request** reads as follows:

"Apparatus for treating tachycardias having cycle lengths within a predetermined range of tachycardia cycle lengths, comprising:

A) means for establishing a plurality of storage locations (fig 5A) each of which corresponds to a different sub-range of tachycardia cycle lengths within said range of tachycardia cycle lengths;
B) means for storing (fig 6), in corresponding ones of said storage locations, corresponding antitachycardia pacing parameters which have been successful in reverting previous tachycardias having cycle lengths that fall in said corresponding tachycardia cycle length sub-ranges; and
C) means for treating subsequent tachycardias using antitachycardia pacing parameters selected from storage locations that correspond to the storage locations corresponding to the tachycardias to be treated, and if the storage locations corresponding to the tachycardias to be treated are empty, for searching said plurality of storage locations until a filled storage location closest to correspondence with the storage locations corresponding to the tachycardias to be treated is found."

Claim 1 according to the appellant proprietor's **second auxiliary request** differs from claim 1 according to the **main request** in that it further comprises the following features:

"D) means for utilizing a range of antitachycardia pacing parameters in the treatment of tachycardias over a period of time, and means for correlating successful antitachycardia pacing parameters in such range with the tachycardia cycle lengths of the tachycardias they successfully revert; and
E) means for over-riding earlier successful antitachycardia pacing parameters that may be stored in given storage locations with later successful antitachycardia pacing parameters that correspond to such storage locations."

Claim 1 according to the appellant proprietor's **third auxiliary request** differs from claim 1 according to the **first auxiliary request** in that it further comprises the following features:

"D) means for utilizing a range of antitachycardia pacing parameters in the treatment of tachycardias over a period of time, and means for correlating successful antitachycardia pacing parameters in such range with the tachycardia cycle lengths of the tachycardias they successfully revert; and
E) means for over-riding earlier successful antitachycardia pacing parameters that may be stored in given storage locations with later successful antitachycardia pacing parameters that correspond to such storage locations."

IX. The appellant proprietor's arguments may be summarised as follows:

E3 taught a device that divided different tachycardia rates into rate classes, and then selected an appropriate therapy based on the rate class into which the tachycardia fell. All the tachycardia rate classes were populated with a corresponding therapy selected by the doctor either during implant or during a follow-up appointment. Thus, E3 made no provision for a situation in which a particular tachycardia rate class did not have an associated therapy. Claim 1 of each request, however, emphasised that the apparatus of the invention searched for a "filled bin" in the event that there were no pacing parameters in the storage locations corresponding to the tachycardias to be treated. Furthermore, the device of claim 1 of any of the requests was also inventive over the prior art owing to its ability to learn over time which therapy suited a particular patient and to adapt to the patient's changing needs over time, unlike E3 which relied on the doctor not only to assign a therapy to each rate range but also to update it.

X. The appellant opponent argued essentially as follows:

The apparatus according to claim 13 of the patent specification comprised, *inter alia*, means for treating subsequent tachycardias "*using antitachycardia pacing parameters selected from storage locations*" which were closest to correspondence with "*the storage locations corresponding to the tachycardias to be treated".* This implied that the apparatus of claim 13 could only identify storage locations which were *"closest to"*

other locations. Claim 1 according to the **main request** and claim 1 of the **second auxiliary request**, however, comprised means for identifying a storage location corresponding to a **tachycardia cycle length** which was "*closest to the newly confirmed tachycardia cycle length".* Thus, the main and the second auxiliary requests were directed to subject-matter falling outside the scope of protection conferred by the granted patent, and were not admissible under Article 123(3) EPC.

Though clause (C) of claim 1 according to the **main** and **second auxiliary requests** were based on the preferred embodiment of the invention, they comprised only some of the features disclosed in connection with such embodiment. This generalisation of a specific embodiment was not admissible under Article 123(2) EPC (cf. T 284/94, OJ EPO 1999, 464). Furthermore, the fact that some essential features of the invention were not specified in the independent claims could also be regarded as an infringement of Articles 83 and 84 EPC.

Claims 1 according to the **first** and the **third auxiliary requests** comprised means for **treating** subsequent tachycardias with pacing parameters stored in corresponding storage locations and for **searching** said storage locations, if the storage locations corresponding to the tachycardias to be treated were empty. Claim 13 of the patent as granted, however, implied that treatment was **always** administered. Thus, the wording of these claims extended the protection conferred by the granted patent (Article 123(3) EPC).

All the apparatus claims resulting from the amendments requested by the appellant proprietor according to the **fourth auxiliary request** violated Article 123 (2) and (3) because they were based on inadmissible claims of the previous requests.

Apart from disclosing a device which divided different tachycardia rates into rate classes and selected an appropriate therapy based on the class into which the tachycardia fell, E3 taught also to replace a stored therapy with a more successful one, according to the "*retry last successful pacing therapy*" ("RLSPT") option or to look for an appropriate therapy in storage locations close to the storage location corresponding to a diagnosed tachycardia according to the "RATCHET" option. Thus, all the functions of the apparatus according to the alleged invention were either known from, or suggested by E3.

Reasons for the Decision

1. The appeal is admissible.

Main Request

2. *Article 84 EPC*

2.1 Claim 1 according to the **main request** comprises clauses (A) and (B) of the apparatus claim 13 of the patent specification and a new clause (C). As stipulated by the Enlarged Board of Appeal in G 9/91 (OJ EPO 1993, 408) "*in case of amendments of the claims or other parts of a patent in the course of opposition or appeal*

proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC" (see point 19 of the reasons).

Hence, a question to be considered in the present case is whether the amended clause (C) satisfies, *inter alia*, the requirements of Article 84 EPC as to the clarity of the subject-matter for which protection is sought and its support in the description.

2.2 As specified in the amended clause (C), the apparatus according to claim 1 of the **main request** comprises means for **treating** a diagnosed tachycardia and for **searching** the pacing parameter to be used for the treatment, whereby the search is defined as follows:

(i) the storage locations are searched to identify the storage location corresponding to the tachycardia to be treated;

(ii) **if no antitachycardia pacing parameter** is stored in the corresponding storage location, the search is directed to identifying a storage location which contains a stored pacing parameter and which corresponds to a tachycardia cycle length which is closest to the newly confirmed tachycardia cycle length.

2.3 An essential aspect of the present invention relates to the determination **by scanning** of a pacing parameter value which is successful in terminating a tachycardia (see patent specification, column 4, lines 11 to 17). This allows a continuous updating of the stored values and the "filling up" of empty storage locations with

appropriate pacing parameters for treating tachycardias of corresponding cycle lengths. In other words, the apparatus of the invention begins treatment of a tachycardia with a stored parameter value which is then changed by scanning through a certain range until the tachycardia is reverted.

2.4 The wording of clause (C) of claim 1 according to the main request, however, may imply that the treatment of a tachycardia could be based only on **one** pacing parameter found in the storage location corresponding to the tachycardia cycle length to be treated, or to the "*closest*" tachycardia cycle length.

2.5 Since the amended clause (C) does not clearly reflect some aspects of the invention which are shown to be essential in the description, claim 1 according to the **main request** does not meet the requirements of Article 84 EPC.

First Auxiliary Request

3. *Article 123 (3) EPC*

3.1 As specified in clause (C), the apparatus according to claim 1 of the first auxiliary comprises means (emphasis added):

- "*for treating subsequent tachycardias using antitachycardia pacing parameters selected from storage locations that correspond to the storage locations corresponding to the tachycardias to be treated*" (*ie* if they are defined), and

- "*if the storage locations corresponding to the tachycardias to be treated are empty, for searching said plurality of storage locations until a filled storage location closest to correspondence with the storage locations corresponding to the tachycardias to be treated is found."*

3.2 Clause (C) of claim 13 of the patent specification reads as follows (emphasis added):

"C) means for treating subsequent tachycardias using antitachycardia pacing parameters selected from storage locations that correspond to, or are closest to correspondence with, the storage locations corresponding to the tachycardias to be treated".

3.3 The wording of claim 1 of the **first auxiliary request** does not specify what happens with the parameter found in the location "*closest to correspondence with the storage locations corresponding to the tachycardias to be treated".* Thus, claim 1 covers also the possibility that the pacing parameter may be further processed before being used for treatment, or even that no treatment follows the search for a filled storage location.

Claim 13 of the patent specification, however, is clearly limited to an apparatus which administers treatment using pacing parameters selected from storage locations "*closest to correspondence with*" the storage locations associated with the tachycardias to be treated, if the latter are empty.

3.4 Thus, contrary to the provisions of Article 123(3) EPC, claim 1 of the **first auxiliary request** has been amended in such a way as to extend the protection conferred by the patent specification.

Second Auxiliary request

4. *Article 123(3) EPC*

4.1 The appellant opponent's objections under Article 123(3) EPC are essentially based on the following considerations:

- though all the embodiments of the invention showed a linear array of storage locations corresponding to an arrangement of tachycardias according to increasing cycle lengths, neither claim 13 of the patent specification nor claim 1 of the **second auxiliary request** specified how the storage locations were arranged, or was limited to an apparatus in which the storage location indexes and the tachycardia cycle lengths increased according to the same linear progression;

- in fact, claim 13 of the granted patent did not necessarily imply that the storage locations which were "*closest to correspondence*" with the storage locations of the tachycardias to be treated contained also tachycardias cycle lengths which were closest to the cycle length of the tachycardia to be treated;

- as specified in clause (C), however, claim 1 of the **second auxiliary request**, comprised means which could always identify the closest cycle length, even if it was not located in the storage location which was closest to the location corresponding to the tachycardia to be treated;

- in other words, the apparatus of claim 13 of the granted patent arrived at the **closest cycle length** only when this was located in the **closest storage location**, whereas the apparatus of claim 1 of the second auxiliary request comprised means which were supposed to find the closest cycle length no matter where it was located;

- for the above reasons, claim 1 of the second auxiliary request extended the protection conferred by the patent specification, and, thus, it was not admissible under Article 123(3) EPC

4.2 One of the essential aspects of the present invention is that treatment of a tachycardia identified by its cycle length should start with the antitachycardia pacing parameter which has succeeded in treating the **same** kind of tachycardia on previous occasions. If no pacing parameter is available for the diagnosed cycle length, the treatment should start with the "next best" pacing parameter, *ie* with a parameter which has successfully treated a **similar** episode of tachycardia, *ie* a tachycardia of a cycle length "*closest*" to the one diagnosed.

4.3 The apparatus claim 13 as granted recites that the treatment is carried out using antitachycardia pacing parameters selected from storage locations defined as follows:

- they correspond to the storage locations corresponding to the tachycardias to be treated, or

- they are closest to correspondence with the storage locations corresponding to the tachycardias to be treated.

In other words, claim 13 does not specify **how** the pacing parameters are actually selected, but limits the selection to parameters located in "bins" which are *"closest to correspondence"* with the location where the appropriate pacing parameter should be stored. In the context of the present invention, such locations can only be those which are associated with "similar" tachycardias, *ie* with tachycardias having **cycle lengths** close to the cycle length of the tachycardia to be treated. This implies that the apparatus according to claim 13 of the patent specification is not restricted to searching for the filled storage location "*closest to*" the empty storage location, no matter how close the corresponding cycle lengths are.

4.4 Claim 1 according to the **second auxiliary request** specifies that the claimed apparatus comprises means for **searching** the storage locations in order to identify a storage location which corresponds to the tachycardia to be treated. In the event that there is no antitachycardia pacing parameter in the identified

storage location, the means for searching the storage locations are able to identify a filled storage location which is *"closest to the newly confirmed tachycardia cycle length"*.

4.5 In other words, both claim 13 as granted and claim 1 of the second auxiliary request specify means for treating tachycardias using the same pacing parameters. Since the latter specifies also means for performing the selection of the parameters referred to in claim 13 as granted, it limits the protection conferred by the granted claim and, thus, it does not infringe Article 123(3) EPC.

5. *Article 123 (2) and Article 84 EPC*

5.1 Claim 1 according to the **second auxiliary request** differs from the apparatus claim 13 of the contested patent in that clause (C) has been reworded and clauses (D) and (E) have been added. The latter two clauses correspond to claims 14 and 15 of the application as originally filed.

As to clause (C), its features can be itemised as follows:

(a) "*means for searching said storage locations to identify a storage location which corresponds to the tachycardia to be treated and*

(b) *for treating the tachycardia using the antitachycardia pacing parameter stored therein, and*

(c) *in the event there is no antitachycardia pacing parameter in the identified storage location, searching said storage locations to identify a storage location which contains a stored antitachycardia pacing parameter and which corresponds to a tachycardia cycle length which is closest to the newly confirmed tachycardia cycle length and*

(d) *for treating the tachycardia using the antitachycardia pacing parameter stored therein".*

5.2 Features (a) to (d) are based on the description of the preferred embodiment given in column 8, lines 40 to 58, of the patent specification, with the difference that "*both upwards and downwards"* referred to the search (feature (a)) and "*numerically*" referred to "*closest*" (feature (c)) have been deleted.

5.3 The appellant opponent has essentially argued that these modifications of the wording used in a preferred embodiment which formed the basis for the amendments constituted an inadmissible generalization of the original disclosure (Article 123(2) EPC).

5.4 According to the preferred embodiment of the invention (patent specification, column 8, lines 20 to 39), cycle lengths are measured to a resolution of 4 ms so that "*one byte with a numerical range of 0 to 255 can represent cycle lengths from 0 to 1020 milliseconds*". An array of 256 "*storage location units or bins*" is used to store the value of the pacing parameter which has proved successful in reverting a tachycardia of corresponding cycle length. If there is a stored pacing

parameter value for a diagnosed tachycardia cycle length, treatment starts at that value. If not, "*the array is searched both upwards and downwards until a filled cycle length bin is found*" (column 8, lines 46 to 47).

5.5 From the description of the contested patent, it is clear that an "*array of 256*" storage locations is just one of the possible embodiments of a memory for storing pacing parameters. If the present invention does not necessarily require a linear "array" of storage locations for its implementation, then also the fact that the array is searched "both *upwards and downward*" cannot be regarded as an essential feature. On the contrary, this terminology would appear inappropriate for storage locations arranged as a matrix.

5.6 In other words, an essential aspect of the present invention is the ability to search a pacing parameter when the storage location corresponding to the diagnosed tachycardia cycle length is empty. How such search is carried out is immaterial for defining the present invention and depends essentially on the particular memory arrangement.

Thus, in the opinion of the Board, an applicant, who has chosen to describe a preferred embodiment with technical details which are **clearly not necessary** to implement the essential aspects of the invention, should not be required under Article 123(2) EPC to introduce all these details into a claim amended on the basis of such an embodiment.

5.7 A further objection raised by the appellant opponent relates to the deletion of "*numerically*" in the expression "*numerically closest to the newly confirmed cycle length*".

5.8 In the opinion of the Board, the use of "*numerically*" in the cited context implies that the cycle lengths are arranged according to a sequence of numbers. In fact, the description, column 8, lines 23 to 25, specifies that "*a numerical range of 0 to 255 can represent cycle lengths from 0 to 1020 milliseconds".* Thus, "*numerically*" could be interpreted as referring to an embodiment that represents increasing (or decreasing) cycle lengths by means of a range of increasing (or decreasing) numbers.

However, as immediately clear to a person skilled in the art, this is not the only possible embodiment of the invention and the elements of a sequence of cycle lengths need not be identified by increasing or decreasing numbers, though it may be the most obvious thing to do. For the same reasons pointed out above, it would seem unfair to ask the appellant proprietor to limit the claim unnecessarily by introducing optional details taken from a particular embodiment, only because the combination of essential features specified in the claim finds support in the same embodiment.

5.9 In the present case, however, the deletion of the word "*numerically"* in the expression "*numerically closest to"* appears to introduce an ambiguity in the amended claim because "*closest to*" taken by itself could be understood in terms of "closeness in time". In other words, this feature of claim 1 could be interpreted as

implying that the pacing parameter used to treat the tachycardia is the one associated with the cycle length which, on a time scale, is *"closest to"* the one diagnosed. It should be noted that this interpretation of the claim would not be void of technical sense in the context of the present invention.

5.10 In the opinion of the Board, this ambiguity in the interpretation of a feature makes the claim unclear within the meaning of Article 84 EPC. In fact, the requirement of clarity implies that each feature of a claim should, as far as possible, be clear *per se*, and that it should be possible to understand the claimed subject-matter without reference to the description.

Third auxiliary Request

6. *Article 123(3) EPC*

6.1 Claim 1 according to the **third auxiliary request** comprises all the features recited in claim 1 of the **first auxiliary request** (clauses (A), (B) and (C)) and the features recited in claims 14 and 15 of the patent as granted.

6.2 As pointed out above, the combination of clauses (A), (B) and (C) defines subject-matter falling outside the terms of the apparatus claim as granted. Hence, claim 1 of the third auxiliary request is not admissible under Article 123(3) EPC.

Fourth auxiliary request

7. *Article 123(2) and (3) EPC*

7.1 Claim 1 of the second auxiliary request amended by inserting the word "*numerically*" before "..*closest...*" according to the appellant proprietor's **fourth auxiliary request** is admissible under Article 123(3) EPC (see item 4.1 to 4.5 above). Furthermore, the claim thus amended overcomes the objection raised by the appellant opponent and concerning the lack of support in the application as originally filed. However, the appellant opponent raised a further objection in the context of the second auxiliary request which applies also to claim 1 of the fourth auxiliary request under consideration.

7.2 According to the appellant opponent, the fact that the claim was amended by adding **only** some features selected from a preferred embodiment of the application as originally filed, constituted an infringement of Article 123(2) EPC.

The first "missing" feature identified by the appellant opponent relates to the fact that "*the confirmed tachycardia cycle length is also held over in temporary storage in case it is needed at the time that the tachyarrhythmia is pace-terminated*" (see patent specification, column 8, lines 50 to 53). As such, it reflects that aspect of the invention which is concerned with updating the pacing parameters in the storage locations.

7.3 Claim 1 according to the fourth auxiliary request, *inter alia*, comprises:

- **means for utilising** a range of antitachycardia pacing parameters in the treatment of tachycardias over a period of time (clause D);

- **means for correlating** successful antitachycardia pacing parameters in such range with the tachycardia cycle lengths of the tachycardias they successfully revert (clause D); and

- **means for over-riding** earlier successful antitachycardia pacing parameters that may be stored in storage locations with later successful antitachycardia pacing parameters that correspond to such storage locations (clause (E)).

7.4 The function of replacing ("*over-riding*") a pacing parameter in a storage location with the latest successful parameter implies necessarily that the information concerning the cycle length of the tachycardia which starts the antitachycardia treatment is somehow stored in a memory. Thus, in the opinion of the Board, the combination of features now set out in clauses (D) and (E) of claim 1 according to the fourth auxiliary request **necessarily** implies that the claimed apparatus also performs the function of temporarily storing the confirmed cycle length "*in case it is needed at the time that the tachycardia is pace-terminated*".

7.5 The appellant opponent further argued that other essential features of the preferred embodiment were not specified in the claim. Such features catered for some special situations which inevitably occurred in the use of the claimed apparatus, such as the fact that no initial values of the pacing parameters were stored in the bins, or that two bins with cycle lengths equally close to an empty bin corresponding to the diagnosed cycle length were found. In this context, the appellant opponent cited T 284/94 (OJ EPO 1999, 464).

7.6 According to the Headnote of T 17/86 (OJ EPO 1989, 297), to which T 284 /94 refers, (emphasis added), "A technical feature taken in isolation from the application as filed can under Article 123(2) EPC be introduced into a claim if the application as filed unmistakably shows that the combination of technical features in the new claim thus amended is sufficient to produce the result sought in the application."

The result sought in the present application is to provide an apparatus which uses a pacing parameter stored in a storage bin to start treating a corresponding tachycardia, and which is able to update the stored values according to the patient's needs or to select an appropriate starting pacing parameter if a storage bin is empty (cf patent specification, column 4, lines 8 to 39).

7.7 In the present case, the person skilled in the art, reading the original disclosure, realises that the features required to achieve the results pointed out above *(ie* the automatic updating of the pacing parameter best suited to start treatment of a certain

tachycardia and the ability of filling out the empty storage locations) are those which are clearly set out in claim 1 according to the fourth auxiliary request. On the other hand, the skilled person cannot expect an apparatus comprising **only** the claimed combination of features to cope with all possible "real-life" situations which go beyond the inventive teaching. For instance, it is evident that at least some bins should be filled with pacing parameters, when the apparatus is operated for the first time, or that, if all bins are empty, there should be some default pacing parameters to start treatment with. Similarly, the skilled person realises that provisions should be made to discriminate between two equally close storage bins.

The preferred embodiment provides a particular solution to the above problems by specifying that:

- "*if no filled bins are found in the array, then scanning is commenced at zero* (patent specification, column 9, lines 44 to 46);

- if two stored parameter values Sm and Sn are at an equal distance from an empty bin, "*then the number of scan steps in going from "Sm" to "Sn" is measured , and if this is less than the number of scan steps in going from "Sn" to "Sm"*, then "Sm" is chosen" (ibid. column 9, lines 23 to 28).

It is, however, implicit that an apparatus having a default parameter value different from zero, or using a different criterion to discriminate between equally close cycle lengths would be a fully operational embodiment of the present invention, in the sense that

it would achieve the results set out in the original application.

7.8 In other words, the subject-matter of claim 1 of the fourth auxiliary request can be considered to provide "a complete solution" (see T 284/94: Headnote) to the problem addressed in the contested patent, as far as the claimed combination of features is "sufficient" to produce the desired result (see T 17/86, Headnote). In the opinion of the Board, this condition is fulfilled even if other trivial features may be necessary to make the claimed apparatus fully operational. Furthermore, it would seem unfair to ask an applicant, who has provided a detailed description of an embodiment and who wishes to use this embodiment as a basis for amending a claim, to include in the amended claim also features of the embodiment which are evidently not directed to achieving the **essential** result of the invention, though they may be necessary to fulfil some additional operational requirements.

7.9 Thus, in line with decision T 17/86, the Board considers that claim 1, which is based on a combination of features selected from the description of a preferred embodiment, is admissible under Article 123(2) EPC since its combination of features is "sufficient" to produce the result sought in the application.

8. *Article 83 EPC*

8.1 The appellant opponent further submitted that, by not comprising all the features of the preferred embodiment, the claim would not define the invention in

a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC). The arguments of the appellant opponent appear to be based on the assumption that if the independent claim did not comprise all the features necessary to solve a particular problem addressed by a detailed embodiment, the claim would cover also other hypothetical undisclosed embodiments of the invention, which the skilled person would not be able to implement.

8.2 According to Article 83 EPC, the **European patent application**, not just the independent claims, must be considered for determining whether a claimed invention is sufficiently disclosed. This implies that the description should include an explanation of at least one way of carrying the invention into effect. However, matters which are common knowledge or routine practice need not be included.

8.3 In the present case, the application as filed comprises a detailed description of a "fully operational" embodiment of the invention. A person skilled in the art, wishing to implement the claimed invention, would immediately realise that an apparatus having **only** the features recited in claim 1 could not work if all bins were empty or it would "lock" if it found two bins equally close to an empty bin. However, it would be a matter of routine practice for the skilled person to make provisions to avoid these problems by defining a default value (*eg* other than zero) for the pacing parameter, if operation starts with all empty bins, and by providing a criterion (*eg* first found or last found

filled bin) to choose between two equally close cycle lengths.

8.4 In the opinion of the Board, the requirement of Article 83 EPC does not imply that an independent claim should be limited to one or more preferred embodiments and exclude further embodiments of the invention which would be **implicit** to the skilled person reading the application as originally filed.

9. *Article 84 EPC*

The Board is satisfied that claim according to the fourth auxiliary request meets the requirements of Article 84 EPC.

10. *Article 54 EPC*

10.1 The essential aspects of the present invention, as set out in the features of the claimed apparatus, may be summarized as follows:

- tachyarrhythmias are defined in terms of their cycle lengths (claim 1, clause (A));

- a particular episode of tachyarrhythmia is classified according to its cycle length (*ibid.* clause (A) and (C));

- each cycle length is associated with a certain value of a **pacing parameter** relating to the pacing stimulus required to terminate the corresponding tachyarrhythmia (*ibid.* clause (B));

- each **pacing parameter value** is stored in a storage bin identified by a particular cycle length (*ibid.* clause (B));

- treatment of a tachycardia episode characterised by a certain cycle length starts with a stimulus having the parameter value stored in the storage bin of corresponding cycle length (*ibid.* clause (C));

- unless the stored parameter is successful in treating the tachycardia, the parameter value is scanned through a predetermined range until the corresponding pacing stimulus terminates the tachyarrhythmia (*ibid.* clause (D));

- the successful parameter value is then stored in the bin associated with the initial episode of tachycardia, whereby an earlier unsuccessful scanning parameter already stored in that bin is overwritten by the newly successful value (*ibid.* clause (D) and (E));

- if the bin corresponding to a detected tachyarrhythmia cycle length is empty, the storage locations are searched to identify a filled bin (*ibid.* clause (C));

- the pacing parameter value for the cycle length which is "numerically closest" to the detected tachycardia cycle length is taken as the starting parameter value to be used for reverting the tachyarrhythmia (*ibid.* clause (C)).

10.2 Document E3 which represents the closest prior art, teaches, *inter alia*, the following:

(i) the heart rate continuum or spectrum is divided, or partitioned, into a multiplicity of regions defining contiguous, successive heart rate ranges (cf column 10, lines 55 to 65);

(ii) although three tachycardia classes are utilised in the preferred embodiment, the actual number of such classes may be more or less than three depending on the judgment of the physician (column 11, lines 6 to 13);

(iii) each tachycardia class is associated with a particular **therapy** (see Figure 2a) or with **a sequence of therapies** (see Figure 2b) according to the physician's prescription, whereby each therapy consists in delivering certain kinds of pacing stimuli to the heart (column 11, lines 47 to 56);

(iv) the sequence in which the selected therapies are delivered to the patient by the cardiac stimulator may be selectively modified according to a plurality of therapy control options which are programmable by the physician (column 14, lines 44 to 49);

(v) each of the therapies is provided with a selectively modifiable fine structure to permit the physician to adapt the treatment afforded by the stimulator to the needs of the patient (column 21, lines 43 to 47).

10.3 The appellant opponent sees no substantial difference between "*therapy*" as specified in E3 and "*antitachycardia pacing parameters*" referred to in claim 1, since a therapy may be defined also in terms of a single pacing parameter and the treatment of a tachycardia by means of a pacing parameter constitutes a therapy.

10.4 According to appellant opponent's interpretation of the wording "*pacing parameter*" and "*therapy*", E3 shows an embodiment (see Figure 2b) in which treatment of a particular class of tachycardias is started with a predetermined pacing parameter (THERAPY- A, THERAPY-B or THERAPY- D) and is continued utilising a predetermined range of pacing parameters (THERAPIES AB, ABC, BC). A first programming option is defined as "*retry exact pacing therapy*" ("REPT") and follows the rule that a particular pacing therapy previously delivered in response to detection of a tachycardia within a specified class is to be redelivered exactly as on the preceding occasion as the first attempt to terminate the arrhythmia, when a successive arrythmia is detected in that class, but only if that therapy was successful in terminating the arrhythmia on the earlier occasion (column 14, lines 58 to 66).

A second programming option defined as "*retry last successful pacing therapy*" ("RLSPT") consists in delivering the last pacing therapy in a certain sequence which was successful in terminating a certain tachycardia when a successive tachycardia episode occurs in the same class (cf column 15, lines 3 to 18).

10.5 Thus, on the assumption that the first therapy in a sequence corresponds to the initial pacing parameter stored in a storage location and that a sequence of therapies is equivalent to a range of pacing parameters, E3 discloses the following combination of features set out in claim 1 of fourth auxiliary request:

- means for establishing a plurality of storage locations each of which corresponds to a different sub-range of tachycardia cycle length within said range of tachycardia cycle lengths (see clause (A) of claim 1);

- means for storing, in corresponding ones of said storage locations, corresponding antitachycardia pacing parameters (clause (B));

- means for searching said storage locations to identify a storage locations which corresponds to the tachycardia to be treated and for treating the tachycardia using the antitachycardia pacing parameter stored therein (clause (C));

- means for utilising a range of antitachycardia pacing parameters in the treatment of tachycardias over a period of time (clause (D)); and

- means for correlating successful antitachycardia pacing parameters in such range with the tachycardia cycle lengths of tachycardias they successfully revert (clause (D)).

10.6 As to clause (E) of the claim relating to "*means for over-riding earlier successful antitachycardia pacing parameters",* the Board notes that it could be regarded as corresponding to the "RLSPT" (*ie "Retry Last Successful Pacing Therapy")* option only if were assumed that "*over-riding"* did not mean "*overwriting"* (cf patent specification, column 4, line 29), and that the successful pacing parameter did not permanently alter the sequence of therapies (*ie* pacing parameters) used to treat a certain class of tachycardias. In fact, an essential difference between the "updating function" of the claimed apparatus, as implied by the combination of the features of clauses (B) and (E), and the "RLSPT" option of E3 is that the latter replaces **only temporarily** the initial therapy selected by the physician but does not "overwrite" it permanently. In other words, the "RLSPT" provides only a "temporary update" of the pacing parameter which is effective only "*on the next detection of an arrhythmia in that class"* (see E3 column 15, lines 12 to 13). If the new starting therapy is not successful in terminating the tachycardia, *"the treatment will thereupon revert to the prescribed therapy delivery sequence for the particular arrhythmia class"* (E3, column 15, lines 15 to 18).

Furthermore, none of the modes of operation of the apparatus shown in E3 covers the possibility that there is no prescribed therapy (*ie* pacing parameter) in the storage location corresponding to the diagnosed tachycardia.

10.7 Since the closest prior art document E3 does not anticipate the combination of features recited in claim 1 according to the fourth auxiliary request, the subject-matter of this claim 1 is new within the meaning of Article 54 EPC.

11. *Article 56 EPC*

11.1 Starting from the teaching of E3, a problem addressed by the contested patent can be defined as providing an apparatus which has the ability to learn over time what pacing parameters are best suited to start an antitachycardia therapy, and which does not require that a therapy be defined for all tachycardia cycle lengths.

11.2 The Board is satisfied that the combination of features recited in claim 1 provides a solution to the above problem.

11.3 The appellant opponent has identified in the control option "RATCHET" in E3 (see column 15, lines 31 to 43) a teaching that would give the skilled person the possibility of arriving at the claimed invention without involving an inventive step. In particular, the appellant opponent has submitted that the "RATCHET" function taught to look for a suitable therapy outside the boundary of a diagnosed cycle length when the therapies associated with that cycle length had not proved successful. It would be a straightforward step for the skilled person to use the same teaching to deal with the fact that no pacing parameter was associated to a diagnosed cycle length. In applying this

principle, the skilled person would inevitably arrive at the claimed subject-matter.

11.4 The "RATCHET" therapy control option implements the rule that "acceleration of a VT [ventricular tachycardia] to a higher class dictates that the initial therapy delivered for the new class be maintained at least at the level of aggressiveness of the therapy to which the therapy sequence for the old class had progressed" (E3, column 15, lines 31 to 36).According to the example of Figure 2b, an acceleration of the tachycardia from TACH -1 (to be treated by THERAPY-A followed by THERAPY-B) to TACH-2 (to be treated by the sequence: THERAPY-A, THERAPY-B and THERAPY-C) would result in the resumption of the (unsuccessful) THERAPY-A without the "RATCHET" option. However, if the "RATCHET" option is selected, the apparatus starts with the THERAPY-B upon detection of an acceleration of the tachycardia from TACH-1 to TACH-2. Thus, as its denomination implies, the "RATCHET" option prescribes that the apparatus will deliver therapy for the new class only in the direction of increasing aggressiveness and not backward from the therapy level reached during treatment in the old class.

11.5 If the "RATCHET" function teaches to consider the therapy in a neighbouring class, it is only to ensure that the treatment of an accelerating tachycardia is continued with the current level of aggressiveness rather than by reverting to the initial less aggressive therapy prescribed for the new class. This option, however, is clearly not meant to cope with the possibility that a storage location may be empty.

11.6 In summary, the teaching of E3 presupposes that a therapy (see Figure 2a) or a set of therapies (see Figure 2b) are defined for treatment of a particular class of tachycardia. If the "RLSPT" option offers the possibility of starting treatment of a subsequent tachycardia in the same class with the last successful pacing therapy, it does not alter the sequence permanently, and thus it does not involve a continuous update of the therapy sequences. Furthermore, E3 does not suggest that some of the storage locations associated with the different tachycardia classes may be left empty by the physician so as to be filled automatically by the apparatus in the course of its normal operation.

11.7 In the light of the evidence and arguments submitted by the appellant opponent, the Board finds that it was not obvious to a skilled person starting from the teaching of E3 to arrive at an apparatus falling within the terms of claim 1 according to the appellant proprietor's fourth auxiliary request. Thus, the subject-matter of this claim involves an inventive step within the meaning of Article 56 EPC.

12. Claims 2 to 9 of the patent as maintained, which correspond to claims 16 to 23 of the granted patent, are dependent and, therefore, their subject-matters also involve an inventive step.

13. In conclusion, the Board finds that the appellant proprietor's fourth auxiliary request is allowable and that the patent can be maintained on the basis thereof.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the following documents:

Claims:
claim 1 according to the **second auxiliary request** filed by letter dated 9 April 2003 with the insertion of the word "numerically" before "closest" according to the **fourth auxiliary request** filed by letter dated 9 April 2003;

claims 2 to 9 of the patent as maintained by the first instance;

Description:
description of the patent as maintained by the first instance with the deletion of the words *"It is also preferable that"* in line 24 of column 4;

Drawings:
Drawings of the patent as maintained by the first instance.

The Registrar: The Chairman:

D. Sauter G. Assi