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D E C I S I O N
of 15 May 1995

Case Number: T 0082/93 - 3.4.1
Application Number: 85112420.6
Publication Number: 0178528
IPC: A61N 1/365, A61N 1/08, A61B 5/02

Language of the proceedings: EN

Title of invention:

Method for adjusting heart/pacer rate relative to right ventricular systolic pressure to obtain a required cardiac output.

Patentee:

Telectronics N.V.

Opponent:

Biotronik Meß- und Therapiegeräte GmbH & Co. Ingenieurbüro Berlin

Headword:

Cardiac pacing/TELECTRONICS

Relevant legal provisions:

EPC Art. 52(4), 84, 123(3)

Keyword:

"Granted patent only containing claims defining a method for treatment of the human body by therapy - claims as granted violate Article 52(4) EPC - proposed amended claims defining a device extend the protection conferred, and violate Article 123(3) EPC - inescapable trap - patent revoked"

Decisions cited:

G 0002 and 0006/88, G 0001/93, T 0378/86, T 0245/87, T 0426/89, T 0820/92, T 0769/92



Case Number: T 0082/93 - 3.4.1

Decision of 10 September 1996
correcting an error in the
D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 15 May 1995

Appellant: Biotronik Meß- und Therapiegeräte GmbH & Co
(Opponent) Ingenieurbüro Berlin
Woermannkehre 1
D-12359 Berlin 47 (DE)

Representative: Christiansen, Henning, Dipl.-Ing.
Pacelliallee 43/45
D-14195 Berlin (DE)

Respondent: Telectronics N.V.
(Proprietor of the patent) De Ruyterkade 58A
P.O. Box 837
Willemstad
Curaçao (NA)

Representative: Brandl, Ferdinand Anton, Dipl.-Phys.
Kuhnen, Wacker & Partner
Alois-Steinecker-Str. 22
D-85354 Freising
München (DE)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office dated
12 November 1992 concerning maintenance of
European patent No. 0 178 528 in amended form.

Composition of the Board:

Chairman: — G. D. Paterson
Members: Y. van Henden
H. Reich

In application of Rule 89 EPC the decision given on 15 May 1995 in case T 82/93-3.4.1 is hereby corrected as follows:

Page 11 lines 17 and 18:

"T 769/93 (to be published in OJ EPO)" is replaced by
"T 769/92, OJ EPO 1995, 525"

The Registrar:

The Chairman:

J. Ruckerl

G. D. Paterson

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Patentee:

Telectronics N.V.

Opponent:

Biotronik Meß- und Therapiegeräte GmbH & Co. Ingenieurbüro Berlin

Headword:

Cardiac pacing/TELECTRONICS

Relevant legal provisions:

EPC Art. 52(4), 84, 123(3)

Keyword:

"Granted patent only containing claims defining a method for treatment of the human body by therapy - claims as granted violate Article 52(4) EPC - proposed amended claims defining a device extend the protection conferred, and violate Article 123(3) EPC - inescapable trap - patent revoked"

Decisions cited:

G 0002 and 0006/88, G 0001/93, T 0378/86, T 0245/87, T 0426/89, T 0820/92, T 0769/93

Headnote:

- I. Under Article 52(4) EPC, a claim is not allowable if it includes at least one feature defining a physical activity or action (e.g. a method step) which constitutes a "method for treatment of the human ... body by therapy" (following Decision T 820/92, OJ EPO 1995, 113). Whether or not the claim includes features directed to a technical operation performed on a technical object is legally irrelevant to the application of Article 52(4) EPC.

- II. The proposed amendment of the claims of a patent during opposition proceedings by way of change of category from a "method of operating a device" to a "device" is in principle not allowable under Article 123(3) EPC.

- III. If a patent as granted only contains claims which, on their proper interpretation, each define a method of operating a device which is in fact a "method for treatment of the human or animal body by therapy or surgery", and such patent is opposed under Article 52(4) EPC, then Articles 52(4) and 123(3) EPC may operate in combination as an inescapable trap resulting inevitably in revocation of the patent, in that:
 - (a) the patent cannot be maintained as granted because its claims define subject-matter which is unpatentable having regard to Article 52(4) EPC;
 - (b) the patent cannot be maintained in amended form with claims which only define the device itself and which no longer contain features defining a therapeutic method of operating it contrary to Article 52(4) EPC, because amendment of the claims as granted by deletion of such "method features" defining therapeutic operation of the device would be contrary to Article 123(3) EPC (Decisions T 378/86, OJ EPO 1988, 386, and T 426/89 OJ EPO 1992, 172 distinguished).



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D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 15 May 1995

Appellant: Biotronik Meß- und Therapiegeräte GmbH & Co
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Curaçao (NA)

Representative: Brandl, Ferdinand Anton, Dipl.-Phys.
Kuhnen, Wacker & Partner
Alois-Steinecker-Str. 22
D-85354 Freising
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Decision under appeal: Interlocutory decision of the Opposition Division
of the European Patent Office dated 12 November
1992 concerning maintenance of European patent
No. 0 178 528 in amended form.

Composition of the Board:

Chairman: G. D. Paterson
Members: Y. van Henden
H. Reich

Summary of Facts and Submissions

- I. Claim 1 of European patent No. 0 178 528 as granted reads as follows:

"A method of operating a pacer in accordance with the required cardiac output while a person is exercising, said pacer being adapted to be implanted in a human body and comprising a pulse generator and control circuitry therein; a pacing lead adapted to be implanted in a heart and having a distal electrode adapted to engage and supply pacing pulses to a right ventricle of the heart; pressure sensing means mounted on said pacing lead for sensing ventricular systolic pressure, wherein said control circuitry further includes means for relating changes in the right ventricular systolic pressure sensed and/or the time derivative of the right ventricular systolic pressure with the required rate needed to supply a desired cardiac output for the change in pressure and means for causing said pacer to pace the heart at the required rate when the heart is not naturally paced while the person is exercising, characterized in that said pressure sensing means (24) is used to sense the right ventricular systolic pressure and this pressure value and/or its time derivative are used to control the pacer rate."

Claims 2 to 11 are dependent upon Claim 1.

- II. The firm Biotronik Meß- und Therapiegeräte GmbH & Co Ingenieurbüro Berlin filed an opposition against this European patent.

The Notice of Opposition requested that the European patent should be revoked in its entirety, because its subject-matter is not patentable having regard to

Articles 52 to 57 EPC. The following three documents were cited as prior art in relation to the claimed subject-matter:

D1: US-A-3 857 399

D2: US-A-3 358 690

D3: Circulation, Vol. 69, No. 4, April 1984, p. 703-710.

The Notice of Opposition contended that the claimed method of operating a pacemaker was distinguished from the pacemaker which is disclosed in document D1 merely by the positioning of the pressure sensor in the right ventricle of a heart rather than the left ventricle. The sensed pressure value is used to control the pacemaker rate. There is thus a functional link between the sensed pressure value and the therapeutic treatment which is applied to the heart (contrary to the factual situation in Decision T 0245/87, OJ EPO 1989, 171, where there was no such functional link between what was measured and the therapeutic treatment which was subsequently applied). The claimed method is therefore a method of treating the human body by therapy, which pursuant to Article 52(4) EPC is to be regarded as not susceptible of industrial application, and therefore not patentable.

The Notice of Opposition also contended that the claimed invention lacked inventive step having regard to documents D1 and D2.

III. In reply, on 20 December 1990 the Proprietor Telectronics N.V. filed an amended set of Claims 1 to 11, defining "A pacemaker for pacing a heart ...", rather than "a method of operating a pacemaker." These amended claims were said not to contravene Article 123(2) EPC, because Claims 1 to 19 as originally filed were "device claims" defining a pacemaker and having features as now

claimed. Moreover, the amended claims were said not to contravene either Article 52(4) EPC or Article 123(3) EPC because Claim 1 as granted represents steps of a technical procedure defining assembling features of a pacer by means of functional features, rather than a method for treatment of the human body by therapy." Thus Claim 1 as granted, when interpreted in accordance with Article 69 EPC, does not define a method, but defines a device, i.e. a pacer, by reference to the "function of its parts" and "by means of some hardware features". However, Claim 1 as granted might suffer from lack of clarity because the claim language does not make clear that the functional features in the characterising part of the claim in fact define a device.

The proposed amendment is intended to meet this lack of clarity and is "only an apparent amendment because granted Claim 1 already relates to a device", for the reasons set out above. In support of these contentions, the Proprietor referred to Decisions T 378/86, (OJ EPO 1988, 386) and T 426/89, (OJ EPO 1992, 172).

The Proprietor also contested the Opponent's allegation of lack of inventive step having regard to the cited documents.

- IV. The Opposition Division issued a communication which indicated that the amended Claim 1 (i.e. "the pacer") lacked clarity, because the pacing "device" to which it is directed is defined by way of "procedural steps" in terms of process features. The communication also stated that the subject-matter of Claim 1 as granted (i.e. the "method" claim) did not appear to contravene either Article 52(4) or Article 56 EPC.
- V. In a reply dated 16 June 1992 the Proprietor filed a new set of Claims 1 to 11 directed to "a method of operating

a pacer", having only minor amendments compared to Claim 1 as granted, and requested maintenance of the patent on the basis of such claims. The Opponent did not file any further submissions.

VI. In its interlocutory decision dated 12 November 1992, the Opposition Division maintained the patent as so amended, with Claim 1 reading as follows:

"1. A method of operating a pacer in accordance with the required cardiac output while a person is exercising, said pacer being adapted to be implanted in a human body and comprising a pulse generator and control circuitry therein;

a pacing lead adapted to be implanted in a heart and having a distal electrode to engage and supply pacing pulses to a right ventricle of the heart;

pressure sensing means (24) mounted on said pacing lead,

characterized by

sensing a right ventricular systolic pressure using said pressure sensing means (24);

forming the time derivative of said right ventricular systolic pressure;

relating changes in the right ventricular systolic pressure sensed and/or the time derivative of said right ventricular systolic pressure with the required rate needed to supply a desired cardiac output for the change in pressure by means of said control circuitry; and

causing said pacer to pace the heart at the required rate when the heart is not naturally paced while the person is exercising."

Compared to Claim 1 as granted, the above claim also includes the step of "forming the time derivative of said right ventricular systolic pressure" in the characterising portion, and the two-part presentation has been amended to recognise the actual content of document D1.

The decision rejected the Opponent's submissions concerning violation of Article 52(4) EPC on the basis that the performance of the claimed steps implies a specific algorithm being implemented in the pacer, and the control of the pacing rate in accordance with a predetermined algorithm is "**a technical operation performed on a technical object**, which cannot be considered as a method for treatment of the human or animal body by therapy in the sense of Article 52 EPC". Thus the claimed subject-matter was held not to be excluded from patentability under Article 52(4) EPC. Furthermore, the decision held that such subject-matter was novel and inventive having regard to the cited documents, in particular because the claimed method included the steps of providing a right ventricular systolic pressure signal, relating changes in said signal and/or its time derivative to a required pacing rate, and controlling the pacer at said rate, and none of such documents hints either at monitoring pressure in the right ventricle, or at monitoring the systolic pressure therein.

VII. The Opponent duly filed an appeal. The Statement of Grounds of Appeal contested the finding that the claimed subject-matter involved an inventive step, with reference to two further documents. The Proprietor

submitted in reply that the appeal should be rejected, because the claimed subject-matter as allowed by the Opposition Division involved an inventive step. Both parties requested oral proceedings on an auxiliary basis.

VIII. The Board issued a communication on 6 March 1995 pursuant to Article 11(2) RPBA, accompanying the summons to oral proceedings, which inter alia stated its preliminary view that "the method claimed in each claim of the set of claims filed on 16 June 1992 (i.e. as maintained by the Opposition Division) on its proper interpretation does define a method which is excluded from patentability under Article 52(4) EPC".

In response thereto, on 27 April 1995 the Proprietor filed a new set of claims as its main request, each being directed to "a pacer", which was said to be characterised by its functional features, namely by the method steps according to Claim 1 as allowed by the Opposition Division. Such "change of category" was said to be allowable in the light of Decisions T 378/86 and T 426/89 (referred to in paragraph III above). Claim 1 of this set reads as follows:

"1. A pacer for pacing a heart in accordance with the required cardiac output while a person is exercising, said pacer being adapted to be implanted in a human body and comprising a pulse generator and control circuitry therein;

a pacing lead adapted to be implanted in a heart and having a distal electrode to engage and supply pacing pulses to a right ventricle of the heart;

pressure sensing means (24) mounted on said pacing lead,

characterized by the following method steps:

sensing a right ventricular systolic pressure using said pressure sensing means (24);

forming the time derivative of said right ventricular systolic pressure;

relating changes in said right ventricular systolic pressure sensed and/or the time derivative of said right ventricular systolic pressure with the required rate needed to supply a desired cardiac output for the change in pressure by means of said control circuitry; and

causing said pacemaker to pace the heart at the required rate when the heart is not naturally paced while the person is exercising."

- IX. Oral proceedings were held on 15 May 1995, both parties being represented.
- X. The Opponent requested that the patent be revoked, initially because Claim 1 as filed on 27 April 1995 requires that the pressure sensor is located in the right ventricle of the heart, the systolic pressure from such ventricle being used to cause the pacemaker to pace the heart at the required rate **while the person is exercising**. Thus such claim defined a method for treatment of the human body by therapy, and is excluded from patentability under Article 52(4) EPC, even though the initial words of the claim were directed to a pacemaker.

If the claims were not excluded from patentability on that basis, the subject-matter of the claims in any event did not involve an inventive step.

During the hearing, the Proprietor withdrew the set of claims filed on 27 April 1995, and requested as the main request that the patent be maintained as granted (i.e. with "method" claims, see paragraph I above). He also filed a new Claim 1 as the basis for a new set of claims constituting an auxiliary request, such new Claim 1 defining a "pacer", and reading as follows:

"A demand pacer for pacing a heart in accordance with the required cardiac output, said pacer being adapted to be implanted in a human body and comprising a pulse generator and control circuitry therein;

a pacing lead adapted to be implanted in a heart and having a distal electrode to engage and supply pacing pulses to a right ventricle of the heart;

pressure sensing means (24) mounted on said pacing lead, adapted to be located within a right ventricle, to thereby sense a right ventricular systolic pressure, wherein said pacer

forms the time derivative of said right ventricular systolic pressure;

relates changes in said right ventricular systolic pressure sensed and/or the time derivative of said right ventricular systolic pressure with the required rate needed to supply a desired cardiac output for the change in pressure by means of said control circuitry;

and generates stimulation pulses at the required rate when the heart is not naturally paced while the person is exercising."

In support of the main request, the Proprietor submitted that Claim 1 as granted defines constructional features of the pacemaker by means of functional features, and its subject-matter is therefore not a method of treatment of the human body, but a device.

In support of the auxiliary request, the Proprietor continued to rely on Decisions T 378/86 and T 426/89 as a basis for submitting that the amended claim 1 did not involve an unallowable change of category causing an extension of protection as compared to Claim 1 as granted, in the sense of Article 123(3) EPC. Furthermore, even if Claim 1 as granted did in part define a therapeutic method, the amended Claim 1 of the auxiliary request did not define any extra subject-matter, but was still defining the same invention and therefore the same subject-matter as in Claim 1 as granted. The removal of the method steps in Claim 1 of the auxiliary request as compared to Claim 1 as granted therefore for this reason also did not involve any extension of protection in the sense of Article 123(3) EPC.

The Proprietor also requested that the following questions be referred to the Enlarged Board of Appeal:

- (1) Does a "method of operating a pacemaker" violate Article 52(4) EPC?
- (2) If yes, does a change of the claim category after grant, from a method of operating a pacemaker to a pacemaker including the method of operating steps as granted, violate Article 123(3) EPC?

XI. The Opponent requested that the main and auxiliary requests be rejected and the patent revoked, because the main request contravened Article 52(4) EPC and the

auxiliary request contravened Article 123(3) EPC. In any event the subject-matter of the patent did not involve an inventive step.

- XII. At the conclusion of the oral proceedings the decision was announced that the Proprietor's request for referral of questions to the Enlarged Board of Appeal is rejected, that the appeal is allowed and that the European patent is revoked.

Reasons for the Decision

Main request:

1. *Therapeutic treatment - ground of opposition under Article 52(4) EPC*

- 1.1 The Opposition Division in its decision rejected this ground of objection, which was initially raised against the claims of the patent as granted (i.e. the patent Proprietor's main request in the appeal proceedings) and was also raised against the amended Claim 1 which was the subject of the main request granted by the Opposition Division, on the ground that the defined method of operating a pacemaker included steps which necessarily implied that an algorithm was implanted in the pacemaker and used to control its pacing rate. Since such control of the pacing rate was **"a technical operation performed on a technical object"**, the Opposition Division held that the claimed method could not be considered as a method for treatment of the human body by therapy in the sense of Article 52(4) EPC, and that it was a method which was susceptible of industrial application in the sense of Article 57 EPC.

However, as pointed out by the Board in its communication dated 6 March 1995 (see paragraph VIII above), whether or not the claim includes features directed to "a technical operation performed on a technical object" is legally irrelevant to the application of Article 52(4) EPC.

In fact, a claim could contain nothing but technical features directed to a technical operation performed on a technical object and a subsequent technical operation performed on a human or animal body, but such a claim would be unallowable under Article 52(4) EPC if it defines a method for treatment of such a body by therapy or surgery.

This is in direct contrast to the legal situation under Article 52(2) EPC, where a claimed invention including a mix of technical and non-technical features may be patentable - see for example Decision T 769/93 (to be published in OJ EPO), where attention is drawn to the different considerations which are applicable under Article 52(2) EPC and Article 52(4) EPC, respectively.

- 1.2 The first sentence of Article 52(4) EPC provides that "Methods for treatment of the human ... body by ... therapy ... shall not be regarded as inventions which are susceptible of industrial application ...". It is well established that the policy underlying the exclusion of such methods from patentability under the EPC is that the **treatment** of human beings by therapy should not fall within the protection which is conferred by a European patent, so that such treatment cannot be in any way inhibited by such a patent.

By way of contrast, the second sentence of Article 52(4) EPC makes it clear that the provision in the first sentence "shall not apply to **products**, in particular

substances or compositions, **for use in** any of these methods" (emphasis added); thus emphasising that the exclusion from patentability set out in the first sentence only applies to **methods** of treatment.

- 1.3 Article 84 EPC requires that the claims of a European patent "shall define the matter for which protection is sought", and Rule 29(1) EPC requires that claims "shall define the matter for which protection is sought in terms of the technical features of the invention". The technical features of an invention may basically be of two kinds, namely physical entities and physical activities. If an invention is defined in a claim solely by features which are physical entities, then the claim as a whole is what is generally described as a "product" claim, and if an invention is defined in a claim solely by features which are physical activities, such a claim is generally described as a "method" claim, or process claim. As stated by the Enlarged Board in Decisions G 2 and 6/88 (OJ EPO 1990, 93 and 114), there are basically two different types of claim, namely a claim to a physical entity (e.g. product, apparatus) and a claim to a physical activity (e.g. method, process, use). These two basic types of claim are sometimes referred to as two possible categories of claim. However, as also stated by the Enlarged Board, "claims including both features relating to physical activities and features relating to physical entities are also possible. There are no rigid lines of demarcation between the various possible forms of claim".

In the present appeal proceedings, claims including features relating to both physical entities and physical activities were referred to as "hybrid" claims.

1.4 Bearing in mind the considerations underlying the exclusion provision in Article 52(4) EPC as set out in paragraph 1.2 above, in the Board's view a claim is not allowable having regard to Article 52(4) EPC if it includes at least one feature defining a physical activity or action (e.g. a method step), and if such activity or action constitutes a "method for treatment of the human body by therapy".

This conclusion is in line with what was stated in Decision T 820/92 (OJ EPO 1995, 113). Following consideration of a number of previous Board of Appeal decisions, paragraph 5.5 of this Decision states that "The decided cases show that in considering whether a request for a particular set of claims is allowable under Article 52(4) EPC, the critical question is whether there is any disclosure of a method **none of whose steps fall under the prohibition of Article 52(4) EPC**, i.e. none of whose steps are either a method for the treatment of the human or animal body by therapy or surgery, or a diagnostic method practised on the human or animal body" (emphasis added).

1.5 In the present case, Claim 1 of the patent as granted is a hybrid claim, in the above sense. It includes a number of features which are physical entities: for example, the "pacer" is defined as comprising "a pulse generator and control circuitry therein"; a "pacing lead"; "pressure sensing means"; and so on. The claim also includes a number of features defining physical activities or actions. Thus the opening words of the claim are "A method of operating a pacer in accordance with the required cardiac output while a person is exercising"; and this method is further defined at the end of the claim as "characterised in that said pressure

sensing means (24) is used to sense the right ventricular systolic pressure and this pressure value and/or its time derivative are used to control the pacer rate".

The Board does not accept the Proprietor's submission to the effect that these features defining physical activities or actions should be interpreted as functional features of the pacer, merely explaining the technical capability of the pacer. On the contrary, in the Board's view the above activities or actions which are set out in the claim consist of the use of a sensed pressure value derived from a particular part of the human body for quantitatively controlling the output of the pacer which is applied to the human body in order to obtain a therapeutic effect. Contrary to the situation in Decision T 0245/87 (OJ EPO 1989, 171), in the present case there is therefore a functional link between the value which is measured and the therapeutic treatment which is applied.

Thus in the Board's view the features of sensing the right ventricular systolic pressure and using this pressure value and/or its time derivative to control the pacer in accordance with the required cardiac output, while a person is exercising, define the use of the pacer to carry out physical actions which constitute a method for treatment of a human body by therapy. Consequently, in the Board's judgment, Claim 1 as granted (and each of its dependent Claims 2 to 11) defines subject-matter which is excluded from patentability by the first sentence of Article 52(4) EPC.

2. *Auxiliary request: Article 123(3) EPC*

2.1 As explained in Decision G 2 and 6/88 (OJ EPO 1990, 93 and 114), when deciding upon the allowability of an amendment requested during opposition proceedings having regard to the provisions of Article 123(3) EPC, "a first step must be to determine the extent of protection which is conferred by the patent before the amendment" (i.e. as granted).

Subsequently, the extent of protection conferred by the patent after amendment must be determined, and compared with the protection conferred by the patent as granted. If the patent after amendment confers the same or less protection as the patent as granted, there is no extension of protection, and the amendment does not contravene Article 123(3) EPC. On the other hand, if the patent after amendment confers additional protection compared to the patent as granted, there is an extension of protection, and the amendment contravenes Article 123(3) EPC.

Furthermore, determination of the extent of protection of the patent has to be carried out in accordance with Article 69(1) EPC and its Protocol.

2.2 In the present case, each of Claims 1 to 11 as granted (see paragraph I above) defines "A method of operating a pacer in accordance with the required cardiac output while a person is exercising ...". As discussed in paragraph 1.5 above, Claim 1 (and each of dependent Claims 2 to 11) is a hybrid claim which includes a number of features defining physical characteristics of the pacer device, as well as features defining physical activities. Thus the subject-matter which is protected by each claim is a pacer having all the physical characteristics which are set out in a number of the

technical features of the claim, **when in use**, that is, when attached to the body of a person who is exercising, and **while** "the pressure sensing means is used to sense the right ventricular systolic pressure and this pressure value and/or its time derivative are used to control the pacer rate". In other words, each of Claims 1 to 11 does not protect a pacer which has the physical characteristics which are defined therein, **unless** it is in use on a person taking exercise and delivering the required cardiac output; the patent therefore confers protection upon a pacer as defined in the claims, **when in use**..

2.3 In contrast, in the Board's view Claim 1 of the auxiliary request (see paragraph X above) only includes technical features which define physical characteristics of the pacer device itself. Thus the pacer is "adapted to be implanted in a human body". Its "pacing lead" is "adapted to be implanted in a heart". Its "pressure sensing means" is "adapted to be located within a right ventricle" of a heart. Such technical features of the pacer are not dependent on its location: they characterise the pacer whether or not it is in use. In fact such features only help to define the physical characteristics of the pacer to a very limited extent. For example, the fact that the pacer is "adapted to be implanted in a human body" essentially means that it is physically suitable for such implantation. The pressure sensing means must be suitable for being located "within a right ventricle". If it is, it would be equally suitable for being located in a left ventricle.

As to the second part of the claim, beginning with the words "wherein the pacer", in the Board's view the subsequent features of the claim ("forms the time derivative of said right ventricular systolic pressure", etc.) are functional characteristics of the pacer.

Thus the claim defines and confers protection upon a "pacer" whether or not the pacer is in use on a human body. The patent confers protection upon the claimed pacer both when it is in use, and when it is ready for use. This claim therefore confers additional protection compared to Claim 1 as granted. Such an extension of protection is contrary to Article 123(3) EPC. Claim 1 of the auxiliary request is therefore not allowable.

- 2.4 It may be added that if the above interpretation of Claim 1 of the auxiliary request is incorrect, for example in that any of the features in the second part of the claim (following "wherein said pacer") on their proper interpretation are not functional characteristics of the pacer but are method steps, then the claim would be unpatentable having regard to Article 52(4) EPC.
- 2.5 Thus in general terms, if a patent as granted only includes claims defining the operation of a device and therefore containing both "device features" and "method features", and the patent as proposed to be amended during opposition proceedings includes claims which only contain "device features", the proposed amendment is not allowable having regard to Article 123(3) EPC, because the patent as granted confers protection upon the device only when it is in use so as to carry out the method, whereas the patent as proposed to be amended would confer protection upon the device whether or not it is in use, and would therefore confer additional protection compared to the patent as granted. In other words, a proposed amendment of the claims of a patent during opposition proceedings by way of change of category from a "method of operating a device" to a "device" is in principle not allowable under Article 123(3) EPC.

2.6 The Proprietor relied upon Decision 426/89 (OJ EPO 1992, 172) in support of the auxiliary request. In that case, Claim 1 of the patent in suit as granted defined a "Method for the operation of a pacemaker for arresting tachycardia ...". It was held that the characterising portion of the claim exclusively contained features defining the functioning of the pacemaker, and was therefore "already a product claim containing a functional definition of a pacemaker" (paragraph 3.1 of the Reasons). Thus the Board of Appeal in that case held that "the seeming change of category does not alter the content of the claim but simply serves to clarify it", and that Claim 1 of the auxiliary request in that case was allowable.

In contrast to the findings in that Decision, in the present case the Board has held that Claim 1 as granted is clear, and that it defines the use of a device to carry out a method of treatment of the human body by therapy, and is not a pure "device claim" since it also includes method steps - see paragraph 1.5 above. Thus such Decision has to be distinguished from the present case.

Similarly Decision T 378/86 (OJ EPO 1988, 386) was relied upon by Proprietor. This Decision was issued before Decision G 2 and 6/88 (referred to above) was issued by the Enlarged Board of Appeal, and does not appear to be fully consistent with the Enlarged Board of Appeal's Decision. Having regard also to the findings made by this Board concerning interpretation of the claims as granted and as amended in the present case, in the Board's view Decision T 378/86 does not assist the Proprietor in the present case.

2.7 In the Board's view, if a granted patent which only contains claims defining a method for treatment of a human or animal body by therapy or surgery using a defined device or apparatus is opposed under Article 100(a) EPC on the ground that the claimed subject-matter is not patentable having regard to Article 52(4) EPC, the patent cannot be amended so as to contain claims defining the device or apparatus (for use in such a method) because such an amendment contravenes Article 123(3) EPC.

Thus in relation to such a patent, Articles 52(4) and 123(3) EPC operate in combination to form what could be regarded as an inescapable trap, somewhat analogously to Articles 123(2) and (3) EPC in the circumstances which were considered in Decision G 1/93 (OJ EPO 1994, 541) - see in particular paragraph 13 of the Reasons.

The Board has noted that in the present case, the application as filed contained Claims 1 to 19 directed to "An apparatus for pacing a heart ...", and Claims 20 to 30 directed to "A method for pacing a heart ...". During the proceedings before the Examining Division, the Examining Division in its first communication stated that Claim 1 (the apparatus claim) lacked novelty in view of document D1 (see paragraph II above), and that an allowable claim could take the form set out in the communication, (namely Claim 1 as eventually granted). The Applicant consequently deleted the apparatus Claims 1 to 19 and filed amended method Claims 1 to 11 as suggested, and the patent was granted containing such Claims 1 to 11. However, as stated in the above Enlarged Board of Appeal Decision G 1/93 "The ultimate responsibility for any amendment of a patent application (or a patent) always remains that of the Applicant (or the Patentee)".

In the present case, although the Board appreciates that the Proprietor was at least to some extent led towards the filing of the claims in the form in which the patent was granted, nevertheless the legal consequences set out above of applying Article 52(4) EPC in relation to the main request and Article 123(3) EPC in relation to the auxiliary request appear to be unavoidable in the context of the present opposition proceedings.

3. With reference to the Proprietor's request that certain questions should be referred to the Enlarged Board of Appeal in the present proceedings (see paragraph X above), the Board rejects this request for the following reasons:

Question (1): In the Board's view, whether a particular claim violates Article 52(4) EPC depends upon its wording and upon the considerations which are set out in paragraphs 1.1. to 1.5 above. These considerations follow from a consistent jurisprudence set out in previous Board of Appeal decisions.

The referral of a question such as suggested by the Proprietor therefore does not appear to the present Board to be appropriate.

Question (2): The principles which are applicable to deciding whether or not a change of claim category after grant is allowable have previously been decided and set out by the Enlarged Board in Decisions G 2 and 6/88 referred to above. Again therefore, referral of a question such as suggested seems to be inappropriate and unnecessary.

4. Having regard to what is set out above, it is not necessary for the Board to decide the question of inventive step of the claimed subject-matter, which was also raised by the Opponent.

Order

For these reasons it is decided that:

1. The request for referral of questions to the Enlarged Board of Appeal is rejected.
2. The appeal is allowed, and the European patent is revoked.

The Registrar:

The Chairman:

M. Beer

G. D. Paterson

