BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

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File Number: T 387/89 - 3.4.1

Application No.: 82 301 160.6

Publication No.: 0 060 117

Title of invention: Synchronized intracardiac cardioverter

Classification: A61N 1/38

DECISION
of 18 February 1991

Applicant:

Proprietor of the patent: Medtronic Inc.

Opponent: Biotechnik GmbH

Headword:

EPC Art. 56, 114

Keyword: "Introduction by the Baord of documents cited in the European Search Report, but not relied upon by the Examining Divison or cited by the opponent" - "Strong reasons that they could affect the decision" - "Inventive step (no)"

Headnote follows

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 387/89 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 18 February 1991

Appellant : (Proprietor of the patent)	Medtronic Inc. 3055 Old Highway Eight P.O. Box 1453 Minneapolis, Minnesota 55 440 (US)
Representative :	Tomlinson, Kerry John Frank B. Dehn & Co., European Patent Attorneys Imperial House, 15-19 Kingsway London EC2B 6UZ (GB)
Respondent : (Opponent)	Biotronik Meß-und Therapiegeräte GmbH & Co. Ingenieurbüro Berlin Sieversufer 8 W-1000 Berlin 47 (DE)
Representative :	Christiansen, Henning, Dipl.-Ing. Patentanwalt Christiansen Pacelliallee 43/45 W-1000 Berlin 33 (DE)
Decision under appeal :	**Decision of Opposition Division of the European Patent Office dated 12 April 1989 revoking European patent No. 0 060 117 pursuant to Article 102(1) EPC.**

Composition of the Board :

Chairman : G.D. Paterson
Members : H. Reich
R. Shukla

Summary of Facts and Submissions

I. The Appellant is the owner of European patent 0 060 117 the grant of which was opposed by the Respondent.

II. In the proceedings before the Opposition Division the Appellant requested maintenance of the patent in amended form on the basis of an amended set of claims filed on 10 December 1987.

Amended Claim 1 reads as follows:

"1. An implantable medical device for the electrical termination of tachyarrhythmia comprising:

sensing means (18) responsive to cardiac depolarizations for producing a sense signal indicative of naturally occurring cardiac activity;

detection means (20) responsive to said sensing means for detecting cardiac tachyarrhythmia for producing a tachyarrhythmia signal indicative of such tachyarrhythmia;

means (24) for timing of a cardioverting pulse within a heartbeat cycle, said means being responsive to said sense signal; and

pulse generator means (32) for delivering the cardioverting pulse to cardiac tissue;

characterised in that said timing means (24) is connected to receive both said sense signal and said tachyarrhythmia signal and arranged to generate a stimulus signal in response to said sense signal and said tachyarrhythmia

signal, said stimulus signal being generated concurrently with each detected depolarization during tachyarrhythmia and in that said pulse generator means (32) delivers said cardioverting pulse in response to said stimulus signal."

Claims 2 to 5 are dependent upon Claim 1.

III. The Opposition Division revoked the patent on the ground that amended Claim 1 was lacking an inventive step having regard to documents:

D2: US-A-3 942 534, and
D3: "Deutsche Medizinische Wochenschrift", No. 14, April 1975, pages 731-734.

IV. The Appellant (Patentee) filed a notice of appeal against this decision including an auxiliary request for oral proceedings and set out grounds why the decision should be set aside. No observations were filed by the Respondent.

V. In a communication accompanying a summons to oral proceedings, the Board drew the Parties' attention to the following additional documents:

D4: US-A-3 952 750; and
D5: EP-A-0 023 134.

These had been cited in the European Search Report. The Board notified the Parties of its provisional view that documents D2 and D3 were less relevant, but that there were strong reasons why Claim 1 could not be maintained having regard to documents D4 and D5. A skilled person could be expected to arrive at the subject-matter of Claim 1 from a consideration of the device shown in document D4, by making the disclosed "means for producing the manually activated signal" "responsive to said (known) sensing means

(producing a sense signal indicative of naturally occurring cardiac activity) for detecting cardiac tachyarrythmia." The corresponding replacement of the known patient-activated means for producing a signal in the device of document D4 by the implanted automatic detection means of tachyarrhythmia known from document D5 might be regarded as a use of a known automatisation technology in a closely analogous situation, which use would be obvious to a skilled person.

VI. In response to this communication the Appellant declared that he would not be attending the oral proceedings, and he withdrew his provisional request for such oral proceedings. He maintained his request to set aside the appealed decision of the Opposition Division and to maintain the patent in its amended form, and he presented his comments supporting such request in written form. Thereupon, the oral proceedings were cancelled by the Board.

VII. In support of his request, the Appellant argued essentially as follows:

(a) There was no disclosure or suggestion in document D4 or document D5 of the specifically claimed arrangement of timing means, sensing means and detection means. In particular, in document D4, there was no disclosure of a means for producing a tachyarrhythmia signal. The disclosed "ready" signal, introduced together with the sense signal into the known timing means, would not be indicative of tachyarrhythmia but only a consequence of the manual activation of the device by an operator and would indicate that the known storage means is ready for discharge.

(b) The device of document D4 being responsive to a number of disorders of the heart rhythm, such as atrial fibrillation, atrial flutter or tachycardia, there would be no reason why one skilled in the art would attempt to modify this circuit so as to produce an automatic device sensitive solely to tachyarrhythmia (tachycardia associated with an irregularity in the normal heart rhythm).

(c) It would not be clear how the inclusion of the automatic detection means (11, 12) for tachyarrhythmia of document D5 into the device of document D4 would be done in practice, due to the fact that in order to control the increase of the energy of subsequent cardioverting pulses manually activating magnet 112 cannot be left out and counter 124 requires not the pulsed output of automatic detecting means (11, 12) but a continuously present signal in the presence of tachyarrhythmia.

VIII. The Respondent requested that the appeal be dismissed without submitting any further comments or arguments.

Reasons for the Decision

1. The appeal is admissible.

2. **Procedural matters**

2.1 The two documents D4 and D5, which are referred to in paragraph V above as having been drawn to the attention of the parties in the Board's communication, were cited in the European Search Report, but were not specifically referred to by the Examining Division during the proceedings before grant. The only document which was specifically referred to

by the Examining Division in its communication prior to grant of the patent was document D2, in order to ensure that it was acknowledged both in the description and within a two-part formulation of the main claim. Document D5 was acknowledged in the description as originally filed.

2.2 In Decision G 1/84 (OJ EPO 1985, 304), the Enlarged Board of Appeal stated that "opposition procedure is not designed to be, and is not to be misused as, an extension of examination procedure". Furthermore, in Decision T 198/88 dated 3 August 1989 (to be published, headnote published OJ EPO 4/1990), it was held that a document taken into account in the procedure before the Examining Division is not automatically evidence to be considered in the opposition procedure, even if indicated as background art in the opposed patent.

Thus, in the Board's view, in opposition cases, neither an Opposition Division nor a Board of Appeal has any duty to re-examine the course of the proceedings before the Examining Division before grant, or to reconsider the relevance of documents cited in the European Search Report, if such documents have not been relied upon by the Opponent to support his grounds of opposition. This is because in opposition proceedings following grant of a patent, both the EPO and the parties are entitled to assume that the application has been properly examined before grant with respect to documents cited in the European Search Report. In particular, documents which are closely relevant and likely to provide grounds for refusal of the application should have been at least the subject of a communication from the Examining Division before grant.

Of course, this is not intended to suggest that either an Opposition Division or a Board of Appeal should be inhibited from relying upon documents which were cited in

the European Search Report and which were not the subject of such a communication. An Opposition Division or a Board of Appeal may introduce such documents into opposition proceedings even if not so relied upon by the opponent, if they have strong reason to consider that such documents do in fact provide evidence in support of a ground of opposition that is of such relevance that it could affect the outcome of the proceedings. So far as an Opposition Division or a Board of Appeal is concerned, in the Board's view this is the principal criterion against which it has to assess whether to introduce such documents into the proceedings under Article 114(1) EPC, (although other factors may also require consideration in particular cases).

2.3 The present case falls within the criterion set out above, since the two documents D4 and D5 cited in the European Search Report, were not referred to by the Examining Division before grant, but were introduced into the appeal stage of these opposition proceedings by the Board of Appeal of its own motion under Article 114(1) EPC as being clearly of such relevance that they could influence the outcome of the decision to be made in the opposition proceedings.

2.4 The Board has also considered whether, having decided to introduce these documents into the proceedings during the appeal stage, it should exercise its discretion under Article 111(1) EPC to remit the case to the first instance for further consideration of these documents, in order to avoid the loss of an instance (see e.g. Decisions T 273/84, OJ EPO 1986, 346, and T 49/85, not published). Having regard to the fact that the Respondent did not ask for such remittal, and also having in mind the history of the case as set out above, the Board has decided not to remit the case.

2.5 Having now carefully considered the Appellant's observations in reply to its communication, in the Board's judgement not only is document D4 the closest prior art, but, furthermore, the combination of documents D4 and D5 is clearly decisive against maintenance of the patent, for the reasons given below.

3. **Novelty**

3.1 Document D4 discloses in accordance with the wording of Claim 1:

"An implantable medical device for the electrical termination of tachyarrhythmia (see D4, column 1, lines 40-43) comprising:

sensing means (130, 132 in Figure 3 of D4) responsive to cardiac depolarisations for producing a sense signal indicative of naturally occurring cardiac activity (column 7, lines 23-28);

means (112, 114, 116, 118, 120, 78, 80; column 7, lines 38-58) for producing a signal ("ready");

means (82) **for timing** of a cardioverting (column 1, line 51) pulse within a heartbeat cycle, said means being responsive to said sense signal (via line 56); and

pulse generator means (78, 84) for delivering a cardioverting pulse (column 1, lines 49-53 and column 8, lines 5-7) to cardiac tissue;

characterised in that

said timing means (82) is connected to receive both said sense signal (via 56) and the (ready) signal (via 80) and arranged to generate a stimulus signal (closing discharge switch 84) in response to said sense signal and said (ready) signal, and in that said pulse generator means (78, 84) delivers said cardioverting pulse in response to said stimulus signal."

3.2 The Board takes the view that (contrary to the Appellant's contention as set out in paragraph VII(a) above) the arrangement of timing and sensing means specifically claimed in Claim 1 is known from document D4.

In the absence of manual activation no signal appears in line 80. In the event of manual activation at least after a delay for completely charging storage means 78 a "ready" signal is transmitted via line 80. A stimulus signal is generated by timing means 82 and a cardioverting pulse is delivered by pulse generator means 84. Hence, the device in document D4 - upon manual activation - is suitable for electrical termination of tachyarrhythmia.

3.3 The subject-matter of Claim 1 differs from the device known from document D4 in that the means for producing a signal are not manually activated by placing command magnet 112 in an appropriate location near reed switch 114 but are:

(a) "detection means responsive to said sensing means for detecting cardiac tachyarrhythmia for producing a tachyarrhythmia signal indicative of such tachyarrhythmia", and

(b) "said stimulus signal is generated concurrently with each detected depolarisation during tachyarrhythmia".

3.4 For the above reasons, the subject-matter of Claim 1 is considered to be novel within the meaning of Article 54 EPC.

4. **Inventive Step**

4.1 Starting from the nearest prior art as disclosed in document D4, the objective problem underlying the present invention as claimed in Claim 1 is to activate in the known device the known means for producing a cardioverting pulse automatically, so that a command signal by the patient is superfluous.

4.2 According to Claim 1, this problem is solved by replacing the known manually activated means for producing the signal by:

"**detection means** responsive to said sensing means for detecting cardiac tachyarrhythmia for producing a tachyarrhythmia signal indicative of such tachyarrhythmia."

Such detection means are known from document D5; see D5, Figure 1, means 11 and 12, and the description, page 6, line 26 to page 7, line 11.

4.3 An automatic detection of the presence of a tachyarrhythmia via the means known from document D5 allows the delivery of the cardioverting pulse at the first malignant tachyarrhythmic event (see D5, page 7, paragraph 1). In the Board's view, this advantage is evident to a skilled person. It is thus obvious to apply this known technology in the closely analogous situation of the device known from document D4, and to combine it with the advantage of a depolarisation-synchronous cardioversion. It is generally known to the expert that with regard to the development of

heart rhythm irregularities, certain forms of flutter and fibrillation are preceded by tachyarrhythmia. Hence, the restriction in applying the teaching of document D5 in the device of document D4 - i.e. detecting solely tachyarrhythmia (see the Appellant's argument in paragraph VII(b) above) - is not regarded as diminishing the utility of the device known from document D4 to such an extent that a skilled person would refrain from such a further application of it. On the contrary, the clearly foreseeable advantage that a prompt termination of tachyarrhythmia may prevent a life-threatening fibrillation will encourage a skilled person to make use of the automatic detection of the very first tachyarrhythmia event according to document D5 in the device known from document D4. Due to the fact that the disadvantages of such a use - i.e. not being able to detect irregularities which do not shorten the interval between two successive R-waves (see D5, page 6, line 26 to page 7, line 17) - are clearly predictable and may correctly be assessed in all their consequences by a skilled person, these disadvantages do not adversely affect the obviousness of the analogous use of the teaching of document D5 in the device of document D4.

4.4 The application of the detector of document D5 in the device of document D4 only exploits the known properties and effects of the known means.

4.5 In the Board's view, the adaptation measures required in combining the teachings of documents D4 and D5 cannot be regarded as surpassing the normal capacities which are to be expected from a skilled person. Connecting the timing means of document D4 to receive the automatically provided tachyarrhythmia onset signal (i.e. the output of means 11 and 12) of document D5 instead of the manually activated signal in order to generate the stimulus signal

concurrently with each detected depolarisation during tachyarrhythmia is regarded as a measure which falls within an expert's normal competence. No further adaptation measures are necessary. Due to the fact that Claim 1 exclusively contains functional features, any detail of the technical realisation of these functions falls outside the subject-matter of Claim 1. In particular, Claim 1 does not even contain a functional statement that the energy of subsequent cardioverting pulses shall be increased, so that it is obvious for the expert that known magnet 112 and counter 124 are technically not essential for the solution claimed in Claim 1 and can be left out. For these reasons, the Appellant's arguments put forward in paragraph VII(c) above have no technical correlation with the subject-matter claimed in Claim 1 and thus cannot be taken into account in evaluating inventive step.

4.6 For the reasons set out above, in the Board's judgement the subject-matter of Claim 1 does not involve an inventive step within the meaning of Article 56 EPC.

5. Consequently, Claim 1 does not meet the requirements of Article 52(1) EPC and cannot form the basis of a patent maintained in amended form according to Article 102(3) EPC.

Claims 2 to 5 cannot be maintained because of their dependence on Claim 1.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar: **The Chairman:**

P. Martorana G.D. Paterson