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D E C I S I O N
of 7 November 2002

Case Number: T 0487/97 - 3.4.1

Application Number: 89306809.8

Publication Number: 0350282

IPC: A61N 1/05

Language of the proceedings: EN

Title of invention:
Pacemaker catheter

Patentee:
CARDIAC CONTROL SYSTEMS, INC.

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

Headword:

-

Relevant legal provisions:
EPC Art. 54, 56, 133(2)

Keyword:
"Novelty (no)"

Decisions cited:
G 0010/91, G 0007/95

Catchword:

-



Case Number: T 0487/97 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 7 November 2002

Appellant: Biotronik Mess- und Therapiegeräte GmbH & Co
(Opponent) Ingeniuerbüro Berlin
Woermannkehre 1
D-12359 Berlin (DE)

Representative: Eisenführ, Speiser & Partner
Pacelliallee 43/45
14195 Berlin (DE)

Respondent: CARDIAC CONTROL SYSTEMS, INC.
(Proprietor of the patent) c/o Nina M. La Fleur
Stutsman & Thames
121 West Forsyth Street
Suite 600
Jacksonville,
Florida 32202 (US)

Representative: -

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 20 March 1997
rejecting the opposition filed against European
patent No. 0 350 282 pursuant to Article 102(2)
EPC.

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal, received on 7 May 1997, against the decision of the opposition division, despatched on 20 March 1997, rejecting the opposition against the European patent No 0 350 282 (application No 89 306 809.8). The fee for the appeal was paid on 7 May 1997 and the statement setting out the grounds of appeal was received on 10 July 1997.
- II. The opposition had been filed against the patent as a whole based on Article 100(a) EPC and concerned, in particular, objections under Article 56 EPC.
- III. In answer to the grounds of appeal and with a view to showing some of the difficulties encountered in producing the invention of the contested patent, the respondent (patentee), by letter dated 10 December 1997, cited the following article published by the inventor:
- A1: *Robert R. Brownlee*: "Toward Optimizing the Detection of Atrial Depolarization with Floating Bipolar Electrodes", *PACE*, Vol. 12, Pages 431 to 442, March 1989
- IV. In response to the Board's communication accompanying the summons to oral proceedings, the representative of the patentee informed the Board by letter dated 22 February 2002 that he would not attend the oral proceedings.
- V. At the oral proceedings, which were held on 26 February 2002, the respondent was not represented and the appellant argued for the first time that the alleged

priority document US 215258 (P1) (filed on 5 July 1988) did not disclose all the features recited in Claim 1 of the contested patent. According to the appellant, only the later priority document US 333085 (P2) (filed on 4 April 1989) gave rise to a priority right for the contested patent and, therefore, document A1 (published in March 1989) constituted prior art under Article 54(2) EPC. Since A1 disclosed a catheter comprising all the features recited in Claim 1 of the patent in suit, the subject-matter of this Claim lacked novelty within the meaning of Article 54(2) EPC.

At the end of the oral proceedings, the Board decided, *inter alia*, that the appeal proceedings would be continued in writing to give the respondent an opportunity to comment on the appellant's new submissions.

- VI. In a communication dated 7 March 2002, the Board noted that an objection under Article 54 EPC had not been substantiated in the notice of opposition and that therefore lack of novelty would be a fresh ground of opposition which could be considered only with the approval of the patentee (respondent).
- VII. In response to the Board's communication of 7 March 2002, the representative of the respondent declared by letter dated 5 April 2002 that he relinquished his representation of the respondent in connection with the present appeal proceedings and asked that future correspondence be directed to the respondent.
- VIII. In a communication dated 23 April 2002, the respondent was invited under Article 133(2) EPC to give notice of appointment of a professional representative within

three months. No reply was submitted within the set time limit.

IX. The appellant requested that the appeal be dismissed and the patent be revoked.

X. The respondent requested by letter dated 10 December 1997 that the appeal be dismissed and the patent be maintained as granted.

By letter dated 22 February 2002, the respondent asked that the merits of the appeal be considered on the basis of the written submissions.

XI. The wording of Claim 1 reads as follows:

"A catheter (40) for a cardiac pacemaker system having a cardiac pacer, for insertion into a patient's heart (30), said catheter comprising:

a single, non-diverging, insulated filament (44) for insertion into the patient's heart (30) through the patient's vascular system, said filament having a distal end, a proximate end, and a proximal portion between said distal and proximate ends;

a first electrode (50) disposed at said distal end of said filament for sensing and pacing the heartbeat of the ventricle (35) of the patient's heart (30) and connectable to a pulse generating unit in said pacer for receiving a stimulating electrical pulse therefrom in response to input signals so as to pace the ventricle of the patient's heart (30);

second and third electrodes (46, 56; 48, 58; 56'; 56''; 58'; 58'') disposed on said proximal portion of said filament (44) and longitudinally spaced from said first electrode (50) and longitudinally spaced from each other for sensing atrial depolarisations having a

particular signature indicative of the extracellular wave forms associated with the intracellular action potential in the atrium of the patient's heart;

first, second and third electrical conductor means (44) within said insulated filament for connecting said first, second and third electrodes (50; 46, 56; 56', 56''; 48, 58; 58'; 56''), respectively, to the cardiac pacer; and characterised by

longitudinal spacing means (47, 57; 57'; D₃) for adapting said second and third electrodes (46, 56; 48, 58; 56', 56''; 58'; 58'') to sense and detect the particular signature indicative of the extracellular potential, as defined by a peak negative to peak positive deflection, being propagated along the surface of the atrium of the patient's heart (30), whereby said second and third electrodes (46, 48; 56; 56'; 56''; 58'; 58'') in use transmit said input signals indicative of a heart beat p-wave to the cardiac pacer,

said longitudinal spacing means comprising an insulating filament separating said second and third electrodes having a length of 1 mm to 10 mm being approximately the length of a peak-negative to peak-positive deflection of the detected extracellular signature associated with the action potential in the atrium of the patient's heart,

said second and third electrodes comprising hemicylindrical electrodes disposed on opposite sides of said insulating filament and having dimensions adapted to minimise field averaging of a bioelectric wave front corresponding to the particular signature of the action potential travelling in the tissue medium of the patient's heart, and

the surface area of each of said second and third electrodes to be exposed to the potential transmitting tissue medium being from substantially 3 mm² to

substantially 7 mm²."

Reasons for the decision

1. The appeal is admissible.
2. *Priority*
 - 2.1 The Board agrees with the appellant that the range of 1 mm to 10 mm specified in Claim 1 of the contested patent is not disclosed in the older priority P1. In fact, this document refers to an "insulated filament having a length of from about 1 mm to about 6 mm" (see Claim 8) or "a length of from about 2 mm to about 3 mm" (see Claim 9). Further values within the former range are given on page 13, line 8 ("on the order of 2 to 3 mm") and line 11 ("4 to 5 mm"), and on page 16, line 9 ("2 to 3 mm") and line 13 ("greater than 3 mm").
 - 2.2 Since P1 (filed on 5 July 1988) does not give rise to a priority right for the contested patent and the second priority document P2 was filed on 4 April 1989, document A1 (published in March 1989) constitutes prior art under Article 54(2) EPC.
3. *Novelty*
 - 3.1 Since an objection under Article 54 EPC was not substantiated in the notice of opposition, lack of novelty has to be regarded as a fresh ground of opposition which may be considered only with the approval of the patentee (respondent) (see G 10/91 (OJ 1993, 420)).

In the present case, the respondent has neither given

nor denied its consent to the introduction of a new ground of opposition. However, the Board is entitled to consider whether the subject-matter of Claim 1 satisfies the requirements of Article 54 EPC, since, as stipulated by the Enlarged Board of Appeal in G 7/95 (OJ 1996, 626), "if the closest prior art document destroys the novelty of the claimed subject-matter, such subject-matter obviously cannot involve an inventive step".

3.2 A1 (see Pages 435 to 438: "The Design of the Bipolar Floating Electrode System") discloses a catheter comprising all the features recited in Claim 1 of the patent in suit and, in particular, an insulating filament having a length ("5 mm or greater" see page 437, left-hand column, second paragraph and page 438, left-hand-column, first line) within the range of 1 mm to 10 mm. Hence, the subject-matter of Claim 1 of the contested patent lacks novelty within the meaning of Article 54 EPC.

4. In summary, the Board finds that the respondent's only request is not allowable and that, therefore, there is no basis for the maintenance of the patent.

Order

For these reasons it is decided:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

Chairman:

R. Schumacher

G. Davies