BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

D E C I S I O N
of 6 December 2004

Case Number: T 0467/02 - 3.4.1

Application Number: 93250365.9

Publication Number: 0606688

IPC: A61N 1/05

Language of the proceedings: EN

Title of invention:
Intravenous cardiac lead with improved fixation

Patentee:
Cardiac Pacemakers, Inc.

Opponent:
Biotronik GmbH & Co. KG

Headword:
-

Relevant legal provisions:
EPC Art. 100(a), 54(3),(4), 56

Keyword:
"EPC Art. 100(a) - Opposition grounds - lack of patentability"
"EPC Art. 54(3),(4) - Novelty - prior European application - no"
"EPC Art. 56 - Inventive step - no"

Decisions cited:
T 0860/93, T 0556/02

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0467/02 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 6 December 2004

Appellant: (Opponent)
Biotronik GmbH & Co. KG
Woermannkehre 1
D-12359 Berlin (DE)

Representative:
Eisenführ, Speiser & Partner
Patentanwälte Rechtsanwälte
Spreepalais am Dom
Anna-Louisa-Karsch-Strasse 2
D-10178 Berlin (DE)

Respondent: (Proprietor of the patent)
Cardiac Pacemakers, Inc.
4100 Hamline Avenue North
St. Paul
Minnesota 55112 (US)

Representative:
UEXKÜLL & STOLBERG
Patentanwälte
Beselerstrasse 4
D-22607 Hamburg (DE)

Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 28 March 2002 rejecting the opposition filed against European patent No. 0606688 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: G. Davies
Members: G. Assi
M. G. L. Rognoni

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 23 April 2002, against the decision of the opposition division, dispatched on 28 March 2002, rejecting the opposition against the European patent No. 0 606 688 (application number 93250365.9). The appeal fee was paid on 23 April 2002. The statement setting out the grounds of appeal was received on the same day.

II. The opposition had been filed against the patent as a whole and was based, *inter alia*, on the ground pursuant to Article 100(a) EPC that the subject-matter of the patent was not patentable within the terms of Articles 52(1), 54 and 56 EPC.

In the decision under appeal, the opposition division held that the grounds for opposition did not prejudice the maintenance of the patent unamended, having regard to, *inter alia*, the following documents:

(E2) EP-B-0 601 339,

(E3) EP-A-0 085 417,

(E10) DE-C-41 04 702.

In the following, the application corresponding to patent E2 will be designated E2'.

III. Oral proceedings were held on 6 December 2004.

IV. The appellant requested that the decision under appeal be set aside and the patent be revoked.

As a main request, the respondent requested that the appeal be dismissed and, as an auxiliary request, that the patent be maintained with an amended claim 1 filed at the oral proceedings and with claims 2 and 3, description and drawings of the patent as granted.

V. The wording of claim 1 of the patent as granted reads as follows:

"*An intravenous lead (110) for use with a cardiac device (30) implantable beneath the skin of a patient, the lead including: at least one electrode (116) carried by the lead and adapted to be coupled to the implantable cardiac device, a lead section (126) having a coiled configuration for making substantially continuous surface contact with inner wall surfaces of an artery or vein after the lead body is fed into the artery or vein, an inner stylet coil (130), and an outer electrically insulative jacket (132) coaxial with and overlying the inner stylet coil, the lead characterized by the inner stylet coil (130) also being coiled to impart the form of the lead coiled section (126) to the lead.*"

VI. The wording of the amended claim 1 according to the respondent's auxiliary request corresponds to that of claim 1 of the patent as granted with the insertion of the following feature immediately after the expression "*characterized by*":
"*the at least one electrode (116) being coaxial with and overlying the outer electrically insulative jacket (132) and*".

Reasons for the Decision

1. The appeal is admissible.

2. *Novelty (Article 54(3),(4) EPC)*

2.1 The content of the European patent application E2', of which the date of priority (11 December 1992) is prior to the dates of priority of the patent in suit and which was published (15 June 1994) after those dates, is comprised in the state of the art pursuant to Article 54(3) EPC. This applies only with regard to the Contracting States DE, FR, GB, IT and NL designated in respect of both the application E2' and the present patent (Article 54(4) EPC).

2.2 When assessing novelty of the subject-matter of claim 1 of the patent as granted, a controversial issue was the interpretation of the claim. According to the appellant, the fact that the intravenous lead "*included*" the features listed in the claim, namely at least one electrode, a lead section having a coiled configuration, an inner stylet coil and an outer electrically insulative jacket, could only mean that the mentioned features were all parts of the lead itself. In particular, the electrode had to be considered as part of the inner stylet coil (see the grounds of appeal, no. 1). The respondent, however, stressed the fact that the electrode was "*carried by the lead*", which fact indicated that the lead and the electrode were separate elements, the lead only "*including*" the coiled lead section, the inner stylet coil and the outer electrically insulating jacket. Thus, the electrode

could not be part of the inner stylet coil (see the respondent's letter of 21 November 2002, no. II).

The alleged ambiguity, therefore, consists in the fact that the claimed feature that the lead "*includes*" at least one electrode appears to be inconsistent, at least from a linguistic point of view, with the further claimed feature that the electrode is "*carried by the lead*". As regards the former feature, the terms "*lead*" and "*electrode*" are *per se* clear to a skilled reader. The verb "*include*", considered in its usual literal sense, means "*comprise or contain as part of a whole*". It follows that the former feature, when taken alone, recites the fact that the electrode is part of a whole represented by the lead. The latter feature, however, leads to a different conclusion. Since the verb "*carry*", in its usual sense, implies that an entity supports another distinct entity, the electrode would not be part of the lead itself.

2.3 In order to resolve this alleged ambiguity, the Board considers that it is appropriate to rely on the generally accepted principle of law stating that the proper interpretation of a document, more specifically any part thereof, is to be derived by having regard to the whole document. In other words, the best interpretation of any part of a document is made when the whole context of the disclosure is taken into account ("*ex praecedentibus et consequentibus optima fit interpretatio*") (T 860/93, OJ 1995, 047, point 5.1 of the reasons; T 556/02, point 5.3 of the reasons). The application of this principle to patent documents, which are intended for a skilled reader, thus entails that the claims should be construed as they would be by

a person skilled in the relevant technical field in the light of the overall content of the patent specification. For apparent reasons, this principle of law finds due application after grant with regard to unamended patent claims, whereas in grant proceedings the requirement of clarity (Article 84 EPC) makes it necessary to draft clear claims that, as far as possible, are comprehensible on the basis of the information provided therein only. Moreover, the application of said principle should not result in an undue limitation of the scope of a broadly drafted claim. It is rather intended to avoid the risk of relying on interpretations, which, privileging a literal interpretation of the claimed subject-matter without having regard to the rest of the patent, would be out of context and not consistent with the rest of the disclosure.

2.4 In the present case, the parties cited some passages of the description in support of their respective interpretations. The appellant, on the one hand, drew attention to the sentence in column 3, lines 12-14 of the published patent specification, according to which the lead 110 (see Figure 1) "*includes the elongated electrode 116*". The Board notes that the same disclosure can be found in column 3, lines 22-24, stating that "*The lead 110, as illustrated in Figure 2, includes an inner stylet coil 130, an outer electrically insulative jacket 132, and the elongated electrode 116*". On the other hand, the respondent underlined the fact that "*The electrode 116 is preferably preformed with its closely spaced turns prior to being mounted upon the lead 110*" (see column 3, lines 36-38), this disclosure being confirmed by the

statement in column 3, lines 47-50, that "*the electrode 116 may be coiled to form a helix having comparatively widely spaced turns prior to the electrode 116 being slid over the insulative jacket 132*".

The application of the above-mentioned principle of law leads to the following considerations as to the alleged ambiguity in claim 1. Indeed, the cited quotations show that the disclosure derivable from the description and the drawings supports both the appellant's interpretation that the electrode may be considered as part of the claimed lead, in particular of the inner stylet coil, and the respondent's interpretation that the electrode is a separate element mounted on the lead, in particular slid over the jacket. Hence, both interpretations can be regarded as being made within the context of the disclosure. Moreover, both of them are technically meaningful. This means that the Board has no reason to disregard one in favour of the other.

2.5 The application E2' (see column 1, lines 1-9; column 4, lines 15-35; Figure 1) discloses an intravenous lead for use with a cardiac device implantable beneath the skin of a patient. The lead "*includes*" an inner stylet coil 2, an outer electrically insulative jacket 3 coaxial with and overlying the inner stylet coil, and an electrode 5 adapted to be coupled to the implantable cardiac device. These elements may be considered to be part of the lead in agreement with the appellant's interpretation. As regards the electrode, it is formed by the distal end of the inner stylet coil and has a coiled configuration for making substantially continuous surface contact with inner wall surfaces of an artery or vein after the lead body is fed into the

artery or vein. Thus, the lead, in particular the inner stylet coil, has a coiled section corresponding to the electrode.

2.6 Hence, in agreement with the appellant's interpretation, the Board concludes that the subject-matter of claim 1 of the patent as granted lacks novelty, having regard to the application E2' for the designated Contracting States DE, FR, GB, IT and NL (Article 54(3),(4) EPC).

2.7 Since the application E2' does not disclose an intravenous lead including the feature that the electrode 5 overlies the outer electrically insulative jacket 3, the subject-matter of claim 1 as amended according to the respondent's auxiliary request is novel over the application E2'.

3. *Inventive step*

3.1 Inventive step has to be assessed having regard to the subject-matter of claim 1 of the patent as granted for the designated Contracting States other than DE, FR, GB, IT, NL, i.e. AT, BE, DK, ES, SE, and also having regard to the subject-matter of claim 1 as amended according to the respondent's auxiliary request.

3.2 The Board considers that document E3 represents the closest state of the art pursuant to Article 54(2) EPC. The respondent, however, contested the relevance of this document. In its view, since this document related to a different technical field concerning spinal stimulation leads, a skilled person would not consider it when assessing inventive step of the claimed subject-matter.

This view is not convincing because it does not properly acknowledge the general teaching derivable from E3. This document (see Title; claim 1; Figures 1 and 2) discloses a "*biomedical stimulation lead*" including an exposed electrode 12 and a lead body 21 that comprises an inner stylet coil (conductor 23 in the form of a helical coil) and an outer electrically insulating jacket (casing 21). The electrode is swaged onto the lead body so that it is coaxial with and overlies the casing (see page 6, lines 3-6). Since the stimulation lead is intended for implantation in a living body, improved anchoring means are provided, which do not traumatize the surrounding body tissue (see page 1, lines 3-8; page 3, lines 2-5). In particular, the lead body is provided with tines 19 preventing lead dislodgement. Moreover, it is preformed into a helical configuration (helix 15) over a portion of its length, the helix efficiently stabilizing the lead both along the axis of the lead and in a direction perpendicular to it (see page 4, lines 18-26; page 7, lines 21-35). The helix may be used alone, i.e. without the tines, or in combination with them (see page 8, lines 12-14 and 21-25). In any case, according to page 8, lines 25-27, the helix formed in the lead body can be used to anchor "*any*" stimulation lead. Although the description of E3 presents all these features in relation to a particular embodiment concerning a spinal lead to be placed within the epidural space, it is clear to the skilled reader that they are equally valid for other explicitly mentioned stimulation leads such as endocardial electrodes and transvenous electrodes (see page 2, lines 9-24 and 35-37).

In summary, document E3 represents a pertinent state of the art disclosing, in general, a biomedical stimulation lead suitable for being used as an intravenous lead adapted to be coupled to an implantable cardiac device implantable beneath the skin of a patient. In such a case, the helix 15 in the lead body would make substantially continuous surface contact with inner wall surfaces of an artery or vein after the lead body is fed into the artery or vein.

3.3 Now, with particular regard to the helix, i.e. the coiled lead section, document E3 (see page 5, lines 29-33) teaches that the casing of the lead body is preferably formed of polyurethane and the helix is formed by moulding the polyurethane in a heated press.

Hence, the intravenous lead according to claim 1 both of the patent as granted for the designated Contracting States AT, BE, DK, ES, SE and of the respondent's auxiliary request differs from the lead known from document E3 in that the inner stylet coil is coiled to impart the form of the lead coiled section to the lead.

However, document E3 itself points to the fact the other materials such as silicone rubber and other methods of forming the helix may be used. As far as the pointer to the manufacturing methods is concerned, it can be understood as implying methods other than moulding for elastically deforming the casing so as to obtain a coiled section of the lead body but also methods relying on structural parts other than the casing and achieving the same effect. With regard to Figures 1 and 2, apart from the casing 21, the only structural part of the lead suitable to be preformed

into a helical configuration is represented by the inner stylet coil 23. Evidence for the fact that a stylet coil can indeed be so shaped is provided by document E10 (see column 1, lines 3-10; column 6, lines 33-36; Figure 1) relating to a coiled implant for an organ duct, in particular a blood vessel. The coiled implant is made of a wire coil or of a thermoplastic tube and, once placed in its position, makes continuous surface contact with the inner wall of the duct or vessel.

In conclusion, for the aim of imparting a coiled configuration to a section of the lead, the claimed choice of the inner stylet coil represents an obvious alternative to the other choice of the casing as suggested by document E3. Moreover, it is noted that the leads according to claim 1 and to document E3 do not include other structural parts, apart from the inner stylet coil and the casing, which might be used for the said aim.

3.4 Hence, the subject-matter of claim 1 of the patent as granted for the designated Contracting States AT, BE, DK, ES, SE and the subject-matter of claim 1 of the respondent's auxiliary request do not involve an inventive step having regard to documents E3 and E10.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

R. Schumacher G. Davies