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Bezeichnung der Erfindung: Body implantable lead
Title of invention:
Titre de l'invention :

Klassifikation / Classification / Classement : A61N 1/05

ENTSCHEIDUNG / DECISION

vom / of / du 27 April 1989

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent /
Titulaire du brevet : Medtronic, Inc. (US)

Einsprechender / Opponent / Opposant : Biotronik Meß- und Therapiegeräte GmbH & Co (DE)

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Article 56 EPC

Schlagwort / Keyword / Mot clé : Inventive step (yes)

Leitsatz / Headnote / Sommaire

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Case Number : T 163 /88 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 27 April 1989

Appellant : (Opponent)
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Decision under appeal : Decision of Opposition Division of the European Patent Office dated 23 February 1988 rejecting the opposition filed against European patent No. 0 064 289 pursuant to Article 102(2) EPC.

Composition of the Board :

Chairman : K. Lederer
Members : E. Turrini
L.C. Mancini

Summary of Facts and Submissions

I. European patent No. 0 064 289 was granted on the basis of European patent application No. 82 103 777.7.

II. The Appellant (Opponent) filed notice of opposition against the European patent, requesting revocation thereof on the ground of non-patentability because of lack of inventive step in view of the prior art document DE-B-1 571 721 (A).

III. The Opposition Division rejected the opposition, document A being considered not relevant concerning the inventive step of the patent in suit.

IV. The Appellant lodged an appeal against the decision of the Opposition Division.

V. In an intermediate communication the Board referred to prior art documents US-A-3 749 101 (B) and "A prototype flexible microelectrode array for implant prosthesis applications", by Martin Sonn et al., published in Medical and Biological Engineering, Nov. 1974 (C). Furthermore, the Board emphasised that Claim 1 did not mention an intermediate sputtered layer, said feature being considered essential in the original description of the invention.

VI. The Respondent (Patentee) in a letter of response filed a new set of claims, with a new Claim 1 including the feature concerning the two sputtered layers.

VII. Oral proceedings were held, during which the Board took note of the fact that document A was no longer discussed, and at the end of which the Appellant requested that the

decision under appeal be set aside and that the patent be revoked, while the Respondent (Patentee) requested that the appeal be dismissed and that the patent be maintained on the basis of:

- Claims 1 to 7 filed on 28 March 1989;
- description as set out in the European patent specification in suit, wherein lines 8 to 32 of column 2 are replaced by page 2a filed at the oral proceedings; and
- one sheet of drawings as in the European patent specification.

VIII. Claim 1 reads as follows:

"A body implantable lead (10) for delivery of stimulation energy to a desired body site of the type having an exposed electrode (30) carried by the lead, said electrode comprising an electrode assembly (38) of a body compatible first material and a second material covering at least partly the exposed portion of said first material, said second material being a noble metal or an alloy thereof, characterized in that the whole exposed portion of said first material is covered by a sputtered intermediate layer (50) of a reactive metal and by said second material which consists of a further sputtered layer (60) of a noble metal or an alloy thereof sputtered over said sputtered intermediate layer (50)."

Claims 2 to 7 are dependent on Claim 1.

IX. In support of his request, the Appellant submitted that firstly, the wording of Claim 1 is not formally acceptable because of the contradiction between the expression "at least partly the exposed portion" and the corresponding

expression of the characterising portion "the whole exposed portion", and secondly, the subject-matter of Claim 1 is obvious due to the following reasons.

Sputtering techniques in the field in which the invention in suit lies are known from document C where a plastic film sputtered with a platinum layer is disclosed. It is also generally known to sputter different types of metallic materials. Furthermore it is not possible to make a clear distinction between one or more sputtered layers because, depending on the duration of the process, it is possible to obtain different layers of ions. It is also generally known in other processes like painting or spraying to use a prime, i.e. an intermediate layer in order to enhance adhesion of the final paint. If the skilled man realises that with the layer of noble metal the adhesion is not satisfactory, he would try as a matter of course to interpose a layer of a second metal which should be reactive.

X. These arguments were contested by the Respondent. As far as the formal remark is concerned, the preamble is covered by document B, from the figures and description of which it is unambiguously deducible the feature that the second material covers part of the exposed portion. The expression "at least partly" in the preamble of Claim 1 renders the claim correctly delimited with regard to document B and allows a correct limitation of the corresponding feature in the characterising portion of the claim obtained by the expression "the whole exposed portion".

Concerning the inventive step, the Respondent stressed the fact that, starting from the content of document B, the invention in suit can only be obtained by the addition of

different steps which are not disclosed or suggested in the known prior art. Firstly, the first material is a metal, while in document C the material is a plastic.

Secondly, there are two sputtered layers of different materials to increase adhesion. None of the cited prior art documents give even a hint at the utilisation of two sputtered layers.

Thirdly, the intermediate layer is chosen as being of reactive metal, which further increases adhesion.

For all these reasons the subject-matter of Claim 1 should be considered inventive.

Reasons for the Decision

1. The appeal is admissible.

2. The Board is satisfied that valid Claim 1, which includes the feature concerning the two sputtered layers is in agreement with Article 123(2) EPC. Also Article 123(3) EPC is satisfied, because the subject-matter of present Claim 1 is restricted with respect to the subject-matter of Claim 1 as granted. The Appellant did not raise any objection concerning these points either. Furthermore, the Board took into consideration the objection of the Appellant concerning clarity (Article 84 EPC), because according to Article 102(3) an amended patent shall comply with the requirements of the EPC. In this respect the Board is of the opinion that the wording of Claim 1 does

not contain any inconsistency, in particular that the expression "the whole exposed portion" is not in contradiction with the expression "at least partly the exposed portion" but represents merely a limitation of the second expression.

3. Novelty.

3.1 Document B discloses a body implantable lead (figures 1 and 2; description: column 1, lines 5 to 11) for delivery of stimulation energy to a desired body site of the type having an exposed electrode (Figure 2) carried by the lead (1), (description: column 2, line 15), said electrode comprising an electrode assembly of a body compatible first material (5) and a second material (7) partly covering the exposed portion of said first material (Figure 2), said second material being a noble metal (description: column 2, line 30).

Thus, the body implantable lead according to document B includes all the features of the preamble of Claim 1.

However, the features of the characterising portion of the claim, in particular the features concerning the sputtering techniques and the presence of two layers are not disclosed by document B.

3.2 Document C refers to a body implantable lead assembly (Abstract: Figure 1) for delivery of stimulation energy to a desired body site of the type having an exposed electrode made by a second material (Abstract: "platinum conductor-elements") covering partly the exposed portion of a body compatible first material (Abstract: "Thin film plastic insulating substrate", i.e. the first material being not metallic it cannot be considered part of the

electrode; "the electrode patterns are defined by photo-lithographic -etching techniques", i.e. the second material covers only part of the first material).

Furthermore the second material is a noble metal ("platinum") in the form of a sputtered layer (Abstract: "metallisation of the substrate accomplished by sputtering"; Figure 9).

Thus, the subject-matter of Claim 1 differs from the device according to document C in that:

- the exposed electrode is carried by the lead (in document C electrode and lead assembly form a unique body);
- the electrode includes also the first material;
- the layer of the second material is sputtered over a sputtered intermediate layer of a reactive metal; and
- the layers cover the whole exposed portion of the first material.

3.3 The remaining cited documents do not come any closer to the claimed subject-matter. In particular, document A on which the Opposition was initially based does not use metals as electrode material but their oxides, which are applied by some atomisation process, and not especially by sputtering, i.e. atomisation by ion bombardement. Finally, these known electrodes are not said to be part of a body implantable lead.

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 In the Board's view, the nearest prior art is disclosed in document B, which covers the preamble of Claim 1.

4.2 Starting from the disclosure of said document, the objective problem which the claimed invention solves is to obtain reliable attachment between first and second material over a long period.

4.3 This technical problem is solved by realising the layer of the second material in form of a sputtered layer and by interposing between the first material and the layer of the second material a sputtered layer made of reactive metal.

4.4 It should be noted that the feature concerning the "whole exposed portion" does not appear as directly related to the technical problem before mentioned, but seems to be rather a free choice of the inventor.

This feature per se cannot therefore contribute to the inventive step of the subject-matter of Claim 1, the more so because for the skilled man it should appear even easier to cover the whole surface rather than only a part of it. Thus, he would be incited to do so.

4.5 As far as the solution of the before mentioned technical problem is concerned, while document C gives a clear hint at realising the second material of the body implantable lead of document B in form of a sputtered layer, none of the cited prior art documents even suggest to insert between the body compatible first material and the second material in the form of a sputtered layer, a further sputtered layer of reactive metal.

It is true, as emphasized by the Appellant, that it is generally known in other layer processing techniques as e.g. spraying or painting, to use intermediate layers in order to enhance adhesion.

There is however no example in the known prior art of realising the sputtering technique with two layers of different materials as proposed by the present invention. Furthermore, the only cited prior art document in the field of the patent in suit is document B issued in 1974, i.e. no document was found which was published in the relatively long period between this date and the priority date of the patent in suit (1981) and which suggested the application of two sputtered layers in order to improve the adhesion of the outer layer to the basic material.

The Board of Appeal sees therefore no reason to consider the solution proposed by the present invention as being a mere working option.

4.6 For these reasons, the subject-matter of Claim 1 is considered to involve an inventive step within the meaning of Article 56 EPC and accordingly Claim 1 is allowable under article 52(1) EPC and, consequently, so are the dependent Claime 2 to 7.

4.7 Thus, the opposition grounds set out in Article 100(a) EPC do not prejudice the maintenance of the patent in amended form.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent in amended form as requested at the oral proceedings.

The Registrar: The Chairman:

F. Klein K. Lederer