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 596/90 - 3.2.2

Application No.: 83 830 149.7

Publication No.: 0 102 328

Title of invention: Method of manufacturing a prosthetic device having a coating of bio-compatible carbonaceous material and a prosthetic device having such a coating

Classification: C23C 14/34, A61F 2/00

D E C I S I O N
of 29 January 1993

Proprietor of the patent: Sorin Biomedica S.p.A.

Opponent: I Carbomedics Inc.
II Balzers AG

Headword:

EPC Article 56

Keyword: "Inventive step (yes)"

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 596/90 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 29 January 1993

Appellant : (Proprietor of the patent)
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Decision under appeal :
Decision of the Opposition Division of the European Patent Office dated 24 April 1990, notified on 28 May 1990, revoking European patent No. 0 102 328 pursuant to Article 102(1) EPC.

Composition of the Board :

Chairman : G. Szabo
Members : P. Dropmann
G. Davies

Summary of Facts and Submissions

I. European patent No. 0 102 328 was granted on 14 October 1987 on the basis of European patent application No. 83 830 149.7 filed on 20 July 1983.

The claims read as follows:

Claims for the Contracting States AT BE CH FR GB IT LI LU NL SE:

"1. Method of manufacturing a prosthetic device including an element having a coating of biocompatible carbonaceous material applied by cathode sputtering, characterised in that:

said element is chosen of a flexible polymeric material, and

cathode sputtering of said coating is effected using a target material (2) selected from the group consisting of graphite, glassy carbon and carbon with a turbostratic structure and by means of ionization of an inert gas.

2. Method according to Claim 1, characterised in that the gas which is ionized is constituted essentially of argon."

Claims for the Contracting State DE:

"1. Method of manufacturing a prosthetic device including an element having a coating of biocompatible carbonaceous material applied by cathode sputtering, wherein said element is chosen of a flexible polymeric material, and cathode sputtering of said coating is effected by means of ionization of an inert gas, characterised in that a target material (2) is used selected from the group consisting of

graphite, glassy carbon and carbon with a turbostratic structure.

2. Method according to Claim 1, characterised in that the gas which is ionized is constituted essentially of argon."

II. Two oppositions were filed against this patent on the grounds of Articles 100(a) and (b) EPC alleging lack of novelty, lack of inventive step and lack of sufficiency of disclosure.

III. By its decision taken at the oral proceedings on 24 April 1990 and notified on 28 May 1990, the Opposition Division revoked the patent. It was held that the method according to Claims 1 and 2 as granted did not involve an inventive step for the following reason:

Starting from document D1 (i.e. Carbon, Vol. 15, 1977, J.C. Bokros "Carbon Biomedical Devices", pp. 355-371), the use of cathode sputtering for depositing biocompatible carbon films on a flexible polymeric substrate, as claimed, was obvious in view of the fact that all the features of Claim 1 missing in D1, i.e. those related to sputtering, could be found in document D2 (i.e. Carbon, Vol. 14, 1976, Z. Marinkovic et al. "Preparation and Properties of Sputtered 'Glassy' Carbon Films", pp. 329-331). There was a specific reference in document D1 to D2.

IV. On 19 July 1990, a Notice of Appeal was filed against the decision of the Opposition Division. The appeal fee was paid on the same date. The Statement of Grounds was received on 25 September 1990.

During the appeal proceedings, the parties referred to the following documents in addition to documents D1 and D2 mentioned above:

(11) FR-A-2 399 237, and its US counterpart

(11 US) US-A-4 164 045,

(10) US-A-3 952 334,

"Williams" D.F. Williams "Biocompatibility of Clinical Implant Materials", Vol. II, Chapter 1: "Carbon in Medical Devices", 1981, CRC Press Inc., Boca Raton, Florida, pp. 3-42,

"Exhibit F" Journal of Bioengineering, Vol. 2, 1978, H.S. Shim et al., "The Wear Behavior of Vacuum-Vapor-Deposited Carbon Films", pp. 341-343,

"Exhibit G" Scanning Electron Microscopy, Vol. II, 1978, H.S. Borovetz et al., "Scanning Electron Microscopic and Surface Analytical Study of an Isotropic Vapor Deposited Carbon Film on Microporous Membranes", pp. 85-94, and

"Exhibit H" Dental Clinics in North America, Vol. 24, No. 3, 1980, J.N. Kent et al., "Pyrolytic Carbon and Carbon-Coated Metallic Dental Implants", pp. 465-485.

V. Oral proceedings were held on 29 January 1993. Although duly summoned, Respondent II (Opponent II) did not attend as previously announced by letter dated 2 November 1992.

VI. In the written submissions and at the oral proceedings, the Appellant essentially argued that, contrary to the findings of the Opposition Division, which appeared to be based on hindsight, a combination of the teachings of documents D1 and D2 would neither be obvious nor lead to the subject-matter of Claims 1 of the patent in suit. As to the reference in document D1 (page 357, third paragraph) to document D2, the Appellant pointed out that the latter document did not correspond to the reference made, since document D2 was solely concerned with a sputtering process, which was a mechanical phenomenon and thereby a "cold" process, and had nothing to do with the evaporation of carbon atoms from a carbon source heated by a high-energy electron beam, i.e. a heating process, which was mentioned in the sentence containing the reference to document D2. Furthermore, this document dealt with sputtering on rigid substrates and indicated that peeling could occur, as well as poor adhesion of the carbon film onto certain substrates. All sputtered carbon films had a grainy "pile of sand" microstructure which certainly precluded an acceptable degree of biocompatibility. It was stated in the abstract of document D2 that potential applications excluded corrosion protection. There was, therefore, no reason to combine the two documents.

Similarly, documents (11) and "Exhibit F", both of which also referred to document D2, clearly taught against the use of sputtering to coat flexible polymeric substrates with carbon. Furthermore, documents "Exhibit G", "Exhibit H" and "Williams" just mentioned the technique of cathode sputtering of a graphite or carbon source as one of a variety of vacuum processes for forming vapour-deposited carbons and confirmed that the trend was in another direction. They did not provide the skilled person with a specific indication that the sputtering technique could be considered a viable solution.

VII. Respondent I, in its counterstatement filed on 14 January 1991 and during the oral proceedings, supported the decision under appeal and maintained that the method claimed in the patent in suit involved no inventive step. According to document D1, vapour-deposited carbons provided a good carbon coating for flexible polymeric devices. The reference in this document to document D2 describing cathode sputtering using targets of polycrystalline graphite, pyrolytic graphite or glassy carbon, gave a clear alternative to the technique mentioned in document D1, which used a high-energy electron beam for evaporating carbon atoms.

All of the elements claimed in the patent were shown to be known from the documents cited during the proceedings. Although the authors of some of these documents had preferred other vapour deposition processes to cathode sputtering, they had clearly investigated the sputtering process and had reported that such a procedure was an appropriate technique for producing carbon-coated prosthetic devices having polymeric substrates.

Respondent I further argued that the closest prior art was represented by document (11) or its US counterpart (11 US). This document was concerned with the manufacturing of bio- and haemocompatible prostheses from flexible polymeric material and also contained a reference to document D2 forming a clear signpost to cathode sputtering. It thus disclosed all of the features claimed, which just had to be combined, and almost deprived the claimed method of novelty. The subject-matter of Claims 1 and 2 was, therefore, clearly obvious.

VIII. Respondent II, in its letter dated 25 January 1991, commented on the Appellant's argument that in those documents which described cathode sputtering as a method

of producing carbon coatings there could also be found some statements or warnings to the effect that such sputtering could result in detrimental effects undesirable for a biocompatible carbonaceous material. Respondent II considered it absurd to draw therefrom the conclusion that these warnings would discourage the skilled person from using cathode sputtering as a method for producing biocompatible carbon coatings.

IX. The Appellant requested that the decision under appeal be set aside and the patent be maintained as granted.

The Respondents requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Sufficiency of the disclosure

This matter was no longer pursued in the appeal. Since what is meant by the term "turbostratic structure" is well-known in the art (cf. e.g. documents D1, page 356 and "Williams", page 6), there is no reason to assume that the disclosure is insufficient to enable the skilled person to carry out the invention claimed. The fact that glassy carbon also has a turbostratic structure and thus falls within the scope of the term "carbon with a turbostratic structure" specified in Claims 1 does not render the disclosure insufficient either.

It is also to be noted that arguing insufficiency on the one hand, and obviousness, on the other, about the same embodiments of a claim is self-contradictory. If something is obvious, this should mean that it is indirectly

available to the public also in the sense that it can be made without undue burden.

3. Novelty

The method according to Claims 1 is novel over the prior art documents mentioned during the proceedings. Indeed, none of the documents discloses a method comprising, in combination, all of the features specified in Claims 1. In particular, this applies to documents (11) and (11 US) which describe the manufacturing of biocompatible prostheses comprising a vapour-deposited carbon coating on flexible polymeric material and further contain, in the introductory part, a reference to document D2 and a general statement to the effect that various techniques have been developed for depositing vapour coatings, for example, sputtering. However, there is no specific disclosure of a combination of the method steps claimed.

4. Closest state of the art

The argument of Respondent I that document (11) or (11 US) represents the closest state of the art is based on the fact that this document contains an expressis verbis reference to document D2 without any preceding statements, which could call into question whether the reference is accurate, as is the case in document D1, page 357, third paragraph, concerning the evaporation of carbon atoms from a carbon source heated by a high-energy electron beam (cf. point VI above). For this reason, and in view of the fact that the contents of documents D1 and (11) are similar as far as the relevant characteristics for assessing the inventive step of the patent in suit are concerned, the Board accepts this approach of Respondent I. However, the Board, when dealing with the question of inventive step, will also consider the approach adopted by

the Opposition Division and based on document D1 as the closest prior art.

Documents (11) and (11 US) state in their introductory parts that, besides the employment of pyrolytic carbon (LTI) coatings to produce biocompatible and thromboresistant surfaces, various other techniques have been developed for depositing vapour coatings, for example, vacuum vapour deposition (VVD), which is also sometimes referred to as vacuum metalizing, physical vapour deposition or evaporative coating, sputtering or ion-plating techniques. In this context, reference is made to document D2. It is further remarked that coatings deposited by such techniques are generally referred to as vapour-deposited carbon coatings and have been utilized in prosthetic devices, as described in document (10). Finally, however, it is stated in the introductory parts that, despite these advances, there are still deficiencies in the provision of certain prosthetic elements such as artificial vascular and patch grafts.

In particular, documents (11) and (11 US) disclose a method of manufacturing flexible, polymeric fabric prostheses, especially vascular grafts, having a coating of biocompatible carbonaceous material (cf. document (11 US), column 1, lines 43-68). The carbon coatings may be provided by vapour-deposition techniques such as described in document (10) to produce strongly adherent carbon coatings (cf. document (11 US), column 4, lines 55-58). They should have a density of about 1.6 g/cm^3 to about 2.0 g/cm^3 (cf. document (11 US), Claim 1 and document (11), page 7, lines 18-22).

5. Problem and solution

The objective technical problem relevant to the method according to the patent in suit may be formulated in the

light of the closest prior art known from document (11) or (11 US). It is to be seen in the provision of a further method of manufacturing a prosthetic device including an element of a flexible polymeric material having a biocompatible carbon coating.

The problem is solved in accordance with Claims 1 for all the designated Contracting States by applying the carbon coating by cathode sputtering. This is effected by using a target material selected from the group consisting of graphite, glassy carbon and carbon with a turbostratic structure and by means of ionization of an inert gas.

6. Inventive step

6.1 In view of the above approach adopted by Respondent I, the question arises whether or not it was obvious to a person skilled in the art and faced with the problem indicated above to deposit the carbon coating not by the technique described in document (10), as suggested in documents (11) and (11 US) as one possibility, but by a particular sputtering technique.

As stated in point 4 above, documents (11) and (11 US) mention sputtering as one of various techniques for depositing vapour coatings and contain a reference to document D2. The latter document describes the preparation and properties of sputtered glassy carbon films with densities of from 0.5 g/cm^3 to 1.79 g/cm^3. They are prepared by sputtering from polycrystalline graphite, pyrolytic graphite or glassy carbon targets in a rarefied Ar atmosphere. The carbon films are deposited on cover glass substrates and on fused quartz. It is, however, pointed out in document D2 that, under certain sputtering

conditions, peeling occurs during or after sputtering. On the other hand, films obtained at higher rf power, which, according to Figure 4 and point 3.3 of D2, leads to lower density, are very stable and peeling does not occur. Furthermore, the higher density carbon films adhere poorly to glass while carbon films sputtered on fused quartz substrates adhere very well. All sputtered carbon films have a grainy "pile of sand" microstructure and porosity is evident. According to the abstract of the document, potential applications exclude corrosion protection.

In view of the properties of sputtered carbon films described in document D2, especially the risk of peeling, poor adhesion to certain substrates, the grainy microstructure (which raises doubts about the suitability of the material for bio- and haemocompatible use), and the fact that potential applications thereof exclude corrosion protection, it cannot be considered obvious to combine the teaching of document (11) or (11 US) with the sputtering technique disclosed in document D2 for depositing bio- and haemocompatible carbon films on flexible polymeric material. These properties would rather dissuade the skilled person from applying this technique for this purpose.

In particular, the reference in documents (11) and (11 US) to document D2 does not, contrary to the opinion of Respondent I, constitute a clear signpost to cathode sputtering, since documents (11) and (11 US) teach that the carbon coating should have a high density of about 1.6 g/cm^3 to 2.0 g/cm^3 while document D2 demonstrates that peeling and adhesion problems, which are detrimental to biocompatibility, may exist with carbon films having higher density.

6.2 A similar objection exists against the alleged obviousness of the combination of documents D1 and D2. The sputtering technique has nothing to do with the evaporation of carbon atoms by a high-energy electron beam (cf. point VI above). Even if, nevertheless, the skilled person were to consider the reference in document D1 to document D2, it is not plausible, given the properties described in document D2, that the skilled person would, as contended by the Respondents, contemplate the cathode sputtering technique as a clear alternative to the technique described in document D1. It would not suggest a satisfactory method for vapour-depositing biocompatible carbons on flexible polymeric prosthetic devices (cf. document D1, in particular page 357, right-hand column, third paragraph, and page 363, last paragraph to page 364, second paragraph). Such possible detrimental effects would not suggest the sputtering technique as an obvious solution to the underlying problem but would rather lead away from the invention.

6.3 Although document "Exhibit F" also contains a reference to document D2, and documents "Exhibit G", "Exhibit H" and "Williams" mention cathode sputtering as one of various techniques of vapour-depositing carbons, it should be borne in mind that all of these documents focus on techniques which essentially differ from the sputtering technique. "Exhibit F" is mainly concerned with the preparation of carbon films by the vacuum vapour deposition technique (VVD) and the wear behaviour of such VVD carbons in comparison with LTI or pyrolytic (Pyrolite) carbons. In "Exhibit G", a study is presented on the haemocompatibility of vacuum vapour-deposited Biolite (ULTI) carbon. "Exhibit H" relates to LTI and ULTI carbon implants. As for the "Williams" document, it distinguishes between LTI, glassy and ULTI carbons. It describes the formation of ULTI carbon as a hybrid process, in which an

isotropic carbon coating is deposited using a catalyst, and mentions cathode sputtering in the context of a variety of vacuum processes for forming vapour-deposited carbons. However, it deals essentially with the properties of LTI and ULTI carbons, which latter carbon is investigated as a coating for flexible polymeric grafts.

Thus, these documents show that there was a trend in another direction pointing away from the invention. Acting against such a trend may be considered to indicate the existence of an inventive step (cf. T 2/81, "Methylenebis (phenyl isocyanate)", OJ EPO 1982, 394).

6.4 Accordingly, the Board finds that the subject-matter of Claims 1 cannot be derived in an obvious manner from the cited state of the art. The claimed method involves an inventive step.

7. The method according to Claims 1 as granted is, therefore, patentable having regard to Article 52(1) EPC.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The patent is remitted to the first instance with the order to maintain the patent as granted.

The Registrar: The Chairman:

N. Maslin G. Szabo

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