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D E C I S I O N
of 1 December 1994

Case Number: T 0858/91 - 3.2.2

Application Number: 88304881.1

Publication Number: 0293256

IPC: A61F 2/12

Language of the proceedings: EN

Title of invention:
Textured surface prosthesis implants and method of making the same

Applicant:
Mentor Corporation

Opponent:

Headword:

Relevant legal provisions:
EPC Art. 56, 111(1)

Keyword:
"Inventive step - no (main request)"
"Decision re. appeals - remittal (yes) (auxiliary request)"

Decisions cited:

Catchword:

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0858/91 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 1 December 1994

Appellant: Mentor Corporation
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Decision under appeal: **Decision of the Examining Division of the European Patent Office dated 1 July 1991 refusing European patent application No. 88 304 881.1 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: P. Dropmann
Members: M. Bidet
J. Van Moer

Summary of Facts and Submissions

I. A Notice of Appeal was filed against the decision of the Examining Division refusing application No. 88 304 881.1 for lack of inventive step (Articles 52(1) and 56 EPC) having regard to document US-A-4 531 244 (D1) and for lack of unity (Article 82 EPC).

II. During the appeal proceedings the Board considered the following document of its own motion:

(D2) G. J. Picha and D. J. Siedlak, "Ion-Beam Microtexturing of Biomaterials", MD&DI (Medical Device and Diagnostic Industry), April 1984, pages 39 to 42.

In a communication of 20 May 1994, the Board informed the Appellant of its provisional opinion that the subject-matter of the product Claims 1 to 14 then on file appeared not to involve an inventive step, either in view of document D2 alone, or in combination with other prior art, for example document D1.

III. Oral proceedings were held on 1 December 1994. During these proceedings the Appellant submitted an amended set of product Claims 1 to 14 according to a **main request**, and an amended set of process Claims 1 to 16 according to an **auxiliary request**.

IV. The Appellant requested that the decision under appeal be set aside and

- as the **main request** that a patent be granted on the basis of said Claims 1 to 14, and

- as the **auxiliary request** that the case be remitted to the first instance for further prosecution on the basis of said Claims 1 to 16.

V. Claim 1 according to the **main request** reads as follows:

"A surgical prosthesis (5) comprising:

an outer membrane comprising a textured exterior surface (7) disposed over at least a portion of said outer membrane, said textured exterior surface (7) being substantially non-absorbent to body fluids and being formed of a plurality of raised portions and indentations, said raised portions and indentations having a width of 0.0003 to 0.10 inches (0.0077 to 2.5 mm); and

a filler material disposed within said outer membrane;

characterised in that the said textured exterior surface comprising raised portions and indentations being substantially free of pores or interstices disposed in a direction primarily parallel to the surface of the prosthesis, said raised portions having a depth of 0.0003 to 0.03 inches (0.0077 to 0.77 mm), and said indentations having a depth of 0.0003 to 0.030 inches (0.0077 to 0.77 mm)."

Claim 1 according to the **auxiliary request** reads as follows:

"A process for making a textured surgical implant comprising:

providing a smooth surface prosthesis shell (10) having an exterior surface;

disposing said shell (10) on a mounting means (12);

disposing a formable, biocompatible material (18) over said shell at least over a portion of said exterior surface;

providing a texturizing means (20);

disposing said texturizing means (20) over said material (18) thereby imprinting in said material a textured surface;

removing said texturing means (20) from said material;

curing said material (18) into said shell (10);

patching said shell (10);

filling said shell (10) with a filler material; and patching said filled shell to retain said filler material in said shell."

VI. The Appellant essentially argued as follows:

The Picha article (D2) represented the most relevant state of the art. While mainly referring to hard-tissue implants, it contained merely a theoretical and very general suggestion that use of ion-beam technology might help in development of soft-tissue implants like mammary prostheses. The only detailed morphology discussed in this article in respect of micro-textured soft-tissue implants was the ion-beam generated, regular pillar structures across the surface of the prosthesis. There was no suggestion in the Picha article as to the features relied on as supporting the inventiveness of the prosthesis according to Claim 1 of the present invention, namely that the surface of the prosthesis was formed of a combination of raised portions and indentations, that the dimensions, i.e. the width and depth, of said raised portions and indentations were within specific ranges, and the feature relating to the lack of permeability of the surface material. The present invention fulfilled a long-felt need and experienced great commercial success as evidenced by a statutory declaration of one of the inventors,

Mr. Purkait. In assessing inventiveness, account should be taken of the grant in the USA of a corresponding patent despite the disclosure in the Picha article.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

2.1 Claim 1 meets the requirements of Article 123(2) EPC. In particular, the features of Claim 1 have their basis in Claims 1 and 31 and at page 11, second paragraph to page 12, first paragraph of the application as originally filed.

2.2 Claim 1 contains the feature that the textured exterior surface is formed of a plurality of raised portions and indentations. This feature is to be interpreted in the light of the original disclosure of the application. According to this disclosure, the textured surface consists of a plurality of substantially microscopic peaks and valleys (cf. page 6, lines 4 to 6). Figure 5 shows such a surface of a texturised patch.

There is no basis in the application as filed for the Appellant's suggestion that there is an imaginary medium plane above and below which, respectively, the raised portions and indentations extent, supporting an alleged distinction between raised portions and indentations. Indeed, the peaks and valleys depicted in Figure 5 can be considered either as raised portions if said imaginary plane is positioned at the bottom of the valleys, or as indentations if it is placed at the top

of the peaks, or as a combination of raised portions and indentations if it is located between the peaks and valleys.

Hence, the protuberances distributed over the envelope of the mammary prosthesis known from document D1 and the pillars and holes of the pillar or pitted morphology of the microtextured surface disclosed in the Picha article D2 (cf. in particular Figures 3 and 4 and page 41, first paragraph) can be considered as "raised portions and indentations" in the sense as that term is used in the present application. This interpretation is supported by the fact that the Appellant itself mentioned the feature concerning the raised portions and indentations in the prior art portion of Claim 1, which has been delineated over the prior art known from document D1.

2.3 It can be left undecided whether the subject-matter of Claim 1 is anticipated by the disclosure of document D1. Taking into account the interpretation set out in paragraph 2.2 above and the fact that according to the wording of Claim 1 the raised portions and the indentations each have a maximum depth of 0.03 inches (0.77 mm), which adds up to a total maximum depth of 0.06 inches (1.54 mm), there may be an overlap of the size ranges of the width and depth of the raised portions and indentations of the claimed prosthesis and the prosthesis according to document D1, whose protuberances have a depth and width each between 1 and 10 mm.

2.4 In any case, the subject-matter of Claim 1 lacks an inventive step in view of the Picha article D2 in combination with document D1.

The Picha article teaches that "controlled ion-beam microtexturing provides unique opportunities to design surfaces that can affect and control the type and degree of fixation and fibrous capsule formation" (cf. page 39, first paragraph). In the context of soft-tissue prostheses it is stated at page 41 that "studies on ion-beam microtextured soft-tissue implants have shown that microtexturing significantly disrupts the formation of fibrous capsules", and hence capsule contracture, and that "microtexturing can alter the foreign body response elicited by an implant, increase cellular activity near the implant surface, and induce capillary formation near the implant and between the pillars". Furthermore, the Picha article discloses under the heading "breast prostheses" that "microtexturing may eliminate many of the complications associated with both smooth and foam prostheses", and that "the ability of a microtextured surface to manipulate the environment surrounding a soft-tissue implant could greatly increase the success rate of many implants, including breast prostheses". In addition, it is pointed out in the first paragraph of page 42 that "by disrupting fibrous capsule formation there is the potential of reducing the incidence of capsule contracture, with better patient acceptability, and of reducing the incidence of capsulectomies and implant replacement, thus reducing morbidity" and that "in addition, the increased vascularity observed around a microtextured implant could play a role in controlling infection".

The acknowledgement of this state of the art in documents US-A-4 889 744, column 3, lines 14 to 29 and US-A-5 007 929, column 3, lines 21 to 36, to which the Appellant has drawn the Board's attention, is thus not complete.

The Board cannot accept the Appellant's argument that the Picha article contains merely a theoretical and very general suggestion that use of ion-beam technology may help in the development of soft-tissue implants. It rather contains precise statements about the observed positive effects of ion-beam microtexturing of soft-tissue implants ("studies on ion-beam microtextured soft-tissue implants **have shown** ..."). It is true that some of the advantages quoted above are linked with the words "may" and "could". However, the same term "may" has been used when mentioning the effects in the present application (cf. page 6, second paragraph and page 11, line 8).

In view of the advantageous effects stated in the Picha article and, in particular, the clear teaching that ion-beam microtexturing of soft-tissue implants does significantly disrupt the formation of fibrous capsules, and hence capsule contracture, the skilled person, faced with the problem of improving soft-tissue implants, would take this teaching into consideration.

The Picha article furthermore contains detailed information as to the structural dimensions of the microtextured surface. According to page 40, first paragraph and Figure 3, the ion-beam etching process is controlled by sputter-resistant masks that make it possible to pattern the target surface with structural dimensions ranging from 10 to several hundred microns, the depth of the etch can typically reach 600 µm. These figures are not restricted to dimensions of hard-tissue prostheses.

When comparing the teaching of the Picha article with the subject-matter of Claim 1, the following facts should be borne in mind:

- The textured surface of the claimed prosthesis can be achieved by etching using ion-beam technology (cf. page 8, line 2), in correspondence with the state of the art according to the Picha article.

- As pointed ut in paragraph 2.2 above, there is no difference between the microtextured or pillar morphology mentioned in the Picha article and the structure comprising raised portions and indentations in accordance with Claim 1.

- The ranges of the width (7.7 to 2500 µm) and depths (7.7 to 770 µm) of both the raised portions and the indentations of the claimed prosthesis overlap those known from the Picha article (i.e. width : 10 to several hundred µm, depth: up to about 600 µm).

- Due to the particular process of texturising the surface of the prior art implant using an ion-beam technique, it is to be assumed that the textured surface of the prior art prosthesis is also substantially free of pores or interstices disposed in a direction primarily parallel to the surface of the prosthesis.

- Claim 1 is not restricted to breast prostheses, it rather comprises also other soft-tissue prostheses (cf. page 6, final paragraph).

Hence, the only difference that may be seen between the claimed and the prior art prostheses concerns their inner structures, the Picha article being silent as to the inner structure of the prior art prosthesis. A structure comprising a filler material disposed within an outer membrane as specified in Claim 1, however, is common in the art of manufacturing mammary prostheses (cf. document D1, column 1, lines 31 to 33).

The Appellant's argument that the inventive step can be seen in the fulfilment of a long-felt need and in great commercial success cannot be accepted by the Board. The technical advantage achieved by the teaching of the present application is neither new nor surprising. Since the teaching of the Picha article and its advantageous effects in soft-tissue prostheses were known three years before the priority date of the present application, no long-felt want can have existed. In that case, commercial success alone is not to be regarded as indicative of inventive step (cf. Guidelines for Examination in the EPO, C-V, 9.9).

Furthermore, the fact that the present application proceeded to grant in the USA, despite the disclosure in the Picha article, can have little influence on the assessment of patentability before the European Patent Office insofar as differences in patent law may have influenced the decision of the US PTMO.

It follows from the preceding considerations that the prosthesis according to Claim 1 cannot be considered as involving an inventive step, since it is obvious to a person skilled in the art (Article 56 EPC).

2.5 Claim 1 according to the main request thus does not meet the requirements of Article 52(1) EPC. Due to the closeness of the claimed prosthesis to the state of the art known from the Picha article D2, there is no space for the grant of a patent for the subject-matter of Claim 1.

3. *Auxiliary request*

Claim 1 according to the auxiliary request corresponds to Claim 11 as originally filed.

As to this process claim, the Examining Division has stated in the decision under appeal that its subject-matter merely refers to a known texturisation procedure.

The Board cannot confirm these findings because there is no document on file which completely anticipates the process according to Claim 1 nor is the Board aware of any such prior art.

The Board thus exercises its power under Article 111(1) EPC and remits the case to the first instance for further prosecution and carrying out an examination as to novelty and inventive step of the process according to Claims 1 to 16 of the auxiliary request. A reasoned assessment should be given if the first instance comes to the conclusion that no patent can be granted.

Order

For these reasons it is decided that:

1. The main request is dismissed.

2. As to the auxiliary request, the decision under appeal is set aside and the case is remitted to the first instance for further prosecution on the basis of Claims 1 to 16 according to the auxiliary request submitted during the oral proceedings.

The Registrar: The Chairman:

S. Fabiani P. Dropmann

15-12-94
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