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D E C I S I O N
of 7 May 2003

Case Number: T 0577/98 - 3.3.2

Application Number: 92102261.2

Publication Number: 0499204

IPC: A61L 27/00

Language of the proceedings: EN

Title of invention:
Bioabsorbable medical implants

Patentee:
United States Surgical Corporation

Opponent:
Deutsche Institute für Textil- und Faserforschung Stuttgart

Headword:
Medical implants/US SURGICAL CORP.

Relevant legal provisions:
EPC Art. 52(1), 54, 56, 100, 111(1), 123(2), (3)
EPC R. 57a

Keyword:
"Inventive step: (no) - addition of a further obvious process step to a process known *per se* is in the present case not inventive; first and second auxiliary requests: idem"

Decisions cited:
T 0789/89

Catchword:
-



Case Number: T 0577/98 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 7 May 2003

Appellant: United States Surgical Corporation
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 26 March 1998
revoking European patent No. 0499204 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: G. F. E. Rampold
S. U. Hoffmann

Summary of Facts and Submissions

I. This appeal is against the decision of the opposition division posted on 26 March 1998 to revoke European patent No. 0 499 204 ("the Patent") entitled "Bioabsorbable medical implants" and based on European patent application No. 92 102 261.2. Opposition to the Patent was originally filed by the respondent (former opponent) which sought revocation in full of the European patent on the grounds of lack of novelty and inventive step (Articles 54, 56 and 100(a) EPC).

II. The patent was granted with 23 claims; the independent claims as granted read as follows:

- "1. A method for making a bioabsorbable composite material for surgical implants, said method comprising:
- a) providing a reinforcing fiber comprising a substantially crystalline bioabsorbable polymer characterized by a melting point, and a matrix fiber comprising a polymer characterized by a glass transition temperature which is lower than the melting point of the reinforcing fiber,
 - b) placing said reinforcing and matrix fibers together in close contiguity to form a hybrid yarn, and
 - c) heating said hybrid yarn under an applied processing pressure to a processing temperature below said melting point of the reinforcement fiber and above said glass transition temperature of the matrix fiber

to consolidate said hybrid yarn to form a bioabsorbable composite material.

12. A method for making a bioabsorbable composite material for surgical implants comprising:
 - a) placing a matrix fiber in close approximation with a crystalline reinforcing fiber to form a hybrid yarn;
 - b) treating the hybrid yarn in a first processing step to cause the matrix material to flow around the reinforcing material to achieve a partial consolidation of the yarn; and
 - c) treating the partially consolidated yarn in a second processing step to achieve a further consolidation of the yarn.

19. A bioabsorbable composite material for surgical implants, said material comprising a hybrid yarn of intimately co-mingled first fibers of a bioabsorbable crystalline polymer characterized by a melting point and second fibers of a bioabsorbable polymer characterized by a glass transition temperature below the melting point of the crystalline polymer, said hybrid yarn being heated under pressure to a processing temperature above the glass transition temperature of the second fibers and below the melting point of the crystalline polymer."

Dependent claims 2 to 11 related to elaborations of the method according to claim 1; dependent claims 13 to 18 to elaborations of the method according to claim 12;

and dependent claims 20 to 23 to elaborations of the composite material according to claim 19.

III. During prosecution of the case before the opposition division the proprietor (appellant) requested according to its main request that the opposition be rejected; in the alternative, it requested that the European patent be maintained in amended form on the basis of the claims in its first or second auxiliary request, both filed during the oral proceedings held before the opposition division on 28 January 1998.

The first auxiliary request consisted of 4 amended method claims based on method claims 12 to 15 as granted, with the sole independent claim reading as follows:

- "1. A method for making a laminated bioabsorbable composite material for surgical implants, comprising:
 - a) placing a matrix fiber in close approximation with a crystalline reinforcing fiber to form a hybrid yarn;
 - b) treating the hybrid yarn in a first processing step to cause the matrix material to flow around the reinforcing material to achieve a partial consolidation of the yarn in flat stock material suitable for laminating; and
 - c) laminating the partially consolidated yarn in a second processing step which is a compression molding step to achieve further consolidation of the yarn.

The second auxiliary request consisted likewise of 4 amended method claims based on method claims 12 to 15 as granted, with the sole independent claim reading as follows:

- "1. A method for making a laminated bioabsorbable composite material for surgical implants, comprising:
- a) placing a matrix fiber in close approximation with a crystalline reinforcing fiber to form a hybrid yarn with void spaces therein;
 - b) treating the hybrid yarn with heat and pressure in a first processing step to cause the matrix material to flow around the reinforcing material to remove some but not all of the void spaces and thereby achieve a partial consolidation of the yarn in flat stock material suitable for laminating; and
 - c) cooling the flat stock material while maintaining the processing pressure
 - d) laminating the partially consolidated yarn with heat and pressure in a second processing step to remove void spaces remaining after the first step thereby to achieve further consolidation of the yarn."

IV. The essence of the reasoning given in the opposition division's decision to revoke the patent was as follows:

As regards the proprietor's main request, the opposition division found that neither the composite material of claim 19 as granted nor the method of its manufacture according to claim 1 as granted was novel

over the bioabsorbable surgical composite material and its manufacturing process disclosed in Example 12 of EP-A-0 204 931, hereinafter referred to as citation (1).

As regards the auxiliary requests, the opposition division reached the conclusion that, in spite of the limitation of the claimed subject-matter to a method for making a laminated bioabsorbable composite material, neither amended claims 1 to 4 in the appellant's first auxiliary request nor those in the appellant's second auxiliary request involved an inventive step in the light of the manufacturing process for the composite material disclosed in Example 12 of citation (1).

V. In its statement setting out the grounds of appeal the appellant requested that the patent be maintained on the basis of a newly amended set of six claims; the sole independent claim read as follows:

- "1. A method for making surgical implants of bioabsorbable composite material comprising:
 - a) placing a matrix fiber in close approximation with a crystalline reinforcing fiber to form a hybrid yarn;
 - b) treating the hybrid yarn with heat and pressure in a first processing step to cause the matrix material to flow around the reinforcing material to achieve a partial consolidation of the yarn forming a material suitable for laminating;
 - c) stacking pieces of said partially consolidated yarn to form layers in a

compression mold with the fibres oriented transversely in one or more of the succeeding layers;

- d) treating the partially consolidated yarn by applying heat and pressure in a second processing step to achieve a further consolidation of the yarn and a lamination of said stack of pieces of said yarn in said compression mold thereby forming said surgical implant."

- VI. With its reply of 4 February 1999 to the grounds of appeal, the respondent filed arguments supporting its request for the appeal to be dismissed. The appellant filed further submissions with its letters of 28 June 1999 and 25 September 2002.
- VII. By its letter dated 31 March 2003, received on 1 April 2003, the respondent (former opponent) withdrew its opposition.
- VIII. In the board's communications dated 25 March 2002, 18 October 2002 and 23 April 2003, the rapporteur raised, *inter alia*, objections under Article 123(2) and (3) EPC to the amended claims filed together with the appeal statement (see V above).
- IX. With its reply to the board's communications, the appellant filed on 25 April 2003 a so-called "New Main Request" comprising six claims, with the sole independent claim reading as follows:
 - "1. A method for making a bioabsorbable composite material for surgical implants comprising:

- a) placing a matrix fiber in close approximation with a crystalline reinforcing fiber to form a hybrid yarn;
- b) treating the hybrid yarn with heat and pressure in a first processing step under vacuum to cause the matrix material to flow around the reinforcing material to achieve a partial consolidation of the yarn forming material suitable for laminating;
- c) stacking pieces of said partially consolidated yarn to form layers in a compression mold with the fibres oriented transversely in one or more of the succeeding layers;
- d) treating the partially consolidated yarn by applying heat and pressure in a second processing step to achieve a further consolidation of the yarn and a lamination of said stack of pieces of said yarn in said compression mold."

X. Oral proceedings were held on 7 May 2003. As a result of the board's objections under Article 123(2) EPC to the above-mentioned claims as raised early on during the oral proceedings, the appellant withdrew all previously filed requests and presented, instead, newly amended main, first and second auxiliary requests. The main request consists of four claims; the sole independent claim reads as follows:

"1. A method for making a bioabsorbable composite material for surgical implants comprising:

- a) placing a matrix fiber in close approximation with a crystalline reinforcing fiber to form a hybrid yarn;
- b) processing multiple said hybrid yarns to orient the fibres either unidirectionally or unidirectionally and transversely, at various cross-over angles, in one or more succeeding layers;
- c) treating the hybrid yarn with heat and pressure in a first processing step under vacuum to cause the matrix material to flow around the reinforcing material to achieve a partial consolidation of the yarn forming a material suitable for laminating;
- d) stacking cut pieces of said partially consolidated yarn as laminae in a compression mold and treating the partially consolidated yarn by applying heat and pressure in a second processing step to achieve a further consolidation of the yarn."

Dependent claims 2 to 4 relate to elaborations of the method according to claim 1.

Claims 1 to 4 in the first auxiliary request correspond to claims 1 to 4 in the above main request, with the following insertion at the end of step (c) in claim 1 indicated in bold italic letters below:

- "c) treating the hybrid yarn with heat and pressure in a first processing step under vacuum to cause the matrix material to flow around the reinforcing material to achieve a partial consolidation of the

yarn forming a material ***containing voids and***
suitable for laminating;"

Claims 1 to 4 in the second auxiliary request correspond to claims 1 to 4 in the above first auxiliary request, with the following additional amendment at the end of step (d) of claim 1 indicated in bold italic letters below:

"d) stacking cut pieces of said partially consolidated yarn as laminae in a compression mold and treating the partially consolidated yarn by applying heat and pressure in a second processing step to achieve a further consolidation of the yarn ***by removing at least 10% of the remaining voids in the partially consolidated hybrid yarn***".

XI. The arguments of the appellant as regards the current requests and related issues can be summarised as follows:

In the decision under appeal the closest state of the art was taken as being citation (1). The question of novelty was thus, in the appellant's opinion, not at issue.

Citation (1) described in Example 12 a method of making a hybrid composite rod composed of glycolide/lactide material containing embedded polyglycolide sutures. The method consisted of hot compression moulding glycolide/lactide copolymer sutures containing 10% by weight of polyglycolide sutures, to cause partial melting of the glycolide lactide fibres. The mould was then cooled rapidly. The appellant argued that the

final product, ie the composite rod in Example 12 of citation (1), was produced by a single-step heat and compression treatment. It further argued that, in contrast to the cited prior art, the claimed method in the patent was a two-step process in which an intermediate product was produced, ie the partially consolidated yarn suitable for laminating. In the claimed method, pieces of this intermediate product were stacked in the compression mould. Heat and pressure were then applied for a second time to produce the final product.

The problem underlying the claimed invention was, in the appellant's opinion, how to make in an economical way implants with curved or non-rectilinear geometry with sufficient strength. The solution was the production of an intermediate product which was partially consolidated. Pieces of this still manipulatable but partially consolidated product were then laid up in a compression mould. The partial consolidation would maintain the relative positions of fibres and yarns within each layer, as it was laid up, on the top of other layers, in the mould. The forming into the surgical material followed as a further heating step under pressure which consolidated the yarn and at the same time produced a laminate from the laid-up pieces of intermediate product.

The opposition division did not, in the appellant's opinion, give due weight to the requirement of the claim for a process step (laminating) after the first step and before the second step. Thus the second processing step was, contrary to the view of the opposition division in the decision under appeal, not a

mere continuation of the first step. In amended claim 1 the recitation of the lamination procedure was expanded and made more explicit by reciting the further step of stacking pieces of said partially consolidated yarn in a compression mould. Thus there could be even less doubt that the second consolidation step in the claimed process was not simply a continuation of the first. This was neither taught nor suggested in the state of the art.

- XII. The arguments of the respondent, presented in its reply to the statement of the grounds of appeal, as regards the issues which are relevant to the present decision, can be summarised as follows:

The appellant's assertion that the surgical implant in Example 12 of (1) was produced by a one-step heat and compression treatment was incorrect. On the contrary, it was clearly said in Example 12 that glycolide/lactide copolymer sutures (matrix fibres) containing polyglycolide sutures as a reinforcing material were heated in a first processing step under vacuum at 185°C for 6 minutes. This treatment caused partial melting of the matrix fibres.

The partially consolidated intermediate product obtained from this first processing step was in the following second processing step no longer designated as "sutures" but correctly as "material". This partially consolidated "material" was placed in a cylindrical mould and subjected in the second processing step to hot compression moulding. This heat and compression treatment disclosed in Example 12 of (1) corresponded thus exactly to the procedure in

the second processing step (step (d)) of the claimed process in the Patent.

The process of Example 12 consisted of the partial melting of the hybrid sutures as the first processing step followed by placing the material obtained from the first step in a compression mould and subjecting it to hot compression moulding. This provided a clear and unambiguous indication that the "partial melting" was not performed in the compression mould and, consequently, that the step of "partial melting" and the subsequent step of "hot compression moulding" were carried out in two distinctly different, consecutive process steps.

The respondent submitted that, in the absence of a substantial difference between the process disclosed in Example 12 of (1) and that of claim 1 in the Patent, the claimed subject-matter was not patentable.

XIII. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or of the first or second auxiliary request, all filed during the oral proceedings.

Reasons for the Decision

1. *The appeal is admissible.*

Admissibility of the appellant's late-filed requests

2. The appellant's current main, first and secondary auxiliary requests were presented for the first time during the hearing before the board and were, accordingly, filed late. Although the board does not condone such lateness *per se*, it considers that in the circumstances of the present case the late-filed requests should be admitted into the proceedings.
- 2.1 By its prompt reply of 25 April 2003 to the board's latest communication dated 23 April 2003 and the submission of the so-called "New main request" (see VIII and IX above), the appellant had clearly made a *bona fide* attempt to deal with the objections raised in the said communication in advance of the oral proceedings. As regards the newly amended requests now on file, the appellant submitted that these were prompted by the board's reservations, expressed during the hearing, as to the compliance of the claims in the above "New main request" with Article 123(2) EPC. This submission appears *prima facie* correct. Moreover, since the exact meaning and impact of the proposed amendments to claim 1 of all current requests (see X above) was immediately clear to the board, it was able to deal with these requests during the hearing and to announce the final decision at the end of the oral proceedings. Coupled with the fact that the respondent and former opponent had withdrawn its opposition prior to the oral proceedings, and thereby ceased to be a party to appeal proceedings as far as the substantive issues (re: existence and scope of the patent right) are concerned (see T 789/89, OJ EPO 1994, 482), the board considers it justified to exercise its discretionary power under Article 111(1) EPC in favour of the appellant.

2.2 The amendments to the claims presently on file can fairly be said to be occasioned by grounds for opposition specified in Article 100(a) EPC and to constitute a *bona fide* attempt on the part of the appellant to overcome the respondent's objections to lack of novelty and inventive step in the opposition and appeal statements. The proposed amendments to the granted patent are thus admissible under the terms of Rule 57a EPC.

Amendments

3. All references below to support for the amendments made to the current method claims 1 to 4 according to the main, first and second auxiliary requests (see X above) are to the application as originally filed.

3.1 Present claim 1 of the main request is based on claim 12 as filed with the following amendments:

- newly introduced **step (b)** - "processing multiple said hybrid yarns to orient the fibres either unidirectionally or unidirectionally and transversely, at various cross-over angles, in one or more succeeding layers" - finds its support in the paragraph bridging pages 11 and 12;
- the process conditions stated in **step (c)** stipulating that the hybrid yarn be treated "under heat and pressure in a first processing step under vacuum", are derived from the disclosure in lines 2 to 4 on page 10;

- amended **step (d)** - "stacking cut pieces of said partially consolidated yarn as laminae in a compression mold and treating the partially consolidated yarn by applying heat and pressure in a second processing step to achieve a further consolidation of the yarn" - results from a combination of step (c) in originally filed claim 12 and the disclosure at lines 9 to 15 ("stacking cut pieces") and lines 22 to 27 on page 10 ("applying heat and pressure");
- dependent claims 2 to 4 are based on dependent claims 13 to 15 in the application as filed.

3.2 Claims 1 to 4 of the first auxiliary request are supported as indicated above for the claims in the main request;

- the additional feature at the end of **step (c)** - "a material containing voids" - can be derived from the disclosure at lines 7 to 9 on page 11 ("typically, the initial process step is believed to remove about 30% to 70% of the void space originally present in the hybrid yarn").

3.3 Claims 1 to 4 of the second auxiliary request are supported as indicated above for the claims in the first auxiliary request;

- the additional feature at the end of **step (d)** - "consolidation of the yarn by removing at least 10% of the remaining voids in the partially consolidated hybrid yarn" - is based on the disclosure at lines 10 to 12 on page 11.

3.4 From the foregoing it follows that all current claims are adequately supported by the disclosure in the application as filed and comply accordingly in these formal aspects with the requirements of Articles 84 and 123(2) EPC.

3.5 Since independent product claims 1 and 19 as granted have been deleted and present process claim 1 of all requests contains in comparison with process claim 12 as granted at least one additional technical feature, the requirements of Article 123(3) EPC are likewise met.

The Patent's subject-matter in the light of the closest state of the art

4. The board concurs with the finding in the decision under appeal that citation (1) represents the closest state of the art to the claimed method in the Patent for making a bioabsorbable composite material for surgical implants.

4.1 Citation (1) discloses a method of preparing a biocompatible resorbable composite material for surgical implants (see especially page 1, lines 1 to 6; page 3, lines 1 to 3; page 4, lines 19 to 31; page 7, line 10, to page 8, line 3). The manufacturing process of Example 12 for producing a surgical composite material in accordance with (1) comprises the consecutive steps of

- (i) combining together glycolide/lactide copolymer sutures (Vicryl®), ie **bioabsorbable matrix fibres**, and 10 wt-% of polyglycolide sutures (Dexon®)

(Size 2), ie **bioabsorbable crystalline reinforcing fibres**, to form **hybrid sutures (a hybrid yarn)** composed of glycolide/lactide copolymer sutures (Vicryl®) and 10 wt-% of polyglycolide sutures - see (1): page 12, Example 12, lines 1 to 2; page 4, line 19, to page 5, line 11;

- (ii) treating the hybrid sutures **under vacuum** at **185°C for 6 minutes** in a first processing step to cause **partial melting** of glycolide/lactide fibre units of (Vicryl®) sutures, ie the bioabsorbable matrix material - see (1): page 12, Example 12, lines 2 to 4;
- (iii) placing the **material** obtained from the preceding step in a **cylindrical compression mould** (length 70 mm, diameter 4.5 mm) - see (1): page 12, Example 12, lines 5 to 6 - and treating this material by applying **heat and pressure of 2000 bar** (ie hot compression moulding) in a second processing step, followed by cooling it rapidly [both the technical expression "compression moulding" and the stipulation of rapidly cooling the "material" necessarily imply the application of heat in this second processing step] to obtain a hybrid composite rod which is composed of self-reinforced glycolide/lactide material into which are embedded polyglycolide reinforcing fibres - see (1): page 12, Example 12, lines 4 to 13.

4.2 **Step (i)** of the process disclosed in (1) corresponds to **step (a)** of the claimed process in the Patent. The basic materials used in (1) for the bioabsorbable matrix fibres and the bioabsorbable crystalline

reinforcing fibres are the same as those used in the Patent for these two types of fibres (see column 3, lines 31 to 45). Figure 1 on page 13 of the Patent in the context of the text in column 3, lines 27 to 29, illustrates a bundle of fibres or **yarn** prior to being processed into a bioabsorbable composite material. This bundle of fibres or yarn illustrated in Figure 1 corresponds to the bundle of fibres or **sutures** used in (1) prior to being processed into a bioabsorbable composite material.

According to "Webster's Ninth New Collegiate Dictionary", 1987,

"yarn" means "a continuous often plied strand composed of either natural or man-made fibers or filaments and used in weaving or knitting to form cloth";

"suture" means "a continuous strand or fibers used to sew parts of the living body".

The Patent itself states that the fibres [used in the Patent] "can be fibers of the type used in manufacturing **suture material**" (see column 3, lines 44 to 45).

It is thus clear that for the purpose of this decision the different designation for the hybrid starting material used in (1) (yarns) and in the Patent (sutures) must be regarded as reflecting a mere difference in wording, but that no difference in substance exists between these two materials.

4.3 **Step (ii)** of the process disclosed in (1) corresponds to **step (c)** of the claimed process in the Patent.

The appellant's main argument presented in writing and during the oral proceedings in favour of novelty and inventive step was that, in contrast to the claimed two-step process in the Patent [see claim 1, steps (c) and (d)], the final surgical implant in the closest prior art of (1), ie the hybrid composite rod in Example 12 of (1), is produced by a single-step heat and compression treatment. The board cannot accept this line of argument and shares on this point the view of the opposition division. In support of its view, the board sees the following considerations as paramount:

- It is explicitly stated in (1) that in the process of Example 12 **the first heating step** [step (ii)] which is intended to cause the **partial melting** of glycolide/lactide fibre units of (Vicryl®) sutures, ie the bioabsorbable matrix material, is carried out under **vacuum at 185°C for 6 minutes**, whereas the forming into the final surgical implant follows as a further heating step (iii) under **pressure of 2000 bar**.

The fact that in the process of (1) the first heating step (ii) is carried out under vacuum and the heat and compression treatment in the second processing step (iii) is carried out under considerable pressure of 2000 bar provides, in the board's judgment, a clear and unequivocal indication that the surgical implant in Example 12 of (1) is produced by a **two-step** heat and compression treatment and that an intermediate product (ie the "material") is obtained from the first heating step (ii);

- the process description in (1) of the first processing step (ii) ("were heated **under vacuum**") versus the second step (iii) ("the material was **compression** moulded") is in the board's opinion self-explanatory of a two-step process;

- a clear distinction is made in (1) between the designation of (A) the starting material (ie "glycolide/lactide copolymer sutures (Vicryl®) containing 10 wt-% of polyglycolide sutures (Dexon®) (Size 2)") which is subjected to the first heat treatment step (ii) in (1), to achieve partial melting of the matrix material, and the designation of (B) the intermediate product (ie "the material") which is obtained from step (ii) and is then subjected in step (iii) to heat and compression treatment;

- the processing conditions used in the first step (ii) in Example 12 of (1), **ie vacuum, 185°C for 6 minutes**, are entirely comparable to those suggested for first processing step (c) in the Patent, **ie vacuum, 60°C to 160°C for from 3 to 10 minutes** (see column 6, lines 34 to 36, 39 to 40);

- it is immediately clear to a person skilled in the art that partial melting of the matrix material in the first processing step (ii) of Example 12 in (1) has the **same effect** as that achieved in the first processing step (c) of the Patent, namely to cause the matrix material to flow around the reinforcing fibres to achieve a partial consolidation of the hybrid yarn;

- it is likewise clear to a person skilled in the art that it is the **intermediate product** (ie the **"material"**) obtained from the first processing step (ii) in (1) which is placed into the cylindrical compression mould prior to entering the second processing step (iii).

4.4 Thus, in view of the foregoing, there is no reasonable doubt that Example 12 of (1) discloses a two-step process in which in the first processing step (ii) a partially consolidated intermediate product is produced. In step (iii) pieces of this intermediate product are placed in a cylindrical compression mould. Heat and pressure are then applied for a second time to produce the final bioabsorbable composite material for surgical implants.

4.5 It follows that **step (iii)** of the process disclosed in (1) corresponds to **step (d)** of the claimed process in the Patent.

The further processing of the partially consolidated material obtained from the first processing step (ii) in a cylindrical compression mould having a length of 70 mm and a diameter of 4.5 mm clearly **implies** the necessity of reducing the size of this material, prior to subjecting it to the second processing step (iii), for example by cutting this material into pieces such that it may be efficiently placed in the particular compression mould for further consolidation by hot compression moulding.

Both Figure 2 of the Patent (see page 13) and Figure 1/1 of (1) illustrate the bioabsorbable

composite material after being processed. These figures provide further evidence that the same product is obtained by the two-step process disclosed in (1) and that the process of (1) is identical to the claimed process in the Patent.

Novelty

5. In summary, from the foregoing it appears clear that step (b) of the claimed process in the Patent ("processing multiple said hybrid yarns to orient the fibres either unidirectionally or unidirectionally and transversely, at various cross-over angles, in one or more succeeding layers" - see X above) is the only technical feature of claim 1 which cannot be derived directly and unambiguously from the process disclosed in Example 12 of citation (1).

5.1 The board is aware that citation (1) already refers to certain advantages associated with a specific orientation of the fibre structures in the surgical implant material (see page 5, lines 7 to 11: "When **strong oriented fiber structures** are bound together <.....>"; page 6, lines 20 to 22: <.....>" the portion of oriented fiber structure is very high <.....>"; page 6, lines 28 to 29: "Typical properties of the materials of this invention are the high content of oriented fibers <.....>"). Since, however, procedural measurements to obtain a specific orientation of the fibre structures in the composite material cannot be derived directly and unambiguously from the disclosure of citation (1) **in the context of the process of Example 12**, the novelty of the claimed process in the Patent can be acknowledged.

Problem and Solution

6. The appellant submitted that the problem underlying the claimed invention was how to make in an economically way implants with curved or non-rectilinear geometry with sufficient strength. The solution, according to the appellant, was the production of an intermediate product which is partially consolidated. The board's observations in 4 to 4.5 above, however, make it clear that the closest state of the art according to citation (1) related to the same problem and had already solved it by the same means.

6.1 It follows that, in the absence of any recognisable advantage or improvement associated with the claimed process in the Patent over the closest state of the art, the objective problem to be solved by the claimed invention in relation to the prior art of (1) must be reduced to one of simply providing a further method of making a bioabsorbable composite material for surgical implants. The solution of the problem was the addition of step (b) to the otherwise known method for producing a bioabsorbable medical implant disclosed in Example 12 of (1) (see 4 to 4.4 and 5 above).

Example 2 of the Patent illustrates a process in accordance with the claimed invention wherein the individual hybrid yarns are oriented unidirectionally in more succeeding layers before being further processed in step (c) of the claimed process into a unidirectional reinforced, partially consolidated thermoplastic material suitable for laminating in following step (d) (see Examples 3 to 5). In view of

the disclosure of the claimed invention and its illustration in the above-mentioned examples of the Patent, the board is satisfied that the problem posed has been plausibly solved. This was anyway not contested by the respondent.

Inventive step

7. It therefore remains to be considered whether the solution claimed involves an inventive step.

Main request

- 7.1 Step (b) relates to the orientation of the fibres either unidirectionally or unidirectionally and transversely at various cross-over angles in one or more succeeding layers of the hybrid yarn prior to its consolidation in order to give a desired alignment of fibres for the product and to form a self-reinforced composite material having strong oriented fibre structures of the reinforcement units (fibres) within the layers of the polymer matrix material.

- 7.2 As has been mentioned in 5.1 above, citation (1) suggests already the advantages associated with a strong oriented fibre structure in the composite material. In this respect the cited document states, *inter alia*:

"When **strong oriented fiber structures** [of the reinforcement units] are bound together with the polymer matrix which has the same chemical element composition as the reinforcing fibers, the composite structure is obtained which has excellent adhesion

between matrix and reinforcement units and therefore also excellent mechanical properties" (see page 5, first paragraph, especially lines 7 to 11); or "By a careful control of heating conditions it is possible to composite samples where the softened or melted surface regions of fibers, threads or corresponding units are very thin and therefore the portion of **oriented fiber structure** is very high leading to materials with high tensile shear, binding and impact strength values" (see page 6, lines 17 to 22); or "Typical properties of the materials of this invention are the high content of **oriented fibers** bound together within the matrix polymer layers between fibers" (see page 6, lines 28 to 30).

- 7.3 From the foregoing it follows that the measurements taken in step (b) and the results thereby achieved were clearly suggested to those skilled in the art by the prior art of (1). The addition of step (b) to the otherwise known method for preparing a composite material for surgical implants cannot therefore form the basis for the acknowledgment of an inventive step.

First auxiliary request

8. This request specifies that the partially consolidated material obtained from step c) of the claimed process in the Patent contains voids (see X above). This specification is based on the disclosures in the description that "typically, the initial process step is believed to remove about 30% to 70% of the void space originally present in the hybrid yarn").

- 8.1 The skilled person already knew from citation (1) that a partially consolidated intermediate product for the claimed process is advantageously obtained by applying heat to the hybrid yarn **such as to cause partial melting of the matrix material**. The simple observation that the partial melting of the matrix material suggested in (1) has the effect of removing only partially (within the broad range of 30% to 70%) the voids present in the particular arrangement of the hybrid yarns before being processed cannot contribute to the acknowledgement of an inventive step.

Second auxiliary request

9. This request specifies (A) that the partially consolidated material obtained from step (c) of the claimed process in the Patent contains voids and (B) stipulates that the partially consolidated material is further consolidated in step (d) and formed into the final composite material "by removing at least 10% of the remaining voids in the partially consolidated hybrid yarn" (see X above).
- 9.1 As regards specification (A) that the partially consolidated material may contain voids, reference is made to the observations in 8.1 above.

The skilled person knew from the prior art of (1) the advantages of preparing the surgical composite material by a two-step process, involving the preparation of a partially consolidated intermediate product. For the skilled practitioner with that knowledge, determination of the degree of further consolidation of the partially consolidated intermediate product required to form in

step (d) of the claimed process a composite material having the desired properties would be merely a matter of routine experimentation, without any inventive effort.

9.2 It follows that the above specifications made to claim 1 of the second auxiliary request cannot, either alone or in combination, support the presence of inventive step.

10. In conclusion, neither the appellant's main request nor its first or second auxiliary request relates to a patentable invention. Thus the appeal must fail on the grounds of lack of inventive step (Article 56 EPC) in respect of all requests.

Order

For these reasons it is decided that:

1. The appeal is dismissed

The Registrar:

The Chairman:

A. Townend

U. Oswald