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D E C I S I O N
of 14 January 2003

Case Number: T 0633/00 - 3.3.3

Application Number: 92106629.6

Publication Number: 0509508

IPC: C08G 63/08

Language of the proceedings: EN

Title of invention:
Block copolymer, method for preparing it and use thereof, surgical article and method for preparing it

Applicant:
United States Surgical Corporation

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 83, 84, 54, 56, 123(2)

Keyword:
"Inventive step - (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0633/00 - 3.3.3

D E C I S I O N
of the Technical Board of Appeal 3.3.3
of 14 January 2003

Appellant: United States Surgical Corporation
150 Glover Avenue
Norwalk,
Connecticut 06856 (US)

Representative: HOFFMANN - EITLE
Patent- und Rechtsanwälte
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Decision under appeal: Decision of the Examining Division of the European Patent Office posted 14 January 2000 refusing European patent application No. 92 106 629.6 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: R. Young
Members: C. Idez
J. De Preter

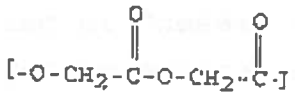
Summary of Facts and Submissions

I. European patent application No. 92 106 629.6, filed on 16 April 1992, claiming the priority of the US patent application No. 686 815 of 17 April 1991 and published under No. 0 509 508 on 21 October 1992, was refused by a decision orally announced on 27 September 1999 and issued in writing on 14 January 2000.

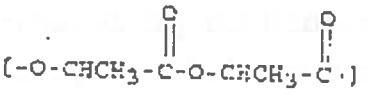
II. The decision was based on a set of Claims 1 to 11, as submitted with a letter dated 14 April 1998.

Claim 1 read as follows:

"A surgical article which consists of a block copolymer consisting of blocks A and B wherein:
(i) block A consists of repeating units having the formula:

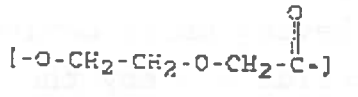


(I), and
(ii) block B consists of ramdomly combined repeating units having the formulae:



(II),

and



(III),

wherein 55-85 weight % of the block copolymer comprises units of formula (I), 1-20 weight % of the block copolymer comprises units of formula (II), and 10-40

weight % of the block copolymer comprises units of formula (III)."

Independent Claim 5 was directed to a method for preparing a bioabsorbable surgical article according to any of Claims 1 to 4.

Claims 2 to 4 and 6 to 11 were dependent claims.

III. The Examining Division rejected the application on the grounds of lack of inventive step of Claim 1.

More precisely, the decision held that D3 (US-A-4 052 988) which disclosed copolymers containing units derived from glycolide, 1,4-dioxanone (PDO) and lactide and their use in flexible surgical articles could be considered as the closest state of the art. It stated that the subject-matter of Claim 1 differed from D3 in that a block copolymer was provided wherein the monomers were present in particular amounts. It held that, in the absence of any evidence showing that these distinguishing features brought a technical effect, the objective technical problem could only be regarded as to provide further bioabsorbable surgical articles. According to the decision under appeal, although D3 mentioned that the amount of comonomers other than PDO should be preferably up to 50% by weight, this document did not prohibit the skilled person from going beyond this amount. Therefore, the decision under appeal held that it would have been obvious for the person skilled in the art to select a block copolymer having units derived from PDO/lactide/glycolide whereby the amount of glycolide was at least 55% by weight in order to provide only further surgical articles made therefrom.

IV. A Notice of Appeal against the decision was lodged on 14 March 2000 by the Appellant (Applicant), the prescribed fee being recorded as paid on the same day. With the Statement of Grounds of Appeal filed on 24 May 2000, the Appellant submitted a set of Claims 1 to 11, which corresponded to the set of Claims 1 to 11 on which the decision of the Examining Division was based.

The arguments presented by the Appellant in the Statement of Grounds of Appeal could be summarized as follows:

(i) Starting from D3, the technical problem could be stated as providing a surgical article having an improved mass loss compared to the prior art which was better able to be rapidly absorbed (i.e much less than 180 days) after exhibiting and maintaining desired tensile properties for a predetermined time in vivo (35 to 70 days).

(ii) Document D3 was principally concerned with sutures having a composition of monomeric polymers of either p-dioxanone, a methyl or ethyl derivative therefrom or dioxepan-2-one.

(iii) It further taught that copolymers of these specific monomers with up to about 50% by weight of other copolymerizable monomers could be used. There was no restriction as to which other copolymerizable monomers could be used other than the fact that the product of polymerization must produce non-toxic and absorbable polymers. The number of possibilities provided in D3 represented therefore a multitude of possibilities.

(iv) The claimed subject-matter related to a composition comprising 55 to 85% by weight glycolide and 1 to 20% by weight lactide, i.e. at least 56% by weight in total of other copolymerizable monomers within the meaning of D3. The incorporation of at least 56% by weight of other copolymerizable monomers was not a possibility at all within the teaching of D3.

(v) Document D3 made no prediction about sutures having more than 50% other copolymerizable monomers.

(vi) Thus, the skilled person would not have searched for other solutions outside the limits imposed in D3 in light of the multitude of possible alternative solutions provided in D3 without inventive step. Hence, the claimed subject-matter was inventive over D3 and all cited prior art.

V. Following a communication from the Board issued on 17 October 2001, and a letter of reply of the Appellant dated 22 March 2002, the Appellant was informed in an annex to the summons to oral proceedings issued on 24 October 2002 about a number of essential questions to be discussed at the oral proceedings scheduled for 14 January 2003. It was, in particular, stressed that there was still no convincing evidence that the claimed measures (i.e. the specific composition of the copolymers according to the application in suit) provided an effective solution to the technical problem stated by the Appellant in the Statement of Grounds of Appeal and that a reformulation of the technical problem in less ambitious terms would appear to be necessary. The Board also drew the attention of the Appellant to the document US-A-5 007 923 (referred to as D4), which related to copolymers of lactide, glycolide and dioxanone and use thereof as absorbable

surgical sutures and also disclosed the specific influence of the glycolide and lactide units on the *in vivo* properties of the sutures.

VI. In its letter dated 10 December 2002, the Appellant commented on document D4 essentially as follows:

(i) Document D4 could be taken for representing the knowledge of the skilled person at the filing date of the application.

(ii) It taught that it was necessary to first obtain an amorphous prepolymer consisting of glycolide and lactide, and in a second step to react the prepolymer with p-dioxanone.

(iii) It explicitly indicated that the amount of lactide and glycolide should not exceed 50% relative to the p-dioxanone polymer, and that the molar ratio lactide/glycolide should be at least 50/50.

(iv) In contrast, the application in suit requested that a block copolymer was formed of blocks A consisting of glycolide in an amount of 55 to 85% by weight and blocks B, which was a prepolymer formed from lactide and polydioxanone, the amount of lactide in the final copolymer being 1 to 20% by weight and the amount of dioxanone being from 10 to 40% by weight.

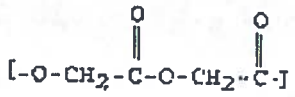
(v) Thus, it was clear that D4 led away from the present application.

The Appellant further stressed that the Young's modulus of the copolyester used in the sutures according to the present application was much higher than that of the copolyester described in document D4.

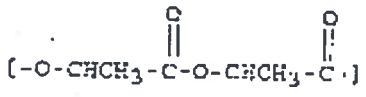
VII. At the oral proceedings held on 14 January 2003, the Appellant filed a new main request based on a set of 9 claims.

Claim 1 reads as follows:

"A bioabsorbable suture which consists of a block copolymer consisting of blocks A and B wherein:
(i) block A consists of repeating units having the formula:

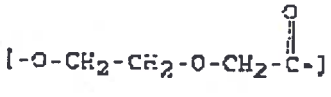


(I), and
(ii) block B consists of ramdomly combined repeating units having the formulae:



(II),

and



(III),

wherein 65-75 weight % of the block copolymer comprises units of formula (I), 3-8 weight % of the block copolymer comprises units of formula (II), and 20-30 weight % of the block copolymer comprises units of formula (III)."

Independent Claim 4 is directed to a method for preparing a bioabsorbable suture according to any of Claims 1 to 3.

Claims 2 to 3 and 5 to 9 are dependent claims.

It also argued essentially as follows:

(i) Starting from D4, the technical problem might be seen as the provision of both monofilament and multifilament bioabsorbable sutures with advantageous flexibility and knot pull fabricated from a copolyester having a very specific combination of flexibility and tensile properties (i.e. elongation, Young's modulus).

(ii) In that respect, Examples 2 and 3 of the application in suit showed that the filament made of the copolyesters according to the invention exhibited after controlled shrinkage and relaxation (i.e. an annealing process) an increase of the elongation and a decrease of the Young's modulus, as well as maintaining good knot pull properties.

(iii) On the contrary, the copolyesters of D4 (see Examples 2 to 5) as well as those disclosed in Examples 7 and 8 of document US-A-4 643 191 (mentioned in column 1, lines 26 to 28 of D4; referred as D5) showed an increase of the Young's modulus and a decrease of the elongation.

(iv) Furthermore, although the amount of glycolide was rather high in the copolyesters according to the application in suit, their flexibility (illustrated by a Young's modulus of the order of 500 000 psi), was still satisfying.

(v) Neither D3 nor D4 provided a pointer to the solution proposed in the application in suit. On the contrary, D3 and D4 would lead the skilled person away from the solution proposed, since they both clearly taught that the total amount of units other than 1,4 dioxanone (i.e. in particular glycolide) must be lower than 50% by weight in order to obtain flexible monofilament and multifilament bioabsorbable sutures.

VIII. The Appellant requested that the decision of the Examining Division be set aside, and a patent be granted on the basis of Claims 1 to 9 submitted at the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. *Wording of the claims*

2.1 Article 123(2) EPC

The amended wording of Claim 1 is based on the following parts of the application documents as originally filed:

Claims 3, 4 and 6; page 2, lines 11 to 13, and 18 to 19; page 3, lines 1 to 11; and page 4, Table 1.

Claims 2 and 3 are based on original Claims 5 and respectively.

Claim 4 is supported by the combination of original Claims 14 and 16.

Claims 5, 6 and 7 are supported by original Claims 17, 18 and 19, respectively.

Lines 16 to 26 on page 3 of the application as originally filed provide a support for Claim 8.

Claim 9 is based on original Claim 15.

Consequently, the requirements of Article 123(2) EPC are met by Claims 1 to 9.

2.2 Article 84 EPC

The Board is satisfied that the wording of Claims 1 to 9 is clear and meets the requirements of Article 84 EPC.

3. *Article 83 EPC*

The application in suit provides precise information regarding the processing conditions (cf. page 1, lines 13 to 23 and 26 to 27, Examples 1 to 3), so that there can be no doubt that a skilled reader would know how to prepare a suture within the terms of the application in suit. It follows that the requirements of Article 83 EPC are regarded as met.

4. *Novelty*

4.1 In its decision, the Examining Division has considered that the subject-matter of the claims then on file was novel over the cited prior art and the Board sees no reason to depart from that view.

4.2 Since the subject-matter of Claims 1 to 9 has been further restricted in comparison to that of the set of claims on which the decision was based, and since the newly introduced document D4 in fact corresponds to the document EP-A-0 440 448 cited as an intermediate document in the European search report, the Board is satisfied that the subject-matter of Claims 1 to 9 meets the requirements of Article 54 EPC.

5. *Problem and solution*

5.1 The application in suit concerns a bioabsorbable suture made of a copolyester of glycolide, lactide and 1,4 dioxanone.

5.2 Such products are known from D3 and D4. Nevertheless, D4 is the only prior art document which exemplifies monofilaments made of copolymers consisting of glycolide, lactide and 1,4-dioxanone repeating units (cf. D4, Examples 1 to 5; column 2, lines 5 to 7). Thus, the Board considers that D4 represents a more appropriate starting point for the assessment of inventive step.

5.3 Starting from D4 the technical problem may be seen in the provision of further flexible bioabsorbable sutures having good knot pull characteristics (cf. application as filed, page 2, lines 18 to 20).

5.4 According to the application in suit, this problem is solved by using of a copolyester consisting of units (I), (II), and (III) as defined in Claim 1 for the manufacture of the sutures.

5.5 Examples 2 and 3 of the application in suit show that the Young's modulus of the copolyester is of the order of 500 000 psi, and this would lead to a satisfying flexibility of the sutures obtained therefrom (in that

respect cf. D3, Claim 1). The knot pull strength of the exemplified monofilament (given as 2.728 lbs for a diameter of about 0.0073 inches i.e. corresponding to a strength of more than 65 000 psi) is well above the value of 30 000 psi as indicated by D3 for an useful suture (cf. D3, column 3, lines 59 to 68) and is of the same order as those of the monofilaments exemplified in D4 (cf. Examples 2 to 5 thereof). In addition, these examples show that, contrary to what is generally observed in the art (cf. Examples 2 to 5 of D4 and Examples 7 to 8 of D5), the copolyesters according to the invention exhibit an increase of the elongation and a decrease of the Young's modulus after annealing treatment.

5.6 It is true that the application in suit provides no evidence of the bioabsorption properties of the claimed sutures. In view of the very high content in glycolide units in the copolyester used for the manufacture of the sutures, it is, however, evident that the claimed sutures are bioabsorbable.

5.7 Thus, taking into account that the weight % ranges of the units (I), (II) and (III) set out for the composition of the copolyester according to the present application are relatively narrow, and that the copolyester used in the Examples 2 and 3 has a content of units (I), (II) and (III) (i.e. 70 wt% of unit (I), 4,5 wt% of unit (II) and 25,5 wt% of unit (III)), falling practically in the middle of the range defined for each of these units in Claim 1, the Board finds it plausible that the claimed measures provide an effective solution of the stated problem over the whole area claimed.

6. *Obviousness*

It remains to be decided whether the solution disclosed in the application as filed was obvious to a person skilled in the art in the light of the cited prior art.

6.1 Document D4 relates to crystalline copolyesters obtained from 1,4-dioxanone and an amorphous lactide/glycolide prepolymer and the use thereof in the manufacture of flexible bioabsorbable sutures. Although D4 generally indicates that the amount of lactide/glycolide prepolymer can vary over a wide range, it clearly teaches that an amount of greater than 50 percent by weight may affect the mechanical properties relative to the 1,4-dioxanone homopolymer (i.e. flexibility and pliability) (cf. column 1, lines 15 to 20; column 2, lines 34 to 47). Furthermore, it also indicates that the amount of glycolide in the prepolymer should not be greater than 50 percent by mole in order to come to a successful polymerization with the 1,4-dioxanone.

6.2 It thus follows that, according to D4, the amount of glycolide in the copolyester should represent at most 25% by weight and that, at least for this reason, D4 would lead the skilled person away from the solution proposed in the application in suit, which requires that the amount of glycolide in the copolyester be in the range 65 to 75% by weight.

6.3 It is also evident, that no information can be found in D4, according to which by increasing the amount of glycolide up to the range of 65 to 75 weight percent, and by copolymerizing it with a prepolymer of lactide with 1,4-dioxanone, a copolyester exhibiting a totally different behaviour in terms of Young's modulus and elongation when submitted to an annealing treatment, and allowing the manufacture of sutures exhibiting a

good flexibility (illustrated by a Young's modulus of the order of 500 000 psi) and good knot pull characteristics (more than 65 000 psi) can be obtained.

6.4 Consequently, D4 itself cannot lead to the solution of the technical problem.

6.5 Document D3 discloses flexible bioabsorbable sutures prepared from polymers of 1,4 dioxanone and exhibiting a Young's modulus of less than 600 000 psi and a knot strength of at least 30 000 psi. Although D3 also refers to sutures made of copolymers of 1,4 dioxanone with lactide and/or glycolide, and indicates that the physical and the chemical properties of such sutures can be controlled by varying the amount of the monomer constituents, it clearly teaches that the total amount of such comonomers should be up to 50% by weight (cf. Claims 1 and 21; column 8, line 64 to column 9, line 15). Thus, at least for this reason D3 will lead the skilled person away from the solution proposed by the application in suit.

6.6 Furthermore, as indicated in D3, a monofilament polyglycolide fiber generally exhibits a Young's modulus in the range of 1 to 2 million psi (column 8, lines 38 to 43), so that it would have been expected that a copolyester containing 70% by weight of glycolide units as shown in Examples 2 and 3 of the application in suit filed would exhibit a Young's modulus greater than at least 700 000 psi, and that, consequently, the obtained suture therefrom would lack the required flexibility.

6.7 There is also no suggestion in D3 as to whether the knot pull strength of the sutures would remain satisfying, when the amount of glycolide units is increased much above 50% by weight in the copolyester used for manufacturing the sutures.

6.8 Thus, for all these reasons, it follows that D3 cannot provide any assistance in the solution of the technical problem.

6.9 The information contained in the documents D1 (EP-A-0 411 545) and D2 (EP-A-0 098 394), considered during the examining procedure, although both being concerned with surgical sutures, is in the Board's view, less relevant, since D1 merely refers to low molecular weight random copolymers of 1,4 dioxanone, lactide and/or glycolide used as coatings for surgical filaments such as sutures, and D2 only relates to copolymers of glycolide with 1,3-dioxanone for the manufacture of sutures.

7. Consequently, the subject-matter of Claim 1 does not arise in an obvious way from the cited prior art. It meets therefore the requirements of Article 56 EPC. Similar considerations apply to the subject-matter of dependent Claims 2 and 3.

By the same token, Claims 4 to 9 which are directed to a method for making a suture according to Claims 1 to 3 meet the requirements of Article 56 EPC.

8. It follows, in view of the above, that the request of the Appellant is allowable.

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 grant a patent on the basis of Claims 1 to 9 submitted at the oral proceedings and after any consequential amendment of the description.

The Registrar: The Chairman:

E. Görgmaier R. Young