

**Internal distribution code:**

- (A) [ ] Publication in OJ  
(B) [ ] To Chairmen and Members  
(C) [X] To Chairmen  
(D) [ ] No distribution

**DECISION**  
of 11 July 2003

**Case Number:** T 0106/03 - 3.3.3

**Application Number:** 97118059.1

**Publication Number:** 0837084

**IPC:** C08G 63/66

**Language of the proceedings:** EN

**Title of invention:**

Biodegradable branched polymers containing units derived from dioxanone and medical/surgical devices manufactured therefrom

**Applicant:**

United States Surgical Corporation

**Opponent:**

-

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 123(2), 56

**Keyword:**

"Amendments - added subject-matter (main request) - yes"  
"Inventive step (first and second auxiliary request) - no"

**Decisions cited:**

G 0010/93

**Catchword:**

-



Case Number: T 0106/03 - 3.3.3

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.3  
of 11 July 2003

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

**Representative:** Marsh, Roy David  
Hoffmann Eitle  
Patent- und Rechtsanwälte  
Arabellastrasse 4  
D-81925 München (DE)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 20 August 2002  
refusing European application No. 97118059.1  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** R. Young  
**Members:** W. Sieber  
R. Moufang

### Summary of Facts and Submissions

I. European patent application No. 97 118 059.1 in the name of United States Surgical Corporation was filed on 17 October 1997, claiming a US priority of 17 October 1996 (US 733683), and was published under No. 0 837 084 on 22 April 1998 (Bulletin 1998/17).

II. By a decision which was announced orally on 24 July 2002 and issued in writing on 20 August 2002, the examining division refused the application. The decision was based on a set of Claims 1 to 9 forming a main request (headed "A"), a set of Claims 1 to 9 forming a first auxiliary request (headed "B"), and a set of Claims 1 to 9 forming a second auxiliary request (headed "C"), all filed on 19 January 2001. Claim 1 of the main request read as follows:

"A biocompatible composition comprising:

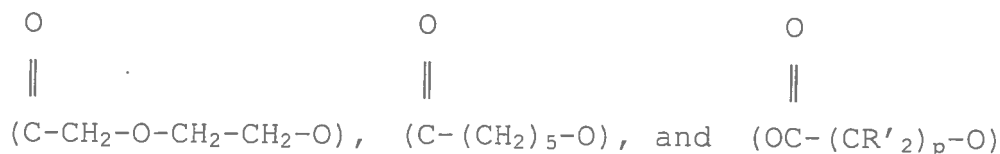
(a) a star polymer of the general formula:



wherein:

n equals 1 to 13;

R<sub>1</sub>, R<sub>2</sub>...R<sub>n+1</sub> are the same or different and selected from the group of a hydrogen atom or (Z)<sub>m</sub>H wherein Z comprises repeating units including one or more member selected from the group consisting of:



wherein p is 3 to 8 and each R' may be the same or different and are individually selected from the group consisting of hydrogen and alkyl having from 1 to 5 carbon atoms, such that at least three of said R<sub>1</sub>, R<sub>2</sub>...R<sub>n+1</sub> groups are other than hydrogen; m is sufficient such that the star polymer has an inherent viscosity in hexafluoroisopropanol at 25°C between about 0.01 and about 0.5 dl/gm; and the m's for each (Z) group may be the same or different,

at least one of said (Z)<sub>m</sub> groups being encapped [sic] with an isocyanate or a diketene acetal; and

- (b) a polysaccharide modified to contain a charge inducing substituent."

Claims 2 to 9 were dependent claims directed to elaborations of the biocompatible composition according to Claim 1.

The claims of the first auxiliary request ("B") corresponded to those of the main claim set apart from the deletion of the words "or a diketene acetal" in Claim 1 (at the end of the definition of component (a)).

The claims of the second auxiliary request ("C") corresponded with those of the first auxiliary request with the further limitation at the end of Claim 1: "wherein the weight ratio of modified polysaccharide to polymer is 1 to 20%".

III. According to the decision, the application was refused on the grounds that

(i) the addition of "diketene acetal" as an alternative endcapping agent in Claim 1 of the main request included unsearched subject-matter which did not combine with the originally claimed group of inventions to form a single inventive concept (Rule 86(4) EPC); and

(ii) the subject-matter of Claim 1 of the first and second auxiliary request was not based on an inventive step (Article 56 EPC) in view of documents D1 and D4:

D1: EP-A-0 693 294; and

D4: US-A-5 502 042.

IV. On 15 October 2002, a notice of appeal against the above decision was filed by the applicant (hereinafter referred to as the appellant), the prescribed fee being recorded as paid on the same day.

In the statement of grounds of appeal, filed on 19 December 2002, the appellant argued in substance as follows:

(i) The applicant had paid a second search fee to obtain a supplementary search for invention II as identified in the Partial European Search Report, ie claims directed to a surgical device comprising a synthetic bioabsorbable polymer and a filler in a specific weight ratio. When assessing the

subject-matter of this second invention, and following the Guidelines for Examination B-III, 3.1, the search examiner would have had to go into the description for the interpretation of the term "synthetic bio-absorbable polymer" and would have found on the bridging paragraph of pages 9 and 10 of the application as filed that the bioabsorbable polymer included a form having endcapped isocyanate groups or diketene acetals. Thus, it was evident that the search covered subject-matter pertaining to "diketene acetal" endcapping, so that the alternative "diketene acetal" endcapping as it appeared in Claim 1 of the main request underlying the decision under appeal should be considered allowable pursuant to Rule 86(4) EPC.

- (ii) Having regard to inventive step, D1 was considered to represent the closest prior art relating likewise to biocompatible compositions, so that the problem of the present application could be seen in providing alternative compositions to those disclosed in D1. Although D1 described the star polymer used as component (a) in the patent in suit and D4 disclosed wound treatment compositions comprising a modified polysaccharide falling within the scope of component (b) in the patent in suit, the combined use of these two components was not contemplated in D1 and/or D4. Thus, the subject-matter of the claims of all requests underlying the decision under appeal was based on an inventive step over the cited prior art.

- V. In a communication dated 30 April 2003 accompanying a summons to oral proceedings, the board objected against the introduction of the term "diketene acetal" into Claim 1 of the main request under Article 123(2) EPC, an issue which was introduced into the proceedings following G 10/93 (OJ EPO 1995, 172). Furthermore, the question was raised whether the subject-matter of all requests was based on an inventive step in view of D1 and D4.
- VI. Oral proceedings were held on 11 July 2003, in the course of which the discussion focussed on the questions whether Claim 1 of the main request met the requirements of Article 123(2) EPC and whether the subject-matter of Claim 1 of the first and the second auxiliary request was based on an inventive step.
- VII. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of claim sets A (main request), B (first auxiliary request) or C (second auxiliary request) underlying the decision under appeal.

### **Reasons for the Decision**

1. The appeal complies with Articles 106 to 108 EPC and Rule 64 EPC and is therefore admissible.

2. *Main request*

2.1 Amendments

2.1.1 The biocompatible composition of Claim 1 is based on Claim 1 as originally filed, containing, in addition, the alternative that at least one of the  $(Z)_m$  groups of the star polymer (a) is endcapped with a diketene acetal. Thus, the decisive question is whether the incorporation of the alternative "diketene acetal endcapping" is directly and unambiguously derivable from the application as filed.

2.1.2 The application as originally filed describes on pages 3 to 6 under the headings "SUMMARY" and "DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS" basically the star polymer (a) itself. On page 9 lines 23 to 24, it is stated that "the star polymers described herein may advantageously be endcapped with isocyanate groups". Furthermore, it is stated in the paragraph bridging pages 9 and 10 of the application as originally filed that "While endcapping with diisocyanate is preferred, it is also contemplated that other agents having at least two reactive sites can be employed for endcapping and for facilitating cross-linking. Suitable other endcapping agents include, for example, diketene acetals such as bis-vinyl-2,4,8,10-tetraoxyspiro-undecane". However, the endcapping described on pages 9 and 10 is not disclosed in the context of a composition as required in Claim 1 but is given in the context of the star polymer only.



2.1.3 On the following pages, various constellations with isocyanate endcapped star polymers are described. Thus, the isocyanate endcapped star polymers can be:

- crosslinked (page 10, line 18 to page 11, line 16),
- admixed with a filler (page 11, line 17 to page 12, line 2),
- chemically altered to provide a desired charge on the polymer (page 12, lines 3 to 26), or
- mixed with a material known to carry a charge, eg a polysaccharide modified to include a charge inducing substituent, to provide a charged composition which enhances wound healing (page 12, lines 27 to 34), or
- mixed with a filler first and thereafter adding a charge inducing reactant (page 13, lines 4 to 11).

Hence, the only passage in the application as originally filed supporting compositions comprising a modified polysaccharide can be found on page 12, lines 27 to 34, which refers exclusively to compositions comprising isocyanate endcapped star polymers. There is no indication, either explicitly or implicitly, that the compositions referred to in this passage encompass compositions comprising diketene acetal endcapped star polymers.

2.1.4 The appellant took the view that a person skilled in the art would understand, when reading the application as a whole, that all explicitly described embodiments

of the star polymer could be used in a composition with the modified polysaccharide. However, the structure of the disclosure does not support this argument. In fact, the description of the application is not particularly oriented to the claimed subject-matter, ie a biocompatible composition comprising a star polymer having a certain general formula and a polysaccharide modified to contain a charge inducing substituent. Moreover, the description is written in a way which does not lead to an idea what has been originally considered as the invention. Thus, although the first sentence of the paragraph headed "BACKGROUND OF THE INVENTION" at page 1 states that "This disclosure relates generally to bioabsorbable polymer compositions", already the sentence following this statement leads away from the claimed compositions by stating "Specifically, this disclosure relates to highly branched or star polymers derived from monomers known to form absorbable polymers". The passage headed "SUMMARY" (pages 3 to 6) does not refer to the compositions of Claim 1 at all, although isocyanate endcapped polymers and modifications thereof are mentioned. Hence, there is no direct and unambiguous link between the modifications described for the star polymer itself and a composition comprising an isocyanate endcapped star polymer and a modified polysaccharide as disclosed on page 12 of the application as originally filed.

- 2.1.5 Summing up, even when reading the application as a whole, the amendment of Claim 1 is not directly and unambiguously derivable from the application as originally filed. Hence, Claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

2.2 It follows from the above that the question whether or not the refusal of the main request by the examining division under Rule 86(4) EPC was justified is moot.

3. *First and second auxiliary request*

3.1 No objections under Articles 123(2), 84 and 54 EPC were raised by the examining division. The board is satisfied that the claims of these requests meet the requirements of the Articles 123(2), 84 and 54 EPC.

3.2 Problem and solution

3.2.1 The claimed bioabsorbable polymer compositions are particularly useful in the manufacture of absorbable surgical devices such as sutures, staples, clips, anastomosis rings, bone plates and screws, matrices for the sustained and/or controlled release of pharmaceutically active ingredients, fabricated at least in part therefrom (page 1, lines 17 to 26 of the application as originally filed).

3.2.2 The decision under appeal and the appellant consider D1 as the closest prior art which discloses bioabsorbable branched or star polymers and medical/surgical devices manufactured therefrom. Preferred embodiments are star polymers endcapped with isocyanate groups (Claim 7; page 6, lines 24 to 37), corresponding exactly to component (a) of Claim 1 of all requests. Furthermore, it is stated on page 7, lines 37 to 39, that one or more medico-surgically useful substances, eg those which accelerate or beneficially modify the healing process when particles are applied to a surgical repair

site, can be incorporated into surgical devices made from the materials described herein.

3.2.3 In the board's view, the closest state of the art is therefore a composition from which a surgical device as described in that passage on page 7 of D1 can be made; in other words, a composition comprising an endcapped star polymer and a medico-surgically useful substance.

3.2.4 The composition claimed in Claim 1 of the first auxiliary request differs from this closest prior art in that a specific medico-surgically useful substance is used in combination with the star polymer (a). Since the application in suit contains no example exemplifying the claimed composition, let alone a comparison of the claimed subject-matter with the closest prior art, it is not possible for the board to recognize any particular technical effect associated with the use of the specific additive (b). Therefore, the objective technical problem can, in the board's view, only be seen in providing alternative compositions to those disclosed in D1.

### 3.3 Inventive step

3.3.1 It remains to be decided whether the proposed solution, ie the addition of a polysaccharide modified to contain a charge inducing substituent, is obvious from the prior art.

3.3.2 Faced with the problem of providing alternative compositions, a person skilled in the art would choose other medico-surgical additives not already explicitly mentioned in D1, in particular following the suggestion

on page 7, lines 37 to 39 of D1, and would inevitably consider the use of the modified polysaccharides disclosed in D4. These modified polysaccharides being identical with component (b) of Claim 1 are used in wound treatment (column 1, lines 8 to 12 of D4). Thus, a person skilled in the art, starting from D1 and being aware of D4, would arrive at something falling within the scope of Claim 1 of the first auxiliary request.

3.3.3 A further incentive to combine the teachings of D1 and D4 can be found in D4, column 4, lines 45 to 46, where it is stated that the modified polysaccharides can be used in combinations with other additives. Furthermore, it is stated in column 7, lines 6 to 10 of D4, that "It will be understood that various modifications may be made to the embodiments disclosed herein. For example, the compositions in accordance with this disclosure can be blended with other biocompatible, bioabsorbable or non-bioabsorbable materials".

3.3.4 During the oral proceedings, the appellant argued that a person skilled in the art would not combine documents D1 and D4 since they were not in the same technical field. While D1 was particularly useful in the manufacture of surgical devices which remained in the human body for a long time, the compositions of D4 were directed to the treatment of wounds which is directed to short term effects. A skilled person would be well aware of the extreme difficulties associated with materials that were designed to stay in the human body and would not consult D4 when looking for alternative compositions of D1. Apart from the fact that this argument is in glaring contradiction to the above cited statements made in both D1 and D4, neither Claim 1 of the first auxiliary

request nor the disclosure of D4 is restricted to surgical devices but each refers to a composition *per se*. Since, furthermore, the alleged difficulties in preparing compositions useful in the manufacture of surgical devices, ie devices designed to stay permanently in the human body, were not substantiated by evidence, the board could not follow this line of argumentation.

3.3.5 In summary, nothing inventive can be seen in the subject-matter of Claim 1 of the first auxiliary request (Article 56 EPC).

3.3.6 Claim 1 of the second auxiliary request differs from Claim 1 of the first auxiliary request only in that a certain range for the weight ratio of the polymer (a) to the modified polysaccharide (b) is introduced. Since, however, no particular effect is associated with this range, nothing inventive can be seen in defining the amounts of components (a) and (b) which would merely be the result of routine experimentation, and the objections raised under Article 56 EPC against Claim 1 of the first auxiliary request consequently apply equally to Claim 1 of the second auxiliary request.

4. For the above given reasons, the main request, the first auxiliary request and the second auxiliary request had to be refused.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

  
E. Gorgmaier

The Chairman:

  
R. Young