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D E C I S I O N
of 26 May 2000

Case Number: T 1032/96 - 3.3.3

Application Number: 91107705.5

Publication Number: 0460428

IPC: C08G 63/08

Language of the proceedings: EN

Title of invention:
Segmented absorbable copolymer

Applicant:
AMERICAN CYANAMID COMPANY

Opponent:
-

Headword:
-

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

Keyword:
"Amendments - deletion of features (yes) - added subject-matter (yes)"
"Claims - clarity (no)"

Decisions cited:
T 0153/85

Catchword:
-



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Chambres de recours

Case Number: T 1032/96 - 3.3.3

D E C I S I O N
of the Technical Board of Appeal 3.3.3
of 26 May 2000

Appellant:

AMERICAN CYANAMID COMPANY
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Representative:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office dated 9 May 1996, issued
in writing on 13 June 1996 refusing European
patent application No. 91 107 705.5 pursuant to
Article 97(1) EPC.

Composition of the Board:

Chairman: C. Gérardin
Members: R. Young
V. Di Cerbo

Summary of Facts and Submissions

- I. European patent application No. 91 107 705.5, with 15 claims, filed on 13 May 1991 and claiming a US priority of 7 June 1990 (US 548801) was published under No. 0 460 428. Claim 1 read as follows:

"A copolymer comprising a bioabsorbable, segmented molecular architecture having at least two different ester linkages, the segmented molecular architecture comprising a plurality of fast transesterifying linkages having a segment length distribution of greater than 1.3, and a plurality of slow transesterifying linkages, with the proviso that for said fast transesterifying linkages consisting essentially of glycolate linkages and the slow transesterifying linkages selected from the group consisting of trimethylene carbonate and caproate linkages, the segment length distribution of said fast transesterifying linkages is up to 2.0 and the number average segment length of said slow transesterifying linkages is greater than 2.5 linkages per segment."

Claims 2 and 3 were dependent claims directed to elaborations of the composition according to Claim 1, Claim 2 in particular being directed to the copolymer of Claim 1 wherein the fast transesterifying linkages comprised lactate and/or glycolate linkages.

Claim 4, an independent claim, was worded as follows:

"An article of manufacture comprising the copolymer of claim 2 wherein the plurality of slow transesterifying linkages are selected from the group consisting of trimethylene carbonate, caproate and dioxanone linkages."

Claims 5 to 10 were dependent claims directed to elaborations of the polymer according to Claims 1 to 3 or the article according to Claim 4.

Claim 11, an independent claim, was worded as follows:

"A process for manufacturing the copolymer of claim 1 comprising:

employing sequential addition of at least two different cyclic ester monomers in at least two stages, the first cyclic ester monomer selected from the group consisting of carbonates and lactones, and mixtures thereof, and the second cyclic ester monomer selected from the group consisting of lactides and mixtures thereof, the sequential addition comprising:

- I. first polymerizing in a first stage at least said first cyclic ester monomer in the presence of a catalyst at a temperature of from about 160 to 220°C. to obtain a first polymer melt;
- II. adding at least said second cyclic ester monomer to the first polymer melt; and
- III. second or more copolymerizing in a second or more stage said first polymer melt with at least said second cyclic ester monomer to obtain a second or more copolymer melt; and

transesterfying the second or more copolymer melt for up to about 5 hours at a temperature of greater than about 180° Centigrade."

Claims 12 to 15 were dependent claims directed to elaborations of the process according to Claim 11.

II. The application was refused by a decision of the Examining Division, dated 9 May 1996, issued in writing on 13 June 1996, on the basis of an amended set of Claims 1 to 14 filed on 9 April 1996, Claim 1 of which read as follows:

"A copolymer comprising a bioabsorbable, segmented molecular architecture having at least two different ester linkages, the segmented molecular architecture comprising a plurality of fast transesterifying lactate and/or glycolate linkages having a segment length distribution of greater than 1.3 but not more than 2.0, and a plurality of slow transesterifying trimethylene carbonate, caproate and/or dioxanone linkages with a number average segment length of greater than 2.5 linkages per segment."

Claim 2 was a dependent claim directed to an elaboration of the copolymer according to Claim 1.

Claim 4, an independent claim, was worded as follows:

"An article of manufacture comprising the copolymer of Claim 1 selected from the group consisting of a molding resin, film, surgical element, controlled release device, and extrusion pellets."

Claims 3 to 8 were dependent claims directed to elaborations of the polymer according to Claims 1 or 2 or the article according to Claim 4.

Claims 9 to 13 corresponded to Claims 11 to 15, respectively, of the application as originally filed (section I., above).

Claim 14, an independent claim, was worded as follows:

"A copolymer obtained by the process of one or several of claims 9 to 13."

According to the decision, neither the requirements of Articles 123(2), 84 (clarity, support), nor 54 (novelty) EPC, nor those of Rules 27(1)(b) and 35(12) EPC were met. In particular, there was lack of clarity, since the parameters "segment length distribution" and "number average segment length" in Claim 1 and elsewhere were uncommon and required much more than the normal skill of the average polymer chemist to calculate them. Furthermore, the subject-matter of all the claims lacked novelty in the light of the disclosure of:

D2: GB-A-2 127 839,

since the process for preparing polymers of glycolide and ϵ -caprolactone according to Example IV of D2 was identical with that claimed in the application. Hence, the resulting copolymer product would inevitably have to be identical with that claimed in Claim 1, the parametric limitations not being able to be taken into account.

Similar considerations applied to the disclosure of:

D3: EP-A-0 098 394,

which described a process for preparing a copolymer of glycolide and trimethylene carbonate in two steps (Example 5).

III. On 30 July 1996, a Notice of Appeal against the above decision was filed, the prescribed fee being paid on the same day.

In the Statement of Grounds of Appeal, filed on 14 October 1996, the Appellant filed a new set of Claims 1 to 13, which it was argued overcame the objections under Article 123(2) and 84 EPC, and a test report which was alleged to demonstrate that D2 and D3 described processes for the production of polymers which fell outside the scope of Claim 1, so that novelty was established.

Claim 1 read as follows:

"A bioabsorbable, segmented binary copolymer, having fast transesterifying glycolate units (G) and slow transesterifying units (C) of caproate or trimethylene carbonate with a number average segment length

$$Lg_n = \frac{I_{GGG} + I_{GGC}}{I_{CGG} + I_{CCG}} + 1$$

of greater than 2.5 units per segment, and a segment length distribution Lg_w / Lg_n of greater than 1.3, but not more than 2.0, whereby Lg_w is defined as

$$Lg_w = \frac{(I_{GGG} + I_{GGC} + I_{CGG})^2 + I_{CGG} I_{CCG}}{I_{CGG} (I_{GGG} + I_{GGC} + I_{CGG} + I_{CCG})}$$

wherein I_{GGG} , I_{GGC} , I_{CGG} , I_{CCG} designate the integrated intensities of the signals of the central carbonyl carbons of the triads GGG, GGC, CGG and CGC in the ^{13}C NMR spectrum of the copolymer."

Claim 2, a dependent claim, was directed to an elaboration of the copolymer according to Claim 1.

Claim 3, an independent claim, was worded as follows:

"An article of manufacture comprising the copolymer of claim 1 selected from the group consisting of a molding resin, film, surgical element, controlled release device, and extrusion pellets."

Claims 4 to 7 were dependent claims directed to elaborations of the article according to Claim 3.

Claim 8, an independent claim, was worded as follows:

"A process for manufacturing the copolymer of claim 1 comprising:

employing sequential addition of two different cyclic ester monomers in at least two stages, the first cyclic ester monomer being selected from the group consisting of trimethylene carbonate and caproate, and mixtures thereof, and the second cyclic ester monomer being glycolide, the sequential addition comprising:

- I. polymerizing said first cyclic ester monomer in the presence of a catalyst at a temperature of from 160 to 220°C to obtain a first polymer melt;
- II. adding said second cyclic ester monomer to the first polymer melt;
- III. copolymerizing said first polymer melt with said second cyclic ester monomer to obtain a second copolymer melt; and

IV. transesterifying the second copolymer melt for up to 5 hours at a temperature of greater than 180° Centigrade."

Claims 9 to 12 were dependent claims directed to elaborations of the process according to Claim 8.

Claim 13 was directed to a copolymer obtained by the process according to any one of Claims 8 to 12.

IV. The Board raised a number of objections, in a communication issued on 8 February 2000 accompanying a summons to oral proceedings set for 26 May 2000, to the new set of claims, in particular as follows:

- (a) Whilst the definition of the parameter "segment length distribution" (Lg_w/Lg_n) in Claim 1 had been clarified as to its meaning, it was no longer unambiguously associated uniquely with the fast transesterifying units, but rather with the slow transesterifying units, and thus comprised added subject-matter (Article 123(2) EPC).
- (b) The contents of the Test Report were not apt to show that the subject-matter of Claim 1 was novel, since it was evident from a number of the illustrative examples in the application itself that the relevant process according to Claim 8 equally failed to generate a copolymer having the parametric requirements defined in Claim 1 of the application in suit.
- (c) The latter finding had negative connotations for the claimed subject-matter, since it was not evident what were its essential features, nor even what particular effect, if any, was associated with the relevant parameters, nor, therefore, what was the nature of the technical problem.

Consequently, there was no justification for withdrawing the objection of lack of novelty, which had been the principal ground of refusal.

- V. With a letter received on 23 May 2000, i.e. three days before the oral proceedings were due to be held, the Appellant filed a further set of Claims 1 and 2 forming an auxiliary request.

Claims 1 and 2, respectively, of this set read as follows:

"1. A process for preparing a crystalline segmented copolymer of ϵ -caprolactone and glycolide by the following sequential charging steps:

- (a) charging ϵ -caprolactone, stannous octoate as a catalyst and lauryl alcohol as an initiator into a stirred polymerization reactor and effecting polymerization at 185°C;
- (b) subsequently charging a mixture of ϵ -caprolactone and glycolide in a weight ratio of 50:50 into the above reactor after completion of step (a) and effecting polymerization at 185°C, whereby the weight ratio of ϵ -caprolactone [sic] to glycolide in the sum of both steps (a) and (b) is 70:30.

2. A process for preparing a crystalline segmented copolymer of glycolide and trimethylene carbonate by the following sequential charging steps:

- (a) charging into a stirred polymerization reactor trimethylene carbonate $\text{SnCl}_2 \cdot 2\text{H}_2\text{O}$ and diethylene glycol, and
- (b) glycolide in one or two charges."

- VI. Oral proceedings were held on 26 May 2000. At the oral proceedings, the representative defended the validity of the claims of the main and auxiliary requests.
- VII. The Appellant requested that the decision under appeal be set aside, and a patent granted on the application in suit, either on the basis of the set of Claims 1 to 13 filed with the Statement of Grounds of Appeal, or, in the alternative, on the set of Claims 1 and 2 filed with the submission of 23 May 2000.

Reasons for the Decision

1. The appeal is admissible.
2. *Main request*

The communication issued by the Board together with the summons to these oral proceedings contained a number of serious objections to the claims (Section IV., above). No arguments were brought in reply, however, until the day of the oral proceedings. Nor, apart from a statement by the representative that an (unspecified) amendment could be undertaken to remove the objection under Article 123(2) EPC, was any convincing argument put forward at the oral proceedings as to why the Board should waive the objections raised in the communication. On the contrary, the representative accepted that there was "a problem" with regard to the values of the parameters "segment length distribution" and "number average segment length" required in the claims and those illustrated in the relevant examples. Consequently, no remedy for the objections under Articles 84 (clarity, support) and 54 (novelty) EPC was put forward.

Hence, the Board found it necessary to refuse the main request.

3. *Auxiliary request*

The claims of this request were filed only three days before the date set for the oral proceedings, in spite of a statement in the communication of the Board accompanying the summons to oral proceedings, according to which "Any further arguments, evidence, amended sets of claims/description should be filed in good time, and in any case at least one month before the date set for oral proceedings.". In this connection, according to the decision T 153/85 (OJ EPO 1988, 001), when deciding an appeal during oral proceedings, a Board of Appeal may refuse to consider alternative claims which have been filed at a late stage, e.g. during the oral proceedings, if such claims are not clearly allowable (Headnote II).

Whilst the letter accompanying the submission referred to the late transferral of the case to the representative because of an illness of a colleague, this does not amount, in the Board's view, to a complete justification as to why this set of claims had been filed at such a late stage of the proceedings. Furthermore, there is no evidence on the file that the first representative intended to make, before the time limit, a detailed submission including an alternative set of claims in reply to the communication of the Board.

The claims must be regarded as late-filed and hence as needing to fulfil the above criterion.

3.1 Admissibility of amendments (Article 123(2) EPC).

Claims 1 and 2 are both independent claims stated, in the submission filed on 23 May 2000, to be based on Example 1, and Examples 5/6, respectively, of the application in suit as originally filed.

Closer examination of these claims shows, however, that they omit all reference to the parameters "number average segment length" and "segment length distribution" (Lg_w/Lg_n) parameters, appearing in Claim 1 of the application in suit as originally filed, and also forming limiting features of the remaining independent Claims 4 and 11 (Section I., above).

It was, furthermore, admitted by the representative of the Appellant at the oral proceedings, that the examples relied upon did not yield a product fulfilling these parameters, as had previously been pointed out, specifically in relation to Examples 5 and 6, in the communication of the Board (paragraph 2.1).

- 3.1.1 These parameters, which are repeated at various points in the description in connection with the copolymer which "has been invented", are not suggested to be optional. On the contrary, they are explicitly stated to be features of the copolymer (page 7, lines 15 to 30) and of the article formed therefrom (page 8, line 24 to page 10, line 8). In particular, the requirements for the segment length distribution to be up to 2.0 and the number average segment length to be greater than 2.5 linkages per segment are stated to be "a material limitation of the invention". Consequently, the parametric limitations must be regarded as having been explained as essential in the application as originally filed.

- 3.1.2 The argument of the representative at the oral proceedings, that the definition of the manufacturing process on page 14 of the application as originally filed did not mention the relevant parameters and therefore stood in contradiction to the remaining disclosure, is not convincing for the following reasons:
- 3.1.2.1 The opening paragraph of the description states, "This invention relates to a method of forming a bioabsorbable copolymer of specific and well defined molecular architecture, to the copolymer made by the method and to a medical or surgical device manufactured from the copolymer." It is consequently evident that the method of manufacture relates to the polymer of specific molecular architecture (i.e. having the relevant parameters as claimed) and to no other.
- 3.1.2.2 Furthermore, the general reference to a "material limitation of the invention" (section 3.1, above), clearly applies, in the Board's view, to all aspects of the claimed subject-matter.
- 3.1.2.3 Consequently, the passage defining the process on page 14 must be read in the context of the foregoing description, and thus as limited to the parameters which are consistently presented as essential both there and in the claims.
- 3.1.3 In other words, the set of Claims 1 and 2 omits a feature of the subject-matter which was presented as essential in the application as originally filed. Consequently, the claims contravene the requirements of Article 123(2) EPC.

3.2 Clarity

Whilst the process claims as originally filed consistently presented the performance of the copolymerisation step in the melt, a fact which also applies to the definition of the latter on page 14 (cf. section 3.1.2, etc., above), and, according to the argument of the representative of the Appellant at the oral proceedings, implicitly also to both Claims 1 and 2, nevertheless none of Examples 1, 5 and 6 mentions the phase in which the copolymerisation is carried out. In particular, none of them mentions the use of a melt. Consequently, it is evident that these examples do not illustrate a process according to Claim 1 or Claim 2. Thus, the claims are inconsistent with the examples upon which they rely (section 3.1, above) and cannot, therefore, be regarded as fulfilling the requirements of Article 84 EPC in relation to clarity.

3.3 In summary, Claims 1 and 2, far from being clearly allowable (T 153/85, supra.) are not allowable under Article 123(2) EPC, and even if this objection had not been maintained, are not allowable under Article 84 EPC.

3.4 In view of the above, it was necessary to refuse the claims of the auxiliary request also.

4. Since there were no other requests on file, it would have been superfluous for the Board to investigate whether the claims, if otherwise allowable, might have contained subject-matter which was novel and inventive.

Order

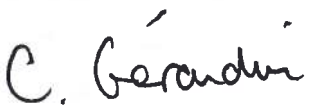
For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

4. 
E. Görgmaier

The Chairman:


C. Gérardin