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Datasheet for the decision of 12 February 2008

Case Number: T 0450/03 - 3.3.02

Application Number: 91303606.7

Publication Number: 0466300

IPC: A61K 47/36

Language of the proceedings: EN

Title of invention:
Biocompatible viscoelastic gel slurries, their preparation and use

Patentee:
GENZYME CORPORATION

Opponent:
Fidia Farmaceutici S.P.A.

Headword:
Viscoelastic gel slurries/GENZYME CORPORAITON

Relevant legal provisions:
EPC Art. 123(2), 123(3), 114(2)

Relevant legal provisions (EPC 1973):
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Keyword:
"Late-filed requests: admissibility (yes) - no substantial amendments"
"Late-filed experimental data: admissibility (no)"
"Main request and auxiliary request 2-11: allowability of amendments (no) - no basis in the application as originally filed for the feature per cent by weight"
"Auxiliary request 1: allowability of amendments (no) - extension of the protection conferred"

Decisions cited:

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Catchword:

-

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Case Number: T 0450/03 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 12 February 2008

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 13 February 2003 concerning maintenance of European patent No. 0466300 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
P. Mühlens

Summary of Facts and Submissions

I. European patent No. 0 466 300 based on application No. 91 303 606.7 was granted on the basis of a set of eight claims.

The independent claims read as follows:

"1. A biocompatible viscoelastic gel slurry comprising a two phase mixture, a first phase being a particulate biocompatible gel phase, said gel phase comprising a chemically crosslinked glycosaminoglycan, or a glycosaminoglycan chemically co-crosslinked with at least one other polymer selected from polysaccharides and proteins, wherein said glycosaminoglycan is hyaluronan or hylan, said gel phase being swollen in a physiologically acceptable aqueous medium and being uniformly distributed in the second phase, and wherein the polymer concentration of the biocompatible gel swollen in the physiologically acceptable aqueous medium is from 0.1 to 10%; and said second phase comprising a polymer solution of a water-soluble biocompatible polymer selected from hyaluronan, hylan, polyvinylpyrrolidone and polyethyleneoxide in said physiologically acceptable aqueous medium, and wherein the polymer solution in the two phase mixture constitutes from 0.01 to 99.5% by weight and the gel phase constitutes the remainder.

5. A method of obtaining a biocompatible viscoelastic gel slurry according to Claim 1, which comprises, in either order
(i) mixing (a) a biocompatible polymeric gel comprising a chemically crosslinked glycosaminoglycan or a

glycosaminoglycan chemically co-crosslinked with at least one other polymer selected from polysaccharides and proteins, wherein said glycosaminoglycan is hyaluronan or hyland, said gel being swollen in a physiologically acceptable aqueous medium and having a polymer concentration of from 0.1 to 10%, with (b) a solution of a water-soluble biocompatible polymer selected from hyaluronan, hylan, polyvinylpyrrolidone and polyethyleneoxide in the same aqueous medium to form a two phase mixture wherein the solution of said biocompatible polymer constitutes from 0.01 to 99.5% by weight and the gel phase constitutes the remainder, and (ii) disintegrating the gel into particles."

II. A notice of opposition was filed on 15 February 1999 by Fidia Spa. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(c) EPC for amendments that contain subject-matter which extends beyond the content of the application as originally filed.

III. The following documents were *inter alia* cited during the opposition and appeal proceedings:

(3) US-A-4 582 865
(4) US-A-4 795 741

IV. In the decision pronounced on 23 September 2002, the opposition division found that, account being taken of the amendments made by the patentee during the opposition proceedings, the patent and the invention to which it related in the form of the first auxiliary request met the requirements of the EPC. Its principal findings were as follows:

In connection with the main request in the form of the claims as granted, the opposition division came to the conclusion that the subject-matter of the main request met the requirements of Articles 123(2) and 54 EPC, but did not involve an inventive step over documents (3) and/or (4).

As for auxiliary request 1, the opposition division held that the newly introduced feature "for implantation into the body" was clear; moreover, the requirements of Articles 123(2) and 54 EPC were also met.

As far as inventive step is concerned, the opposition division defined example 23 of document (3) as closest prior art and concluded that neither document (3) nor (4) contained any incentive that two phase viscoelastic gel slurries, having a polymer concentration as defined in claim 1 of auxiliary request 1, displayed unexpected rheological and/or diffusion properties. As a consequence, an inventive step was acknowledged.

V. The opponent lodged an appeal against that decision.

VI. With his letter dated 5 February 2008, the respondent (patentee) filed a new main request as well as ten auxiliary requests.

VII. At the oral proceedings of 12 February 2008, the respondent filed a new auxiliary request 2 and renumbered auxiliary requests 2 to 10 as filed with the letter of 5 February 2008 to auxiliary requests 3 to 11.

VIII. The wording of claim 1 of the requests on file is as follows:

(a) Main request:

"1. A biocompatible viscoelastic gel slurry for implantation into the body comprising a two phase mixture, a first phase being a particulate biocompatible gel phase, said gel phase comprising a chemically crosslinked glycosaminoglycan, or a glycosaminoglycan chemically co-crosslinked with at least one other polymer selected from polysaccharides and proteins, wherein said glycosaminoglycan is hyaluronan or hylan, said gel phase being swollen in a physiologically acceptable aqueous medium and being uniformly distributed in the second phase, and wherein the polymer concentration of the biocompatible gel swollen in the physiologically acceptable aqueous medium is from 0.1 to 10%; and said second phase comprising a polymer solution of a water-soluble biocompatible polymer selected from hyaluronan, hylan, polyvinylpyrrolidone and polyethyleneoxide in said physiologically acceptable aqueous medium, and wherein the polymer solution in the two phase mixture constitutes from 1 to 95% by weight and the gel phase constitutes the remainder."

(b) Auxiliary request 1:

Claim 1 of auxiliary request 1 is identical to claim 1 of the main request except that the term "by weight" after the concentration range of 1 to 95% was deleted.

(c) Auxiliary request 2:

"1. A biocompatible viscoelastic gel slurry for implantation into the body comprising a two phase mixture, a first phase being a particulate biocompatible

gel phase, said gel phase comprising a chemically crosslinked glycosaminoglycan, wherein said glycosaminoglycan is hylan, said gel phase being swollen in a physiologically acceptable aqueous medium and being uniformly distributed in the second phase, and wherein the polymer concentration of the biocompatible gel swollen in the physiologically acceptable aqueous medium is from 0.1 to 10%; and said second phase comprising a polymer solution of a water-soluble biocompatible polymer which is hylan, in said physiologically acceptable aqueous medium, and wherein the polymer solution in the two phase mixture constitutes from 1 to 95% by weight and the gel phase constitutes the remainder."

(d) Auxiliary request 3:
Claim 1 of auxiliary request 3 is identical to claim 1 of the main request except that the term "gel slurry for implantation into the body" was replaced by "gel slurry for use in medicine".

(e) Auxiliary request 4:
Claim 1 of auxiliary request 4 is identical to claim 1 of the main request except that the term "biocompatible polymer selected from hyaluronan, hylan, polyvinylpyrrolidone and polyethyleneoxide" was replaced by "biocompatible polymer selected from hyaluronan and hylan".

(f) Auxiliary request 5:
Claim 1 of auxiliary request 5 is identical to claim 1 of auxiliary request 4 except that the concentration of the water-soluble biocompatible polymer selected from hyaluronan and hylan is limited to 0.01 to 10%.

(g) Auxiliary request 6:
Claim 1 of auxiliary request 6 is identical to claim 1 of auxiliary request 4 except that the concentration of the water-soluble biocompatible polymer selected from hyaluronan and hylan is limited to 0.02 to 5%.

(h) Auxiliary request 7:
Claim 1 of auxiliary request 7 is identical to claim 1 of the main request except that the term "and proteins" was deleted.

(i) Auxiliary request 8:
Claim 1 of auxiliary request 8 is identical to claim 1 of the main request except that the term "or a glycosaminoglycan chemically co-crosslinked with at least one other polymer selected from polysaccharides and proteins" was deleted.

(j) Auxiliary request 9:
"1. A biocompatible viscoelastic gel slurry for implantation into the body comprising a two phase mixture, a first phase being a particulate biocompatible gel phase, said gel phase comprising a chemically crosslinked glycosaminoglycan, or a glycosaminoglycan chemically co-crosslinked with at least one other polymer selected from polysaccharides and proteins, wherein said glycosaminoglycan is hylan, said gel phase being swollen in a physiologically acceptable aqueous medium and being uniformly distributed in the second phase, and wherein the polymer concentration of the biocompatible gel swollen in the physiologically acceptable aqueous medium is from 0.1 to 10%; and said second phase comprising a polymer solution of a water-

soluble biocompatible polymer which is hylan, in said physiologically acceptable aqueous medium, and wherein the polymer solution in the two phase mixture constitutes from 1 to 95% by weight and the gel phase constitutes the remainder."

(k) Auxiliary request 10:
"1. A biocompatible viscoelastic gel slurry comprising a two phase mixture, a first phase being a particulate biocompatible gel phase, said gel phase comprising a chemically crosslinked glycosaminoglycan, or a glycosaminoglycan chemically co-crosslinked with at least one other polymer selected from polysaccharides and proteins, wherein said glycosaminoglycan is hyaluronan or hylan, said gel phase being swollen in a physiologically acceptable aqueous medium and being uniformly distributed in the second phase, and wherein the polymer concentration of the biocompatible gel swollen in the physiologically acceptable aqueous medium is from 0.1 to 10%; and said second phase comprising a polymer solution of a water-soluble biocompatible polymer selected from hyaluronan and hylan, in said physiologically acceptable aqueous medium, and wherein the polymer solution in the two phase mixture constitutes from 1 to 95% by weight and the gel phase constitutes the remainder, for use in the treatment of osteoarthritis."

(l) Auxiliary request 11:
Claim 1 of auxiliary request 11 is identical to claim 1 of auxiliary request 10 except that the concentration of the water-soluble biocompatible polymer selected from hyaluronan and hylan is limited to 0.01 to 10%.

IX. The appellant's arguments can be summarised as follows:

a) In connection with the admissibility of the respondent's claims, it was held that all requests had been filed very late: the main request and auxiliary requests 1 and 3 to 11 with the letter dated 5 February 2008, auxiliary request 2 only at an advanced stage of the oral proceedings. No explanations had been given for the late filing or for the reasons for the amendments. As a consequence, the requests were not admissible.

b) As far as the experimental data filed in the course of the appeal procedure are concerned, the appellant argued that the data filed by the respondent with letter dated 17 August 2007 and with letter dated 11 January 2008 were late filed and therefore not admissible. In connection with the latter data, it was additionally argued that the evidence was presented in the form of a huge amount of rough data without any comments or explanations, which made it impossible for the appellant to react accordingly, in particular within the short period of time which was left. As a consequence, the appellant was deprived of the right to be heard.

c) Regarding claim 1 of the main request, it was held that the introduction of "by weight" after the concentration range of 1 to 95% was not allowable under Article 123(2) EPC.

d) As regards auxiliary request 1, the deletion of the feature "by weight" resulted in a widening of the

protection conferred which was not allowable under Article 123(3) EPC.

e) As for the requirements of Article 123(2) EPC in connection with claim 1 of auxiliary request 2, the same reasoning as given for claim 1 of the main request applied. In addition, the combination of hylan as crosslinked polymer with hylan as water-soluble polymer had not been originally disclosed.

X. The respondent's arguments can be summarised as follows:

a) In connection with the admissibility of the claims, it was held that, although the requests had been filed at a late stage of the proceedings, no substantial amendments had been made as compared to the previous requests.

b) As far as the experimental data filed in the course of the appeal procedure are concerned, the respondent argued that the experimental data filed with letter of 11 January 2008 were a reaction to the appellant's argument that the technical effects shown in the examples were not representative for the claims in their entirety. Moreover, the appellant had also filed experimental data very late.

c) Regarding the objections raised under Article 123(2) EPC in connection with claim 1 of the main request, reference was made to the gel slurries according to Tables 1-4, wherein the content of the components in the mixtures were expressed as per cent by weight. In view of the fact that the examples normally are deemed to represent the most authentic disclosure of the

invention, the person skilled in the art, reading the original application as a whole, would deduce directly and unambiguously that the concentration of the polymer solution and the gel phase was expressed in terms of per cent by weight.

d) As regards auxiliary request 1, the deletion of the feature "by weight" did not result in an extension of the protection conferred, as the concentration range of the polymer solution in the gel slurry was simultaneously restricted from 0.01-99.5% to 1-95%.

e) As for the amendments made in claim 1 of auxiliary request 2, reference was made to the arguments developed in connection with claim 1 of the main request. In addition, it was emphasised that claim 1, being restricted to gel slurries comprising hylan both as crosslinked and as water-soluble polymer, was now much closer to the examples according to Tables 1-4. As a consequence, these examples were representative for the entirety of the subject-matter as claimed.

f) In connection with auxiliary requests 3-11, no further arguments were submitted.

XI. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the patent be maintained in amended form on the basis of the main or the first auxiliary request filed with letter dated 5 February 2008, or on the basis of the second auxiliary request filed in the oral proceedings, or on the basis of the third to eleventh auxiliary requests filed as second to

tenth auxiliary requests with letter dated 5 February 2008.

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility of the respondent's main request and auxiliary requests 1 to 11:*

2.1. Apart from the correction of a typing error in claim 5, the present main request is identical to former auxiliary request 1 which the opposition division has found to meet the requirements of the EPC. As a consequence, the present main request is admissible.

2.2. The further amendments made in auxiliary requests 1 to 11 were made as a precautionary measure against possible objections in connection with Articles 84, 123(2), 123(3), 54 and/or 56 EPC. All the amendments were of a clear and simple nature and hence easy to handle so that the appellant-opponent was not taken by surprise in spite of the fact that auxiliary requests 1 and 3 to 11 were filed only one week before the oral proceedings and auxiliary request 2 only at an advanced stage of the oral proceedings. As a consequence, auxiliary requests 1 to 11 are also admissible.

3. *Admissibility of experimental data filed in the course of the appeal procedure:*

3.1. During the appeal proceedings, experimental data were filed by the respondent with letter dated 12 January

2004, with letter dated 17 August 2007 and with letter dated 11 January 2008.

The appellant filed experimental data with letter dated 10 September 2007 and 18 January 2008.

3.2. The board concluded that the experimental data filed with letter dated 11 January 2008 and with letter dated 18 January 2008 were submitted very late so that in each instance the other party did not have sufficient time to check them and to react accordingly. As a consequence, they were not admitted into the proceedings (Article 114(2) EPC).

4. *Main request - amendments (Article 123(2) EPC):*

As compared to claim 1 of the application as originally filed, the following features were, among others, introduced into claim 1 of the main request:
(a) 0.1 to 10% (polymer concentration of the gel)
(b) 1 to 95% (polymer solution in the two-phase mixture)
(c) by weight (in reference to 1 to 95%)
It therefore has to be examined, whether these features are individually disclosed in the application as originally filed and, if in the affirmative, whether there is a basis for the specific combination of these features.

4.1. As far as feature (a) is concerned, reference is made to page 14, lines 22-29, where the range of 0.1 to 10% is disclosed as preferred range for hylan and hyaluronan pure and mixed gels.

4.2. The basis for feature (b) can be found on page 16, lines 19-22 of the application as originally filed, where the range of 1 to 95% is disclosed as a more preferred range.

4.3. Feature (c) is only mentioned in Tables 1-4 which relate to specific examples. There are no passages in the claims or in the general part of the description, where the concentration range of 1 to 95% of the polymer solution is further defined, either by the feature "by weight" or by any other unit. It therefore has to be evaluated, whether or not the person skilled in the art, trying to interpret the range of 1 to 95% as mentioned in present claim 1, would unequivocally apply the definition as given in Tables 1-4 to this general range and exclude any other interpretation.

The respondent argued that the examples constituted the most authentic part of the invention, as a consequence, the skilled person would turn to them in order to find the missing information, all the more so, as they were the only source providing a definition at all for the concentration range of 1 to 95%.

When reading the application as originally filed as a whole in order to interpret the claims, the person skilled in the art will in the present case take into account the heterogeneity of the claimed product: the products of the present invention can be used as implants for a wide variety of different applications which include e.g. controlled drug release, soft tissue augmentation or control of cell movement (see page 4, line 15 to page 5, line 2 of the application as originally filed) which require different gel forms

covering the range from hard fragile gels to very soft deformable fluid-like gels (see page 12, lines 8-12 of the application as originally filed). As a consequence, structurally very different gel slurries are encompassed by claim 1.

In contrast thereto, the gel slurries of examples 1 to 4, to which Tables 1 to 4 refer, cover only a very limited portion of the subject-matter as claimed, in particular in terms of the crosslinked polymer (which is hylan crosslinked with a chemical crosslinking agent in all the said examples 1 to 4), and in terms of the polymer concentration in the gel (which in the said examples cover the range of 0.27% (example 1) to 0.85% (example 3) as compared to a range of 0.1-10% as claimed). As a consequence, the examples 1 to 4 listed in Tables 1 to 4 are not representative for the entire subject-matter of the claims.

As was mentioned above, the present invention includes fluid-like gels, for which the calculation of the concentration in per cent by volume is technically reasonable. For other non-fluid gels according to the present invention, the calculation by per cent by weight may be preferable. The person skilled in the art, taking into consideration the heterogeneity of the gel slurries as claimed, would therefore conclude from the absence of a further definition for the general concentration range of the polymer solution that the range of 1 to 95% is valid for **any** unit including w/w, w/v or v/v. This interpretation is further corroborated by the fact that present claim 1 comprises another concentration range (0.1 to 10% polymer concentration in the swollen gel)

devoid of any further definition, which is therefore also open to any unit that is technically reasonable.

As a consequence, by introducing the term "by weight" into claim 1, a new selection was made for which there is no basis in the application as originally filed. Therefore, the subject-matter of claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

4.4. In the light of the above finding, it is not necessary to examine, whether the combination of features (a) - (c) as defined above is specifically disclosed in the application as originally filed.

5. *Auxiliary request 1 - extent of protection conferred (Article 123(3) EPC):*

5.1. Article 123(3) EPC requires that the claims of a patent may not be amended during opposition proceedings in such a way as to extend the protection conferred. In order to decide whether or not the amendments are allowable under Article 123(3) EPC, it is therefore necessary to compare the protection conferred by the entirety of the claims before amendment, i.e. as granted, with that of the new claims after amendment.

5.2. Claim 1 as granted relates to a gel slurry, wherein the polymer solution in the two phase mixture constitutes from **0.01 to 99.5%** **by weight** and the gel phase constitutes the remainder,

whereas

claim 1 of auxiliary request 1 concerns a gel slurry, wherein the polymer solution in the two phase mixture constitutes from **1 to 95%** and the gel phase constitutes the remainder (emphasis added by the board).

5.3. By deleting the feature "by weight", the extent of protection is *prima facie* enlarged, as the concentration range in question can now be expressed by any unit which is common in the field (such as w/w, w/v, v/w or v/v). Unless the density of both the swollen gel phase and the polymer equals 1, different results, and as a consequence, different compositions are obtained by switching from one unit (e.g. w/w) to another one (e.g. v/v). Therefore, by extending the basis for calculating the concentration from percent by weight to percent in general, claim 1 indeed comprises now *prima facie* gel slurries that were not included in the subject-matter of the claims as granted.

5.4. The respondent pointed out that, compared to the claims as granted, the concentration range for the polymer solution was narrowed down from 0.01-99.5% to 1-95%. As the polymers used for the gel slurries were polyanionic and thus absorbed large quantities of water, the densities of the resulting gel particles as well as of the polymer solution were mandatorily close to 1. As a consequence, no matter which unit was used for expressing the concentration within the more limited range of 1-95% in claim 1 of auxiliary request 1, it was always within the range of 0.01-99.5% by weight as defined in the claims as granted.

5.5. This argument cannot be followed for the following reasons:

5.5.1. Firstly, it is emphasised that, as was already mentioned in paragraph 4.3 above, the subject-matter of the present claims covers a wide variety of compositions which can be used for very different applications. As a consequence, structurally very different polymers are encompassed by the subject-matter as claimed. Although the list of polymers specifically mentioned in claim 1 is short (hyaluronan and hylan for the crosslinked polymer; hyaluronan, hylan, polyvinylpyrrolidone and polyethyleneoxide for the water-soluble polymer), there may be considerable structural variations even within one type of polymer, which in the case of the gel forming polymer include e.g. molecular weight, degree and type of crosslinking, amount and type of polymer co-crosslinked with hylan or hyaluronan or the method of extracting the hyaluronan or hylan. In view of this considerable heterogeneity, as far as the polymeric structure is concerned, it is not credible that the density of all the gel slurries encompassed by the subject-matter as presently claimed is close to 1.

5.5.2. Secondly, it is noted that the claim language does not exclude the presence of additional substances in both the particulate gel phase and in the outer phase of the polymer solution. As these additional substances are not defined, they include components which may modify the density to a considerable extent. It is additionally pointed out that high proportions of these additional substances may be present in both phases, as the concentration of the water-soluble polymer is not defined and the concentration of the crosslinked polymer in the particulate gel phase may be as low as 0.1%. It

follows therefrom that large amounts of these additional substances may be present.

5.6. As a consequence, despite the limitation in connection with the concentration range, the deletion of the feature "by weight" leads to an extension of the protection conferred. Therefore, the requirements of Article 123(3) EPC are not met.

6. *Auxiliary request 2 amendments - (Article 123(2) EPC):*

6.1. Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that both the crosslinked polymer and the water-soluble polymer is hylan. In view of these additional limitations, the reasoning developed in paragraph 4.3 above in connection with the introduction of the feature "by weight" does not automatically apply to claim 1 of the present auxiliary request 2. In particular, the question, whether or not Tables 1-4 are representative of gel slurries which now comprise hylan in both phases is in need of further considerations.

6.2. As was already explained in paragraph 4.3 above, all the examples 1 to 4, to which Tables 1-4 refer, concern gel slurries comprising hylan crosslinked with a chemical crosslinking agent in the particulate gel phase, wherein the polymer concentration is between 0.27% (example 1) and 0.85% by weight (example 3). In each of these examples 1 and 3, as well as in example 2, where the polymer concentration is 0.47%, hylan is used as water-soluble polymer in the outer phase as in present claim 1. Example 4, to which Table 4 refers, is no longer relevant for the subject-matter as claimed in auxiliary request 2, as there PVP and Polyox are used as water-

soluble polymers. In view of these facts, the board is of the opinion that a concentration range of 0.27 to 0.85%, which can be accepted on account of the three individual concentrations of 0.27%, 0.47% and 0.85% of examples 1 to 3, is not representative for the entire range of 0.1 to 10% as claimed. Moreover, said examples do not include gel slurries comprising auto-crosslinked hylan, either. As the examples 1 to 3, to which Tables 1-3 refer, are not representative for the subject-matter as claimed in auxiliary request 2 in its entirety, the introduction of the feature "by weight" into present claim 1 is still not allowable under Article 123(2) EPC.

6.3. In the light of the above finding, it is not necessary to examine, whether the selection of hylan for both the crosslinked and the water-soluble polymer leads to a new combination of features that is not specifically disclosed in the application as originally filed.

7. *Auxiliary requests 3 to 8:*

The argumentation in connection with Article 123(2) EPC as developed in paragraph 4 above in connection with claim 1 of the main request applies *mutatis mutandis* to each claim 1 of auxiliary requests 3 to 8. The amendments made therein do not change the facts and arguments with regard to the non-compliance with the requirements of Article 123(2) EPC caused by the introduction of the feature "by weight".

8. *Auxiliary request 9:*

The subject-matter of claim 1 of auxiliary request 9 is identical to the subject-matter of claim 1 of auxiliary request 2, except that it additionally comprises hylan co-crosslinked with at least one other polymer selected from polysaccharides and proteins. As a consequence, the argumentation in connection with Article 123(2) EPC as developed in paragraph 6 above in connection with claim 1 of auxiliary request 2 applies *mutatis mutandis* to claim 1 of auxiliary request 9.

9. *Auxiliary requests 10 and 11:*

The argumentation in connection with Article 123(2) EPC as developed in paragraph 4 above in connection with claim 1 of the main request applies *mutatis mutandis* to each claim 1 of auxiliary requests 10 and 11. The amendments made therein do not change the facts and arguments with regard to the non-compliance with the requirements of Article 123(2) EPC caused by the introduction of the feature "by weight".

10. As none of the requests on file meets the requirements of Article 123 EPC, a discussion of the further objections raised by the appellant is not necessary.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

A. Townend U. Oswald