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D E C I S I O N
of 31 October 2000

Case Number: T 1156/97 - 3.3.3

Application Number: 92307249.0

Publication Number: 0530987

IPC: C08L 67/04

Language of the proceedings: EN

Title of invention:
Degradable polymer composition

Applicant:
MITSUI CHEMICALS, INC.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 54(2); 56

Keyword:
"Novelty (yes)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-



Case Number: T 1156/97 - 3.3.3

D E C I S I O N
of the Technical Board of Appeal 3.3.3
of 31 October 2000

Appellant: MITSUI CHEMICALS, INC.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office dated 10 April 1997,
issued in writing on 10 July 1997 refusing
European patent application No. 92 307 249.0
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: C. Gérardin
Members: R. Young
A. Lindqvist

Summary of Facts and Submissions

I. European patent application No. 92 307 249.0, filed on 7 August 1992, claiming a JP priority of 8 August 1991 (JP 199163/91) and published under No. 0 530 987, was refused by a decision of the Examining Division dated 10 April 1997 and issued in writing on 10 July 1997. The decision was based *inter alia* on a Main request consisting of a set of Claims 1 to 8 filed on 29 March 1996, Claim 1 of which read as follows:

"1. A degradable polymer composition comprising a mixture of starch or modified starch and a thermoplastic polymer composition essentially consisting of polylactic acid having a molecular weight of 50,000 - 1,000,000 or a lactic acid-hydroxycarboxylic acid copolymer having a molecular weight of 50,000 - 1,000,000."

Claims 2 to 6 were dependent claims directed to elaborations of the degradable polymer composition according to Claim 1.

Claim 7, and independent claim read as follows:

"A method for the production of a degradable polymer composition according to any one of the preceding claims comprising blending the thermoplastic polymer composition and starch and/or modified starch."

Claim 8 was a dependent claim direct to an elaboration of the method according to Claim 7.

The decision was also based on a series of auxiliary requests, namely a First auxiliary request, Auxiliary requests A, B and C; and Auxiliary request 5, as follows:

- First auxiliary request; this request differed from the main request in that the alternative embodiment "or a lactic acid-hydroxycarboxylic acid copolymer" mentioned in Claim 1 was restricted to "or a lactic acid-glycolic acid copolymer";
- Auxiliary request A: This request differed from the main request in that it was limited to the addition of **modified** starch;
- Auxiliary request B: This request differed from the main request in that the alternative embodiment "copolymer" in Claim 1 was limited by the feature "primarily comprising lactic acid";
- Auxiliary request C: This request differed from the main request in that the alternative embodiment "copolymer" in Claim 1 was deleted;
- Auxiliary request 5: This request differed from the main request in that polylactides as disclosed in the prior art had been disclaimed.

II. According to the decision, the subject-matter claimed in the application in suit, although novel, did not involve an inventive step in the sense of Article 56 EPC, having regard to the following state of the art:

D1: EP-A-407 617;

D2: US-A-3 850 863;

D3: WPIL, AN=90 315322 (42), Derwent publications Ltd, London, GB, & JP-A-2222421 (Chuko Kasei Kogyo K. K.), 05.09.1990; and

D4: H.S. Katz and J.V. Milewski, "Handbook of Fillers for Plastics", Van Nostrand Reinhold Company, New York, 1987, page 423.

In particular, the technical problem starting from D1, as the closest state of the art, which disclosed polylactide compositions already having improved degradability or hydrolysability, was to provide further degradable polylactide compositions since there was no evidence on file that the addition of starch or modified starch brought about any additional effect. With regard to the feature by which the subject-matter of Claim 1 differed from D1, i.e. that the polylactide composition also contained starch, it was known from D2, D3 and D4 that naturally occurring polymers, such as starch, could be added to polymer compositions. Hence, an obvious solution of the technical problem would have been to add starch to polylactide compositions according to D1.

Alternatively, starting from the technical problem as described in the application in suit itself, which arose from polylactide compositions without starch, the aim was to provide a polylactide composition exhibiting improved degradability, and the solution was to add starch. It was, however, known from D4, that the addition of starch to non-degradable polymers rendered them degradable (cf. application in suit, page 2, lines 2 to 5).

The argument that polylactic acid was not a "truly biodegradable" polymer, but rather hydrolysed non-enzymatically, in contrast to those of D2 and D3, which were "truly biodegradable", so that the addition of starch would not bring about any change in their degradability, was not accepted, even in the light of an experimental report filed with the submission of 27 March 1996. This was because:

- (i) Polylactic acid was commonly considered to be a biodegradable polymer, belonging to the group of polyhydroxyalkanoates; and
- (ii) The experiments in the report dated 27 March 1996 did not belong to the prior art but rather (a) reflected later findings of the Applicant, (b) had not been carried out under standard conditions, and (c) gave ambiguous results.

Finally, the argument that the cited abstract of D3 was erroneous in its reference to the biodegradability of the polymer being "enhanced" (as opposed to "controlled") was not accepted, since the full translation filed by the Applicant also seemed flawed.

Consequently, the main request did not involve an inventive step.

A similar conclusion applied to Auxiliary request A, since no additional effect over and above that for starch was shown for "modified starch"; to the First auxiliary request and auxiliary requests B and C, respectively, since the restriction they included did not involve a distinguishing feature; and to Auxiliary request 5, since the disclaimer was objectionable under

Article 123(2) EPC and in any case did not affect the inventive step objection.

Quite apart from the above, the term "molecular weight" in Claim 1 of all the requests was not clear in the sense of Article 84 EPC.

- III. On 18 September 1997, a Notice of Appeal against the above decision was filed, the prescribed fee being paid on the same day.

The Statement of Grounds of Appeal, filed on 19 November 1997, in which the Appellant (Applicant) contested the grounds for refusal, was accompanied by two sets of Claims 1 to 8 forming a main request and a first auxiliary request, respectively, and by an experimental report, concerning the effect of adding a modified starch to polylactic acid, in particular upon the degree of necessity of providing a compatibility enhancer, as well as two samples of polymeric products so produced.

- IV. Following the issue, on 11 August 2000, of a communication by the Board, raising *inter alia* the issue of lack of novelty of the claimed subject-matter over the disclosure of D1 and pursuing the issue of lack of inventive step in relation to the same disclosure, the Appellant filed, on 2 October 2000, a further submission which was accompanied by four new sets of claims, forming a main request and three auxiliary requests, respectively, as well as a further experimental report (Reference Example 1).

- V. Oral proceedings were held before the Board on 31 October 2000. At the oral proceedings, the Appellant

presented a further set of Claims 1 to 5 forming a main and sole request. Claim 1 of this set reads as follows:

"1. A microbiologically degradable polymer composition consisting essentially of a mixture of: a modified starch selected from the group consisting of oxidized starch, acetylated starch, etherified starch, crosslinked starch and cationic starch; and polylactic acid having a molecular weight of 50,000 - 1,000,000 or a copolymer of lactic acid and other hydroxycarboxylic acid having a molecular weight of 50,000 - 1,000,000."

Claims 2 and 3 are dependent claims directed to elaborations of the microbiologically degradable polymer composition according to Claim 1.

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

"4. A method for the production of a microbiologically degradable polymer composition according to any one of the preceding claims comprising blending the polylactic acid or copolymer of lactic acid and other hydroxycarboxylic acid and modified starch."

Claim 5 is a dependent claim directed to an elaboration of the method according to Claim 4.

The arguments submitted orally and in writing by the Appellant may be summarized as follows:

- (a) The main claim had been restricted to the case where the starch component was a specified "modified starch", differing from anything disclosed in D1. Furthermore, none of D2, D3 and D4 disclosed polylactic acids. Consequently, there

was novelty.

- (b) As to inventive step, whereas the application in suit concerned the problem of enhancing the degradation rate of artefacts made from polylactic acid in the environment, D1 was concerned with biocompatible polymers which were non-enzymatically hydrolysed *in vivo*. The latter had consequently been tested under conditions which differed from the more alkaline conditions encountered in the environment. The compositions according to D1 would not degrade effectively in soil, as was demonstrated by Reference Example 1, accompanying the Statement of Grounds of Appeal. Thus, the disclosure of D1 did not solve the problem addressed by the application in suit, nor did it suggest the simple method of mixing polylactic acid with a modified starch from the list given in the claims, all of the components, furthermore, being commercially available.
- (c) The disclosures of D2 and D3 did not on the one hand concern polylactic acid, nor on the other hand state that the addition of starch improved biodegradability of the polymers they did disclose. On the contrary, a closer examination of Examples 47 to 64 of D2 showed that starch was one of the worst performing of the additives tested with regard to enhancement of biodegradability. Furthermore, the experimental data filed with the submission of 27 March 1996 showed that the biodegradability of the polymers disclosed in D2 and D3 was in fact unaffected by addition of starch (Statement of Grounds of Appeal, page 5).

- (d) Whilst D4 referred generally to the fact that starches had been proposed as a filler for rendering plastics biodegradable, and more particularly to its being successfully "compounded" with, e.g. polyethylene, the general validity of this statement was denied by the description of the prior art in the following document:

D6: EP-A-0 444 880,

which had been cited in the European Search report, and according to which articles in the form of a sheet or film wherein polyethylene was incorporated with 6-25% by weight of starch were not completely biodecomposable (page 2, lines 21 to 25). This was corroborated by Comparative Example 3 according to the application in suit in which a film hot-pressed from a pellet containing 60 g polyethylene and 40 g of soluble starch maintained its shape in a compost at 40°C even after six months. The disclosure of D4 had to be seen in the light of this contradicting evidence.

- (e) The term "molecular weight" in all the requests had been used without qualification in the relevant state of the art including a granted European patent belonging to the Appellant, so that its unqualified use corresponded to normal practice in the field. The term should not be regarded as unclear.

VI. The Appellant requested that the decision under appeal be set aside, and a patent granted on the basis of Claims 1 to 5 of the main request filed during oral

proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. *Admissibility of amendments*

Claim 1 is supported by a combination of Claims 1 and 6 of the application as originally filed, read in conjunction with the list of modified starches bridging pages 4 and 5 of the description as originally filed (printed specification, column 3, lines 14 to 21), as well as the reference to "microbiologically decomposable polymers" on page 3, line 20 of the description as originally filed (printed specification, column 2, line 26), the terms "decomposable" and "degradable" being, in the context of the application in suit, synonymous,

Claims 2 and 3 correspond to Claims 2 and 3 of the application as originally filed, subject to the introduction of the term "microbiologically" in conformity with amended Claim 1.

Claims 4 and 5 correspond to Claims 7 and 8 of the application as originally filed, subject to amendments providing consistency with the amended Claim 1.

Since all the claims find a basis in the documents of the application as originally filed, the amendments are admissible under Article 123(2) EPC.

3. *Clarity; interpretation*

3.1 The objection, in the decision under appeal, to the unqualified use of the term "molecular weight" in Claim 1 of all the requests was based on the concept that a different, more precise expression of the molecular weight was required than that which had been given, since the term "molecular weight of 50,000 to 1,000,000" indicated only that polymers with a very low molecular weight were excluded (Reasons for the Decision, point 3.1, final paragraph).

The Board concurs entirely with the latter part of this finding, since it is evident from the disclosure of the application in suit, that no particular limitation is imposed upon the molecular weight of the polymer (sentence bridging pages 5 and 6). Whilst the preferred molecular weight is stated usually to be from 50,000 to 1,000,000 (page 6, lines 1 to 2), this is only a preferable range to provide a compromise avoiding unpractically low strength and excessively high melt viscosity (page 6, lines 2 to 6). On the contrary, it is evident that the only sense in which a molecular weight of 50,000 or more can be regarded as essential to the definition of the invention is to confine it to the area of occurrence of the technical problem. In the latter connection, it is stated that, "The degradation rate of polymer primarily comprising polylactic acid is almost determined by the hydrolysis rate of polylactic acid, and is relatively slow as compared with that of other microbiologically decomposable polymers." (page 3, lines 17 to 20; printed specification, column 2, lines 23 to 27). Furthermore, "Particularly in the case of polylactic acid having a high molecular weight, for example 50,000 or more, the degradation rate is remarkably slow and it is hence desired to find a method for accelerating the decomposition." (page 3,

lines 21 to 24; printed specification, column 2, lines 28 to 32).

Thus, it is evident that subjective considerations determined the effective onset of the problem with which the application in suit is concerned, since the problem of slow degradation does not arise or does not arise sufficiently acutely to make it desirable to find a solution, with polylactic acids of low molecular weight, but on the contrary occurs at a molecular weight of 50,000 or more.

The Board is in this connection unable to discern any element of contradiction which would constitute a source of obscurity with regard to the kind of polylactic acids covered by Claim 1. Nor does the Board see any reason to justify the demand, in the decision under appeal, for a more precise definition of the molecular weight containing further information e.g. concerning the distribution of chain length within the polymer, since this is irrelevant to the nature of the technical problem.

Indeed, the Board is unable to discern any source of obscurity at all in the simple expression of molecular weight as stated in Claim 1, particularly since this would appear to do no more than reflect the practice in countless other documents including those mentioned by the Appellant, in which a similar broad statement of molecular weight is expressed. Consequently the definition of "molecular weight" in Claim 1 meets the requirement of clarity pursuant to Article 84 EPC.

3.2 As regards the term "microbiologically degradable" used in Claim 1 in relation to the polymer composition, it

has been the consistent position of the Appellant, that polylactic acid is not a "truly biodegradable" polymer in the sense that it can be completely converted to carbon dioxide and energy by microorganisms such as bacteria, fungi and algae, since it hydrolyses non-enzymatically (Statement of Grounds of Appeal, paragraphs 4.1.2 and 4.2.3). The Board sees no reason to doubt the validity of this submission, especially since it is corroborated by the disclosures of D1 in relation to lactic acid polymers (page 2, lines 8 and 9; page 3, lines 3 and 2 from the foot of the page); of D2 in relation to "truly biodegradable" polymers such as epsilon-caprolactone, and naturally occurring biodegradable products such as tree bark, corn starch etc., (column 1, lines 23 to 29; column 3, lines 42 to 53), and of D5 in relation to the nature of biodegradability itself (page 13/29, left column, "Biodegradability").

In this connection, it is evident from the statement in the description, that "the hydrolysis rate of polylactic acid...is relatively slow as compared to that of other microbiologically decomposable polymers", that the term "microbiologically decomposable" can apply to polylactic acid itself, only in the sense of a comparison of its rate of degradation with that of other polymers which are biodegradable by microorganisms when placed in a relevant moist environment such as soil or sea water (cf. page 2, lines 15 to 17).

Thus, it is evident that the epithet "microbiologically degradable" in Claim 1 refers to the polymer composition as a whole and not specifically to the lactic acid polymer or copolymer component thereof.

In summary, Claim 1 is directed to a composition containing a lactic acid polymer or copolymer which is not itself "truly biodegradable" but which, in combination with the other component(s) of the composition, becomes an integral component of a composition which is indeed microbiologically degradable.

4. *Late-filed document*

The Appellant referred, for the first time at the oral proceedings, to the following document:

D6: EP-A-0 444 880.

The reference was cited in support of an argument concerning the extent of the general knowledge of the person skilled in the art in relation to the expected effects of incorporating starch in a sheet or film of polyethylene (page 2, lines 21 to 29).

Whilst D6, a document cited in the European search report, did not form part of the proceedings, in that it was not referred to in the decision under appeal, or indeed any other communication of the Examining Division, nevertheless the acknowledgment of prior art which it contains formed a relevant source of information upon which the Appellant wished to rely at the oral proceedings, and the Board sees no reason to exclude this. Consequently, the content of the document is introduced into the proceedings under Article 114(1) EPC.

5. *Novelty*

Whilst no objection of lack of novelty had been raised against the subject-matter claimed in the application in suit in the decision under appeal, and none arises, in the view of the Board, in relation to the disclosure of D6 (which in any case only forms state of the art in the sense of Article 54(3) EPC), nevertheless such an objection had been raised by the Board, in relation to D1, in its communication issued on 11 August 2000. It is only in respect of this latter objection that the issue of novelty needs to be addressed in the present decision.

5.1 According to D1, the hydrolysability of a biocompatible polyester having recurring structural units derived from glycolic acid and/or lactic acid, for use in medical devices such as surgical sutures, matrices of sustained release preparations and an internal split-plate in fracture care, is improved in that the polymer chain contains an introduced saccharide bonded thereto (page 1; "Technical Field"). In particular, a lactic homopolymer of high molecular weight may be processed into biocompatible plates for use in fracture care (page 9, second paragraph, last sentence).

The saccharide is of generally low toxicity and may be mono-oligo- or polysaccharide, or a glucoside. The polysaccharide may be amylose, dextran, starch, pullulan, cellulose or galactan (paragraph bridging pages 9 and 10). The amount of saccharide may be from 0.001 to 1% by mole per mole of glycolide and/or lactide where strength is required of the biocompatible polyester. For applications where strength is not required, the saccharide can be used in a hydroxyl

group concentration of about 100% by mole per mole of glycolide and/or lactide (last two paragraphs on page 10; first complete paragraph on page 11). The biocompatible polyester thus obtained consists essentially of a structure wherein a saccharide skeleton is bonded to the molecular structure of the polymer (page 12, second complete paragraph). Where the polymerisation is carried out in the presence of a polysaccharide, the polymer has a structure wherein polyester chains are extended from a polysaccharide chain like a comb. Increase in the amount of polysaccharide leads to a shorter length of polyester chains bonded to the polysaccharide skeleton (page 14, second complete paragraph).

The difference in polymer structure is shown by different properties, for example, improvement in hydrolysability, reduction in melt viscosity, improvement of solubility in solvents, and lowering or elimination of melting point in the polyester (page 13 penultimate complete paragraph).

According to the examples, the hydrolysability of the polyester product was measured in terms of percentage molecular weight retention of a film sample in the presence of a phosphoric acid/citric acid buffer solution having a pH of 7.3 at 37°C for a specified time (page 15 and 16, paragraph "Hydrolysability").

In particular, a polylactic acid product, formed by reacting lactide with 0.02 weight % of starch and having a molecular weight of 30,000, a melting point of 173°C and being insoluble in methanol, had a molecular weight retention of 20% after hydrolysis for two weeks (Table 1; Example 4). Furthermore, such a product

formed by reacting lactide with 0.02 weight % of dextrin, having a molecular weight of 110,000, a melting point of 177°C and being insoluble in methanol had a molecular weight retention of 83% after hydrolysis for two weeks (Table 1; Example 5). Finally, such a product formed by reacting lactide with 0.02 weight % of dextran, having a molecular weight of 54,000, a melting point of 176°C and being insoluble in methanol, had a molecular weight retention of 65% after hydrolysis for two weeks (Table 1; Example 6).

- 5.2 Whilst the most relevant disclosure of D1 mentions the reaction product of starch, dextrin and dextran, respectively, with lactide, all of which may be regarded as esterified products of some kind, none of them corresponds to the only such species recited in Claim 1 in the application in suit, which is acetylated starch. Nor does D1 disclose a physical mixture of a relevant modified starch with a lactic acid polymer. Consequently, the disclosure of D1 is not novelty destroying for Claim 1 of the application in suit. Similar considerations apply to the subject-matter of the dependent Claims 2 and 3 and also to the method according to Claims 4 and 5, which both require the formation of a composition according to Claim 1.

Since no other objection of lack of novelty has been raised, the subject-matter claimed in the application in suit is held to be novel.

6. *The application in suit; the technical problem*

The application in suit relates to a degradable polymer composition consisting essentially of a modified starch and polylactic acid having a molecular weight of 50,000

to 1,000,000 or a copolymer of lactic acid and other hydroxycarboxylic acid having a molecular weight 50,000 to 1,000,000 (Claim 1).

The problem addressed by the application in suit is that, whilst the lactic acid polymer completely degraded, in a period of about a year (a) in an animal body or (b) when placed in a moist environment such as soil or sea water, the degradation rate of the polymer being almost completely determined by the hydrolysis rate of polylactic acid, this was relatively slow. Particularly in the case of polylactic acid having a high molecular weight, for example 50,000 or more, the degradation rate was remarkably slow and it was hence desired to find a method for accelerating the decomposition (page 2, lines 12 to 18; page 3, lines 17 to 24).

- 6.1 Aspect (a) of the problem is solved according to D1, which, by common consent, represented the closest state of the art, by modifying the structure of the lactic acid polymer so that the polymer chains are extended from the polysaccharide chain like a comb, and the non-enzymatic (*in vivo*) hydrolysis rate is improved (section 5.1, above).
- 6.2 Compared with this state of the art, the technical problem objectively arising may be seen in aspect (b) referred to above, i.e. in improving the degradation rate not in an animal body ("*in vivo*") but in a moist environment such as soil or sea water, without changing the remaining properties and in a simple way which does not involve altering the polylactic acid molecule.
- 6.3 The solution proposed according to Claim 1 of the

application in suit is:

- (i) To choose, as modified starch, a member selected from the group consisting of oxidised starch, acetylated starch, etherified starch, cross-linked starch and cationic starch; and
- (ii) To combine this with the lactic acid polymer by physical admixture and not by chemical reaction; so that
- (iii) The resulting composition is microbiologically degradable in a relevant moist environment such as soil or sea water.

6.4 It can be seen from the examples of the application in suit, in particular Examples 5 and 6, that a physical mixture of 40 g of poly-L-lactic acid having an average molecular weight of 120,000 and 60 g of carboxymethylated starch (Example 5) or acetylated starch (Example 6), having been uniformly kneaded at 190°C, extruded, cut into a pellet and hot-pressed at 180°C into a film having a thickness of 25 µm, after being buried in a compost at 40°C for a degradation test disappeared after about a week, whereas a similar film, consisting only of poly-L-lactic acid, after being subjected to a similar degradation test, still retained its shape after six weeks (Comparative Example 1). It can, furthermore, be seen from the Reference Example 1, filed with the submission of 27 September 2000, that a product of reacting L-lactic acid with approximately 0.02% by weight of starch, analogously to the procedure exemplified in D1, also still retained its shape after six weeks in a compost at 40°C. In other words, the compositions according to

the application in suit not only degrade more rapidly in a relevant moist environment than does pure polylactic acid, but such a composition also degrades more rapidly than a product according to the closest prior art. Thus, it is credible to the Board that the claimed measures provide an effective solution of technical problem.

7. *Inventive step*

7.1 There is no hint to the solution of the technical problem in D1, since the latter does not set out to provide a composition which is microbiologically degradable in the sense of the application in suit, but rather to enhance the rate of non-enzymatic ("in vivo") hydrolysis. In any case, there is no disclosure or suggestion to replace the reaction product of starch etc., and lactide with a physical mixture of a relevant modified starch and a lactic acid polymer. On the contrary, the teaching of D1 is to avoid long molecular chains of polylactic acid by forming a comb-like structure in which shorter such chains are extended from the polysaccharide chain, whereby an increase in the amount of polysaccharide leads to shorter length of the chains bonded to the polysaccharide skeleton and thus to a lower effective molecular weight (page 4, second complete paragraph).

7.2 According to D2, there are disclosed blends comprising a biodegradable thermoplastic oxyalkanoyl polymer such as epsilon-caprolactone homopolymer and naturally occurring biodegradable material such as corn starch, hydroxypropylcellulose, Douglas fir bark, brewer's yeast or shredded paper for use as mulch films, transplanter containers, or other disposable containers

(column 1, lines 23 to 29; column 3, lines 42 to 53; column 11, 12, Table VI).

Not only does the disclosure fail to mention lactic acid polymers, but it exclusively concerns polymers which, in contrast to lactic acid polymers, are truly biodegradable. Furthermore, there is no statement or, indeed suggestion, in D2, that the addition of the naturally-occurring component actually enhances the biodegradability of the oxyalkanoyl polymer referred to. Finally, there is no mention of a modified starch falling within the terms of the solution to the technical problem.

- 7.2.1 The argument in the decision under appeal, that the evidence filed by the Appellant (then the Applicant) on 29 March 1996, according to which the addition of starch to a poly epsilon-caprolactone according to D2 did **not** enhance biodegradability, was not relevant, because it did not belong to the state of the art, is not convincing to the Board, for the following reason. There is in any case no suggestion in the state of the art represented by D2 that the addition of the naturally-occurring second component, such as starch, enhances the biodegradability of the polymers disclosed. On the contrary, closer examination of the results shown in Table VI shows that, of the various naturally occurring additives, starch apparently provides the lowest weight loss in the series tested (Example No. 50: weight loss of only 6.2% after two months using 20% corn starch and 80% poly epsilon-caprolactone; compared with, say, Example No. 55: weight loss of 40.4% using 20% brewer's yeast and 80% poly epsilon-caprolactone). Whilst the biodegradability tests according to the submission of 29 March 1996 were

carried out in "compost", as opposed to with specific, named microorganisms as in D2, they are relevant to the technical problem, sufficiently precise, and in any case have the same significance as the latter tests, namely that the absence of any hint in D2 to the relevant effect is merely a reflection of the absence, in reality, of the relevant effect, should the skilled person choose to investigate the matter further.

7.2.2 The further argument, that the skilled person would not have understood the difference between a "truly biodegradable" polymer such as poly epsilon-caprolactone according to D2 and a lactic acid polymer according to the application in suit, since the latter were widely referred to as being "biodegradable" is also not convincing to the Board, since the skilled person cannot be assumed to be the victim of a misapprehension concerning some relevant fact in the art, even if widely held.

7.2.3 Consequently, there is no hint to the solution of the technical problem in the teaching of D2.

7.3 Similar considerations apply to the disclosure of D3, which relates to a biodegradable composite material characterised by coating, on a substrate primarily consisting of a vegetable fibre, an aqueous emulsion of a copolymer of polyhydroxybutyric acid-polyhydroxyvaleric acid, since (a) the latter polymers are, like those according to D2, "truly biodegradable", in contrast to those according to the application in suit, as would be well understood by the skilled person (section 7.2.2, above); and (b) the evidence filed by the Appellant on 29 March 1996 confirms that there is in fact no enhancement of biodegradability of such

copolymers by addition of starch.

- 7.3.1 The argument in the decision under appeal, according to which the statement, in a sworn translation of the Japanese document D3 by the Appellant, filed on 12 March 1997, that the reference to the addition of natural high polymers such as starch was to "control" the biodegradation rate in the soil, rather than it being "enhanced", as stated in the abstract cited in the proceedings, could not be taken into consideration, in view of some further unclarity in the former, is not, in the Board's view, a sufficient reason for ignoring not only the relevant passage of the sworn translation (which was not unclear) but also the relevant evidence filed by the Appellant confirming that no such effect is obtained, and for which no valid reason for putting in doubt has been given.
- 7.3.2 Consequently, there is no hint to the solution of the technical problem in the teaching of D3.
- 7.4 The general statement in D4, that starch has been added as a filler for rendering plastics biodegradable (page 423) is extremely vague. Furthermore, to the extent that it is made in connection with a particular polymer, only polyethylene is specifically mentioned as being able to be degraded. In this connection, however, the acknowledgement of prior art in D6 makes it clear, in relation to the addition of starch to this same polyethylene, even in high quantities of 6 to 25% by weight, that such products still maintain their structure and are not disintegrated into pieces even if the contained starch is completely biodecomposed (D6, page 2, lines 21 to 25). Hence, the general statement in D4 cannot be regarded as being either sufficiently

reliable to be regarded as generally true, or, to amount, therefore, to a relevant hint to the skilled person in the direction of solving the technical problem.

7.5 In summary, the solution of the technical problem does not arise in an obvious way from the state of the art. Thus, the subject-matter of Claim 1 involves an inventive step. By the same token, the subject-matter of dependent Claims 2 and 3 also involves an inventive step. Furthermore, the subject-matter of Claims 4 and 5, which are limited to the formation of a composition according to Claim 1, equally involves an inventive step.

8. In view of the above, the Main request is allowable. It is not, therefore, necessary for the Board further to consider the claims of the auxiliary requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division with the order to grant a patent on the basis of Claims 1 to 5 submitted as main request during oral proceedings, after any consequential amendment of the description.

The Registrar:

The Chairman:

E. Görgmaier

C. Gérardin