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D E C I S I O N
of 18 September 2000

Case Number: T 1107/97 - 3.3.3

Application Number: 93116263.0

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IPC: C08G 63/06

Language of the proceedings: EN

Title of invention:

Polyhydroxycarboxylic acid and purification process thereof

Applicant:

MITSUI CHEMICALS, INC.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 84

Keyword:

"Claims - clarity (yes)"
"Claims - novelty (yes)"
"Claims - inventive step (yes)"

Decisions cited:

G 0010/93

Catchword:

-



Case Number: T 1107/97 - 3.3.3

D E C I S I O N
of the Technical Board of Appeal 3.3.3
of 18 September 2000

Appellant: MITSUI CHEMICALS, INC.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office dated and issued in
writing on 23 June 1997 refusing European patent
application No. 93 116 263.0 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. 93 116 263.0, filed on 7 October 1993, claiming a JP priority of 9 October 1992 (JP 271477/92) and published under No. 0 591 978, was refused by a decision of the Examining Division issued on 23 June 1997. The decision was based on a set of Claims 1 to 6, which had been filed on 18 December 1996. Claim 1 read as follows:

"A purification process of a polyhydroxycarboxylic acid having a inherent viscosity of 0.1 to 5.0 dl/g comprising contacting the solid polyhydroxycarboxylic acid with an inorganic acid in the presence of an organic solvent, wherein the polyhydroxycarboxylic acid to be purified is not dissolved in the organic solvent."

Claims 2, 3 and 4 were dependent claims directed to elaborations of the process according to Claim 1.

Claim 5, an independent claim, read as follows:

"A purified product obtainable by a process according to any of the claims 1 to 4."

Claim 6 was a dependent claim directed to a preferred embodiment of the product according to Claim 5.

II. The grounds of refusal relied upon in the decision were:

(i) lack of clarity (Article 84 EPC);

(ii) lack of novelty having regard to the disclosures

of

D1: EP-A-0 469 520; and

D2: EP-A-0 270 987; as well as

(iii) lack of inventive step having regard to the disclosure of

D3: US-A-3 629 202,

if necessary in combination with D2.

In relation to the ground (i) of refusal, the decision held as follows.

- (a) It was neither clear why the term "solvent" was used in Claim 1 if the polymer should not dissolve in it, nor how the polymer would be prevented from dissolving in it, where the latter was a well-known solvent, such as acetone, for e.g. polylactic acid. Consequently, it had to be assumed that at least a part of the polymer dissolved.
- (b) The application evidently related only to the purification of polymers of **aliphatic** hydroxycarboxylic acids, yet this feature, which was consequently essential, had not been included in Claim 1.
- (c) It was not credible that contacting the polymer in the form of a solid block with a small amount of an acid, as referred to in the description, could reduce to any noticeable extent the

catalyst content of the polymer, since the catalyst residues could only be removed efficiently from a finally divided polymer. Consequently, the feature of bulk density of the polymer was an essential feature which should have been included in Claim 1 properly to define the subject-matter for which protection was sought.

With regard to the ground (ii) of refusal, D1 was held to be novelty-destroying for the subject-matter of product Claims 5 and 6, since it was immaterial by what process the polymers had been purified, and D2 for the subject-matter of process Claims 1, 2 and 4, taking into account the lack of clarity objections, since the border between the subject-matter claimed in the application in suit and the disclosure of D2 was vague.

As regards the ground (iii) of refusal, D3 was considered to be the closest state of the art, from which the process according to the application in suit differed only in that a polyester derived from a hydroxycarboxylic acid was submitted to the purification step and in that an inorganic acid was used for treating the polymer. Since, however, in both D3 and the application in suit the problem to be solved was the same, and it had neither been alleged nor demonstrated that the inorganic acids unexpectedly led to any particular technical effect, such as more efficient removal of catalyst, such inorganic acids being used in similar processes according to D2, the application in suit merely represented an obvious extension of the teaching of D3 and was thus devoid of inventive merit.

III. On 27 August 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 9 October 1997, was accompanied by an amended set of Claims 1 to 6 together with revised pages of description, and an extract from Römpp's Chemie Lexikon, page 2396 relating to "Lösungsmittel" (solvent).

The amended claims were identical with those underlying the decision under appeal, except that the term "polyhydroxycarboxylic acid" had been replaced by "aliphatic polyhydroxycarboxylic acid".

The Appellant argued in substance as follows.

(i)(a) There was no unclarity in the term "solvent", since the term had been used as meaning a "common organic solvent", as defined in Römpp's Chemie Lexikon (page 2396). It was furthermore clear from the fact that the latter listed several kinds of typical organic solvents, that the term "organic solvent" was used as a general term, irrespective of the solubilising properties of the individual solvents with respect to different substances and notwithstanding the fact that there were many substances known not to be dissolved by at least some of the classes of the chemical compounds listed. The usage of the term was no different from that in D3 which defined several solvents which were used to swell, but not dissolve the polymer, or indeed in the decision under appeal itself, which found that aqueous solutions of mineral acids were not soluble in

"common organic solvents". The role of the organic solvent in the process according to the application in suit was to facilitate the contact of the inorganic acid with the metal catalyst and transport the former into the inside of the polymer.

The choice of a suitable solvent could easily be made by someone of average skill in the art. Several examples were discussed in the description, and in a further document (D2) referred to in the description. The latter document stated that the solubility of the polymers was strongly dependent upon their composition and could be determined by easy experiments. Consequently, whether a specific organic solvent was a polymer solvent or not could be found out by someone of skill in the art without difficulties or undue burden.

In view of the above, it was evident that the use of the term "organic solvent" in Claim 1 was not obscure.

- (b) The amendment to Claim 1 to include a restriction to "aliphatic" polymers overcame the relevant objection raised in the decision under appeal.
- (c) The feature of the upper limit of the bulk density was not necessary properly to define the subject-matter for which protection was sought. It was clear from D3, for instance, that whilst the physical form of the polymer would require the choice of suitable treatment

conditions, a polymer of a certain physical form was not generally excluded as a starting material for the purification process according to the application in suit.

In summary, the requirements of Article 84 EPC were met by Claim 1.

- (ii) With regard to the finding of lack of novelty, the Appellant argued substantially as follows:
 - (a) The decision under appeal had acknowledged novelty in respect of the method claims, but found lack of novelty in the product claims. Since the claimed process was different from that according to D1, however, the products obtained were also different. Hence, the novel process led to a novel product.
 - (b) Although it had been found that the process according to Claims 1, 2 and 4 lacked novelty in the light of D2, the prior art method required a complete dissolution of the polymer, whereas according to the claimed method, a solid polymer was treated. Consequently, the two methods were based on different principles, there being no vagueness in the border between the two methods. Thus, D2 was not novelty-destroying for the process according to the application in suit.
- (iii) With regard to the finding of lack of inventive step, starting from D3, which, according to the decision under appeal, was the closest state of the art, the skilled person wishing to devise a

further purification process of an aliphatic polyhydroxycarboxylic acid would have to consider at least three modifications of the prior art method:

- (a) Application of the method to a different class of compounds;
- (b) Selection of the physical form of the compounds to be treated; and
- (c) Development of a different purification system.

None of these modifications was, however, suggested by D3. Nor would a combination with the disclosure of D2 assist the skilled person, because the latter also related to a process in which the polymer was completely dissolved.

Consequently, the process according to the application in suit was based on an inventive step.

IV. In a further submission, received on 24 November 1997, the Appellant filed two further sets of claims to form a first and second auxiliary request respectively, each set of claims being accompanied by amended pages of description. The first auxiliary request was a set of Claims 1 to 4, corresponding to Claims 1 to 4 filed with the Statement of Grounds of Appeal, the product Claims 5 and 6 of the latter having been deleted. The second auxiliary request was a set of Claims 1 to 3.

V. Finally, with a submission received on 28 July 2000, the Appellant replaced all the claims on file by two

further amended sets of claims, consisting of a set of Claims 1 to 4 forming a main request and a set of Claims 1 to 3 forming an auxiliary request, each accompanied by amended pages of description.

Claim 1 of the main request reads as follows:

"1. A process for removing a catalyst from an aliphatic polyhydroxycarboxylic acid having an inherent viscosity of 0.1 to 5.0 dl/g obtained by polymerisation using the catalyst, comprising contacting the solid aliphatic polyhydroxycarboxylic acid with an inorganic acid in the presence of an organic solvent, wherein the aliphatic polyhydroxycarboxylic acid to be purified is not dissolved in the organic solvent."

Claims 2 to 4 are dependent claims directed to elaborations of the process according to Claim 1.

VI. The Appellant requested that the decision under appeal be set aside, and a patent granted on the basis of the claims according to the main request, or in the alternative, on the basis of the claims according to the auxiliary request, both filed on 28 July 2000 (letter dated 28 July 2000).

Reasons for the Decision

1. The appeal is admissible.
2. *Admissibility of amendments (main request)*

Claim 1 differs from Claim 1 underlying the decision under appeal only in that the general formulation "a purification process of an aliphatic polyhydroxycarboxylic..." has been replaced by a more specific reference to "a process for removing catalyst from an aliphatic polyhydroxycarboxylic acid ... obtained by polymerisation using the catalyst,...".

The essence of the term "purification" is in this connection implicit in the reference to removing catalyst, so that the deletion of this term does not lead to any inconsistency with the disclosure as originally filed. Furthermore, the latter reference finds a basis in the first paragraph of the "summary of the invention" on page 4 of the description of the application in suit as originally filed.

Claims 2 to 4 correspond to Claims 2 to 4, respectively, underlying the decision under appeal subject to the deletion, consistently with Claim 1, of the term "purification" before "process".

According to the decision under appeal, the amendments to the claims were allowable under Article 123(2) EPC. The Board sees no reason to take a different view of the matter, and the further amendment of Claim 1 referred to above is also allowable under Article 123(2) EPC for the reasons given. Thus, the claims are admissible under Article 123(2) EPC.

3. *Clarity (main request)*

- (a) With regard to the term "organic solvent" in Claim 1, the Board sees no reason to depart from the normal rule of interpretation that a word is to be construed as having its natural and ordinary meaning, unless otherwise indicated. In this connection, there is nothing in the description to suggest another usage of the term "organic solvent" in the relevant context than that which would be generally understood as the natural and ordinary meaning. Such a meaning would correspond, in the Board's view, to a dictionary definition, such as that filed by the Appellant together with the Statement of Grounds of Appeal (Römpps Chemie Lexikon, pages 2396 to 2399), in which the German equivalent term "Lösungsmittel" (corresponding to the English "solvents" - see page 2398, right-hand column, line 9) is defined. It is evident from this definition that substances are to be understood in the broadest sense which are capable of bringing others by physical means into solution, and in a narrower sense inorganic and organic liquids, which are able to dissolve other gaseous, liquid or solid substances.

There is, however, no reference in the definition to particular quantitative capabilities of dissolving specific substances. Thus, the extent of dissolution of a substance is not an essential component of the definition of a "solvent". Hence, the question of whether a substance is completely or incompletely dissolved in a "solvent" has no bearing on the clarity of the

latter term.

Consequently, the Board is unable to support the criticism, in the decision under appeal, that the term "solvent" was rendered obscure by the simple fact that the polymer was not dissolved in it (reasons for the decision, point 3.1). Nor is there any support, evidential or otherwise, for the speculation, in the same section of the decision, that the effect of the invention (the removal of catalyst residues) would most probably not be achieved unless at least a part of the polymer dissolved in such a solvent (point 3.1, third paragraph).

In summary, there is no contradiction in the requirement, in Claim 1, for the polymer to be present in, but not dissolved by, the "solvent". Thus the term "organic solvent" in Claim 1 is clear in the sense of Article 84 EPC.

- (b) The basis for the objection, in the decision under appeal, to the absence, from Claim 1, of a limitation to "aliphatic" polyhydroxycarboxylic acids, has been removed by the introduction, into claim 1, of the relevant limitation. Consequently, this ground of refusal of the application has been adequately met (Reasons for the decision, point 3.2).
- (c) The assertion, in the decision under appeal, that the polymer must necessarily be in powder form for an efficient removal of the catalyst is not supported by so much as a scrap of evidence. Nor is it supported by the teaching of the

application in suit, which presents the bulk density consistently as a preferred feature. On the contrary, according to the evidence of the disclosure of D3, cited in the decision under appeal as the closest state of the art (Reasons for the decision, point 5), "catalyst residues may be removed by extraction either from the solid polymer or from a solution. When extracting from a solid polymer, the form of the polymer is immaterial except that the catalyst residues may be extracted at a faster rate when the ratio of surface to volume of the polymer is made larger.". Thus, it is evident from the relevant state of the art, that a particular form of the polymer is not necessary.

For the above reasons, the Board is unable to support the finding of the decision under appeal, that the bulk density limitation according to claim 3 was an essential feature (Reasons for the decision, point 3.3). Hence, the absence of this feature from Claim 1 does not lead to any lack of clarity in the sense of Article 84 EPC.

In summary, the claims of the application in suit meet the requirements of clarity set out in Article 84 EPC.

4. *Novelty (main request)*

4.1 The finding, in the decision under appeal, of lack of novelty on the basis of the disclosure of D1, was directed only to the subject-matter of Claims 5 and 6, which related to a product *per se*. Such product claims are, however, no longer present in the application,

since only the process claims have been retained. No objection on the basis of the disclosure of D1 was, however, raised, in the decision under appeal, to the subject-matter of these claims, and the Board sees no reason to take a different view. Consequently, the subject-matter of Claims 1 to 4 is novel in the light of the disclosure of D1.

4.2 According to D2, there is disclosed a method for preparing catalyst-free re-absorbable homopolymers or copolymers, comprising dissolving the catalyst-containing polymer in an organic solvent which is immiscible with water, bringing the resultant solution into contact with water or an aqueous layer containing an inorganic acid, a water soluble organic acid or a water soluble complexing agent, separating the organic layer and isolating the polymer by a process known *per se* (Claim 9). The solution of the catalyst-containing polymer is a dilute solution having a concentration not exceeding 10% by weight, and preferably having a concentration between 0.5 and 4% by weight, more preferably between 0.5 and 2% by weight (page 7, lines 12 to 22).

4.2.1 Thus it is an essential requirement of the method according to D2, that the polymer is fully dissolved. This is in contrast to Claim 1 of the application in suit which requires that the polymer is a solid and is not dissolved in the organic solvent.

4.2.2 The argument in the decision under appeal, that the question of the state of dissolution of the polymer was rendered vague by an obscurity in the term "solvent" in Claim 1 of the application in suit is not applicable for the reasons given (section 3(a), above).

4.2.3 Consequently, the disclosure of D2 is not novelty destroying for the subject-matter of Claims 1 to 4.

4.3 In summary, the subject-matter claimed in the application in suit is novel.

5. *Inventive step (main request)*

The application in suit is concerned with a process for removing catalyst from a polyester having an inherent viscosity of 0.1 to 5.0 dl/g, comprising contacting the solid polyester with an acid in the presence of an organic solvent, wherein the polyester to be purified is not dissolved in the organic solvent (Claim 1). Such a process is, however, known, for instance from the disclosure of D3, which, according to the decision under appeal, represented the closest state of the art.

5.1 According to D3, there is described a method for reducing the catalyst concentration in a polyester having an inherent viscosity of at least 0.3 derived from a dicarboxylic acid and glycol (e.g. polyethylene terephthalate) which comprises the steps of contacting the polyester in finely divided form with a mixture of a treating agent having an ionization constant of about 2×10^{-1} to 2.5×10^{-6} , in particular acetic acid, acetic anhydride, isobutyric acid and formic acid, and sufficient solvent power alone or in combination with a swelling solvent for the polymer to diffuse through the polyester solid polymer, and separating the metal residues and treating agent from the polyester (Claim 1; and column 2, lines 31 to 37). According to a typical example (Example I) a copolyester of terephthalic acid containing 295 ppm (parts per million) of tin contains only 48 ppm

residual tin after treatment for 3.5 hours on a steam bath with glacial acetic acid. According to a particularly advantageous example (Example XXV), the tin content of a terephthalate copolyester is reduced from 340 ppm to 9 ppm by refluxing with a mixture of acetic anhydride and glacial acetic acid (285:15 by volume) for about 3.5 hours. The treatment results in polyesters of improved thermal and hydrolytic stability.

5.2 The application in suit, by contrast, relates to a process of purifying polyhydroxycarboxylic acid which is used as a biodegradable polymer for medical plastics and substitute for general purpose resin which has an extremely low content of catalyst (page 1, paragraph 1). In this connection, in the case of slow-release medicines, the polymer is decomposed whereas the catalyst remains intact in the tissue. To this extent, the polymer cannot be used because of toxicity of the catalyst (page 2, lines 2 to 5). The polyesters according to D3 are not, however, stated to be biodegradable, and there is no reference to medicinal use. Consequently, the primary aspect of the problem addressed by the application in suit is not recognisable from the disclosure of D3.

5.3 Even if this had been the case, and an attempt were made to establish a technical problem based on the goals which D3 and the application in suit have in common, namely the provision of improved mechanical and thermal properties (application in suit, page 10, lines 13 to 17), it is evident from the examples according to the application in suit, that the reduction in residual metal, e.g. tin content, of a polyhydroxycarboxylic acid, is far greater than that

disclosed in the examples according to D3. In particular, according to a typical example (Example 1 in conjunction with Table 1) an initial tin content of 560 ppm is reduced to 4 ppm by treatment with a mixture of 0.5 N hydrochloric acid and ethanol (1/1) at only 35°C for one hour. Furthermore, according to Example 11 in conjunction with Table 1, a tin content of 1500 ppm in a polyhydroxycarboxylic acid copolymer is reduced to only 3 ppm after treatment for four hours at 35°C with a 0.5 N hydrochloric acid/ethanol (2/1) mixture.

Thus, it is evident that the process according to the application in suit is capable of effecting a reduction in residual metal catalyst content of the order of factor of 10 greater than the best example according to D3 (Example XXV).

- 5.3.1 In view of the above, a relevant statement of problem with respect to the disclosure of D3, taking into account the above increased efficiency of catalyst removal, would have to be formulated in terms of "an improved process for removing residual catalyst from a polyester, further allowing a more demanding spectrum of applications".
- 5.3.2 The solution to this problem proposed according to Claim 1 of the application in suit, is to replace the polyethylene terephthalate polymers exemplified in D3 by a biodegradable aliphatic polyhydroxycarboxylic acid, and the organic acid by an inorganic acid.
- 5.3.3 There is, however, no suggestion in D3, either that the scope of application of the method could be extended to biodegradable polyhydroxycarboxylic acids according to the application in suit, or that the specific organic

acids referred to D3 could be replaced by an inorganic acid, let alone that an improved removal of residual metal catalyst would thereby result.

5.3.4 Consequently, there is no hint to the solution of the technical problem in the disclosure of D3.

5.4 Nor is there any hint in this direction in D2, since it is an essential requirement of the latter, that the polymer first be fully dissolved, preferably as a dilute solution, in the organic solvent, and the solution extracted.

5.4.1 The argument in the decision under appeal, that the distinction between having the polymer in solution and having the polymer in non-dissolved form was obscure is irrelevant in view of the finding under clarity (section 3., etc., above).

5.4.2 In any case, to the extent that some part of the polymer might be dissolved in the solvent, such part falls outside the scope of the solution to the technical problem as presented in Claim 1, since the latter requires the polymer to be present in solid, undissolved form.

5.5 In summary, the solution of the technical problem does not arise in an obvious way from the state of the art. Consequently the subject-matter of Claim 1, and therefore of dependent Claims 2 to 4, involves an inventive step within the meaning of Article 56 EPC.

6. It follows from the above, that the main request must be allowed. It is not, therefore, necessary for the Board further to consider the claims of the auxiliary request.

7. With regard to the description, whilst the Board sees no objection to the incorporation of the amended pages 1, 3, 4, 4a, 4b and 5 filed as an attachment to the claims of the main request with the submission of 28 July 2000, nevertheless it notes that a reference remains in the description on page 8, lines 2 and 3, to the use of organic acids such as acetic acid and p-toluenesulfonic acid. These fall outside the scope of Claim 1 and should presumably be cancelled in the course of consequent amendment of the description. This issue is introduced into the proceeding in accordance with G 10/93 (OJ EPO 1995, 172).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is referred back to the Examining Division with the order to grant a patent on the basis of Claims 1 to 4 of the main request filed on 28 July 2000, after any necessary consequential amendment of the description.

The Registrar:

The Chairman:

E. Görgmaier

C. Gérardin