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**Datasheet for the decision
of 10 November 2009**

Case Number: T 0959/08 - 3.3.03

Application Number: 99108344.5

Publication Number: 0953589

IPC: C08G 63/80

Language of the proceedings: EN

Title of invention:

Process for preparing aliphatic hydroxycarboxylic acid polyesters

Applicant:

Mitsui Chemicals, Inc.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 84, 83

Relevant legal provisions (EPC 1973):

-

Keyword:

"Claims - functional feature - result to be achieved understanding and implementing a functional feature"

Decisions cited:

T 0068/85, T 0435/91, T 0713/98

Catchword:

-



Case Number: T 0959/08 - 3.3.03

D E C I S I O N
of the Technical Board of Appeal 3.3.03
of 10 November 2009

Appellant: Mitsui Chemicals, Inc.
5-2, Higashi-Shimbashi 1-Chome
Minato-ku
Tokyo (JP)

Representative: Strehl Schübel-Hopf & Partner
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Decision under appeal: Decision of the Examining Division of the
European Patent Office dated 27 November 2007
and posted 17 December 2007 refusing European
application No. 99108344.5 pursuant to
Article 97(1) EPC 1973.

Composition of the Board:

Chairman: R. Young
Members: W. Sieber
C. Vallet

Summary of Facts and Submissions

I. European patent application No. 99108344.5, filed on 28 April 1999 in the name of Mitsui Chemicals, Inc., claiming four Japanese priorities, and published under number EP 0 953 589 A2, was refused by a decision of the Examining Division which was announced orally on 27 November 2007 and issued in writing on 17 December 2007. The decision was based on a main request and an auxiliary request, the latter being presented during the oral proceedings on 27 November 2007.

Claim 1 of the auxiliary request read as follows (underlined text shows the difference over Claim 1 of the main request):

"A process for producing aliphatic polyesters having a weight-average molecular weight (Mw_2) that falls within a numerical range as defined by the following numerical formula (2) and numerical formula (3) and having at least 50 % of aliphatic hydroxycarboxylic acid units, which comprises polymerizing a crystallized, aliphatic polyester prepolymer having a weight-average molecular weight (Mw_1) that falls within a numerical range as defined by the following numerical formula (1) and having at least 50 % of aliphatic hydroxycarboxylic acid units, in a solid phase in the presence of a volatile catalyst being an organic sulfonic acid compound selected from the group consisting of alkanesulfonic acids having from 1 to 10 carbon atoms, halogen-substituted alkanesulfonic acids, benzenesulfonic acid and benzenesulfonic acid derivatives, naphthalenesulfonic acid and naphthalenesulfonic acid derivatives, wherein the

volatile catalyst is removed during the solid phase polymerization by evaporation at a temperature not higher than the melting point of the polymer by adjusting the type and the amount of the catalyst, the flowing gas and the pressure:

$$2 \times 10^3 \leq Mw_1 \leq 1 \times 10^5 \quad (1),$$

$$5 \times 10^4 \leq Mw_2 \leq 1 \times 10^6 \quad (2),$$

$$Mw_1 < Mw_2 \quad (3),$$

the weight-average molecular weight (Mw) being determined by gel permeation chromatography at a column temperature of 40°C, using chloroform as the solvent by comparison with the molecular weight of a standard sample of polystyrene, and a residual percentage of the catalyst, R, in the product, which is defined by the following numerical formula (10), being at most 50%:

$$R [\%] = C_A [\text{ppm}] \div C_B [\text{ppm}] \times 100 \quad (10)$$

wherein R is the residual percentage of the catalyst [%], and this constitutes an index of the variation in the catalyst concentration before and after the solid-phase polymerization, C_B [ppm] is the theoretical catalyst concentration in the case where all the catalyst as fed into the reaction system before solid-phase polymerization is to remain in the product, aliphatic polyester, and this is represented by the following numerical formula (11), and C_A [ppm] is the actual catalyst concentration in the aliphatic polyester as finally obtained after the solid-phase polymerization, and this is represented by the following numerical formula (12):

$$C_B \text{ [ppm]} = W_B \text{ [g]} \div W_P \text{ [g]} \times 10^6 \quad (11)$$

wherein W_B [g] is the total weight of the catalyst as fed into the reaction system before the solid-phase polymerization, and W_P [g] is the weight of the aliphatic polyester as finally obtained after the solid-phase polymerization,

$$C_A \text{ [ppm]} = W_A \text{ [g]} \div W_P \text{ [g]} \times 10^6 \quad (12)$$

wherein W_A [g] is the weight of the catalyst having remained in the aliphatic polyester as finally obtained after the solid-phase polymerization, and W_P [g] is the weight of the aliphatic polyester as finally obtained after the solid-phase polymerization."

II. According to the decision of the examining division, Claim 1 of the main and the auxiliary requests did not fulfil the requirements of Article 84 EPC. In particular, Claim 1 of neither request provided enough information for the person skilled in the art of how to achieve the desired value of R.

III. On 19 February 2008, the appellant (applicant) filed a notice of appeal against the above decision with simultaneous payment of the prescribed fee.

A statement setting out the grounds of appeal was filed on 22 April 2008. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the claims of the auxiliary request before the examining division. A clean copy

thereof was refiled along with the statement of grounds of appeal.

The arguments of the appellant, as far as they are relevant to this decision, may be summarized as follows:

It was admitted that Claim 1 contained a functional feature which defined a result to be achieved, namely the feature

"wherein the volatile catalyst is removed during the solid-phase polymerisation by evaporation at a temperature not higher than the melting point polymer by adjusting the type and the amount of the catalyst, the flowing gas atmosphere and the pressure".

However, this functional feature met the requirements of Article 84 EPC since it was in line with the established jurisdiction of the Boards of Appeal, *inter alia* T 68/85. It was apparent that the reaction parameters such as reaction time, reaction temperature and flowing rate atmosphere were adjusted in combination in the solid phase polymerization. The person skilled in the art could easily achieve the desired value by adjusting these reaction parameters according to the description and his knowledge. It was within the ordinary skill of the artisan to determine and to calculate, with reasonable experiments, those aliphatic polyesters which had the desired percentage of residual R. Further, in solid phase polymerization, the residual percentage of the catalyst R in the polylactic acid could be monitored by absorbing the catalyst removed from the reaction system with flowing gas into water or the liquid alkaline solution and

- determining the amount of catalyst absorbed by using an appropriate method, eg quantitative titration by acid.
- IV. In a communication dated 28 August 2009 accompanying a summons to oral proceedings, the board drew the appellant's attention to an inconsistency regarding the definition of R in formula (10). In particular, it was pointed out that the combination in Claim 1 of a rather general process requiring no specific sequence of addition of the catalyst with a parameter which required that the catalyst was added at a specific point of the reaction amplified an unclarity already present in the application as filed. As regards the definition of the result to be achieved in Claim 1, objections were raised with regard to the process features "evaporation" and "pressure". Further, attention was drawn to the fact that the claimed process had to fulfil - simultaneously - two conflicting requirements, namely, on the one hand, the presence of enough catalyst to effectively catalyze the reaction, and, on the other hand, the removal of the catalyst during the reaction. The application as filed appeared to be completely silent on this aspect. Thus, it was rather questionable whether a skilled person was indeed in a position to implement the functional feature without undue burden.
- V. In its reply dated 6 October 2009, the appellant filed amended pages 1 and 4 of the claims, and requested that the decision under appeal be set aside and a patent be granted on the basis of the following claims:

- Claim 1 (page 2), Claims 2-7, Claim 8 (pages 3, 5 and 6), Claims 9-17 filed with letter dated 22 April 2008,
- Claim 1 (page 1), Claim 8 (page 4) filed with letter dated 6 October 2009.

Claim 1 as amended read as follows:

"A process for producing aliphatic polyesters having a weight-average molecular weight (Mw_2) that falls within a numerical range as defined by the following numerical formula (2) and numerical formula (3) and having at least 50 % of aliphatic hydroxycarboxylic acid units, which comprises polymerizing a crystallized, aliphatic polyester prepolymer having a weight-average molecular weight (Mw_1) that falls within a numerical range as defined by the following numerical formula (1) and having at least 50 % of aliphatic hydroxycarboxylic acid units, in a solid phase in the presence of a volatile catalyst, ie a catalyst capable of vaporizing away from the reaction system during the reaction, the volatile catalyst being an organic sulfonic acid compound selected from the group consisting of alkanesulfonic acids having from 1 to 10 carbon atoms, halogen-substituted alkanesulfonic acids, benzenesulfonic acid and benzenesulfonic acid derivatives, naphthalenesulfonic acid and naphthalenesulfonic acid derivatives, wherein the volatile catalyst is removed during the solid phase polymerization by evaporation at a temperature of not higher than the melting point of the polymer by adjusting the type and the amount of the catalyst, the

flowing gas atmosphere having a flow rate of 0.02 to 200 ml/min, per gram of the prepolymer:

$$2 \times 10^3 \leq Mw_1 \leq 1 \times 10^5 \quad (1),$$

$$5 \times 10^4 \leq Mw_2 \leq 1 \times 10^6 \quad (2),$$

$$Mw_1 < Mw_2 \quad (3),$$

the weight-average molecular weight (Mw) being determined by gel permeation chromatography at a column temperature of 40°C, using chloroform as the solvent by comparison with the molecular weight of a standard sample of polystyrene, and a residual percentage of the catalyst, R, in the product, which is defined by the following numerical formula (10), being at most 50 %:

$$R [\%] = C_A [\text{ppm}] \div C_B [\text{ppm}] \times 100 \quad (10)$$

wherein R is the residual percentage of the catalyst [%], and this constitutes an index of the variation in the catalyst concentration before and after the solid-phase polymerization,

C_B [ppm] is the theoretical catalyst concentration in the case where all the catalyst as fed into the reaction system before solid-phase polymerization is to remain in the product, aliphatic polyester, and this is represented by the following numerical formula (11), and C_A [ppm] is the actual catalyst concentration in the aliphatic polyester as finally obtained after the solid-phase polymerization, and this is represented by the following numerical formula (12):

$$C_B [\text{ppm}] = W_B [\text{g}] \div W_P [\text{g}] \times 10^6 \quad (11)$$

wherein W_B [g] is the total weight of the catalyst as fed into the reaction system before the solid-phase polymerization, and W_P [g] is the weight of the aliphatic polyester as finally obtained after the solid-phase polymerization,

$$C_A \text{ [ppm]} = W_A \text{ [g]} \div W_P \text{ [g]} \times 10^6 \quad (12)$$

wherein W_A [g] is the weight of the catalyst having remained in the aliphatic polyester as finally obtained after the solid-phase polymerization, and W_P [g] is the weight of the aliphatic polyester as finally obtained after the solid-phase polymerization."

VI. On 10 November 2009, oral proceedings were held before the board where the discussion focussed on the issue as to whether or not the functional feature in Claim 1 defining a result to be achieved met the requirements of Article 84 and/or 83 EPC. In particular, the board drew the appellants attention to the complete absence of a coherent and convergent teaching in the application as filed, and the equivocal presentation of various process variables in the description (such as the melting point of the polymer, the pressure), which was, to say the least, not very helpful for finding a technical concept fit for generalization how to reliably and consistently get the desired result. In this context, also the comparative example filed by the appellant on 10 August 2006 during examination was discussed.

The thrust of the appellant's argument was that a person skilled in the art would know from his general knowledge and the information provided in the

application as filed how to achieve the desired result, once he has understood the general concept of the invention, namely the removal of the catalyst.

The board drew the appellant's attention also to an unclarity in the definition of R in formula (10), being the result of the combination of a rather general process requiring no specific sequence of addition of the catalyst with a parameter which required that the catalyst was added at a specific point of the reaction.

Reasons for the Decision

1. The appeal is admissible.
2. Claim 1 relates to a process for producing high molecular weight aliphatic polyesters having at least 50% of aliphatic hydroxycarboxylic acid units, whereby a crystallized, low molecular weight aliphatic polyester prepolymer having at least 50% of aliphatic hydroxycarboxylic acid units is polymerized in solid phase in the presence of a volatile catalyst. At the same time, the process has to be conducted in such a way that the residual percentage of the catalyst, R, in the product, which is defined by the following formula (10), is at most 50%:

$$R [\%] = C_A [\text{ppm}] : C_B [\text{ppm}] \times 100,$$

C_B [ppm] being the theoretical catalyst concentration in the case where all the catalyst as fed into the reaction system **before** solid phase polymerization is to

remain in the product, and C_A [ppm] being the actual catalyst concentration in the product.

- 2.1 Thus, the process of Claim 1 is characterized by a functional feature directed to a result to be achieved, namely the residual percentage of the catalyst, R. As pointed out in T 65/85 (OJ EPO 1987, 228, point 8.4.3 of the reasons), such a functional definition of a claim feature "must stop short where it jeopardises the clarity of a claim as required by Article 84 EPC. That clarity demands not only that a skilled person be able to understand the teaching of the claim but also that he be able to implement it. In other words, the feature must provide instructions which are sufficiently clear for the expert to reduce them to practice without undue burden, if necessary with reasonable experiments."

Whilst it is true that the requirement of implementing a functional feature of a claim is an issue relating to Article 84 EPC, this requirement, viewed in relation to the disclosure as a whole, is also highly relevant to the question of sufficiency in the sense of Article 83 EPC. Hence, as pointed out in T 435/91 OJ EPO 1995, 188, headnote and point 2.2.1 of the reasons), the definition of a component by its function "is not sufficient if the patent discloses only isolated examples but fails to disclose, taking into account, if necessary, the relevant common general knowledge, any technical concept fit for generalisation, which would enable the skilled person to achieve the envisaged result without undue difficulty within the whole ambit of the claim containing the "functional" definition." Regarding the overlapping aspects of Articles 84 and 83 EPC, reference may also be made to T 713/98 of

17 January 2002, not published in the OJ EPO, point 3.2 of the reasons.

2.2 In the present case, Claim 1 refers to various process features for achieving the desired result, namely removing the volatile catalyst during the solid phase polymerization by evaporation at a temperature not higher than the melting point of the polymer by adjusting the type and the amount of the catalyst, and the flowing gas atmosphere having a flow rate of 0.02 to 200 ml/min per gram of prepolymer. However, these process features are defined in such general terms that a person skilled in the art is left with a considerable number of variables which would have to be adjusted in order to arrive at the desired result. In other words, Claim 1 itself does not provide any meaningful instruction to achieve the desired result.

2.3 Furthermore, these rather general process features of Claim 1 which could be varied in order to achieve the desired result are not explained more fully in the original description. In fact, the relevant passages in the description merely indicate that variables like the temperature, the catalyst, the flowing gas and the pressure may have an influence on R, but the description is conspicuously devoid of any concrete, coherent and convergent teaching how to reliably and consistently get the desired result.

Moreover, when discussing the individual variables, the description is equivocal rather than providing clear further instructions. With regard to the temperature, for example, Claim 1 requires the temperature to be not higher than the temperature of the melting point of the

polymer. By contrast the description as filed states in the paragraph bridging pages 1 and 2 that the solid phase polymerization is carried out at a temperature not higher than the melting point of the **prepolymer**, or at page 24, first full paragraph, that the temperature should not be higher than the melting point (T_m) of the **polymer (including the prepolymer and the reaction product, aliphatic polyester)**. Since it is common general knowledge that the melting points of the prepolymer (low molecular weight), the resulting polymer (high molecular weight) and the polymer mixture are not identical, the application as filed refers in the end to three different temperatures whereby it is not clear which one should be followed.

Further, according to the application as filed, the solid phase polymerization could be carried out under reduced pressure, whereby "The degree of reduced pressure in the reaction system for solid-phase polymerization under reduced pressure could be suitably determined, in consideration of the polymerization rate, the type and the amount of the volatile catalyst used, the vaporization rate and efficiency of the volatile catalyst to vaporize away from the reaction system that contains the polyester formed in the step of dehydrating polymerization, the rate and the efficiency of removing water having been formed through the solid-phase polymerization, and the final weight-average molecular weight (M_w) of the product, aliphatic polyester" (page 28, first full paragraph). Although this paragraph is remarkably free of tangible process measures, the person skilled in the art would deduce from this paragraph (also taking into account the common general knowledge) that a reduced pressure

facilitates the evaporation of the volatile catalyst. But the application as filed also contains the bewildering statement that "In general, the volatile catalyst used could hardly vaporize away from the reaction system in solid-phase polymerization under reduced pressure" (page 29, first full paragraph). When the appellant's attention was drawn to this inconsistency, the appellant declared that the statement on page 29 of the application was an obvious error, but, at the same time, deleted the process variable "pressure" from Claim 1. Thus, it is not clear as to whether (according to the description) or not (according to Claim 1) pressure, and in particular reduced pressure, is a suitable process variable for achieving the desired result.

The thrust of the appellant's defence was that the person skilled in the art would know how to carry out the process in order to obtain the desired result. However, in the absence of any convincing evidence and in view of the rather vague and even equivocal description, the appellant's argument is not convincing.

- 2.4 In order to illustrate the invention, the appellant has filed during examination (10 August 2006) a comparative example where polylactic acid was produced in the same way as in Example C-1 of the application as filed except that the solid phase polymerization was carried out under conditions so that the catalyst did not volatilize enough. In the comparative example R was 78%. The solid phase polymerization step in these two examples can be outlined as follows:

- (i) In Example C1 of the application this step comprises two successive steps. In the first step, the reaction is carried out at 760 mmHg (1013 hPa), at a temperature of 140°C, and a nitrogen flowing rate of 5 ml/min for 40 h. In the second step, the reaction is continued at 760 mmHg (1013 hPa), at a temperature of 160°C, and a nitrogen flowing rate of 200 ml/min for 60 h.

- (ii) In the comparative example, the solid phase polymerization is carried out in a single step at 760 mmHg (1013 hPa), at a temperature of 140°C, and a nitrogen flowing rate of 5 ml/min for 60 h.

The above comparison shows that Example C-1 differs from comparative example in

- the reaction scheme,
- the overall reaction time (100 h vs. 60 h),
- the elevated temperature (160°C vs. 140°C), and
- the higher nitrogen flowing rate (5 ml/min vs. 200 ml/min).

Thus, various process parameters have been adjusted in order to obtain the desired result. It is, however, not apparent which one of these parameters is decisive in achieving the desired result or whether it is the combination of all adjustments which provides the desired result. In this context, it is noteworthy that two of the parameters, ie the temperature and the flowing rate, are well within the general limits indicated in Claim 1, whereas the other two parameters, namely the reaction scheme and the reaction time, are not even dealt with in the description as possible factors having an influence on the desired result.

Hence, the information provided with the additional comparative example is likely to raise more questions than it answers when trying to find a technical concept fit for generalisation how to reliably and consistently get the desired result.

2.5 Finally, it is conspicuous to the board that, in order to achieve the desired result, the claimed process has to fulfil - simultaneously - two conflicting requirements. On the one hand, there must be enough catalyst species in the system in order to effectively catalyze the reaction. On the other hand, the catalyst species has to be removed during the solid phase polymerization in order to obtain the required R value. In this connection, the appellant argued that a person skilled in the art would know how to run such a process. For example, a skilled person would choose a catalyst that could be removed but was not too volatile. Or if, the catalyst were too volatile, more catalyst would have to be added during the solid phase polymerization. However, the application as filed is completely silent about this aspect. Further, there is no prior art available which is concerned with this, in a way, paradoxical situation. Hence, the appellant's unsubstantiated assertion in this connection is not convincing.

2.6 In summary, although the appellant argued that the functional definition in Claim 1 would be allowable in view of the case law of the Boards of Appeal (*inter alia* T 68/85, *supra*), the above analyses reveals just the opposite. In the present case, neither Claim 1 itself nor the description nor the additionally filed

comparative example provide a coherent technical concept fit for generalization, which would enable the person skilled in the art to achieve the desired result without undue burden. The lack of any tangible technical concept is even further compounded by a vague and equivocal description. Consequently, the functional claim wording directed to a result to be achieved in Claim 1 does not fulfil the requirements of Articles 84 and 83, respectively (following T 68/85 and T 435/91, *supra*).

2.7 Furthermore, it is conspicuous to the board that Claim 1 combines a rather general polymerization process requiring no particular point in time of the addition of the catalyst with a parameter whose calculation refers to a particular point in time of the catalyst addition, namely before the solid phase polymerization.

Although this combination has a basis in the application as filed (Claim 1 as filed provides a basis for the general process, Claim 7 as filed for the parameter, and page 19, lines 7-13 for the addition before the solid phase polymerization), this combination leads nevertheless to an unclarity in Claim 1 as can be seen from the following example.

Claim 1 covers the possibilities that the catalyst may be added before and/or during the solid phase polymerization. If, however, all the catalyst is added during the solid phase polymerization, it is not possible any more to calculate the parameter R according to formula (10), because the divisor of the equation becomes 0 (ie no catalyst before the solid

phase polymerization). It is common general knowledge that such a situation is mathematically not defined, because a division is only defined for divisors $\neq 0$. Thus, also for this reason, Claim 1 does not clearly define the scope of the subject-matter claimed, contrary to Article 84 EPC.

It might be worth pointing out that the possibility of adding the catalyst during the solid phase polymerization is not just a hypothetical possibility excogitated by the board to the disadvantage of the appellant. In fact, this possibility is explicitly mentioned in Claim 8 ("C_B [ppm] ... before and/or during dehydration polycondensation" and "W_B [g] ... before and/or during the dehydrating polycondensation") of the claim set pursued by the appellant in appeal and in the application as filed on the passage bridging pages 8 and 9 ("... the catalyst as fed into the reaction system during the solid-phase polymerization ...").

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

E. Görgmaier

R. Young