BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

| A | | B | | C | X |
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File No.: T 0581/91 - 3.3.3

Application No.: 83 306 762.2

Publication No.: 0 108 635

Classification: C08G 63/10

Title of invention: Absorbable bone fixation device

**D E C I S I O N**
of 4 August 1993

Applicant: Johnson & Johnson Products Inc.

Proprietor of the patent:

Opponent: 01) Boehringer Ingelheim Zentrale GmbH
02) Stamicarbon bv

Headword:

**EPC:** Art. 54, 56, 123; R. 88

Keyword: "Amendment requested as obvious error under Rule 88 EPC (not allowed); reference to balance of probability not appropriate" - "Novelty (yes)" - "Inventive step (main request: no); general problem not solved; solution of the residual problem not inventive" - "Inventive step (auxiliary request: yes); departure from prior art teaching"

**Headnote**
**Catchwords**

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 0581/91 - 3.3.3

# D E C I S I O N
## of the Technical Board of Appeal 3.3.3
## of 4 August 1993

**Appellant:** (Proprietor of the patent)
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**Representative:**

**Decision under appeal:** **Decision of the Opposition Division of the European Patent Office dated 17 April 1991, posted on 11 June 1991 revoking European patent No. 0 108 635 pursuant to Article 102(1) EPC.**

**Composition of the Board:**

**Chairman:** F. Antony
**Members:** C. Gérardin
F. Benussi

## Summary of Facts and Submissions

I. The mention of the grant of the patent No. 108 635 in respect of European patent application No. 83 306 762.2 filed on 7 November 1983 and claiming the priority of 8 November 1982 from an earlier application in the United States, was published on 8 June 1988 on the basis of nine claims.

Claim 1, after deletion of a superfluous "a" before the word "catalyst" in the second paragraph, read as follows:

"A process of forming a high molecular weight polylactide polymer: having an inherent viscosity(IV), measured as a 1% w/v solution in chloroform at a temperature of 25°C, of between 4.5 and 10; the unreacted monomer content (UM) of the polymer being less that 2% based on the total weight of the reaction product; and the polymer being capable of being used as a resorbable bone fixation device, comprising;

polymerising L(-)lactide monomer containing up to 10% by weight of a compatible comonomer in an inert atmosphere, in the presence of a catalyst which is present in a monomer to catalyst molar ratio of from 1,000 to 300,000 and at a temperature from 105°C to 170°C, wherein the temperature and monomer to catalyst molar ratio falls within the Curve A of Figure 1, characterised in that:

the polymerisation is carried out for from 42 to 120 hours and the catalyst is stannous octoate, antimony trifluoride, powdered zinc, dibutyl tin oxide or stannous oxalate."

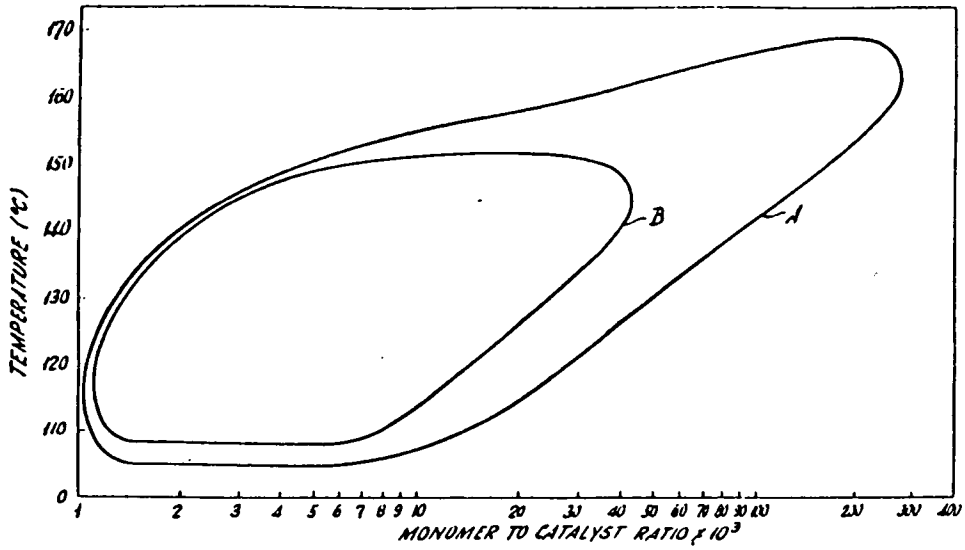


**Figure 1**

Claims 2 to 6 were dependent claims concerning preferred embodiments of the process according to Claim 1. Claim 7 was an independent claim directed to a resorbable bone fixation device made from a poly L(-)lactide polymer as defined in Claim 1. As to dependent Claims 8 and 9, they specified particular requirements to be met by the polymer used in the bone fixation device according to Claim 7.

II. On 7 January 1989 and 6 March 1989 two Notices of Opposition were filed against the grant of the patent and revocation thereof in its entirety was requested for non-compliance with the requirements specified under Article 100 EPC, more specifically for lack of novelty and inventive step (Article 100(a)EPC) as well as for insufficient disclosure of the invention (Article 100(b)EPC). These objections, which were emphasised and elaborated in later submissions as well as during oral proceedings, were based essentially on the following documents:

(1) DE-A-2 809 034;

(2) Contemporary Topics in Polymer Science, 1987, 2, 251, Biodegradable polymers for sustained drug delivery by A. Schindler et al.;

(3) Polymer, 1979, 20, 1459, Biodegradable polymers for use in surgery - polyglycolic/poly(lactic acid) homo- and copolymers:1 by D.K. Gilding et al.;

(5) Batelle, Columbus Laboratories, Columbus Ohio, 16 February 1972, Preparation and evaluation of glycolic and lactic acid-based polymers for implant devices used in management of maxillofacial trauma, part I, by R.G. Sinclair et al.;

(6) Polymer, 1982, 23, 1587, Biodegradable materials of poly(L-lactic acid): 1. Melt-spun and solution-spun fibres by B. Eling et al.;

(8) Journal of Polymer Science, Polymer Chemistry Edition, 1979, 17, 2593, Polylactide. II. Viscosity-Molecular Weight Relationships and Unperturbed Chain Dimensions by A. Schindler et al.;

(10) Makromolekulare Chemie, Supplement 5, 1981, 30, Stereoregular bioresorbable polyesters for orthopaedic surgery by M. Vert et al.

In the course of the opposition procedure Opponent 2 expressed some doubts about the concentration of 1% of the solution used to measure the inherent viscosity; although it was not technically impossible to perform this measurement at such a concentration, the time actually needed suggested that a lower concentration was probably intended in the patent in suit. The Patentee thereafter argued that the value of 1% was indeed an obvious error within the terms of Rule 88 EPC and that the inherent viscosity measurements were in fact carried out in a 0.1% solution. Accordingly this value was introduced into the independent claims of the various

sets of claims discussed during oral proceedings on 17 April 1991 before the Opposition Division.

III. By a decision delivered at the end of these oral proceedings, with written reasons posted on 11 June 1991, the Opposition Division revoked the patent on the grounds that, on the one hand, the amendment of the concentration contravened Article 123 EPC, and, on the other hand, the subject-matter of each of the sets of claims in part was not novel and for the rest did not involve an inventive step. More specifically, it was stated in this decision that the amendment of the concentration was objectionable in several respects, because (i) it could not be regarded as the correction of an obvious error (Rule 88 EPC), (ii) the new figure was neither explicitly,nor implicitly disclosed in the original application (Article 123(2)EPC), and (iii) it extended the protection conferred beyond that of the patent as granted (Article 123(3)EPC).

IV. The Appellant (Patentee) thereafter filed a Notice of Appeal against this decision on 2 August 1991 and paid the prescribed fee at the same time.

(i) Together with the Statement of Grounds of Appeal filed on 15 October 1991 the Appellant submitted a new set of claims, wherein the concentration of the solution at which the inherent viscosity of the polylactide polymer was measured had been maintained as 0.1% w/v; alternatively, it requested that Claim 1 be amended so that the concentration for the inherent viscosity measurement was changed from 0.1% to 1%.

During oral proceedings held on 4 August 1993 the allowability of the value 0.1% was discussed extensively; after an intermediate deliberation

the Board decided that it contravened Article 123 EPC and that, consequently, it could not be allowed.

(ii) This led the Appellant to file two new sets of claims to be considered as main request and auxiliary request.

Claim 1 of the main request (after correction of the spelling error: "fluoride") reads as follows:

"A process for forming a high molecular weight polylactide polymer capable of being used as a resorbable bone fixation device, the process comprising:

bulk polymerising L(-)lactide monomer containing up to 10% by weight of a compatible comonomer in an inert atmosphere, in the presence of a catalyst which is stannous octoate, antimony trifluoride, powdered zinc, dibutyl tin oxide or stannous oxalate, at a temperature of 105°C to 155°C for 50 to 120 hours; wherein the molar ratio of monomer to catalyst is from 1,100 to 45,000 and the temperature and monomer to catalyst ratio fall within Curve B of Figure 1,

thereby to produce directly a polylactide polymer having an inherent viscosity (IV), measured as a 1% w/v solution in chloroform at a temperature of 25°C, of between 4.5 and 10 and an unreacted monomer content of less than 2% based on the total weight of the reaction product."

Claims 2 to 8 are dependent claims directed to specific embodiments of the process according to the main claim.

As to Claim 1 of the auxiliary request, it differs from the above claim by the following additional step: ... ", and forming the direct product of the polymerisation step into a resorbable bone fixation device capable of maintaining a tensile strength of at least 9.81 MPa (100 kg/cm$^2$) for eight weeks after implantation into an animal body."

Claims 2 to 7 are dependent claims directed to specific embodiments of the process according to the main claim.

(iii) The Appellant argued that in spite of the fact that the concentration now mentioned in the main claims did not correspond to the concentration originally intended, there was no inconsistency or insufficiency within the meaning of Article 83 EPC, for there was enough evidence in the file that inherent viscosity was not so much dependent on concentration.

(iv) In support of the patentability of the subject-matter as defined in either of the requests the Appellant put forward that novelty could not be denied, since the inherent viscosity in document (1) and the reaction duration in document (6) were both lower than in the patent in suit. Regarding the issue of inventive step, it had to be appreciated that in view of the teaching of documents (2),(3),(5),(6) and (8) the skilled person at the priority date of the patent in suit would have expected any

polylactide polymer to contain a high amount of unreacted monomer. The possibility of obtaining without additional purification step and under specific reaction conditions not suggested in the prior art, in particular not in documents (6) and (10), a product directly suitable as a resorbable bone fixation device had consequently to be regarded as inventive.

V. In their written submissions the Respondents (Opponents) maintained all the objections raised in the course of the opposition procedure. During oral proceedings, which Respondent 2 did not attend (cf. letter received on 22 July 1993), Respondent 1 first argued on the basis of alleged insufficiency, since the range of inherent viscosity as defined in the main claims was not commensurate with the values in the examples.

It then contended that document (1) on its proper construction was novelty destroying, since the object of the process in this citation was to prepare a high molecular weight polymer, which meant that neither the inherent viscosity value of 0.3 in the description (page 13, paragraph 2), nor the value of 2.3 in the Comparative Example (Table I) could be regarded as final values. Although the minimum reaction time of 50 hours required in the patent in suit might formally be novel over the duration of 48 hours mentioned in document (6), such a small difference could not be regarded as inventive. On the one hand, products having the desired degree of purity could be obtained by following the teaching of this citation; on the other hand, the control of the essential features, namely the high molecular weight and the low residual monomer content of the polylactides, by appropriate selection of the ratio monomer: catalyst was self-evident for the skilled person.

VI. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of Claims 1 to 8 filed during oral proceedings as main request, or on the basis of Claims 1 to 7 (not 1 to 8 as indicated erroneously in the minutes of the oral proceedings) filed during oral proceedings as auxiliary request.

The Respondents requested that the appeal be dismissed.

## Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is admissible.

Procedural Matters

2. In support of their contentions the parties filed no less than 15 new documents in the course of the appeal procedure and even referred to two earlier documents which had already been disregarded by the Opposition Division as late and lacking relevance. The Board has examined all these late-filed citations in order to determine their relevance, namely their evidential weight compared with that of the documents filed in time, and has found that they were not sufficiently relevant to be taken into consideration. These documents, therefore, will be disregarded pursuant to Article 114(2)EPC.

3. Since a concentration of 1% as disclosed in the original and granted versions is now indicated in the main claim of both requests, the question of the admissibility of the amendment of the concentration of the solution at which the inherent viscosity of the polylactide is

measured is no longer an issue of the present decision. However, in view of the importance assigned to that issue by the parties in both their written and oral submissions, the Board deems it appropriate to make the following comments:

The technical report filed by Opponent 2 on 28 March 1990 in the course of the opposition procedure specifies that a concentration of 1% in chloroform gives rise to solutions of such a high viscosity that the time needed to determine the inherent viscosity is extremely long. In practice, i.e, when repeating Experiment 24 of the patent in suit, the measurement would require 280 hours, which is obviously impractical and casts strong doubts on the concentration actually mentioned in the patent in suit. However, the mere fact that the notional reader may easily realise that there is a mistake in the concentration used does not provide a clear and unambiguous answer as to what this concentration should have been. Even though the value of 0.1% proposed by the Appellant can indeed be regarded as the most probable value in that it would be in line with an easily explainable typing error, it is by no means the only concentration mentioned in technical literature; as evident from the numerous documents filed by the Respondents, concentrations of 0.2 or 0.3% are just as common and thus from a merely technical viewpoint must be regarded as equally plausible corrections. This shows that the amendment requested by the Appellant is not the only possible answer to the uncertainty as to the exact concentration to be used to measure the inherent viscosity. It follows that the correction is not obvious in the sense that it is not immediately evident that nothing else would have been intended than what is offered as the correction, i,e. that the criteria for a correction within the terms of Rule 88 EPC are not met.

This conclusion is in line with the unpublished decision T 113/86 of 28 October 1987, wherein the Board considered that amendments requested by a Patentee should not be allowed if there was the slightest doubt that the unamended patent could be construed differently to the patent as amended (Reasons for the Decision, point 2.2).

The balance of probabilities referred to by the Appellant during oral proceedings is not an appropriate criterion to apply in the present case. In the unpublished decision T 383/88 of 1 December 1992, wherein the Board was faced with a similar request to allow an amendment under Rule 88 EPC which might contravene Article 123 EPC, the Board decided that it was not the balance of probabilities, but a more rigorous standard, i.e. one equivalent to "beyond reasonable doubt" which had to be applied (Reasons for the Decision, point 2.2.2, third paragraph). For the reasons given above, it is clear that this stringent condition is not met in the present case.

For these various reasons the Board took the view that in the present case the correction of the concentration as requested by the Appellant was not allowable under Rule 88 EPC.

Sufficiency of description

4. The fact that the concentration of the solution used to measure the inherent viscosity of the polylactide is not the same in the main claim, where it is 1%, and in the experimental section of the patent, where it must have been lower (0.1% or any other value of the same order of magnitude), does not result in an impossibility for the skilled person to carry out the process as claimed in any of the requests.

The main reason is that the inherent viscosity is not a parameter affecting the actual reaction conditions in the preparation of the polymer, but a feature of a product already prepared. Being an indirect measurement of the molecular weight of this product, it can be regarded as a test carried out to ensure that the reaction product is within the scope of Claim 1; the fact that this test may be impractical as the result of a too high viscosity of the 1% solution is irrelevant for the preparation of the polymer.

Besides, the concentration of the solution has only a limited influence on the actual value of inherent viscosity. This is evident from the technical report filed by Opponent 2 on 27 March 1990, which shows that the inherent viscosity measured as 1% solution in chloroform is 5.2 (average of two measures), whilst it is 8 when measured as 0.1% solution. This is confirmed by Example 2 of the patent in suit, wherein the polymer is said to have an inherent viscosity of 5.26 and an intrinsic viscosity of 5.50; since the latter corresponds to an inherent viscosity extrapolated to zero concentration, the influence of the concentration used in the examples of the patent in suit, whether it was 0.1% or another value of the same order of magnitude, on the value of inherent viscosity can be seen to be relatively weak.

It follows that no objection arises having regard to the disclosure of the invention (Article 83 EPC).

Main request

5. The objection of lack of novelty with regard to the disclosure of document (1) maintained by Respondent 1 during oral proceedings cannot be accepted by the Board.

According to the general teaching of this citation L(-) lactide is subjected to a polycondensation reaction in an inert atmosphere, in the presence of a catalyst and at temperatures between 80 and 130°C. The resulting polymer should have an inherent viscosity of at least 0.3 measured at 25°C as a 0.1% solution in chloroform or hexafluoroisopropanol (page 13, paragraph 2). This is more than one order of magnitude below the minimum inherent viscosity required in the patent in suit and corresponds thus to a rather low molecular weight material.

This finding is confirmed in Example 1, wherein the reaction occurs in the presence of a stannous octoate catalyst and 5 mole % ethinyloestradiol, i.e. a compound which by virtue of its two hydroxyl groups will function as a chain terminator. This effect is shown quite clearly in Table 1, page 16, in which the inherent viscosity in the Comparative Example carried out without ethinyloestradiol is much higher. Besides limiting the degree of polycondensation this compound also prevents the L(-)lactide from being completely used up, whereby the amount of residual monomer is increased, which again is contrary to the goal aimed at in the patent in suit. Under these circumstances, the fact that the reaction time is 96 hours, thus within the terms of the patent suit, is clearly irrelevant.

Both the process features and the final product according to document (1) and the patent in suit are thus different, so that novelty of the claimed subject-matter can be acknowledged.

6. The patent in suit concerns a process for the preparation of high molecular weight polylactide polymers capable of being used as a resorbable bone fixation device. Such a process is described in document

(6) which the Board, like the Opposition Division, regards as the closest state of the art. According to this citation L(-)lactide is polymerised at 130°C for 48 hours in the presence of stannous octoate as a catalyst, the latter being used at a concentration between 2 x $10^{-5}$ and 1 x $10^{-4}$ moles per mole of monomer (page 1587, right-hand column, paragraph 4). By adjusting the molecular weight of the resulting polylactide within specific ranges corresponding in particular to intrinsic viscosities comprised between 3.8 and 8.2 as measured at 25°C as a 0.1% w/v solution in chloroform, the mechanical properties, in particular the tensile strength of the fibres made therefrom, can be optimised (page 1587, left-hand column, paragraph 3; page 1588, left-hand column, paragraph 3 in conjunction with right-hand column, Table 1; page 1589, Table 2); this is an essential parameter, when applications such as implants for orthopaedic surgery are envisaged (page 1587, left-hand column, paragraph 2). In order to meet the corresponding purity criteria, however, the polymer at the end of the actual polymerisation reaction has to be subjected to a purification step by dissolution in dichloromethane and subsequent precipitation with methanol, whereby the residual lactide monomer is eliminated (passage bridging the pages 1587 and 1588).

In the light of this prior art shortcoming the technical problem underlying the patent in suit may thus be seen in the definition of a simplified process for the preparation of equally pure polylactides, which does not require a final purification step.

According to the main claim this problem is to be solved by a process "comprising" polymerising L(-)lactide for 50 to 120 hours at a temperature and a monomer to catalyst ratio falling both within Curve B of Figure 1,

which gives rise to a polymer having an unreacted monomer content of less than 2% based on the total weight of the reaction product.

7. As pointed out by the Board during oral proceedings, because of the word "comprising" which leaves open the possibility of having one or several additional step(s), a purification step following the actual polycondensation step is not at all excluded. In that case, the advantage in terms of simplicity over the prior art does not exist and the claimed process is nothing but an alternative to the known process; more specifically, since according to document (6) the monomer to catalyst ratio is comprised between 10 000 and 50 000 at a temperature of 130°C and thus falls partly within Curve B of Figure 1, the Appellant's contribution is reduced to a longer reaction time, namely 50 to 120 hours instead of 48 hours. In view of the above-noted advantage of a high molecular weight as well as a low residual monomer content, an increase of the reaction time must be regarded as self-evident for the skilled person. In the Board's view thus, such a technical measure does not involve an inventive step.

For this reason the main request has to be rejected.

Auxiliary request

8. The issue of novelty of the process as defined in the main claim not having been raised, it is enough to state that the above considerations concerning the main request apply here as well and that, consequently, the requirements of Article 54 EPC are met.

9. It still remains to be decided whether this subject-matter involves an inventive step having regard to the

teaching of the documents relied upon by the Respondents.

9.1 In contrast to the wording of Claim 1 according to the main request, the process as defined according to the auxiliary request, although the same ambiguous word "comprising" is used as well, does not leave open the possibility of a purification step following the polymerisation. As specified in Claim 1, L(-)lactide is first subjected to a bulk polymerisation reaction and the resulting product is then formed directly into a resorbable bone fixation device; because of the word "directly" preceding the processing or shaping of the polymer, the claimed process can only be regarded as a two-step process consisting of a polymerisation step and a processing or shaping step.

In the present case, thus, following the Appellant's contention, the polymerisation product can be assumed to have directly the desired properties, which means that there is no reason to carry out a subsequent purification step and to interpret the main claim accordingly, as in the main request. This means as well that the combination of process features as recited in Claim 1 provides an effective solution to the above-defined technical problem.

9.2 The fact that by performing a polymerisation of L(-)lactide according to the teaching of document (6) the product directly obtained may not in fact require a final purification step does not speak against the inventiveness of the claimed process.

This consideration is based on the experimental results of the test report submitted by Respondent 2 (see point 4 above), according to which a non-purified polylactide would have a residual monomer content of

only 0.6 or 0.8%, thus less than the minimum required in the patent in suit. As pointed out by the Appellant, however, this information was not available at the date of publication of document (6); the notional reader had thus no reason to give to this citation an interpretation contrary to its actual disclosure, i.e. to assume that the degree of purity of the polylactide was in fact acceptable in spite of the underlined need of purification. In other words, to deviate from the literal teaching of document (6) published in 1982 on the ground of results of experiments carried out in 1990 would go against the principle that a document should be interpreted in the technological context of its date of publication (cf. decision T 613/88 of 28 August 1989, point 2.4; not published), i.e. in the light of common general knowledge at that date. Accordingly, the technical problem underlying the patent in suit has to be defined in positive terms, namely the definition of a simplified process, not just a further or alternative process.

9.3 The numerous documents relied upon by the Respondents provide evidence that at the priority date of the patent in suit the presence of residual unreacted monomer in polylactides was a common shortcoming of the various processes for the preparation of these polymers, and that these impurities had to be eliminated by a specific treatment subsequent to the polymerisation step.

Like document (6), document (2) regards a purification step as necessary, since residual dilactide contained in improperly purified polymer degrades relatively fast due to the facile formation of lactoyllactic acid which catalyses further polymer degradation (page 256, paragraph 5).

According to document (3) the polymerisation of lactide in the presence of tin catalysts is followed by a removal step of the monomer by refluxing the crushed polymerisation mixture in a 50:50 mixture of ethyl acetate/60 to 80°C petroleum ether (page 1460, right-hand column, paragraph 4; page 1462, left-hand column, paragraph 3).

The post-treatment described in document (5) combines pulverisation and vacuum heating to remove deleterious surface moisture and any residual monomer to 0.5 percent or less, whereby good physical properties are achieved (page 5, paragraph 2).

Following the disclosure of document (8) the polymers are freed from residual dilactide by precipitation of methylene chloride solutions in methanol, followed by washing with water in a blender (page 2593, paragraph 4).

Similarly, document (10) mentions that residual L(-)lactide monomer has to be removed from polylactides before implantation occurs, either by dissolution/ precipitation or by solid/liquid extraction in the case of non-soluble crystalline materials (page 34, paragraph 2).

All these prior art documents, whether they refer to processes carried out at laboratory scale or at larger scale, provide thus evidence that at the priority date of the patent in suit it was common practice to have the polymerisation step followed by a purification step; in that respect, they merely confirm the disclosure of document (6).

9.4 In contrast to these convergent prior art teachings the patent in suit proposes to control the residual monomer

content by defining a certain relationship between the temperature and the monomer: catalyst ratio (Curve B), and by carrying out the polymerisation over an extended period. As appreciated in the unpublished decision T 45/85 of 28 July 1987 (cf. point 8), such a departure from the prior art practice must be regarded as indicative of an inventive step.

For this reason, the Board concludes that in the present case the process as defined in Claim 1 of the auxiliary request meets the requirements of Article 56 EPC.

10. Claim 1 being allowable, the same applies to dependent Claims 2 to 7, which are directed to preferred embodiments of the subject-matter of Claim 1 and whose inventiveness is supported by that of the main claim.

11. Although the claims according to the auxiliary request meet the criteria of patentability, the patent cannot be maintained on that basis yet, in the absence of an adapted description. The case is thus remitted to the first instance for that purpose.

**Order**

**For these reasons, it is decided that:**

1. The decision under appeal is set aside.

2. The main request is rejected.

3. The case is remitted to the first instance with the order to maintain the patent on the basis of Claims 1 to 7 filed during oral proceedings as auxiliary request, and a description yet to be adapted.

The Registrar: The Chairman:

E. Görgmaier F. Antony