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Datasheet for the decision
of 9 July 2008

Case Number:	T 1115/03 - 3.3.03
Application Number:	98203427.4
Publication Number:	0893462
IPC:	C08G 63/08
Language of the proceedings:	EN

Title of invention:
Continuous process for the manufacture of lactide and lactide polymers

Applicant:
CARGILL, INCORPORATED

Headword:
-

Relevant legal provisions:
EPC Art. 56, 76(1), 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step - yes - after amendment"
"Amendments - added subject-matter - no"
"Divisional application - extension beyond the content of the earlier application as filed - no"

Decisions cited:
G 0001/05, T 0665/97

Catchword:
-

Case Number: T 1115/03 - 3.3.03

DECISION
of the Technical Board of Appeal 3.3.03
of 9 July 2008

Appellant:	CARGILL, INCORPORATED 15407 McGinty Road West Minnetonka MN 55440 (US)
Representative:	Portal, Gérard Cabinet Beau de Loménie 158, rue de l'Université F-75340 Paris Cédex 07 (FR)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office dated 1 April 2003 and posted 12 May 2003 refusing European application No. 98203427.4 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman:	R. Young
Members:	M. C. Gordon
	E. Dufrasne

Summary of Facts and Submissions

I. European Patent Application no. 98203427.4 is a divisional application of European Patent Application no. 93903632.3, filed on 22 January 1993. The parent application was refused by a decision of the examining division, posted 30 December 1996 which decision was upheld on appeal (decision T 665/97 of 13 October 1998, not published in the OJ EPO).

The applicant is Cargill, Incorporated. The application claims priority from five US patent applications (US 07/825,059 of 24 January 1992; US 07/927,149 of 7 August 1992; US 07/926,901 of 7 August 1992; US 07/935,566 of 24 August 1992 and US 07/935,059 of 24 August 1992).

The application had 30 claims. Claim 1 read as follows:

"A process for preparing a polylactide; the process including: providing a crude lactide mixture including lactide comprising meso-lactide and at least one of L-lactide and D-lactide; said process being characterized by steps of:

(a) purifying the crude lactide mixture by distillation in a distillation system into at least two distilled fractions comprising:
   (i) a low-boiling fraction; and
   (ii) an intermediate boiling fraction including purified polymer grade lactide, without a step of solvent extraction of the crude lactide mixture or recrystallization of the crude lactide mixture; and
(b) reacting the purified polymer grade lactide to form polylactide."

Claim 2, which was also an independent claim differed from claim 1 in that it was directed to a process for preparing "polymer grade" lactide and in that the second step (b) was omitted.

Claims 3-9 were dependent on claims 1 or 2.

Claim 10-12, also dependent on claims 1 or 2 defined further aspects of the process in more detail and read as follows:

"10. A process according to claim 1 or 2, said process comprising the steps of:

(a) providing a source of lactic acid in a hydroxylic medium;

(b) concentrating the lactic acid in the hydroxylic medium by evaporating a substantial portion of the hydroxylic medium to form a concentrated lactic acid solution;

(c) polymerizing lactic acid in the concentrated lactic acid solution of step (b) by further evaporation of the hydroxylic medium to form polylactic acid molecules having an average molecular weight of between about 100 and about 5000; and

(d) forming a crude lactide in the presence of catalyst means for catalyzing the depolymerization of the polylactic acid molecules to form lactide molecules."

"11. A process according to claim 10, wherein the crude lactide formed in step (d) is a vapor being subsequently partially condensed to remove volatile contaminants to form a condensed partially purified liquid lactide, the condensed partially purified liquid lactide then being purified".

"12. A process according to claim 1 or 2, said process comprising the steps of:

(a) providing a source of the ester of lactic acid;

(b) forming a condensation reaction by-product and polylactic acid in the presence of first catalyst means for catalyzing the condensation of molecules of the ester of lactic acid to form polylactic acid, wherein the molecules of polylactic acid have an average molecular weight of between about 100 and about 5,000; and

(c) forming a crude lactide from the polylactic acid molecules in the presence of second catalyst means for catalyzing the depolymerization of polylactic acid to form the crude lactide."

Claim 13 was dependent on claim 12. Claims 14-16 were dependent on claim 13.
Claims 17-23 were directed to preferred embodiments of the subject matter of claims 1 and 2.
Claim 24 was an independent claim and read as follows:
"A process for producing polylactic acid by dehydration condensation of lactic acid, said process being characterized by steps of:
(a) providing a source of lactic acid solution containing water produced by dehydration condensation of lactic acid;
(b) continuously removing the water contained in the lactic acid solution and water generated by dehydration condensation of lactic acid; wherein the dehydration condensation of lactic acid is provided in a dehydration condensation reactor."

Claims 25-30 were directed to preferred embodiments of the process of claim 24.

II. The application was refused by a decision of the examining division dated 1 April 2003 and issued in writing on 12 May 2003.

The decision was based on sets of claims forming a main request (claims 1-25) submitted with letter dated 3 March 2003 and a first auxiliary request (claims 1 to 40), submitted during oral proceedings before the examining division.

Claim 1 of the main request differed from claim 1 as originally filed *inter alia* in that it was directed to a "process for the continuous conversion of a crude lactic acid feed in a hydroxylic medium to a purified lactide of at least 99% by weight" whereby the final step of polymerising the purified lactide to polylactic acid was specified to be optional. Regarding the production of the lactide, it was specified that lactic acid was initially concentrated by evaporation and polymerised by further evaporation to a polylactic acid of Mn between 100 and 5000 prior to forming the crude lactide. The lactide forming step was specified to occur in a "lactide reactor" in the presence of a catalyst for depolymerization of the polylactic acid. Further the following features were specified in the final part of the claim relating to the purification of the lactide:

"(i) purging at least a portion of the metal ion impurities from the lactide reactor; and

(ii) volatilizing at least water, lactic acid and lactide in the lactide reactor to form a crude lactide vapor stream and removing the crude lactide vapor stream from the lactide reactor; and,

- purifying the said crude lactide vapor stream to at least 99% by wt. pure lactide by distillation to separate water and lactic acid from lactide;

(i) said step of distilling including feeding the crude lactide vapor stream, or partially condensing the said vapor stream and feeding a resulting condensate, into a distillation system and removing from the distillation system at least:

(A) an overhead stream including lactic acid and water; and

(B) a purified lactide stream;

- said steps of forming a crude lactide and purifying the crude lactide being conducted in the absence of any step of: (1) lactide crystallization; and (2) solvent extraction to purify the lactide by extraction of the purified lactide from the crude lactide mixture."

Claims 2-18 were directed to preferred embodiments of the process of claim 1 whereby claim 13 was directed to an embodiment whereby the crude lactide was directly fed as a vapour stream from the lactide reactor to the distillation system and claim 14 was directed to an embodiment whereby the stream from the lactide reactor was partially condensed before being fed to the distillation system (cf original claim 11 reported in section I above).

Independent claim 19 was directed to a process for the continuous conversion of an ester of lactic acid to a purified lactide, at least 99% pure wherein the purification of the lactide was accomplished by

distillation. The various steps set out in claim 1 were not however specified in this claim.
Claims 20-25 were directed to preferred embodiments of the process of claim 19.

Regarding the auxiliary request, claims 1-40 substantially corresponded to claims 1-25 of the main request whereby independent claims 1 and 19 had each been divided into two independent claims.

The following documents, cited in the European Search Report were referred to in the examination procedure and will be referred to in the present decision as indicated:

D1: EP-A-275 581;
D2: EP-A-261 572;
D3: Lipinsky, E.S., Sinclair, R. G., "Is Lactic Acid a Commodity Chemical?", Chem. Eng. Progress, Aug. 1986 pp. 26-32;
D4: WO-A-88/10260;

(a) The decision held that claims 1, 15, 17 and 18 of the main request did not meet the requirements of Art. 76(1) EPC.
(b) The subject matter of claims 1, 2 and 19 of the main request were held not to meet the requirements of Art. 84 since it was not clear whether these related to a process for preparing lactide or to a process for preparing polylactide.
(c) Novelty of the subject matter of the claims according to the main request was acknowledged.
(d) The subject matter of the claims of the main request was held not to be founded on an inventive step. In T 665/97 (with respect to the parent case, see section I above) it had already been held that

the purification of a crude lactide by distillation did not involve an inventive step. The *ratio decidendi* of this decision was held to apply to the present case insofar as it was identical to the parent application. The features added to the claim compared to the claims on which the Board decided in the case of the parent application, namely:

a) crude lactic acid feed in hydroxylic medium;
b) concentrating by evaporation;
c) polymerisation to polylactic acid by further evaporation;
d) polylactic acid has Mn 100-5000;
e) catalysed depolymerisation of polylactic acid to crude lactide;
f) purging;
g) volatilizing the crude lactide mixture;
h) details about the distillation step, including description of streams;

were held either to be disclosed in D1 (features a, b, c, e) or to be obvious *per se* (features d, f, g, h).

(i) Regarding the details of the distillation step, in particular features (g) and (h) above (see also section "ii" of claim 1 of the main request - recited above) it was held that these, although not mentioned or suggested in the closest prior art (D1) - since this did not contemplate distillation - related nevertheless merely to common characteristics of distillation processes which were available in common reference books.

(ii) The argument of the applicant that the subject matter of the operative claims was distinguished from the prior art by several features, which could not all be retrieved from a single piece of prior art was held not to be convincing. The examining division held that the mere accumulation of distinguishing features could never be the sole reason for an inventive step.

(iii) It was further held that the applicant had failed to demonstrate how the distinguishing features over the prior art (i.e. features d, f, g, h - see above) - singly or in combination - contributed to the solution of a technical problem which would be different from that formulated in T 665/97 and why such a solution should be unexpected.

(e) With regard to the auxiliary request, it was held that the claims thereof met the requirements of Art. 76(1), 123(2), 84 and 54 EPC. However, by reference to the reasons given for the main request it was held that this subject matter did not satisfy the requirements of Art. 56 EPC.

(f) Accordingly the application was refused.

III. An appeal against this decision was filed on 10 July 2003, the prescribed fee being paid on the same day.

IV. The statement of grounds of appeal was received on 22 September 2003.

(a) Two sets of claims were submitted as a main and a first auxiliary request, each having 40 claims. These were stated to be amended versions of the claims according to the first auxiliary request submitted during the oral proceedings before the examining division. The details of these claims are however not of relevance for the present decision.

(b) According to the appellant the problem underlying the application was to form high purity lactide from commercially available lactic acid or lactic acid ester to produce polylactide polymers suitable as a cost-competitive replacement for petrochemical-based polymers in an industrial process which was simple and economical (see application as filed, page 6 lines 28-37). Further this continuous process should permit the production of lactide polymers from crude lactic acid feed (application, page 7 lines 3-5). A further problem was to provide a highly purified lactide from a crude lactide composition. The prior art D1, D2 and D4 employed either solvent extraction or recrystallisation, i.e. low temperature or "cold" processes which were complicated, time consuming and were associated with problems such as low yield (product loss during the purification) and the need to eliminate solvents.

Although D2 did refer to "distilling off" the lactide this was in fact a flash volatilisation. Such a process resulted in a crude lactide since it did not accomplish separation of the lactide from the other components of the depolymerised mixture, namely water, lactic acid, linear lactic acid oligomers and low molecular weight polymers. Such crude lactide was unsuitable for polymerisation as it contained water, lactic acid and low molecular weight oligomers of lactic acid, reference being made to the application in suit (page 12, lines 23-27 and page 14 line 8 ff of the of the application).

D3 referred to traditional purification methods involving precipitation of lactate salts and discussed the need for these to be superseded by better technology. The emphasis of D3 was on developing solvent extraction methods. Various improvements were envisaged including distillation, which were however all presented only in the manner of desiderata. There was no explanation as to how the skilled person would in practice employ distillation as a method for purifying crude lactide.

The application in suit also addressed a second problem, namely the formation of high purity lactide in a simple and economical process while removing lactide oligomers, which problem was not disclosed in the prior art.
Thus neither of the problems underlying the application was derivable from any of the prior art documents.

(c) The claimed solution to these problems was not obvious.
D1, D2 and D4 proposed either solvent extraction or recrystallisation processes to purify lactide. The statement in D3 "distillation can be combined with dehydration to yield lactide for use in polyester production" was submitted to relate to a step similar to the "distilling off"/vaporisation step of D2 (see above).

Despite the fact that D3 had been available to the authors of D1, D2 and D4, they employed only "cold" purification processes. D1 further warned of decomposition or hydrolysis of the crude lactide when dissolved in the organic liquid.
Since the prior art was restricted to "cold" processes these teachings did not render it obvious to employ a process in which the purification of the crude lactide was performed by a distillation system with separation into a plurality of streams.
In any case the skilled person would not have expected a distillation process to be possible since it was believed that heating would result in side reactions leading to polymerisation of lactide during distillation. It was also believed that the narrow difference between melting point and boiling point of lactide streams would potentially result in solid plugging problems, so precluding the use of a distillation system.
Further it was unobvious for the skilled person to provide a **continuous process** (emphasis of the appellant), which would directly use commercially available lactic acid or an ester thereof and further use the crude lactide stream (containing impurities), resulting from the depolymerisation step as a crude feed to the distillation step.
The prior art taught away from the invention since it disclosed nothing more relevant than purification by recrystallisation (D2, D4) or by solvent extraction (D1, D3) despite the fact that D3 had been published before the filing dates of D1, D2 and D4.

Thus the claimed invention provided for the first time an unobvious solution in a continuous process of preparation of highly purified lactide which could be used on an industrial scale, which was simple and economical and could be operated at large scale.

(d) Unobviousness could also be recognised on the basis that a technical prejudice had been overcome. As lactide was known to be heat sensitive the skilled person would not have considered heating, e.g. distillation as a technique for purifying crude lactide. It was known that heat accelerated degradation of lactide. Further, impurities (lactic acid and oligomers and water) tended to react with the ester groups in the lactide to cause undesired reactions, which tendency increased with increasing temperature and time. As the skilled person was concerned with the heat sensitivity of lactide it would not be expected that distillation would be a properly adapted technique for purifying lactide from a crude mixture containing lactide, lactic acid, water and oligomers of lactic acid. Accordingly there was no reason for the skilled person to contemplate distillation when the prior art taught recrystallisation or solvent extraction (D1, D2, D4).

(e) Further arguments were also submitted with respect to the first auxiliary request.

V. In a communication dated 12 September 2005, accompanying a summons to attend oral proceedings, the Board raised a number of objections pursuant to Art. 76(1) and 123(2) in respect of the claims of the

main and auxiliary requests.
Further it was provisionally held that the subject matter of the operative claims did not appear to be founded on an inventive step. Further, the Board expressed doubts as to whether, in the light of the claims then on file, the requirements of Art. 83 and 84 EPC were met.

VI. The procedure was then stayed (communication dated 11 November 2005 and telephone consultation of 13 December 2005) because a question had been referred to the Enlarged Board of Appeal concerning the situation where the claims of a divisional application as filed did not meet the requirements of Art. 76(1) EPC, which was an issue in the present case (see section V above).
Following issue of the decision of the Enlarged Board (G 1/05, dated 28 June 2007, and published in OJ EPO 2008, 271) in which it was ruled that amendment of a divisional application to comply with the requirements of Art. 76(1) EPC was possible, proceedings in the present case were resumed (communication of the Board dated 2 August 2007).

VII. Together with a letter dated 30 November 2007 the appellant submitted sets of claims forming a main and a first auxiliary request, consisting of 24 and 23 claims respectively.

(a) The appellant made extensive submissions with respect to the objections raised pursuant to Art. 76(1) and 123(2) EPC.

(b) With respect to inventive step the non-obviousness of the features of either directly feeding the crude lactide vapour stream to the distillation system or partially condensing the vapour stream into a condensed crude lactide which was then fed into the distillation system were emphasised. In this connection it was submitted that it was more conventional to feed a liquid solution to a distillation system and that the feeding of a lactide vapour stream was not obvious. Similarly it was submitted that performing a partial condensation, which was explained to eliminate the majority of water and the impurities remaining as vapour which could be recycled back while the partially condensed crude lactide was fed into a distillation system was not obvious in particular with respect to the general idea of distillation set out in D3.

In this connection, it was further reiterated that although all of D1, D2 and D4 were filed after publication of D3 none of these employed distillation to effect purification. Further none of these documents disclosed a continuous process.

VIII. On 28 April 2008 the Board issued a summons to attend oral proceedings, scheduled for 9 July 2008.

IX. In a letter dated 4 July 2008 the appellant made further submissions with respect to inventive step.

D1 was considered to represent the closest state of the art. This related to a process for purifying lactide, the aim being to avoid recrystallisation due to the high losses associated therewith. The solution proposed according to D1 was to employ solvent extraction. This appeared from the examples not to be a continuous process. There was no suggestion in D1 that crude lactide could be purified by distillation of crude lactide vapour or of partially condensed crude lactide (cf section VII.(b) above).

Crude lactide contained impurities, in particular water and acidic impurities as shown by D1. This impaired polymerisation, resulting in low polymer molecular weight as shown by examples 6 and 7 of the application. Thus crude lactide had to be purified before being subjected to polymerisation to produce a high molecular weight polymer. D1 accomplished this by solvent extraction which was not a continuous process and had further disadvantages, namely the need to handle large quantities of liquids and the need to treat or dispose of the generated salts and waste water.

Hence the objective technical problem was to provide a continuous economical process of manufacture of lactide with a higher purity, i.e. less hydroxyl content.

The appellant had discovered that crude lactide could not be condensed and then purified by distillation. Instead the crude lactide vapours had to be distilled or at most the crude lactide had to be only partially condensed before being distilled in order to obtain highly purified lactide in acceptable yields. A test report was provided to demonstrate this. This fact had not been recognised in any of D1-D4. This - previously unknown - problem had been solved according to the application in suit by distilling the crude lactide vapours or a partially condensed lactide. The evidence in the application and the further data attached to the letter of 4 July 2008 showed that a highly purified product could be obtained in high yield when operating according to this method. The prior art had failed to recognise that condensed crude lactide could not be purified by distillation and hence there was no teaching how to improve the yield of the distillation in the art.

X. Oral proceedings were held on 9 July 2008.

(a) Following discussion of the objections pursuant to Art. 76(1) and 123(2) EPC the appellant submitted a new set of claims 1-23 as a main request replacing that filed with the letter of 30 November 2007. The auxiliary request filed on 30 November 2007 was maintained.

Claim 1 of the main request read as follows:

"A process for the continuous conversion of a crude lactic acid feed, in a hydroxylic medium, to a purified lactide, of at least 99% by wt pure lactide, said process comprising the steps of :

a) providing a source of lactic acid in solution in a hydroxylic medium containing 1% to 99% by wt., lactic acid;

b) concentrating the lactic acid in the hydroxylic medium by evaporating a substantial portion of the hydroxylic medium to form a concentrated lactic acid solution;

c) polymerising lactic acid in the said concentrated lactic acid solution by further evaporation of the hydroxylic medium to form in said medium polylactic acid molecules having an average molecular weight of between 100 and 5,000;

d) continuously forming crude lactide, in a lactide reactor, from said polylactic acid molecules, while simultaneously and continuously feeding a catalyst for catalysing the depolymerisation of the polylactic acid molecules, to form crude lactide vapor stream which is continuously removed from the lactide reactor; said step of forming crude lactide also including purging impurities of high-boiling polylactic acid or other non-volatile impurities from the lactide reactor;

and

e) purifying the said crude lactide vapor stream, to at least 99% by wt. pure lactide by distillation;

i) said step of distilling including feeding the crude lactide vapor stream into a distillation system, or feeding the crude lactide vapor stream directly to a partial lactide condenser in which the lactide condenses and is fed to a distillation system, and the majority of the water and other impurities remaining as vapors are recycled back to the lactide reactor or other upstream process equipment; and removing from the distillation system at least three component streams:

A) an overhead low boiling stream or distillate stream containing components having a lower boiling point than a lactide including lactic acid, water or other solvent and condensation reaction-by-products which may be present within the system;

B) a purified lactide stream removed from the column as an intermediate-boiling sidedraw stream; and

C) a high boiling bottoms stream containing components which are higher boiling than a lactide."

Claims 2-13 were dependent claims whereby claim 13 was directed to a process including the further step of polymerising the purified lactide to form polylactide.

Claim 14 was an independent claim directed to a process analogous to that of claim 1 wherein an ester of lactic acid was employed as the starting material. Claim 14 read as follows:

"A process for the continuous conversion of an ester of lactic acid to a purified lactide, at least 99% by weight pure lactide, said process comprising the steps of :

a) providing a source of the ester of lactic acid;

b) forming a condensation reaction by-product and polylactic acid in the presence of first catalyst means for catalysing the condensation of molecules of the ester of lactic acid to form polylactic acid, wherein the molecules of polylactic acid have an average molecular weight of between 100 and 5,000;

c) forming a crude lactide from the polylactic acid molecules in the presence of second catalyst means for catalysing the depolymerisation of polylactic acid to form the crude lactide;

d) purifying the said crude lactide to form a substantially purified lactide by distilling the crude lactide, as defined in anyone of claims 1 to 12."

Claims 15 to 23 were dependent claims directed to preferred embodiments of the process of claim 14 whereby claim 23 was directed to a process including the further step of polymerising the purified lactide stream to form polylactide.

After deliberation the Board announced that the amended claims met the requirements of Art. 76(1) and 123(2) EPC.

(b) The Board was also satisfied that its concerns with respect to Art. 83 and 84 EPC (cf section V above) did not arise in respect of the claims of the (new) main request.

(c) Novelty objections had not been raised by the first instance, and the Board was satisfied that the subject matter of the claims of the main request was not anticipated by any of the cited documents.

(d) With regard to inventive step, the appellant submitted that the aim of the closest prior art, D1, was to avoid recrystallisation, which was achieved by using solvent extraction. The objective technical problem compared to D1 was to provide a continuous economical process for producing in high yield and purity (>99%), and in particular having a lower content of hydroxy groups. This problem was set out on page 19 lines 4-9 of the application (i.e. the original typescript). At page 19 lines 15 and 16 it was explained that the claimed process permitted crude lactic acid to be employed. The problem was also derivable from page 46 lines 3ff where it is taught that the purity of the lactide was important. This problem was solved in an unobvious manner by the claimed process. Direct condensation of the lactide was not possible; either the vapours had to be distilled or at most only partially condensed prior to distillation. The effect of this was shown in the data filed with the letter of 4 July 2008. The data reported in Table II constituted the entirety of the dataset an excerpt of which had been reported in example 12 of the application. The critical point was to ensure that the water- and hydroxy-containing compounds were removed prior to distillation of the lactide vapour. This led to control of acidic impurities which was critical.

With regard to the difference in distillation as employed in D1 and that in the application it was explained that in D1 the distillation step was carried out to obtain crude lactide, but that purification of the lactide was not effected by distillation. On the contrary water remained in the lactide resulting from this distillation. The inventors of D1 had not been aware of the need to remove water. The comparative examples A-D of the letter of 4 July 2008 corresponded closely to what had been done in D1. Other documents - D2 and D4 - continued to use recrystallisation to purify lactide even though D1 showed that the evolution of technology was away from this. The appellant had identified the need to remove low molecular weight impurities prior to distilling the lactide. This requirement had not been recognised in the prior art.

XI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request (claims 1 to 23) filed during the oral proceedings or, in the alternative, on the basis of the auxiliary request (claims 1 to 23) filed with letter dated 30 November 2007.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. ***Art 76(1) and 123(2) EPC.***

The descriptions of the parent application and the (divisional) application in suit are identical. The page and line references given relate to the - identical - originally filed typescripts of the parent and divisional applications (and thus to the publication WO-A-93/15127 of the parent application). The claims of the parent and divisional applications differ.

2.1 Claim 1

2.1.1 "*A process for the continuous conversion of a crude lactic acid feed, in a hydroxylic medium, to a purified lactide, of at least 99% by wt pure lactide, said process comprising the steps of*:"
Art. 76(1) EPC: Parent application claim 7, first paragraph ("substantially" has been deleted since this term is rendered redundant by the specification of the

percentage purity of the lactide). The specified degree of purity is disclosed at page 13 line 35.
Art 123(2) EPC: Claims 9 and 10 - which are dependent on claim 1 (see section I above) disclose processes whereby crude lactide is obtained by providing a source of crude lactic acid feed in solution in a hydroxylic medium and generating a crude lactide mixture from said lactic acid feed. Claim 11 discloses that the crude lactide obtained according to the process of claim 10 is then purified (see section I above).

The specified degree of purity is disclosed at page 13 line 35, as indicated above.

While the term "conversion" itself is not employed in the original description it is apparent that the consequence of the process specified, in particular in claims 9 and 10 is that crude lactic acid undergoes conversion into crude lactide, which according to claim 11 is then purified.
Specifically:

- It is in any case clear from the "Summary of the Invention" on page 7 and following that the process begins with a crude lactic acid feed source or crude lactic acid feed (page 7 lines 5 and 6); that the crude lactic acid or source of lactic acid could also be an ester of lactic acid (page 7 lines 11 and 12); and that the term "polylactic acid" includes polymer chains as formed from the polymerisation of an ester of lactic acid (page 9 lines 27 to 34).
- Furthermore, according to page 11, lines 22-25 polylactic acid is fed to a lactide reactor; and a catalyst is simultaneously and continuously

fed to the lactide reactor. Heat is added to vaporise the crude lactide which is continuously removed from the lactide reactor, thus driving the depolymerisation reaction, resulting in the net production of lactide as the contents of the lactide reactor seek equilibrium (sentence bridging pages 11 and 12).

- Whilst the latter passage generally follows a reference to Figure 1 at page 10 lines 14 to 15 which provides "a preferred flowchart of the overall process disclosed herein", it is evident that this flowchart presents, at the left-hand side, the overall sequence of steps of the conversion claimed.
  This clearly in the Board's view covers the fate of both the lactic acid feed and the lactic ester feed.

Accordingly the technical features of the original disclosure provide a basis for the term "conversion" whether starting from crude lactic acid or esters thereof.

The feature that the process is "continuous" is disclosed at page 1 lines 6-9 in the section "Field of the Invention" which states: "The present invention relates to processes for the continuous production of lactide and lactide polymers from crude lactic acid and esters of lactic acid.". The same disclosure is provided at page 7 lines 3-6 under "Summary of the invention".

2.1.2 "*a) Providing a source of lactic acid in solution in a hydroxylic medium…*"

Art. 76(1) EPC: Parent application as originally filed

claim 7(a);
Art. 123(2) EPC: Divisional application as filed claim 9(a) and claim 10(a).

2.1.3 *"containing 1% to 99% by wt., lactic acid ;"*
Art. 76(1) EPC: This feature is disclosed at page 22 lines 15, 16, 22, and 23 of the parent application. This passage relates to Figure 2, the "overall schematic flowchart encompassing the preferred process disclosed herein" (page 22 lines 12, 13). By describing the flowchart in these terms it is apparent that the flowchart is to be understood as providing a framework for the presentation of individual preferred features of the claimed process. Accordingly it is permissible in this case to take in isolation from this "overall schematic" teaching certain specific features, e.g. the concentration of lactic acid in the lactic acid feed.
Art. 123(2) EPC: as noted above the description of the parent and divisional applications are identical. Accordingly the indicated parts of the description of the divisional application provide the necessary disclosure pursuant to Art. 123(2) EPC.

2.1.4 "*b) concentrating the lactic acid in the hydroxylic medium by evaporating a substantial portion of the hydroxylic medium to form a concentrated lactic acid solution;*"
Art. 76(1) EPC: Parent application claim 7(b);
Art. 123(2) EPC: Divisional application claim 10(b).

2.1.5 "*c) polymerising lactic acid in the said concentrated lactic acid solution by further evaporation of the hydroxylic medium to form in said medium polylactic acid molecules having an average molecular weight of*

between 100 and 5,000;"
Art. 76(1) EPC: Parent application claim 7(c);
Art. 123(2) EPC: Divisional application claim 10(c).

2.1.6 "*d) continuously forming crude lactide,*"
Art. 76(1) EPC: Disclosed in claim 7(d) of the parent application. The feature that the process is carried out "continuously" is disclosed in the preamble of claim 7.
Art. 123(2) EPC: Claim 10(d) of the application as filed. The feature that the process is continuous is disclosed at with page 1 lines 6 to 9 of the description as explained in section 2.1.1 above.

2.1.7 "*in a lactide reactor, from said polylactic acid molecules, while simultaneously and continuously feeding a catalyst for catalysing the depolymerisation of the polylactic acid molecules, to form crude lactide vapor stream which is continuously removed from the lactide reactor; said step of forming crude lactide also including purging impurities of high-boiling polylactic acid or other non-volatile impurities from the lactide reactor;*"
Art 76(1) EPC: Page 11 line 22-page 12 line 1 of the description of the parent application. The feature of a purge stream is disclosed at page 12 lines 10-15 of the description as a preferred embodiment. The fact that the reaction is a depolymerisation is stated at page 12 at line 2 (see section 2.1.1 above).
Art. 123(2) EPC: *idem.*

2.1.8 "*and*
e) purifying the said crude lactide vapor stream, to at least 99% by wt. pure lactide by distillation;"

Art. 76(1) EPC: Parent application claim 7(e); Page 12 line 27-29. The degree of purification is disclosed at page 13 line 35.
123(2) EPC: divisional application as filed claim 1(a), claim 2(a) and the indicated parts of the description.

2.1.9 *"i) said step of distilling including feeding the crude lactide vapor stream into a distillation system, or feeding the crude lactide vapor stream directly to a partial lactide condenser in which the lactide condenses and is fed to a distillation system, and the majority of the water and other impurities remaining as vapors are recycled back to the lactide reactor or other upstream process equipment;"*
Art. 76(1) EPC: Parent application Page 12 line 27 - page 13 line 3. In particular, this passage discloses that the lactide is fed directly to a distillation system, or in a preferred embodiment fed to a partial condenser in which the lactide condenses and the majority of the water and other impurities remain as vapours and are recycled back. Since the embodiment with a partial condenser is a preferred embodiment it is apparent that this includes all the aforementioned steps, differing only in the explicitly indicated feature. Accordingly this embodiment also includes the step of that of directly feeding the lactide to the system.
Art. 123(2) EPC: Divisional application *idem.*

2.1.10 *"and removing from the distillation system at least three component streams:*

A) an overhead low boiling stream or distillate stream containing components having a lower boiling point than a

> *lactide including lactic acid, water or other solvent and condensation reaction-by-products which may be present within the system;*
>
> *B) a purified lactide stream removed from the column as an intermediate-boiling sidedraw stream; and*
>
> *C) a high boiling bottoms stream containing components which are higher boiling than a lactide."*

Art. 76(1) EPC: Parent application Page 13 lines 9-28;
Art. 123(2) EPC: Divisional application *idem*.

2.2 Claim 2 (concentrating and polymerising carried out in a pre-polymer reactor):
Art. 76(1) EPC: Parent application page 10 line 14 to page 11 line 13 and page 25 lines 33-37.
These passages refer to figures 1 and 2 which provide a basis for the reasons given in sections 2.1.1 and 2.1.3 above.
Art. 123(2) EPC: Divisional application as filed, *idem.*

2.3 Claim 3 (polymerisation of lactic acid by forming a polylactic acid medium prior to provision of polylactic acid in the lactide reactor):
Art. 76(1) EPC: parent application claim 1 ("Hydroxylic medium) within which, according to claim 1(c) polylactic acid is formed, i.e. a "medium" containing polylactic acid; also page 11 lines 2 and 22-24.
Art. 123(2) EPC: divisional application claim 10(c) page 11 lines 2, 22-24.

2.4 Claim 4 (content of lactic acid in lactic acid source):
Art. 76(1) EPC: parent application page 22 lines 22-25

(see also comments re generality of figure 2 in section 2.1.3 above).
Art. 123(2) EPC: *idem.*

2.5 Claim 5 (between polymerising lactic acid and formation of crude lactide the polylactic acid medium is directed to a hold tank):
Art. 76(1) EPC: The "hold tank" is disclosed in figure 2 and in the part of the description relating to said figure 2, at page 25 line 16 and page 26 lines 26-31. It is further explicitly stated at page 26 line 29 that the hold tank is only a preferred embodiment and hence is not presented as a mandatory feature of the schematic that is figure 2. Regarding the status of figure 2 see section 2.1.3 above.
Art. 123(2) EPC: *idem*.

2.6 Claim 6 (addition of the catalyst prior to introduction of the composition to the lactide reactor):
Art. 76(1) EPC: Parent application page 26 line 34 to page 27 line 4 of the application as filed. See also comments regarding generality of figure 2 in section 2.1.3 above.
Art. 123(2) EPC: divisional application as filed: *idem*.

2.7 Claim 7 (specifying that the distillation system includes more than one column):
Art. 76(1) EPC: parent application page 29 line 28 (with reference to the generality of figure 2 - see section 2.1.3 above).
Art. 123(2) EPC: *idem.*

2.8 Claim 8 (system uses one distillation column):
Art. 76(1) EPC: page 29 line 28 the disclosure

"Applicants recognize that the distillation system **may** include more than one distillation column or a flash drum" (emphasis of the Board). The use of the term "may" indicates that this is an option - the unambiguous alternative thereto being a single column. Re the status of the reference to figure 2 see section 2.1.3 above.
Art. 123(2) EPC divisional application as filed *idem.*

2.9 Claim 9 (nature of the catalyst):
Art. 76(1) EPC: disclosed at page 27 lines 44-46 of the parent application as filed.
Art. 123(2) EPC: divisional application as filed *idem*.

2.10 Claim 10 (feeding the crude lactide vapour directly to the distillation system):
Art. 76(1) EPC: parent application as filed page 12 line 27-29;
Art. 123(2) EPC: divisional application as filed *idem.*

2.11 Claim 11 (nature of the hydroxylic medium):
Art. 76(1) EPC: parent application as filed at page 22 lines 17-20. Regarding the status of references to Figure 2 in the cited passage see section 2.1.3 above.
Art. 123(2) EPC: divisional application as filed *idem*.

2.12 Claim 12 (system with a top-mounted column to create a single enclosed area…)
Art. 76(1) EPC: Parent application as filed: page 14 lines 19-24.
Art. 123(2) EPC: divisional application as filed *idem*.

2.13 Claim 13 (further step of polymerising the purified lactide stream):

Art. 76(1) EPC: Parent application as filed, claim 1(f).
Art. 123(2) EPC Divisional application as filed
claim 1(b).

2.14 Claim 14 (process starting from an ester of lactic acid):
Art. 76(1): Parent application as filed claim 12. The purity of the purified lactide is disclosed at page 13 line 35 of the parent application as filed
Art. 123(2) EPC: Divisional application as filed, claim 12. Purity disclosed at page 13 line 35 of the divisional application as filed. The step of purifying by distillation is disclosed by means of the dependency of claim 12 on claims 1 and 2 in the light of the disclosures referred to in sections 2.1.1 and 2.1.3 above.

2.15 Claim 15 (specifying the nature of the ester of lactic acid):
Art. 76(1) EPC: Parent application as filed, claim 13.
Art. 123(2) EPC: Divisional application as filed, claim 13.

2.16 Claim 16, (source of ester is a single ester or a mixture of esters plus lactic acid):
Art. 76(1) EPC: Parent application as filed, claim 14.
Art. 123(2) EPC: Divisional application as filed, claim 14.

2.17 Claim 17 (specific esters of lactic acid):
Art. 76(1) EPC: Parent application as filed, claim 15 and page 7 lines 12-15.
Art. 123(2) EPC: Divisional application as filed, page 7 lines 12-15.

2.18 Claim 18 (ester of lactic acid in solution in a hydroxylic medium in an amount of 20% by weight or more of solution):
Art. 76(1) EPC: Parent application as filed claim 16.
Art. 123(2) EPC: Divisional application as filed, claim 15.
The upper limit of 100% by weight has been deleted compared to the parent and divisional applications as originally filed. This deletion does not however result in an extension of scope since the originally disclosed upper limit, corresponded to the maximum mathematically possible and thus was in effect redundant.

2.19 Claim 19 (specifying the details of the step of forming the polylactic acid from the ester of lactic acid):
Art. 76(1) EPC: Claim 17 of the parent application as originally filed.
Art. 123(2) EPC: claim 16 of the divisional application as originally filed.

2.20 Claim 20 (specifying that the same catalyst provides the first and second catalyst means [of the process of claim 15]):
Art. 76(1) EPC: Parent application as filed claim 18 and page 19 line 29 to page 20 line 3.
Art. 123(2) EPC: Divisional application as filed, page 19 line 29 to page 20 line 3.

2.21 Claim 21, (catalyst has acid functionality):
Art. 76(1) EPC: Parent application as filed, page 19 line 35 to page 20 line 3.
Art. 123(2) EPC: Divisional application as filed, *idem*.

2.22 Claim 22 (process to be adopted when a soluble catalyst is employed):
Art. 76(1) EPC: Parent application as filed page 16 lines 14-19.
Art. 123(2) EPC: Divisional application as filed *idem.*

2.23 Claim 23 (process of claims 14-22 including the further step of polymerising the purified lactide stream):
Art. 76(1) EPC: Parent application claim 12, in particular part (e) thereof, page 7 line 15ff in combination with page 7 line 4.
Art. 123(2) EPC: Divisional application as filed claim 12 by the dependency on claim 1, in particular part (b) thereof, and the passages of the description indicated above.

2.24 The Board is therefore satisfied that the claims of the main request satisfy the requirements of Art. 76(1) and 123(2) EPC.

3. ***Art. 83 EPC, Art. 84 EPC***

The (amended) claims according to the main request do not give rise to any objections pursuant to Art. 83 or Art. 84 EPC.

4. ***Art. 54 EPC***

Novelty objections had not been raised by the first instance and the Board is satisfied that none of the documents cited by the first instance disclose a process according to either claim 1 or claim 14 of the main request. Accordingly the subject matter of the operative claims is novel.

5. ***Art. 56 EPC***

5.1 *The application in suit, the technical problem*

5.1.1 According to the section of the application entitled "Description of the Prior Art" problems of waste disposal have led to the need for development of biodegradable polymers which can be used as replacements for non-biodegradable or partially-biodegradable petrochemical based polymers.

5.1.2 Polymers of lactic acid are biodegradable. Hitherto known processes for producing polymers from lactic acid however were directed to small volume high value products e.g. for use in the medical industry.

5.1.3 Thus there was a need for a viable, cost-competitive process for the continuous manufacture of purified lactide and lactide polymers from lactic acid, said polymers having physical properties suitable for replacing petrochemical-based polymers in packaging, paper coating and other non-medical industry applications.

5.1.4 It is explained however that high molecular weight lactic acid polymers cannot be prepared directly from lactic acid, but have to be produced via lactide, i.e. a lactic acid dimer. Impurities in the lactide can give rise to problems in the further polymerisation.

5.1.5 Thus there was a need for a process to produce sufficiently pure lactide on an industrial basis.

5.1.6 The process proposed according to the application in suit to address this problem involves the steps of (see operative claim 1):

- polymerising lactic acid or an ester thereof to polylactic acid;
- converting this in a lactide reactor to lactide; and
- vaporising the lactide and continuously removing this from the reactor.

The crude lactide is either fed to a distillation system as a vapour or is subjected to partial condensation by means of which the lactide condenses and the majority of water and other impurities are recycled back. The condensed crude lactide is then fed directly to a distillation system for purification (page 11, line 22 to page 12 line 9; page 12 line 23 to page 13 line 9).

5.1.7 According to page 18 line 36 to page 19 line 4 of the application side reactions resulting in ring opening of the lactide and polymerisation of lactic acid can occur during distillation of the lactide. It was however discovered that feeding a lactide vapour stream or a liquid crude lactide stream after partial condensation to remove water and lactic acid vapour to the distillation system permitted purification of lactide on a conventional distillation system (page 19 lines 4-14).

In other words according to the application in suit relevant major impurities such as water and lactic acid are separated from the crude lactide vapour stream before the latter is fully condensed, leading to a significant reduction of impurity loading in the lactide products.

5.1.8 Example 12 of the application, and the additional data submitted with the letter of 4 July 2008, which was submitted to be based on the same dataset from which the results reported in example 12 were derived (see section X.(d) above), demonstrate the effect of acidic impurities in the lactide submitted to distillation on the quality of the resulting product.

According to example 12 of the application at an acid content of 19 meq [COOH]/mol lactide the oligomer content of the residue from distillation was 0.5% with 92% of the charge being taken overhead (i.e. the yield). With an acidic impurity content of 43 meq [COOH]/mol lactide the oligomer content of the residue from distillation increased to 7.6% and the percent of charge taken overhead was reduced to 80%. According to the supplementary data provided with the letter of 4 July 2008 the purity of this second batch was 99% with a distillate yield of 80 wt%. The further data submitted with the 4 July 2008 letter showed that employing a crude lactide feed with increased content of acidic impurities, specifically at levels of 206, 186, 211 or 200 meq [COOH]/mol lactide resulted in a reduction of the purity of the resulting lactide to values between 76.1 and 92.6 wt.% and also depressed the yield of the distillation to values between 19 and 64 wt.%.

Examples 6 and 7 of the application demonstrate the effect of the level of impurities (water, lactic acid) in the lactide subjected to polymerisation. It is shown in example 7 on page 54 of the application that when either of these is present at a "high" level - defined as 5.9-8.5 meq/mol for water and 0.9-1.3 meq/mol for lactic acid, the molecular weight of the resulting polylactic acid is reduced compared to using lactide having defined "low" levels of the said impurities (1.8-3.7 meq/mol for water and 0.1-0.2 meq/mol for lactic acid). Specifically with both levels of impurity at the "low" level molecular weights of above 130,000 are obtained. However the highest value obtained when one of these was "high" (lactic acid) is 89,800. When both impurities are present at the "high" level molecular weights of ca 34,000 are obtained. The results further show that increasing (doubling) the amount of catalyst does not compensate for the negative effects of the impurities present (last 4 entries in the Table on page 54 of the application).

5.1.9 These data therefore demonstrate that the step of reducing the content of acidic impurities in the lactide submitted to distillation does indeed result in the benefits put forward in the application. Firstly it is shown that this results in a significantly purer lactide after distillation. Secondly the consequence of employing this purer lactide for polymerisation is shown to result in a higher polymer molecular weight.

5.1.10 This evidence renders it credible that the aim of the application (see section 5.1.3 above) is achieved by the claimed measures.

5.2 *The closest prior art*

5.2.1 According to the appellant the closest prior art is represented by the teaching of D1. This relates to the preparation of high molecular weight polylactic acid. The envisaged field of use is in the pharmacy and medical fields (D1, column 4, lines 24-34). It is explained that high molecular weight polylactic acid can be virtually exclusively obtained from lactide, provided that this does not include impurities which interfere with the progress of the polymerisation (D1 col. 1 lines 14-33). D1 teaches that the literature proposes recrystallisation. This however results in considerable loss of material (D1 col. 1 lines 37 - col. 2 line 9). As a solution to this, a method is proposed according to D1 involving solvent extraction of a solution of the polylactic acid in a water-immiscible organic solvent with water containing a basic substance which is not soluble in the organic solvent. The lactide is then isolated from the organic phase.

According to part 1 of example 1 of D1 lactide is prepared from lactic acid by "distillation" whereby a leading fraction is first collected, followed by the main fraction. It is however evident from example 1 of D1 that this "distillation" does not accomplish purification but is merely the recovery of the crude lactide from the lactide reactor. This product is subjected to complete condensation (D1, example 1 first part). The purification of the lactide obtained takes place in the subsequent step of solvent extraction.

That this "distillation" does not result in purification is confirmed in a qualitative manner by the fact that the "distillate" has to be subjected to further purification, i.e. solvent extraction and in a quantitative manner from the data of D1. Specifically, not only is the level of acidic impurities in this "distilled" product higher than that which is demonstrated according to the application in suit to be acceptable in the lactide subjected to polymerisation, it is also higher than the level of impurities present in the **crude** lactide product which is subjected to distillation according to the application in suit. This is derivable from the reported titration results in D1:

- The "distilled" fraction of D1, example 1 was reported as having on titration a base consumption of 380 meq per kg of lactide, which corresponds to 54.7 meq/mol, meaning that the content of acidic impurities in said fraction was 54.7 meq/mol.
- As noted above, example 12 of the application shows a content of acidic impurities in the crude (i.e. partially condensed) lactide prior to distillation of 43 meq/mol, i.e. lower than that of acidic impurities in the "distilled" lactide of D1.
- According to the application in suit, the specific distillation step by means of which water and acid impurities in the lactide vapour coming from the lactide reactor are removed - in a single step - involves at most partial condensation of the lactide from the vapour issuing from the lactide reactor. This partial condensation step yields a "crude" lactide which is then subjected to a further purification step of distillation. The process of the application in suit results after distillation of this partially condensed lactide in a lactide product of greater than 99% purity (acidic impurity level 4.4 meq/mol) as is convincingly demonstrated by the supplementary data of 4 July 2008. This degree of purity enables immediate polymerisation to a polylactide of usefully high molecular weight as illustrated in example 14 of the application in suit.

- In contrast thereto the process of D1 employs complete condensation of the lactide vapour produced, yielding a product having a level of acidic impurities of 54.7 meq/mol, i.e. a factor of 10 higher than the impurity level of the lactide which is shown in the supplementary data of 4 July 2008 to be acceptable for direct polymerisation of the lactide.
- Further in view of the data submitted as Table II with the letter of 4 July 2008 showing that the yield and purity of the product resulting from distillation decreases in the cases where the product recovered from the lactide reactor is subjected to complete condensation, i.e. having an increased content of acid impurities content, it is not even certain that the "distilled", fully condensed, product of D1 would be susceptible of further purification by a further distillation process.

Accordingly D1 does not teach purification of crude lactide by distillation or even that distillation would be a possible route to effect purification. There is no teaching in D1 relating to the specific manner in which such a distillation for the purposes of purification would have to be carried out, i.e. the need to control the content of impurities in the lactide subjected to distillation - see section 5.1.8 above, which according to the operative claims is accomplished by partial rather than full condensation of the lactide resulting form the lactide reactor (see section X.(a) above).

5.2.2 D2 and D4 disclose only the purification of lactide by recrystallisation, i.e. relate to the technique identified as prior art in D1 and therefore relate to an even more remote technology.

5.2.3 D3 discusses the potential of lactic acid polymers, produced in large quantities at low prices, for use in packaging and consumer goods, i.e. the same problem which is addressed by the application in suit. In the section entitled "In conclusion" it is stated that distillation could be combined with dehydration to provide lactide for use in polyester production. However this appears to be an entirely speculative statement. No details of the distillation are provided. It is further disclosed that the lactide could be "further purified by redistillation or in some instances crystallisation". However again there is no discussion of how this "redistillation" could be accomplished or what factors would have to be considered. Accordingly even the speculation of D3 does not envisage a process in which a **single** distillation step starting from a vapour and separating acidic impurities and water prior to complete condensation would yield a lactide sufficiently pure to be subjected to polymerisation to yield a high molecular weight polylactic acid as demonstrated in the examples of the application in suit.

5.2.4 In the light of the foregoing the Board is satisfied that the document proposed by the appellant, D1, does represent the closest state of the art.

5.3 *The objective technical problem, its solution*

The closest prior art D1 discloses a batch process, operated on a scale of a few tens of grams for obtaining purified lactide, the envisaged end use being in the medical field. Compared to D1 the technical problem to be solved by the application in suit can be formulated as proposed by the appellant (see section 5.1.3 above) namely as to provide an economical continuous process for the production of lactide for making lactide polymers having physical properties suitable for replacing petrochemical-based polymers in packaging, paper coating and other non-medical industry applications.

The data in the application and that submitted subsequently render it convincing that this problem is in fact solved by the measures specified in the operative claims of the main request, namely by a continuous process involving distillation in which the lactide is either passed directly to the distillation system as a vapour or is partially condensed to remove water and acidic impurities as vapours before the (partially) condensed lactide is subjected to distillation.

5.4 *Obviousness*

None of the cited documents disclose a process for purifying lactide by distillation. Although D3 broadly envisages such a process, as explained above this is in the nature of a speculative desideratum and there are no technical details relating to how this might - even in principle - be accomplished. In particular there is no recognition either in D3 or in any other of the documents cited of the need to control the impurity content of the lactide subjected to distillation, which aspect as shown by the evidence in the application in suit is critical for the success, and is reflected in the operative claims. Thus even if D3 does render it -

at least in principle - obvious to try to purify lactide by distillation the skilled person would still have to overcome further obstacles which are not even recognised let alone solved by the teaching of D3 or indeed any other of the cited documents in order to realise such a process as claimed.

5.5 Accordingly the subject matter of claim 1 of the main request is considered to be founded on an inventive step.
As independent claim 14 relies through its dependency upon claim 1 for the details of the purification step this conclusion applies also to the subject matter of claim 14.

6. Under these circumstances it is not necessary to deal with the auxiliary request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent on the basis of the main request (claims 1 to 23) filed during the oral proceedings and after any necessary consequential amendment of the description and of the drawings.

The Registrar: The Chairman:

E. Görgmaier R. Young