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**Datasheet for the decision  
of 13 September 2022**

**Case Number:** T 0309/17 - 3.3.02

**Application Number:** 10715379.3

**Publication Number:** 2414384

**IPC:** C07K14/00, C12P21/00

**Language of the proceedings:** EN

**Title of invention:**  
CONTROL OF COPOLYMER COMPOSITIONS

**Patent Proprietor:**  
Momenta Pharmaceuticals, Inc.

**Opponents:**  
Page White & Farrer Limited  
Synthon B.V.  
Actavis Group PTC ehf

**Headword:**

**Relevant legal provisions:**  
EPC Art. 54, 56, 83  
RPBA 2020 Art. 13(2)

**Keyword:**

Novelty  
Inventive step  
Sufficiency of disclosure  
Amendment to appeal case

**Decisions cited:**

T 2191/13, T 1229/17

**Catchword:**



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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Case Number: T 0309/17 - 3.3.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.02**  
**of 13 September 2022**

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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
6 December 2016 concerning maintenance of the  
European Patent No. 2414384 in amended form.

**Composition of the Board:**

**Chairman** M. O. Müller  
**Members:** S. Bertrand  
P. de Heij

## Summary of Facts and Submissions

I. The appeals of opponents 1 and 2 and the patent proprietor are against the interlocutory decision of the opposition division that European patent No. 2 414 384 in amended form according to the version of auxiliary request 2 then on file met the requirements of the EPC.

II. Claim 1 according to the version of auxiliary request 2 then on file reads as follows:

*"1. A method for preparing a composition comprising purified glatiramer acetate, comprising:*

*polymerizing N-carboxy anhydrides of L-alanine, benzyl-protected L-glutamic acid, trifluoroacetic acid (TFA) protected L-lysine and L-tyrosine to generate a protected copolymer (Intermediate-1); treating Intermediate-1 to partially depolymerize the protected copolymer and deprotect benzyl protected groups thereby generating a partially depolymerized product (Intermediate-2); treating Intermediate-2 to deprotect TFA-protected lysines thereby generating glatiramer acetate; and purifying the glatiramer acetate to create purified glatiramer acetate, wherein water is present during at least a portion of the depolymerization step, wherein the water present during at least a portion of the depolymerization step is controlled to be within a predetermined range that is 4 - 25% w/w against Intermediate-1 so as to yield purified glatiramer acetate with pyroglutamate concentration of 2000-7000 ppm and an Mp of 5,000-9,000 Da."*

III. The following documents are referred to in the decision:

D3	WO 2009/129018 A1
D5	WO 2009/016643 A1
D7	WO 95/31990 A1
D23	Data from example 1 and figure 2 of the patent
A034	Web page from <a href="http://www.medicines.ie">http://www.medicines.ie</a> : Sanofi, Copaxone <sup>®</sup> 20 mg/ml
A035	Copaxone <sup>®</sup> 20 mg/ml Solution for Injection, Pre-filled Syringe.

D3 was published on 22 October 2009, i.e. between the priority dates (3 April 2009 and 30 September 2009) and the filing date (5 April 2010) of the patent.

IV. The opposition division's conclusions included the following:

- The subject-matter of claim 1 according to the version of auxiliary request 1 then on file did not involve an inventive step in view of D1 as the closest prior art.
- The claims of the version of auxiliary request 2 then on file met the requirements of Article 123(2) EPC, and the subject-matter of these claims was novel and involved an inventive step in view of D1 as the closest prior art. The invention as defined in the claims of this auxiliary request was sufficiently disclosed within the meaning of Article 83 EPC.

- V. In its statement of grounds of appeal, opponent 1 submitted, *inter alia*, documents A034 and A035 (denoted D33 and D34 by opponent 1).
- VI. In its reply to the grounds of appeal, the patent proprietor submitted new auxiliary requests 1 to 7.
- VII. In a further letter dated 30 July 2021, the patent proprietor submitted auxiliary requests AR1a to AR7a.
- VIII. In preparation for the oral proceedings, scheduled at the parties' requests, the board issued a communication pursuant to Article 15(1) RPBA 2020.
- IX. In a further letter, the patent proprietor submitted the decision and minutes of case T 1229/17, together with a copy of the claims held allowable by the deciding board.
- X. Summons for attending oral proceedings to be held by videoconference were issued with notice of less than two months before the date of the oral proceedings, only after the parties had given their consent to such a short notice period by telephone. Opponent 1 informed the board and the parties that it would not be attending the oral proceedings.
- XI. In a letter, opponent 2 disputed the patent proprietor's submissions regarding T 1229/17.
- XII. Oral proceedings before the board were held by videoconference on 13 September 2022 in the absence of opponent 1 in accordance with Rule 115(2) EPC and Article 15(3) RPBA 2020. During the oral proceedings the patent proprietor renamed auxiliary request 1, auxiliary request 1a and auxiliary request 2 as the

main request, main request a and auxiliary request 1 respectively.

XIII. Claim 1 of the main request is identical to claim 1 of auxiliary request 2 as upheld by the opposition division but for the feature "*so as to yield purified glatiramer acetate with pyroglutamate concentration of 2000-7000 ppm and Mp of 5,000-9,000 Da*", which is not present in the main request. Claim 1 of auxiliary request 1 is identical to claim 1 of auxiliary request 2 as upheld by the opposition division.

XIV. The patent proprietor's case, where relevant to the present decision, can be summarised as follows:

Main request

- Inventive step - claim 1
  - The subject-matter of claim 1 involved an inventive step in view of D1 as the closest prior art.
  - The distinguishing features of claim 1 over claim 42 of D1 were the water content for step (b) and the control of the amount of water.
  - The example of the patent and D23 showed that a glatiramer acetate ("GA") product having a desired pyroglutamate ("pyro-Glu") content of 2 000 to 7 000 ppm and a desired Mp of 5 000 to 9 000 Da over a longer reaction time could be prepared by adding water during the depolymerisation step. The objective technical problem was to control the process better in order to achieve a more consistent product and to make the desired product more reliably.



- The controlled addition of an amount of 4 to 25% w/w water in the process identified in D1 for solving the technical problem was not obvious.

Auxiliary request 1

- Admittance of the added subject-matter objection
  - The objection raised by opponent 2 during the oral proceedings should not be admitted into the proceedings under Article 13(2) RPBA 2020.
- Novelty - claim 1
  - The subject-matter of claim 1 of auxiliary request 1 was novel in view of D1, D3, D5 and D7.
  - The claimed range of water could not be regarded as a selection from a range of 0-100% w/w. None of D1, D3, D5 and D7 discloses any amount of water based on the protected copolymer being added during the depolymerisation step.
- Inventive step - claim 1
  - The distinguishing feature over D1 was that water was present during at least a portion of the depolymerisation step, in an amount within the range of 4-25% w/w, so as to yield GA with a pyro-Glu concentration of 2 000-7 000 ppm and an Mp of 5 000-9 000 Da.
  - The objective technical problem was the provision of a process for preparing a GA product having a desired pyro-Glu content and a desired Mp over a longer reaction time.
  - Claim 1 only covered embodiments where the water content was such that the obtained product had

the preferred pyro-Glu and Mp values as now specified in the claim.

- None of the prior art documents cited by the opponents taught how to solve the objective technical problem.
- The subject-matter of claim 1 involved an inventive step in view of D1 as the closest prior art.
- D3 did not form part of the prior art under Article 54(2) EPC since claim 1 was entitled to the priority date of 30 September 2009.
- The subject-matter of claim 1 involved an inventive step in view of D7 as the closest prior art for the same reasons as those given in view of D1 as the closest prior art.
- Sufficiency of disclosure
  - Even if the example of the patent did not disclose the temperature and reaction time, it was a routine action of the skilled person to determine them. The description of the patent (see paragraph [0005]) contained additional information regarding these parameters.

XV. The opponents' cases, where relevant to the present decision, can be summarised as follows:

Main request

- Inventive step - claim 1
  - The subject-matter of claim 1 did not involve an inventive step in view of D1 as the closest prior art.

- Claim 42 of D1 disclosed a process for preparing GA.
- The distinguishing feature of claim 1 over claim 42 of D1 was the water content for the depolymerisation step.
- The problem formulated by the patent proprietor was not solved over the whole scope of claim 1 of the main request. The objective technical problem in view of D1 was simply the provision of an alternative.
- The controlled addition of an amount of 4 to 25% w/w water in the depolymerisation step of the process identified in D1 represented an arbitrary measure for the skilled person.

#### Auxiliary request 1

- Admittance of the added subject-matter objection
  - There was no basis in the application as filed for the range of 4 to 25% w/w water content in combination with the ranges of the pyro-Glu content and Mp. This objection was raised in response to the preliminary opinion regarding added subject-matter in the board's communication pursuant to Article 15(1) RPBA 2020. The objection should be admitted.
- Novelty - claim 1
  - The subject-matter of claim 1 of auxiliary request 1 was not novel in view of D1, D3, D5 and D7.

- Inventive step - claim 1
  - The subject-matter of claim 1 did not involve an inventive step in view of D1, D3 and D7 as the closest prior art.
- Sufficiency of disclosure
  - There was no information in the single example of the opposed patent as regards the temperature and reaction time, such that the skilled person could not carry out the invention.

XVI. The parties' relevant requests were as follows:

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of one of the claim sets of the main request, main request a or auxiliary requests 1, 1a, 2, 2a, 3, 3a, 4, 4a, 5, 5a, 6 or 6a, the main request and auxiliary requests 1 to 6 having been filed as auxiliary requests 1 to 7 respectively with the proprietor's reply to the opponents' grounds of appeal and main request a and auxiliary requests 1a to 6a having been filed as auxiliary requests 1a, 2a, 3a, 4a, 5a, 6a and 7a respectively with the patent proprietor's letter of 30 July 2021.

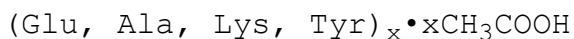
Opponents 1 and 2 requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

## Reasons for the Decision

Main request (filed as auxiliary request 1, "AR1", claims 1-24 submitted with the reply to the grounds of appeal)

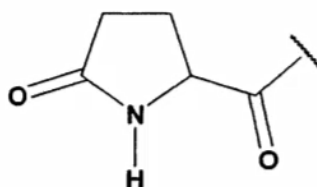
1. Claim 1 of the main request relates to a method of preparing a composition comprising purified glatiramer acetate.

Glatiramer acetate ("GA" in the following) is an acetate salt of synthetic polypeptides derived from four amino acids: L-glutamic acid (Glu), L-alanine (Ala), L-tyrosine (Tyr), and L-lysine (Lys). The structural formula of GA is as follows:



L-pyroglutamic acid ("pyro-Glu" in the following) is a component of GA.

Pyro-Glu has the following formula:



The claimed method comprises a first step of polymerisation to obtain intermediate-1, a second step of depolymerisation of intermediate-1 and deprotection of the benzyl-protected groups of intermediate-1 to generate intermediate-2, during at least a portion of which depolymerisation step water is present (*"wherein the water present during at least a portion of the depolymerization step is controlled to be within a predetermined range that is 4-25% w/w against*

*Intermediate-1*"). Then in a third step, *intermediate-2* (comprising TFA-protected lysine units) is deprotected to generate GA, which is purified in a fourth step.

According to the invention (paragraph [0013] of the patent), by properly controlling the amount of water present during the depolymerisation step and the duration of the depolymerisation step, it is possible to produce GA with a specified pyroglutamate ("pyro-Glu") content and a specified peak molecular weight ("Mp").

#### Inventive step

2. Opponents 1 and 2 objected to the inventive step of claim 1 of the main request in view of D1 as the closest prior art.

#### 2.1 Closest prior art

D1 is concerned, *inter alia*, with a method for preparing and purifying GA. This therefore corresponds to the aim of the present invention.

Thus, the board sees no reason to deviate from the selection of D1 as the closest prior art.

Claim 42 of D1 discloses a process for preparing GA. The process comprises the following steps:

- (a) polymerisation of N-carboxy anhydrides of tyrosine, alanine, benzyl-protected L-glutamate and trifluoroacetic acid (TFA)-protected lysine to form a protected GA,
- (b) deprotection of the benzyl- and TFA-protected GA using hydrobromic acid (HBr) in acetic acid to form a TFA-protected GA,

(c) reacting the TFA-protected GA with aqueous piperidine to form a solution of GA, and

(d) purifying the solution of GA.

The above four steps of claim 42 of D1 correspond to the four steps of the method of claim 1 of the main request, except that there is no explicit disclosure of depolymerisation in the second step ((b)) and no explicit disclosure of water during this second step.

According to paragraph [0015] of the patent, the treatment of the protected GA with HBr in acetic acid results in the cleavage of the benzyl-protected group on the glutamic acids as well as cleavage of peptide bonds throughout the polymer. Thus, step (b) of claim 42 of D1, comprising the reaction of the protected GA with HBr in acetic acid, also implicitly discloses the depolymerisation of the protected GA. Therefore, this step (b) corresponds to the second step of claim 1 of the main request. This was common ground between the parties.

D1 further discloses that the deprotection of the protected GA in step (b) results in the formation of an aqueous mixture of trifluoroacetyl polypeptides (see page 15, line 32, to page 16, line 4). The fact that the mixture is aqueous implies that at least during a portion of the depolymerisation step water was present, as required by claim 1.

## 2.2 Distinguishing features

D1 does not disclose any water content for the depolymerisation step. Thus, the distinguishing feature of claim 1 is the water content "4-25% w/w against Intermediate-1".

The patent proprietor argued that the water mentioned in D1 ("aqueous") resulted from a quenching step carried out after the depolymerisation step. The process of D1 thus additionally differed from the claimed process in that water was not present during depolymerisation and further in that the water content was not controlled.

The board does not agree with these arguments.

Quenching as referred to by the patent proprietor is not disclosed at all in the cited passage of D1 (i.e. page 15, line 32, to page 16, line 4). For this reason alone, the patent proprietor's argument relating to quenching must fail.

Furthermore, the cited passage in D1 (i.e. page 15, line 32, to page 16, line 4) explicitly states that step (b) results in an aqueous mixture ("to form an aqueous mixture..."). If a step results in an aqueous mixture, water must inevitably be present during at least part of the step, i.e. at the beginning, during or at the end of step (b).

With regard to the notion "**controlled** to be within a predetermined range", as explained in the board's communication under Article 15(1) RPBA 2020, any addition of any amount of water or an aqueous composition (ranging from a drop to an excess) to a reaction mixture is considered by the skilled person in organic chemistry to be "controlled". Furthermore, if



anything, "controlled" implies that the water content is as intended by the person carrying out the process. This intention exists only in the person's mind and hence constitutes a non-technical purely mental aspect of the claimed subject-matter. Such a purely mental feature cannot distinguish the claimed subject-matter from the prior art, as has been set out in detail in decision T 2191/13 (points 12.3 and 12.4 of the Reasons).

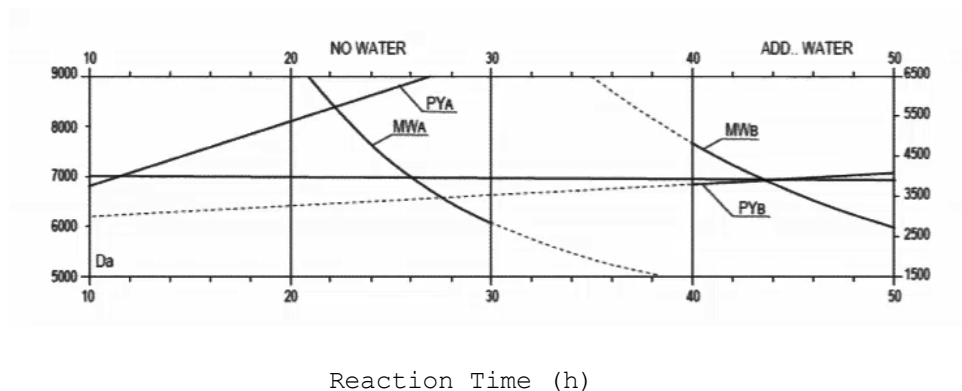
### 2.3 Objective technical problem

According to the patent proprietor, the technical problem is to control a process better in order to achieve a more consistent product and to make the desired product more reliably.

The patent proprietor explained that obtaining a consistent product in a reliable way was possible since the claimed process allowed a product with a pyro-Glu content in the desired range of 2 000-7 000 and a molecular weight  $M_p$  in the range of 5 000-9 000 to be obtained over a longer reaction time (hereinafter, the two ranges for the pyro-Glu content and molecular weight  $M_p$  will be referred to as the "desired range" or "desired ranges"). In this respect the patent proprietor relied on the data in the example of the patent and in D23.

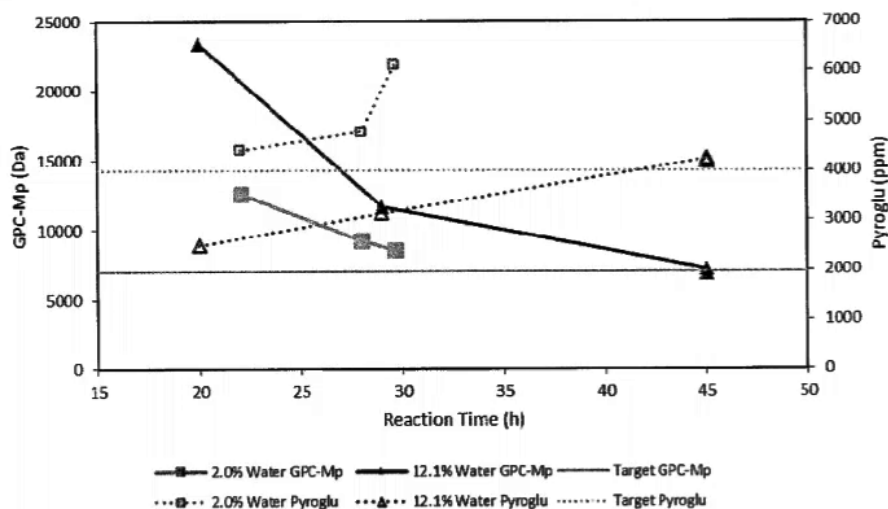
Example 1 of the patent contains two experiments on the depolymerisation of "Intermediate-1", i.e. the protected GA. The two experiments are carried out without water (in the case of comparative example (A)) and with the addition of 16% w/w water (as according to claim 1 of main request, in the case of experiment (B)). Figure 2 of the patent shows the results of these experiments. Figure 2 as adapted by opponent 2 is

reproduced below. The patent proprietor has not contested the correctness of the adaptation.



The amount of pyro-Glu ( $PY_A$ ) in the first experiment ("no water", comparative) increases faster than the amount of pyro-Glu ( $PY_B$ ) in the second experiment ("add water", as claimed). The  $M_p$  of GA in the first experiment ( $MW_A$ ) starts its decrease earlier than in the second experiment ( $MW_B$ ). This graph shows that the desired pyro-Glu content and  $M_p$  are obtained over a longer reaction time when 16% w/w water is added to the depolymerisation step in comparison with a process with no water added.

In D23, two additional experiments were carried out with 2.0% w/w water (comparative example, value is outside of the range defined in claim 1) and 12.1% w/w water (value according to claim 1 of the main request):



The above results show that the preparation with 12.1% w/w water (as claimed) affords a longer period of time in which the concentration of pyro-Glu (open triangles) and the Mp (solid triangles) are within the desired ranges, as compared with the results obtained with 2.0% w/w water (comparative, open and closed squares).

The board thus accepts that for the particular embodiments discussed above, these data show that the selection of the water content within the range defined in claim 1 results in the pyro-Glu content and Mp being within the desired ranges for a longer reaction time. This was not disputed by opponent 2.

However, as submitted by opponent 2, this effect is not obtained over the whole scope of claim 1 of the main request. Indeed, claim 1 of the main request requires the claimed amount of water to be controlled only "during at least a portion of the depolymerization step". The claim thus covers the addition of water at any time, such as only after a reaction time of 35 hours. In this case, the above effect of maintaining the pyro-Glu content and Mp within the desired ranges for a longer reaction time is not achieved. More specifically, as follows from D23, table 1, if water is

not added until a reaction time of 35 hours has passed (see curve "0% w/w water added"), the pyro-Glu content is above 7 000 ppm and thus above the upper limit of the desired range, and the molecular weight  $M_p$  is below 5 000 Da, thus below the desired range. If then, after a reaction time of 35 hours, water was added, the pyro-Glu content would increase further (albeit possibly less steeply) and thus could not come back into the desired range. Equally, the molecular weight  $M_p$  would decrease further (albeit possibly less steeply) and thus could not come back into the desired range. This was undisputed by the patent proprietor.

Consequently, the above effect of maintaining the pyro-Glu content and molecular weight  $M_p$  within the desired ranges for a longer reaction time cannot be considered when formulating the objective technical problem. There is thus no evidence that supports the formulation of the technical problem as per that of the patent proprietor, namely to control a process better in order to achieve a more consistent product and to make the desired product more reliably. Instead, the objective technical problem can merely be seen to be the provision of an alternative process.

#### 2.4 Obviousness

In the absence of any effect obtained over the entire scope of claim 1 (see point 2.3 above), the addition of an amount of 4 to 25% w/w water in the depolymerisation step of D1 represents an arbitrary measure for the skilled person. Such an arbitrary addition of the water content is within the routine capabilities of the skilled person and thus cannot contribute to inventive step.

The patent proprietor submitted that according to T 1229/17, it was not obvious to assay GA for its pyro-Glu content and that it was not obvious that GA contained pyro-Glu. Therefore, it was not obvious to take any measure to control its formation during the depolymerisation step.

The board disagrees.

The claims considered in T 1229/17 relate, *inter alia*, to a method of selecting a batch of a composition comprising GA by measuring its pyro-Glu content. Decision T 1229/17 is thus not relevant because the claims in the present case concerned a method of preparing a composition comprising GA without referring to any pyro-Glu content as in decision T 1229/17. For this reason alone, decision T 1229/17 is not relevant to the assessment of the obviousness of the subject-matter of claim 1 of the main request.

Thus, the subject-matter of claim 1 of the main request does not involve an inventive step within the meaning of Article 56 EPC.

3. The main request is not allowable.

*Main request a (filed as auxiliary request 1a)*

4. Claim 1 of main request a differs from claim 1 of the main request in that the range of 4-25% w/w water has been amended to 5-25% w/w water.
5. This amendment was made to safeguard the fact that the subject-matter of claim 1 enjoyed the priority date of the patent such that D3 was not prior art under Article 54 (2) EPC and was hence irrelevant for inventive step (see point 3 of the patent proprietor's letter of 30 July 2021).

6. This amendment was not intended to establish inventive step in view of D1 as the closest prior art. In fact, the same line of reasoning as made for the main request above applies. More specifically, in the same way as for the main request, the water content as claimed is an arbitrary selection which does not contribute to an inventive step.

*Auxiliary request 1 (filed as auxiliary request 2, "AR2", claims 1-19 submitted with the reply to the grounds of appeal)*

Added subject-matter

7. During the oral proceedings before the board, opponent 2 raised an objection of added subject-matter against claim 1 of auxiliary request 1.
  - 7.1 This objection was raised for the first time during the oral proceedings. Since it was made after notification of the summons to oral proceedings, it represents an amendment of opponent 2's case. Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted pursuant to Article 13(2) RPBA 2020 (which applies to the present proceedings in accordance with Article 25(3) RPBA 2020 since the summons to oral proceedings had been notified after 1 January 2020). According to Article 13(2) RPBA 2020, any amendment to a party's appeal case made after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances which have been justified with cogent reasons by the party concerned.

Auxiliary request 1 was filed with the reply to the grounds of appeal. The objection raised against this request under Article 123(2) EPC could thus have

already been made on receipt of the auxiliary request, i.e. before the summons to oral proceedings.

Opponent 2 submitted that the objection was made in reaction to the preliminary opinion regarding added subject-matter in the board's communication pursuant to Article 15(1) RPBA 2020, in particular as a result of the board's preliminary opinion that the version of claim 22 of the main request then on file added subject-matter.

Claim 22 of the main request then on file (patent as granted) requires a water content of 11.2% w/w against intermediate-1 to be present during the depolymerisation. In its communication pursuant to Article 15(1) RPBA 2020 (point 18), the board observed that this water content was not based on the application as filed. More specifically, this water content was disclosed in the application as filed only in combination with other features which were missing from claim 22. The passage on page 3, lines 7 to 10, disclosing a water content of "11.2% w/w against Intermediate-1", is not, however, the basis for a water content of "4-25% w/w against Intermediate-1", the basis being on page 2, lines 25 to 29. There is therefore no relationship between the observation made by the board in its communication as regards the passage on page 3, lines 7 to 10, of the application as filed and the disclosure of a water content of 4-25% w/w on page 2, lines 25 to 29. Furthermore, in its communication the board simply reiterated what opponent 1 had stated in a much earlier submission, namely in its reply to the grounds of appeal (point 3.1). It is not conceivable to the board how the objection now made by opponent 2 can be a reaction to an objection made by opponent 1. Irrespective of this, opponent 2 should have made its objection in direct reaction to that of

opponent 1, rather than waiting until the latest possible time, namely during the oral proceedings before the board.

- 7.2 For these reasons, the board has decided not to admit opponent 2's added subject-matter objection into the appeal proceedings in accordance with Article 13(2) RPBA 2020.

#### Novelty

8. Opponent 1 objected to the novelty of the subject-matter of claim 1 of auxiliary request 1 in view of D1, D3, D5 and D7. In its written submissions, opponent 2 objected to its novelty in view of the disclosures in documents D1 and D7 as well, and in addition based a novelty objection on document D6, but these objections were not maintained during the oral proceedings.
9. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in the additional feature "*so as to yield purified glatiramer acetate with pyroglutamate concentration of 2000-7000 ppm and an Mp of 5,000-9,000 Da*".
- 9.1 Claim 1 of auxiliary request 1 thus not only requires that the amount of water during the depolymerisation step is 4-25% w/w, but that it is such as to yield a product with a pyro-Glu content of 2 000-7 000 ppm and an Mp of 5 000-9 0000 Da.

As set out above, D1 neither discloses the water content nor the exact point in time when it is added, let alone that water is added at such a point in time during the reaction that a pyro-Glu content and an Mp within the two ranges specified in claim 1 of AR1 results.



9.2 In the same way as D1, D3, D5 and D7 disclose the presence of water during the depolymerisation step. Also in the same way as D1, none of D3, D5 and D7 discloses the amount of water. There is thus no explicit disclosure in these documents of an amount of water falling within the claimed range of 4-25% w/w. This was common ground between the parties.

9.3 Opponent 1 submitted that the presence of water in D1, D3, D5 and D7 implied an amount of water in the range of >0-100% w/w. The water content in claim 1 of auxiliary request 1 did not represent a novel selection as regards the water content. The range of 4-25% w/w in claim 1 of auxiliary request 1 was not narrow compared to the theoretical range of >0-100% w/w. The lower limit of 4% w/w was not far removed from the lower limit of >0. Finally, the claimed range was not purposive.

The board does not agree. There is no direct disclosure in these documents of any range of the amount of water. For that reason alone, the present case does not represent a selection invention and the case law on the selection from a broad range does not apply. This was set out in the board's communication pursuant to Article 15(1) RPBA 2020 and was not disputed by opponent 1.

9.4 Opponent 1 further submitted that if water was added for the quenching step disclosed in D3, the water concentration would inevitably transitorily pass through a concentration of 4-25% w/w.

The board does not share this view.

First, opponent 1's submission is an unsubstantiated allegation. The passage from page 8, line 24, to page 9, line 1, of D3 discloses that the partial depolymerisation reaction is quenched with cold water ("*After the reaction is quenched with cold water.*"). However, it has not been established by opponent 1 that water was added to the reaction mixture in D3 (see paragraph [0028]). It is not excluded from that passage in D3 that the reaction mixture is poured into water.

Furthermore, should the reaction mixture of D3 be poured into water, a transitory water concentration of 4-25% w/w would not be achieved since water would always be in excess during the step of adding the reaction mixture to water. Thus, there is no direct and unambiguous disclosure of a transitory pass of the water concentration through a concentration of 4-25% w/w.

Finally, a product with a pyro-Glu content of 2 000-7 000 ppm and an Mp of 5 000-9 000 Da, as required by claim 1 of auxiliary request 1, is not disclosed in paragraph [0028] of D3.

The same applies to the disclosure of D5 (page 6, lines 8 to 11) and D7 (page 9, lines 7 to 9). D5 and D7 disclose that the reaction mixture is poured into water. As set out above, adding the reaction mixture to water cannot imply a transitory water concentration of 4-25% w/w.

Therefore, the board concludes that the subject-matter of claim 1 of auxiliary request 1 is novel in view of D1, D3, D5 and D7.

Inventive step

10. Opponents 1 and 2 objected to the inventive step of the subject-matter of claim 1 of auxiliary request 1 in view of D1 and D3 as the closest prior art. Opponent 1 also objected to the inventive step of the subject-matter of claim 1 of auxiliary request 1 in view of D7 as the closest prior art.

11. Inventive step in view of D1 as the closest prior art

11.1 For the same reasons as given above for the main request, D1 can be considered to represent the closest prior art.

11.2 Distinguishing features

As set out above, the subject-matter of claim 1 differs from D1 in terms of the water content and the pyro-Glu content and the molecular weight  $M_p$  recited in claim 1 of auxiliary request 1. Opponent 1 argued that the preferred ranges were inherent features because documents such as D3 and A034 disclosed that the commercially available GA fell within those ranges. However, the ranges are not disclosed in D1, nor has it been argued that the process of D1 necessarily results in a product within the preferred ranges.

11.3 Objective technical problem

As set out above, since claim 1 of auxiliary request 1 includes the ranges as a result to be achieved, the claim only covers embodiments in which the water content is such that the obtained product has the preferred pyro-Glu and  $M_p$  values as now specified in claim 1 of auxiliary request 1. It thus excludes an embodiment wherein water would be added after a reaction time of 35 hours (see point 2.3 above). The

conclusion given above for the main request, namely that the effect of maintaining the pyro-Glu content and molecular weight Mp within the desired ranges over a longer reaction time is not obtained over the entire scope of claim 1 of the main request, thus does not apply to claim 1 of auxiliary request 1. The objective technical problem is now indeed the provision of a process by which the pyro-Glu content and molecular weight Mp can be maintained within the desired ranges over a longer reaction time.

#### 11.4 Obviousness

Opponents 1 and 2 relied on D3, A034 and A035 for the assessment of obviousness of the solution proposed by claim 1 of auxiliary request 1.

D3 (table on page 14) discloses that Copaxone® (a commercially available GA) has an Mp of 5 000-9 000 Da and a pyro-Glu content of 2 500-6 500 ppm. Likewise, A034 (point 2 on page 1) and A035 (point 2 on page 1) disclose the Mp of Copaxone® as being in the range of 5 000-9 000 Da.

However, none of the prior-art documents cited by the opponents teaches that the water content solves the objective technical problem, i.e. results in a GA product having the pyro-Glu content and molecular weight Mp within the desired ranges over a longer reaction time. The skilled person starting from D1 and confronted with the objective technical problem would thus not have applied the claimed water content to achieve a pyro-Glu content and molecular weight Mp as disclosed in these documents over a longer reaction time. Therefore, the subject-matter of claim 1 of auxiliary request 1 involves an inventive step.

12. Inventive step in view of D3 or D7 as the closest prior art

D3 (claim 32 and paragraph [0028]) and D7 (examples 3 and 4) disclose methods for preparing GA by the polymerisation of N-carboxy anhydrides of L-alanine, benzyl-protected L-glutamic acid, TFA-protected L-lysine and L-tyrosine, partial depolymerisation of the resulting protected copolymer and deprotection of benzyl protected groups, removal of the TFA-group on the lysine and purification of the resulting GA. D3 and D7 do not disclose any water content for the depolymerisation step to yield a product with a pyro-Glu content of 2 000-7 000 ppm and an Mp of 5 000-9 0000 Da. The distinguishing feature over each of D3 and D7 thus is at least the water content.

12.1 Consequently, the same reasoning as that given in view of D1 as the closest prior art applies to the subject-matter of claim 1 with regard to either of D3 and D7 taken as the closest prior art. Opponent 2 has argued that D3 would prompt the skilled person to vary the water content during the depolymerisation step if they would like to control the combination of pyro-Glu content and the molecular weight Mp (reply section 122). However, there is no reason to assume that the skilled person would have done so to achieve a GA product having the pyro-Glu content and molecular weight Mp within the desired ranges over a longer reaction time. Thus, the subject-matter of claim 1 of auxiliary request 1 involves an inventive step in view of these documents.

12.2 The patent proprietor had argued that D3 was not prior art under Article 54(2) EPC and thus not citable in the assessment of inventive step. There was no need to discuss this issue since it was found that the subject-

matter of claim 1 of auxiliary request 1 involves an inventive step in view of D1 in combination with D3 or in view of D3 as the closest prior art.

13. In light of the above, the board concludes that the subject-matter of claim 1, and by the same token of dependent claims 2-19, involves an inventive step within the meaning of Article 56 EPC.

#### Sufficiency of disclosure

14. Opponent 1 argued that in view of the single example in the patent, the skilled person did not know what temperature and reaction time were needed to carry out the claimed process.

- 14.1 According to the board, there is no reason to assume that the invention as defined in claim 1 of auxiliary request 1 is insufficiently disclosed.

The temperature and the reaction time are disclosed in paragraph [0005] of the patent, for example. As submitted by the patent proprietor, no evidence that the process of claim 1 of auxiliary request 1 could not be reproduced at certain reaction temperatures or with certain reaction times was provided by opponent 1. This was set out in the board's communication pursuant to Article 15(1) RPBA 2020 and was not disputed by the opponents. Consequently, the objection must fail.

The board concludes that the invention as defined in claim 1 of auxiliary request 1 is sufficiently disclosed within the meaning of Article 83 EPC.

15. In view of the above, auxiliary request 1 is allowable.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent with
  - the claims of auxiliary request 1, filed as auxiliary request 2 with the patent proprietor's reply to the opponents' statements of grounds of appeal,
  - description pages 2, 3 and 5 as annexed to the minutes of the oral proceedings before the opposition division,
  - page 4 of the patent as granted, and
  - figures 1 and 2 of the patent as granted.

The Registrar:

The Chairman:



N. Maslin

M. O. Müller

Decision electronically authenticated