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**Datasheet for the decision
of 12 September 2006**

Case Number: T 1274/04 - 3.3.10

Application Number: 97905454.1

Publication Number: 0826664

IPC: C07C 233/47

Language of the proceedings: EN

Title of invention:

Process for the preparation of N-omega-trifluoroacetylated
basic amino acids

Patentee:

KANEKA CORPORATION

Opponent:

Degussa AG

Headword:

Process for the preparation of N-omega-trifluoroacetylated
basic amino acids/KANEKA

Relevant legal provisions:

EPC Art. 56, 123(2)

Keyword:

"Main and auxiliary requests 1 and 2: inventive step (no) -
effect not made credible within the whole scope of claim -
reformulation of technical problem - obvious solution"
"Auxiliary requests 3 and 4: added subject-matter (yes)"

Decisions cited:

T 0201/83

Catchword:

-



Case Number: T 1274/04 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 12 September 2006

Appellant: KANEKA CORPORATION
(Patent Proprietor) 2-4, Nakanoshima 3-chome
Kita-ku
Osaka-shi, Osaka 530-8288 (JP)

Representative: Vossius & Partner
Siebertstrasse 4
D-81675 München (DE)

Respondent: Degussa AG
(Opponent) Benningsenplatz 1
D-40474 Düsseldorf (DE)

Representative: -

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
19 August 2004 concerning maintenance of the
European patent No. 0826664 in amended form.

Composition of the Board:

Chairman: R. Freimuth
Members: J.-C. Schmid
P. Schmitz

Summary of Facts and Submissions

- I. The Appellant (Proprietor of the patent) lodged an appeal on 25 October 2004 against the interlocutory decision of the Opposition Division, posted on 19 August 2004, which found that the European patent No. 826 664 as granted was not inventive, but that it could be maintained in the form as amended during opposition proceedings according to the then pending second auxiliary request.
- II. Notice of opposition had been filed by the Respondent (opponent) requesting revocation of the patent in suit in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC) based *inter alia* on documents
- (1) EP-A-0 239 063,
 - (3) Journal of Organic Chemistry, vol. 53, (1988), pages 836 to 844 and
 - (4) Canadian Journal of Chemistry, vol. 46, (1968), pages 1047 to 1051.
- III. The patent was granted on the basis of thirteen claims, independent claim 1 reading as follows:
- "1. A process for preparing N⁰-trifluoroacetyl-basic amino acid from a basic amino acid and a trifluoroacetic ester which comprises: adding successively a trifluoroacetic ester to a basic aqueous liquid containing a basic amino acid and a basic pH adjusting agent at a concentration at which a total weight of the basic amino acid is 5 to 40% (w/v) relative to the volume of a charged solvent while

maintaining the pH of the aqueous liquid in a range of 10.6 to 11.4 and the temperature at 20°C or lower, thereby performing the reaction, and crystallizing and collecting N⁰-trifluoroacetyl-basic amino acid from the aqueous liquid after the reaction."

The Opposition Division found that the subject-matter of claim 1 of the patent as granted was novel, in particular with respect to document (1) where there was no disclosure of maintaining the pH within the range indicated in claim 1, but that it did not involve an inventive step (Article 56 EPC). Document (1) was considered to be the closest prior art. In the light of that document, the technical problem underlying the patent in suit was seen in providing an improved process for preparing N⁰-trifluoroacetyl-basic amino acids, wherein high yields were achieved while maintaining high selectivity and wherein the reaction product exhibited improved filtering properties. The Opposition Division held that having regard to document (4), which taught the skilled person in which pH range the acetylation could be carried out selectively and in very good yields, and to document (3) which taught that the acetylation reaction disclosed in document (4) could be the trifluoroacetylation of amino acids, it would have only been a matter of routine to find the best pH range for optimal yield and selectivity.

IV. At the oral proceedings before the Board, held on 12 September 2006, the Appellant defended the maintenance of the patent in suit on the basis of the claims as granted, or, subsidiarily, on the basis of

auxiliary requests 1 to 4 which were former auxiliary requests 2 to 5 submitted on 11 August 2006.

Claim 1 of auxiliary request 1 differed from granted claim 1 exclusively in that the successive addition of the trifluoroacetic ester was performed "over a range of 1/4 to 8 hours."

Claim 1 of auxiliary request 2 differed from that of the auxiliary request 1 exclusively in that "the successive addition of the trifluoroacetic ester to the basic aqueous liquid is performed while stirring at an agitation power of not less than 1/10 kW/m³."

Claim 1 of auxiliary requests 3 and 4 differed from that of the auxiliary requests 1 and 2, respectively, exclusively in that the temperature was maintained at "4°C to 20°C".

V. The submissions of the Appellant can be summarized as follows:

As regards inventive step the Appellant held that document (1) was the closest prior art. The difference with respect to the claimed subject-matter was the combination of a particular temperature range with a particular pH range and the way of adding trifluoroacetic ester in the aqueous solution.

The Appellant argued that the meaning of the expression "adding successively", in the present case, was clear and related to an addition with an intentionally reduced rate or over an intentionally extended period of time and excluded the addition in one portion. It

referred furthermore to the methods of addition specifically exemplified in paragraph [0028] and the examples of the specification of the patent in suit.

Starting from document (1) the Appellant defined the technical problem underlying the invention according to claim 1 as granted and as amended in auxiliary request 1 as the provision of an improved process wherein the precipitate during the reaction was suppressed while maintaining high ω -selectivity in a high yield. It stressed that in view of the examples of the patent in suit and the comparative data submitted on 29 December 2004 it was clear that this problem was solved by the features of independent claim 1 according to any request. The Respondent's data designed to show that a precipitate occurred when operating the process within the ambit of claim 1 were not reliable, since the operation of the process in the Respondent's experiments differed from the operation of the process in the examples of the patent in suit in several aspects; in particular it was not clear whether the reaction mixture was stirred and, in the affirmative, which agitation power was used. Furthermore, even if a precipitate was formed in the experiments of the Respondent, it did not block the agitation, so that the desired effect, i.e. suppression of the formation of a precipitate in the form of whip and cake, was nevertheless achieved, contrary to the result in comparative example 1 of the patent in suit where stirring became impossible due to the precipitation of a whip-like product.

Claim 1 of auxiliary request 2 differed further from the process disclosed in document (1) by the indication

of a particular agitation power. One reason of the precipitation observed in the Respondent's experiments could be an insufficient agitation power causing a local decrease of the pH value and a lower yield. In support of its argumentation and in order to demonstrate the critical significance of the power of the agitation on the increase of the yield, the Appellant submitted experimental data with its letter of 10 August 2006 (see table B on page 8), wherein the operation of the processes differed from each other only by a different agitation power, showing an increase of yield when increasing the agitation power.

The lower limit of the reaction temperature of 4°C introduced into claim 1 of auxiliary requests 3 and 4 could be derived from original examples 2 and 8 to 11 following decision T 201/83 (OJ EPO 1984, 489).

VI. At the oral proceedings before the Board, the Respondent did not maintain its objection of lack of novelty with respect to document (1). As regards inventive step, the Respondent held that the claimed subject-matter lacked an inventive step with respect to document (1).

The meaning of the expression "adding successively" was ambiguous since there was no clear definition for it. It submitted comparative data on 4 May 2005 in order to show that the advantageous effect alleged by the Appellant was not obtained within the whole scope claimed. There was no significant improvement for a process wherein trifluoroacetic ester was added over a certain period of time with respect to a process wherein trifluoroacetic ester was added at once.

With respect to the power of agitation, the Respondent calculated that according to document

(10) Ullmann's Encyclopedia of Industrial Chemistry, fifth Edition, (1988), Volume B2, Chapter 25, Stirring, page 25-1 to 25-11,

the agitation power corresponding to a vigorous stirring (700 min^{-1}) for a homogenous system was of about 0.870 kW/m^3 .

It submitted that this was in line with document

(11) Heuristics in Chemical Engineering, which is an on-line reproduction of a section of the book Chemical Process Equipment Selection and Design by Standley Walas, Butterworth-Heinemann, 1990,

which reflected the common general knowledge of the skilled man and which reported that a homogeneous reaction required usually an agitation intensity varying from 0.1 to 0.3 kW/m^3 , whereas reactions where slurries were involved, required an agitation power about 10 times superior. Thus, stirring at an agitation power of not less than $1/10 \text{ kW/m}^3$ as indicated in claim 1 of auxiliary request 2 was not a distinguishing feature with respect to the process of document (1) and, thus, could not support inventive step.

VII. The Appellant requested that the decision under appeal be set aside and that the patent be maintained as granted, or, subsidiarily, on the basis of renumbered auxiliary requests 1 to 4 filed on 11 August 2006.

The Respondent requested that the appeal be dismissed.

VIII. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Novelty*

Although raised as a ground for opposition, the Respondent did not maintain the objection of lack of novelty with respect to document (1), the Opposition Division having rejected this ground. Nor has the Board any reason to take a different view. Thus, it is not necessary to give reasons in detail for the conclusion that the subject-matter of claim 1 is novel.

3. *Inventive step*

3.1 In accordance with the "problem-solution approach" applied by the Boards of Appeal to assess inventive step on an objective basis, it is in particular necessary to establish the closest state of the art, to determine in the light thereof the technical problem which the invention addresses and successfully solves, and to examine the obviousness of the claimed solution to this problem in view of the state of the art.

- 3.2 The Board considers, in agreement with the Parties, that document (1) represents the closest state of the art, and, hence, the starting point in the assessment of inventive step. That document discloses a process for preparing N⁰-trifluoroacetyl-basic amino acid comprising reacting a trifluoroacetic ester with a basic amino acid in a basic aqueous liquid (claim 1), the reaction being carried out within a pH range of 8 to 11 (claim 4, page 5, line 35) at a temperature of 0°C to room temperature. According to example 2 the reaction starts at a pH value of 10.5, which is maintained within a pH range from 8 to 10 by adding alkali, while the concentration is about 17% (w/v), followed by crystallisation.
- 3.3 In view of this state of the art, the technical problem underlying the patent in suit, as formulated by the Appellant in the patent specification (paragraph [0012]) and during the oral proceedings before the Board, was to provide an improved process for preparing N⁰-trifluoroacetyl-basic amino acid wherein the precipitation of the product during the reaction is suppressed while maintaining high ω-selectivity and a high yield.
- 3.4 The patent in suit proposes as the solution the process according to claim 1 which is characterized by the combination of a temperature at 20°C or lower with a pH range of 10.6 to 11.4, and by maintaining that particular pH range while performing the reaction.
- 3.4.1 The Appellant argued that the proposed solution, i.e. the claimed process, further differed from the process disclosed in document (1) by the way of adding

trifluoroacetic ester, i.e. doing it "successively". This feature was said to also characterize the solution and the Appellant relied thereon to support inventive step of the subject-matter claimed over the closest prior art document (1). The Respondent, however, discarded that feature from the characterizing portion of the process claimed for the reason that it was unclear and ambiguous.

3.4.2 A claim comprising an unclear technical feature entails doubts as to the subject-matter covered by that claim, all the more if this feature is essential with respect to the invention. The principle of legal certainty requires therefore identification of the meaning of that particular feature in order to determine without any doubt whether it characterizes the subject-matter of present claim 1 or not. That feature of "adding successively", hence, needs closer examination.

3.4.3 The meaning of a term or an expression used in a feature of a claim depends in particular on the definition thereof generally accepted by those skilled in the relevant art, requiring as a general rule that use should be made of technical terms generally accepted in the field in question.

The Appellant has neither alleged, let alone provided any evidence of, any generally applicable qualitative definition for the expression "adding successively" as such, nor is the Board aware of any. Thus, that feature cannot be accorded any definition having general validity.

3.4.4 The Appellant is unable to rely on the description of the patent in suit to clarify the unclear term "successively" defining the operation of the claimed process since the description is indeed silent about any qualitative definition of that feature, merely some individual examples having been listed (page 5, lines 16 to 21, examples). Therefore the description does not provide any indication for identifying the meaning of that unclear term.

The Appellant argued that the meaning of the expression "adding successively", in the present case, nevertheless, was clear and related to an addition with an intentionally reduced rate or over an intentionally extended period of time and excluded the addition in one portion. However, the Appellant concedes thereby that there are the untraceable thoughts of the individual operator determining that intention which does not allow on the objective basis of common general knowledge to establish unambiguously whether to qualify or to disqualify any adding as being "successively". As a consequence of the lack of definition, any action of adding is open to the labelled arbitrarily "successively" or not depending exclusively on the mental label the operator wishes to apply, thereby rendering that feature meaningless.

3.4.5 Thus, the Board concludes that the term "successively" intended to define the way of adding trifluoroacetic ester in the claimed process cannot characterize the solution proposed, i.e. define the process claimed, and ,thus, cannot be taken into account for the assessment of inventive step.

3.5 The Respondent provided evidence, namely the test report submitted on 4 May 2005, to show that the technical problem defined above (point 3.3) was not successfully solved within the whole scope of claim 1.

The test report shows that in a process according to claim 1, wherein N⁰-trifluoroacetyl-basic amino acid is prepared from a solution of L-lysine (the basic amino acid) at a concentration of 25% w/v and at a pH value of 11, to which trifluoroacetic ethyl ester is added during a period of time of 1, 10, 15, 60 and 300 minutes respectively, while maintaining the aqueous solution at pH 11, a precipitate occurs when the reaction temperature is 0°C.

This result demonstrates that the alleged improvement of suppressing precipitation is not achieved, i.e. the purported technical problem is not successfully solved by the process within the whole scope of claim 1.

The Appellant's argument to refute the Respondent's test report that the operation of the process by the Respondent was not identical to that of the examples of the patent in suit, cannot convince the Board.

The test report of the Respondent is pertinent since the operation of the process is within the ambit of the claimed process and there is no need to reproduce exactly the conditions used in examples of the patent in suit. The issue discussed between the Parties of whether or not (strong) agitation was to be used during the reaction is irrelevant in the present case since no agitation is required by the claimed process.

With respect to the Appellant's argumentation that the presence of a precipitate would not offset the purported improvement since there was no formation of whip or cake blocking agitation, the Board notes that this submission is based on comparative example 1 set forth in the patent in suit. However, that comparative example does not represent a fair comparison with the closest prior art, since there is no pH control during the reaction. Moreover, it cannot disqualify the results of the Respondent's test report showing that within the scope claimed unwanted precipitation was not suppressed. Consequently, that argument of the Appellant should be rejected.

3.6 Since in the present case the technical effect on which the inventive step is based, namely suppression of the precipitate during the reaction, is not achieved throughout the entire ambit of the claimed subject-matter, the technical problem as defined above (see point 3.3) needs to be redefined in a less ambitious way, and in view of the teaching of document (1) can merely be seen as providing a further process for preparing N⁰-trifluoroacetyl-basic amino acid while maintaining yield and selectivity.

3.7 It remains to be decided whether or not the proposed solution to the objective technical problem, namely the process according to claim 1, is obvious in view of the state of the art.

Document (1) describes a process for preparing an N⁰-trifluoroacetyl-amino acid which comprises selectively introducing a trifluoroacetyl group at the ω-position of a basic amino acid (page 1, lines 1 to 5). The

trifluoroacetic acid ester is added to the basic amino acid at a temperature of 0°C to room temperature (page 5, lines 25 to 33), preferably within a pH range of 8 to 11 (page 5, lines 33 to 38), while the pH value is maintained during the reaction by the addition of a solution of NaOH (example 2).

Thus any process so covered, including a process operated at a temperature of 20°C or lower while maintaining the pH value in a range between 10.6 and 11 is within the ambit envisaged by the general disclosure of documents (1) and is taught to be suitable for preparing selectively N⁰-trifluoroacetyl-basic amino acid.

The choice of specific reaction conditions within the ambit of documents (1) , e.g. the combination of a particular temperature range while maintaining a particular pH range, as indicated in present claim 1 has not been shown to result in any technical benefit vis-à-vis the closest prior art. Therefore this choice cannot be treated as either critical or purposive for solving the objective problem underlying the patent in suit, but merely as an arbitrary restriction of no technical significance.

On this basis, the arbitrary choice of reaction conditions, i.e. of a specific temperature and pH range, envisaged by the general disclosure of documents (1) can only be seen as lying within the routine activity of the skilled person faced with the objective problem of providing a further process for preparing N⁰-trifluoroacetyl-basic amino acid without requiring any inventive ingenuity.

For these reasons, the subject-matter of claim 1 is obvious in the light of documents (1).

- 3.8 As a result, the Respondent's main request is not allowable for lack of inventive step pursuant to Article 56 EPC.

Auxiliary request 1

4. *Amendments*

Claim 1 of auxiliary request 1 differs from that of the main request exclusively in that the trifluoroacetic ester is added over a range of 1/4 to 8 hours. This amendment is supported by page 13, line 14 of the application as filed and thus satisfies the requirement of Article 123(2) EPC.

As this amendment results in a restriction of the claimed scope, the requirement of Article 123(3) EPC is consequently also satisfied.

5. *Inventive step*

- 5.1 The test report provided by the Respondent still shows that the technical problem defined in point 3.3, i.e. the improvement of suppressing precipitation, is not successfully solved within the scope of restricted claim 1, since precipitation has also been shown to occur when the addition of ethyl trifluoroacetate is carried out within the period of time indicated in claim 1 as amended, i.e. 15 minutes (1/4 hour), 60 minutes (1 hour) and 300 minutes (5 hours).

5.2 Accordingly, the finding in point 3.6 above that the purported technical effect is not achieved throughout the entire ambit claimed holds good also for this request resulting in the same conclusion that the problem underlying the patent in suit needs to be redefined. The objective technical problem, thus, remains to provide a further process for preparing N⁰-trifluoroacetyl-basic amino acid while maintaining yield and selectivity.

5.3 The process of document (1) is not limited to any period of time for adding trifluoroacetic ester. The limitation to a particular period of time for adding trifluoroacetic ester in claim 1 as amended has not been shown to be linked to any technical effect. Thus, the choice of the particular period of time for adding trifluoroacetic ester is to be considered neither as critical nor as purposive for solving the objective problem underlying the patent in suit, but merely as an arbitrary restriction of no technical significance.

The considerations concerning inventive step with respect to the main request is neither based on nor affected by the indication of the period of time for adding trifluoroacetic ester. Thus, the choice which was made of adding trifluoroacetic ester during a given period of time can neither provide the claimed process with any inventive ingenuity as that choice is arbitrary and, thus, within the routine of a skilled person.

5.4 For these reasons the conclusion in point 3.7 above applies to this request as well.

In these circumstances, the Appellant's auxiliary request 1 is rejected for lack of inventive step pursuant to Article 56 EPC.

Auxiliary request 2

6. *Amendments (Article 123 EPC)*

Claim 1 of auxiliary request 2 differs from that of the auxiliary request 1 only in that the successive addition of the trifluoroacetic ester to the basic aqueous liquid is performed while stirring at an agitation power of not less than 1/10 kW/m³. This amendment is based on original claim 2 and thus satisfies the requirement of Article 123(2) EPC.

As this amendment results in a restriction of the claimed scope, the requirement of Article 123(3) EPC is consequently also satisfied.

7. *Inventive step*

7.1 In view of document (1), which remains to be the closest prior art, the Appellant defined the technical problem during the oral proceedings before the Board as to provide an improved process for preparing N⁰-trifluoroacetyl-basic amino acid with higher yield and wherein the precipitation of the product during the reaction is suppressed.

7.2 The solution is the process according to claim 1 which is characterized, in addition to the combination of a temperature at 20°C or lower while maintaining a pH

range of 10.6 to 11.4 and a period of time of 1/4 to 8 hours for the addition of the trifluoacetic ester as in the previous request, in particular by stirring at an agitation power of not less than 1/10 KW/m³.

The Appellant indicated at the oral proceedings before the Board, that the inventive ingenuity of this proposed solution was based on the feature of applying the particular agitation power as defined above.

- 7.3 In order to support that submission the Appellant filed a test report on 11 August 2006 comprising table B wherein the agitation power varied while all other reaction conditions were kept unchanged. These comparative data show that stirring at a power of 1/10 and 1/3 kW/m³, i.e. within the ambit of the process of claim 1 as amended, the yields obtained were 62.5% and 66.8%, respectively, while stirring at a power of 1/20 kW/m³, i.e. outside of the scope of claim 1, the yield was only 45.9%.

However, this effect has not been demonstrated with respect to document (1), which is the closest prior art. Document (1) discloses that trifluoroacetic ester is added to the basic amino acid in aqueous medium with **vigorous stirring** (see the example 2, page 7, line 28).

In these examples of document (1) the reaction mixture is a slurry due to occurring precipitations. According to the patent-in-suit (specification page 5, line 27 and 28) the agitation power used to "vigorously stir" that slurry reaction mixture in the closest prior art document is "stronger" than that required to stir the reaction mixture of the claimed process, since the

latter is in a "good liquid condition". Thus, the feature of "vigorously stir[ring]" in document (1) means in the sense of the patent-in-suit an agitation power superior to that necessary in the claimed process. This finding is in line with common general knowledge represented inter alia by document (11) identifying an agitation power of 0.1 to 0.3 kW/m³ for a homogeneous reaction mixture and an about ten times higher agitation power for slurries.

However, the only comparative example in table B of the Appellant's test report uses an agitation power of 1/20 kW/m³ which is much lower than that used for "vigorously stir[ring] the slurries described in document (1) and which is also below the claimed lower limit for that power. Accordingly, as also conceded by the Appellant during the oral proceedings before the Board, that agitation power of 1/20 kW/m³ used in the comparative example does not reflect the closest prior art with the consequence that the comparison made is unfair and inadequate for properly demonstrating any improvement of the claimed process vis-à-vis document (1).

- 7.4 Therefore, the finding in point 3.6 above that the purported technical effect has not been shown to be achieved in view of the closest prior art holds good for this request as well, resulting in the same conclusion that the problem underlying the patent-in-suit needs to be redefined. The objective technical problem remains to provide a further process for preparing N⁰-trifluoroacetyl-basic amino acid while maintaining yield and selectivity as defined in point 3.6 above.

7.5 As specified in point 7.3 above, a process involving an agitation power within the range indicated in claim 1, is already described in document (1). The introduction of a further technical feature not distinguishing the claimed subject-matter from document (1) cannot confer inventive ingenuity to the claimed process over that prior art.

In these circumstances, the Appellant's auxiliary request 2 is not allowable for lack of inventive step pursuant to Article 56 EPC as well.

Auxiliary requests 3 and 4

8. *Amendments*

8.1 The fresh amendment in claim 1 of these requests concerns the lower limit of the temperature range of 4°C. According to the Appellant this amendment is based on examples 2 and 8 to 11 of the original application which disclose the operation of the process at 4°C.

8.2 In order to determine whether or not an amendment offends against Article 123(2) EPC it has to be examined whether technical information has been introduced which a skilled person would not have objectively and unambiguously derived from the application as filed.

8.3 The examples 2 and 8 to 11 in the application as filed disclose the preparation of a particular N⁰-trifluoroacetyl-basic amino acid starting from one single amino acid and using particular reaction

conditions. Each of these examples describes the process in detail for the preparation of a single N⁰-trifluoroacetyl-basic amino acid and, in combination with the particular temperature of 4°C, indicates numerous further specific technical features, e.g. operation at particular pH values and particular agitation power values.

A generalisation of these originally disclosed examples has thus been made in claim 1 since any amino acid is encompassed by that claim and since those further specific technical features disclosed in combination with the particular temperature of 4°C have been omitted.

- 8.4 According to the decision T 201/83 (*loc. cit.*), referred to by the Appellant, such a generalisation resulting from an amendment of the lower limit of a range in a claim can be allowable on the basis of a particular value described in a specific example, provided the skilled man could have readily recognised this value as not so closely associated with the other features of the example as to determine the effect of that embodiment of the invention as a whole in a unique manner and to a significant degree.

However, in the present case, the temperature value is closely associated with the individual amino acid used and with the further specific features given in the examples, since as is apparent from the examples and as indicated by the Appellant in its argumentation with respect to inventive step, there is a close technical relationship between the temperature and the pH value, as well as the agitation power, the choice of a

particular combination thereof being causal for the results achieved by the process.

Thus, the Board holds that the temperature of 4°C is only originally disclosed in the particular context of the given examples and that the skilled person derives from the disclosed processes nothing more than the bare disclosure of all their technical characteristics in their particular combination.

To separate this temperature value of 4°C from the particular individual amino acid and from a specific operation of the process originally disclosed and to generalize that temperature over the whole scope of claim 1 covering processes with different amino acids and with other pH values, as well as other values of agitation power, thus provides the skilled person with technical information which is not directly and unambiguously derivable from the application as filed.

- 8.5 As a consequence the amendment in the claim 1 of these requests setting 4°C as the lower limit of the temperature range of the claimed process cannot be based on the disclosure of examples 2 or 8 to 11 of the original application, but is an undue generalisation thereof which extends beyond the content of the application as filed.

Hence, these requests must be rejected pursuant to Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

C. Moser

R. Freimuth