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**Datasheet for the decision
of 12 April 2019**

Case Number: T 0492/14 - 3.3.02

Application Number: 06793364.8

Publication Number: 1926502

IPC: A01N59/00, A61L2/22, A61L2/18

Language of the proceedings: EN

Title of invention:

AQUEOUS SOLUTION SUITABLE FOR THE CHEMICAL STERILIZATION OF
PACKAGING MATERIALS, PROCESS FOR ITS PREPARATION AND ITS USE

Patent Proprietor:

SOLVAY SA

Opponents:

ARKEMA FRANCE
FMC Foret, S.A.

Headword:

Relevant legal provisions:

EPC Art. 54, 56, 83
RPBA Art. 13(1), 13(3)

Keyword:

Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Late-filed argument - admitted (no)
Late-filed document - admitted (yes)

Decisions cited:

G 0007/93, T 0990/96, T 1085/13, T 1209/05, T 1652/08,
T 1253/09

Catchword:



Beschwerdekammern

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Case Number: T 0492/14 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 12 April 2019

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
20 December 2013 concerning maintenance of the
European Patent No. 1926502 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appeals by opponents 1 and 2 lie from the interlocutory decision of the opposition division, according to which European patent N° 1 926 502 in its form modified on the basis of the then pending fourth auxiliary request and the invention to which it relates meets the requirements of the EPC.
- II. By letter dated 13 June 2014, opponent 2 withdrew its appeal. By letter dated 8 October 2014, it withdrew its opposition.
- III. The following documents are referred to in the present decision:
- | | |
|-----|--|
| D1 | US 2004/47755 A1 |
| D4 | EP 0 635 273 A1 |
| D22 | "Determination of Dry residue in Hydrogen Peroxide" |
| D29 | "Food Chemical Codex", p.496-497 |
| D41 | "Résultats de test d'utilisation d'une composition aqueuse de peroxyde d'hydrogène stabilisée pour le conditionnement aseptique par trempage de matériaux d'emballage" |

The opposition division came to, *inter alia*, the following conclusions:

- The invention of claims 1 and 8 according to the then pending main request met the requirements of Article 83 EPC.
- D41 was not admitted into the proceedings.
- The subject-matter of claim 1 of the fourth auxiliary request was novel and involved an

inventive step starting from D4 as the closest prior art.

- IV. The fourth auxiliary request found allowable by the opposition division contains eight claims, independent claim 1 reciting as follows:

"1. Use of an aqueous solution comprising hydrogen peroxide and at least one foodstuff-compatible stabilizer, characterized in that the said solution without the foodstuff-compatible stabiliser has a maximum phosphorous content expressed as PO_4^{3-} of 10 mg/kg, and presents a dry residue at 105 °C of at most 10 mg/kg, and said solution contains from 1 to lower than or equal to 8 mg per kg H_2O_2 solution of the foodstuff-compatible stabiliser for the chemical sterilization of packaging materials."

- V. In its statement setting out the grounds of appeal, opponent 1 (hereinafter "appellant") contested the reasoning of the opposition division and submitted that the invention of claims 1 and 8 was not sufficiently disclosed and that the subject-matter of claims 1-8 did not involve an inventive step starting from D4 as the closest prior art.

- VI. The patent proprietor (hereinafter "respondent") filed a response to the statement of grounds of appeal along with the first to seventh auxiliary requests. Its main request corresponds to the fourth auxiliary request held allowable by the opposition division.

- VII. In its preliminary opinion of 4 March 2019, the board, *inter alia*, concurred with the opposition division that measuring the dry residue content would not have been

an undue burden and that sufficiency of disclosure could depend on the admittance of D41.

- VIII. By letter dated 28 March 2019, the appellant presented a new inventive-step attack based on an alleged public prior use.
- IX. Oral proceedings before the board were held on 12 April 2019.
- X. The appellant's arguments, where relevant to the present decision, may be summarised as follows:
- The content of the dry residue depended on the drying time at 105°C. The method disclosed in the description of the patent (paragraph [0013]) only mentioned a drying time of "at least one hour". The dry residue content significantly varied depending on whether a drying time of 2, 10 or 16 hours was applied at 105°C as evidenced by D22.
 - The invention could not be performed over the whole scope of claim 1, in particular not as defined in dependent claim 8.
 - Document D41 was *prima facie* relevant as it showed that the result referred to in claim 8 was not achieved. According to G1/03, this implied a lack of sufficiency of disclosure. D41 was carried out by another company and was filed as soon as the results reported in D41 were available. The opposition division's arguments were based on technical features not disclosed in the patent.
 - The public prior use (document D35) could be considered as the closest prior art, considering the preliminary opinion of the board sent with the communication in preparation for the oral proceedings.

- The claimed subject-matter also lacked an inventive step when document D4 was considered the closest prior art, alone, or, alternatively, in combination with D1. It would have been obvious to reduce the content of the stabiliser to the values disclosed in D1.

XI. The respondent's arguments, where relevant to the present decision, may be summarised as follows:

- Regarding the dry residue, it was common general knowledge to perform the measurement only when constant weight was reached.
- D41 was not *prima facie* relevant. If it were relevant, it would be a matter of inventive step.
- D35 was not a suitable springboard for the evaluation of inventive step; it was difficult to analyse the commercial product disclosed in the document. In view of its late filing, it should not be admitted.
- The surprising beneficial effect corroborated by the experimental results filed by letter of 28 June 2012 at first instance and resubmitted with the letter of 5 April 2019 was achieved by the hydrogen peroxide solution according to the invention.
- D1 was concerned with processes involving a dip bath, while D4 was concerned with a spray application. The invention provided by the patent related to the use of a composition for both applications. Paragraphs [0007] and [0008] of D1 taught that both processes involved different concentrations of the stabiliser.

XII. The parties' final requests were the following:

The appellant requested that:

- the decision under appeal be set aside and the patent be revoked
- the opposition division's decision not to admit document D41 be set aside, alternatively that document D41 be admitted into the appeal proceedings
- the defence of the respondent, based on the experimental results, not be admitted into the appeal proceedings
- documents D32 to D40, D42, D43 be admitted into the appeal proceedings, and that the case be remitted to the opposition division for the examination of a new inventive step attack based on these documents
- auxiliary requests 4 to 7 not be admitted into the appeal proceedings on the principle of *non-reformatio in peius*
- the respondent's statement regarding D35 be recorded in the minutes.

The respondent requested that:

- the appeal be dismissed and, as the main request, the patent be maintained in amended form on the basis of the "fourth auxiliary request", held allowable by the opposition division, or auxiliarily according to any of the first to seventh auxiliary requests filed with the response to the statement of grounds of appeal
- document D41 not be admitted into the appeal proceedings, implying that the opposition division's decision not to admit this document be confirmed
- documents D32 to D40, D42, D43 not be admitted into the appeal proceedings

- if the new inventive step attack based on an alleged public prior use supported by *inter alia* document D35 were to be admitted, the case be remitted to the opposition division for examination of this attack.

Reasons for the Decision

1. Admittance

1.1 Admittance of the new inventive-step attack based on an alleged public prior use

In the context of this attack, the appellant relied on documents D32 to D40, D42 and D43 filed on 18 October 2013 during the opposition phase. In the statement of grounds of appeal, the appellant did not rely on this inventive-step attack. It was only filed at a later stage of the appeal proceedings, namely by letter dated 28 March 2019.

The appellant argued that the attack was to be considered a response to the board's preliminary opinion identifying the distinguishing features and the decision T 1085/13 referred to. This decision reversed the case law according to older decision T 990/96 on which the appellant had based its first attack, considering D4 as the closest prior art. The alleged prior use was a more promising closest prior art for evaluating inventive step of the invention.

The board does not agree. The appellant's new attack is put forward very late in the proceedings, roughly two weeks before oral proceedings before the board. It represents an amendment of the appellant's appeal case,

and its admittance is at the board's discretion under Article 13(1) and (3) RPBA. The appellant's argument regarding T 1085/13 cannot be accepted since the two distinguishing features that the board had identified in its communication applying T 1085/13 are identical to those identified by the opposition division in its decision. The cited decision T 1085/13 thus cannot be considered a reason for justifying the late filing of the new inventive-step attack. The new attack raises complex new issues, such as whether the alleged public prior use forms prior art, whether it can be taken as the closest prior art, what the distinguishing features are, what problem is solved, and whether the claimed subject-matter would have been obvious when starting from the alleged public prior use and taking this problem into account. The board therefore decided not to admit the new inventive-step attack into the proceeding according to Article 13(1) and (3) RPBA.

1.2 Admittance of D41

D41 was filed by the opponent (appellant) during opposition proceedings on 15 October 2013, i.e. less than one month before the oral proceedings. The opposition division did not admit D41 into the proceedings.

With its statement of grounds of appeal, the appellant requested to admit this document into the appeal proceedings.

According to e.g. G 7/93, T 1209/05, T 1652/08 and T 1253/09, the board shall overrule the way in which an opposition division has exercised its discretion when deciding not to admit a document only if it concludes that the first-instance department did so based on the

wrong principles or in an unreasonable way. Thus, in the present case, it must be determined whether the opposition division applied the wrong principle or applied the right principle but in an unreasonable way.

In section 2.2.2.2 of its decision, the opposition division analysed D41 and came to the conclusion that also when taking this document into account, there would have been no undue burden for the skilled person to carry out the claimed use. This implies that the opposition division considered D41 not to be relevant. In section 6.2.12, the opposition division stated that the document was late filed and that, since the proprietor did not have time to contest the results of D41, this document was not admitted into the proceedings.

The relevance of a document and when it is filed are the right principles to be applied by a first-instance department when deciding on admittance. Furthermore, these principles had not been applied by the opposition division in an unreasonable way. The appellant's arguments made in this respect are not convincing:

The appellant argued that the filing of the tests in D41 had been triggered by third-party observations. It had filed the results reported in D41 as soon as they had become available after the third-party observation had been filed. In this respect, it must be taken into account that the tests were carried out by a different company and that it took quite some time for them to be finalised. However, it is the responsibility of an opponent to present all attacks within the nine-month opposition period (Article 99(1) and Rule 76(2)(c) EPC). An opponent cannot benefit from the submissions of a third party to justify any such attacks at a later

stage. The opposition division's finding that the tests in D41 had been filed late and, considering the limited possibilities of the proprietor to formulate an adequate response, that the document was not admissible is thus reasonable.

The appellant further argued that D41 showed that a composition as claimed did not have a stability as required by claim 8 of the main request. Contrary to what was stated in the opposition division's decision, the skilled person would not have been able to select operating conditions, such as the number of materials to be sterilised, to achieve a stability as required by claim 8 (claim 11 in the claim request underlying the opposition division's decision). D41 thus showed that the invention defined in this claim was insufficiently disclosed. According to the appellant, it was therefore *prima facie* relevant, contrary to the opposition division's decision. However, the examples in the patent (see paragraph [0032]) in fact show that operating conditions can be chosen for at least 120 h of operation without losing performance. Thus, on the basis of the evidence at hand and in view of the short time between the filing of D41 and the oral proceedings, the opposition division's decision that D41 was not relevant was not unreasonable.

In view of this, the board decided not to admit D41 into the proceedings, thus confirming the opposition division's decision not to admit this document.

1.3 Admittance of the defence filed by the respondent on 5 April 2019

The respondent filed on 5 April 2019, i.e. one week before oral proceedings before the board, experimental

results previously submitted during the opposition phase to support the inventive step of the invention. The results demonstrated a surprising beneficial effect of a low amount of stabiliser on the stability of a hydrogen peroxide solution according to the invention. The respondent argued that the tests had been filed during the first-instance proceedings, were considered by the opposition division in its decision and thus did not constitute new matter added to the file.

In the board's view, the respondent's defence is an amendment of the respondent's case that was filed late in the appeal proceedings. As argued by the appellant, the attack of lack of inventive step had been raised in the statement setting out the grounds of appeal filed on 17 April 2014, and the defence could have been filed with the reply to the statement setting out the grounds of appeal. There is no reason apparent to the board, and none was given by the respondent, why it waited almost five years for filing such a defence.

For these reasons, the board decided not to admit the respondent's defence based on the experimental results (Article 13(1) and (3) RPBA).

2. Main request - inventive step

2.1 The invention

The invention as defined in claim 1 of the main request concerns the use of an aqueous solution comprising hydrogen peroxide and from 1 to lower than or equal to 8 mg per kg H₂O₂ solution of at least one foodstuff-compatible stabiliser for the chemical sterilisation of packaging materials. The solution without the foodstuff-compatible stabiliser has a maximum

phosphorous content expressed as PO_4^{3-} of 10 mg/kg and presents a dry residue at 105 °C of at most 10 mg/kg.

The aim of the invention lies in compositions suitable for the chemical sterilisation of packaging materials in both dip bath and spray processes (paragraphs [0007] and [0009] of the patent).

2.2 The closest prior art

With the new inventive-step attack based, on *inter alia*, D35 not having been admitted into the proceedings, both parties indicated D4, and in particular the compositions in examples 1 and 4, as the closest prior art for the subject-matter of claim 1 of the main request.

In the same way as the patent, D4 aims at avoiding deposits in spray process equipment (page 2, lines 29-31). The board thus sees no reasons to deviate from the parties' position.

2.3 Distinguishing features

2.3.1 Examples 1 and 4 of D4 disclose aqueous compositions comprising hydrogen peroxide and 26 mg/kg of aminotrismethylene phosphonic acid ("*acide amino-tris-méthylènephosphonique*"). The dry residue of this composition (including the aminotrismethylene phosphonic acid) is 20 mg/kg (example 1) and 25 mg/kg (example 4). The compositions are used in a spray process for the chemical sterilisation of packaging materials (example 1, lines 25-29, on page 4).

It is undisputed that the aminotrismethylene phosphonic acid used in the examples of D4 corresponds to the

additive used in the examples of the patent and is a foodstuff-compatible stabiliser according to claim 1.

2.3.2 It was further common ground between the parties that the subject-matter of claim 1 at issue differs from the compositions of examples 1 and 4 in the amount of the foodstuff-compatible stabiliser (1 to 8 mg/kg vs 26 mg/kg in the examples) and in the maximum phosphorous content expressed as PO_4^{3-} (10 mg/kg in claim 1 of the patent, not disclosed in the examples of D4).

2.3.3 It was a matter of dispute between the parties whether the dry residue of the composition without stabiliser was an additional distinguishing feature. The respondent submitted that it could not be concluded that the values disclosed in examples 1 and 4 of D1 (20 mg/kg and 25 mg/kg), measured at 110°C and based on the stabilised composition, corresponded to the values measured at 105°C for the composition without the stabiliser as required by claim 1.

The appellant argued that the values of 20 and 25 mg/kg for the dry residues of the stabilised composition in examples 1 and 4 of D4 corresponded to a dry residue lower than 10 mg/kg for the composition without stabiliser as required by claim 1. The fact that the dry residue content (20 or 25 mg/kg) was lower than the amount of the stabiliser (26 mg/kg) was explained by the decomposition of the stabiliser.

The appellant's argument cannot be accepted in the absence of credible evidence. It cannot be determined from the disclosure of D4 how much of the stabiliser decomposes in examples 1 and 4 of D4 and how much remains. If, for example in example 1 of D4, the amount of the decomposed stabiliser counts for 20 mg/kg, only

6 mg/kg stabiliser would remain in the final dry residue. In this case, the dry residue content without the stabiliser would be 14 mg/kg (dry residue reported in example 1 (20 mg/kg) minus dry residue resulting from non-decomposed stabiliser (6 mg/kg)), i.e. above the upper limit of claim 1. Hence, it cannot be assumed that in examples 1 and 4 the composition without the stabiliser would have the required dry residue at 105°C of at most 10 mg/kg.

The appellant argued that the dry residue was an impurity that following T 990/96 did not count as a distinguishing feature. However, firstly, the dry residue is not an impurity but represents what is left of the composition after drying. Secondly, following the more recent decision T 1085/13, even if it were, the dry residue and thus the impurity would distinguish the claimed subject-matter from D4.

Consequently, the dry residue of the solution without the stabiliser is an additional distinguishing feature of the subject-matter of claim 1 in view of D4.

2.4 Formulation of the technical problem

The appellant argued that no effect was achieved by the distinguishing features. It submitted that the examples of the patent did not fall within the scope of claim 1 in view of the amount of 10 mg/kg of the stabiliser, which is higher than the one required by claim 1 (1 to 8 mg/kg). It argued that the percentage referred to in the example (see paragraph [0031]: "*Then, aminotrismethylene phosphonic acid was added as stabiliser in an amount of 10 mg in the form of a 50 % wt aqueous solution per kg of H₂O₂ solution...*") referred to the concentration of the aminotrismethylene

phosphonic acid as such. Consequently, the stabiliser amount was 10 mg/kg which was above the upper limit of 8 mg/kg defined in claim 1.

The board does not agree. The percentage of 10 mg/kg in paragraph [0031] of the patent pertains to the concentration of the 50 wt% aqueous solution mentioned in paragraph [0031]. The concentration of aminotrismethylene phosphonic acid in this composition is thus half of 10 mg/kg, i.e. 5 mg/kg.

This amount falls within the range according to claim 1 ("*from 1 to lower than or equal to 8 mg per kg H₂O₂ solution*"). Hence, the examples of the patent are in accordance with the invention defined in claim 1.

Paragraph [0032] of the patent states that the stabilised compositions were used in dip bath aseptic packaging machines and in spray aseptic packaging machines and that both types of machines were operated for at least 120 h without losing performance.

Thus, the examples show that the stabilised hydrogen peroxide composition as defined in claim 1 is suitable for both a dip bath process and a spray process.

The objective technical problem is thus the provision of a sterilisation composition suitable for both a dip bath process and a spray process.

2.5 Obviousness of the solution

2.5.1 The appellant argued that it would have been obvious from D4 to reduce the amount of the stabiliser and the phosphorous content expressed as PO_4^{3-} . D4 taught that the hydrogen peroxide compositions should have a high

degree of purity. Reference was made to the passages of D4 on page 3, lines 43-47, and page 4, lines 15-17. This confirmed the standard of the food industry. According to the appellant, the skilled person would have used any purification method known in the art at the priority date of the patent such as purification by reverse osmosis using a membrane and would thus have obtained a hydrogen peroxide composition having the purity required by claim 1. It further argued that D4 taught to reduce the amount of the stabiliser considering the results presented in example 5 in conjunction with example 2 of D4 and that the stability of the hydrogen peroxide solution depends on the chemical nature of the stabiliser and the amount of it. It argued that increasing the purity of the ingredients and optimising the amount of the stabiliser in the context of the invention did not achieve any improvement and would have represented laboratory routine for the skilled person.

The appellant's argumentation is unconvincing. Firstly, while D4 does teach to use hydrogen peroxide solutions having a high purity, it does not teach to reduce the amount of the stabiliser. Example 5 of D4 only shows that the stability of the composition of example 2 using 9 mg/kg of sodium stannate is increased in comparison to the compositions of examples 1, 3 and 4 (1% loss of hydrogen peroxide vs 1.1 or 3 %). However, example 2 is a comparative example which does not represent any embodiment of D4. Furthermore, sodium stannate causes clogging of the spray equipment (see the passage on page 4, lines 42-44 of D4). Therefore, the skilled person, faced with the technical problem posed, would not have regarded comparative example 2 of D4 a successful embodiment and would thus have disregarded it in view of the clogging of the spray

equipment. D4 is concerned with a process using hydrogen peroxide solution stabilised with an organic phosphonic acid (see claim 1 of D4) and not with a metal stannate.

The skilled person considering D4 alone would not have found in it any teaching or hint to reduce the amount of the stabiliser to a value falling within the range referred to in claim 1 of the main request.

Furthermore, D4 is only concerned with the chemical sterilisation of packaging material involving a spray process. No reference is made to a dip bath process in D4. As expressed in the patent in paragraphs [0003] and [0004], both processes require different amounts of stabilisers. The skilled person could not have thus predicted from the teaching of D4 whether the compositions taught in it are suitable for a dip bath process. Consequently, D4 alone would have not led the skilled person towards the invention defined in claim 1.

- 2.5.2 The appellant argued that document D1 disclosed sterilisation compositions based on hydrogen peroxide and comprising a low amount of foodstuff-compatible phosphonic acid for use in spraying as well as a dip bath process. The amount of the foodstuff-compatible phosphonic acid was as low as 1 ppm, as disclosed in claim 1 or paragraph [0013] of D1. According to the appellant, the skilled person would have considered D1 and applied a stabiliser amount as low as 1 ppm, which is as required by claim 1.

However, contrary to the appellant's arguments and as submitted by the respondent (X, *supra*), while D1 refers to both processes in the background of the invention (paragraphs [0006] to [0008]), it teaches a composition

suitable to dip bath technology only (see paragraphs [0014], [0015], [0018]; claims 4, 5). Furthermore, it emphasises the difference of the concentration of the stabiliser between both processes. Both processes have different requirements. The spray process requires a low amount of inert material largely originating from the stabilisers whereas the dip bath process requires a more highly stabilised hydrogen peroxide solution (see paragraphs [0007] and [0008]). The compositions disclosed in the examples of D1 are thus only suitable for the dip bath process. The compositions comprise 250 to 1000 μl of "*an aqueous 50% strength solution of aminotris(methylene phosphonic acid)*" (see paragraphs [0021] and [0022]), thus corresponding to about 125, 250 or 500 mg/kg of H_2O_2 solution (owing to the concentration of the phosphonic acid in the stabiliser composition and not considering the density of the whole solution of example 1).

D1 does not teach a single stabilised hydrogen peroxide solution which would have been suitable at the same time for a dip bath process and a spraying process. D1 proposes, therefore, no straightforward possibility that the skilled person would have immediately considered to solve the technical problem posed (2.4, *supra*).

Consequently, it cannot be derived from the combination of teaching of D4 and D1 that it would have been obvious to reduce the amount of the stabiliser, the amount of dry residue and the maximum phosphorous content expressed as PO_4^{3-} to provide a sterilisation composition suitable for a dip bath process and a spraying process.

2.6 For the reasons expressed above, the subject-matter of claim 1 and, by extension, all remaining claims of the main request involves an inventive step.

3. Sufficiency of disclosure (Article 100(b) EPC) - main request

3.1 Claim 1 refers to an aqueous solution presenting a dry residue at 105°C of at most 10 mg/kg.

3.1.1 The appellant argued that the content of the dry residue depends on the drying time at 105°C and that the measuring method disclosed in the description of the patent (paragraph [0013]) only mentions a drying time of "at least one hour". The appellant referred to the results set forth in the figure of D22 and argued that the dry residue content significantly varies depending on whether a drying time of 2, 10 or 16 hours is applied at 105°C. The skilled person would not therefore have been in a position to carry out the invention.

3.1.2 However, as already set out in the board's preliminary opinion, it was common practice in measuring the dry residue to dry the sample to be measured until its weight is constant. The skilled person would thus have performed the measurement of the dry residue only when constant weight was reached. This is confirmed by D29. D29 refers to the description, identification, assay, impurities and specific tests of hydrogen peroxide. Among the tests disclosed in the document, "residue on evaporation" is mentioned, and the sub-paragraph "Analysis" refers to "continue drying to constant weight at 105°C".

- 3.1.3 Consequently, there is no ambiguity as regards the measuring of the amount of dry residue and thus no insufficiency arising out of any ambiguity.
- 3.1.4 Therefore, the invention as defined in claim 1 is sufficiently disclosed.
- 3.2 The appellant also objected to claim 8 for lack of sufficiency of disclosure.
 - 3.2.1 Claim 8 requires that the claimed use occurs in a dip bath aseptic packaging process and that during at least 120 h operation of this process, the hydrogen peroxide concentration does not differ from the initial value by more than 10%.
 - 3.2.2 The appellant based its argumentation on D41, arguing that the result to be obtained according to claim 8 (stability of hydrogen peroxide during operation) could in fact not be achieved.
 - 3.2.3 Since D41 is not admitted into the proceedings, there is no reason to assume that the result defined in claim 8 cannot be obtained. There is thus no reason either to assume that the invention as defined in dependent claim 8 is insufficiently disclosed.
- 3.3 Therefore, the ground under Article 100(b) EPC does not prejudice the maintenance of the patent on the basis of the main request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



N. Maslin

M. O. Müller

Decision electronically authenticated