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Datasheet for the decision of 14 September 2015

Case Number: T 0111/12 - 3.3.07

Application Number: 05792230.4

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Title of invention:
STABILISED OXYGEN RELEASING COMPOSITION

Applicant:
Ngen Pharmaceuticals N.V.

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
Novelty - main request (no)
Inventive step - (no)

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Case Number: T 0111/12 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 14 September 2015

Appellant: (Applicant)	Ngen Pharmaceuticals N.V. Landhuis Joonchi Kaya Richard Ji Beaujon z/n Curaçao (AN)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 5 August 2011 refusing European patent application No. 05792230.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	J. Riolo
Members:	R. Hauss
	D. T. Keeling

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division, pronounced on 19 July 2011 and posted on 5 August 2011, refusing European patent application No. 05 792 230.

II. The documents cited in the examination and appeal proceedings included the following:

D1: US 6 017 515 A

D3: US 2002/0068041 A1

D4: WO 96/02624 A1

D10: Test data mentioned in the applicant's letter of 17 June 2011, pages 2 to 4, with figures 1 to 3 filed on 19 July 2011

D12: Test data concerning citrate mentioned in the statement setting out the grounds of appeal on pages 2 to 3, with figures 4 to 7

D14: Test data mentioned in the appellant's letter of 19 August 2015, pages 3 to 5

III. The decision under appeal was based on an amended main request and two auxiliary requests.

Claim 1 of the main request reads as follows:

"1. Stabilised liquid oxygen releasing composition, said composition comprising

a component (a) selected from the salts consisting of cations A_n^+ and anions derived from halogen oxides according to the general formula $[O_m X]^-$, wherein A is a metal selected from Groups 1 or 2 of the Periodic System of the Elements, X is a halogen atom, m = 1 - 4, n = 1 or 2,

a component (b) selected from the group of oxygen donors,

a component (c) selected from the group of oxygen donor stabilising agents, and

a component (d) selected from the group of liquid binders,

said oxygen donor stabilising agents being selected from the group consisting of chelating organic acids and their pharmaceutically acceptable salts,

wherein the chelating organic acids are selected from carboxylic acids containing one or more hydroxy groups and polycarboxylic acids containing one or more hydroxyl groups."

Claims 1 of the then pending auxiliary requests correspond to claim 1 of the main request but specify that the chelating organic acids are selected from carboxylic acids containing one or more hydroxy groups (first auxiliary request) or that the chelating organic acid is gluconic acid (second auxiliary request).

IV. According to the decision under appeal, the subject-matter of claim 1 of the main request lacked novelty over example II of document D1, which disclosed a mixture comprising (a) sodium hypochlorite, (b) sodium perborate tetrahydrate, (c) sodium citrate and (d) glycerol and sodium carboxymethylcellulose.

Example II of document D1 also anticipated the subject-matter of claim 1 of the first auxiliary request, since sodium citrate disclosed in D1 was covered by the definition "(salts of) carboxylic acids containing one or more hydroxy groups" according to claim 1 of that request.

The composition of claim 1 of the second auxiliary request differed from the composition of example II of document D1 in the mandatory presence of gluconic acid or gluconate.

Document D1 was regarded as the closest prior art. The experimental data provided by the applicant (D10) did not establish conclusively that the addition of gluconic acid or a salt thereof to the composition disclosed in example II of D1, or the replacement of citric acid in that composition by gluconic acid or a salt thereof, would improve the stability of the composition. The objective technical problem with regard to the teaching of D1 was thus to be defined as the formulation of an alternative composition. Since document D1 did not restrict additives and it could be derived from the prior art (in particular documents D3 and D4) that gluconic acid and its salts could be added to oxygen-releasing compositions, it was obvious to the skilled person, seeking to solve the objective technical problem, to add gluconic acid or gluconate to the compositions disclosed in document D1.

V. The appellant (applicant) lodged an appeal against the examining division's decision of refusal. With the statement setting out the grounds of appeal the appellant also submitted an amended main request and four auxiliary requests.

Claim 1 of the new **main request** is identical to claim 1 of the main request previously considered in the decision under appeal (see point III above).

Both the terms "hydroxy" and "hydroxyl" are employed in claim 1. Since "hydroxy" designates a chemical functional group -OH and "hydroxyl" usually refers to the radical ·OH, the term "hydroxyl" has evidently been used erroneously for "hydroxy", since it can be excluded that the radical was meant in the context of "polycarboxylic acids containing one or more hydroxy[l] groups".

Claim 1 of the **first auxiliary request** corresponds to claim 1 of the main request but further specifies that:

"the molar ratio of component (b) to component (c) is 0.1-5.0 (b) to 1.0 (c)".

Claim 1 of the **second auxiliary request** corresponds to claim 1 of the main request, with the following limitations:

"wherein the chelating organic acids are selected from polycarboxylic acids containing one or more hydroxyl groups,

wherein the molar ratio of component (b) to component (c) is 0.1-5.0 (b) to 1.0 (c)."

Claim 1 of the **third auxiliary request** corresponds to claim 1 of the main request, with the following limitations:

"wherein the chelating organic acids are selected from carboxylic acids containing one or more hydroxy groups,

wherein the molar ratio of component (b) to component (c) is 0.1-5.0 (b) to 1.0 (c)."

Claim 1 of the **fourth auxiliary request** corresponds to claim 1 of the main request, with the following limitations:

"wherein the chelating organic acid is gluconic acid,

wherein the molar ratio of component (b) to component (c) is 0.1-5.0 (b) to 1.0 (c)."

VI. In a communication issued in preparation for oral proceedings and advising the appellant of the board's preliminary opinion, the points mentioned included the following:

- With regard to the discussion of novelty (main request) and the appellant's argument that oxygen donor

stability was a distinguishing feature of the claimed composition, the board observed that the application did not define any criteria for assessing oxygen donor stability (points 1.3 to 1.5 of the communication).

- With regard to the discussion of inventive step (auxiliary requests), the technical problem might be defined as the provision of further liquid oxygen-releasing compositions or as the provision of stabilised liquid oxygen-releasing compositions based on the combination of halogen oxide salts and per-compounds. In the latter case, the questions to be answered were whether the addition of component (c) in order to provide the required stabilisation was obvious in the light of the prior art, e.g. documents D3 and D4, and whether it required inventive skill to identify the appropriate amount or ratio of such stabilising compounds (points 3.5 to 3.8 of the board's communication).

VII. With letter dated 19 August 2015, the appellant submitted new test results (D14).

VIII. Oral proceedings took place on 14 September 2015.

IX. The appellant's arguments may be summarised as follows:

Main request - novelty

The requirement in claim 1 that component (c) be "selected from the group of oxygen donor stabilising agents" implied that (c) must be present in sufficient quantity for stabilising a composition comprising an oxygen donor. In example II of document D1, sodium citrate was used in a concentration not sufficient to stabilise the oxygen donor (sodium perborate) or to act as a buffering agent; hence, novelty was established

by component (c) being defined as an oxygen donor stabilising agent.

The argument that the citrate concentration of D1 was too low to provide a stabilising effect was supported by experimental data provided in D12 and D14:

- The appellant conceded that, due to an error of calculation, the concentration of citrate of 0.0028% by weight chosen for the comparative sample tested according to D12 was not the same as the concentration disclosed in example II of D1. The stability data obtained according to D12 with four different concentrations of citrate could however be plotted as a logarithmic correlation. On that basis, it could be estimated that, at the correct concentration of sodium citrate of 0.017% by weight, active oxygen recovery (AOR) after 31 days would be about 40%, which showed that the composition according to D1 was not stable.

- Those results were confirmed by the results of an additional experiment (D14) which had been carried out with a composition corresponding to the mixture of constituents (a) and (b) as described in example II of document D1, giving 94% AOR after eight days and 78% after 29 days.

It could be concluded in any case that example composition II of D1 did not exhibit long-term stability.

Auxiliary requests - inventive step

The objective technical problem was to improve the stability of compositions known from D1. Document D1 itself did not contain any teaching with regard to oxygen donor stability, and did not teach that citric acid, or citrate, could act as a stabilising agent.

Even if certain prior-art documents suggested using chelating organic acids such as citric acid or gluconic acid or their salts for that purpose, those acids were mentioned in the prior art among many other stabilising agents. It was thus not obvious for the skilled person to select, specifically, chelating organic acids as defined in claim 1 of each of the first to fourth auxiliary requests for the required purpose. Nor was it suggested anywhere in the prior art to employ a molar ratio of component (b) to component (c) as low as 0.1-5.0 (b) to 1.0 (c).

X. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims of the main request or of one of the four auxiliary requests, all filed with the statement setting out the grounds of appeal.

Reasons for the Decision

1. Main request - novelty

1.1 According to example II of D1, two constituents (a) and (b) having the following compositions are prepared:

Constituent (a):

5 ml 4% sodium hypochlorite in water
2 mg sodium citrate
4 mg sodium fluoride (0.4% solution in water)
4 mg sodium carboxymethylcellulose
2.5 ml glycerol
2.5 ml 70% sorbitol in water

Constituent (b):

3 g sodium perborate tetrahydrate
2 mg sodium citrate
4 mg sodium carboxymethylcellulose

5 ml glycerol
5 ml 70% sorbitol in water
2 mg magnesium sulphate or sodium sulphate

A preparation for bleaching teeth is prepared by placing equal amounts of constituents (a) and (b) in a mixing tray, after which the two constituents are mixed for 10 seconds with the aid of a spatula. The mixture obtained is applied to the inside of a silicone sleeve, which is fitted on the tooth and which must preferably remain in place for at least 8 hours. Subsequently, the silicone sleeve is removed and the mouth is rinsed (D1: column 9, line 39 to column 10, line 14).

1.2 Sodium hypochlorite (present in "constituent (a)" according to example II of D1) meets the definition of component (a) in present claim 1. Sodium hypochlorite is also the most preferred embodiment of component (a) according to the present application (page 5: lines 12 to 13).

Sodium perborate tetrahydrate (present in "constituent (b)") corresponds to oxygen donor component (b) of present claim 1. Sodium perborate is also the most preferred embodiment of component (b) according to the present application (page 5: lines 12 to 13).

Sodium citrate (present both in "constituent (a)" and in "constituent (b)") is a pharmaceutically acceptable salt of citric acid, which is both a chelating organic acid and a carboxylic acid containing three carboxy groups and one hydroxy group. Hence, sodium citrate is covered by the definition of compounds which may be selected as oxygen donor stabilising agents according to component (c) of present claim 1.

Glycerol (present in both "constituent (a)" and "constituent (b)") is a preferred liquid binder according to component (d) of present claim 1 (see the present application, page 8: lines 15 to 17).

Claim 1 of the present main request does not define any requirements concerning viscosity, so the claimed composition is not distinguished in this respect from the example composition of D1. According to page 1, lines 20 to 29 of the present description, the liquid composition according to the invention may be of low viscosity or it may be a product having viscosity properties and flow characteristics that are comparable with those of rather thick to highly viscous, optionally thixotropic, liquids such as gels, pastes, suspensions, dispersions or emulsions.

1.3 According to the decision under appeal, the disclosure of the tooth-bleaching mixture of constituents (a) and (b) in example II of document D1 thus anticipates the subject-matter of claim 1, since the mandatory features of claim 1 are present.

1.4 The appellant has argued that the requirement in claim 1 that component (c) be "selected from the group of oxygen donor stabilising agents" implies that said component (c) must be present in a quantity sufficient for stabilising a composition comprising an oxygen donor component (b). According to the appellant, sodium citrate is used in example II of D1 in a concentration which is insufficient to stabilise the oxygen donor (sodium perborate) or to act as a buffering agent.

1.5 Hence according to points 1.3 and 1.4 above, two different interpretations of the wording of claim 1 have been proposed:

(i) The term "oxygen donor stabilising agents" merely serves to designate the group of chelating organic acids selected from carboxylic acids containing one or more hydroxy groups and polycarboxylic acids containing one or more hydroxy groups, and their pharmaceutically acceptable salts, or

(ii) said term further implies that component (c) must be present in a quantity sufficient to stabilise oxygen donor component (b) in the composition.

1.5.1 In case (i), claim 1 lacks novelty over the mixture described in example II of document D1, because sodium citrate, being the salt of a hydroxy carboxylic acid which is also a chelating agent, meets the definition of component (c).

1.5.2 In case (ii) it would have to be established whether the example composition of D1 contains a stabilising amount of (c). The appellant has submitted experimental data (documents D12, D14) in order to show that the composition of D1 is not stable.

Data according to D12

The comparative sample which the appellant reports having tested for stability (D12: page 2, bottom paragraph) is described as containing:

3.0 wt% sodium perborate monohydrate
0.0028 wt% sodium citrate
20.0 wt% glycerol
ad 100.0 wt% water,
adjusted to pH = 6 with sulphuric acid or sodium hydroxide.

Hence, as conceded by the appellant, said sample is not representative, with regard to its qualitative and quantitative composition, of the mixture described in

example II of D1 (see point 1.1 above). In particular, the concentration of sodium citrate of 0.0028% by weight does not correspond to the amounts indicated in D1, and hypochlorite is absent. Furthermore, the concentration of glycerol is lower and sorbitol and sodium carboxymethyl cellulose are absent, resulting in a lower viscosity of the formulation.

According to the appellant, the stability data (in terms of % active oxygen recovery or "% AOR") which were obtained according to D12 with 0.0028% by weight and further concentrations of sodium citrate (0.5%, 1.5% and 2.5% by weight in otherwise identical compositions) can be plotted as a logarithmic correlation. On that basis, an estimate for active oxygen recovery could be obtained by interpolation for the concentration of sodium citrate corresponding to the mixture of example II of D1 (0.017% by weight according to the appellant's calculation).

The board cannot agree with that approach, since there are several factors involved which may give rise to uncertainty about the result. Firstly, it is not certain from the available information that the omission of hypochlorite (component (a)) from the tested samples did not affect the test results, in particular as document D1 teaches that components (a) and (b) may behave differently in combination, as opposed to separately, with regard to the bleaching action obtained (D1: column 8, lines 39 to 60). Secondly, it would have been appropriate to reproduce the viscosity of example composition II of D1 in the tested samples, as the appellant argued previously that viscosity may affect the test results (see the appellant's letter of 19 August 2015, page 5). Thirdly, the logarithmic correlation proposed by the appellant (see Attachment A to the appellant's letter of

25 August 2015) is an estimate based on as few as four measurements (as it was not mentioned that the average of several samples was taken, each value may be the result of one isolated measurement). Only one of those measurements was obtained with a low concentration of citrate, while the interpolation would be carried out in a section of the curve which links minor changes in a low citrate concentration to major changes in stability. For all the above-mentioned reasons, it is not certain that the relevant "steep" part of the curve has a reliable empirical basis to provide meaningful results.

Thus the board is of the opinion that no conclusive data about the example composition of D1 can be obtained from the tests reported in D12.

Data according to D14

According to the experiment reported in D14, "an actual composition according to example II of D1 (...) in which the two components as described were mixed together" was tested. The experiment is thus relevant, since example II of D1 was reproduced. The composition was reported to provide 94% AOR after eight days of storage and 78% AOR after 29 days.

Following the appellant's interpretation, the question decisive for novelty is whether, based on these results, the composition of example II of D1 is stable or unstable with regard to the oxygen donor.

As previously mentioned in the board's written communication (see point VI above), neither the claims nor the application as a whole establish defined criteria for assessing oxygen donor stability. While there can be no doubt that quick-reacting compositions would generally not be regarded as stable, the application does not define any minimum

requirements according to which a composition providing a slower reaction is to be considered as stable.

It is evident from the disclosure of D1 that the mixture of example II is not quick-reacting, since it is to be applied on teeth, and a contact time of at least eight hours is foreseen (D1: column 10: lines 10 to 11). This information, already present in D1, is only confirmed by the test results reported in D14: it cannot be affirmed that a composition showing the above-mentioned values of 94% AOR after eight days of storage and 78% AOR after 29 days would inevitably be regarded as unstable by a skilled person. After all, an appreciable oxygen donor activity was still present in the tested composition after about a month. The answer to the question whether the composition is (sufficiently) stable must rather depend on specific criteria required e.g. for a particular use. Since however no such criteria have been defined in the present case, the relevant requirements are not clear. The alleged implicit feature requiring stabilisation cannot therefore be used to distinguish the claimed composition from the prior-art composition.

The appellant also argued that an apparently enhanced AOR in the sample composition according to D1 could be due to a high viscosity giving rise to reduced reaction rates. Furthermore, the tested composition did not exhibit long-term stability.

However, no comparison with a corresponding composition without citrate has been carried out. Thus while the appellant's test shows that the oxygen donor in the composition according to example II of D1 is stabilised to an appreciable extent, it has not been shown that citrate could not act in those conditions as a stabilising agent. Lastly, long-term stability cannot

serve as a distinguishing feature of the composition of claim 1 over the prior art, because claim 1 does not contain any explicit or implicit requirement with regard to long-term stability.

1.6 The relevance of a buffering effect (see point 1.4 above) is not explained in the present application - it is merely mentioned in example 1 that perborate was found to be more stable at acidic pH. Nor does claim 1 of the main request include any technical feature requiring a buffering effect. Hence the appellant's argument relating to lack of citrate buffer capacity in the composition of D1 does not concern a distinguishing feature of claim 1 in comparison with the disclosure of D1 and is thus not relevant to the assessment of novelty.

1.7 For the reasons explained under points 1.2 to 1.6, the board has come to the conclusion that the subject-matter of claim 1 of the main request lacks novelty over the disclosure of document D1 (Articles 52(1) and 54 EPC).

2. Auxiliary requests - novelty

2.1 The mixture according to example II of document D1 contains 4 mg of sodium citrate, but which form of sodium citrate is not mentioned. Evidently, the molecular weights of, e.g., monosodium citrate or trisodium citrate dihydrate differ. In any case however, the molar ratio of sodium perborate tetrahydrate (component (b)) to sodium citrate (component (c)) in the mixture of D1 is higher than 1000:1. Thus, the lower ratio (b):(c) of 0.1:1.0 to 5.0:1.0, which is a mandatory feature in claim 1 of each of the auxiliary requests, is a distinguishing feature over the mixture disclosed in example II of D1.

2.2 The mandatory presence of gluconic acid according to claim 1 of the fourth auxiliary request is a further distinguishing feature.

2.3 As a consequence, the subject-matter of claim 1 of each auxiliary request is novel over the mixture of constituents (a) and (b) disclosed in example II of document D1 (Articles 52(1) and 54 EPC).

3. First auxiliary request - inventive step

Present application

3.1 The present application relates to a stabilised liquid oxygen-releasing composition, intended to be suitable in particular for pharmaceutical, cosmetic and food applications (see page 1, lines 6 to 8 of the description). The composition's oxygen-releasing activity is based on the combination of a salt having an anion derived from a halogen oxide (component (a)) and an oxygen donor (component (b)). Dental care, e.g. tooth bleaching, skin care and use in ointments are mentioned as possible uses (see page 7 and the examples). The composition can be viscous to pasty or of low viscosity (page 1, lines 20 to 29).

The required stabilisation is supposed to be provided by a component (c) which is an oxygen donor stabilising agent selected from certain chelating organic acids. Claim 1 of the first auxiliary request specifies further that "the molar ratio of component (b) to component (c) is 0.1-5.0 (b) to 1.0 (c)".

Closest prior art

3.2 Document D1, mentioned on page 1 of the present application, discloses the same type of oxygen-releasing composition and has previously been regarded

as the closest prior art for the assessment of inventive step. The board sees no reason to differ.

3.3 Document D1 discloses compositions for bleaching teeth or for treating skin complaints and mucous membrane disorders and teaches that the combination of a halogen oxide salt (component (i) according to document D1, corresponding to component (a) according to the present application) and a borate, in particular a perborate (component (ii) according to document D1, corresponding to component (b) according to the present application), usually combined with a binder or gelatinous thickener (components (iii) and (iv) according to document D1, corresponding to component (d) according to the present application), is advantageous. It is also possible to use, instead of borates, other inorganic compounds which have a bleaching action, for example percarbonate or peroxyhydrates (D1: column 3: lines 33 to 35; column 4, lines 42 to 46). The activity of the compositions is attributed to oxygen release; according to D1, a good and long-lasting effect going beyond the combined mechanisms of components (a) and (b) is obtained (D1: column 8, lines 39 to 60). Preparations containing either component (a) or component (b) should however be stored separately, or the composition obtained after mixing such preparations should be refrigerated (D1: column 2, lines 18 to 27).

Technical problem and solution

3.4 Based on that information, the skilled person would be motivated to look for a way of stabilising compositions containing both components (a) and (b), in order to simplify storage and application. This is acknowledged in the present application, where it is stated that a composition comprising both components (a) and (b) is

desired which is stable during storage, releases the active component in a controlled manner and shows a long-lasting effect (see the description, page 2, lines 19 to 24).

3.5 The composition defined in claim 1 of the first auxiliary request differs from the mixture according to example II of document D1 in the lower molar ratio of oxygen donor component (b) (perborate) to oxygen donor stabilising component (c) (citrate), the claimed ratio being in the range of 0.1:1 to 5:1, instead of more than 1000:1 as in the composition of D1 (see point 2.1 above).

D1 does not contain any teaching about oxygen donor stabilising agents and does not disclose that citrate could act as a stabilising agent.

Since compositions containing citric acid (a chelating acid with three carboxy groups and one hydroxy group) are covered by claim 1, the difference of such embodiments over the mixture of example II of D1 consists only in the molar ratio of (b) to (c). Since the presence of citric acid is not mandatory, part of the claimed scope furthermore differs from example composition II of D1 in the presence of a different chelating organic acid (as component (c) of claim 1). For example, the selection of chelating organic acids defined in claim 1 also covers hydroxy monocarboxylic acids, such as gluconic acid.

3.6 The alleged technical effect obtained in the composition according to claim 1 is improved stability of the oxygen donor (b), in comparison with prior-art compositions containing components (a) and (b).

3.7 Although the appellant has not presented experimental data providing a direct comparison with the closest

prior art (i.e. example composition II of document D1), the board proceeds upon the assumption, in the appellant's favour, that the alleged technical effect is actually achieved by the claimed composition.

On that basis, the technical problem to be solved starting from the teaching of D1 is the provision of stabilised liquid oxygen-releasing compositions based on the combination of halogen oxide salts and per-compounds.

3.8 The solution to that problem, as defined in claim 1 of the first auxiliary request, involves the presence, in such compositions, of citric acid or other chelating hydroxy carboxylic acids or their salts, at a molar ratio which corresponds to one fifth to ten times the amount of the oxygen donor compound.

Obviousness of the solution

3.9 Document D3 discloses tooth-bleaching compositions based on a hydrogen peroxide-containing compound, further containing a thickening agent, an agent for stabilising the hydrogen peroxide-containing compound and a calcium chelating agent (D3: claim 1). D3 teaches that calcium chelating agents such as citric acid and its salts or gluconic acid and its salts may also act as stabilising agents for the peroxide (D3: paragraphs [0021] and [0022]; claims 8 and 9). According to example formulation 1B of D3 (table 1), hydrogen peroxide and citric acid are employed at a molar ratio of about 100:1.

3.10 Document D4 discloses oxidising cleaning compositions typically based on peroxygenated compounds including perborates, peroxides or hydrogen peroxide, which may also be used on human tissue or teeth (D4: page 8,

lines 18 ff; page 17, line 27 to page 18, line 25). Thickeners or gelling agents and stabilisers of the oxidising agent may be present. Examples of stabilisers are gluconic acid, sodium gluconate or citrates (D4: page 28, lines 7 to 16).

3.11 As can be derived from points 3.5, 3.9 and 3.10, while oxygen donor stabilising agents are not discussed in document D1 itself, it was nevertheless known from the prior art, in particular documents D3 and D4, that organic chelating acids, in particular hydroxy (poly)carboxylic acids such as citric acid or gluconic acid and their salts, act as oxygen donor stabilising agents. As a consequence, it would not have required inventive skill to select those known oxygen donor stabilising agents to be used in the claimed composition for the purpose of stabilising the oxygen donor.

The appellant's argument that other stabilising agents were also disclosed in the prior art is not convincing, since inventiveness cannot be based on a mere arbitrary selection from several known equivalent options. It has not been shown after all that hydroxy (poly)carboxylic acids such as citric acid or gluconic acid are more effective than the other stabilising agents disclosed in D3 and D4. In that context, the tests reported in document D10 are not pertinent, since the tested compositions do not contain a component (a) according to claim 1 and always contain citrate in combination with the tested stabilising agent.

In the absence of any specific reason for preferring one or the other, the arbitrary selection of any one of the known alternative solutions to the technical problem that are equally obvious in view of the prior

art requires no particular skill, and for this reason does not involve an inventive step.

3.12 The skilled person would of course be aware that the molar ratio of component (b) to component (c) may affect the level of stabilisation obtained, and would attempt to find an appropriate ratio, by routine testing. This is part of the general technical knowledge which can be expected of the skilled person. The board therefore considers that it would not require inventive skill to identify an appropriate amount or ratio of the stabilising agent.

While a ratio of 0.1-5.0 to 1.0 is not expressly disclosed in documents D3 or D4, nothing would prevent the skilled person from working in that range. Nor has it been shown that a molar ratio of (b):(c) lower than 5:1 provides any surprising technical effect compared to a somewhat higher ratio such as 8:1, or that a molar ratio of (b):(c) of about 100:1 (as chosen in D3) would not have a stabilising effect. Thus, as mentioned above, the skilled person would in any case look for, and be able to determine, an appropriate ratio of (b) to (c); moreover, the precise delimitation of the range as defined in claim 1 must be regarded as arbitrary in the absence of proof of any particular technical effect.

3.13 In conclusion, neither the selection of hydroxy carboxylic acids or hydroxy polycarboxylic acids as stabilising component (c) nor the definition of the specified range of the molar ratio of components (b) and (c) can provide an inventive contribution.

3.14 For these reasons, the subject-matter of claim 1 of the first auxiliary request does not involve an inventive step (Articles 52(1) and 56 EPC).

4. Second auxiliary request - inventive step

4.1 Claim 1 of the second auxiliary request corresponds to claim 1 of the first auxiliary request, with the additional restriction of the selection of the chelating organic acids to polycarboxylic acids containing one or more hydroxyl groups. Since citric acid falls within that definition, said restriction does not add a further distinguishing feature to the composition defined by claim 1 of the first auxiliary request.

4.2 Hence the assessment of inventive step remains unchanged. The subject-matter of claim 1 of the second auxiliary request does not involve an inventive step within the meaning of Article 56 EPC, for the same reasons as set out in the context of the first auxiliary request (see points 3.1 to 3.13 above).

5. Third auxiliary request - inventive step

5.1 Claim 1 of the third auxiliary request corresponds to claim 1 of the first auxiliary request, with the further condition that the chelating organic acids are to be selected from carboxylic acids containing one or more hydroxy groups.

5.2 The board takes the view that the term "carboxylic acids" would be understood, in its usual sense, to include polycarboxylic acids; thus the deletion of the option that the chelating organic acids of component (c) are selected from hydroxy polycarboxylic acids does not alter the claimed scope. In contrast, the appellant has argued that the term "carboxylic acids" only covers monocarboxylic acids (such as gluconic acid).

5.3 Since the assessment of inventive step provided above in the context of the first auxiliary request also takes into account embodiments comprising a hydroxy monocarboxylic acid as component (c) (see points 3.5 and 3.11 above), such as gluconic acid, the limitation intended by the appellant cannot however introduce any new aspect into the discussion.

5.4 Hence the assessment of inventive step remains unchanged. The subject-matter of claim 1 of the third auxiliary request does not involve an inventive step within the meaning of Article 56 EPC, for the same reasons as set out in the context of the first auxiliary request (see points 3.1 to 3.13 above).

6. Fourth auxiliary request - inventive step

6.1 Claim 1 of the fourth auxiliary request corresponds to claim 1 of the first auxiliary request, with the condition that the chelating organic acids are to be selected from gluconic acid.

6.2 For the reason explained in the context of the third auxiliary request (see point 5.3), the assessment of inventive step as provided above already covers that possibility and - as the selection of gluconic acid does not provide any further specific technical effect- is therefore not affected by the limitation in scope.

The subject-matter of claim 1 of the fourth auxiliary request does not involve an inventive step within the meaning of Article 56 EPC, for the same reasons as set out in the context of the first auxiliary request (see points 3.1 to 3.13 above).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated