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Datasheet for the decision of 30 October 2018

Case Number: T 0674/14 - 3.3.01

Application Number: 05077972.7

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Language of the proceedings: EN

Title of invention:

Composition comprising polyunsaturated fatty acids, proteins, manganese and/or molybden and nucleosides/nucleotides for treating dementia

Patent Proprietor:

N.V. Nutricia

Opponent:

ABBOTT LABORATORIES

Relevant legal provisions:

EPC Art. 100(c), 123(2), 100(a), 52(1), 56
RPBA Art. 12(4)

Keyword:

Amendments - added subject-matter (yes)
Inventive step - (no)
Late-filed evidence - submitted with the statement of grounds of appeal

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Case Number: T 0674/14 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 30 October 2018

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	V.O. P.O. Box 87930 2508 DH Den Haag (NL)
Respondent: (Opponent)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park IL 60064 (US)
Representative:	Boult Wade Tennant LLP Verulam Gardens 70 Gray's Inn Road London WC1X 8BT (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 January 2014 revoking European patent No. 1800675 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	A. Lindner
Members:	R. Hauss
	P. de Heij

Summary of Facts and Submissions

I. European patent No. 1 800 675 was granted with a set of thirteen claims. Independent claims 1 and 12 read as follows:

Claim 1

Nutraceutical or pharmaceutical composition comprising

a) a lipid fraction comprising at least one of docosahexaneoic acid (DHA), docosapentaenoic acid (DPA) and eicosapentaenoic acid (EPA);

b) a protein fraction comprising proteinaceous material from non-human origin which provide at least cysteine and/or taurine;

c) a mineral fraction comprising at least one of manganese and molybdenum; and

d) a compound selected from the group of nucleobases, nucleosides and nucleotides

for use in the treatment of dementia.

Claim 12

Ready to drink neutraceutical or pharmaceutical liquid that comprises per 100 ml

Energy	*100 kcal*	
Protein	*3.06 g*	*(casein, whey 80/20)*
Carbohydrates	*13.3 g*	*(maltodextrins, sucrose)*
Fat	*3.73 g*	*(fish oil, phospholipids)*
DHA	*0.96 g*	
EPA	*0.24 g*	
Uridine monophosphate	*0.5 g*	*(disodium salt)*
Choline	*0.32 g*	
Vitamin E	*32 mg*	*alpha-tocopherol*
Vitamin C	*64 mg*	
Selenium	*48 µg*	

Vitamin B6	*0.8 mg*
Folic acid	*0.32 mg*
Vitamin B12	*2.4 µg*
Magnesium	*20 mg*
Zinc	*1.2 mg*
Manganese	*0.3 mg*
Molybdenum	*10 µg*

II. The patent was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.

III. The documents referred to in the opposition proceedings included the following:

D2: WO 03/037 320 A1

D5: WO 03/041 701 A2

D6: EP 0 891 719 A1

D13: Test Report first filed on 27 August 2010

D14: Test Report first filed on 11 August 2008

D15: Test Report first filed on 11 October 2013

D14a: Copy of D14 with supplementary information, first filed on 28 November 2013

D16: Test Report first filed on 28 November 2013

IV. The decision under appeal is the decision of the opposition division revoking the patent, announced on 29 November 2013 and posted on 23 January 2014.

The decision is based on the patent proprietor's main request (for rejection of the opposition) and seven auxiliary requests.

Auxiliary requests VI and VII were filed during oral proceedings before the opposition division. Except for clerical errors, claim 1 of auxiliary request VI was identical to claim 1 as granted.

V. According to the decision under appeal, independent claims 11 and 12 as granted (main request) both contained added subject-matter (Article 100(c) EPC). Since one or both of these claims were present in identical wording in each of auxiliary requests I to V, the same objection applied to those auxiliary requests.

Late-filed documents D14a, D15 and D16 relating to tests carried out by the patent proprietor were not admitted into the proceedings (Article 114(2) and Rule 116(1) EPC).

The subject-matter of the claims of auxiliary request VI did not involve an inventive step, starting from the technical teaching of document D5 (Article 56 EPC). The objective technical problem to be solved was the provision of alternative compositions comprising DHA, EPA and nucleotides for use in the treatment of dementia, Alzheimer's disease or impaired memory function. The addition of a protein fraction comprising cysteine or taurine and a mineral fraction comprising at least one of manganese and molybdenum in order to solve that problem was an arbitrary selection from ingredients commonly used in nutritional and nutraceutical compositions (such as, for instance, described in document D2) and was therefore obvious.

Auxiliary request VII (filed during oral proceedings before the opposition division) was not admitted into the proceedings, since it could not *prima facie* overcome the objections concerning lack of inventive step.

VI. The patent proprietor (appellant) filed an appeal against that decision. With its statement setting out the grounds of appeal, the appellant submitted an amended main request, eleven auxiliary requests and two further test reports numbered **D17** and **D18**. The appellant also re-submitted documents D14a, D15 and D16.

VII. With a letter dated 31 August 2018, the appellant submitted amended sets of claims as its new main request and first to eleventh auxiliary requests replacing the requests previously on file.

Claim 12 of the main request is identical to claim 12 of the patent as granted (see point I above).

Claims 1 of both the main request and the first auxiliary request are identical to claim 1 of the patent as granted (see point I above).

VIII. Oral proceedings before the board were held on 30 October 2018. In the course of the oral proceedings, the appellant withdrew its second to eleventh auxiliary requests.

IX. The respondent's (opponent's) arguments, as far as relevant to the present decision, may be summarised as follows:

Main request: claim 12 - amendments

Claim 12 broadly corresponded to claim 9 of the application as filed. However, in the original claim it was indicated that the ready-to-drink liquid comprised, per 100 ml, 3.73 g fat "comprising" 0.96 g DHA and 0.24 g EPA, while according to claim 12 of the main request these amounts of DHA and EPA were in addition to the 3.73 g fat. Thus the deletion of the term

"comprising" introduced added subject-matter with regard to the composition of the liquid.

Since claim 12 was clear in listing DHA and EPA separately from the fat, the reader would have no reason to try and find a different interpretation of the claim in the description. The fact that the description, for instance in paragraph [0031] of the patent specification, indicated that the lipid fraction comprised certain long-chain polyunsaturated fatty acids did not alter the disclosure of claim 12 in that respect, particularly since claim 12 used the term "fat" rather than "lipid fraction". The fact that the composition according to example 3 of the patent had a degree of similarity to that of claim 12 did not mean that a skilled person would automatically disregard the wording of claim 12 and instead ascribe to it a meaning such that it covered the composition of example 3.

Admission of evidence

The opposition division had exercised its discretion appropriately in not admitting late-filed documents D14a, D15 and D16 into the proceedings, and there was no reason for the board to overrule the opposition division's decision in that regard.

The new test reports D17 and D18, intended by the appellant to address the issue of inventive step, should have been filed at a much earlier stage in the first-instance proceedings. Moreover, both lacked relevance.

Claim 1 - inventive step

The claimed composition differed from the disclosure of document D5 in the mandatory presence of the mineral fraction (i.e. component (c)). While the appellant considered that the presence of the protein fraction

(i.e. component (b)) was a further difference, the definition of that fraction in claim 1 covered any protein used in food manufacture, and document D5 itself recommended, on page 8, the addition of proteins or peptides, which would typically, and inevitably, contain cysteine.

The experimental results reported in documents D14 and D17 were not relevant. Document D14 related neither to a composition as defined in claim 1 nor to a technical effect taught in the patent, nor did it show statistically significant results. Document D17, which compared a composition "B" according to claim 1 with a composition "A" containing only components (a) and (d), likewise related to a technical effect not taught in the patent in suit (namely, increased receptor activity).

In any case, the definition of claim 1 covered compositions that had no component in common with composition B of D17. Even were the board to acknowledge that a technical effect had indeed been shown in D17 for composition B, it had nevertheless not been made credible that such an effect was achieved across the entire scope claimed.

Thus the objective technical problem was the provision of an alternative composition for the treatment of dementia.

Components (b) and (c) were usual components of nutritional supplements. Hence their addition to the compositions of document D5 to provide alternative compositions was an arbitrary and obvious choice. In addition to the fact that document D5 itself taught the addition of proteins or peptides, it was moreover known from document D6 that both cysteine and manganese supported total methionine metabolism, and that

impaired functioning of total methionine metabolism had been associated with neurological diseases such as Alzheimer's disease. Their known utility in achieving the same therapeutic benefit would have provided the person skilled in the art with a further incentive to introduce those components.

X. The appellant's arguments, as far as relevant to the present decision, may be summarised as follows:

Main request: claim 12 - amendments

It was common knowledge that the caloric value of proteins and carbohydrates was 4 kcal/g and that of fat was 9 kcal/g. Claim 12 of the main request specified that the ready-to-drink liquid comprised 100 kcal energy per 100 ml. 3.06 g protein, 13.3 g carbohydrates and 3.73 g fat, as also specified in claim 12, added up to 99 kcal/100 ml, which was in line with the required total of 100 kcal/100 ml. On the basis of that calculation, it was evident that the respondent's interpretation of claim 12, according to which 0.96 g DHA and 0.24 g EPA were to be added to the fat, was erroneous, because that would lead to the addition of another 10.8 kcal, amounting to a caloric value of 110 kcal/100 ml, well above the specified 100 kcal. Furthermore, long-chain polyunsaturated fatty acids (such as DHA and EPA) were considered to be part of the fat, or lipid, fraction throughout the description (paragraphs [0031], [0036], [0051], table 2 and example 3), which was moreover in line with the normal understanding of those terms in the art, where they were often used interchangeably. The person skilled in the art reading the patent in suit with a mind willing to understand would therefore conclude that the DHA and EPA must be included in the total amount of 3.73 g fat.

Admission of evidence

Document D14a only contained supplementary information regarding D14 and did not place an undue burden on the respondent. Documents D14a, D15 and D16 had been provided as early as possible after the summons to oral proceedings indicating the opposition division's preliminary opinion had been issued, given that the appellant's research facilities were being relocated at that time. The opposition division's discretionary decision not to admit those documents was therefore not justified.

Document D17 had been filed in response to the opposition division's inventive-step assessment in the decision under appeal, which - for the first time in the proceedings - used document D5 as the starting point.

Document D18 was intended to address the objection, previously raised by the respondent and by the opposition division, that the results presented in document D13 were not conclusive.

Claim 1 - inventive step

Document D5 represented the closest prior art. The claimed composition differed from the disclosure of D5 in the mandatory presence of components (b) and (c). The experimental results reported in documents D14 and D17 (relating to neurite formation and cholinergic receptor activity) supported the credibility of the appellant's claim that the compositions according to the invention would provide improved efficacy in the treatment of dementia. The respondent had not provided any evidence in support of its allegation that such benefit would not be obtained over the entire scope claimed. The objective technical problem was to improve

the working of nerve cells in relation to dementia, in particular to improve the receptor function. The solution to that problem as defined in claim 1, which involved the addition of components (b) and (c), was not obvious, since the prior art did not provide any pointer suggesting that those components might prove useful in solving the objective technical problem.

XI. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the set of claims of the main request or, alternatively, the set of claims of the first auxiliary request, both submitted with the letter of 31 August 2018.

XII. The respondent (opponent) requested that the appeal be dismissed.

Within the purview of this request, the respondent also requested that documents D14a, D15, D16, D17 and D18 not be admitted into the proceedings.

Reasons for the Decision

1. Admissibility of the appeal

The appeal complies with Articles 106 to 108 and Rule 99 EPC and is therefore admissible.

2. Main request: claim 12 - amendments

2.1 Claim 12 requires the presence, per 100 ml, of 3.73 g fat, 0.96 g DHA and 0.24 g EPA. These are listed as separate items, adding up to 4.93 g of material (see point I above).

The corresponding passage in claim 9 of the application as filed specifies 3.73 g fat "comprising" 0.96 g DHA and 0.24 g EPA, i.e. a total of 3.73 g of material, 2.53 g of which is not DHA or EPA. In present claim 12, the term "comprising" was however deleted.

Hence, according to the list of ingredients, the composition of present claim 12 contains a larger amount of non-DHA/EPA "fat" material (3.73 g) than disclosed in the application as filed (2.53 g).

2.2 The appellant argued that a person skilled in the art studying claim 12 would notice that this quantitative composition would result in a higher caloric value than the value of 100 kcal/100 ml indicated in the claim, and would therefore infer that the total amount of fat of 3.73 g must include the DHA and EPA, based on the usual understanding in the technical field (which was also reflected in various passages of the description) of what constituted a fat - or lipid - fraction.

2.3 The board does not find this argument convincing, for the following reasons:

2.3.1 Claim 12 of the main request lists DHA and EPA as separate components, on the same level as, and in addition to, the "fat" component. While the ingredient list in current claim 12 may not be in conformity with a total caloric value of 100 kcal/100 ml, it does not follow from that discrepancy that nothing else could have been intended than that the DHA and EPA must be part of the fat component, in spite of being listed as separate components. Alternative explanations may be that the value of 100 kcal/100 ml is erroneous, or that it was intended for general orientation rather than as an exact value.

2.3.2 There is no universally accepted understanding that "lipid" means the same as "fat", considering that fats are commonly regarded as a sub-group of the more broadly defined group of lipids. Nor does the patent in suit define or state that these terms are to be used interchangeably for the purposes of the patent.

2.3.3 The passages in paragraphs [0031], [0036] and [0051] of the patent specification cited by the appellant mention, in a general way, a lipid fraction containing polyunsaturated fatty acids. These passages do not relate at any point to the quantitative composition of a specific ready-to-drink liquid such as is defined in claim 12, and, moreover, they use a different terminology, since a "lipid fraction" is not identical to "fat" (see point 2.3.2 above). Table 2 discloses the composition of two diets compared in an animal study, which has no relation to the composition of claim 12. The composition of example 3 differs from the composition according to claim 12 in that it includes additional components, and the fat component explicitly comprises DHA and EPA. Thus it is not apparent to the board that these unrelated passages from the description could somehow change the meaning of the definition of claim 12.

2.4 For these reasons, the board arrives at the conclusion that claim 12 covers liquids comprising, per 100 ml, 3.73 g fat and in addition 0.96 g DHA and 0.24 g EPA.

2.5 As a consequence, claim 12 is directed to subject-matter extending beyond the content of the application as filed (Articles 100(c) and 123(2) EPC).

3. Admission of evidence (Article 12(4) RPBA)

3.1 Documents D14a, D15, D16, D17 and D18 were filed by the appellant with its statement setting out the grounds of appeal (see point VI above). Pursuant to Article 12(1), (2) and (4), second half-sentence, RPBA, they are thus, in principle, to be taken into account in the proceedings. However, Article 12(4), first half-sentence, RPBA confers on the board the discretionary power to hold inadmissible evidence which could have been presented or was not admitted in the first-instance proceedings.

3.2 Documents D14a, D15 and D16

3.2.1 D14a, D15 and D16 are test reports which were presented by the appellant in support of inventive step but were not admitted in the first-instance proceedings (see point V above).

3.2.2 Document D15 was filed seven weeks before the date of oral proceedings before the opposition division. Documents D14a and D16 were filed on the day before the oral proceedings. While D15 and D16 provided new experimental data, D14a contained the same data as test report D14 (first filed in 2008) but additionally indicated the nutrient concentrations employed.

3.2.3 The opposition division considered that the objection of lack of inventive step had been an issue in the proceedings from the very start; thus the evidence addressing it could and should have been filed at an earlier stage, and in particular in reply to the notice of opposition. Even if it had been necessary to carry out further tests after the opposition division had issued its preliminary opinion (more than five months before the date of the oral proceedings), the relocation of the appellant's research laboratories

would at least not have prevented it from outsourcing the experimental work required. Document D14a, since it related to the experiments already presented in D14, could certainly have been filed in due time. As it was, the opposing party could not fairly be expected to defend its position against comparative tests filed at short notice. Moreover, the content of documents D14a, D15 and D16 was *prima facie* not relevant, as it did not relate to a direct comparison with any of the prior-art compositions which might conceivably be used as a starting point for the assessment of inventive step.

3.2.4 On that basis, the board considers that the opposition division used the correct criteria when exercising its discretion in not admitting documents D14a, D15 and D16, and that it did not exercise its discretion in an unreasonable way.

3.2.5 Subsequently, the appellant did not explain why the reasoning presented in the decision under appeal resulted in new circumstances or issues which might have necessitated the re-submission of documents D14a, D15 and D16 at the appeal stage.

3.2.6 For these reasons, the board finds it appropriate not to overturn the opposition division's decision on late-filed evidence and exercises its discretion pursuant to Article 12(4) RPBA to the effect of not admitting documents D14a, D15 and D16 into the proceedings.

3.3 Documents D17 and D18

3.3.1 Unlike documents D14a, D15 and D16, documents D17 and D18 were filed for the first time with the appellant's statement setting out the grounds of appeal.

3.3.2 According to the appellant, test report D17 was presented in reaction to the opposition division's decision, for the first time in the proceedings using document D5 as the starting point for assessing inventive step. Since there is no document on file from which it could be derived that the inventive-step approach starting from D5 was introduced at an earlier date than the day of the oral proceedings before the opposition division, the board considers that the appellant could not have presented a test report addressing the issues raised by that approach at an earlier time. Hence, the criteria of Article 12(4), first half-sentence, RPBA are not met, and the board has no reason to hold document D17 inadmissible.

3.3.3 Document D18, which provided further data to address the objection that the results presented in document D13 were inconclusive, was likewise not rejected by the board. In the discussion of inventive step, the appellant ultimately did not rely on D18.

4. Auxiliary request: claim 1 - inventive step

Patent in suit

4.1 The patent in suit aims to provide neutraceutical and pharmaceutical compositions that can improve membrane composition and functioning of cells, in particular with the aim of improving cognitive function and treating dementia (see paragraphs [0001], [0019], [0028]; claim 1).

4.2 In order to achieve that aim, claim 1 defines a neutraceutical or pharmaceutical composition comprising four mandatory components (a), (b), (c) and (d) for use in the treatment of dementia.

Starting point in the prior art

4.3 It was common ground that document D5 was a suitable starting point for the assessment of inventive step.

4.4 D5 relates to the use of polyunsaturated fatty acids and one or more specified components having a beneficial effect on total methionine metabolism in the manufacture of a preparation for improving the action of receptors, in particular for improving the sensitivity of receptors to neurotransmitters (see D5: claim 1; page 1, lines 4 to 5, and page 3, lines 24 to 27). In one embodiment, the preparation contains a combination of DHA and EPA as polyunsaturated fatty acids and is to be used in the treatment of dementia (see D5: claim 13).

D5 teaches that "the chronic dietary intake of essential polyunsaturated fatty acids can modulate learning and memory processes by being incorporated into neuronal and glial plasma membranes" (see D5: page 10, lines 31 to 32).

Since nucleotides play an important role in the formation of the neurotransmitter acetylcholine, it is preferable to incorporate nucleotides in the preparations. Preferably the products contain at least 50 mg nucleobases, including uridine or cytidine, per daily dose (see D5: page 9: lines 19 to 25).

Furthermore, the preparations according to D5 preferably contain precursors of neurotransmitters, specifically certain amino acids (Trp, Phe, Tyr) or their functional equivalents. The functional equivalents are preferably proteins, hydrolysed proteins or peptides (see D5: page 7, line 29, to page 9, line 11; in particular page 8, lines 28 to 31).

Objective technical problem and solution

4.5 It was common ground that D5 disclosed the combination of at least components (a) and (d) according to present claim 1 in a preparation for the treatment of dementia (see paragraph 4.4 above).

4.6 The claimed composition differs from that disclosure of D5 in the mandatory presence of components (b) and (c).

4.7 The appellant contended that the compositions according to claim 1 improved the working of nerve cells in relation to dementia, in particular the receptor function, in comparison with the compositions according to D5. The appellant relied on documents D14 and D17 in support of this alleged advantage.

4.7.1 Document D14 states that a relevant *in vitro* model for Alzheimer's disease is the pheochromocytoma cell (PC12 cell), which forms neurites upon incubation with nerve growth factor. D14 relates to a study examining the effect of nutrients according to component (a), (b) or (c) of claim 1 on the formation of neurites in PC12 cells, in which the nutrients were tested in combinations of two or three. D14 concludes that incubation with a combination of (a) DHA, (b) cysteine and (c) $MnCl_2$ resulted in a significant increase of a parameter (the synapsin I/β-actin ratio) reflecting the total amount of neurites generated, whereas incubation with combinations of only two of those nutrients had no effect in comparison with control unincubated cells.

4.7.2 Document D17 reports an experiment in which nerve growth factor (NGF: 50 ng/ml) differentiated PC12 cells (rat pheochromocytoma cells) were cultured in a medium containing, as additional nutrients, either (a) DHA, (b) cysteine, (c) manganese and (d) uridine

(nutrient combination B), or only DHA and uridine at the same concentrations as in the first medium (nutrient combination A). D17 concludes that supplementation with nutrient combination B increased the activity of muscarinic receptors significantly compared to combination A.

4.8 If comparative tests are chosen to demonstrate inventive step on the basis of an improved effect, the nature of the comparison must be such that the alleged advantage or effect is convincingly shown to have its origin in the distinguishing feature of the claimed subject-matter compared with the closest prior art (see Case Law of the Boards of Appeal of the European Patent Office, 8th edition 2016, I.D.10.9).

Furthermore, it must be credible that the effect is obtained over the entire scope claimed for it to be taken into account in determining the objective technical problem.

4.9 Therefore, irrespective of whether a specific technical effect can indeed be derived from the data reported in documents D14 or D17 and linked to a distinguishing technical feature, it also has to be established whether those data can make it credible that the alleged effect would be obtained over the entire scope of claim 1.

4.10 As correctly pointed out by the respondent, the studies carried out by the appellant do not cover the entire scope of alternative options for components (a), (b), (c) and (d) mentioned in claim 1. The definition of claim 1 covers, for instance, a composition containing (a) DPA, (b) taurine, (c) molybdenum and (d) adenosine. None of those components were used in the studies reported in D14 or D17 (or, for that matter, D13).

No explanation was provided why it would be reasonable to predict that a technical effect linked, for instance, to the presence of cysteine or manganese would also be obtained with taurine or molybdenum.

4.11 The board has therefore arrived at the conclusion that the experimental data provided by the appellant are not suitable for demonstrating a technical effect over the entire scope claimed.

4.12 In the absence of a specific effect or advantage obtained over the entire scope claimed, the objective technical problem is to provide an alternative composition for use in the treatment of dementia.

4.13 It was not contested that that problem is solved by the subject-matter of claim 1, directed to compositions including a specific protein fraction (b) and a specific mineral fraction (c) as mandatory components.

Obviousness of the solution

4.14 Proteins are a normal component in food and are also a common ingredient of neutraceutical and pharmaceutical compositions. Document D5 itself suggests that proteins may be included in its compositions as a preferred component (see D5: page 8, lines 29 to 31, and point 4.4 above). As acknowledged in the patent in suit (see paragraph [0067]), all proteins that are typically used in food manufacture provide cysteine. Document D6 (see D6: claim 1 and table 1) discloses nutritional compositions comprising cysteine or cysteine-rich proteins or peptides in combination with vitamins and minerals.

4.15 Both manganese and molybdenum are trace elements commonly known to be used in food supplements.

For instance, document D2, which relates to pharmaco-dietary preparations, mentions vitamins, minerals and oligo-elements including molybdenum and manganese as conventionally used components of such preparations (see D2: page 3, lines 3 to 10, and page 6: table).

4.16 Thus components (b) and (c) are an arbitrary selection from the group of obvious components the person skilled in the art would consider in order to provide an alternative composition. No specific reason is known which would have deterred the person skilled in the art from incorporating components (b) and (c) into the compositions according to claim 1, in order to provide alternative compositions for use in the treatment of dementia.

4.17 As a consequence, the subject-matter of claim 1 of the first auxiliary request does not involve an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated