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Datasheet for the decision of 13 February 2015

Case Number: T 0378/13 - 3.3.07

Application Number: 07120681.7

Publication Number: 1911442

IPC: A61K9/107, A61P25/28, A23L1/302, A23J7/00, A23L1/304

Language of the proceedings: EN

Title of invention:
Preparation for the prevention and/or treatment of dementia syndromes

Patent Proprietor:
N.V. Nutricia

Opponent:
Fresenius Kabi Deutschland GmbH

Relevant legal provisions:
EPC Art. 54, 76(1), 100(a), 111(1), 123(2)
RPBA Art. 12(4)

Keyword:
Novelty - second (or further) medical use
Late-filed request -
submitted with the statement of grounds of appeal
Divisional application - added subject-matter (no)
Amendments - added subject-matter (no)
Appeal decision -
remittal to the department of first instance (yes)

Decisions cited:
T 0286/09

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Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0378/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 13 February 2015

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Opponent)	Fresenius Kabi Deutschland GmbH Else-Krömer-Strasse 1 61352 Bad Homburg (DE)
Representative:	Fresenius Kabi Deutschland GmbH Patent Department Else-Kröner-Straße 1 61352 Bad Homburg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 13 December 2012 revoking European patent No. 1911442 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	D. Boulois
Members:	D. Semino
	W. Ungler

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies against the decision of the opposition division announced at the oral proceedings on 14 November 2012 to revoke European Patent 1 911 442. The patent derived from European patent application n° 07 120 681.7, which was filed as a divisional of European patent application n° 01 928 256.5, and was granted on the basis of 18 claims, claim 1 reading as follows:

"1. Preparation for use in the prevention and/or treatment of dementia syndromes, comprising the following fractions:
a) long-chain polyunsaturated fatty acids comprising at least one of the ω-3 fatty acids eicosapentaenoic acid and docosahexaenoic acid;
b) phospholipids, which fraction contains at least two different phospholipids, selected from the group consisting of phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine;
c) compounds which are a factor in methionine metabolism, which fraction contains at least folic acid."

The patent included two further independent claims, claim 13 directed to a preparation for use in the treatment and/or prevention of vascular disorders and claim 18 in the form of a Swiss-type claim.

II. A notice of opposition was filed in which revocation of the patent in its entirety was requested on the grounds of lack of novelty and of inventive step, of insufficiency of disclosure and of extension of the subject-matter beyond the content of the parent application as filed (Article 100(a), (b) and (c) EPC).

III. The decision was based on four sets of claims filed as main request and auxiliary requests 1, 2 and 2* during the oral proceedings before the opposition division on 14 November 2012.

Claim 1 of the main request corresponded to claim 1 as granted; in that request amendments were present only in dependent claims 2 and 9, while claims 12 to 18 were deleted. The claims of auxiliary request 1 corresponded to those of the main request with the specifications in claim 1 that the use comprises "preventing/treating cognitive degeneration in persons at risk for Alzheimer's disease or vascular dementia" and that fraction c) "contains at least 200 µg folic acid per daily dose" and corresponding adaptations in the dependent claims. The claims of auxiliary request 2 corresponded to those of the main request with the specification that fraction c) "contains at least 400 µg folic acid per daily dose" and corresponding adaptations in the dependent claims. The claims of auxiliary request 2* corresponded to those of the main request with the specifications in claim 1 that fraction c) "contains at least 200 µg folic acid per daily dose" and that "the preparation is in liquid, concentrate or powder form" and corresponding adaptations in the dependent claims.

IV. In the decision the following documents were cited *inter alia*:

D1: S. Kalmijn et al., American Journal of Epidemiology, Volume 145(1), 1997, pages 33 to 41
D4: S. Kalmijn et al., Annals of Neurology, Volume 42(5), 1997, pages 776 to 782

D5: W. B. Grant, Alzheimer's Disease Review, Volume 2, 1997, pages 42 to 55
D28: WO-A-94/05319
D36: US 6,069,138
D37: WO-A-98/50052
D38: M. Lucock, Molecular Genetics and Metabolism, Volume 71, 2000, pages 121 to 138
D41A: "Enhanced migration of human vascular endothelial cells after nutrient supplementation", Paul Savelkoul et al. submitted by the patent proprietor by letter of 14 September 2012
D41B: "Enhanced migration of human vascular endothelial cells after nutrient supplementation. Part 2: Folic acid concentration dependencies", Paul Savelkoul et al. submitted by the patent proprietor by letter of 14 September 2012

V. The decision under appeal can be summarised as follows:

a) The main request met the requirements of Articles 76 and 123(2) EPC. However, claim 1 of that request lacked novelty over D1, D4 and D5, which disclosed the use of fish for the treatment and prevention of dementia, whereby fish contained all ingredients of the claimed composition, as confirmed by several prior art documents. It was also not novel over D36 and D37, which disclosed in example II a composition with all the required ingredients and in the general part of the description that the examples were intended to be used to increase the melatonin secretion and therefore to prevent or treat Alzheimer's disease.

b) Auxiliary request 1 met the requirements of Articles 76 and 123(2) EPC. However, claim 1 was not clear in view of the wording "in persons at

risk for Alzheimer's disease" and still not novel over D36 and D37, which specifically disclosed a range of 100 to 600 µg per capsule of folic acid.

c) Auxiliary request 2 was not admitted into the proceedings, as it was considered as having *prima facie* serious deficiencies in terms of Article 54 EPC in view of the restriction of the amount of folic acid to "at least 400 µg per daily dose".

d) Claim 1 of auxiliary request 2* still lacked novelty over D36, as the content of the soft gelatin capsule could be regarded as a "concentrate".

VI. The appellant lodged an appeal against that decision. With the statement setting out the grounds of appeal, the appellant filed eight sets of claims as main request and first to seventh auxiliary requests respectively.

The main request corresponded to the main request on which the decision was based. Claim 1 of the first auxiliary request corresponded to claim 1 of the main request with the specification that fraction c) "contains at least 200 µg folic acid per daily dose". Claim 1 of the fourth auxiliary request corresponded to claim 1 of the first auxiliary request with the specification that fraction a) comprises "ω-3 and ω-6 fatty acids" and that "the daily dosage of the total of eicosapentaenoic acid, docosahexaenoic acid, dihomogammalinolenic acid and arachidonic acid is at least 120 mg". Claim 1 of the fifth auxiliary request corresponded to claim 1 of the main request with the specification that said preparation comprises "per daily dose at least 120 mg of long-chain

polyunsaturated fatty acids; at least 200 mg phospholipids; at least 200 µg folic acid; and at least 0.5 g citrate". Claim 1 of the sixth auxiliary request corresponded to claim 1 of auxiliary request 1 on which the decision was based.

VII. With letter of 2 February 2015 the appellant filed a further piece of prior art (D46: Prescrire International, December 1998, Volume 7(38), pages 180 to 187) and requested remittal of the case to the first instance for the analysis of inventive step.

VIII. Oral proceedings were held on 13 February 2015. The appellant withdrew at these proceedings the second and third auxiliary requests. During the oral proceedings an objection under Articles 76(1) and 123(2) EPC against claim 1 of the fourth auxiliary request was discussed *inter alia*, after the appellant had been given time on request to prepare on the issue.

IX. The arguments of the appellant can be summarised as follows:

Main request and first auxiliary request - novelty

a) The general description of documents D36 and D37 lacked a direct and unambiguous disclosure of the three fractions in combination and of their use for the specific treatment. In particular, the documents did not disclose the treatment of dementia syndromes and the mere observation on Alzheimer's disease at the end of the description indicated simply that Alzheimer's disease was an interesting special case and did not imply a treatment of Alzheimer's disease with the disclosed compositions. The documents did not

disclose the specific fractions as active ingredients in the specific treatment, which is what is required by the case law for lack of novelty in the field of medical nutrition (see in particular T 286/09 of 9 December 2009). Example II was not linked to any specific use or target group, let alone to a mere remark at the end of the description, and the experiments in the documents were directed to poor sleepers and not to Alzheimer's patients. The skilled person would not interpret documents D36 and D37, which were related to the regulation of melatonin secretion, to be directed to the treatment of Alzheimer's disease also in view of the common general knowledge, as represented e.g. by document D46. That document expressed doubts on low levels of melatonin as being a cause of the disease and warned against the use of melatonin as a supplement due to side effects in patients with hypertension or other cardiovascular problems. In this respect the use of melatonin as a supplement or of a composition regulating melatonin did not make any difference. The arguments equally applied to claim 1 according to the main request and to the first auxiliary request.

Fourth to sixth auxiliary requests - admittance

b) Documents D36 and D37, which were filed very late in opposition proceedings, so that they were not dealt with in the communication sent by the opposition division and were discussed only at the oral proceedings, were the basis for a completely new line of attack, which was difficult to deal with and played a central role in the decision. In view of that it was legitimate for the appellant

to await the decision of the opposition division and file auxiliary requests dealing with those issues when filing the statement of grounds. On that basis the fourth and fifth auxiliary requests had to be admitted into the proceedings. The sixth auxiliary request was already the subject of the opposition proceedings and its admittance was therefore not into question.

Fourth auxiliary request - amendments

c) It was abusive from the side of the respondent to introduce a new objection concerning extension of subject-matter only at the oral proceedings before the Board, all the more as it was not only directed to the amendments in the fourth auxiliary request. On that basis the objection should not be admitted into the proceedings. In any case the added feature was a preferred feature both in the parent and in the divisional applications as originally filed which was unambiguously linked to the other features of claim 1. As to the overall combination of features, it derived from claims 1, 4 and 5 of the parent application with the indication of the preferred disease (dementia syndromes) according to the field and the summary of the invention, the choice of the preferred compound which is a factor in methionine metabolism (folic acid) and the indication of the preferred quantities of folic acid and ω-3/ω-6 fatty acids. The arguments were even stronger with respect to the divisional application as filed, as its claim 1 included already most of the amendments. On that basis there was no extension of subject-matter beyond the content of the parent

or of the divisional applications as originally filed.

Remittal

d) Once novelty was acknowledged, the issue of inventive step was not a straightforward one. It was debatable whether documents D36 and D37 analysed for novelty were to be taken as the closest prior art or rather document D28 as discussed also in writing. Moreover, the relevance of the available experimental data and the possible combination with the available prior art were also complicated issues. That difficult analysis was not undertaken by the opposition division as documents D36 and D37, as well as D38 used in combination with D28 and D41A/D41B relating to experimental data, were filed after its communication in preparation of oral proceedings. On that basis the issue of inventive step should be allowed two readings and the case should be remitted to the first instance.

X. The arguments of the opponent (respondent) can be summarised as follows:

Main request and first auxiliary request - novelty

a) Example II of D37 described a soft gelatin capsule containing brain-derived phospholipids and 100-600 µg folic acid. The brain-derived phospholipids contained the two ω-3 fatty acids of fraction a) and all four phospholipids of fraction b) of claim 1 according to the main request and to the first auxiliary request. In view of that the composition of example II had all the ingredients of claim 1

according to those requests. In addition D37 expressly mentioned Alzheimer's patients as a particularly preferred target group due to the antioxidant, radical-scavenging effects of the compositions disclosed therein. That disclosure provided a clear link between the compositions disclosed in D37 and the treatment of Alzheimer's disease. Not making that link could only be the result of a reading of the document with a mind unwilling to understand. All the information necessary to arrive at lack of novelty according to the criteria of the case law, including those specific to second medical use claims, were therefore present in the document. In addition D37 included more data than the patent itself relating to symptoms of Alzheimer's disease including lack of sleep and disorientation. The conclusion reached was not changed by the content of document D46, which related to the administration of melatonin as a supplement and not to a composition regulating the endogenous secretion of melatonin. The document addressed a completely different mechanism and confirmed that the lack of melatonin in Alzheimer's patients was a known fact. On that basis the preparation of claim 1 of the main request and of the first auxiliary request lacked novelty over document D37.

Fourth to sixth auxiliary requests - admittance

b) The fourth to sixth auxiliary requests, which were filed only in appeal and were meant to overcome the novelty objection with respect to documents D36 and D37, should have been filed in opposition proceedings. While it was true that the documents were not filed with the notice of opposition, they

were filed two months before the oral proceedings and the appellant had repeated opportunity to file auxiliary requests after the documents were filed. The filing only at the appeal stage together with the request to remit amounted to an abuse of the proceedings, all the more as the amendments were only of formal nature and no evidence had been submitted to substantiate an effect related to the added features and justify the presence of an inventive step. By means of this conduct the appellant could manage to have documents D41A and D41B admitted into the proceedings in spite of their late filing in opposition.

Fourth auxiliary request - amendments

c) If the fourth auxiliary request were to be admitted into the proceedings, then it was legitimate to raise a new objection related to extension of its subject-matter beyond the content of both the parent and the divisional applications as filed. Claim 1 of the fourth auxiliary request differed from claim 1 of the parent application in many respect and included at least six amendments which were taken from different unrelated parts of the original application while omitting features disclosed in combination with the added ones. On that basis its subject-matter was a mosaic of different embodiments of the parent application and extended beyond the content of the parent application as filed. Similar considerations applied with respect to the divisional application as originally filed, so that the subject-matter of claim 1 also extended beyond the content of the divisional application as filed.

Remittal

d) The amendments which were introduced to formally establish novelty did not change the subject-matter of claim 1 and were never shown to contribute to the presence of an inventive step. Moreover, no data which could be relevant for the added feature were available and the issue of inventive step had been discussed at length during the written opposition proceedings both by the parties and by the opposition division. In view of that and considering the general interest to bring proceedings to an end, a decision on inventive step should be taken by the Board and the case should not be remitted.

XI. The appellant requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the main request, or on the basis of the first, fourth, fifth, sixth or seventh auxiliary requests as filed with the statement setting out the grounds of appeal. Furthermore, remittal of the case to the department of first instance was requested for the purpose of discussing the issue of inventive step.

XII. The respondent requested that the appeal be dismissed and the request for remittal of the case to the department of first instance be refused. In addition the respondent requested that the fourth, fifth and sixth auxiliary requests as well as documents D41A and D41B not be admitted into the proceedings.

Reasons for the Decision

Main request - novelty

1. Document D37 relates to the use of phospholipids rich in long chain-polyunsaturated fatty acids derived from animal brains or hen's eggs for the manufacture of a pharmaceutical and/or dietetic composition intended to regulate melatonin secretion (page 3, lines 5 to 9). The phospholipids may be combined with other accessory active ingredients such as vitamins including folic acid (page 3, line 30 to page 4, line 5).

1.1 An exemplary composition of D37 is disclosed in example II, which concerns a gelatin capsules based on high arachidonic acid and docosahexaenoic acid content brain phospholipids, including among others 10-300 mg brain-derived phospholipids and 100-600 µg folic acid (page 5, lines 1 to 13). As the brain phospholipids contain eicosapentaenoic acid and docosahexaenoic acid as well as phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine (see tables on page 6 of D37), the composition of example II of D37 is a preparation comprising the three fractions of claim 1 of the main request with all the required compounds, which was not disputed by the parties.

1.2 In D37 it is additionally specified that (page 13, lines 15 to 19):

"The antioxidant effect of melatonin and its free radical scavenger activity make it possible to use the pharmaceutical compositions of the present invention to slow down ageing processes. Alzheimer's disease is a particularly interesting case: in this disease, the nigh-time secretion of melatonin is almost absent."

1.3 The Board considers this last paragraph as a clear indication of the use of the compositions disclosed in D37 (including its examples, such as example II) for the treatment and/or prevention of Alzheimer's disease, which is a dementia syndrome.

1.4 While it is true that D37 does not include any example in which dementia syndromes, such as Alzheimer's disease, have been treated with the disclosed compositions, but only tests related to poor sleepers, this equally applies to the patent in suit, which discloses exemplary preparations, but no tests concerning their use in treatment or prevention of dementia syndromes. Therefore if the teaching of the patent is credible with regard to the medical use of the composition (as the Board considers it is the case), the same applies to the teaching of D37 by virtue of the clear indication in the cited paragraph (see point 1.2).

1.5 This conclusion cannot be changed by the disclosure of document D46, whose admittance into the proceedings has not been contested by the parties in spite of its late filing.

1.6 Document D46 is a scientific paper concerning the use of melatonin as a dietary supplement or as a drug (see title and abstract). It mentions an information campaign launched by the National Institute on Aging, as part of the National Institutes of Health (NIH) and "warning consumers against the use of hormones (including melatonin) to slow ageing, underlining the lack of studies proving either efficacy or long-term safety" (page 184, central column, second paragraph). It indicates that "Low levels of melatonin have been

observed in Alzheimer's disease, Parkinson's disease, severe strokes and coronary failure. However, there is no evidence that this is a cause rather than an effect" (page 184, central column, last but one paragraph). It also mentions an information report aimed at the general public, in which "the NIH noted that, on the basis of animal studies, melatonin can cause vasoconstriction and may, therefore, prove harmful in patients with hypertension or other cardiovascular problems" (page 186, left column, second full paragraph).

1.7 The Board is of the opinion that, in view of the fact that document D46 is directed to the direct administration of melatonin and gives no indications for compositions influencing its secretion, such as the one of D37, neither the document itself, nor the information therein related to information campaigns and reports of the NIH can have an impact on the reading of document D37 by the person skilled in the art. There is in particular no fact that would make the clear sentence in D37 not credible or would change its meaning.

1.8 The conclusion of lack of novelty with respect to document D37 is also not in contrast with the reasoning in T 286/09 (*supra*) cited by the appellant. In that case a claim directed to the use of a prebiotic in the manufacture of a medicament for decreasing inflammatory process in an elderly human was found to be novel with respect to a document which disclosed the administration of a composition including among others a prebiotic to persons with an immune condition associated with ageing and leading to an increase of inflammatory response, but did not disclose that the prebiotic as such, or any other ingredient of the

composition, had any effect *per se* in alleviating the condition. This was to be contrasted with the claim under analysis, which concerned the effect of a prebiotic for decreasing the inflammatory process, which effect was shown in the patent in suit by means of a report on a study where the diet of elderly people was supplemented by a prebiotic and a clear effect was observed in terms of decreasing the inflammatory process that could only be attributed to the prebiotic (see in particular point 2.3.1 in the grounds).

1.9 In the present case the second medical use is not related to a specific ingredient of the composition of the prior art, but to a mixture of fractions, which largely correspond to the key ingredients present also in the prior art document. Moreover, the disease mentioned in the prior art documents exactly falls under the class of diseases mentioned in the claim and no tests are present in the patent to show the effect either of the single fractions (and their ingredients) or of the combination of the fractions. In the present case, therefore, contrary to the situation in T 286/09, the disclosure in the patent is in no way different from the one in the prior art.

1.10 In view of that the preparation of claim 1 of the main request is not novel over the disclosure in D37.

First auxiliary request - novelty

2. Claim 1 of the first auxiliary requests corresponds to claim 1 of the main request with the specification that fraction c) "contains at least 200 µg folic acid per daily dose".

2.1 As example II of document D37 indicates that the quantity of folic acid in the composition is 100-600 µg, therefore including a specifically disclosed value in the range of claim 1 of the first auxiliary request (600 µg), this claim lacks novelty for the same reasons as outlined for claim 1 of the main request (see point 1, above).

Fourth to sixth auxiliary requests - admittance

3. The fourth to sixth auxiliary requests were filed by the appellant with the statement of grounds. The fourth and fifth auxiliary requests were clearly meant to overcome the lack of novelty with respect to documents D36 and D37 as expressly declared by the appellant in the statement of grounds, while the claims of the sixth auxiliary request corresponded to those of auxiliary request 1 on which the decision was based.

3.1 The Board finds that the fourth and fifth auxiliary request can be seen as a legitimate reaction of the appellant to the decision under appeal. While it is true that the appellant had opportunities to file auxiliary requests addressing the lack of novelty over document D36 and D37 before the first instance, the fact that the documents were filed after the communication of the opposition division in preparation to the oral proceedings, so that they were discussed at the oral proceedings for the first time together with the relevance and the complexity of the issue constitute a sufficient justification for the appellant to await for the decision and file the appropriate requests at the beginning of the appeal proceedings.

3.2 On that basis the Board finds it appropriate to exercise its discretion by admitting the fourth and fifth auxiliary requests into the proceedings.

3.3 As to the sixth auxiliary request, apart from the change in numbering, it corresponds to a request which was decided upon by the opposition division (see point VI, above). On that basis it is part of the proceedings and does not fall under the power of the Board under Article 12(4) of the Rule of Procedure of the Boards of Appeal.

Fourth auxiliary request - amendments and novelty

4. Once the fourth auxiliary request is admitted into the proceedings and it is to be analysed whether it may be the basis for maintenance of the patent in amended form, there is no doubt that one of the criteria it has to meet resides in the requirements of Article 123(2) EPC and, being the application from which the patent originates a divisional application, also of Article 76(1) EPC.

4.1 While it is true that the respondent raised an objection under Article 76(1) EPC and a corresponding one under Article 123(2) EPC only at the oral proceedings, the Board considers that in case of amendments the appellant-proprietor must be prepared to indicate the basis for the amended claim both in the parent application and in the divisional application as filed without any need of adjournment of the proceedings, all the more if the requested time to prepare on the issue is given during the oral proceedings, as was the case here (see point VIII, above). In this respect it is irrelevant whether the objection is only related to the amendment as such or

also to its combination with the remaining features of the claim.

4.2 On that basis the Board finds it appropriate to admit the objections under Articles 76(1) and 123(2) EPC into the proceedings.

5. Claim 1 of the fourth auxiliary request corresponds to claim 1 of the parent application with the amendment of the treated disease ("dementia syndromes" instead of "vascular disorders"), the specification that fraction a) comprises "ω-3 and ω-6 fatty acids, comprising at least one of the ω-3 fatty acids eicosapentaenoic acid and docosahexaenoic acid", that fraction c) contains specifically "at least 200 µg folic acid per daily dose" and that "the daily dosage of the total of eicosapentaenoic acid, docosahexaenoic acid, dihomogammalinolenic acid and arachidonic acid is at least 120 mg".

5.1 The first three amendments, which were already largely present in claim 1 as granted, focus the claim on the core of the invention as presented in the parent application, since they specify the preferred disease correlated to vascular disorders (see "Background of the invention", page 1, lines 5 to 9 of the parent application), the preferred components of fraction a) (see page 6, lines 12, 13, 24 and 25) and the preferred compound of fraction c) in the preferred quantity (see page 8, lines 23 to 25). The resulting combination cannot be seen therefore as the mosaic of arbitrarily selected features not correlated to each other, but as the limitation of the claim to a specific preferred embodiment, which as such is directly and unambiguously derivable from the parent application as filed. In this respect there is no further feature in the cited

passages that is disclosed as necessarily linked to the added ones and is missing from claim 1.

5.2 As to the final feature which appears in claim 1 of the fourth auxiliary request, the same can be said, as it also specifies what is presented in the parent application as the preferred dosage of the preferred ω-3/ω-6 fatty acids (see page 6, line 30).

5.3 On that basis the Board concludes that the subject-matter of claim 1 of the fourth auxiliary request does not extend beyond the content of the parent application as filed, so that the requirements of Article 76(1) EPC are met.

6. With regard to the requirements of Article 123(2) EPC, claim 1 of the fourth auxiliary request corresponds to claim 1 of the divisional application as filed with a subset of the amendments indicated with respect to claim 1 of the parent application as filed (see point 5, above), namely the specification that fraction a) comprises "ω-3 and ω-6 fatty acids", that the quantity of folic acid in fraction c) is "at least 200 µg" and that "the daily dosage of the total of eicosapentaenoic acid, docosahexaenoic acid, dihomogammalinolenic acid and arachidonic acid is at least 120 mg".

6.1 Since the description of the divisional application as filed is practically identical to the description of the parent application as filed and in particular contains all the passages cited above (see points 5.1 and 5.2) with respect to the preferred features (see page 1, lines 5 to 9; page 6, lines 9, 10, 20, 21, 25 and 26; page 8, lines 17 to 19 of the divisional application as filed), the same arguments as presented with regard to the analysis of extension of subject-

matter with respect to the parent application as filed apply to the analysis with respect to the divisional as filed with the consequence that claim 1 of the fourth auxiliary request also meets the requirements of Article 123(2) EPC.

7. In view of the amendments in claim 1 of the fourth auxiliary request, no novelty objection was raised by the respondent with respect to this claim. The Board has no reason to take a different view.

Remittal

8. Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of a case. The essential function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

8.1 In particular, remittal is considered by the boards in cases where a first-instance department issues a decision against a party solely upon some issues which are decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issues is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111(1) EPC).

8.2 The observations made above apply in full to the present case. The opposition division decided that the subject-matter of the requests which were admitted into the proceedings was not novel, but did not consider the issue of inventive step. This issue, however, formed, *inter alia*, the basis for the request that the patent be revoked in its entirety and must therefore be considered as an essential substantive issue in the present case.

8.3 None of the specific reasons invoked by the respondents is considered by the Board strong enough to justify a deviation from these principles. The relevance of the introduced amendments on the issue of inventive step and the relevance of the data available on file cannot be evaluated without going into the merit of the issue. As to the discussion which took place in writing during opposition proceedings including a preliminary opinion of the opposition division, it is relevant to note that it did not take into account documents D36 to D38 and D41A/D41B which were filed by the parties after the preliminary opinion was sent and were not debated at the oral proceedings as to their relevance to inventive step. Moreover, any discussion in writing by the opposition division before the oral proceedings does not change the fact that the decision did not take position on the issue.

9. Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances of the present case, it is appropriate to remit the case to the opposition division for the analysis of inventive step on the basis of the claims of the fourth auxiliary request.

10. As the case is remitted for the analysis of inventive step and documents D41A and D41B were cited by the parties only in respect of this issue, there is no need for the Board to decide on their admittance into the proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

S. Fabiani D. Boulois

Decision electronically authenticated