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Datasheet for the decision of 28 February 2020

Case Number: T 2169/16 - 3.3.01

Application Number: 08766834.9

Publication Number: 2170316

A61K31/557, A61K31/7072, IPC:

A23L1/30, A23L1/304, A23L1/302,

A61P25/28

Language of the proceedings: ΕN

Title of invention:

Improving memory in subjects with mini-mental state examination of 24-26

Patent Proprietor:

N.V. Nutricia

Opponents:

Fresenius Kabi Deutschland GmbH Société des Produits Nestlé S.A.

Relevant legal provisions:

EPC Art. 83 RPBA Art. 12(4), 13(1)

Keyword:

Sufficiency of disclosure - (no) Late-filed auxiliary requests - admitted (no)



Beschwerdekammern **Boards of Appeal** Chambres de recours

Boards of Appeal of the European Patent Office Richard-Reitzner-Allee 8 85540 Haar **GERMANY**

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Case Number: T 2169/16 - 3.3.01

DECISION of Technical Board of Appeal 3.3.01 of 28 February 2020

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 25 July 2016 revoking European patent No. 2170316 pursuant to

Article 101(3)(b) EPC.

Composition of the Board:

Chairman A. Lindner Members: R. Hauss

P. de Heij

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Summary of Facts and Submissions

- I. European patent No. 2 170 316 (the patent in suit) was granted with a set of nine claims.
- II. Two oppositions were filed, opposing the patent 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. In the course of the opposition proceedings, the patent proprietor requested the rejection of the oppositions (main request) and submitted three sets of claims as auxiliary requests.
- IV. Claim 1 of auxiliary request 3 reads as follows:
 - 1. A composition comprising:
 - a. uridine or uridine phosphate; and
 - b. docosahexaenoic acid and/or eicosapentaenoic acid
 for use in
 - (i) improving delayed recall function and/or
 - (ii) the treatment and/or prevention of an impaired delayed recall function of a subject,
 - wherein said composition is enterally administered to the subject, and wherein said subject has a mini-mental state examination [sic] of 24-26.

This claim is identical to claim 1 as granted except that claim 1 as granted does not include the requirement regarding the mini-mental state examination score of 24 to 26.

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- V. "Mini-mental state examination" is abbreviated as
 "MMSE" in the following.
- VI. The documents cited in the opposition proceedings included the following:

D9: Dissertation Sarah Holguin, MIT (Feb 2008)

D11: WO 2006/127620 A2

D12: WO 2007/073178 A2

D13: Am J Epidemiol 145(1), 33-41 (1997)

D19: Alzheimer's & Dementia 4, S153-S168 (Jan 2008)

D30: Alzheimer's & Dementia 6, 1-10 (Jan 2010)

D31: European Journal of Pharmacology <u>585</u>, 197-207 (available online 4 March 2008)

VII. The decision under appeal is the decision of the opposition division revoking the patent. It was announced on 14 June 2016 and posted on 25 July 2016.

According to the decision under appeal:

- (a) the claims of the main request and auxiliary requests 1 and 2 contained added subject-matter (Article 123(2) EPC);
- (b) that objection did not apply to the claims of auxiliary request 3;
- (c) the subject-matter claimed in auxiliary request 3 was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC);
- (d) the subject-matter claimed in auxiliary request 3 met the requirement of novelty (Article 54 EPC) but lacked an inventive step having regard to the state of the art (Article 56 EPC).
- VIII. The patent proprietor (appellant) filed an appeal against this decision.

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- IX. With the statement setting out the grounds of appeal, the appellant submitted four sets of claims as its main request and auxiliary requests 1 to 3.
- X. Both respondents (opponent 1 and opponent 2) replied in writing to the statement setting out the grounds of appeal.
- XI. By letter dated 29 June 2017, the appellant submitted two further sets of claims as auxiliary requests 4 and 5.
- XII. Oral proceedings before the board of appeal took place on 28 February 2020.

At the outset of the oral proceedings, the appellant withdrew the main request and auxiliary request 1. Previous auxiliary request 2 became the new main request. Auxiliary requests 3, 4 and 5 were renumbered as auxiliary requests 1, 2 and 3, respectively.

Claim 1 of the **main request** is identical to claim 1 of former auxiliary request 3 considered in the decision under appeal (see point IV above).

Claim 1 of auxiliary request 1 reads as follows:

- 1. A composition comprising:
 - a. uridine or uridine phosphate; and
 - b. docosahexaenoic acid and/or eicosapentaenoic acid
 for use in
 - (i) improving delayed recall function and/or
 - (ii) the treatment and/or prevention of an impaired delayed recall function of a subject,
 - wherein said composition is enterally administered to the subject, and wherein said subject has a mini-mental state examination [sic] of 24-26,

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and wherein the composition further comprises phospholipids, choline, vitamin E, vitamin C, selenium, vitamin B12, vitamin B6 and folic acid.

Claim 1 of auxiliary request 2 reads as follows:

- 1. A composition comprising:
 - a. uridine or uridine phosphate; and
 - b. docosahexaenoic acid and/or eicosapentaenoic acid
 - for use in the treatment and/or prevention of an impaired delayed recall function of a subject,
 - wherein said composition is enterally administered to the subject, and wherein said subject has a mini-mental state examination [sic] of 24-26.

Claim 1 of auxiliary request 3 reads as follows:

- 1. A composition comprising:
 - a. uridine or uridine phosphate; and
 - b. docosahexaenoic acid and/or eicosapentaenoic acid
 - for use in the treatment and/or prevention of an impaired delayed recall function of a subject,
 - wherein said composition is enterally administered to the subject, and wherein said subject has a mini-mental state examination [sic] of 24-26,
 - and wherein the composition further comprises phospholipids, choline, vitamin E, vitamin C, selenium, vitamin B12, vitamin B6 and folic acid.
- XIII. The appellant's arguments, as far as relevant to the present decision, may be summarised as follows:

Interpretation of claim 1 - main request

Both uses defined in claim 1 (namely, (i) improving delayed recall function and (ii) treating/preventing impaired delayed recall function) were therapeutic, if nothing else because the subjects of claim 1 were

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defined as having an MMSE score of 24-26 and therefore as having a pathological condition. Thus, claim 1 was a purpose-limited product claim correctly drafted in the format for further medical use according to Article 54(5) EPC.

Sufficiency of disclosure - main request

It was evident from prior-art documents D9, D11, D12, D13 and D19 that the mandatory components of claim 1 (a. uridine or uridine phosphate and b. docosahexaenoic acid and/or eicosapentaenoic acid) were active agents which could improve memory function. The therapeutic benefit of this ingredient combination for delayed recall function was therefore plausible; furthermore, it was credibly demonstrated by the clinical study described in example 2 of the application as filed and the patent in suit, in which a composition conforming to claim 1 had been tested. The favourable results reported in example 2 were corroborated by additional data obtained in another clinical study described in post-published document D30.

Admission of auxiliary requests 1, 2 and 3

Auxiliary request 1 addressed the respondents' objection that example 2 failed to establish a causal relationship between the claimed components a. and b. and the claimed effect by including all further ingredients which had been varied in the clinical study of example 2 as mandatory components of the claimed composition. This request had been filed at the earliest opportunity in the appeal proceedings, namely with the statement setting out the grounds of appeal. Since the opposition division had decided the issue of sufficiency of disclosure in favour of the appellant,

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it had been unnecessary to file such a request during the proceedings at first instance.

Auxiliary requests 2 and 3 addressed the respondents' argument that improving delayed recall function was not necessarily a therapeutic use, which had been made in the context of an objection of lack of novelty, by deleting this option from the claims. This objection had not been discussed by the opposition division, which had instead decided, in the appellant's favour, that subjects having an MMSE score of 24-26 were considered to have a delayed recall function, by which the use according to option (i) was in any case rendered therapeutic. Thus it had not become necessary for the appellant to file auxiliary requests 2 and 3 during the proceedings at first instance. Since these requests addressed a new objection not discussed by the opposition division, they should be admitted into the proceedings.

XIV. The arguments presented by the respondents may be summarised as follows:

Sufficiency of disclosure - main request

The composition tested in the clinical study described in example 2 (the only passage of the patent in suit and the underlying patent application that contained experimental data) had eleven active components, eight of which were not listed in claim 1 of the main request as mandatory components. The comparative composition which had been administered to the control group of the study did not contain these eleven components. It was moreover part of the skilled person's common general knowledge (represented by the review article D31) that the additional components might well have an impact on brain function. Hence, it had not been shown that any effect or benefit observed was indeed achieved by the

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administration of uridine or its phosphate together with docosahexaenoic and/or eicosapentaenoic acid. Consequently, the alleged technical effect had not been rendered plausible in the application as filed.

For this reason, the appellant's supplementary data provided in post-published document D30 should not be taken into account. In any case, D30 merely described another clinical study comparing a composition having the same eleven active ingredients as the composition of example 2 with a control composition lacking those ingredients. Due to this experimental set-up, D30 could not demonstrate any more than example 2 that there was a therapeutic effect linked specifically to the combination of uridine and/or uridine phosphate with docosahexaenoic and/or eicosapentaenoic acid.

Admission of auxiliary requests 1, 2 and 3

The objection relating to insufficiency of disclosure had been raised by the respondents at the very outset of the proceedings at first instance. Auxiliary request 1, addressing this objection for the first time by adding the relevant ingredients of example 2 to the claims as mandatory components, should therefore have been presented in the proceedings at first instance. Furthermore, claim 1 of auxiliary request 1 did not correspond to any of the claims of the patent as granted. While granted claim 3 recited the ingredients in question, it employed the wording "the composition comprises one or more of", which did not require all of these ingredients to be present.

With auxiliary request 1, the appellants were thus presenting a fresh case.

As early as in its notice of opposition, respondent - opponent 1 had argued that claim 1 as granted related in one aspect to the improvement of delayed recall

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function in healthy individuals, and that, therefore, the claims could not benefit from the legal fiction of Article 54(5) EPC. This had consequences for the assessment of novelty since any prior-art composition containing the required mandatory components and suitable for improving delayed recall function was novelty-destroying. If the appellant intended to address this objection by restricting the claims to the therapeutic indication of treating or preventing impaired delayed recall, it should have filed auxiliary requests with this amendment early in the proceedings at first instance. During the appeal proceedings, no new procedural development had occurred that could justifiably have triggered the submission of auxiliary requests 2 and 3 by the appellant.

- XV. The parties' requests, as far as relevant for the outcome of the present decision, were the following:
 - (a) 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 claims of the main request (filed as auxiliary request 2 with the statement setting out the grounds of appeal);
 - or, in the alternative, on the basis of the claims of auxiliary request 1 (filed as auxiliary request 3 with the statement setting out the grounds of appeal);
 - or, in the further alternative, on the basis of the claims of auxiliary requests 2 or 3 (filed as auxiliary requests 4 and 5 with the appellant's letter dated 29 June 2017).
 - (b) Both respondents (opponent 1 and opponent 2) requested that the appeal be dismissed.

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Within the purview of this request, both respondents requested that auxiliary requests 1, 2 and 3 not be admitted into the proceedings.

Reasons for the Decision

- 1. Admissibility of the appeal
 - The appeal complies with Articles 106 to 108 EPC and Rule 99 EPC and is therefore admissible.
- 2. Sufficiency of disclosure main request

Interpretation of claim 1 and requirements for sufficiency

- In the context of the assessment of novelty, the respondents argued, in their submissions filed in writing, that claim 1 was not restricted to a further medical use. In one aspect, the claim related to the treatment of healthy subjects since treatment option (i) (i.e. improving delayed recall function) was not necessarily therapeutic and subjects with an MMSE score of 24-26 did not necessarily suffer from impaired delayed recall. The respondents considered that, as a consequence, the claim could not benefit from the legal fiction of Article 54(5) EPC but related to a composition which was merely suitable for the purpose of improving delayed recall function.
- 2.2 While the board did not take any decision regarding this point and its implications for novelty, the issue of sufficiency of disclosure was discussed and examined on the basis of the assumption (in conformity with the appellant's interpretation of claim 1) that both options (i) and (ii) in claim 1 were therapeutic applications and that the claim format corresponded to that provided for in Article 54(5) EPC (composition

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for specific use in a method referred to in Article 53(c) EPC).

- According to the established case law of the boards of appeal, attaining the specified therapeutic effect is regarded as a functional technical feature of such a purpose-limited product claim. The functional technical feature must be taken into account in the assessment of sufficiency and patentability of the claimed subject-matter. Sufficiency of disclosure must be satisfied at the effective date of the patent, i.e. on the basis of the information provided in the patent application as filed, together with the common general knowledge then available to the person skilled in the art.
- 2.4 It therefore has to be established whether the application as filed discloses the efficacy of the claimed composition for the specified therapeutic purpose, taking into consideration the information provided in the application as filed and the common general knowledge of the person skilled in the art.

Disclosure in the application

- 2.5 Example 2 of the application as filed describes a clinical study carried out with drug-naive very mild Alzheimer's disease subjects with an MMSE score of 24 to 26. The outcome measure was a (delayed) verbal memory task (derived from Wechsler Memory Scale-Revised). The composition administered to the group receiving "active product" was a drink according to the formula of example 1, containing inter alia:
 - docosahexaenoic acid
 - eicosapentaenoic acid
 - uridine monophosphate
 - phospholipids

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- choline
- vitamin E
- vitamin C
- selenium
- vitamin B12
- vitamin B6
- folic acid

The "control product" administered to the control group of the study was an iso-caloric drink according to example 1, but without these eleven ingredients.

- 2.6 While it was in dispute among the parties whether a significant difference between the treatment groups was indeed observed in respect of changes in delayed recall memory function, this issue can be left undecided in view of the following considerations.
- 2.7 A technical effect cannot be convincingly linked to a particular technical feature if several features were varied in the comparison. As a matter of principle, the study set-up of example 2 cannot therefore show that any therapeutic benefit observed was causally linked to the administration of a combination of docosahexaenoic and/or eicosapentaenoic acid with uridine phosphate (i.e. the mandatory components specified in claim 1), since these are not the only components which were varied between the active product and the control product.

Common general knowledge

2.8 The appellant argued that in conjunction with the study of example 2, the disclosure of prior-art documents D9, D11, D12, D13 and D19 would have rendered it at least plausible that docosahexaenoic acid, eicosapentaenoic acid and uridine were key

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contributors which produced the desired effect on delayed recall function.

- 2.9 According to established case law, the content of specialist journals or patent specifications does not usually belong to the common general knowledge of the average skilled person. Rather, common general knowledge is typically found in basic handbooks, monographs, encyclopedias, textbooks and reference books. None of the documents cited by the appellant is of that type. D9 is a thesis, D11 and D12 are patent applications and D13 and D19 are scientific articles. As the board is not aware of any special circumstances which might suggest otherwise, these documents are not considered to represent common general knowledge. Hence, their disclosure may not be used to supplement the information provided in the application as filed.
- 2.10 By contrast, document D31 is a review article published before the filing date of the patent in suit. It was not disputed that D31 represents the skilled person's common general knowledge at the relevant date.
- 2.11 According to D31, epidemiological evidence links nutrition to the incidence and risk of Alzheimer's disease. Studies suggest that dietary components can stimulate membrane formation and synapse formation as well as improve behaviour and cerebrovascular health (D31: Abstract). They can influence brain structure and function and may contribute to the prevention of dementia (page 198, column 1, lines 22 to 38).

Antioxidants (including vitamins C and E) or vitamins such as folate and B vitamins are components with potential benefit for Alzheimer's disease (page 200, column 1, lines 31 to 48; page 202, column 2, lines 3 to 14).

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Phospholipids are major components of neuronal membranes and synapses, a critical precursor in phospholipid synthesis being choline (page 201, column 2, lines 7 to 20).

D31 also mentions polyunsaturated omega-3 fatty acids, in particular docosahexaenoic and eicosapentaenoic acid, as components relevant for membrane composition and fluidity (page 201, column 1, lines 35 to 50), and uridine as being a precursor to phosphatidylcholine (page 201, column 2, lines 30 to 39).

- 2.12 Thus, it can be derived from D31 that it was common knowledge that docosahexaenoic acid, eicosapentaenoic acid and uridine were nutritional components believed to affect the cognitive function of the brain and to be potentially beneficial against dementia.
- 2.13 However, the same was known about other components of the active product of example 2, in particular choline, phospholipids, folate, B vitamins and vitamins C and E, which were present in the active product of example 2 in non-negligible amounts (e.g. 400 mg of choline per 125 ml of the product).
- Therefore, the additional ingredients cannot be ignored as irrelevant to the outcome of the clinical study described in example 2 especially since, according to D31, the available evidence suggested that combinations of nutrients may be rather more effective than single components and that there may be synergies (see D31: page 201, column 1, lines 6 to 12, page 202, column 2, line 48 to page 203, column 1, line 40; page 203, column 2, lines 15 to 28).
- 2.15 The person skilled in the art studying example 2 of the application in light of common general knowledge would thus not have been able to attribute any observed

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clinical effect specifically to the activity of one or more of the mandatory components of claim 1 (docosahexaenoic acid, eicosapentaenoic acid and uridine phosphate).

- 2.16 Furthermore, document D31 does not discuss the potential impact of any of the components mentioned on delayed recall function, let alone in human subjects having an MMSE score of 24 to 26. Nor does the treatment or prevention of dementia and Alzheimer's disease, as discussed in D31, imply that there must inevitably be an impact on delayed recall function. The impairment of delayed recall is merely one aspect or symptom of cognitive impairment which may occur (albeit a typical and relevant one).
- 2.17 Accordingly, none of the eleven characteristic components of the "active product" of example 2 (see point 2.5 above) were actually known to have an effect on delayed recall function.
- 2.18 For these reasons, example 2 of the application as filed, in light of common general knowledge as represented by D31, does not render it credible that the administration specifically of docosahexaenoic acid and/or eicosapentaenoic acid in combination with uridine or uridine phosphate will have the desired effect of improving delayed recall function and treating or preventing impaired delayed recall function.

Supplementary evidence (D30)

2.19 Irrespective of whether it would in these circumstances be appropriate to take additional (post-filed) evidence into consideration at all, the content of document D30 relied on by the appellant would not, in any case, be

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able to overcome the objection of insufficient disclosure, for the following reasons:

- of the two mandatory components of claim 1 was not observed in isolation. As in example 2 of the application underlying the patent in suit, the "active product" tested according to D30 contained docosahexaenoic acid, eicosapentaenoic acid, uridine monophosphate, phospholipids, choline, vitamin E, vitamin C, selenium, vitamin B12, vitamin B6 and folic acid, whereas the "control product" did not contain any of these components.
- The subjects taking part in the clinical study of D30 had an MMSE score of 20 to 26, which does not allow any conclusion to be drawn about the more restricted group having an MMSE score of 24 to 26.

Conclusion

- 2.20 For these reasons, since the causal link between the mandatory technical features of the claimed composition and the desired therapeutic benefit was not rendered credible, the subject-matter of claim 1 is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).
- 3. Admission of auxiliary request 1
- 3.1 The set of claims of auxiliary request 1 was filed for the first time with the appellant's statement setting out the grounds of appeal. This request attempts to overcome the objection regarding insufficiency of disclosure discussed in section 2 above by defining phospholipids, choline, vitamin E, vitamin C, selenium, vitamin B12, vitamin B6 and folic acid as further mandatory components of the claimed composition.

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(Incidentally, according to claim 1 of auxiliary request 1, only one of docosahexaenoic acid and eicosapentaenoic acid must be present; this aspect is, however, irrelevant to the present decision).

- 3.2 Article 12(4) RPBA 2007 gives the board the discretion to hold a request inadmissible if it could have been presented in the proceedings at first instance. The relevant question is whether, in the circumstances of the specific case, the appellant could have been expected to present its request during the proceedings at first instance.
- In point 4 of its submission filed with the notice of opposition, on the topic of sufficiency of disclosure, respondent-opponent 1 raised the objection that, due to the presence of further active ingredients in the tested product and their absence in the control product, example 2 of the patent did not show that the alleged therapeutic effect of improving delayed recall function could be achieved by administering specifically components a. and b. of claim 1 (uridine or uridine phosphate and docosahexaenoic acid and/or eicosapentaenoic acid).
- 3.4 With its reply to the notices of opposition, the appellant requested the rejection of the oppositions and did not file any auxiliary request.
- 3.5 In the communication annexed to the summons to attend oral proceedings dated 29 October 2015, the opposition division did not give a preliminary opinion on the issue in question. Nor did the opposition division provide further comments in writing before the oral proceedings of 14 June 2016.
- 3.6 Thus, in the proceedings at first instance, the appellant was aware of the objection in question and

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could not be certain that it would be unnecessary to file a claim request to address it.

Including the active ingredients of example 2 in the claim was furthermore an obvious way of addressing the objection.

Yet the appellant failed to file a claim request with this amendment during the proceedings at first instance.

- 3.7 As it turned out, the opposition division eventually decided in the appellant's favour on this issue (see the minutes of the oral proceedings of 14 June 2016, points 20, 22, 25 and 40 and the decision under appeal, reasons 6.4.4). The appellant's argument that, therefore, a pertinent claim request would in any case not have been discussed by the opposition division cannot succeed, because this argument is based on hindsight regarding the outcome of the opposition proceedings.
- 3.8 The board arrived at the conclusion that, in the circumstances described above (see points 3.3 to 3.6), the appellant ought to have filed a pertinent claim request in the proceedings at first instance.
- 3.9 The board therefore found it appropriate to hold auxiliary request 1 inadmissible, pursuant to Article 12(4) RPBA 2007.
- 4. Admission of auxiliary requests 2 and 3
- 4.1 Auxiliary requests 2 and 3 were not filed with the statement setting out the grounds of appeal, but with a later submission of the appellant (see point XI above).

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- 4.2 These requests correspond to the main request and auxiliary request 1, respectively, with the difference that the indication for use in improving delayed recall function (i.e. option (i)) has been deleted.
- 4.3 This amendment is intended to address an objection by the respondents regarding lack of novelty. This objection was based on an interpretation of claim 1 according to which the use for improving delayed recall function in subjects with an MMSE score of 24 to 26 included the treatment of healthy subjects, so that the scope of claim 1 covered any composition (e.g. fish) which was merely suitable for such a non-therapeutic use and contained the mandatory components a. and b..
- 4.4 This objection was raised and discussed in the proceedings at first instance (see the notice of opposition of respondent-opponent 1, final paragraph of point 5.2 and point 3 and the decision under appeal, point 17.2.3).
- 4.5 The opposition division did not give a preliminary opinion on this issue before the oral proceedings of 14 June 2016.
- Thus, the appellant was aware of the objection in question during the proceedings at first instance and could not be certain that it would be unnecessary to file a claim request to address it.

Deleting use option (i) was also an obvious way of addressing the objection.

Yet the appellant never filed a claim request deleting option (i), such as present auxiliary request 2, during the proceedings at first instance, nor was such a

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request submitted with the statement setting out the grounds of appeal.

- 4.7 According to the decision under appeal (Reasons 6.5.4), the opposition division finally arrived at the conclusion that the definition of the subjects as having an MMSE score of 24-26 was sufficient for claim 1 of former auxiliary request 3 (identical to claim 1 of the present main request) to fulfil the requirements for a medical use. It was therefore unnecessary for the opposition division to elaborate on whether the use (i) "in improving delayed recall function" as such (without considering this specific group of subjects) could be non-therapeutic. The argument was, however, known and it was an integral part of the respondents' novelty attack. As a consequence, the appellant's argument that auxiliary request 2 addressed an issue never discussed by the opposition division must fail.
- 4.8 Since the objection had been known for years, the fact that respondent-opponent 1 re-iterated the same objection in its reply to the statement setting out the grounds of appeal (see the respondent's letter of 18 April 2017, section 6, paragraph bridging pages 7 and 8) cannot be regarded as an unexpected procedural development which would justify, in response, the submission of a new auxiliary request by the appellant.
- 4.9 Thus, the board found it appropriate to exercise its discretion pursuant to Article 13(1) RPBA by not admitting auxiliary request 2 into the proceedings. Auxiliary request 3 combines the amendments of auxiliary requests 1 and 2 and was not admitted for the same reasons as set out with regard to those two requests.

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Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow A. Lindner

Decision electronically authenticated