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Datasheet for the decision of 16 December 2025

Case Number: T 0010/24 - 3.3.04

Application Number: 14815077.4

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Language of the proceedings: EN

Title of invention:

COMPRISING A URIDINE SOURCE AND AN OMEGA-3 PUFA FOR IMPROVING COORDINATION, BALANCE, GRIP STRENGTH OR FINE MOTOR SKILLS

Patent Proprietor:

N.V. Nutricia

Opponent:

ABBOTT LABORATORIES

Relevant legal provisions:

RPBA 2020 Art. 12(1)(a), 13(2)
EPC Art. 100(b), 83, 54, 56, 84

Keyword:
Ground for opposition under Article 100(b) EPC - new ground for opposition (no)
Main request, auxiliary requests 1 and 2 - sufficiency of disclosure (no)
Auxiliary request 3 - sufficiency of disclosure, novelty, inventive step (yes)
Auxiliary request 3 - clarity - objection not permissible in accordance with G 3/14
Late-filed lines of argument - submitted during oral proceedings - admitted (no)

Decisions cited:
G 0002/21, G 0003/14, T 1779/21, T 0609/02, T 0182/89

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Case Number: T 0010/24 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 16 December 2025

Appellant: (Opponent)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park IL 60064 (US)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Respondent: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	V.O. P.O. Box 87930 Carnegieplein 5 2508 DH Den Haag (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 November 2023 rejecting the opposition filed against European patent No. 3077005 pursuant to Article 101(2) EPC**

Composition of the Board:

Chair	M. Pregetter
Members:	S. Albrecht
	M. Blasi

Summary of Facts and Submissions

I. European patent No. 3 077 005 ("patent") was granted on European patent application No. 14 815 077.4 ("application as filed").

The patent was granted with a set of 19 claims. Claim 1 as granted is the sole independent claim and reads as follows:

"1. A combination of a uridine source selected from the group of uridine, deoxyuridine, cytidine, deoxycytidine, UMP, UDP, UTP, CMP, CDP, CTP, dUMP, dUDP, dUTP, dCMP, dCDP and dCTP, wherein optionally one or more hydroxyl moieties of the (deoxy)ribose of said uridine source are acylated with a C1-C24 carboxylic acid,
an omega-3-polyunsaturated fatty acid having 18-24 carbon atoms, which omega-3 polyunsaturated fatty acid is selected from the group consisting of docosahexaenoic acid (DHA), docosapentaenoic acid (DPA) and eicosapentaenoic acid (EPA), and
a butyrate producing dietary fibre
for a use selected from the group consisting of:

- the prevention or treatment of a disturbance in coordination of limbs in a mammal;
- the prevention or treatment of a disturbance in equilibrium in a mammal;
- the prevention or treatment of a disturbance in limb strength, in particular forelimb grip strength in a mammal;
- the prevention or treatment of a disturbance in a fine-motor skill in a mammal; and

- the prevention or treatment of a disturbance in a gross-motor skill in a mammal."

II. Opposition proceedings were based on the grounds for opposition under Article 100(a) (lack of novelty and lack of inventive step) and Article 100(b) EPC.

III. The documents filed during the opposition proceedings include the following:

D2: US 8,283,335 B2
D3: H. Hara et al., J. Nutr. 128, 1998, 688-93
D4: T.R. Licht et al., BMC Microbiology 10, 2010, article number 13 (11 pages)
D6: M. Cansev et al., *Neurosci Res*. 62(3), November 2008, 206-9
D7: R. St. Laurent et al., *Neuroscience* 246, 2013, 382-90
D9: M.J. Hopkins et al., Applied and Environmental Microbiology, April 2003, 1920-7
D10: Test report "Effects of a diet comprising a uridine source, an omega-3 fatty acid and butyrate producing fibre on grip strength" filed by the respondent on 26 September 2022

IV. The opponent's appeal is against the opposition division's decision to reject the opposition.

In the decision under appeal, the opposition division found, *inter alia*, that the claimed invention was sufficiently disclosed and that the claimed subject-matter was novel over document D2 and involved an inventive step starting from that document.

V. In the statement of grounds of appeal, the opponent ("appellant") requested that the decision under appeal

be set aside and that the patent be revoked in its entirety.

VI. With the reply to the statement of grounds of appeal, the patent proprietor ("respondent") requested that the appeal be dismissed and that the patent be maintained as granted (main request), implying that the opposition be rejected. As an auxiliary measure, the respondent requested that the patent be maintained in amended form on the basis of one of the sets of claims of auxiliary requests 1 to 20, filed with the reply to the notice of opposition and refiled with the reply to the statement of grounds of appeal.

The subject-matter of claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the mammal has been specified as suffering from a neurological disorder.

The same amendment has been made to claim 1 of each of auxiliary requests 2 and 3. Moreover, in claim 1 of auxiliary request 2 the list of disturbances to be treated or prevented has been limited to disturbances in coordination of limbs, equilibrium and limb strength. In claim 1 of auxiliary request 3, the list of disturbances to be treated or prevented has been further restricted to disturbances in coordination of limbs and equilibrium.

With the reply to the statement of grounds of appeal, the respondent additionally filed two documents:

D27: "47600 – Mouse Rota-Rod", copy of internet page https://web.archive.org/web/20131123022726/http://www.ugobasile.com/catalogue/category/motory_coordination__grip_strength__activity/product/47600_mouse_rota_rod.html

D28: "Rotarod performance test", copy of internet page https://web.archive.org/web/20130905180904/https://en.wikipedia.org/wiki/Rotarod_performance_test

VII. The Board summoned the parties to oral proceedings as per their corresponding requests.

VIII. In a communication pursuant to Article 15(1) RPBA issued on 15 July 2025 ("Board's communication"), the Board drew the parties' attention to the points to be discussed during the oral proceedings.

IX. Oral proceedings took place before the Board on 16 December 2025 in the presence of both parties. At the end of the oral proceedings, the Chair announced the Board's decision.

X. The appellant's written and oral submissions relevant to this decision may be summarised as follows.

Respondent's request that the ground for opposition under Article 100(b) EPC not be admitted into the proceedings

The ground for opposition under Article 100(b) EPC had always been in the opposition proceedings, so the respondent's request did not need to be considered.

Even if that were not the case, the Opposition Division had discretion to admit a new ground for opposition. There had been no attempt by the respondent to argue that, even if the Opposition Division had had to exercise its discretion in admitting Article 100(b) EPC as a ground for opposition, the Division had done so inappropriately.

Main request, auxiliary requests 1 to 3 – sufficiency of disclosure

From the Enlarged Board's review in paragraphs 73 to 77 of its decision G 2/21 (OJ EPO 2023, A85), it could clearly be seen that the burden of proof was on the respondent to show that the claimed therapeutic uses were credible.

However, the experimental data disclosed in Examples 1 and 5 of the application as filed did not credibly show that the claimed combination was effective in the prevention or treatment of each of the disturbances recited in claim 1 of the main request (e.g. disturbances in coordination of limbs, equilibrium and limb strength).

- First, Examples 1 and 5 did not demonstrate that the improvements in performance observed in a mouse model of Parkinson's disease subjected to a rotarod test were caused by the presence of the butyrate-producing fibres. Diet 2 was the only tested diet which contained butyrate-producing fibres. However, the presence of these fibres was only one of several differences between diet 2 and the control diet (or diet 1). Therefore, the improvement observed with diet 2 in Example 5 could be

attributed to other differences between diet 2 and the control diet (or diet 1).

- Second, the patent itself (see paragraphs [0013], [0015], [0016] and [0018]) disclosed the rotarod test only for evaluating equilibrium, referring explicitly to other, distinct tests for measuring the further individual skills recited in claim 1 of the main request.

- Third, the various skills set out in claim 1 were all different (see paragraphs [0012], [0016], [0017] and [0065] of the patent). By contrast, the rotarod test used in Examples 1 and 5 produced a single read-out (i.e. the length of time the animal remains on a rotating rod before falling off), which did not allow any meaningful conclusion to be drawn as to the effect, if any, of the tested compositions (diets 1 and 2) on each of the five individual skills recited in claim 1 of the main request.

Admittance of the appellant's two lines of argument presented at the oral proceedings

The two lines of argument relating to (i) claim breadth in view of disease pathologies underlying the disturbances and (ii) the suitability of the mouse model of the examples outside the Parkinson's disease setting were merely a further permissible development of the arguments on sufficiency of disclosure set out in the written appeal proceedings. Hence, these lines of argument did not constitute an amendment to the appellant's appeal case within the meaning of Article 13(2) RPBA.

Auxiliary request 3 – Novelty

Examples 1, 3 and 4 of document D2, when considered in the overall context of the document, anticipated the subject-matter of claim 1.

Auxiliary request 3 – Inventive step

Starting from document D2 as the closest prior art, the objective technical problem to be solved by the claimed invention was to provide an alternative composition for preventing or treating a disturbance in motor skills. The solution proposed in claim 1 would have been obvious in view of document D2 either alone or in combination with documents D3, D4, D6, D7 and/or D9.

XI. The respondent's written and oral submissions relevant to this decision may be summarised as follows.

Respondent's request that the ground for opposition under Article 100(b) EPC not be admitted into the proceedings

The ground for opposition under Article 100(b) EPC was inadmissible because the appellant only made a conditional objection in the notice of opposition. Accordingly, this ground for opposition had not been invoked within the deadline for filing notice of opposition. Even if it were considered that the appellant had intended to invoke this ground in the notice of opposition, the ground should be deemed inadmissible because it had not been sufficiently substantiated in the notice of opposition.

Main request, auxiliary requests 1 to 3 – sufficiency of disclosure

The appellant, who bore the burden of proof, did not present any arguments or evidence that would raise serious doubts about the suitability of the combination recited in claim 1 of the main request for treating or preventing each of the disturbances set out in this claim.

On the basis of the patent's disclosure (e.g. paragraphs [0013] and [0065]) and the common general knowledge reflected in documents D27 and D28, the skilled person would understand that all the skills set out in claim 1 came into play when an animal walked on a rotating rod.

As a consequence, the performance improvement observed in Examples 1 and 5 of the application as filed using a rotarod test was indicative of an improvement in all the individual skills involved in staying on a rotating rod, including limb strength. The post-published evidence in document D10 could thus be used to confirm that the composition of claim 1 of the main request was suitable for improving grip strength. The fact that diets 1 and 2 tested in Examples 1 and 5 differed from each other on account of more than just the presence of the butyrate-producing fibres did not matter for sufficiency of disclosure.

Admittance of the appellant's two lines of argument presented at the oral proceedings

These lines of argument represented a complete change to the appellant's appeal case and should therefore not be admitted into the proceedings.

Auxiliary request 3 – Novelty

Document D2 did not disclose a combination for a use according to claim 1. The examples of this document merely described formulation examples and did not indicate that the disclosed formulations were intended to have an effect on motor skills, let alone demonstrate that any such effect was achieved.

Auxiliary request 3 – Inventive step

Starting from document D2 as the closest prior art, the opposition division correctly formulated the objective technical problem as to provide an effective composition for preventing or treating a disturbance in at least one of the skills specified in claim 1. The solution proposed in claim 1 was not rendered obvious by the prior art relied on by the appellant. None of documents D2, D3, D4, D6, D7 or D9 would have given the skilled person a reasonable expectation that the compositions disclosed in document D2 could be successfully used for any of the therapeutic purposes defined in claim 1.

XII. The parties' final requests relevant to this decision were as follows.

The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

The appellant further requested that the respondent's request that the ground for opposition under Article 100(b) EPC be declared non-admissible be refused and that the Board fully consider the

appellant's arguments of lack of sufficiency of disclosure.

The respondent requested that the appeal be dismissed, alternatively that the patent be maintained in amended form on the basis of one of the sets of claims of auxiliary requests 1 to 20, filed with the reply to the notice of opposition and refiled with the reply to the statement of grounds of appeal.

The respondent further requested that the ground for opposition under Article 100(b) EPC not be admitted into the proceedings.

Reasons for the Decision

1. The appeal is admissible.

Respondent's request that the ground for opposition under Article 100(b) EPC not be admitted into the proceedings

2. In its communication (see points 1 to 3), the Board stated the following:

"*1. The opposition division decided to admit this ground for opposition [ground for opposition under Article 100(b) EPC] into the proceedings and dealt with it on substance (see points 1.2 and 2 of the appealed decision), thus making it part of the proceedings and of the decision on which the appeal proceedings are based (Article 12(1)(a) RPBA).*

2. Against the background that Rule 81(1) EPC empowers opposition divisions to also examine grounds for opposition not invoked by an opponent of its own motion, the question of whether the ground for

opposition under Article 100(b) EPC had indeed been invoked within the deadline for filing notice of opposition and whether this ground had initially been sufficiently substantiated in the notice of opposition does, after all, not appear to be relevant in the circumstances of the present case.

3. Hence the Board sees no basis for excluding this ground for opposition from the appeal proceedings."

3. At the oral proceedings the respondent did not present any arguments, referring instead to its written submissions on this issue (see reply to the statement of grounds of appeal, pages 2 and 3).

4. Given these circumstances, the Board sees no reason to deviate from its preliminary opinion set out in its communication (see point 2. above). It follows that the ground for opposition under Article 100(b) EPC is part of the decision on which the appeal proceedings are based (Article 12(1)(a) RPBA).

Main request (patent as granted)
The subject-matter of claim 1

5. It was not in dispute that claim 1 is a purpose-limited product claim in accordance with Article 54(5) EPC directed to a combination of compounds for use in preventing or treating five alternative disturbances in which the limbs play a role (see point I. above).

6. According to established case law of the boards of appeal, when assessing purpose-limited product claims in the format of Article 54(5) EPC pertaining to a therapeutic use, attaining the claimed therapeutic effect is a functional technical feature of the claims.

6.1 In the case at issue, the feature providing for the claimed therapeutic effects is a combination of three compounds ("claimed triple combination"):

- a uridine source as defined in claim 1
- an omega-3 polyunsaturated fatty acid selected from docosahexaenoic acid (DHA), docosapentaenoic acid (DPA) and eicosapentaenoic acid (EPA)
- a butyrate-producing dietary fibre

6.2 Hence, the claimed triple combination as a whole must provide for the prevention or treatment of each of the disturbances recited in claim 1. By contrast, claim 1 does not require that the individual components of this combination by themselves treat or prevent one or more of these disturbances.

Sufficiency of disclosure of the invention defined in claim 1 (Article 100(b) EPC)

7. In the following, the Board will focus on the subject-matter of claim 1 directed to the claimed triple combination for use in preventing or treating a disturbance in limb strength.

The Enlarged Board's considerations concerning sufficiency of disclosure set out in decision G 2/21

8. In support of its case on insufficiency of disclosure, the appellant made reference to decision G 2/21, points 73 to 77 of the Reasons. In this section, the Enlarged Board of Appeal deals with case law on sufficiency of disclosure, in particular concerning second medical use claims where the notion of "plausibility" has been used.

8.1 Specifically, in point 74 of this decision the Enlarged Board confirms the relevant case law:

- that "*a technical effect, which in the case of for example a second medical use claim is usually a therapeutic effect, is a feature of the claim, so that the issue of whether it has been shown that this effect is achieved is a question of sufficiency of disclosure under Article 83 EPC*",

  and

- that "*it is necessary that the patent at the date of its filing renders it credible that the known therapeutic agent, i.e. the product, is suitable for the claimed therapeutic application*".

8.2 Next (see points 75 and 76 of decision G 2/21), the Enlarged Board refers to decision T 609/02 to illustrate the applicable law, analysing a series of board of appeal decisions in line with decision T 609/02.

8.3 From its considerations in points 74 to 76, the Enlarged Board concludes the following in point 77:

"*The reasoned findings of the boards of appeal in the decisions referred to above make clear that the scope of reliance on post-published evidence is much narrower under sufficiency of disclosure (Article 83 EPC) compared to the situation under inventive step (Article 56 EPC). In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, the proof of a claimed therapeutic*

effect has to be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved. A lack in this respect cannot be remedied by post-published evidence."

8.4 The expression "proof of a claimed therapeutic effect" in point 8.3 above cannot be interpreted as a deviation from the established case law in the context of second medical uses; it does not apply a stricter requirement than the established case law prior to decision G 2/21. Rather, by referring in the same sentence to a particular situation in which "in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved", the Enlarged Board confirmed that the disclosure of experimental evidence of the claimed therapeutic effect in the application as filed is not always required to establish that this effect has been sufficiently disclosed (see also Case Law of the Boards of Appeal, 11th edn, 2025, hereinafter "Case Law", II.C.7.2.3 with reference to decision T 1779/21). At the same time, technical information must be available in the patent at its filing date rendering it credible to the skilled person that the claimed product (substance or composition) is suitable for the claimed therapeutic application (see point 8.1 above; hereinafter "credibility requirement").

Application to the case at issue of the Enlarged Board's considerations concerning sufficiency of disclosure set out in decision G 2/21

9. In the case at issue, the technical information in the patent at its filing date relied on by the respondent in support of its case does not render it credible to the skilled person that the claimed triple combination is suitable for preventing or treating a disturbance in limb strength.

(a) Technical information in the patent at its filing date (i.e. the application as filed) relied on by the respondent in support of the sufficiency of disclosure of the claimed prevention or treatment of a disturbance in limb strength

10. Like the patent, the application as filed contains two experimental examples, i.e. Examples 1 and 5 (hereinafter "Examples 1 and 5"). Both examples make use of the rotarod test in a mouse model of rotenone-induced Parkinson's disease, i.e. a neurological disorder. In this test, mice are placed on an accelerating rod with gradually increasing speeds. The rodent's ability to remain on the rotating rod (time to first fall) was recorded for a maximum of 5 minutes.

10.1 In Example 1, four experimental groups of mice were used (see Table 1 of the application as filed). Two groups were injected with rotenone ("rotenone groups") and two with vehicle ("vehicle groups"). In each of the rotenone and vehicle groups, one group received a control diet and the other one an "active diet". Compared with the control diet, the active diet additionally comprises a uridine source (UMP disodium),

and its polyunsaturated acids include EPA and DHA (see Table 2 of the application as filed). As illustrated in Figure 1 of the application as filed, rotenone-treated mice fed with an active diet remained on the rod longer than rotenone-treated mice fed with a control diet.

10.2 In Example 5, six experimental groups of mice were used (see Table 3 of the application as filed) of which three were injected with rotenone ("rotenone groups") and three with vehicle ("sham groups"). In each of the rotenone and sham groups, a first group received a control diet, a second group received "diet 1" (i.e. the active diet of Example 1) and a third group received "diet 2". Figure 2 of the application as filed shows that rotenone-treated mice fed with diet 1 remained on the rod significantly longer than rotenone-treated mice fed with a control diet. Rotenone-treated mice fed with diet 2 remained on the rod even longer than rotenone-treated mice fed with diet 1.

11. Hence, Examples 1 and 5 demonstrate that rotenone-treated mice fed diets 1 and 2 perform better in a rotarod test than those fed a control diet.

12. At the same time, as correctly observed by the appellant, these examples are not suitable for demonstrating that the observed performance improvement is caused by the presence of the butyrate-producing fibres in diet 2. However, claim 1 does not require that the butyrate-producing fibres by themselves have a therapeutic effect in one or more of the therapeutic indications recited in claim 1 (see point 6.2 above). As acknowledged by the appellant at the oral proceedings, the improvement observed in Example 1 with diet 1 compared with the control diet can be attributed

to the presence of UMP disodium, EPA and DHA in this diet. UMP, EPA and DHA belong to two of the three mandatory components of the claimed triple combination (see point 6.1 above). In the absence of any evidence demonstrating that adding butyrate-producing fibres to diet 1 would cancel out the improvement observed in Example 1 with UMP, EPA and DHA, the Board is satisfied that the experimental data in Example 1 credibly show that a combination falling within the ambit of claim 1 gives rise to the performance improvement observed in this example.

(b) The application as filed does not render it credible that the improved performance of the mice observed in Example 1 (or Example 5) using the rotarod test reflects an improvement in limb strength

13. In a first line of argument, the respondent submitted that according to established case law an objection of a lack of sufficient disclosure presupposed that there were serious doubts, substantiated by verifiable facts. The burden of proof was on an opponent to establish that the skilled person reading the patent would be unable to carry out the invention (see also T 182/89, OJ 1991, 391). In the case at issue, the appellant had not created any serious doubts regarding the credibility of the claimed therapeutic uses. In particular, the appellant had not shown that it was not credible, on the basis of the disclosure of the patent and common general knowledge, that the claimed prevention or treatment of a disturbance in limb strength could be achieved.

14. These arguments are not found persuasive. As explained under point 8. above, sufficiency of disclosure

requires foremost that the patent at the date of filing (i.e. the application as filed) renders it credible that the known therapeutic agent is suitable for the claimed therapeutic application. A mere assertion that a claimed therapeutic effect has to be regarded as having been demonstrated as long as it has not been disproven is not sufficient to meet this credibility requirement.

15. In the case at issue, the Board concurs with the appellant that the application as filed does not render it credible that the improved performance of the mice observed in Example 1 (or Example 5) using the rotarod test reflects an improvement in limb strength.

15.1 Specifically, page 4, lines 1 to 3 of the application as filed discloses that the rotarod test used in Examples 1 and 5 is suitable for testing equilibrium in a mammal. By contrast, the application as filed makes no mention of this test in the context of limb strength. Instead, the application as filed (see page 4, line 28 to page 5, line 3) explicitly refers to a different test for determining this skill in rodents, i.e. a calibrated grip strength tester.

15.2 Likewise, page 11, lines 16 to 20 of the application as filed expressly presents the experimental examples (i.e. Examples 1 and 5 using the rotarod test) as illustrating improved coordination (of the limbs) and/or equilibrium. No reference is made in this context to limb strength, which is not mentioned until later in a separate and distinct sentence (see page 11, lines 26 to 27 of the application as filed). Unlike page 11, lines 16 to 20 of the application as filed, this sentence does not refer to the experimental examples but merely expresses the inventors' own,

personal considerations that "*butyrate-producing fibre may have a beneficial effect on limb grip strength or fine motor skills*".

15.3 The aforementioned disclosures dealt with in points 15.1 and 15.2 above do not support the assertion that the rotarod test used in Example 1 (and Example 5) is suitable for determining whether the tested diets (e.g. diet 1) improve the animal's limb strength compared with the control diet. Rather, they imply the contrary.

15.4 The same holds true for the common general knowledge reflected in documents D27 and D28.

15.4.1 Document D27 discloses the features and benefits of a mouse rotarod apparatus marketed by the company Ugo Basile. As submitted by the respondent at the oral proceedings, this document describes the rotarod technique as essential for screening drugs which have side effects on motor coordination.

15.4.2 Document D28 is an excerpt from Wikipedia on the rotarod performance test. Like the application as filed (see point 15.2 above), this document discloses the rotarod test as being suitable for evaluating the effects of a treatment (e.g. an experimental drug) on equilibrium and coordination in a rodent.

15.5 By contrast, neither document D27 nor document D28 discloses the rotarod test as being suitable for investigating the effects of a treatment on limb strength. Furthermore, like the application as filed, document D27 explicitly refers to a different test for determining forelimb grip strength in rodents (i.e. a grip strength meter).

15.6 In light of the above considerations, the Board finds that the application as filed does not credibly show that the improved performance of the mice observed in Example 1 (or Example 5) reflects an improvement in limb strength.

16. The respondent submitted that walking on a rotating rod for a certain period of time required various skills – not only equilibrium and coordination of limbs but also grip strength. Moreover, since the rotarod apparatus had a non-slip surface (see paragraph [0104] of the patent and the picture of the rotarod apparatus in document D27), some grip strength (mice clutching on the non-slip surface of the rod) would be beneficial for rotarod performance. This performance was measured as a time to failure. Hence, failure was very likely when a separate skill was insufficient. Any time such skill was needed but not sufficiently present, failure occurred. Thus, if performance improved (as observed in Examples 1 and 5), this meant that all the individual skills and their interaction had improved.

17. The Board does not agree.

17.1 As explained under point 15. above, the application as filed and the common general knowledge presented in documents D27 and D28 do not disclose limb strength in the context of the rotarod test. Instead, they expressly present the length of time an animal remains on a rotating rod before falling off (i.e. the animal's performance in the rotarod test) as a measure of the animal's balance and limb coordination.

17.2 Against this background, the facts put forward by the respondent in support of its contention that the performance improvement observed in Example 1 (and

Example 5) constitutes an improvement not only in balance and coordination of limbs but also in limb strength do not suffice to render the claimed prevention or treatment of a disturbance in limb strength credible.

18. It follows that the application as filed does not render it credible to the skilled person that the claimed triple combination is suitable for use in preventing or treating a disturbance in limb strength. This lack of sufficiency cannot be remedied by post-published evidence D10, which the respondent considered to be proof of the claimed therapeutic effect of preventing or treating a disturbance in limb strength in a mammal.

Overall conclusion on sufficiency of disclosure of the main request

19. For the reasons set out above, the subject-matter of claim 1 directed to the claimed triple combination for use in preventing or treating a disturbance in limb strength lacks sufficiency of disclosure. As a consequence, the ground for opposition under Article 100(b) EPC prejudices maintenance of the patent as granted.

Auxiliary requests 1 and 2
Sufficiency of disclosure – claim 1 – Article 83 EPC

20. The subject-matter of claim 1 of each of auxiliary requests 1 and 2 is directed, *inter alia*, to the claimed triple combination for use in preventing or treating a disturbance in limb strength in a mammal suffering from a neurological disorder.

21. The respondent did not present any arguments beyond those already submitted with respect to the subject-matter of claim 1 of the main request.

22. As a consequence, the subject-matter of claim 1 of each of auxiliary requests 1 and 2 lacks sufficiency of disclosure for the same reasons as the subject-matter of claim 1 of the main request.

Auxiliary request 3
The claimed subject-matter

23. As explained in point VI. above, the subject-matter of claim 1 of auxiliary request 3 differs from claim 1 of the main request in that the mammal has been specified as suffering from a neurological disorder. Moreover, the list of disturbances to be treated or prevented has been restricted to disturbances in coordination of limbs and equilibrium.

Sufficiency of disclosure – Article 83 EPC

24. In the Board's judgement, the disclosures on page 4, lines 1 to 3 and page 11, lines 16 to 20 of the application as filed (see points 15.1 and 15.2 above) render it credible that the improved performance of the mice observed in Example 1 (or Example 5) reflects an improvement in coordination of the limbs and equilibrium in a mammal suffering from a neurological disorder. Moreover, the common general knowledge reflected in documents D27 and D28 (see points 15.4.1 and 15.4.2 above) confirms that the rodent's performance in the rotarod test is a measure of its balance and limb coordination.

25. In view of the foregoing, the appellant's argument that the single read-out produced by the rotarod test did not allow any meaningful conclusion to be drawn as to the effect, if any, of the tested compositions (diets 1 and 2) on each of the individual skills of coordination of limbs and equilibrium cannot succeed.

26. As regards the patent's explicit disclosure in paragraph [0016] of a test other than the rotarod test for measuring coordination of limbs, it is true that this paragraph not only makes no mention of the rotarod test but also explicitly refers to a different test for determining coordination of limbs, i.e. rapidly alternating and point-to-point movements. However, it appears doubtful that the latter test is suitable for rodents. More importantly, documents D27 and D28 explicitly disclose the rotarod test as being suitable for evaluating the effects of a treatment on coordination in a rodent (see points 15.4.1 and 15.4.2 above). As a consequence, the disclosure of paragraph [0016] of the patent does not cast doubt on the suitability of the rotarod test for determining coordination of limbs in a rodent.

27. The Board, therefore, concludes that the application as filed renders it credible to the skilled person that the claimed triple combination is suitable for use in preventing or treating the disturbances recited in claim 1, i.e. a disturbance in coordination of limbs and a disturbance in equilibrium in a mammal suffering from a neurological disorder.

28. It follows that the invention defined in claim 1 of auxiliary request 3 is sufficiently disclosed.

Admittance of the appellant's lines of argument presented for the first time at the oral proceedings (Article 13(2) RPBA)

29. At the oral proceedings, the appellant presented, *inter alia*, lines of argument relating to (i) claim breadth in view of disease pathologies underlying the disturbances and (ii) the suitability of the mouse model of the examples outside the Parkinson's disease setting in support of its case on the lack of sufficiency of disclosure of the invention defined in claim 1 of the main request.

30. As conceded by the appellant, the aforementioned two lines of argument were presented for the first time at the oral proceedings before the Board.

31. Under Article 13(2) RPBA as in force since 1 January 2024, any amendment to a party's appeal case made after notification of a communication under Article 15(1) RPBA is, in principle, not to be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

32. The appellant argued that the aforementioned two lines of argument did not constitute an amendment to its appeal case within the meaning of Article 13(2) RPBA. Rather, they were merely a further permissible development of its arguments on sufficiency of disclosure presented in writing.

33. The Board does not agree.

33.1 The appellant's submissions put forward in the written appeal proceedings in the context of sufficiency of disclosure include arguments relating to the breadth of

claim 1 of the main request in view of the number of skills recited in this claim. However, none of these arguments addresses claim breadth in view of disease pathologies underlying the disturbances.

33.2 Likewise, in the written appeal proceedings, the appellant questioned the suitability of the mouse model of the examples of the patent for demonstrating the treatment or prevention of the disturbances set out in claim 1 of the main request. However, none of these arguments pertains to the suitability of this model for demonstrating the claimed therapeutic effects outside the Parkinson's disease setting.

33.3 As a consequence, the appellant's two lines of argument presented at the oral proceedings are not merely a development of its arguments on sufficiency of disclosure presented in writing but amount to an amendment to its appeal case within the meaning of Article 13(2) RPBA.

34. Any such amendment may be admitted at the Board's discretion only if there are exceptional circumstances justified by cogent reasons. However, the appellant has not made the Board aware of any such circumstances.

35. Therefore, the Board, exercising its discretion under Article 13(2) RPBA, decided not to admit the appellant's two lines of argument presented at the oral proceedings into the appeal proceedings.

Auxiliary request 3
Novelty over document D2 – Article 54 EPC

36. In line with the consistent view in the case law of the boards, for an invention to lack novelty, its

subject-matter must be directly and unambiguously derivable from the prior art (see also Case Law, section I.C.4.1, fourth paragraph).

37. In the case in hand, contrary to the appellant's view, the claimed subject-matter is not directly and unambiguously derivable from Examples 1, 3 and 4 of document D2, considered in the overall context of this document.

37.1 Document D2 is a US patent specification. The invention forming the subject of this document is a lipid fraction for brain function support (see title, claims 1 and 12).

37.2 Examples 1, 3 and 4 of document D2 describe formulations comprising this lipid fraction for use in specified subject groups.

37.2.1 Specifically, Example 1 is directed to a drink for use in a prodromal dementia patient. This drink is administered to a prodromal dementia patient "*to see the effect on brain function and in particular better social skills, more activities and fitness and better cognitive function, and a better alertness and ability to concentrate and pay attention*".

37.2.2 Example 3 discloses a liquid for use in a person suffering from cognitive decline.

37.2.3 Example 4 is directed to a liquid drink for supporting brain function in the elderly.

37.3 To the appellant's benefit, the Board accepts that each of the formulations of Examples 1, 3 and 4 comprises a uridine source, an omega-3 polyunsaturated fatty acid

and a butyrate-producing fibre according to claim 1. Unlike Examples 1 and 3, however, Example 4 does not refer to a mammal suffering from a neurological disorder and therefore, for this reason alone, cannot anticipate the subject-matter of claim 1.

37.4 Turning to the claimed therapeutic uses (see point 23. above), the appellant did not point the Board to any passage in document D2 disclosing the treatment or prevention of a disturbance in equilibrium in a mammal suffering from a neurological disorder.

37.5 As regards the claimed treatment or prevention of a disturbance in coordination of limbs in such a mammal, the appellant referred to column 7, line 38 of document D2. This disclosure forms part of a passage in column 7, lines 30 to 40. This passage is a general description of the term "support of brain function" and reads:

"*Support of brain function is meant to be an improvement of skills is related to activities of daily living, cognition, social skills, decision making skills, motoric skills and abilities to live independently from the help of others. Such improvement can be measured by determination of the abilities of the persons to practice them. Activities of daily living include instrumental activities, operational activities, and basal activities. These activities include the ability to use household appliances, to coordinate one's movements, to make rapid movements, to walk, do the laundry, do the dishes, to apply hygienic practices, to travel, etcetera.*"

37.6 As can be seen from point 37.5 above, the term "support of brain function" is not limited to the improvement of

skills related to activities of daily living, e.g. coordination of one's movements (i.e. coordination of limbs), but also includes the improvement of various other, distinct skills such as cognition, social skills and decision-making skills. All of these are disclosed at the same level of preference, i.e. there is no suggestion in the passage referred to in point 37.5 above that the lipid fraction disclosed in document D2 is particularly suitable for improving coordination of one's movements.

37.7 By contrast, Example 1 (see point 37.2.1 above) explicitly refers to a subgroup of the skills disclosed in column 7, lines 30 to 40 of document D2; this subgroup does not include coordination of one's movements. Moreover, the formulations of Examples 1, 3 and 4 are tailored to different subject groups (see points 37.2.1 to 37.2.3 above). In light of these facts, it is not directly and unambiguously derivable from the disclosure of document D2 that the formulations of Examples 1 and 3 improve coordination of one's movements in the specified patient groups.

37.8 Referring to the case law of the boards of appeal (see Case Law, section I.C.4.1), the appellant argued that, for novelty, the technical disclosure in a prior-art document must be considered as a whole in the overall context. There was no indication in document D2 that, for example, some compositions only supported some of the activities mentioned in column 1, lines 22 to 45, column 7, lines 30 to 40, or claims 10 and 11. On the contrary, all the compositions had all the specified therapeutic uses.

37.9 Undisputedly, section I.C.4.1 of the Case Law states that the technical disclosure in a prior-art document

must be considered as a whole. However, this section equally states that according to established case law, it is a prerequisite for the acceptance of lack of novelty that the claimed subject-matter is directly and unambiguously derivable from the prior art.

37.10 In the case at issue, the appellant has not pointed to any passage in document D2 that would suggest that all the compositions disclosed in this document (e.g. the formulations of Examples 1 and 3) improve all the skills reported in this document. Rather, the fact that the skills specified in Example 1 do not include coordination of limbs, and the fact that the formulations of Examples 1, 3 and 4 are tailored to different subject groups (see under point 37.2 above), point to the contrary.

37.11 As a consequence, the appellant's arguments in support of its objection of lack of novelty fail to convince the Board.

38. It follows that document D2 does not directly and unambiguously disclose the subject-matter of claim 1.

Auxiliary request 3
Inventive step – Article 56 EPC
The closest prior art

39. Both parties analysed inventive step starting from document D2 as the closest prior art. The Board sees no reason to differ.

40. As explained under point 37. above, the subject-matter of claim 1 differs from the disclosures of Examples 1 and 3 of document D2 on account of the claimed purpose,

i.e. preventing or treating a disturbance in coordination of limbs or a disturbance in equilibrium.

Objective technical problem and solution

41. Formulating the objective technical problem effectively solved by the claimed subject-matter entails determining the technical effect(s) or result(s) achieved by and linked to the distinguishing feature(s).

42. The technical effects linked to the distinguishing feature identified in point 40. above are that the claimed triple combination is therapeutically effective in preventing or treating a disturbance in coordination of limbs and a disturbance in equilibrium. For the reasons provided above under sufficiency of disclosure (see points 24. to 28. above), the Board is satisfied that these effects are achieved.

43. Starting from document D2, the objective technical problem to be solved by the claimed subject-matter is thus to provide a composition which is therapeutically effective in preventing or treating the aforementioned disturbances in a mammal suffering from a neurological disorder.

44. In the statement of grounds of appeal (see page 9), the appellant defined the objective technical problem as to provide an alternative composition for preventing or treating a disturbance in motor skills or limb strength (e.g. a disturbance in coordination of limbs or equilibrium). In support of its case, the appellant argued that document D2 already taught the improvement of motor skills (e.g. coordination of limbs).

45. The Board does not agree. The appellant's formulation of the objective technical problem as an alternative composition presupposes that document D2 already discloses an improvement in coordination of limbs that is of a therapeutic nature. However, the appellant did not identify any disclosure in document D2 from which the skilled person would have directly and unambiguously derived that the improvement in skills disclosed in column 7, lines 30 to 40 is indeed therapeutic. Undisputedly, column 7, lines 41 to 46 of document D2 states that brain function is also supported in patients suffering, *inter alia*, from a neurological disorder. However, this statement does not necessarily imply that this support is of a therapeutic nature.

46. The solution proposed to the objective technical problem defined in point 43. above is the composition recited in claim 1, i.e. the claimed triple combination.

Obviousness of the proposed solution

47. The proposed solution would not have been obvious having regard to the prior art cited by the appellant.

47.1 With regard to document D2 itself, the appellant contended that the skilled person would have made the link between the examples (i.e. Examples 1, 3 and 4) and the general description of document D2 (e.g. column 7, line 38) in an obvious manner. However, for the reasons set out in point 37.10 above, this argument cannot succeed.

47.2 The secondary documents relied on by the appellant do not prejudice the inventive step of the subject-matter of claim 1 either.

47.2.1 Document D6 (see summary) reports that administering UMP and DHA in a rat model of Parkinson's disease with unilateral 6-hydroxydopamine-induced striatal lesions partially restores dopaminergic neurotransmission in these rats.

47.2.2 Document D7 (see title) describes a study testing the administration of sodium butyrate on locomotor impairment in a rotenone-induced Drosophila model of Parkinson's disease. The results of this study show that sodium butyrate provides a significant improvement in climbing ability and in the odds of reaching the top section of the test apparatus for flies fed rotenone-supplemented food (see the last paragraph on page 384 and Figure 2). On the basis of these results, the authors of document D7 conclude that sodium butyrate is a therapeutic candidate for an environmental toxin-induced motor impairment observed in Parkinson's disease.

47.2.3 Hence, like the patent, documents D6 and D7 refer to animal models of Parkinson's disease. Moreover, like the mice in Examples 1 and 5 of the patent, the flies tested in document D7 have rotenone-induced Parkinson's disease.

47.2.4 However, the appellant did not point the Board to any passage in either of these two documents disclosing coordination of limbs or equilibrium. Nor did the appellant explain why the beneficial effects observed with UMP and DHA in document D6 (partial restoration of dopaminergic neurotransmission) and with sodium

butyrate in document D7 (improved locomotion) are indicative of an improvement in coordination of limbs and/or equilibrium. In the absence of any such explanation, the Board is not persuaded that, on the basis of the results disclosed in documents D6 and D7, the skilled person would have had a reasonable expectation that a composition comprising UMP, DHA and sodium butyrate (or a butyrate-producing fibre), e.g. the formulation of Example 3 of document D2, would be therapeutically effective in preventing or treating a disturbance in coordination of limbs or a disturbance in equilibrium.

47.2.5 As a consequence, the subject-matter of claim 1 would not have been obvious having regard to document D2 taken in combination with documents D6 or D7.

47.2.6 Turning to document D3, this document (see title) investigates the effect of caecal fermentation products of sugar-beet fibre on plasma cholesterol concentration in rats. Document D4 (see title) studies the role of apple pectin on the caecal environment of conventional rats. Document D9 (see title) pertains to an *in-vitro* study investigating the effects of non-digestible oligosaccharides on colonisation resistance against *Clostridium difficile* in normal and antibiotic-treated faecal cultures.

47.2.7 As can be seen from point 47.2.6 above, the teachings of these three documents are more remote than those of documents D6 and D7. Consequently, document D3, D4 or D9 cannot render the subject-matter of claim 1 obvious either.

48. The Board therefore concludes that the subject-matter of claim 1 involves an inventive step.

Auxiliary request 3
Clarity

49. In the written proceedings (see page 3, fifth paragraph of the appellant's letter dated 30 August 2024), the appellant raised an objection under Article 84 EPC against the inclusion of the trade mark Nutriose® in claim 1 of auxiliary request 14.

50. This same trade mark is mentioned in claim 7 of auxiliary request 3.

51. In decision G 3/14 (OJ EPO 2015, A102, Order) it was held that, in considering whether, for the purposes of Article 101(3) EPC, a patent as amended meets the requirements of the EPC, the claims of the patent may be examined for compliance with the requirements of Article 84 EPC only when, and then only to the extent that, the amendment introduces non-compliance with Article 84 EPC.

52. In the case in hand, the trade mark Nutriose® already formed part of the subject-matter of claim 9 as granted. As a consequence, the appellant's objection under Article 84 EPC is not permissible under decision G 3/14.

Overall conclusion

53. The invention defined in claim 1 of auxiliary request 3 is sufficiently disclosed (Article 83 EPC). Moreover, the subject-matter of this claim is novel and involves an inventive step (Article 56 EPC).

54. As a consequence, there is no need to consider the lower-ranking auxiliary requests 4 to 20.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in amended form with claims 1 to 17 of auxiliary request 3 filed with the reply to the statement of grounds of appeal, and a description and drawings to be adapted thereto if necessary.

The Registrar: The Chair:

I. Aperribay M. Pregetter

Decision electronically authenticated