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Datasheet for the decision of 12 May 2025

Case Number: T 0738/23 - 3.3.07

Application Number: 16703463.6

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Language of the proceedings: EN

Title of invention:
MEDIUM CHAIN FATTY ACIDS AND THEIR TRIGLYCERIDES FOR TREATING ANXIETY

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponent:
N.V. NUTRICIA

Headword:
Triglycerides for treating anxiety/ NESTLE

Relevant legal provisions:
EPC Art. 56, 123(2), 54, 83

Keyword:

Main request - Inventive step (Yes)
Main request and auxiliary request 1 - Claim 3 not novel
Auxiliary request 2 - Novelty and Inventive Step (Yes)
Auxiliary request 2 - Amendments (Yes)
Auxiliary request 2 - Sufficiently disclosed (Yes)

Decisions cited:

T 0286/09, G 0002/10

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Case Number: T 0738/23 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 12 May 2025

Appellant: (Opponent)	N.V. NUTRICIA Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Respondent: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	Rupp, Christian Mitscherlich PartmbB Patent- und Rechtsanwälte Karlstraße 7 80333 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 20 February 2023 rejecting the opposition filed against European patent No. 3259029 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	L. Basterreix

Summary of Facts and Submissions

I. European patent No. 3 259 029 B1 was granted on the basis of a set of 8 claims.

Independent claims 1 and 3 as granted read:

"1. A MCFA for use in treating and/or preventing anxiety wherein the MCFA is decanoic acid or octanoic acid and wherein the MCFA is in the form of a medium chain triglyceride (MCT)."

"3. A composition comprising a MCFA as defined in any one of claims 1 to 2 for use in treating and/or preventing anxiety."

In said claims, "MCFA" stands for medium chain fatty acid and "MCT" stands for medium chain triglycerides.

II. An opposition was filed under Article 100 (a), (b) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.

III. The present appeal lies from the decision of the opposition division to reject the opposition.

IV. The documents cited during the opposition proceedings included the following:

D1: Page KA et al., "Medium-Chain Fatty Acids Improve Cognitive Function in Intensively Treated Type 1 Diabetic Patients and Support In Vitro Synaptic

Transmission During Acute Hypoglycemia", DIABETES, VOL. 58, MAY 2009, pp. 1237-1244;
D3: Sushant S et al., "Significance of Go ghrita in Lifestyle and Psychological Disorders", Int. J. Ayu Pharm. Chem. 2015 Vol 3, issue 1, 177- 187;
D3b: "Panchagavya Ghrita Medicinal Uses and Health Benefits", (October 2012);
D3c: Yadav et al., "Brahmi Ghrita (Sneha Kalpana) in mental disorders", 978-3-659-15604-5 (2013);
D4: Shinohara H et al. Medium-chain fatty acid containing dietary oil alleviates the depression-like behaviour in mice exposed to stress due to forced swimming. Journal of functional foods 5, 2012, 601 -606
D5: Lambrechts D. et al. The ketogenic diet as a treatment option in adults with chronic refractory epilepsy: Efficacy and tolerability in clinical practice. Epilepsy Behav 2012, 1-5
D8: Studzinski C et al. Induction of ketosis may improve mitochondrial function and decrease steady state amyloid-beta precursor protein (APP) levels in the aged dog. Brain Research 1226 (2008) 209-217
D9: EP 2204172 A1
D10: WO2013186570 A1
D11: File S et al. A review of 25 years of the social interaction test, European journal of Pharmacology 463 (2003) 35 - 53;
D12: Kaidanovich-Beilin O et al. Assessment of social interaction behaviors; Journal of Visualized Experiments (48) e2473, 2011
D13: Sussman D. et al. 2015. Gestational ketogenic diet programs brain structure and susceptibility to depression & anxiety in the adult mouse offspring, Brain Behav. 5, e00300.
D16: Invitrogen, Product information sheet, IRS-1 [pS312] ELISA Kit

D17: Suzanne M. de la Montea, Ming Tonga, VanAnh Nguyena, Mashiko Setshedib, Lisa Longatoa, and Jack R. Wands ; "Ceramide-Mediated Insulin Resistance and Impairment of Cognitive-Motor Functions", J Alzheimers Dis. 2010 ; 21(3): 967-984. doi: 10.3233/ JAD-2010-091726
D18: Clement J., "Digestion and absorption of dietary triglycerides", J. Physiol. (Paris), 1976, 72(2): 137-170;
D19: "Fats and fatty acids in human nutrition Report of an expert consultation" FAO Food and Nutrition Paper, 2010;
D20: Akoh C.C. et al., "FoodLipids Chemistry, Nutrition, and Biotechnology", Marcel Dekker Inc., 2002
D21: Soares J. K.B. etal., "Anxiety behavior is reduced, and physical growth is improved in the progeny of rat dams that consumed lipids from goat milk: An elevated plus maze analysis", Neuroscience Letters, 2013, 552: 25-29;
D22: Breckenridge W.C. et al., "Molecular weight distributions of milk fat triglycerides from seven species", Journal of Lipid Research, 1967, 8: 473-478
D23: Fiona Hollis, Ellen Siobhan Mitchell, Carles Canto, Dongmei Wang, Carmen Sandi; "Medium chain triglyceride diet reduces anxiety-like behaviors and enhances social competitiveness in rats", Neuropharmacology 138 (2018) 245-256

V. According to the decision under appeal, D18-D20 and D21-D22 were admitted into the proceedings.

The subject-matter of claims 4 and 5 of the patent found a basis in the application as filed and thus the claims met the requirements of Article 123(2) EPC.

The requirements of Article 83 EPC were met in view of the experimental evidence of the patent and on file.

D3 did not belong to the state of the art under Article 54(2) EPC and could not be novelty-destroying. D1, D3b and D3c did not take away the novelty of the granted claims.

With regard to inventive step, D9 was the closest prior art, rather than D1, D3, D4, D5, D8, D10 or D13. The problem was the provision of alternative fatty acid esters for the effective treatment of anxiety. The claimed solution was not obvious in view of the cited documents D8, D10, D1, D3b, D3c, D4-D6, D7 or D13, D18-D20.

VI. The opponent (herein after the appellant) filed an appeal against said decision.

VII. With its reply to the statement setting out the grounds of appeal dated 15 September 2023, the patent proprietor (hereinafter the respondent), filed auxiliary requests 1-12.

Independent claim 1 of auxiliary requests 1 and 2 read as follows, the differences, unless otherwise indicated, relating to a comparison with the main request (patent as granted):

Auxiliary request 1

Claim 1 has been amended by the introduction of the feature of granted dependent claim 2, namely **"and wherein each of the fatty acid moieties of the MCT comprise the same number of carbons".**

Claim 2 of auxiliary request 1 corresponds to claim 3 as granted.

Auxiliary request 2

Claim 1 of auxiliary request 2 was identical to claim 1 as granted.

Claim 3 had been amended by the feature **"wherein the composition comprises decanoic acid and octanoic acid".**

VIII. A communication from the Board, dated 10 January 2025, was sent to the parties.

IX. Oral proceedings took place on 12 May 2025.

X. The arguments of the appellant may be summarised as follows:

Main request - Inventive step

In the absence of any technical effect, the problem over D9 was the provision of an alternative form or source of decanoic and octanoic acid for the treatment of anxiety. The use of MCT was obvious in particular in view of the teaching of D18.

No technical effect was shown over D5 either, and the solution was obvious, for instance in view of D20.

Main request and auxiliary request 1 - Novelty

Claim 3 of the main request and claim 2 of auxiliary request 1 lacked novelty over D21.

Auxiliary request 2 - Article 123(2) EPC

Claim 3 added new subject-matter. The description as filed never mentions directly and unambiguously a composition comprising MCTs and free fatty acid.

Auxiliary request 2 - Inventive step

The subject-matter of claim 3 could not be inventive over D21 combined with D9.

Auxiliary request 2 - Sufficiency of disclosure

Example 1 of the patent did not prove a technical effect in the high anxiety group. The naming of the allocated groups of animals into innate anxiety groups, i.e. anxiety phenotyping, in Example 1 was at odds with the way it is pursued in D14 and the groups HA and LA were incorrectly assigned. An obvious error occurring in Figure 1 was not directly and immediately identifiable. Moreover, even if it could be established that an error occurred, its correction was not obvious. Figure 3 did not show the technical effect over the whole scope of claim 1.

Figure 3A did not show any effect for a group specifically, and there was no significant difference shown in Figure 3B.

Figures 2 and 4-6 did not show an effect on anxiety.

XI. The arguments of the respondent may be summarised as follows.

Main request - Inventive step

There were two distinguishing features between the claimed subject-matter and the disclosure of D9, in particular in view of Table 1, namely the use of saturated compounds and the use of the compounds in the form of MCT. There was no incentive starting from example 2 of D9 to use MCT instead of the preferred ester compounds of D9. D18 also provided a disincentive to use MCT instead of fatty acids.

D5 was not a relevant closest prior art, since relating to the treatment of epilepsy, and since the results on the treatment of anxiety were not statistically significant.

Main request - Novelty

In D21, the active agent was linolenic acid, and there was no disclosure that MCT could be active for the treatment of anxiety.

Auxiliary request 2 - Article 123(2) EPC

There was a clear disclosure for claim 4 in the original claims.

Auxiliary request 2 - Inventive step

D21 did not disclose a combination of MCT and fatty acids. The further addition of fatty acids led to an improved effect on the treatment of anxiety. The solution was not obvious. Moreover, the addition of

octanoic acid and decanoic acid was not an arbitrary addition, since corresponding to the MCT present in the composition.

Auxiliary request 2 - Sufficiency of disclosure

There was an obvious error in Figure 1 and the correction was obvious, in particular in view of D14. This error did furthermore not affect the remaining results disclosed in the patent.

The remaining figures showed clearly an effect on anxiety or on the pharmacological pathway involved in anxiety by the MCT. This effect was confirmed by the teaching of D23.

XII. Requests

The appellant requested that the decision under appeal be set aside and the patent be revoked. The appellant requested also that document D24 not be admitted into the appeal proceedings and that their technical expert, Mr Broersen, be allowed to speak during the oral proceedings.

The respondent requested that the appeal be dismissed, alternatively that the decision under appeal be set aside and the patent be maintained according to the sets of claims filed as auxiliary requests 1-12 with letter of 15 September 2023. The respondent furthermore requested not to admit appellant’s request to let their technical expert speak during the oral proceedings.

Reasons for the Decision

1. Main request - Inventive step

1.1 The claimed invention relates to the field of treating anxiety and anxiety disorders.

1.2 The opposition division considered in its decision that D9 was the closest prior art.

In its written submissions, the appellant maintained that the claims lack inventive step over D1, D3, D4, D5, D6 or D9, but made a complete assessment on inventive step only over D9 and D5 in its statement of grounds of appeal. The appellant assessed also inventive step of specifically claim 3 over D21 as the closest prior art.

1.2.1 The Board considers that D1, D3, D4 or D6 cannot be considered as realistic starting points for the assessment of inventive step for the following reasons.

D1 relates to the use of MCT to improve cognitive function in diabetic patients, but does not relate to the treatment of anxiety. Consequently, D1 cannot be a suitable starting point for the assessment of inventive step.

D3 is not a state of the art document according to Article 54(2) EPC and cannot serve as closest state of the art.

D3b relates to the treatment of mental disorders by use of go ghrita, namely clarified butter fat. Anxiety is

mentioned in a list of diseases; D3c gives the composition of go ghrita which comprises *inter alia* triglycerides, diglycerides, monoglycerides or free fatty acids (see D3c page 179). However, D3b does not identify which ingredient in go ghrita might be responsible for the anti-anxiety effect and is therefore not relevant for this reason.

D4 relates to the treatment of depression by medium chain fatty acid-containing oil. D4 mentions on page 602 the use of the elevated plus maze test, i.e. the EPMT test (see point 2.4) and states in point 3.1 that the time spent in open arms in the EPMT was not statistically significant, which does not allow a conclusion with regard to the effectiveness of the tested compounds in the treatment of anxiety. D4 discloses that the lack of anxiety in the mouse model might be due to the species difference. In view of these results, the Board concurs with the opposition division that it is not possible to conclude that the composition used in D4 has any efficacy in treating or preventing anxiety.

1.2.2 Inventive step will be assessed therefore starting from D9 and D5.

1.3 D9 as closest state of the art to claim 1

1.3.1 D9 discloses an agent having a neurotrophic factor-like activity. Said agent can activate signal transmission through a MAP kinase information transmission path, resulting in a possibility of clinical applications to a nervous disorder caused by degeneration of nerve cells or cellular death, such as *inter alia* anxiety disorders (see par. [0003], [0004], [0008]-[0011]).

Said agent having a neurotrophic factor-like activity contains as active ingredient C8 or C10 to C12 fatty acids or esters thereof, such as in particular n-octanoic acid methyl ester, n-octanoic acid ethyl ester, 3,7-dimethyloctanoic acid ethyl ester, or geranic acid ethyl ester, each of which has 8 carbon atoms (C8), or decanoic acid methyl ester, decanoic acid ethyl ester, trans-2-decenoic acid, trans-2-decenoic acidmethyl ester, trans-2-decenoic acid ethyl ester, trans-2-decenoic acid-2-decenyl ester, trans-2-decenoic acid cyclohexyl ester, trans-2-decenoic acid octyl ester, trans-2-decenoic acid isopropyl ester, trans-3-decenoic acid methyl ester, trans-3-decenoic acid ethyl ester, trans-9-decenoic acid, rans-9-decenoic acid methyl ester, or trans-9-decenoic acid ethyl ester, each of which has 10 carbon atoms (C10) (see par. [0008]).

Table 1 of D9 also considers the use of octanoic acid and decanoic acid as compound 36 and compound 1. Figures 1 to 3 show that the compounds of Table 1 activate MAP kinases (phosphorylated) with the exception of compound 21; for octanoic acid and decanoic acid, the numerical value expressing the ratio of phosphorylated MAP kinases is around one. Trans-2-decenoic acid esters (compound Nos. 7, 8, 47, 48, 53 and 54) showed numerical values higher than two. In particular, trans-2-decenoic acid ethyl ester has an activity higher than 11, whereas trans-2-decenic acid methyl ester was around 6. Also, decanoic acid methyl ester, decanoic acid ethyl ester, trans-2-decenoic acid, trans-9-decenoic acid methyl ester, trans-9-decenoic acid ethyl ester, trans-10-undecenoic acid methyl ester, trans-10-undecenoic acid ethyl ester, geranic acid ethyl ester and 3,7-dimethyloctanoic acid ethyl ester showed high activities.

The only compound of D9 explicitly tested for the treatment of anxiety is compound 8, i.e. trans-2-decenoic acid ethyl ester, which was tested in Example 2 through the elevated maze plus test. The examples show that compound 8 suppressed the anxiety symptom in mice.

It can be concluded from Table 1 and Figures 1-3 that decanoic acid or octanoic acid are not the preferred and more active agent having a neurotrophic factor-like activity, since they show numerical value of activity of around one. It appears however that both compounds present a low but effective activity on the MAP kinase information transmission path, and thus potentially on anxiety disorders.

The Board concurs with the opposition division that D9 is a suitable starting point for the assessment of inventive step. This document does not relate to the use of triglyceride esters of octanoic acid and decanoic acid. It rather discloses the ethyl and methyl esters of fatty acids (including decanoic and octanoic acid), and the octanoic and decanoic acids as such, and the therapeutic uses of these substances.

1.3.2 The appellant defines the problem as the provision of an alternative form or source of decanoic and octanoic acid for the treatment of anxiety.

The respondent defines the problem as the provision of an alternative compound for preventing or treating anxiety.

1.3.3 The solution to any of these problems is the use of triglyceride esters of octanoic acid and decanoic acid for the treatment of anxiety.

1.3.4 The contested patent provides a comparison of the effects observed with a diet of 5% medium chain triglycerides (40:60 of octanoic acid triglyceride and decanoic acid triglyceride) versus a control diet with 5% of sunflower oil (cf. par. [0093] of the specification), but no comparison with the effect of the esters or specific fatty acids disclosed in D9. It is therefore impossible to conclude to the existence of an improved effect over the products of D9.

In view of the effect shown in the examples and Figures of the contested patent, in particular Figures 3A, 3B, 4 and 5-8, the Board is however convinced that the MCT as claimed have an effect on anxiety.

Thus, the technical problem can be defined as the provision an alternative form of decanoic and octanoic acid for the treatment of anxiety.

1.3.5 With regard to obviousness, the appellant considers that the solution is obvious over D9 as such or in combination with common general knowledge, as shown in D18, D19 and D20, or in combination with D5, D8 or D10, or in combination with D1, D3bc or D4.

(a) The Board notes first that there is no measurement of anxiety in example 1 of D9, and that the compounds 1 and 36 disclosed in example 1, i.e octanoic acid and decanoic acid, are not the most effective compounds for the MAP kinase activation. Moreover, only compound 8 is tested effectively and successfully in D9 in the treatment of anxiety (see

example 2); there is no experiment on the treatment of anxiety with any other compound disclosed in D9.

Since D9 connects the MAP kinase activation with various nervous disorders including neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis (ALS), Huntington's disease, progressive supranuclear palsy (PSP), diabetic neuropathy, or a mental disease, such as depression or anxiety disorder (neurosis) (see D9, par. [0009] or [0011]), **it is not possible to find in D9 a conclusive teaching that compounds 1 or 36, i.e octanoic acid and decanoic acid, may be effectively efficient in the treatment of anxiety.** This is only demonstrated for compound 8 which is 10 times more active on the MAP kinase activation (see Figure 1). There is therefore no incentive in D9 for testing octanoic acid or decanoic acid in the treatment of any disease related to this pharmacological pathway.

There is furthermore no incentive or suggestion in D9 to use triglycerides. The purpose of D9 is to search medical drugs having a neurotrophic factor-like activity. Paragraph [0003] explains that neurotrophic factors encounter difficulty in accessing the brain, because they cannot pass through the blood-brain barrier. As a result, the research has focused on low molecular weight drugs. Accordingly, D9 warns against the use of large molecules since there is a high risk that such molecules would not pass the blood brain barrier and hence be without effect. Indeed, there is no indication in D9 that the triglycerides of the fatty acids and esters disclosed therein would

maintain the biological activity. **For this reason alone, the claimed solution does not appear to be obvious over D9.**

(b) It is known from common general knowledge that MCTs are metabolised by hydrolysis to yield free fatty acids, such as octanoic acid and decanoic acid, as corroborated by D18, D19 and D20.

(i) As can be seen in Figure 1 and at p. 140 and 141 of D18, during the digestion of MCTs, the MCFAs are cleaved off of the glycerol backbone; this process starts in the stomach and continues in the small intestine.

(ii) D19 is a book relating to fats and fatty acids in nutrition and teaches on pages 21-22 that triglycerides are the most common form of dietary fats found in food and this applies to medium-chain fatty acids.

(iii) D20 deals with structure lipids, which are triacylglycerols and teaches for instance that MCFA C6-C12 are a source of fatty acids for structured lipids (Chapter 28, para. II.A.2).

However, none of documents D18-D20 suggest that MCFAs when presented in the form of MCT can be used instead of the corresponding fatty acids or esters disclosed in D9 in the treatment of anxiety. The underlying question is indeed not whether the skilled person may provide dietary lipids but whether there is any pointer in any of these

documents that the administration of MCT would be effective in the treatment of anxiety.

Moreover, D18 (see page 142, Tableau I) indicates that the percentages of free fatty acids generated by digestion of the triglycerides in a rat experiment is quite low and lies between a minimum of 13.8 and a maximum of 27.2 percent of the total administered triglycerides (see the percentage given in the different studies of Table 1 of D18); in other words only a low proportion of fatty acids are released and potentially absorbed by the enterocytes. This is a clear indication to a skilled person that triglycerides would be less effective than fatty acids. Accordingly a skilled person would be encouraged to use fatty acids as such rather than the corresponding triglycerides.

Consequently, there would be no motivation for a skilled person to replace the fatty acids as disclosed in D9 by their corresponding MCTs as an alternative for the treatment of anxiety.

(c) No suggestion for using C8 and/or C10 MCT in the treatment of anxiety can be found in the remaining cited documents, namely D5, D8, D10, D1, D3bc or D4.

(i) D5 relates to the treatment of chronic refractory epilepsy by a ketogenic diet; the ketogenic diet was a MCT diet, without indication of the specific nature of the MCT.

(ii) D8 discloses that MCTs improves the mitochondrial function (see the Abstract).

(iii) D10 discloses the use of decanoic acid, preferably in the form of triglycerides (p.

8, l. 9-18) in the treatment of a disease associated with mitochondria dysfunction (p. 7, l. 1-3).

(iv) D1 shows that MCTs are a suitable form of providing decanoic and octanoic acid in the context of a medical nutritional composition for improving cognitive functions in diabetic patients.

(v) D3b/c also proves that triglycerides is a suitable form of providing fatty acids in a medical nutritional and specifically refers to the use in treating anxiety, without however identifying the compounds possibly involved in this effect.

(vi) D4 relates to the treatment of depression with a nutritional composition comprising MCTs of decanoic and octanoic acid (Abstract and p. 602, left column). This document does not refer to the treatment of anxiety.

1.3.6 Hence, none of the cited documents is considered to be relevant for the assessment of obviousness of the claimed solution.

Consequently, the claimed solution is not obvious over D9 and claim 1 of the main request is inventive over D9.

1.4 Document D5 as the closest prior art to claim 1

1.4.1 D5 relates to the treatment of chronic refractory epilepsy by a ketogenic diet, i.e. a high fat, low protein and low carbohydrate diet. According to the authors, the patients showed a significant reduction in seizures after a one year diet (see abstract). The

ketogenic diet was a MCT diet, **without indication of the specific nature of the MCT** (see point 2.3). An improvement in mood and anxiety appears to have been found for 15,7% of the patients (see point 3.2).

The opposition division considered that D5 did not relate to the treatment of anxiety *per se* but only to a special patient group thereof, namely patients with epilepsy that suffer from anxiety and that any conclusion drawn in D5 can not be extrapolated to all anxiety patients.

The Board disagrees on this point with the conclusions of the opposition division. Claim 1 of the main request does not comprise any restriction as to the type of anxiety disorder or to a group of patients.

The Board however agrees with the argument of the respondent that **D5 does not credibly demonstrate that a MCT diet is effective in the reduction of anxiety in adults with chronic refractory epilepsy.**

Indeed, as highlighted by the respondent, the authors of D5 explain on page 3, point 3.2 that "Nine patients (60%) reported an improved arousal during treatment... With regard to mood, we found an improvement of depressed mood of 34%, **an improvement of tension and anxiety of 15.7%**, a decrease of fatigue of 21.1% and an improvement of activity of 12.6%. **Despite the results, none of those changes were significant, probably as a result of the small sample size in the study.**".

From this, it is clear that no significant effect was found on anxiety in the treatment of chronic refractory disease. Consequently, the technical difference between claim 1 and D5 is that D5 does not disclose the use of

octanoic acid and/or decanoic acid in MCT form and does not report an effective treatment of anxiety.

1.4.2 According to the appellant, the technical problem may be phrased as the selection of a chain length in an MCT for treating anxiety.

The respondent defines the problem as the provision of a composition or compound that allows to effectively treat anxiety.

In view of the distinguishing technical features and the experimental results disclosed in the patent the Board considers that the technical problem over D5 is as defined by the respondent.

1.4.3 The claimed solution is not obvious over D5. There is no suggestion in D5 for the use of specific MCFA, particularly octanoic acid or decanoic acid, in the form of a medium chain triglyceride for the prevention and/or treatment of anxiety.

Moreover, considering the ineffectiveness and non-tolerability of the MCT diet in general (see Table 3 of D5), it appears even questionable whether the skilled person would have considered at all a MCT diet.

For these reasons, the skilled person would not see any reason to associate the teaching of D5 to the teaching of D9, which does anyway not give a further incentive to select octanoic acid or decanoic acid as MCFA for the MCT.

Consequently, claim 1 of the main request is inventive over D5, and the main request meets the requirements of Article 56 EPC.

2. Main request - Novelty

2.1 Claim 3 of the main request is drafted under the format prescribed under Article 54(5) EPC and relates to "a composition comprising a MCFA as defined in any one of claims 1 to 2 for use in treating and/or preventing anxiety".

In view of the reference to claims 1, the claimed composition must comprise triglycerides of decanoic or octanoic acids.

Whereas claim 1 relates specifically to decanoic or octanoic acid in the form of MCT for the treatment of anxiety, claim 3 more broadly encompasses any composition comprising the same compounds as in claim 1, potentially along with additional substances, for the same therapeutic application.

This is illustrated for instance by the subject-matter of dependent claim 4 dependent on claim 3 which claims the additional presence of octanoic acid or decanoic acid as such.

2.2 D21 discloses a study investigating the impact of a diet containing goat milk fat (GMF) on *inter alia* the anxiety behaviour in rats (see Abstract); the study compared the effects of a control diet and a GMF diet on rats. Table 1 gives the fatty acids composition of the diets and shows that the GMF comprised inter alia C8 and C10 fatty acids (octanoic and decanoic acids). These fatty acids are known to be in the form of triglycerides in the goat milk, as confirmed by D22 (see for instance Table 1 of D22 which gives the fatty acid composition of the milk fat triglycerides).

The anxiety behaviour was tested on the elevated plus maze test (EPM). Compared to the controls, the rats that consumed GMF showed an increased time spent in the open arms of the maze and less time in the central part of the maze, which demonstrates an exploratory and anxiolytic effect of the GMF diet (see "Discussion"). The study D21 attributes the effects shown by the GMF to the presence of linoleic acid (CLA) in the GMF, since it can influence physical growth and brain development, but mentions that the results shown in the study will stimulate further investigation aiming the CLA use.

Accordingly, D21 discloses the use of a composition comprising *inter alia* octanoic acid and decanoic acid in the form of triglycerides for the prevention or treatment of anxiety.

Although D21 does not attribute the anxiolytic effect of the GMF to the octanoic and decanoic acids in the form of MCT, a composition comprising octanoic and decanoic acids in the form of MCT for use in the prevention or treatment of anxiety cannot be regarded as novel because D21 discloses the occurrence of this effect in a composition comprising the same triglycerides.

2.3 The opposition division concluded that claim 3 was novel over D21 and referred in this regard to the decision T 286/09. The Board disagrees with this conclusion.

In case T 286/09, the claim was in the format of a Swiss type claim and related to the use of **a specific substance**, i.e. a prebiotic, for the manufacture of a medicament for decreasing inflammatory process. The

cited prior art was a composition for decreasing the inflammatory process including optionally among other compounds a prebiotic. The Board concluded in this case that the skilled person could not know from the prior art that the prebiotic, which was an optional ingredient, had an effect on inflammatory process because the prior art advocated the use of the prebiotic for a specific different purpose, namely to "provide up to 5% of the energy of the composition" (see decision point 2.3.2).

The present case differs from the case T 286/09 in that claim 3 does not relate to the therapeutic use of a substance but rather to the therapeutic use of any composition comprising specific substances.

2.4 Consequently, the subject-matter of claim 3 is not novel over the disclosure of D21, and the main request does not meet the requirements of Article 54 EPC.

3. Auxiliary request 1 - Novelty

The same conclusion regarding novelty over D21 applies to auxiliary request 1, whose claim 2 is identical to claim 3 of the main request. Consequently, auxiliary request 1 does not meet the requirements of Article 54 EPC.

4. Auxiliary request 2 - Article 123(2) EPC

4.1 The subject-matter of claim 3 was objected to by the appellant.

4.2 Claim 3 reads as follows:

"3. A composition comprising a MCFA as defined in any one of claims 1 to 2 for use in treating and/or preventing anxiety, wherein the composition comprises decanoic acid and octanoic acid."

This claim results from the combination of claims 3 and 4 as granted.

4.3 A basis for the subject-matter of claim 3 is to be found *expressis verbis* in original claims 5 and 6.

Additionally, the teaching in the original disclosure, p. 7, l. 29, to p. 8, l. 22, specifically addresses the possibility of "spiking" a composition with MCFAs.

Consequently, the subject-matter of claim 3 is disclosed directly and unambiguously in the original application, and auxiliary request 2 meets the requirements of Article 123(2) EPC.

5. Auxiliary request 2 - Novelty

5.1 The novelty of claim 3 of auxiliary request 2 over D21 was objected to by the appellant. There were no further objections to the novelty of auxiliary request 2.

5.2 Claim 3 relates in a clear way to a composition comprising simultaneously the claimed MCFA, i.e. octanoic acid and decanoic acid, both in the form of MCT and of free fatty acids. The subject-matter of this claim is therefore not limited to the presence of MCT as argued by the appellant.

5.3 There is no disclosure in D21 of MCT and fatty acids in such a combination. Consequently, the subject-matter of

claim 3 is novel over D21, and auxiliary request 2 meets the requirements of Article 54 EPC.

6. Auxiliary request 2 - Inventive step

6.1 Claim 1 of auxiliary request 2 is identical to claim 1 of the main request. Accordingly, this claim complies with the requirements of inventive step for the same reason.

The opponent considered that claim 3 of auxiliary request 2 was not inventive starting from document D21 as the closest prior art.

6.2 D21 does not identify the component of goat milk fat which may be responsible of the shown effect on anxiety. It does not mention in particular that the MCTs of octanoic acid or decanoic are directly responsible of the technical effect. However, it suggests that conjugated linolenic acid may be involved in the effect (see abstract).

With regard to the subject-matter of claim 3 of auxiliary request 2, D21 does not disclose the further presence of octanoic acid or decanoic acid in the composition.

6.3 The appellant and the respondent disagreed on the effect shown by the distinguishing features.

The appellant considers in particular that no effect has been shown and that the problem of the subject-matter of claim 3 of auxiliary request 2 over D21 remains the provision of an alternative composition.

The respondent considers that the addition of fatty acids has an effect and defines the problem regarding the subject-matter of claim 3 as the provision of an improved composition for the treatment of anxiety.

6.4 As discussed in relation to the main request (see point 1.3.4 above) the experimental data disclosed in the patent demonstrates the effectiveness of the claimed composition in the treatment or prevention of anxiety. The Board considers therefore that for the subject-matter of claim 3 the technical problem can be defined as the provision of an alternative composition for treating or preventing anxiety.

In D21, there is no indication that octanoic or decanoic acid in MCT form can be useful in the prevention and/or treatment of anxiety; it is neither suggested in D21 that decanoic acid or octanoic acid, in the form of MCT or free acids, may have any anxiolytic effect. Table 1 of D21 or Table 2 of D22 show that the goat milk fat contains a long list of fats in triglyceride form, and there is no pointer in any of these documents to the potentially active ingredient in the treatment of anxiety, except for conjugated linolenic acid. Thus, the skilled person seeking to develop a composition for treating anxiety would have no motivation to add octanoic acid or decanoic acid to the composition of D21.

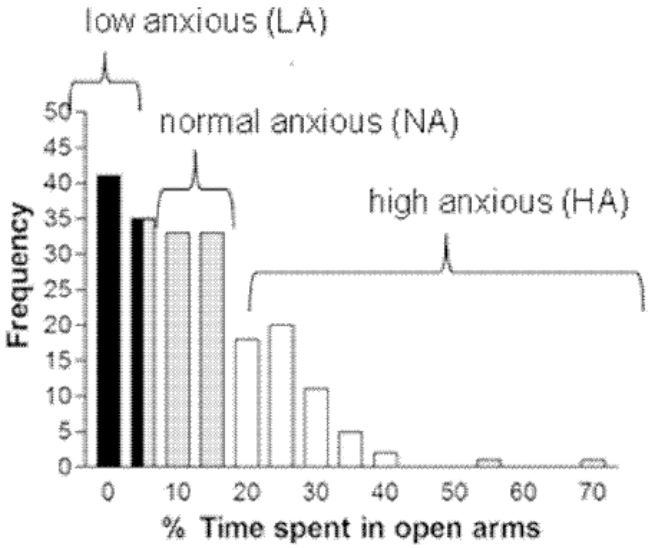
Moreover, the addition of octanoic acid or decanoic acid in the claimed composition cannot be seen as an arbitrary modification. These fatty acids correspond to the claimed MCT and contribute therefore to the claimed technical effect. There is furthermore no suggestion in any cited documents, in particular D21 or D18 to add these particular fatty acids.

Consequently, the subject-matter of claim 3 is not obvious over D21 and auxiliary request 2 meets the requirements of Article 56 EPC.

7. Auxiliary request 2 - Sufficiency of disclosure

7.1 The requirements of sufficiency of disclosure are met in view of the examples and Figures of the contested patent.

7.2 Figure 1 is a representation of the results of the elevated plus maze (EPM) test performed on rats. The EPM apparatus consists of four arms, i.e. two open arms and two closed arms, and the test measures the time spent by the rats in the open and closed arms. Accordingly, the rats were evaluated via the EPM test and were subdivided in tertiles of anxiety levels, namely high anxiety (HA), normal anxiety (NA) and low anxiety (LA), according to their anxiety-like behaviour; the animals that suffer from anxiety would prefer to spend most time in closed arms and less in the open arms, as confirmed by the teaching of D14. Figure 1 represents the percentage time spent in open arms by the tested rats.



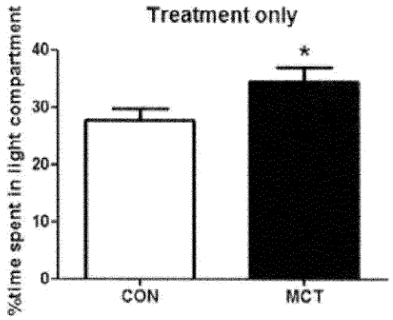
The opposition division considered that Figure 1 was clearly erroneous (see page 5 of the decision). However, this error could not be corrected in an obvious manner, since several corrections were proposed. Specifically, the opposition division idntified a mistake in the labelling of the x and y axis of Figure 1, whereas the respondent argued that the labels "HA" and "LA" were incorrectly interchanged in Figure 1.

The Board considers however that the discussion on Figure 1 appears irrelevant on the point of sufficiency of disclosure. The Board notes indeed that the experiments or data linked with Figure 1 do not relate to any group of animals having received MCT or to the administration of MCT and therefore do not relate directly to the claimed subject-matter. Moreover, the Board sees no reason to believe that the error in Figure 1 would affect all the examples, as argued by the appellant. It is possible to interpret all remaining examples and figures independently from Figure 1.

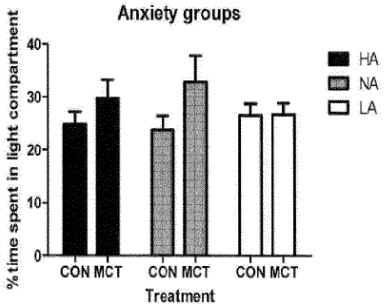
7.3 Figures 3A and 3B show the results of the light dark box test, namely the percentage of time spent by the rats in the light compartment in control versus MCT-treated rats. Figures 3A and 3B show a convincing effect on rats fed with MCT, since the time spent in the light compartment is clearly increased in particular in the HA and NA groups.

FIGURE 3A & FIGURE 3B

A)



B)



The Board does furthermore not see in the absence of an effect on the low anxiety group (LA) evidence that the claimed composition are not effective in the treatment and/or prevention of anxiety. The demonstration of an effect on the HA and NA is sufficient.

The appellant questioned the statistical relevance of these results. However, Figure 3B shows a significant

improvement for the NA and HA groups. In the Board's view, these generic considerations on statistical aspects do not represent serious doubts about the effectiveness of the treatment.

7.4 Figure 4 is a comparison on the social interaction test (see par. [0095] of the specification) on rats with HA, NA and LA levels. The diagram of Figure 4B after treatment by MCT shows an improvement in the social preference on HA animals. D11 indicates that an increase in social interaction is indicative of an anxiolytic effect (see Background), which appears to confirm an effect linked with the administration of MCT and the results observed on such type of tests.

7.5 Figures 5-8 also show an increase of respectively ßHB, IRS-1 levels, complex 1 protein expression, and ketones and HB after a period of treatment with MCT. These results show that the administration of MCT is potentially useful in alleviating the anxiety disorders via the energy and metabolic processes, the increase in brain βHB, and the alteration of the mitochondrial activity via the IRS-1 pathway (see par. [0030]-[0032] of the specification). The requirements of sufficiency of disclosure are met also in view of these *in vitro* results. In this regard the Board notes that the demonstration of a pharmaceutical effect *in vitro* may support the sufficiency of disclosure of a therapeutic application. The Board does not see any reason to doubt that the pharmacological data were convincing, and no evidence of the contrary was brought by the appellant.

7.6 The results shown in Figures 3-8 are confirmed by the teaching of the post-published document D23, which confirms the relevance of the elevated plus maze test

in the assessment of alleviation of anxiety, and the effectiveness of MCT as an anxiolytic diet (see for instance Figure 2).

7.7 An objection of lack of sufficiency of disclosure presupposes that there are serious doubts, substantiated by verifiable facts, which is not the case in the present case. In view of Figures 3-8, it is clear that the claimed invention can be considered as enabled.

Consequently the requirements of Article 83 EPC are met.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division with the order to maintain the patent on the basis of the claims of auxiliary request 2 filed on 15 September 2023, and a description to be adapted if necessary.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated