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Datasheet for the decision of 4 May 2022

Case Number: T 0299/18 - 3.3.09

Application Number: 09824548.3

Publication Number: 2351491

IPC: A23L1/29, A23L1/30, A61K31/23, A61P3/00

Language of the proceedings: EN

Title of invention:
CONCENTRATED LIQUID DIET

Patent Proprietor:
The Nisshin OilliO Group, Ltd.

Opponent:
Société des Produits Nestlé S.A.

Headword:
Concentrated liquid diet/NISSHIN OILLIO

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 100(a), 56

Keyword:
Late-filed evidence - submitted with the statement of grounds of appeal
Late-filed facts - admitted (no)
"post-published" evidence taken into account - (yes)
Inventive step - unexpected improvement shown - (yes)

Decisions cited:
T 0939/92, T 1329/04

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Case Number: T 0299/18 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 4 May 2022

Appellant: (Opponent)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Respondent: (Patent Proprietor)	The Nisshin OilliO Group, Ltd. 23-1, Shinkawa 1-chome Chuo-ku Tokyo 104-8285 (JP)
Representative:	Müller-Boré & Partner Patentanwälte PartG mbB Friedenheimer Brücke 21 80639 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 1 December 2017 rejecting the opposition filed against European patent No. 2351491 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	F. Rinaldi
	D. Rogers

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the opponent (appellant) against the opposition division's decision to reject the opposition against European patent No. 2 351 491.

II. In the notice of opposition, the opponent had requested that the patent be revoked in its entirety based on Article 100(a) EPC for lack of inventive step, among other things.

III. The documents cited during opposition proceedings included:

D1: WO 2007/000529 A2

D3: WO 2007/080149 A2

D6: A. C. Bach *et al.*, "The usefulness of dietary medium-chain triglycerides in body weight control: fact or fancy?", Journal of Lipid Research, 37, 1996, 708-726

D7: US 2006/0167094 A1

D8: J. A. Heydinger *et al.*, "Medium chain triacylglycerols", Journal of Food Lipids, 3, 1996, 251-257

D9: EP 0 843 972 A1

Annex I: "Test for investigating discomfort of the upper abdomen in humans"

The patent proprietor filed Annex I in reply to the notice of opposition.

IV. With the statement setting out the grounds of appeal, the appellant filed the following document, among other documents:

D12: WO 2007/115282 A2

V. With the reply to the statement setting out the grounds of appeal, the patent proprietor (respondent) filed auxiliary requests 1 to 5.

VI. Claim 1 of the patent as granted (main request) reads:

"*A concentrated liquid diet having a total amount of a medium-chain fatty acid having 8 carbon atoms and a medium-chain fatty acid having 10 carbon atoms included as constitutive fatty acids of a triglyceride being 2.5 to 8.0 g per 100 kcal of the energy of the concentrated liquid diet, the concentrated liquid diet having in the total mass of the medium-chain fatty acid having 8 carbon atoms and the medium-chain fatty acid having 10 carbon atoms a rate of the medium-chain fatty acid having 10 carbon atoms being no less than 60% by mass, and a rate of the medium-chain fatty acid having 8 carbon atoms being no greater than 40% by mass.*"

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

- D12 was feasible as the closest prior art and was to be admitted into the proceedings.
- The claimed subject-matter lacked inventive step starting from any one of D1, D3, D8 and D9 as the closest prior art. There was no evidence that a technical effect or an improvement was achieved across the scope claimed. The results in tables 2, 7 and 8 of the patent and in Annex I did not

support such a conclusion. The subject-matter of the main request was obvious.

VIII. The respondent's arguments relevant to the present decision may be summarised as follows:

- D12 was not to be admitted into the proceedings.
- The claims of the main request involved an inventive step. D3 was the closest prior art. The technical problem set out in the patent, namely to provide a nutritional composition that was less likely to strain the stomach, was solved. This was demonstrated in tables 2, 7 and 8 of the patent and in Annex I.

IX. Final requests

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

The respondent requested that the appeal be dismissed (main request), or alternatively that the patent be maintained on the basis of any one of auxiliary requests 1 to 5, filed with the reply to the statement setting out the grounds of appeal.

Reasons for the Decision

1. *The patent*

1.1 The patent is directed to concentrated liquid diets which comprise a large amount of medium-chain fatty acids. The diets are intended for use in the

nutritional support of elderly people or hospitalised patients, for example. Medium-chain fatty acids efficiently supply energy but may induce discomfort of the upper abdomen (such as a heavy stomach feeling and irritation of the stomach) when ingested at a single time and in large amounts. The patent aims to provide a concentrated liquid diet that contains a large amount of medium-chain fatty acids and is less likely to strain the stomach (paragraphs [0002] to [0005]).

1.2 Claim 1 of the patent as granted further defines the concentrated liquid diets.

(a) The diets are rich in medium-chain fatty acids having 8 carbon atoms (i.e. C8 fatty acid) and 10 carbon atoms (i.e. C10 fatty acid), i.e. 2.5 to 8.0 g per 100 kcal.

(b) Moreover, the C10 fatty acid is no less than 60% by mass and the C8 fatty acid is no greater than 40% by mass of the total mass of C8 and C10 fatty acid. In other words, the mass ratio of C8 to C10 fatty acid is from 40:60 to 0:100.

2. *Non-admission of D12*

2.1 The parties disagreed as to whether D12, filed with the statement setting out the grounds of appeal, was admissible. The appellant filed it as an additional closest prior-art document and based an inventive-step objection on it.

2.2 It can be seen from the decision under appeal that the opponent did not rely on one single document as the closest prior art, but on several documents. Clearly, the opponent's view throughout the opposition

proceedings was that there were more documents which represented the closest prior art. The inventive-step objections discussed in the decision involved four different documents, used as the closest prior art: D1, D3, D8 and D9. None of the inventive-step objections raised in the opposition proceedings was successful.

2.3 The opposition division maintained the patent as granted. The main request on appeal is unchanged: the respondent is still requesting that the patent be maintained as granted. Therefore, there is no change to the claims that justifies additional documents being filed.

2.4 Nevertheless, by filing D12 for the first time on appeal, the appellant sought to introduce yet another document as the closest prior art. Therefore, it presented a fresh case by raising a new inventive-step objection against the claims as granted.

2.5 The board sees no reason why the opponent, which was of the opinion that there were several documents representing the closest prior art, did not file all the documents it wished to have considered with the notice of opposition. At the least, it should have done so in the course of the opposition proceedings. There is also no explanation as to why D12 could not have been filed earlier.

2.6 Therefore, the further document that the appellant presented as the closest prior art, D12, could and should have been filed during the opposition proceedings.

2.7 For completeness, the following additional observations are made as regards the disclosure and the teaching of D12.

2.7.1 The appellant's understanding of D12 was that

- the document related to high-fat nutritional drinks comprising medium-chain triglycerides,
- the compositions disclosed had particular use in feeding the elderly, and
- all the fatty acid groups of the triglyceride could be chosen to have 10 carbon atoms.

2.7.2 However, as the respondent argued, the appellant has construed the disclosure of D12 in the manner of a mosaic, by combining several separate embodiments and selecting the passages that suited its purpose from the entire disclosure.

2.7.3 In more detail, claim 1 of D12 is directed to a nutritional drink that provides specified physiological levels of β-hydroxybutyrate and comprises, among other specified ingredients, medium-chain triglycerides with fatty acids having 5 to 12 carbons atoms. The aim of D12 is to treat or prevent cognitive impairment, not to overcome discomfort of the upper abdomen or strain on the stomach. D12 exemplifies a wide range of dosage forms and concentrations for the medium-chain triglycerides (example 2). The fatty acids may or may not include fatty acids with 10 carbon atoms. For instance, it may include only fatty acids with 6 carbon atoms. No preference is indicated (paragraphs [0046] and [0047]).

2.7.4 Therefore, the disclosure in D12 is not exclusively directed to high-fat nutritional drinks comprising

medium-chain triglycerides in which all the fatty acid groups of the triglyceride have 10 carbon atoms. In this respect, D12 is not a more promising springboard than D3.

2.8 To conclude, D12 is not admitted into the appeal proceedings (Article 12(4) RPBA 2007).

3. *Main request - inventive step*

3.1 The appellant contested the opposition division's decision on inventive step. In its view, claim 1 as granted and dependent claims 2 to 4 lacked inventive step.

3.2 Selection of the closest prior art

3.2.1 The appellant argued, as in the decision under appeal, that any one of D1, D3, D8 and D9 could be used as the closest prior art.

3.2.2 The board agrees with the opposition division and the respondent that D3 is the closest prior art. D3 relates to methods and compositions for providing nutrition rich in lipids to stressed or critically ill patients (paragraphs [0001], [0015] and [0020]). This purpose is similar to that of the patent.

3.2.3 The board explained in its communication under Article 15(1) RPBA 2020 that none of D1, D8 and D9 related to a concentrated liquid and consequently did not qualify as the closest prior art. In particular:

- D1 related to the treatment of keratinous dryness,

- D8 was a scientific publication on medium-chain triacylglycerols, their nutritional benefits and their use in various food applications, and
- D9 related to the treatment of metabolic syndrome, in particular to a food composition beneficial in lowering lipid levels in blood plasma, and was not a more promising springboard than D3.

3.2.4 The board has no reason to revisit this assessment because the appellant has not provided any counter-arguments in this regard.

3.3 The distinguishing feature(s)

3.3.1 Paragraph [0055] of the closest prior art, D3, discloses the composition Peptamen® 1.5, which comprises:

- an energy density of 1.5 kcal/ml,
- a protein source which provides 18% of total energy, and
- a lipid source which contains 70% medium-chain triglycerides, i.e. fractionated coconut oil and palm kernel oil, and 30% long-chain triglycerides.

3.3.2 It is uncontested that a distinguishing feature of claim 1 is that the concentrated liquid diet has a ratio of C10 fatty acid of no less than 60% by mass and a ratio of C8 fatty acid of no greater than 40% by mass in the total mass of C8 and C10 fatty acid. In other words, D3 does not disclose feature (b) identified in point 1.2 above.

3.3.3 With regard to feature (a) identified in point 1.2 above, in view of the board's conclusion on inventive step set out below, it is not necessary to decide

whether this feature is a further distinguishing feature of claim 1.

3.4 What is the technical problem?

3.4.1 In paragraph [0005], the patent addresses the problem of providing a concentrated liquid diet that contains a large amount of medium-chain fatty acid and is less likely to strain the stomach.

3.4.2 In the decision under appeal, the opposition division examined the experimental results in tables 2, 7 and 8 of the patent and in Annex I. It then concluded (in point 3.3.3) that

"*the objective as posed in the patent specification of providing a concentrated liquid diet to reduce stomach strain is plausibly achieved across the whole of the scope claimed of the patent as granted*".

3.4.3 The appellant argued that the results in tables 2, 7 and 8 of the patent and in Annex I did not support the conclusion that the problem was solved across the whole of the scope claimed.

3.4.4 The contested evidence supporting a technical effect is discussed in points 3.5 to 3.7 and the conclusions are drawn in point 3.8, as all set out below.

3.5 Results in table 2 of the patent

3.5.1 Table 2 shows the results of experiments in which compositions are fed to rats and the effects on the gastric mucosa are analysed. Two types of composition are compared:

- On the one hand, three compositions (reference examples 1 to 3) are examined. They comprise a ratio of n-octanoic acid (a C8 fatty acid) to n-decanoic acid (a C10 fatty acid) of 40:60, 20:80 and 0:100, respectively. The three compositions have the ratio of medium-chain fatty acid called for in claim 1, i.e. they are compositions representing the invention.

- On the other hand, a comparative composition is examined which comprises a ratio of n-octanoic acid to n-decanoic acid of 60:40. This composition does not fall under claim 1.

3.5.2 The compositions representing the invention are found to cause a lower number of areas of patchy redness in the rats' gastric mucosa. The results are described as being significantly different as compared with the results of the comparative composition.

3.5.3 The appellant argued that these results were irrelevant because they did not demonstrate an effect on humans. However, it provided no evidence that the analysis of the rats' gastric mucosa is from a scientific viewpoint unsuitable for demonstrating how the compositions representing the invention behave in the human body.

3.5.4 Therefore, it can be acknowledged that

- the number of areas of patchy redness in the rats' gastric mucosa is an indicator of stomach strain and
- the results in table 2 would be expected to be observed on humans ingesting the compositions.

3.5.5 The board also agrees with the respondent that the morphological/cellular response shown in table 2 indicates discomfort in a subject, regardless of whether the subject is a human or a rat.

3.5.6 On the basis of the results in table 2 alone, it is credible that the compositions in claim 1 are less likely to strain the stomach.

3.6 Results in tables 7 and 8 of the patent

3.6.1 The patent sets out further experiments in which human panellists assess discomfort in the upper abdomen after ingesting several compositions. The panellists assign a value to individual evaluation items (e.g. feeling irritation in the upper abdomen, getting nausea, belching); the higher the value, the higher the level of discomfort.

Tables 7 and 8 set out, for each composition,
(i) the sum of values the panellists assigned to each individual evaluation item, and
(ii) a total score, which is the total sum of the values the panellists assigned.

The compositions tested correspond to those identified in point 3.5.1 above (reference examples 1 to 3 and the comparative composition). The compositions in tables 7 have a concentration of medium-chain fatty acid of 2.8 g per 100 kcal of the energy of the concentrated liquid diet. The compositions in table 8 have a higher concentration of medium-chain fatty acid, 5.6 g per 100 kcal.

3.6.2 The compositions representing the invention are generally found to have a lower score; in other words, they cause less discomfort.

3.6.3 The appellant's view was that these results did not support the conclusion that the problem set out in the patent was solved across the whole of the scope claimed. It made the following arguments.

- The number of panellists was small and their assessment was subjective.
- The results in tables 7 and 8 did not show a statistically significant difference for all the compositions representing the invention. This in particular concerned the compositions having a mass ratio of C8 to C10 fatty acid of 40:60 or 20:80.
- The changes in values for individual evaluation items did not correlate with changes in mass ratio of C8 to C10 fatty acid. It was not possible to determine from the data in tables 7 and 8 which evaluation item may be improved for any diet falling within the scope of claim 1.
- The experiments in tables 7 and 8 were carried out with octanoic acid and decanoic acid, but there was no evidence that the results were achievable with any C8 and C10 fatty acid.

3.6.4 However, the appellant's arguments are not convincing.

3.6.5 There is no indication that the number of panellists is unsuitable for the purpose of demonstrating the effect of the invention. Furthermore, it is unavoidable that discomfort in the upper abdomen is assessed according to subjective evaluations, which may not be as repeatable or reproducible as data obtained from measuring an invariable sample.

3.6.6 Nevertheless, as the respondent argued, it is conclusive that a human panellist may experience an overall reduction in discomfort due to subtle influences from each of the evaluation items and that this is reflected in the total score. In view of this, it is justified that the total score be given more weight than the assessment of the individual evaluation items. In this context, it is observed that the aim of the patent is not to address specific aspects such as reducing nausea or belching.

3.6.7 Furthermore, the results in tables 7 and 8 may not show a statistically significant difference that stands up to strict, mathematical scrutiny of the data. Nevertheless, they show a clear trend to the naked eye. The trend which is derivable when evaluating the total score in tables 7 and 8 does not contradict the results in table 2. On the contrary, taken together, these results additionally support the conclusion reached based on the tests shown in table 2, namely that all the compositions representing the invention cause less discomfort, i.e. less stomach strain, than the comparative composition.

3.6.8 The appellant's speculative argument that the results in tables 7 and 8 may not be obtained for any C8 or C10 fatty acid is based on abstract considerations and is not convincing either. Claim 1 relates to a concentrated liquid diet which comprises C8 and C10 fatty acid and defines an amount of it (2.5 to 8.0 g per 100 kcal). A skilled reader of claim 1 would immediately think of octanoic acid and decanoic acid in this context. Moreover, the appellant has not explained what C8 and C10 substances that comply with the

definition of claim 1 it had in mind when it presented its argument.

3.6.9 To conclude, the results in tables 7 and 8 further support the conclusion that the compositions in claim 1 are less likely to strain the stomach.

3.7 Annex I

3.7.1 The patent proprietor filed Annex I in reply to the notice of opposition. These tests are similar to those in tables 7 and 8; however, the compositions representing the invention comprise a mass ratio of n-octanoic acid to n-decanoic acid of 30:70 and C8 and C10 fatty acid at 7.4 g per 100 kcal of the energy of the concentrated liquid diet.

3.7.2 As in the results in tables 7 and 8, the compositions representing the invention are generally found to have a lower score (i.e. they cause less discomfort) and to have a total score that is significantly different ($P < 0.05$) as compared with the comparative composition.

3.7.3 Here, the appellant's criticism was that:

- according to established case law (T 939/92 and T 1329/04) "post-published" evidence could not be used to demonstrate a technical effect that was not made "plausible" in the application as filed, and
- the tests were carried out with a mass ratio of n-octanoic acid to n-decanoic acid of 30:70, which had not been exemplified in the patent.

3.7.4 However, these arguments failed to convince the board.

3.7.5 As explained above in points 3.5 and 3.6, the patent as well as the application as filed include sufficient evidence supporting the conclusion that the compositions in claim 1 solve the problem set out in the patent, namely to reduce stomach strain. In view of this, the proof of the effect does not reside exclusively in "post-published" evidence, i.e. Annex I filed after the date of filing and not publicly available prior to that date. The effect is already credible based on the application as filed.

3.7.6 In T 939/92 the competent board's reasoning was that, as no evidence had been submitted in order to demonstrate a certain effect, the latter could not be taken into account (Reasons for the Decision, point 2.6.4). Therefore, this decision does not support the appellant's view that evidence filed after the date of filing, such as Annex I in the present case, should not be considered.

3.7.7 T 1329/04 concerns a specific situation in which, in view of the common general knowledge, there were serious doubts as to whether the problem was credibly solved. The supporting evidence provided in that case, filed after the date of filing and not publicly available prior to that date, was the first disclosure going beyond speculation (Reasons for the Decision, point 12). The present case is different. Given the disclosure in the application as filed, the board cannot identify such serious doubts.

3.7.8 The appellant argued that compositions with a mass ratio of n-octanoic acid to n-decanoic acid of 30:70 were not exemplified in the patent. Therefore, Annex I was not relevant.

3.7.9 The opposite is true. First, the compositions examined in Annex I fall under claim 1. Second, they include a mass ratio of C8 fatty acid of 30%. This is close to the end point of the mass ratio of C8 to C10 fatty acid of 40:60, which the appellant regarded as critical (see point 3.6.3 above). Third, the C8 and C10 fatty acid is in the composition at 7.4 g per 100 kcal, which means at a concentration towards the upper end of the range called for in claim 1. Therefore, the results in Annex I fill a (potential) gap in terms of the evidence provided. They further endorse the conclusion that reducing stomach strain is achieved across the whole of the scope claimed.

3.7.10 For the sake of completeness, the board observes that in Annex I the total score of the compositions representing the invention is significantly different ($P < 0.05$) as compared with the comparative composition. Nevertheless, in the context of the present case, strict statistical considerations are not considered to be decisive when assessing the corroborative value of the evidence (see point 3.6.7 above).

3.7.11 To conclude, Annex I additionally confirms the results given in tables 2, 7 and 8 of the patent.

3.8 Concluding remarks on the evidence

3.8.1 As explained above in points 3.5 and 3.6, the patent includes evidence supporting the conclusion that the compositions in claim 1 reduce stomach strain. This is further corroborated by the results in Annex I. There is also no verifiable evidence demonstrating that the effect might not be achieved across the whole of the scope claimed.

3.8.2 In particular, the appellant has not prepared its own tests which would support its position. Its objections were restricted to criticising, presenting allegations and attempting to raise doubts based on the patent proprietor's experimental results.

3.8.3 Therefore, on the basis of the evidence before the board, it can be concluded that the compositions in claim 1 reduce stomach strain.

3.9 Formulation of the technical problem

The technical problem identified in the patent (see point 3.5.1 above) and acknowledged by the opposition division (see point 3.5.2) need not be reworded.

3.10 Obviousness

3.10.1 There is no suggestion in the cited prior art of solving the technical problem by modifying the mass ratio of C10 and C8 fatty acid as set out in claim 1.

3.10.2 In particular, as already explained in the opposition division's decision, neither D6 nor D7 is concerned with the same problem or provides an incentive to modify the mass ratio of C8 to C10. The subject-matter of claim 1 is not obvious over D3 either alone or in combination with D6 or D7.

3.10.3 The same reasoning applies to D1, D8 and D9. None of these documents relates to the problem of providing a concentrated liquid diet which reduces discomfort of the upper abdomen. Their disclosure would not have motivated the skilled person to modify the mass ratio of C8 to C10 fatty acid.

3.11 Therefore, the subject-matter of claim 1, and also of dependent claims 2 to 4, involves an inventive step. The ground for opposition under Article 100(a) EPC in conjunction with Article 56 EPC does not prejudice the maintenance of the patent as granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Nielsen-Hannerup A. Haderlein

Decision electronically authenticated