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**Datasheet for the decision
of 11 January 2021**

Case Number: T 1388/17 - 3.3.09

Application Number: 06749290.0

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A61P3/02, A61P9/10

Language of the proceedings: EN

Title of invention:
COMPOSITION FOR NUTRITIONALLY IMPROVING GLUCOSE CONTROL AND
INSULIN ACTION

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
ABBOTT LABORATORIES
N.V. Nutricia

Headword:
Composition for nutritionally improving glucose control and
insulin action/NESTLÉ

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 11, 12(1)(a), 12(2)

Keyword:

Inventive step - obvious alternative

Remittal - special reasons for remittal (no)



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Case Number: T 1388/17 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 11 January 2021

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 20 February
2017 revoking European patent No. 1868454
pursuant to Article 101(3)(b) 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 patent proprietor (appellant) against the decision of the opposition division to revoke European patent No. 1 868 454.
- II. In their respective notice of opposition, opponents 1 and 2 (respondents 1 and 2) had requested revocation of the patent in its entirety based on, *inter alia*, Article 100(a) EPC for lack of inventive step.
- III. The documents submitted during the opposition proceedings included:
- 01-D13 B. Sears et al., "The Zone", first edn., New York: HarperCollins Publishers Inc., 1995, 65 to 76, 137, 138
- 01-D15 Committee on use of dietary reference intakes in nutrition labeling food and nutrition board, "Dietary reference intakes", Washington D.C.: The National Academies press, 2003, 186, 187
- 01-D17 B. Vessby, "Dietary fat and insulin action in humans", British Journal of Nutrition, 83(1), 2000, S91 to S96
- 01-D19 B. Sears et al., "The Zone", first edn., New York: HarperCollins Publishers Inc., 1995, 152 to 160
- 01-D13 and 01-D19 are different pages of the same book. In the following, these two documents are referred to jointly as 01-D13/D19.

IV. In the decision under appeal, the opposition division used O1-D13/19 as the closest prior art. It decided, among other things, that several of the requests before it lacked inventive step over O1-D13/19 in combination with O1-D17.

V. With the statement setting out the grounds of appeal, the appellant filed a main request and auxiliary requests 1 to 5. Furthermore, it filed a main request-a and auxiliary requests 1-a and 2-a in reply to the board's communication in preparation for the oral proceedings, under cover of a letter dated 1 July 2020.

VI. Relevant for the present decision is solely the wording of claim 1 of auxiliary request 5. It reads:

"A nutritional formulation or composition comprising:

- a. a protein source;
- b. a fat source; and
- c. a carbohydrate source,

wherein the protein source, the fat source and the carbohydrate source are in a ratio of 1:1:1, each comprising one third of the total calories of the composition, and wherein the fat source is comprised of about 2% to about 10% of the total calories of the composition in the form of linoleic acid (18:2), for use in lowering insulin resistance."

VII. Oral proceedings were held before the board.

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

Inventive step

The closest prior art was the "Italian study" disclosed in O1-D13/19. The distinguishing features of claim 1 were the nutritional composition or formulation (in the study a diet was used), the calorie ratio of 1:1:1 and the content of linoleic acid. The technical problem was the provision of a composition for the management of insulin resistance and for maintaining optimal kidney function. The patent, in particular studies 12 and 17, showed that the technical problem was solved. The skilled person would have had no motivation to change the calorie ratio of the closest prior art and add linoleic acid to the composition. Neither O1-D15 nor O1-D17 suggested that linoleic acid influenced insulin resistance.

Remittal

The opposition division's decision on lack of inventive step was based on O1-D13/D19 as the closest prior art in combination with O1-D17. To examine the combination of the closest prior art with O1-D15 would go beyond a review of the decision under appeal. If the board found that the main request was inventive over O1-D13/D19 in combination with O1-D17, and the board was going to consider inventive step in light of document O1-D15, the case should be remitted to the department of first instance for further prosecution.

- IX. The respondents' arguments relevant to the present decision may be summarised as follows.

Inventive step

The closest prior art was O1-D13/19 and the only distinguishing feature was the content of linoleic acid. No technical effect over the prior art had been demonstrated, in particular nothing had been shown

about kidney function. The technical problem was the provision of an alternative formulation or composition for managing insulin resistance. The calorie ratio of claim 1 was suggested in O1-D13/19. O1-D15 or O1-D17 taught to add linoleic acid to the composition.

Remittal

The case should not be remitted because O1-D13/D19 in combination with O1-D15 had been discussed during the oral proceedings before the opposition division.

X. The parties' final requests.

The appellant requested

that the decision under appeal be set aside and that the patent be maintained upon the basis of the main request or, alternatively, one of auxiliary requests 1 to 5 (filed with the statement of grounds of appeal) or main request-a, or auxiliary requests 1-a or 2-a (filed under cover of a letter dated 1 July 2020).

The respondents requested that the appeal be dismissed.

Reasons for the Decision

1. The patent in suit relates to a nutritional composition for improving glucose and insulin balance in an individual (paragraph [0001]). In particular, it concerns a composition or dietary regimen aimed at increasing insulin sensitivity and lowering insulin resistance (paragraph [0012]).

2. *Inventive step - auxiliary request 5*

2.1 It was common ground between all parties that:

- of all requests before the board, auxiliary request 5 had the most restricted claim 1
- if claim 1 of auxiliary request 5 lacked inventive step, the same conclusion applied to the higher-ranking requests.

The board arrived at the conclusion that claim 1 of auxiliary request 5 lacks inventive step, as is explained in the following. Thus, the same conclusion applies to the higher-ranking requests.

2.2 Closest prior art and distinguishing features

2.2.1 In the decision under appeal, the closest prior art was document O1-D13/19.

2.2.2 In the statement setting out the grounds of appeal, the appellant doubted that O1-D13/19 was suitable as the closest prior art. However, it did not suggest a different document. At the oral proceedings, it argued that the closest prior art was only a specific element within the disclosure of O1-D13/19, namely a study described in that document (the "Italian study"). In its view, the distinguishing features of claim 1 were the:

- nutritional composition or formulation (in the study a diet was used)
- protein source, the fat source and the carbohydrate source in a calorie ratio of 1:1:1
- content of linoleic acid.

2.2.3 O1-D13/19 consists of an array of pages taken from the book "The Zone". This book is on a diet for achieving several health benefits by maintaining the body's eicosanoids in balance, which is referred to as "the Zone". Chapter 7 (pages 65 to 76) describes favourable and ideal caloric compositions of the diet in terms of protein, fat and carbohydrate ("the Zone-favourable diet"). Among other health benefits, the diet prevents hyperinsulinaemia (page 137 and 138).

2.2.4 Relevant for insulin resistance is the section with the title "The Zone-favorable Type II diabetic study" (pages 152 to 160). Page 152 discloses that throughout the book, the "constant theme has been the importance of controlling insulin so as to maintain a favorable eicosanoid balance". Next, two studies are described carried out on Type II diabetic patients: a study of the University of Naples from 1992 ("Italian study") and the author's study from 1994 ("pilot study"). In both studies, a Zone-favourable diet (protein to carbohydrate calorie ratio of 0.75) is compared to an ADA diet (high carbohydrate, low fat).

The Italian study took place in a metabolic ward in which each patient's meals were controlled. Within 15 days of the study, significant reductions in blood insulin levels, triglycerides and insulin resistance were observed in patients on a Zone-favourable diet compared to those on an ADA diet.

The results of the Italian study support the results of the pilot study, carried out later. The pilot study lasted several weeks and the Zone-favourable diet was administered in the form of an experimental candy bar which replaced the ward's diet ("a Zone-favorable meal in disguise"). Pages 153 to 159 discuss further results

of the pilot study, such as the levels of triglycerides and insulin. On page 160, the authors concluded that "[t]aken together, our pilot study and the Italian trial strongly indicate that a Zone-favorable diet can reduce insulin levels without reliance on drugs".

2.2.5 Therefore, the disclosure of these two studies must be read together. The skilled reader would have learnt from these two studies that a Zone-favourable diet is suited to lower insulin resistance and it may be administered as a single nutritional formulation or composition (e.g. a candy bar). Such a nutritional formulation or composition replaces the diet. This is the disclosure regarded as the closest prior art.

2.2.6 Throughout the appeal proceedings, a controversial issue was whether the calorie ratio of claim 1 constituted a further distinguishing feature. However, there is no need to answer this. The board accepts, in favour of the appellant, that the distinguishing features over the closest prior art are:

- the protein source, the fat source and the carbohydrate source in a calorie ratio of 1:1:1 (in the closest prior art it is 30:30:40, i.e. the protein source and the carbohydrate source are in a calorie ratio of 0.75)
- the concentration of linoleic acid (18:2) (not disclosed in the closest prior art)

2.3 The technical problem

2.3.1 The appellant argued that the technical problem was the provision of a composition for the management of insulin resistance and for maintaining optimal kidney function. In its view, this technical problem was

derivable from the patent in suit, paragraph [0045] and study 17 (paragraphs [0117] to [0119]).

2.3.2 However, the closest prior art already teaches a composition for the management of insulin resistance. As regards this technical effect, there is no evidence that the distinguishing features provide a contribution or an improvement over the closest prior art. In this context, the following is observed:

- The patent in suit itself confirms that for addressing insulin resistance what matters is the protein to fat calorie ratio of 1:1 (paragraphs [0043] and [0044]). This ratio is the same as in the Zone-favourable diet.
- There is no disclosure in the patent in suit that the protein to carbohydrate calorie ratio influences insulin resistance.
- In the patent in suit, there is no comparison of a Zone-favourable diet with a diet based on the calorie ratio of claim 1.
- Study 17 is the patent's only study with a diet having the calorie ratio of claim 1. But in this study, this diet is compared with a low carbohydrate diet (20% carbohydrate, 40% protein, 40% fat) and a high carbohydrate diet (60% carbohydrate, 20% protein, 20% fat), not with a Zone-favourable diet.
- Paragraph [0045] discloses that with a higher intake of linoleic acid (18:2) insulin resistance decreases. However, the Zone-favourable diet already reduces insulin resistance. The appellant could not show that the levels of linoleic acid of claim 1 provide a technical effect on insulin resistance going beyond the closest prior art.

2.3.3 Turning to the alleged effect on kidney function, the only conclusion presented in study 17 is that "the low carbohydrate diet (protein 40%) increased kidney weight, suggesting a decrease in kidney function" (paragraph [0119]). As regards the other two diets examined in study 17, i.e. the diet with the calorie ratio of claim 1 and the high carbohydrate diet, there is no disclosure on kidney function.

2.3.4 To demonstrate an effect on kidney function, the appellant referred to study 12 of the patent in suit. In this study, five diets were examined, including a Zone-favourable diet. The kidney weight measured after administration of the Zone-favourable diet (study 12, table 7, lines 45 and 46) was higher than shown in study 17 (table 34) after administration of the diet with the calorie ratio of claim 1. The appellant concluded from this comparison that the Zone-favourable diet led to reduced kidney function.

2.3.5 However, comparing these two studies does not lead to a meaningful conclusion on kidney function.

Although the same type of mice (C57BL6J) is used in study 12 and 17, these are different sets of experiments. The appellant did not show that the design of the two studies was the same and that they can be compared. On the contrary, the initial body weight of the mice in study 12 (Zone-favourable diet) is 21.9 g, but in study 17 (calorie ratio of claim 1) it is 38.9 g (table 34, line 19). This confirms that the two studies cannot be compared.

Furthermore, the only conclusion on kidney function in study 12 is that "high protein seemed to raise kidney weights, which is a consistent finding in our studies.

That observation raises many questions about safety and kidney damage in the long run, so protein levels much above 30% are questionable" (paragraph [0092]). In this study, "high protein" refers to a diet in which 30% of the total calories are proteins. This is the case in the Zone-favourable diet, but in claim 1 the value is even slightly higher: one third. Therefore, if anything, the skilled person would have expected a higher risk of kidney damage after administration of a diet with the calorie ratio of claim 1.

In summary, the patent's disclosure does not allow to conclude that the features of claim 1 have any effect, let alone a beneficial effect, on kidney function.

2.3.6 Thus, the patent in suit does not support the appellant's ambitious technical problem, in particular as regards any effect on kidney function. Instead, the objective technical problem consists in providing an alternative composition for lowering insulin resistance. There is no reason to doubt that this technical problem is solved.

2.4 Obviousness

2.4.1 The appellant argued that the skilled person would have had no motivation to modify the protein to fat to carbohydrate calorie ratio of the closest prior art (30:30:40) and provide the calorie ratio of claim 1 (1:1:1).

2.4.2 However, O1-D13/19 already suggests the calorie ratio of claim 1.

2.4.3 In chapter 7 (pages 65 to 76) of O1-D13/19 (figures 7-3 and 7-4), the Zone-favourable diet is described as a

diet in which the calorie ratio of protein to fat to carbohydrate is 30:30:40. This chapter bears the title "Boundaries of the Zone" and describes the calorie compositions of various diets, e.g. the Zone-favourable diet and a typical high carbohydrate diet. On page 72, it is underlined that the protein to fat calorie ratio is 1:1, as is the case in several other diets. As to the protein to carbohydrate calorie ratio (in the following: protein-to-carbohydrate ratio), the ideal value is 0.75. But there is "a range of beneficial protein-to-carbohydrate ratios that are still Zone-favorable – between about 0.6 and 1.0" (page 65, third and fourth paragraph and figure 7-1). The same information is conveyed in figure 7-6 (page 75): in the diagram of this figure, the protein-to-carbohydrate ratio between 0.6 and 1.0 indicates the "Boundaries for Entry into the Zone". Page 76 (second full paragraph) explicitly instructs the reader to "maintain that target ratio of protein-to-carbohydrate between 0.6 and 1.0, with an ideal target ratio of 0.75".

From all this information in chapter 7, the skilled reader would have concluded that the ideal Zone-favourable diet has a protein to fat to carbohydrate calorie ratio of 30:30:40. But they would also have taken into account the protein to fat calorie ratio of 1:1 and the protein-to-carbohydrate ratio of between 0.6 and 1. From these two ratios, they would have understood that a diet with a protein to fat to carbohydrate calorie ratio of 1:1:1 would still provide the effects of the Zone-favourable diet.

2.4.4 The appellant argued that according to O1-D13/19, the width of protein-to-carbohydrate ratio for entering the Zone was dependent on the individual's genes and insulin response. In its view, the value range of the

protein-to-carbohydrate ratio of between 0.6 and 1 was only applicable to specific individuals.

However, the protein-to-carbohydrate ratio of between about 0.6 and 1 is explicitly disclosed as beneficial (page 65, fourth paragraph). The following two paragraphs describe that the width of the range depends on the individual's insulin response. If low, the person could eat more carbohydrates and still maintain a protein-to-carbohydrate ratio suitable for entering the Zone. In other words, if the individual's insulin response is low, the protein-to-carbohydrate ratio may be low (i.e. 0.6). But this statement, and the following paragraphs on page 66, do not detract from the fact that the beneficial protein-to-carbohydrate ratios that are still Zone-favourable encompass the value 1.0. This statement is found throughout chapter 7, at the beginning, on page 65, and at the end, on pages 75 and 76.

- 2.4.5 The appellant also argued that the term "between about 0.6 and 1.0" for the protein-to-carbohydrate ratio on page 65 of O1-D13/19 would usually be interpreted to mean values greater than 0.6 and lower than 1.0. In its view, the boundary value of 1.0 had to be crossed to arrive in the favourable zone.

However, the appellant's interpretation is not persuasive. The appellant did not explain why this is the usual interpretation and why it applies to this passage. Moreover, there is nothing in O1-D13/19 to support the appellant's view that stepping on the border (i.e. precisely the value 1.0) amounts to going outside the range of a beneficial protein-to-carbohydrate ratio. Firstly, the value range is preceded by the qualifier "about". Secondly, the

sentence "Not higher, not lower." right after the range of beneficial protein-to-carbohydrate ratios (page 65, fourth paragraph) indicates instead that the value 1.0 is included in the range.

- 2.4.6 The following concerns the second distinguishing feature, namely the amount of linoleic acid in the fat source of about 2% to about 10% of the calories in the composition.

The appellant argued that there was no suggestion in the prior art to add linoleic acid to a composition having the calorie ratio of claim 1. It also submitted that O1-D15 referred to recommended daily intakes and was silent on insulin resistance.

- 2.4.7 This is not convincing. In the composition referred to in claim 1, the fat source supplies one third of the total calories. As the opposition division correctly noted, the human body cannot produce linoleic acid. This is an essential fatty acid. The skilled person providing a nutritional formulation which replaces a diet that is administered over a prolonged period would have observed conventional dietary recommendations. Therefore, they would have used linoleic acid as part of the fat source and provided it in appropriate amounts. Suitable amounts (5% to 10% based on the energy, i.e. calories) are disclosed on page 187 of O1-D15, a handbook on dietary reference intakes. This book is considered common general knowledge which would have been known to the skilled person. The amounts disclosed in O1-D15 fall within the amount of linoleic acid given in claim 1.

- 2.4.8 The appellant's argument that O1-D15 does not mention insulin resistance is not relevant. The closest prior

art already solves this technical problem, and the problem that the skilled person would have had to solve was merely to provide an alternative formulation or composition. Moreover, there is nothing in the art, and in particular not in the closest prior art or O1-D15, to suggest that including linoleic acid as part of the fat source would provide adverse effects on insulin resistance.

2.4.9 In summary, it would have been obvious for the skilled person to modify the closest prior art by providing the protein source, the fat source, and the carbohydrate source in a calorie ratio of 1:1:1 and a fat source with linoleic acid in an amount described in claim 1.

2.5 Therefore, the subject-matter of claim 1 of auxiliary request 5 lacks an inventive step (Article 56 EPC). As explained above (point 2.1), the same conclusion applies to all higher-ranking requests in the proceedings.

3. *No remittal*

3.1 The appellant requested that if the board found that the main request was inventive over document O1-D13/D19 in combination with O1-D17, and the board was going to also consider inventive step in light of document O1-D15, that the case be remitted to the department of first instance for further prosecution. In support of this request, it submitted that the purpose of the appeal proceedings was to review the decision under appeal. The opposition division's reasoning for concluding that claim 1 of the requests under examination lacked inventive step was based on document O1-D13/D19 as the closest prior art in combination with

O1-D17. To use O1-D15 with the closest prior art would go beyond a mere review of the decision under appeal.

- 3.2 At the oral proceedings, the appellant did not object to discussing auxiliary request 5 at the beginning of the oral proceedings. The appellant clarified that its intention was to prevent the examination of a claim based on O1-D13/19 as the closest prior art in combination with O1-D15.
- 3.3 It is true that in accordance with Article 12(2) RPBA 2020 the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner.
- 3.4 However, in accordance with Article 12(1) (a) RPBA 2020, appeal proceedings must be based on "the decision under appeal and minutes of any oral proceedings before the department having issued that decision".
- 3.5 Under these provisions, there is no reason to disregard O1-D15. At the oral proceedings before the opposition division, the opponents discussed inventive step using this document in combination with the closest prior art O1-D13/19. Opponent 1's view was that O1-D15 taught "useful amounts of linoleic acid". This is manifest from the minutes (point 3.4). The decision under appeal also refers to this document (page 18, second and third paragraph).
- 3.6 In accordance with Article 11 RPBA 2020, the board must not remit a case "unless special reasons present themselves for doing so".
- 3.7 The board fails to see that the use of a different secondary document (O1-D15) instead of the one which

the opposition division used in finding that the requests before them lacked inventive step (O1-D17) constitutes special reasons for remittal. This is all the more so because O1-D15 had been discussed during the opposition proceedings and the opposition division had also acknowledged this, both in the minutes and the decision. Moreover, the appellant had ample time to address this document and did so after receiving the board's communication under Article 15(1) RPBA. There, the board drew the parties' attention to this document and the point it wished to discuss ("the feature that greater than about 2% the total calories of the composition are in the form of linoleic acid appears to correspond to a conventional dietary recommendation (O1-D15)", point 3.5.2).

3.8 To conclude, there is no reason to remit the case to the opposition division.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



A. Nielsen-Hannerup

A. Haderlein

Decision electronically authenticated