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Datasheet for the decision of 14 March 2023

Case Number: T 2733/19 - 3.3.07

Application Number: 12786858.6

Publication Number: 2768324

A61K35/20, A61P3/04, A23L33/19, IPC:

A23L33/10

Language of the proceedings: ΕN

Title of invention:

USE OF WHEY PROTEIN MICELLES FOR ENHANCING ENERGY EXPENDITURE AND SATIETY

Patent Proprietor:

Société des Produits Nestlé S.A.

Opponent:

Arla Foods amba

Headword:

Whey protein micelles/NESTLE

Relevant legal provisions:

EPC Art. 100(b)

Keyword:

Sufficiency of disclosure - main request (yes)

Decisions cited:

T 0789/89, T 0629/90



Beschwerdekammern **Boards of Appeal** Chambres de recours

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

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Case Number: T 2733/19 - 3.3.07

DECISION of Technical Board of Appeal 3.3.07 of 14 March 2023

Société des Produits Nestlé S.A. Appellant:

Entre-deux-Villes (Patent Proprietor)

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Representative: Rupp, Christian

> Mitscherlich PartmbB Patent- und Rechtsanwälte

Sonnenstraße 33 80331 München (DE)

Respondent: Arla Foods amba Sønderhøj 14 (Opponent) 8260 Viby J (DK)

Representative: Guardian

> IP Consulting I/S Diplomvej, Building 381 2800 Kgs. Lyngby (DK)

Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 7 August 2019 revoking European patent No. 2768324 pursuant to

Article 101(3)(b) EPC.

Composition of the Board:

A. Usuelli Chairman

Members: J. Molina de Alba

L. Bühler

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Summary of Facts and Submissions

I. The decision under appeal is the opposition division's decision revoking European patent No. 2 768 324. The decision was based on the patent as granted (main request) and the claims of ten auxiliary requests.

The patent had been granted with seven claims. Granted independent claims 1 and 6 read as follows:

- "1. Whey protein micelles for use in the prevention or treatment of overweight and/or obesity in a subject, wherein the whey protein micelles are administered to said subject in combination with a meal, wherein the meal comprises whey protein isolates, native or hydrolyzed milk proteins, free amino acids, or a combination thereof."
- "6. Non-therapeutic use of whey protein micelles to increase satiety and/or postprandial energy expenditure in a subject, wherein the whey protein micelles are administered to said subject in combination with a meal, wherein the meal comprises whey protein isolates, native or hydrolyzed milk proteins, free amino acids, or a combination thereof."
- II. The following documents are referred to in this decision:
 - D1 EP 1 839 492
 - D6 K.J. Acheson *et al.*, Am J Clin Nutr, 2011, 93, 525-34
 - D7 WO 2011/112695
 - D22 EP 2 768 323

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III. In the decision under appeal, the opposition division held that the subject-matter of the main request was not sufficiently disclosed. The patent did not make credible that the combination of whey protein micelles with a meal as defined in claims 1 and 6 achieved the intended effects, i.e. preventing or treating overweight and/or obesity (claim 1) and increasing satiety and/or postprandial energy expenditure (claim 6).

For the same reasons, the subject-matter of auxiliary requests 1 to 8 was also not sufficiently disclosed. The two additional auxiliary requests were not admitted into the opposition proceedings.

- IV. The patent proprietor (appellant) filed an appeal against the opposition division's decision. With the statement of grounds of appeal, the appellant maintained the requests on which the decision under appeal was based and filed additional claim requests.
- V. In its reply to the statement of grounds of appeal, the opponent (respondent) requested that the appeal be dismissed.
- VI. The board scheduled oral proceedings in line with the parties' requests and gave its preliminary opinion on the case.
- VII. Oral proceedings were held before the board on 14 March 2023. During the oral proceedings, the respondent withdrew its opposition, thus ceasing to be a party to this appeal proceedings. At the end of the oral proceedings, the board announced its decision.

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

The subject-matter of claim 1 as granted was sufficiently disclosed. Whey was known to provide health benefits including muscle development, weight management and satiety (patent, paragraph [0005]). The energy expenditure and satiating effect of protein-rich meals were higher than those of carbohydrate-rich meals, especially when the protein was whey (D6, cited in paragraph [0006] of the patent). The example and Figures 1 to 3 of the patent demonstrated that the high postprandial peaks of plasma amino acid concentrations produced by meals containing whey protein isolates (WPI) or whey protein micelles (WPM) were similar, the peak of WPM being delayed by approximately 30 minutes. Therefore, the combination of WPM and WPI in a meal produced elevated plasma amino acid concentrations for an extended period of time compared to WPI alone. This implied a higher energy expenditure, muscle protein synthesis and satiety (patent, paragraphs [0016] and [0017]), which were directly linked to a reduced caloric intake and an increase of lean body mass.

The composition of the meal defined in claim 1 did not need to be limited. The skilled person knew what meals could be reasonably used in the context of the prevention or treatment of overweight and obesity.

The subject-matter of claim 6 as granted was also sufficiently disclosed. D6 showed in Figure 2 and Table 4 that whey protein produced both energy expenditure and satiety. It was not necessary to show that whey protein had a better performance than other proteins.

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IX. The appellant requested was that the decision under appeal be set aside and that the patent be maintained as granted.

Reasons for the Decision

- 1. At the end of the oral proceedings before the board, the respondent withdrew its opposition and ceased to be a party to these appeal proceedings (T 789/89, OJ EPO 1994, 482, headnote). The withdrawal of the opposition did not terminate the proceedings since the opposition division had revoked the patent and this decision had been appealed (T 629/90, OJ EPO 1992, 654, headnote). Therefore, the appeal proceedings were continued with the appellant as the sole party.
- 2. Sufficiency of disclosure (Article 100(b) EPC) patent as granted
- 2.1 The opposition division held that the subject-matter of independent claims 1 and 6 as granted was not sufficiently disclosed. It did not dispute that the skilled person was able to prepare whey protein micelles (WPM) and to combine them with a meal comprising whey protein isolates (WPI), native or hydrolysed milk proteins, free amino acids, or a combination of these. The issue at stake was whether the combination of WPM with the meal defined in the claims was suitable for preventing or treating overweight and obesity (claim 1) and for increasing satiety and postprandial energy expenditure (claim 6).
- 2.2 The patent discloses in paragraphs [0002], [0003] and [0006] the common general knowledge that overweight and

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obesity develop when energy intake is greater than energy expenditure and that an increased proportion of proteins in a meal reduces the energy intake in two ways. On the one hand, proteins stimulate energy expenditure in the postprandial period because the energy cost of digesting, absorbing and metabolising proteins is greater than that of digesting, absorbing and metabolising carbohydrates or fats. On the other hand, proteins are more satiating than carbohydrates and fats.

This common general knowledge was also disclosed in document D6 (page 525, left-hand column, first paragraph to right-hand column, first paragraph; page 532, right-hand column, second paragraph), cited in paragraph [0006] of the patent, and was confirmed by the respondent in the written appeal proceedings (reply to the statement of grounds of appeal, page 17, last paragraph) and at the oral proceedings before the board.

2.3 It follows that increasing the proportion of proteins in a meal results in an increase in postprandial energy expenditure and satiety and, consequently, has a beneficial effect in preventing or treating overweight and obesity. This is in line with the conclusion in D6, page 525, right-hand column, lines 2 to 5, that "isocaloric diets composed of more protein than habitually consumed should provide potential benefits for those with, or susceptible to, metabolic dysregulations associated with obesity-related disorders".

As WPM is a form of whey protein, its incorporation into a meal increases the postprandial energy expenditure and satiety of the meal and is a suitable

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measure for preventing or treating overweight and obesity. Therefore, in light of the common general knowledge alone, the subject-matter of claims 1 and 6 as granted is sufficiently disclosed.

The opposition division (decision under appeal, point 3.4) acknowledged that proteins in general, and whey protein in particular, are known to provide an optimised balance between energy intake and energy expenditure. However, it considered that the combination of WPM with the meal of claim 1 would not be suitable for preventing or treating obesity in three circumstances: if obesity had a genetic or endocrine origin, if the caloric content of the meal was excessive, or if the patient had a sedentary lifestyle. As claim 1 did not contain any limitations related to these circumstances, it was not credible that the combination of WPM with the meal of claim 1 was generally suitable for preventing or treating obesity.

The board disagrees. The postprandial energy expenditure of a protein is the energy cost of digesting, absorbing and metabolising the protein, processes that occur irrespective of the patient's level of physical activity and genetic or endocrine conditions. Therefore, the combination of WPM with a meal will increase the protein content of the meal and consequently postprandial energy expenditure and satiety, even if the patient does not exercise regularly or has a genetic or endocrine disorder.

With regard to the alleged need for limiting the caloric content of the meal in claims 1 and 6, the board notes that the increase in energy expenditure and satiety of the meal resulting from the incorporation of WPM will arise irrespective of the total energy content

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of the meal. Therefore, WPM will provide a benefit for the prevention or treatment of obesity by reducing the total energy intake, even if this intake is high. But more importantly, considering the patient's circumstances, the skilled person in the field of nutritional health will know the type and caloric content of the meals adequate for each patient. It cannot be assumed that because the meal of claim 1 is not explicitly limited in its caloric content, the skilled person would not know which meals to prescribe or would consider meals that are unreasonable and go against the effect intended by the treatment.

2.5 The opposition division (decision under appeal, points 3.5.1 to 3.5.3) also examined whether the experimental evidence in the patent, in particular the different postprandial kinetics of WPM and WPI shown in Figures 1 to 3, made credible that the combination of WPM with the meal of claim 1 was suitable for preventing or treating obesity. It concluded that this was not the case.

As explained above (point 2.3), the subject-matter of claim 1 is sufficiently disclosed in light of the common general knowledge alone. The different kinetics of WPI and WPM do not play any role for sufficiency since the suitability of the combination of WPM with the meal of claim 1 for preventing or treating obesity lies on the principle that proteins increase postprandial energy expenditure and satiety compared to carbohydrates and fats. Whether the increase in energy expenditure and satiety produced by WPM is higher or lower than the increase produced by WPI or any other protein source is irrelevant to this issue.

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2.6 The arguments on sufficiency of disclosure put forward by the former respondent in the appeal proceedings were also based on the lack of limitation of the meal in claims 1 and 6 and on an alleged lack of experimental evidence showing a relationship between the different kinetics of WPI and WPM shown in Figures 1 to 3 of the patent and the prevention or treatment of obesity.

As indicated above (points 2.3 and 2.4), in this case, neither experimental evidence nor a limitation of the meal of claims 1 and 6 is required for acknowledging sufficiency of disclosure.

- 2.7 Therefore, the ground for opposition of Article 100(b) EPC does not preclude the maintenance of the patent as granted.
- 3. Continuation of the proceedings (Article 111(1) EPC)

The only ground for opposition dealt with in the decision under appeal was sufficiency of disclosure, but the grounds of lack of novelty and inventive step had also been raised in the opposition proceedings. Therefore, the question arose whether the case should be remitted to the opposition division for the assessment of novelty and inventive step.

The appellant and the former respondent had requested (appellant's letter dated 2 February 2023, point 1; reply to the statement of grounds of appeal, point 1.2) that if the patent was found to meet the requirement of sufficiency of disclosure, the board continue the examination of the case. Therefore, after having concluded at the oral proceedings that the patent invention was sufficiently disclosed, the board

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continued the examination of the case as to novelty and inventive step (Article 100(a) EPC).

4. Novelty (Articles 100(a) and 54 EPC) - patent as granted

The former respondent had argued (reply to the statement of grounds of appeal, points 4.1 and 4.2) that documents D1 and D7 anticipated the subject-matter of claim 1 as granted. The documents had very similar disclosures and were directed to the preparation and uses of WPM starting from whey proteins. In the former respondent's view, the decisive passages for novelty were paragraph [0040] of D1 and paragraph [0095] of D7. These passages taught that one of the health benefits of whey proteins was "the control of blood glucose such that they are suitable for diabetics". The former respondent considered that the control of blood glucose suitable for diabetics was an implicit disclosure of "suitable for the treatment and/or prevention of overweight and/or obesity" because the treatment of overweight and obesity was based on a control of blood glucose levels. Therefore, the edible products containing WPM illustrated in the examples of D1 (Examples 9, 16, 17 and 20) and D7 (Examples 5, 8, 9, 16, 17, 19 and 20), which could be ingested in combination with a meal, anticipated the subject-matter of claim 1 as granted.

This argument is not convincing. Even if the control of blood glucose and the prevention or treatment of overweight and obesity may be related, they are different indications. In general, the prevention and treatment of overweight and obesity does not require a control of blood glucose levels but a control of the balance between energy intake and expenditure. In

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contrast, D1 and D7 refer to the control of blood glucose in the context of diabetes, a condition in which the control of blood glucose is of paramount importance for preventing a broad range of serious health consequences such as hyperosmolar coma, nephropathy, retinopathy, etc. At least for this reason, D1 and D7 do not anticipate the subject-matter of the claims as granted.

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5. Inventive step (Articles 100(a) and 56 EPC) - patent as granted

In these appeal proceedings, the former respondent raised an inventive-step objection starting from document D6 as the closest prior art. However, the former respondent's formulation of the objective technical problem and its subsequent discussion of obviousness were not directed to the prevention or treatment of overweight and obesity but to the control of blood glucose in subjects predisposed to or suffering from insulin resistance, metabolic syndrome, glucose intolerance and type 2 diabetes (see reply to the statement of grounds of appeal, page 18, paragraphs 2 to 6). Therefore, the former respondent's objection was not suitable for substantiating a lack of inventive step of the subject-matter of claims 1 and 6 as granted.

This deficiency in the former respondent's objection was noted by the appellant in its letter dated 16

November 2020 (page 18, paragraph 5) and by the board in its communication in preparation for the oral proceedings (point 4), but the respondent did not react to this point it its subsequent submissions. Therefore, the board agrees with the appellant that there is no

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valid inventive-step objection on file in these appeal proceedings.

6. It follows from the above that none of the grounds for opposition raised in these appeal proceedings (Articles 100(a) and (b) EPC) precludes the maintenance of the patent as granted.

Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The patent is maintained as granted.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Usuelli

Decision electronically authenticated