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**Datasheet for the decision
of 15 February 2024**

Case Number: T 2066/21 - 3.3.09

Application Number: 12773336.8

Publication Number: 2768322

IPC: A23L33/19, A61K35/20, A61P21/06

Language of the proceedings: EN

Title of invention:
WHEY PROTEIN MICELLES AGAINST MUSCLE ATROPHY AND SARCOPENIA

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
Fresenius Kabi Deutschland GmbH
Arla Foods amba

Headword:
Whey protein micelles against muscle atrophy or sarcopenia/
NESTLÉ

Relevant legal provisions:
EPC Art. 100(c), 123(2)

Keyword:
Amendments - allowable (no)



Beschwerdekammern

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Case Number: T 2066/21 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 15 February 2024

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
19 October 2021 concerning maintenance of the
European Patent No. 2768322 in amended form.**

Composition of the Board:

Chairman A. Haderlein
Members: F. Rinaldi
 D. Prietzel-Funk

Summary of Facts and Submissions

- I. This decision concerns the appeals filed by all of the parties to the opposition proceedings (the patent proprietor and opponents 1 and 2). The appeals aim at setting aside the opposition division's interlocutory decision that the European patent as amended met the requirements of the EPC.
- II. Opponent 1 requested in its notice of opposition that the patent be revoked under Article 100(c) EPC.
- III. In the decision under appeal, the opposition division found that claim 1 of the patent as granted (main request) did indeed involve added subject-matter. However, the version of auxiliary request 1 pending at that time was found to be allowable.
- IV. During the appeal proceedings, the patent proprietor filed several claim requests. Its final requests were the main request (patent as granted) and auxiliary request 9 as filed with its reply to the opponents' statement setting out the grounds of appeal.
- V. The claims relevant to this decision are claim 1 of the main request and claim 1 of auxiliary request 9.

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

"Whey protein micelles in combination with whey protein in the form of whey protein isolates and/or milk, for use in the treatment and/or prevention of a medical condition selected from muscle atrophy or sarcopenia in

a patient, wherein the whey protein micelles are to be administered to the patient in a daily dose of at least 20 g dry weight."

Claim 1 of auxiliary request 9 is based on claim 1 of the patent as granted but contains the following additional feature:

"wherein the whey protein micelles are administered to the patient in combination with a meal".

VI. Final requests

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of auxiliary request 9 as filed with its reply to the opponents' statement setting out the grounds of appeal.

Opponents 1 and 2 requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

1. *Patent*

1.1 According to paragraph [0001], the patent relates to whey protein micelles for use in the treatment of a condition linked to a reduced concentration of plasma amino acids in a patient. The patent specifies that the condition is muscle atrophy or sarcopenia.

1.2 Claim 1 of the patent as granted involves the use of whey protein micelles in combination with whey protein in the form of whey protein isolates and/or milk.

2. *Main request - amendments*

2.1 In the decision under appeal, the opposition division decided that claim 1 of the main request involved added subject-matter. The combination of whey protein micelles with whey protein isolates and/or milk was only disclosed in the context of administering a meal. Furthermore, the application as filed contained no disclosure of a meal consisting exclusively of the protein combination of claim 1. Therefore, the term "comprising" in granted claim 1 could not be interpreted as "consisting of". The term "meal" was not redundant and for this reason it was not possible to delete it.

2.2 The patent proprietor contested this finding and argued as follows. Firstly, the application as filed provided a literal disclosure that the meal mentioned therein consisted only of the whey proteins of claim 1. Secondly, the skilled person would have understood that whey protein micelles and whey protein in the form of whey protein isolates and/or milk were the only active substances of medical use claim 1. Therefore, the meal was not a mandatory feature of the administration set out in claim 1. Hence, it was possible to disregard or delete the feature relating to the meal without adding subject-matter.

2.3 The question is how the application as filed discloses the administration of whey protein micelles in combination with whey protein in the form of whey protein isolates and/or milk.

- 2.4 The focus of the application as filed is on the use of whey protein micelles. The invention is based on the finding that whey protein micelles consumed as part of a meal induce the same high plasma aminoacidemia as an iso-caloric and iso-nitrogenous control meal with whey protein isolates. This disclosure is found in the application as filed, e.g. in the figures and in the passage bridging pages 5 and 6. Starting at the bottom of page 9, it is then set out that most meals comprise proteins from different sources (milk, plant and/or animal) and that advantageously whey protein micelles are administered in combination with such a meal. This is stated to modify the postprandial plasma amino acid peak.
- 2.5 The description of embodiments of whey protein micelles in combination with whey protein in the form of whey protein isolates and/or milk begins on page 10 of the application as filed. It is stated there that whey protein micelles are administered with a meal comprising whey proteins in the form of whey protein isolates or milk.
- 2.6 A corresponding disclosure is also found in dependent claim 6 of the application as filed. This is the only claim of the application as filed that mentions whey protein isolates. The disclosure there is that the meal which comprises whey protein micelles also comprises whey protein isolates.
- 2.7 Also in light of the example of the application as filed, the skilled person would have no reason to interpret the expression "meal" as consisting solely of whey protein micelles and whey protein. The experiments in the example involve a meal that includes

considerable amounts of other nutrients (lipids, carbohydrates and fibres).

- 2.8 As an intermediate conclusion, there is no disclosure supporting the allegation that a meal within the context of the application as filed can consist solely of whey protein micelles and whey protein in the form of whey protein isolates and/or milk. Instead, the application as filed discloses meals that comprise other ingredients (proteins from other sources, carbohydrates, fats, fibres).
- 2.9 The patent proprietor referred to a passage starting on page 11, line 23, of the application as filed. In its view, this passage, and in particular the expression "such a meal", provided a literal disclosure for the meal consisting of whey protein micelles in combination with whey protein in the form of whey protein isolates and/or milk.
- 2.10 The passage cited by the patent proprietor reads as follows:

"In a further aspect, the invention relates to a meal replacement comprising whey protein micelles which further comprises whey protein isolates, hydrolyzed milk proteins, free amino acids or any combination thereof.

As indicated above, it is of an advantage to combine the administration of whey protein micelles with whey proteins in the form of WPI, milk and/or even free amino acids to optimally induce and extend a hyper-aminoacidemia upon consumption of such a meal."

2.11 This passage again underscores, as does the rest of the description, the fact that the combination of proteins of claim 1 are provided as a meal (replacement). The patent proprietor's understanding of the term "such a meal" in this context is not convincing. This interpretation does not take account of what the skilled person understands, having read the entire application. As is unambiguously disclosed throughout the application as filed, the administration and the effects observed occur following the administration of a meal.

2.12 In view of this, the patent proprietor's argument that whey protein micelles and whey protein are the sole active substances, meaning that the meal is irrelevant and the feature can be disregarded, is not conclusive either. The invention disclosed in the application as filed concerns the effect of a meal comprising whey protein micelles and whey protein in the form of whey protein isolates and/or milk and its postprandial effect.

2.13 In conclusion, the ground for opposition under Article 100(c) EPC prejudices the maintenance of the patent as granted.

3. *Auxiliary request 9 - amendments*

3.1 The feature added to claim 1 of auxiliary request 9 further specifies that the whey protein micelles are administered to the patient in combination with a meal.

3.2 Opponent 1 was of the opinion that this request should not be admitted into the proceedings. In view of the conclusion on allowability, the admittance of this request need not be examined.

- 3.3 As explained above, an amendment to claim 1 that does not disclose a meal comprising whey protein in the form of whey protein isolates and/or milk adds subject-matter.
- 3.4 The patent proprietor argued that claim 1 required whey protein micelles to be administered in combination with a meal. Since the whey protein micelles were administered in combination with whey protein in the form of whey protein isolates and/or milk, all whey proteins were necessarily part of the meal.
- 3.5 This reasoning is not convincing. The feature added to claim 1 implies a certain administration pattern of the daily dose of whey protein micelles in relation to the meal. However, claim 1 still does not define that the meal comprises whey protein micelles and in particular whey protein in the form of whey protein isolates and/or milk. On the contrary, the claim covers therapeutic applications in which neither whey protein micelles nor whey proteins in the form of whey protein isolates and/or milk are comprised in the meal.
- 3.6 In sum, the amendment made to claim 1 is not directly and unambiguously derivable from the application as filed. Claim 1 of auxiliary request 9 therefore involves added subject-matter (Article 123(2) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



K. Götz-Wein

A. Haderlein

Decision electronically authenticated