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**Datasheet for the decision  
of 31 January 2024**

**Case Number:** T 1670/22 - 3.3.09

**Application Number:** 15790998.7

**Publication Number:** 3220751

**IPC:** A23K20/163, A23L33/00,  
A23L33/19, A23L33/21, A23C9/13,  
A61K38/01, A61K35/20,  
A23K20/147

**Language of the proceedings:** EN

**Title of invention:**  
COMPLEXES OF WHEY PROTEIN MICELLES AND PECTIN AND BODY MUSCLE  
PROTEIN SYNTHESIS

**Patent Proprietor:**  
Société des Produits Nestlé S.A.

**Opponent:**  
N.V. NUTRICIA

**Headword:**  
Electrostatic complexes/NESTLÉ

**Relevant legal provisions:**  
EPC Art. 54(2), 56, 83  
RPBA 2020 Art. 12(2), 12(4)

**Keyword:**

Main Request: Sufficiency of Disclosure - (yes); Inventive Step  
- (yes)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
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Case Number: T 1670/22 - 3.3.09

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.09**  
**of 31 January 2024**

**Appellant:** N.V. NUTRICIA  
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**Respondent:** Société des Produits Nestlé S.A.  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 22 April 2022  
rejecting the opposition filed against European  
patent No. 3220751 pursuant to Article 101(2)  
EPC.**

**Composition of the Board:**

**Chairman** A. Haderlein  
**Members:** A. Veronese  
R. Romandini

## Summary of Facts and Submissions

- I. The appeal was filed by the opponent (appellant) against the opposition division's decision to reject the opposition filed against the European patent.
- II. With its notice of opposition the opponent had requested revocation of the patent in its entirety on the grounds under Article 100(a) (lack of novelty and lack of inventive step), 100(b) and 100(c) EPC.
- III. Claims 1, 10 and 11 as granted read:
- "1. Composition comprising electrostatic complexes of whey protein micelles and pectin for use in the treatment or prevention of a condition selected from the group consisting of sarcopenia and muscle atrophy, wherein the weight ratio of whey protein micelles to pectin in the composition is between 30:1 and 0.8:1, and the whey protein micelles are obtainable by adjusting the pH of a demineralized native whey protein aqueous solution to a value between 5.8 and 6.6 and subjecting the aqueous solution to a temperature between 80 and 98°C for a period of between 10 seconds and 2 hours."*
- "10. Non-therapeutic use of a composition comprising electrostatic complexes of whey protein micelles and pectin to maintain weight, increase muscle mass or increase muscle strength wherein the weight ratio of whey protein micelles to pectin in the composition is between 30:1 and 0.8:1, and the whey protein micelles are obtainable by adjusting the pH of a demineralized native whey protein aqueous solution to a value between 5.8 and 6.6 and subjecting the aqueous solution*

*to a temperature between 80 and 98°C for a period of between 10 seconds and 2 hours."*

*"11. Food composition comprising electrostatic complexes of whey protein micelles and pectin wherein the weight ratio of whey protein micelles to pectin in the composition is between 30:1 and 0.8:1, and the whey protein micelles are obtainable by adjusting the pH of a demineralized native whey protein aqueous solution to a value between 5.8 and 6.6 and subjecting the aqueous solution to a temperature between 80 and 98°C for a period of between 10 seconds and 2 hours, wherein the total content of whey protein micelles in the composition is at least 5 wt.%."*

IV. The documents submitted during the opposition proceedings included:

- D1: Dissertation from K.A. Oduse, "Whey protein concentrate and pectin complexes: Fabrication, characterization and applications", Heriot-Watt University, School of Life Sciences, Edinburgh, UK, 8 August 2016
- D1a: Extract from the register of the Heriot-Watt University electronic library relating to D1
- D2: EP 2 583 563 A1
- D3: F.N. Souza et al., Food Research International, 2012, No. 49, pages 560-566
- D4: S. Zhang et al., Food Function, 2014, No. 5, pages 102-110
- D6: EP 1839 492 A1
- D9, D10 and D11: regression analysis of the data in the patent, filed by the proprietor by letter dated 9 March 2021

V. In its decision the opposition division found *inter alia* that:

- The claimed invention was sufficiently disclosed. The patent application made it plausible that the claimed composition was suitable to treat the claimed conditions.
- D1 was rendered available to the public on 9 October 2015, i.e. when it was submitted to the library of Heriot-Watt University. Since the claimed subject-matter enjoyed a priority right, D1 was not part of the state of the art under Article 54(2) EPC.
- The claimed subject-matter involved an inventive step over D2, the closest prior art, whether alone or in combination with the other cited prior art documents. Neither D2, D3 nor D4 provided any incentive to prepare the claimed electrostatic complexes.

VI. With its statement of grounds of appeal the appellant filed the following document:

D15: US 6,475,539 B1

VII. The appellant's arguments can be summarised as follows:

- D15 should be admitted into the appeal proceedings.
- The claimed invention was not sufficiently disclosed. The patent did not make it plausible that the claimed composition was suitable to treat muscle atrophy and sarcopenia; the tests in healthy minipigs were unsuitable to show this effect.

Furthermore, the claims encompassed amounts of complex which were not effective.

- The claimed subject-matter was not novel over D1. D1 was available to the public before the filing date of the application for the opposed patent and was part of the state of the art because the claimed invention did not enjoy a priority right.
  
- The claimed composition did not involve an inventive step over D2, the closest prior art. It differed from that of D2 in that it contained "electrostatic complexes" of whey protein micelles. The tests in the patent were not suitable to show an improvement over the prior art. Thus, the problem was to provide an alternative composition and food for the claimed uses. D1, D3, D4 and D15 provided the incentive to replace the whey protein micelles of D2 with the claimed complexes and to arrive at the claimed solution.

VIII. The proprietor/respondent's arguments may be summarised as follows:

- D15 should not be admitted into the proceedings.
  
- The invention was sufficiently disclosed. The patent taught how to prepare the claimed composition. The tests in the patent and common general knowledge made it credible that this composition induced the claimed effects.
  
- D1 was not rendered available to the public before the filing date of the application for the opposed patent and was not part of the state of the art.

- The claimed invention involved an inventive step starting from D2, the closest prior art. D2 did not disclose the claimed complexes. Example 4 of the patent and D5 showed that these complexes improved postprandial hyperaminoacidemia, reducing the tailing-off effects observed with uncomplexed whey protein. The problem was to provide an improved composition and a food for the claimed therapeutic and non-therapeutic uses. Neither D2 nor the other cited documents provided a hint towards the claimed solution.

### **Reasons for the Decision**

#### 1. *Sufficiency of disclosure*

- 1.1 The appellant disputed the opposition division's finding that the claimed subject-matter was sufficiently disclosed. It argued that the patent did not provide evidence that the purported therapeutic treatment could be achieved, let alone across its entire scope, because the results of the tests carried out on healthy minipigs did not make the treatment of muscle atrophy and sarcopenia plausible.
- 1.2 This argument is not convincing.
- 1.3 The opposed patent relates to a composition for treating and preventing conditions linked to reduced muscle mass and muscle protein synthesis. The composition comprises electrostatic complexes of whey protein and pectin; see paragraph 1 and claim 1.
- 1.4 Example 1 of the patent describes the synthesis and the characteristics of the claimed complexes. There is no

reason to doubt that the skilled person could produce these complexes without undue burden at the filing date.

- 1.5 Example 2 describes tests in minipigs, which show that the blood concentration of leucine, a branched amino acid, increases after the administration of the claimed complex.
- 1.6 As stated in the description of the patent, before the filing date it was well known that foods comprising proteins, such as whey protein, are a source of essential amino acids and promote the synthesis of muscular mass. The relevance of branched amino acids, in particular leucine, for increasing muscle mass is also explained in this section; see the "Background of the invention" and in particular paragraphs [0004] to [0007].
- 1.7 For these reasons, the results in the patent make it credible that administering the claimed composition, comprising whey protein complexes, increases the amino acid concentration in the blood and induces beneficial effects in subjects suffering from conditions characterised by reduced muscle mass, like sarcopenia and muscle atrophy. There is no reason to believe - nor has any evidence been provided - that the results observed in minipigs cannot be generalised to other subjects. There is also no reason to believe that whey protein, when administered in complex form, will not work as an amino acid source promoting the growth of muscle mass.
- 1.8 The appellant also argued that the claimed invention was not sufficiently disclosed because claims 1 and 10 did not specify the amount of complex in the

composition and encompassed amounts which were not effective. Referring to paragraphs [0045] and [0052] and claim 9, the appellant submitted that the patent taught that the total quantity of whey protein micelles in the composition had to be at least 5 wt%. Claims 1 and 10 were not limited by this content and thus encompassed amounts that were not effective.

- 1.9 This argument is not persuasive either. Firstly, paragraph [0045] states that the total amount of complex in the composition "may" be at least 5 wt%. Thus, lower concentrations are not ruled out. From this teaching the skilled person would understand that the amount of micelles in the composition may also be lower than that indicated in paragraph [0052] and claim 9.
- 1.10 Furthermore, the patent provides guidance as to the quantities of micelles and complexes needed to carry out the invention; see paragraph [0040] and example 2. The skilled person would therefore find sufficient information to carry out the invention. It is worth noting that they would avoid concentrations of the complex which are extremely low or extremely high and hence *prima facie* ineffective. Focusing deliberately on compositions comprising negligible or extremely high quantities of complexes would merely be an attempt to tear down the invention rather than build it up, on the basis of the information given. Extremely low or high concentrations of the complex represent embodiments that the skilled person would carefully avoid when construing the claims in a technically sensible manner, relying on the teaching of the patent and common general knowledge.

1.11 For these reasons it is concluded that the claimed invention is sufficiently disclosed (Articles 100(b) and 83 EPC).

2. *Public availability of document D1*

2.1 D1 is the manuscript of a dissertation filed by Mr K.A. Oduse at Heriot-Watt University in Edinburgh, UK. D1a is an extract from the register of the electronic library of Heriot-Watt University.

2.2 The respondent contested the opposition division's finding that D1 was rendered available to the public in October 2015- the date indicated as "date issued" in D1a and as "date submitted" in the declaration signed by the author when filing the manuscript with Heriot-Watt University; see the declaration on page vi of D1.

2.3 The respondent's arguments were not contested and there is good reason to assume that the manuscript was not made available to the public at an earlier date.

2.4 As noted by the respondent, on page vi of D1, Mr Oduse, the author of the manuscript, declares that:

*"My thesis for the award referred to, deposited in the Heriot-Watt University Library, should be made available for loan or photocopying and be available via the Institutional Repository, subject to such conditions as the Librarian may require."*

2.5 This declaration is based on a pre-printed form issued by Heriot-Watt University and makes it more likely than not that the university set specific conditions for rendering the document available to the public and that, when the thesis work was handed over to the

Heriot-Watt University library, it was not automatically rendered available to the public.

2.6 As argued by the respondent, this may have been conditional on an agreement by an adviser or other responsible person at the institute who had to decide that the content of the work could be rendered available to the public. D1a mentions the names of two contributor advisers.

2.7 For these reasons, it is credible that, as argued by the respondent, the manuscript was submitted to Heriot-Watt University in October 2015, corresponding to the entry "dc.date.issued 2015-10" in D1a, but was not rendered accessible to the public at least up to 8 August 2018, corresponding to the entries "dc.date.available 8 August 2018" and "dc.date.accessioned 8 August 2018" in D1a. This date is after the filing date of the application for the opposed patent.

2.8 Therefore, it is concluded that D1 is not part of the state of the art.

### 3. *Novelty*

3.1 The appellant held that the claimed subject-matter lacked novelty over the teaching of D1. However, since D1 is not part of the state of the art, this attack fails.

### 4. *Inventive step*

4.1 The invention on which the opposed patent is based relates to a composition comprising electrostatic complexes of whey protein micelles and pectin for

treating and preventing conditions characterised by reduced concentrations of plasma amino acids and loss of muscle mass, namely sarcopenia and muscle atrophy. The composition aims at increasing the blood concentration of amino acids and at promoting the synthesis of proteins in the organism. The patent teaches that sustained high aminoacidemia is most favourable for maximising the synthesis of muscle protein and for maintaining and even enhancing the muscle mass. The composition according to the invention is to be administered by consumption with the meal; see paragraphs [0001], [0014], [0018] to [0021], [0037] and [0038], the examples and the claims.

*The closest prior art*

- 4.2 The opposition division decided that D2 was the closest prior art. The parties did not contest this, and the board sees no reason to deviate from this choice.
- 4.3 D2 discloses the preparation of compositions comprising whey protein micelles for treating conditions associated with a reduced concentration of plasma amino acids, including muscle atrophy and sarcopenia. The micelles are prepared at a controlled pH at a temperature of 80-98°C, carrying out essentially the same process described in the opposed patent. Furthermore, D2 teaches that administering the whey protein micelles with the meal induces a sustained amino acid response which can prolong the anabolic processes and increase muscle protein synthesis; see paragraphs [0001], [0004], [0012], [0013], [0014] and [0018], the examples and the claims.

*Distinguishing features*

- 4.4 The subject-matter of independent claims 1, 10 and 11 differs from the teaching of D2 in that the claimed composition comprises an "electrostatic complex" of whey protein micelles and pectin instead of a composition comprising whey protein micelles, as such, as disclosed in D2.

*Technical effect*

- 4.5 Example 2 of the opposed patent describes experiments in which test compositions were administered to minipigs together with the meal. After the compositions were administered, the blood concentration of leucine, a branched amino acid, was monitored over time.
- 4.6 The tests compare the effects of i) a composition comprising a complex of whey protein micelles and pectin according to the invention and ii) whey protein micelles in uncomplexed form. The results are shown in Figure 4 of the patent and in the regression analysis conducted on the raw data of the patent, shown in the figures of D9, D10 and D11.
- 4.7 The curves show that a complex of whey protein micelles and pectin reduces the tailing-off effect observed when whey protein micelles are administered in uncomplexed form; see the last part of the curves shown in the aforementioned documents.
- 4.8 Similar results were observed in the experiments described on page 5 of D5, in which the total amount of amino acids was monitored over time.

4.9 The appellant criticised the aforementioned results, arguing essentially the following:

- The alleged reduction of the tailing-off was based on one single data point and only in healthy minipigs.
- Only leucine was measured in the example of the patent.
- Figure 4 of the patent did not show any error bar.
- The figure in D5 contained error bars, but these indicated that there was no significant difference between the composition according to the invention and the reference one, which comprised whey protein micelles in uncomplexed form.

4.10 In its opinion, the results presented by the respondent should be disregarded for these reasons.

4.11 These arguments are not persuasive. Despite the fact that the effect is based on few data points, the results shown in the patent and in D5, as a whole, make it more likely than not that a composition comprising the claimed complex provides a more sustained elevation of blood amino acid compared with the composition comprising whey protein micelles in uncomplexed form, and thus that the claimed composition improves postprandial aminoacidemia, decreasing the tailing-off effect observed with the reference composition.

4.12 Moreover, there is no reason to assume that the results obtained in healthy minipigs cannot be obtained in other subjects, including humans, affected by sarcopenia and muscle atrophy.

- 4.13 The appellant also submitted that the claims specified how to prepare whey protein micelles but not how to make the electrostatic complexes formed between the micelles and pectin. According to the description, the complexes had to be prepared at a pH at which the two components carried opposite charges. Since claim 1 did not specify this pH, it encompassed compositions which did not comprise the complex and did not induce the purported technical effect.
- 4.14 This contention is not persuasive. The skilled person understands that the electrostatic complex of claim 1 is a molecular entity formed by the association of micellar whey protein and pectin, which have opposite charges and are kept together by electrostatic forces. Therefore, the skilled person understands what the claimed electrostatic complex is and also that it can only be formed at a pH at which the two components have opposite charges. Thus, the claims do not encompass anything other than the aforementioned electrostatic complex.
- 4.15 For these reasons the results in the patent and in D5 make it credible that, compared with the comparative composition, which represents the closest prior art, the claimed composition induces a more sustained aminoacidemia, which results in:
- an advantageous effect in the treatment of conditions related to muscle wasting, such as sarcopenia and/or muscle atrophy, as defined in claim 1 and

- an advantageous effect in non-therapeutic applications aimed at increasing muscle mass and strength and maintaining body weight

*Technical problem addressed*

- 4.16 In view of the aforementioned results, the problem addressed cannot simply be regarded as "the provision of an alternative composition for maintaining an elevated concentration of amino acids in a subject", as proposed by the appellant. Rather, it must be regarded as providing an improved composition, preferably in the form of a food, which is effective for inducing the therapeutic and the non-therapeutic effects mentioned in claims 1 and 10.

*Non-obviousness of the proposed solution*

- 4.17 The appellant argued that, starting from D2 and taking account of the teaching of D1, D3, D4 and D15, the skilled person would have considered using complexes of whey protein micelles and pectin in place of the whey protein micelles described in D2.
- 4.18 This argument is not persuasive.
- 4.19 D1 is not relevant because, as mentioned above, it is not part of the state of the art.
- 4.20 D3 does not mention whey protein micelles, let alone their complexes with pectin. In fact, D3 relates to the preparation of substantially different products, namely microparticles comprising a hardened core made of pectin coated with whey protein; see paragraphs 2.1.1, 2.1.3 and 2.2. The whey protein used for the coating is in either heat-treated or native non-heated form. The

heated whey protein was subjected to a heating step at 80°C for 15 minutes. However, the pH, which according to the patent is eminently important to form whey protein micelles, is not indicated. Thus, there is no evidence that micelles were formed during the heating step. Nor is there any evidence that micelles and their complexes were formed when the hardened pectin cores were suspended with the whey protein concentrate. Moreover, D3 does not mention any effect of the disclosed microparticles on postprandial aminoacidemia or muscle growth, let alone the treatment of diseases such as sarcopenia and muscle atrophy. Hence, D3 does not contain any pointer towards the claimed solution.

- 4.21 D4 discusses the effect of pectin on the *in vivo* digestion of whey protein. However, it does not contain any pointer towards the claimed solution either, at least because it does not mention either whey protein micelles or conditions leading to their formation, let alone to the formation of complexes of whey protein micelles and pectin as called for in claim 1. The appellant refers to the whey protein/polysaccharide complexes described on page 103 of D4. Yet the process used to prepare these complexes involves dissolving whey protein at ambient temperature in water (i.e. at a neutral pH) and subsequent contact with pectin. The mixture containing the complex is then heated at 85°C; afterwards the pH is adjusted to between 6 and 7. These conditions are not comparable with the claimed ones, in which the pH of a whey protein solution is adjusted to between 5.8 and 6.6 and the solution is heated to 80°C to 98°C for 10 seconds to 2 hours. Thus, it cannot be assumed that whey protein micelles or their complexes with pectin were formed in the process described in D4.

Hence, D4 does not contain any pointer towards the claimed solution.

4.22 The appellant filed D15 with its statement of grounds of appeal and referred to it in its inventive step discussion. However, since D15 is not admitted into the appeal proceedings, as explained below, it is not taken into account for assessing inventive step.

4.23 For these reasons, it is concluded that the skilled person starting from D2 and confronted with the problem would not have arrived at the claimed solution without inventive effort. Accordingly, the claimed subject-matter involves an inventive step over the cited prior art documents. This conclusion applies to independent claims 1, 10 and 11, as well as to the dependent claims, which are more limited in scope (Article 56 EPC).

## 5. *Admission of D15*

5.1 With its statement setting out the grounds of appeal the appellant filed D15 and requested that it be admitted into the appeal proceedings. The appellant submitted that D15 taught that pectin can be used to stabilise proteins, including whey proteins. Therefore, in its opinion, it would have been obvious to combine the whey protein micelles of D2 with the pectin described in D15. This would have resulted in an electrostatic attachment of the pectin to the surface of the whey protein micelles and a consequent stabilising effect of the whey protein. The appellant also argued that, in view of the opposition division's preliminary opinion, there was no need to file D15 during the proceedings before the opposition division. In its opinion, D15 was filed as a direct response to

the contested decision and had to be admitted into the appeal proceedings.

- 5.2 This argument fails to persuade the board. Firstly, it is not clear from the appellant's statement of grounds of appeal which specific point of the decision under appeal is addressed by the filing of D15. It is therefore not clear why the filing of this document should be regarded as a direct response to that decision. As far as D15 might address an argument relating to the stabilisation of whey protein, it is noted that the respondent had already explained that whey protein micelles were more stable when complexed with pectin in its reply to the notice of opposition, dated 23 February 2021; see page 9, section 5.1, fourth paragraph. Thus, the argument relating to protein stabilisation had been made before the decision under appeal was issued. Hence, there was no reason to file D15 only when filing the statement of grounds of appeal.
- 5.3 Furthermore, D15 relates to the use of pectin to control the viscosity and enhance the physical stability of beverages comprising high amounts of proteins; see column 4, lines 58 to 62 and column 12, lines 30 to 32. It does not relate to the stabilisation of whey protein micelles and whey proteins, as such. Therefore, the teaching of D15 is not *prima facie* relevant to the case in hand.
- 5.4 For these reasons D15 is not admitted into the appeal proceedings (Article 12(2) and (4) RPBA 2020).

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



K. Götz-Wein

A. Haderlein

Decision electronically authenticated