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**Datasheet for the decision  
of 13 November 2025**

**Case Number:** T 1396/23 - 3.3.09

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**Language of the proceedings:** EN

**Title of invention:**  
USE OF WHEY PROTEIN MICELLES AND POLYSACCHARIDES FOR IMPROVING  
INSULIN PROFILE

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

**Opponent:**  
Fresenius Kabi Deutschland GmbH

**Headword:**  
Improving insulin profile/NESTLÉ

**Relevant legal provisions:**  
EPC Art. 56, 83

**Keyword:**

Main request: sufficiency of disclosure and inventive step -  
(yes)

**Decisions cited:**

T 1065/23

**Catchword:**

A substance or composition that induces a therapeutic effect when used to replace a known essential nutrient in a nutritional composition may be considered a "substance or composition" within the meaning of Article 54(5) EPC (See reasons 1.7 - 1.13).



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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Case Number: T 1396/23 - 3.3.09

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.09**  
**of 13 November 2025**

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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 30 May 2023  
rejecting the opposition filed against European  
patent No. 3220752 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 against the opposition division's decision rejecting the opposition filed against the European patent.

II. Claims 1 and 6 of the opposed patent read:

*"1. Composition comprising polysaccharides and whey protein micelles for use in the treatment or prevention of a disorder linked to an increase in plasma postprandial insulin selected from the group consisting of diabetes, for example gestational diabetes; impairment of glucose metabolism; hyperinsulinemia or insulin resistance, in a subject; wherein the polysaccharides have a negative zeta potential at a pH value in the range 2.5 to 4.5 and are selected from the group consisting of alginate, xanthan, pectin, gum karaya, gum Arabic and carrageenan; the weight ratio of whey protein micelles to polysaccharide is between 30:1 and 0.8:1; 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, and the polysaccharides and whey protein micelles are in the form of polysaccharide-whey protein micelle complexes."*

*"6. Process for forming polysaccharide-whey protein micelle complexes comprising the steps of;*

*a. forming whey protein micelles 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.*

*b. combining polysaccharides with an aqueous dispersion of whey protein micelles to form a composition comprising an aqueous dispersion of polysaccharides and whey protein micelles, wherein the polysaccharides have a negative zeta potential at a pH value in the range 2.5 to 4.5 and are selected from the group consisting of alginate, xanthan, pectin, gum karaya, gum Arabic and carrageenan; and the weight ratio of whey protein micelles to polysaccharide is between 30:1 and 0.8:1*

*c. if the pH of the composition comprising an aqueous dispersion of polysaccharides and whey protein micelles is not already between 2.5 and 4.5, then adjusting the pH of the composition to between 2.5 and 4.5 to form polysaccharide-whey protein micelle complexes."*

III. 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 inventive step) and 100(b) (lack of sufficiency).

IV. The documents submitted during the opposition proceedings included:

D1: EP 1839492 A1

D3: WO 2013/057232 A1

D4: WO 2010/112430 A1

D5: The British Nutrition Foundation, 1990, p. 37-40

D6: E. Dickinson, Soft Matter, 2008, vol. 4, p. 932-942

D7: US 6,355,612 B1

D8: J. Mouecoucou et al., J. Dairy Sci., 2003, vol. 86, No. 12, p. 3857-3865

- D9: S. Zhang et al., Food Funct., 2014, vol. 5, p. 102-110
- D10: S. Zhang et al., J. Anim. Sci, 2014, vol. 92, E-Suppl. 2 / J. Dairy Sci. vol. 97, E-Suppl. 1, 0329, p. 163
- D11: S. Zhang et al., Food Funct., 2014, vol. 5, No. 8, p. 1829-38
- D12: R. Tuinier et al., Biomacromolecules 2002, vol. 3, p. 632-638
- D13: C.G. de Kruif et al., Food New Zealand, May/June 2005, p. 23-30
- D14: EP 2074891 A1
- D15: AU 2014253468

V. In its decision, the opposition division found *inter alia* the following.

- The claimed invention was sufficiently disclosed. The lower insulin levels observed when administering the claimed whey protein complexes, as compared with whey protein isolates, made it credible that the claimed compositions improved insulin sensitivity and preserved pancreatic function. The patent provided sufficient information to enable a skilled person to prepare compositions suitable for achieving the stated therapeutic effects.
- The claimed subject-matter involved an inventive step over the cited prior-art documents. D3, which, like the opposed patent, related to the use of whey protein micelles to decrease plasma postprandial insulin, was the closest prior art. D7, D13 and D14 related to different effects and were not suitable starting points. The claimed subject-matter differed from the teaching of D3 in that the whey

protein micelles (WPM) were in complex form with the carbohydrate. The tests in the patent made it credible that the claimed complex reduced postprandial insulin to a greater extent than uncomplexed whey protein isolate (uncomplexed WPI) and uncomplexed whey protein micelles. The objective technical problem was "the provision of an improved whey protein micelle-containing composition for treating diabetes, impaired glucose metabolism, hyperinsulinemia, or insulin resistance by yielding a lower postprandial insulin response". D3 did not suggest preparing the claimed complexes to solve this problem, either alone or in combination with the other cited documents.

VI. The **appellant's arguments** which are relevant for the decision may be summarised as follows.

- The invention was insufficiently disclosed. Claim 1 was formulated in the second medical use format under Article 54(5) EPC. However, it did not specify the patients for which treatment was intended, the form of the composition or the nature and minimum amount of the micellar whey protein-polysaccharide complex in the composition. The claimed complex was a nutritional ingredient, not a therapeutically active agent. Since it could not reach the bloodstream, it could not lower the postprandial insulin response induced by a meal. No test was provided in which a pathologic insulin response was induced after ingestion of a meal, nor one containing a slow protein such as casein that caused a moderate insulin release. The observed effects were only observed in minipigs and could have been induced merely by delayed gastric emptying. The effective doses were not specified.

For these reasons, the claimed therapeutic effect could not be achieved and the claimed invention could not be carried out.

- The claimed invention did not involve an inventive step starting from D3, the closest prior art. The claimed subject-matter differed from the teaching of D3 in that the whey protein micelles were in complexed form. The test with meal C showed that complexation was not associated with the purported effect. The problem could be regarded, at most, as the "reduction of postprandial insulin response of a specific composition comprising WPM". The claimed solution was obvious. D5 to D15 showed that polysaccharides slowed gastric emptying by increasing viscosity, and that they formed complexes with proteins, including whey proteins, slowing down their digestion. As a consequence, they also decreased postprandial insulinaemia. It would thus have been obvious to add polysaccharides to the compositions of D3 to obtain this effect. The micellar whey proteins of D3 could be expected to behave like known non-micellar whey proteins.

VII. The **respondent's arguments** which are relevant for the decision may be summarised as follows.

- The claimed invention was sufficiently disclosed. Claim 1 was in the second medical use format. It defined the patients to be treated, complexes of whey protein micelles and how to prepare them. The tests in the patent confirmed that complexes were formed. More than one protein could bind to a single polysaccharide chain. Claim 1 excluded an excess of polysaccharide which could induce thickening and gelation. The patent showed that the

claimed complexes induced a lower insulin response than isocaloric compositions comprising whey protein isolates and uncomplexed whey protein micelles (uncomplexed WPM). Thus, less insulin was required to clear the same amount of glucose. A cornerstone of diabetes therapy was reducing the insulin response to avoid insulin resistance. Healthy minipigs were suitable models for human responses. Thus, the claimed therapeutic effect was credible. The patent showed how to carry out the invention. There was no need to explicitly mention the effective amount of complex in the claim or to exclude additional ingredients.

- The claimed invention involved an inventive step over D3, the closest prior art. It differed from the teaching of D3 in that the whey protein micelles were complexed with polysaccharides, in the specified ratio. The complexation reduced the postprandial insulin release required to clear the same amount of glucose. Since glycaemia remained unaffected, the observed effect could not be attributed to gelation or delayed gastric emptying. Moreover, there was no evidence that polysaccharides induced gelation in the tested compositions. In the case of meal C, the complexation occurred during digestion. The objective technical problem was providing an improved whey-based composition for treating diabetes by reducing postprandial plasma insulin levels. None of the cited documents suggested replacing whey protein micelles with their complexes to achieve this effect. Only D3 and D15 disclosed whey protein micelles, but not in complex form. The known effects of polysaccharides on gastric emptying, insulinaemia and protein

digestion could not be expected to apply to compositions comprising complexes of whey protein micelles.

### ***Requests***

- VIII. The opponent (appellant) requested that the decision be set aside and that the patent be revoked in its entirety.
- IX. The patent proprietor (respondent) requested that the appeal be dismissed or, alternatively, that the patent be maintained on the basis of one of the auxiliary requests MRa, AR 1 to AR 22 or the corresponding requests AR 1a to AR 22a, filed with the reply to the statement of grounds of appeal.

### **Reasons for the Decision**

#### **Main request** (the patent as granted)

1. *Sufficiency of disclosure*
  - 1.1 The appellant contested the opposition division's finding that the invention defined in claim 1 of the opposed patent was sufficiently disclosed. While the appellant did not dispute that claim 1 related to a medical use and was drafted as per Article 54(5) EPC, it submitted that the claimed therapeutic effect could not be achieved and that the invention could not be carried out by the skilled person. In particular, the appellant argued as follows.
    - The tests in the patent did not make it credible that the claimed whey protein micelle-polysaccharide complexes were formed. Thus, it was

not credible that the complexes induced the observed effect on postprandial insulinaemia. The nature of the complexation and the physical form of the composition were not described either.

- The claimed compositions were unsuitable to induce the claimed therapeutic effect. Whey proteins and whey protein micelle complexes (WPM complexes) were nutrients, not therapeutically active agents. They were more likely to induce than reduce the release of insulin. WPM complexes could not reach the bloodstream and reduce the postprandial insulin response induced by a meal. Unlike drugs, they did not act on a specific target linked to a particular disease. Thus, they could not be used to decrease the postprandial insulin release induced by a meal.
  
- The effects observed in the tests in the opposed patent were obtained by comparing the claimed WPM complex with uncomplexed WPM and with a whey protein isolate, which were digested quickly. No decrease in insulin would have been observed if the WPM complex had been compared with slowly digested proteins like casein. This was evident from D4. An effect could only be demonstrated relative to a "well-defined comparator" that induced a stronger pathological insulin response. No "comparator" was specified in claim 1. The observed results reflected, at most, delayed gastric emptying and slower protein digestion of complexed whey protein micelles (complexed WPM) compared with uncomplexed WPM or whey protein isolate. This was confirmed by paragraph [0014] of the patent. Since claim 1 did not specify the "comparator", a therapeutic effect could not be achieved across the entire scope claimed.

- Claim 1 did not specify the minimum amount of WPM complex necessary to induce the alleged therapeutic effect and did not limit the quantity of additional ingredients.
- The tests were only performed in healthy minipigs. As far as an effect could be acknowledged, it could only be preventive, not therapeutic.

1.2 The board is not convinced by these arguments.

1.3 Claim 1 defines the relevant ingredients, namely complexes between whey protein micelles and specific polysaccharides. The skilled person would understand that a complex is a molecular entity formed by an association between two or more entities, in this case the whey protein micelles and polysaccharides. The ratio of these components and how they can be prepared is specified in claim 1.

1.4 The opposed patent teaches how to prepare the claimed whey protein micelle-polysaccharide complexes, and the results of the light-scattering tests described in examples 1 and 2 and Figures 1 to 5 make it credible that complexes are formed in accordance with the teaching of the patent. Figures 1 and 4 show that, at a pH between 2.5 and 4.5, whey protein micelles and two of the claimed polysaccharides, pectin and carrageenan, have opposite charges and can thus form electrostatic complexes. Figures 2, 3 and 5 confirm that the complexes are formed at the claimed whey protein micelle/polysaccharide ratios. The pattern of the peaks at different ratios in Figure 2, and the disappearance of the peak at pH 4.5 in Figure 5, indicate that WPM complexes were formed. As explained by the respondent,

the size of the complexes increases as the quantities of whey protein micelles increase, because more micelles bind to one single polysaccharide chain. The fact that the claimed weight ratio does not necessarily reflect the stoichiometry between polysaccharides and whey protein micelles is irrelevant. What counts is that the tests make it credible that complexes are formed within the claimed ratios. As explained by the respondent, these ratios exclude the presence of an excess of polysaccharide which could induce thickening or gelation or form aggregates without binding to the micelles.

- 1.5 The appellant asserted that the results in Figures 1 to 5 were not conclusive. The claimed complexes had not been characterised. Only qualitative indications on aggregation at different weight ratios could be inferred from the described light-scattering tests. There was also no evidence that whey protein micelle complexes were formed in the tested meals, which were heat-treated and comprised other ingredients in addition to those claimed.
  
- 1.6 These arguments are not persuasive. As explained above, the patent describes numerous tests and a credible explanation of the observed results. The appellant set out a lengthy analysis of the tests and proposed alternative interpretations of the results. The appellant also mentioned further tests which, in its opinion, should have been conducted to rule out those alternative interpretations. However, it did not provide evidence that convinced the board that the respondent's interpretation of the results was incorrect.

- 1.7 What remains to be decided is whether it is credible that the claimed complexes are suitable for carrying out the therapeutic treatment specified in claim 1.
- 1.8 The appellant did not contest that claim 1 defined a therapeutic method of treatment pursuant to Article 54(5) EPC. It argued, however, that the effect induced by WPM complexes described in the opposed patent was not therapeutic. The claimed complexes provided nutrition but were unsuitable to prevent the claimed conditions, even less so to treat them. Besides that, the purported effect was only observed by reference to a "comparator", namely whey protein isolate or uncomplexed whey protein micelles, which was not defined in claim 1. No effect would have been observed in comparison with other proteins like casein which, as shown in D4, were digested more slowly than whey protein isolate.
- 1.9 These arguments are unconvincing because they fail to consider the framework of the claimed invention and how it would be implemented by the skilled person in the relevant field. Sufficiency of disclosure is not assessed on the basis of the literal wording of the claims taken in isolation. The teaching of the entire patent specification, including the description and any drawings, must be taken into account. The disclosure as a whole is addressed to the skilled person, who may rely on common general knowledge to supplement the information provided in the patent (see Case Law of the Boards of Appeal, 10th edition, sections II.C.3.1 and II.C.4.1).
- 1.10 On reviewing the description of the opposed patent, it becomes immediately apparent that the invention relates to a nutritional composition comprising whey proteins.

Proteins are essential nutrients, and whey proteins are among the most preferred protein sources because they provide all essential amino acids, are easily digestible and are natural, cost-effective by-products of cheese production.

- 1.11 The patent explains that, prior to the filing date, whey protein isolates were considered not only to be essential nutrients but also to be beneficial in reducing the risk of, and treating, metabolic diseases associated with high-fat diets and/or elevated postprandial insulin levels, such as diabetes (see paragraphs [0005] and [0006] and the references cited in those paragraphs). On this basis alone, it is reasonable to assume that the claimed WPM complexes, which contain whey proteins, could likewise induce these effects.
- 1.12 Furthermore, when consulting the description of the opposed patent, the skilled person understands that the claimed WPM complexes are intended to replace the whey proteins conventionally used as a protein source in nutritional compositions. The purpose of doing so is to provide a nutritional composition containing a whey protein source that induces a reduced, yet still adequate, insulin response, thereby preserving pancreatic function and improving insulin sensitivity (see paragraphs [0003] to [0008] and [0014], as well as example 3 of the opposed patent).
- 1.13 In other words, the patent teaches that using the claimed WPM complexes rather than conventional whey proteins is beneficial for subjects who are at risk of or suffer from the diseases indicated in claim 1. It is immaterial what the underlying mechanism of action is, and also whether the complexes act on a specific target

and whether a comparator such as whey protein isolate or uncomplexed WPM is explicitly mentioned in claim 1 - the skilled person would appreciate that the claimed WPM complexes are intended to be incorporated into a nutritional composition in place of whey proteins in order to achieve the stated therapeutic effect. In the context of the invention, the claimed compositions comprising WPM complexes can thus be regarded as "a substance or composition" within the meaning of Article 54(5) EPC that is used to carry out the claimed therapeutic method.

- 1.14 The tests in example 3 of the patent show that meal D - comprising lipids, maltodextrin (a carbohydrate) and a complex of whey protein micelles and pectin (one of the claimed polysaccharides) - induces a substantially lower insulin response compared with isocaloric and isonitrogenous control meals A and B, which comprise uncomplexed WPM or whey protein isolates; see Figure 6. Moreover, Figure 7 shows that the glucose clearance is substantially the same with all the tested compositions. This indicates that less insulin is required to clear glucose from blood after ingestion of meals comprising the WPM complexes.
- 1.15 The test in example 3 shows that meal C - comprising uncomplexed WPM and carrageenan (another claimed polysaccharide) - induces substantially the same effects as meal D comprising the WPM complexes. As explained by the respondent, it is credible that, in the case of meal C, the claimed complexes were formed when this meal reached the acid environment of the stomach.
- 1.16 The appellant disputed the statistical significance of the results in Figure 6, arguing that the pattern of

insulin release observed after administration of whey protein isolates and uncomplexed WPM differed from that shown in Figure 1 of D3.

1.17 These arguments cannot be accepted either. As noted by the respondent, taking into account that:

- meals A and B induce a similar pattern of insulin release with a peak after 30 minutes, which is similar to that shown in Figure 1 of D3, and that
- this peak is not induced by meals C and D,

it is credible that the results are significant and provide reliable evidence that complexed WPM induce less of an insulin release than whey protein isolates and uncomplexed WPM.

1.18 It is also noted that, since the experimental set-up in the patent is different from that in D3, some deviations in the observed insulin release profiles do not undermine the credibility of the results presented in the opposed patent. It is uncontested that claim 1 does not exclude the presence of other ingredients inducing insulin release. However, even if any were present, a reduction in insulin levels would still be expected when the claimed complex is used to replace uncomplexed whey proteins.

1.19 The appellant argued that no effect would have been observed over casein, which was digested more slowly than whey proteins. However, this is incorrect, as Figure 2 of D4 shows that the insulin responses induced by casein and whey protein micelles are very similar. Furthermore, as already explained above, what counts is that an effect is observed when replacing the whey

proteins conventionally used in nutritional compositions.

- 1.20 It is undisputed that optimising the insulin response by improving the body's sensitivity to insulin is a cornerstone of diabetes therapy. A reduction in insulin demand following a meal is beneficial in patients affected by or at risk of developing insulin resistance, type 2 diabetes and other associated metabolic diseases. Accordingly, the results of the tests described in the patent make it credible that the claimed composition is suitable for treating and preventing the diseases indicated in claim 1.
- 1.21 The appellant argued that a decrease in postprandial insulin release could be harmful for a patient already affected by diabetes, and therefore the claimed treatment could not be carried out in such patients. This argument is not persuasive. As the respondent noted, the finding that postprandial insulin release is reduced while plasma glucose levels remain substantially unchanged shows that less insulin is needed to clear the same amount of glucose from the blood. In other words, insulin sensitivity is improved (see also paragraph [0003] of the patent). This effect is beneficial for patients already suffering from the claimed disorders as it enhances glucose clearance and helps prevent the existing disease from worsening.
- 1.22 The appellant criticised that the tests had been conducted exclusively on healthy minipigs, arguing that the observed results could not be extrapolated to humans, particularly individuals affected by metabolic diseases. It further submitted that the effective dosage required to carry out the claimed treatment was not specified.

1.23 However, the appellant has not provided any evidence that minipigs are unsuitable as animal models for the claimed therapeutic uses. It is standard practice to employ animal models, including minipigs, to evaluate the therapeutic effects of active agents. Consequently, in view of the teaching of the patent specification and this common general knowledge, it is credible that the observed reduction in postprandial insulin would also occur in humans at risk of or affected by the relevant diseases. Moreover, although claim 1 does not specify the effective amount of the relevant agents, it is standard practice in second medical use claims not to indicate specific dosages, provided that the skilled person can carry out the invention in practice. In the case in hand, the patent describes the composition of the tested meals. While the weight of the minipigs used in the tests is not explicitly indicated, their average weight can be estimated. Additionally, the patent provides guidance on suitable daily dosages of whey proteins per kilogram of body weight for treated subjects (see paragraphs [0028] and [0053]).

1.24 For these reasons, it is concluded that, on the basis of the teaching of the patent and the common general knowledge at the filing date, the skilled person would be able to carry out the claimed invention. Accordingly, the requirement of sufficiency of disclosure is satisfied. No objections regarding lack of sufficiency were raised against claim 6 as granted.

## 2. *Inventive step*

2.1 The claimed invention relates to a composition comprising WPM complexes (complexes of whey protein micelles and polysaccharides) and to its use in

treating or preventing diabetes and other associated metabolic diseases. The appellant contested the opposition division's finding that the subject-matter of claim 1 involved an inventive step over the prior art.

*Closest prior art*

- 2.2 The opposition division held that D3 represented the closest prior art, and the parties relied essentially on this document as the starting point for assessing inventive step.
- 2.3 Like the opposed patent, D3 relates to the use of whey protein in micellar form to decrease postprandial plasma insulin and to treat or prevent disorders associated with elevated postprandial insulin, such as type 2 diabetes, insulin resistance and metabolic syndrome. As stated in D3, the invention relies on the finding that whey protein micelles - when included in an isocaloric and isonitrogenous meal - significantly reduce the postprandial plasma insulin response compared with whey protein isolates; see page 5, lines 11 to 28, the examples and the claims.
- 2.4 Since D3 relates to a composition comprising whey protein micelles for essentially the same purpose as the invention in the opposed patent, the board sees no reasons to deviate from the opposition division's choice of this document as the closest prior art.
- 2.5 The appellant argued that D7 could also serve as a reasonable starting point to assess inventive step. D7 teaches the use of polysaccharides to slow down the digestion of "fast proteins", induce satiety and reduce food intake and postprandial plasma amino acid levels

(see abstract and summary of the invention). Among a long list of mentioned conditions, only a passing reference is made to obesity (column 5). However, D7 does not mention reducing postprandial insulinaemia or treating diabetes or the other claimed conditions. Moreover, the proteins in D7 are not in micellar form. Accordingly, D7 does not constitute a reasonable starting point for assessing inventive step.

*Distinguishing features*

2.6 The subject-matter of claim 1 differs from the teaching of D3 on account of the following.

- Whey protein micelles are used in the form of a complex with a polysaccharide.
- The polysaccharide has a negative zeta potential at a pH value in the range of 2.5 to 4.5 and is selected from the group consisting of alginate, xanthan, pectin, gum karaya, gum Arabic and carrageenan.
- The weight ratio of whey protein micelles to polysaccharide is 30:1 to 0.8:1.

*Technical effect*

2.7 As already stated above in the context of sufficiency of disclosure, the results of the tests in Figures 1 to 5 of the patent provide evidence that whey protein micelles form electrostatic complexes with the claimed polysaccharides. Figure 6 shows that compositions comprising the WPM complexes reduce postprandial insulinaemia compared with corresponding ones comprising whey protein isolates or uncomplexed WPM.

The fact that, as shown in Figure 7, glucose clearance is substantially unchanged indicates that, when the whey protein micelles are complexed, less insulin is required to clear glucose from the blood after a meal. This makes it credible that the claimed composition is more effective than compositions comprising uncomplexed WPM, as described in D3, at optimising postprandial insulin response and treating and preventing the metabolic diseases listed in claim 1.

2.8 The appellant noted that meal C, which did not contain complexes and was therefore outside the claimed scope, induced the same effects as meal D, which did contain the complexes. It argued that the formation of complexes was not associated with a technical effect, further submitting that conditions in the stomach could vary between subjects, so complexes might not necessarily form under all conditions.

2.9 These arguments are not convincing. As already explained above, it is credible that although meal C did not contain complexes, such complexes were formed *in vivo*, after ingestion, at the pH of the stomach. Thus, even if meal C is considered to be outside the claimed scope, the effects observed after ingestion of meal C are induced by WPM complexes. Meal C demonstrates that the effect can be achieved irrespective of whether the complex is formed before or after ingestion. Since it is well known that the pH of the stomach is typically acidic, and the patent shows that the relevant complexes are formed under acidic conditions, the respondent's interpretation of the results is credible in the absence of any concrete evidence to the contrary.

- 2.10 The appellant further argued that the observed effects could equally be explained by an increase in viscosity and consequent delay in gastric emptying caused by the added polysaccharide. Polysaccharides were known thickening agents capable of increasing viscosity and slowing protein digestion. This provided an additional reason to doubt that the effects observed in the patent were attributable to the WPM complexes.
- 2.11 These arguments are not convincing either. As submitted by the respondent, the fact that whey protein micelles were used in excess in most tests, combined with the observation that no increase in viscosity was detected, makes it credible that the observed effect originated from the WPM complexes themselves rather than from any viscosity increase induced by the polysaccharide. It is further noted that the preferred viscosity of the compositions according to the invention is relatively low, as shown in paragraph [0023] of the patent, and that no gelation occurred even upon heating, as shown in paragraph [0026].
- 2.12 Referring to Figure 5 of the opposed patent, the appellant argued that, assuming that WPM complexes were formed, such complexes would also be present in compositions comprising a 50:1 whey protein micelle/polysaccharide ratio, which was outside the claimed scope. In the appellant's view, this showed that the boundaries defining the claimed ratio were selected arbitrarily and were not associated with the claimed effect.
- 2.13 This argument is not persuasive either. The mere fact that the cut-off values of the claimed whey protein micelle/polysaccharide ratio exclude a composition which contains WPM complexes and is capable of

achieving the claimed effect does not, in itself, render the selection of these cut-off values "arbitrary" or make the claimed subject-matter obvious over the prior art. What is decisive is that the effect obtained when operating within the claimed range exceeds that achievable on the basis of the prior-art teaching (see decision T 1065/23, points 5.19 to 5.21 of the reasons). As explained, this is credibly demonstrated by the results discussed above.

*Underlying technical problem*

- 2.14 Taking into account the aforementioned results, the objective technical problem starting from D3 as the closest prior art can be considered to be providing an improved whey-based composition for treating diabetes and the other associated metabolic disorders specified in claim 1 by optimising the postprandial insulin response.
- 2.15 This means that the appellant's less ambitious formulation of the technical problem as merely achieving a "reduction of postprandial insulin response of a specific nutritional composition comprising WPM" is not convincing.

*Non-obviousness of the claimed solution*

- 2.16 The appellant argued that, starting from D3, which taught, as the closest prior art, that the postprandial insulin response of whey protein isolates was reduced by micelle formation, the skilled person seeking to further reduce the postprandial insulin response of whey protein micelles, would have considered adding polysaccharides. The prior art provided several pointers towards this approach, as follows.

- Polysaccharides were known to act as thickening agents, increasing the viscosity of nutritional compositions.
- Increased viscosity was believed to slow carbohydrate absorption and gastric emptying, thereby reducing postprandial hyperglycaemia and insulinaemia.
- Certain polysaccharides, such as pectin, were reported to form electrostatic complexes with proteins, slowing their metabolism and digestibility, and could be used to design healthier foods.
- The isoelectric points of whey protein and whey protein micelles were similar.

2.17 In the appellant's view, the skilled person would have expected that adding the claimed polysaccharides to the whey protein micelle compositions of D3 would decrease their viscosity, induce the formation of protein-polysaccharide complexes and reduce the postprandial insulin release. In this context, the appellant drew attention to the following prior-art documents.

- D5 taught that polysaccharides increased the viscosity of protein compositions, delayed gastric emptying and reduced postprandial hyperglycaemia and insulinaemia. Irrespective of whether complexes with whey protein micelles were formed, polysaccharides were expected to raise the viscosity of whey protein micelle compositions and to induce the relevant therapeutic effect.

- D6 taught that charged polysaccharides formed strong electrostatic complexes with oppositely charged proteins. As shown in Figure 12, complexed proteins were less exposed to degradation in the gastrointestinal tract and were consequently digested more slowly. Although D6 related to  $\beta$ -lactoglobulin, whey protein micelles would also have been expected to form complexes with charged polysaccharides, as their isoelectric point was similar. D8 and D9 confirmed that protein digestion was slowed by electrostatic complexation of proteins by polysaccharides.
  
- D7 taught the addition of polysaccharides to slow the digestion of "fast proteins", induce satiety and reduce food intake, which was beneficial in treating obesity, a known risk factor for type 2 diabetes. D7 demonstrated that the formation of complex coacervates between proteins and polysaccharides slowed digestion. Although D7 did not explicitly mention a reduction in insulin levels, it provided the link between slowed digestion and lowered postprandial insulinaemia, thereby offering a pointer towards the claimed solution.
  
- D10 described the pH-triggered intragastric gelation of whey protein and alginate induced by electrostatic complexation. It also discussed the potential effects of gelation on protein digestion and postprandial glycaemic response. Although D10 referred to whey protein isolates rather than whey protein micelles, the skilled person would have expected similar effects to occur with whey protein micelles as their isoelectric point was similar.

- D12 disclosed the electrosorption of pectin onto casein micelles, demonstrating that polysaccharides could form complexes with micellar proteins.
- D13 described the formation of complex coacervates between whey proteins and various anionic polysaccharides, such as gum Arabic, at pH values below the isoelectric pH of the whey proteins. It indicated the pH ranges suitable for obtaining the complex and taught that, by selecting different combinations of proteins and polysaccharides, it was possible to design healthy food systems tailored to consumer needs.
- D14 described compositions that enhanced the feeling of satiety and were thus suitable for treating diseases associated with obesity and overweight and, indirectly, diabetes. The compositions comprised negatively charged carbohydrates, such as pectin, together with proteins. These slowed digestion and delayed gastric emptying, thereby pointing towards the claimed solution.
- D15 advocated the use of whey proteins, including in micellar form, to control blood glucose. It further mentioned the use of polysaccharide thickeners such as pectin and carrageenan. The skilled person would have expected these compounds to form complexes and, consequently, a reduction in gastric emptying and slower protein digestion.

2.18 Taking into account the teaching of these documents, the appellant argued that, starting from D3 and faced with the underlying problem, the skilled person would have included polysaccharides in the compositions of D3

and prepared complexes as defined in claim 1. This approach would inevitably have led to the claimed solution.

2.19 These conclusions are not convincing.

2.20 Firstly, as noted by the respondent, the formation of a complex between whey protein micelles and polysaccharides had been documented for the first time in the application for the opposed patent as filed. None of the prior-art documents disclosed complexes of polysaccharides with whey proteins in micellar form, let alone any information on their biological properties. D12 describes complexes between pectin and micellar casein, but not micellar whey. Moreover, in view of the different spatial geometry and charge distribution of whey protein micelles, the skilled person would not have expected the interactions between polysaccharides and these micelles to be the same as those with uncomplexed whey protein or with micellar casein. The properties of the obtained complexes and their biological effects could not be predicted before the filing date either. The finding that compositions comprising WPM complexes reduce postprandial insulin levels without substantially changing the glycaemic response is highly surprising. It indicates that when the claimed complexes are present, less insulin is required to clear the same amount of glucose from blood after meals.

2.21 The skilled person could not predict this effect from the teaching of the cited prior art. As shown below, none of the cited documents provides a reasonable expectation that the underlying technical problem could be solved by providing the claimed composition.

- 2.22 Concerning D5, as noted by the respondent, the last paragraph of page 37 in section 6.1.2 explicitly states that changes in viscosity do not necessarily correlate with the rate of gastric emptying and postprandial glycaemia, as previously shown with guar gum. Low concentrations of certain viscous polysaccharides, such as locust gum, may even accelerate gastric emptying. The first sentence of section 6.1.3 confirms that "[t]here is little evidence that polysaccharides reduce the rate of digestion of food in the gut".
- 2.23 Moreover, although polysaccharides may increase the viscosity of solutions, the skilled person would not have expected this effect to occur in the presence of protein micelles, particularly when the micelles are present in larger amounts, as is the case in the compositions used for the tests reported in the opposed patent. Indeed, D5 does not describe compositions comprising proteins capable of inducing the relevant effects, let alone such proteins in micellar form.
- 2.24 As noted above, there is no evidence that the reduction in postprandial insulin observed in the patent was caused by a supposedly predictable increase in viscosity and a general slowing of the digestive process.
- 2.25 Even if it were accepted that, as per the teaching of the prior art, the skilled person would have decided to add polysaccharides to the compositions described in D3, they would have added them in large amounts, in excess, to effectively increase viscosity and induce gelation. In doing so, they would not have arrived at a composition having the claimed whey protein micelle/polysaccharide ratio, which explicitly excludes the presence of large excesses of polysaccharides.

Consequently, the prior art does not provide any pointer towards the composition defined in claim 1. It follows that a combination of D3 with D5 does not render the subject-matter of claim 1 obvious.

2.26 D6 describes the formation of electrostatic complexes between polysaccharides and proteins and the formation of coacervates that encapsulate and protect proteins from enzymatic reaction. However, the mere fact that the isoelectric point of  $\beta$ -lactoglobulin is similar to that of whey protein micelles does not imply that these substances will interact with polysaccharides in the same way. As noted by the respondent during the oral proceedings, page 932 of D6, right-hand column, teaches that developing these complex materials is challenging, and page 936, right-hand column, suggests that the protection of proteins from degradation can depend on which side of the protein is bound to the polysaccharide and whether its binding sites are blocked. This renders it difficult to predict whether, and to what extent, complexed whey proteins in micellar form would be protected against being broken down during digestion. This uncertainty is confirmed by the conclusions on page 941, which states that "although preliminary experiments are starting, the full testing of the underlying hypothesis awaits consolidation and that there are still difficult challenges ahead".

2.27 Moreover, the complexes of polysaccharides and  $\beta$ -lactoglobulin described in D6 form coacervates, which result in the protein being encapsulated and protected from degradation. As explained at the top of page 936 of D6, coacervates arise from "the spontaneous phase separation of a solution of protein + polysaccharide into a solvent-rich phase and a solvent-depleted liquid phase". No coacervation was observed when the whey

protein micelles were complexed with polysaccharides in the tests described in the opposed patent. Thus, even if the skilled person had combined whey protein micelles with polysaccharides, the observation that no coacervates were formed would have discouraged the skilled person from investigating whether the protein was protected from degradation or whether insulin release was affected.

- 2.28 It is also noted that, although D6 discusses the possibility of exploiting interfacial protein-polysaccharide interactions to engineer delivery vehicles of nutrient agents, it does not provide any incentive to use the described compositions for slowing down digestion, even less so for decreasing postprandial insulinaemia or developing foods for diabetic patients.
- 2.29 Similar considerations apply to D13, which, like D6, relates to the formation of coacervates between whey proteins and anionic polysaccharides. However, like D6, D13 does not disclose any complex with whey protein micelles or address the problem of lowering the postprandial insulin response or developing foods for diabetic patients. Its focus is instead on forming capsules for encapsulating lemon oil, for example, to impart flavour on cheese and other foods. For these reasons, a combination of D3 with D6 or D13 does not render the subject-matter of claim 1 obvious.
- 2.30 Similar arguments apply to D7, which teaches the use of polysaccharides to slow down the digestion of "fast proteins", induce satiety and reduce food intake. However, the proteins in D7 are in microparticle form. The size and the properties of the microparticles differ substantially from those of the protein micelles

of D3. Furthermore, D7 requires the microparticles to be thermodynamically unstable in order to form complexes, whereas D3 describes the micelles as being physically stable. Consequently, the teaching of these two documents cannot be combined. Lastly, D7 does not mention lowering the insulin response or treating diabetes. Thus, a combination of D3 with D7 cannot render the subject-matter of claim 1 obvious.

2.31 Similar considerations apply to D8 and D9. The appellant again relied on the incorrect assumption that, owing to the similar isoelectric points of whey protein and whey protein micelles, similar electrostatic complexation would be expected between the whey protein micelles of D3 and the polysaccharides described in D8 and D9. However, as discussed above, a similar isoelectric point does not mean that the proteins will interact in the same manner. Furthermore, these documents mention neither postprandial insulin nor diabetes. Thus, starting from D3, the skilled person would not have had a reasonable expectation of solving the underlying problem by relying on the teaching of D8 or D9. The same considerations apply to D10, which does not even mention the physical state of the whey proteins studied.

2.32 No different conclusions would be reached in the light of D14, which discloses compositions comprising a coacervate formed by a negatively charged carbohydrate and a protein, such as whey protein, for increasing satiety and preventing obesity. However, like the other prior-art documents, D14 does not mention micellar proteins or any process leading to micelle formation. The observed effects appear to be associated with an increase in viscosity induced by the coacervate, which was not observed with the claimed WPM complexes. While

D14 mentions, in passing, the potential relevance of obesity to the development of diabetes, it does not disclose any effect on postprandial insulin. For these reasons, a combination of D3 with D14 does not render the subject-matter of claim 1 obvious.

2.33 D15 relates to the preparation of shelf-stable whey protein compositions that have a high protein content and provide a nutritional supplement for medical purposes as well as for sport and fitness enthusiasts. The focus is on achieving a high concentration of whey proteins while ensuring stability, acceptable taste and appealing organoleptic properties (paragraphs [0001], [0012] to [0015]). Paragraph [0053] notes that whey proteins may *inter alia* have beneficial properties to control blood glucose in diabetic patients. However, this teaching does not go beyond that of D3 or the background knowledge mentioned in the opposed patent. Paragraphs [0030] and [0038] mention the optional presence of thickening agents, such as carrageenan, but there is no disclosure of complexes with whey proteins, let alone in micellar form. In an attempt to bridge the gap between D3 and D13, the appellant argued that, on the basis of the common general knowledge represented by D6, the skilled person would have expected electrostatic complexes to be formed between whey proteins and polysaccharides. However, this argument is clearly based on hindsight. As already mentioned above, D6 does not provide any incentive to pursue such complexes. Consequently, a combination of D3 with D15 does not render the subject-matter of claim 1 obvious.

2.34 For these reasons it is concluded that, as already decided by the opposition division, the subject-matter of claim 1, as well as its dependent claims 2 to 5, which are more limited in scope, involves an inventive

step. Since the composition of claim 1 is novel and involves an inventive step over the prior art, the process for providing that composition, as defined in claims 6 and 7, necessarily involves an inventive step.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:



K. Götz-Wein

A. Haderlein

Decision electronically authenticated