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Case Number: T 1628/23 - 3.3.07

Application Number: 13757439.8

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Language of the proceedings: EN

Title of invention:
USES OF CASEIN COMPOSITIONS

Patent Proprietor:
Fonterra Co-Operative Group Ltd

Opponent:
N.V. NUTRICIA

Headword:
Casein compositions/FRONTERRA

Relevant legal provisions:
EPC Art. 83, 54, 56
RPBA 2020 Art. 12(4), 12(6)

Keyword:
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)
Amendment to case

Decisions cited:
G 0002/88, G 0006/88, T 1523/07

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Case Number: T 1628/23 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 6 November 2025

Appellant: (Opponent)	N.V. NUTRICIA Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
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Representative:	Forresters IP LLP Skygarden Erika-Mann-Straße 11 80636 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 7 July 2023 rejecting the opposition filed against European patent No. 2822568 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	M. Steendijk
	S. Ruhwinkel

Summary of Facts and Submissions

I. European patent 2 822 568 ("the patent") was granted with fifteen claims.

Claim 1 as granted defines:

"Use of a casein composition for increasing the blood serum concentration of free leucine in a subject, wherein the casein composition comprises or the casein is in the form of a calcium depleted milk protein concentrate or isolate (MPC or MPI), the casein being 10 to 100% calcium depleted, having a degree of hydrolysis less than 1 % and having an unmodified phosphorylation pattern; and wherein the use is not for the purpose of carrying out therapy on the human or animal body."

Claim 2 as granted defines:

"Use of a casein composition for increasing the rate of gastric emptying following ingestion of the composition, increasing the digestibility of a protein composition, or increasing the rate of delivery of amino acids to the blood, wherein the casein composition comprises or the casein is in the form of a calcium depleted milk protein concentrate or isolate (MPC or MPI), the casein being 10 to 100% calcium depleted, having a degree of hydrolysis less than 1 % and having an unmodified phosphorylation pattern; and wherein the use is not for the purpose of carrying out therapy on the human or animal body."

Claim 15 as granted defines:

"A casein composition for the use in a) preventing or treating cachexia in a subject, b) preventing or treating sarcopenia in a subject, c) increasing the rate of recovery following surgery in a subject, or d) increasing the rate of recovery following injury in a subject, by increasing the blood serum concentration of free leucine in the subject; wherein the casein is 10 to 100% calcium depleted, has a degree of hydrolysis less than 1 % and has an unmodified phosphorylation pattern; and wherein the casein composition comprises or the casein is in the form of a calcium depleted milk protein concentrate or isolate (MPC or MPI)."

II. The patent was opposed on the grounds that its subject-matter lacked novelty and inventive step, that the claimed invention was not sufficiently disclosed and that the patent comprised subject-matter extending beyond the content of the application as filed.

The opposition division decided to reject the opposition.

The opposition division cited *inter alia* the following documents:
D3: Reprod. Nutr. Dev. (2005), 45, 473-483
D4: Dairy Science and Technology, second edition, Walstra, 2006
D7: The Journal of Nutrition (2009), 139:1707 -1713
D8: Dairy Sci. Technol. (2010), 90:169 -179
D10: WO 2012/008858 A1
D11: EP 2622971 B1
D12: Scand. J. Med. Sci. Sports (2011), 1-13
D13: WO 01/041578 A1
D14: J. Dairy Sci. (2018), 101:6842-6852

D15: The Journal of Nutrition (2019) 149:1511 -1522.
D16: Affidavit from Mr. Fanning concerning US16/214771.

The opposition division arrived at the following conclusions:

(a) Documents D14-D16 were admitted into the proceedings.

(b) The patent as granted did not comprise subject-matter extending beyond the application as filed.

(c) The patent as granted sufficiently disclosed the claimed invention.

Examples 1 and 3 and Figures 1 and 5 of the patent demonstrated that the free leucine level in the blood serum increased after ingestion of calcium depleted MPC to a greater extent than following ingestion of standard MPC or calcium caseinate. This effect on free leucine levels was indicative of an increased rate of gastric emptying as defined in claim 2. In view of the role of leucine in the stimulation of muscle synthesis, the further effects relating to muscle synthesis as defined in claim 12 and claim 15 were also sufficiently disclosed.

The patent furthermore provided a definition of the calcium depletion as well as specific instructions on how the calcium depleted casein compositions can be prepared. The defined level of calcium depletion did therefore not present the skilled person with an undue burden when carrying out the claimed invention.

The term "satiety" referred to the feeling of fullness between meals, while the term "satiation" described the sensation of fullness during ingestion of a meal. The increase in satiety and the reduction in satiation, both defined as resulting from elevated blood serum leucine levels in Claim 12, were therefore not contradictory.

(d) The subject-matter of the claims as granted was new over the prior art.

Document D7 described the use of micellar casein without reference to MPC or MPI and without disclosure of any level of calcium depletion as defined in the claims as granted.

Document D13 described the use of calcium depleted MPC/MPI in cheese manufacture. Document D13 did not describe the actual consumption or any effect of the described composition and did not reveal the effect of increasing blood serum levels of free leucine.

(e) The subject-matter of the claims as granted also involved an inventive step.

Document D7 described the increase in the free leucine concentration in blood serum and the stimulation of muscle protein synthesis following the ingestion of micellar casein. In view of the similarity in purpose, document D7 qualified as a suitable starting point for the evaluation of inventive step regarding the subject-matter of claims 1 and 15, the difference concerning the replacement of micellar casein in document D7 by calcium depleted MPC/MPI. Document D13 did not

represent an equally suitable starting point, because it did not address a purpose similar to that of the use of the claims. As demonstrated in Figures 1 and 5 of the patent, the use of calcium depleted MPC/MPI provided for an increased level of free leucine levels compared to standard MPC. The objective technical problem was formulated as the provision of an improved casein composition, which acts like a fast protein such as whey protein. Neither document D7 itself nor any of documents D10 and D13 provided the skilled person with any motivation to replace the micellar casein of document D7 with calcium depleted MPC, let alone any expectation of success regarding the fast digestion and absorption kinetics. Similar considerations applied when starting from document D12, which described the intake of whey and caseinate before and after heavy exercise and the response thereto in levels of free leucine and muscle protein synthesis.

Document D11 described the combination of casein or caseinate as a coagulating protein with pea or soy protein as an anti-coagulating protein to prevent or reduce the protein coagulation in the stomach and thereby increase the rate of gastric emptying. Document D11 could be considered as closest prior art for the subject-matter of claim 2, the difference concerning the use of calcium depleted MPC or MPI according to claim 2 instead of the combination of casein and an anti-coagulating protein in document D11. The objective technical problem concerned the provision of an alternative casein composition for increasing the rate of gastric emptying. The prior art provided the

skilled person with no reason for using calcium depleted MPC or MPI as a solution to this problem.

III. The opponent filed the appeal against the opposition division's decision, maintaining that the patent did not sufficiently disclose the claimed invention and that its subject-matter lacked novelty and inventive step.

IV. The opponent filed *inter alia* the following additional documents with the statement of grounds of appeal:

A19: Handbook of Hydrocolloids, second edition, 2009, chapter 13, "Milk proteins"
A20: WO 2008/026940
A21: WO 2008/063089

V. With the statement of grounds of appeal, the opponent contested the findings in the decision under appeal concerning the requirements of sufficiency, novelty and inventive step

VI. In its communication under Article 15(1) RPBA, the Board issued a preliminary opinion indicating that the appeal should be dismissed.

VII. Oral proceedings were held on 6 November 2025.

VIII. The arguments of the appellant-opponent relevant to the present decision are summarized as follows:

(a) Admittance documents

Documents A20 and A21 described the same calcium depleted milk protein concentrate as described in document D13. The filing of documents A20 and A21

was justified in response to the finding in the decision under appeal that document D13 did not anticipate the subject-matter of granted claims 1 and 2. This finding was based on the consideration that document D13 disclosed the use of calcium depleted milk protein concentrate in the manufacture of cheese, but did not describe the consumption of the cheese, which was only expressed during the oral proceedings before the opposition division. Documents A20 and A21 were *prima facie* relevant, because they explicitly disclosed the ingestion of products comprising calcium depleted milk protein concentrate.

(b) Sufficiency

The claims did not specify the baseline level for the increase in blood leucine levels defined in claims 1 and 15 and the increase in the rate of gastric emptying defined in claim 2. It was evident that the administration of any source of leucine would increase blood leucine levels. However, in view of the margins of error in the results from Examples 1 and 3 reported in Figures 1-4 and 5-7 the patent failed to demonstrate any significant increase in the levels of blood leucine from calcium depleted MPC relative to standard MPC and calcium caseinate. It was therefore not credible that the use of calcium depleted MPC would increase the rate of gastric emptying, for instance with respect to standard MPC.

It was not plausible from the application as filed that the use of the defined composition could achieve an increase in the concentration of free leucine in the blood serum of up to 400 µmol/L as

defined in claim 6 as granted. Examples 1 and 3 of the patent only demonstrated increases of 70 and 240 µmol/L (see Figures 1 and 5) and example 3 demonstrated no increase over the use of sodium caseinate (see Figures 5-7).

It was not plausible from the application as filed that an increase in blood leucine concentration would achieve the effect of an increase in muscle protein synthesis underlying the use as defined in claims 12 and 15, considering that document D15 indicated that the use of calcium depleted MPC provided higher leucine concentrations than conventional MPC, but did not provide a higher anabolic response and considering that document D12 indicated in a similar manner that higher leucine concentrations from administration of whey protein with respect to casein did not result in a higher muscle protein synthetic response.

The effects in claim 12 concerning reduced satiation (meaning a reduction in the feeling of having enough), and increased satiety (meaning an increase in the feeling of having enough) remained contradictory.

The patent did not disclose how the skilled person should determine a 10-100% calcium depletion, considering that, as indicated in document D8, simple ultrafiltration of milk already suffices for a 10% depletion in calcium levels, that according to document D3 the calcium content of cow milk itself may vary more than 10% and that claim 14 defines a content of up to 3 g calcium/100 g casein, which would according to document D4 correspond to the calcium content of normal casein.

The results of Example 4 in Figure 8 of the patent, which showed a similar coagulation profile for calcium-depleted casein and sodium caseinate, together with the findings in document D14 indicating comparable digestibility of calcium-depleted MPC and sodium caseinate, raised serious doubts about any enhancement in the rate of gastric emptying and digestibility as defined in granted claim 2.

(c) Novelty

Document D7 anticipated the subject-matter of the claims as granted, because this document described an increase in the blood leucine concentration in elderly men following ingestion of micellar casein together with a subsequent muscle protein synthetic response. As indicated by document A19, micellar casein as described in document D7 corresponded to casein in MPC. As indicated by document D8, such casein was at least 10% depleted in calcium with respect to skimmed milk powder (SMP) and would therefore, in line with paragraph [0023] of the description of the patent, be encompassed by the definition of casein compositions in the claims of the patent.

Document D13 anticipated the subject-matter of claims 1 and 2 as granted. The addition of calcium depleted MPC in the production of cheese as described in document D13 resulted in a casein composition as defined in the claims as granted, which as a matter of course was intended for consumption and which by law of nature increased blood leucine concentrations following its

consumption. The considerations in T 1523/07 concerning implicit disclosure applied. As argued during the first-instance proceedings, a similar objection applied based on document D10, which described a liquid nutritional composition comprising calcium depleted MPC.

(d) Inventive step

Document D7 already described the utility of micellar casein to increase blood leucine levels and muscle protein synthesis. No comparison between the efficacy of increasing blood leucine levels by calcium depleted MPC as defined in the claims and by micellar casein as described in document D7 had been provided. Examples 1 and 3 of the patent did not include micellar casein. Moreover, taking account of the reported margins of error, the results from Examples 1 and 3, presented in Figures 1 and 5–7 of the patent, did not demonstrate any improvement relative to standard MPC. Insofar as the claimed subject-matter differed from document D7, the objective technical problem could only be seen in the provision of an alternative composition for increasing blood leucine levels and muscle protein synthesis. The solution as defined in the claims of the patent was obvious in view of document D10, which described the use of calcium depleted MPC in a liquid nutritional composition to provide significant amounts of protein, for instance to athletes and the elderly, or document D13, which described the use of calcium depleted MPC in producing cheese, which evidently also represented an edible source of protein.

For similar reasons the skilled person would arrive in an obvious manner at the claimed subject-matter starting from document D12, which described the use of casein to increase blood leucine levels and to stimulate muscle protein synthesis.

Insofar as document D13 could not be considered to disclose the specific utility of the calcium depleted MPC as claimed, this document still represented an alternative suitable starting point. The skilled person would understand that the cheese product comprising calcium depleted MPC as described in document D13 necessarily resulted in an increase in blood leucine concentration upon ingestion. The claimed subject-matter only differed in the administration of the cheese to a subject. The objective technical problem concerned the uptake of leucine in the subject's blood. The solution by ingestion of the cheese was obvious, because the cheese was evidently intended for consumption. Similar considerations also applied starting from document D10.

Document D11 described an increased rate of gastric emptying and reduced coagulation in the stomach resulting from the combination of coagulating casein with anti-coagulating pea or soy protein. The subject-matter of claim 2 differed from this teaching in that it relates to the use of calcium depleted MPC. Starting from document D11, the skilled person would as a matter of obviousness turn to calcium depleted MPC as described in documents D10 and D13 as an alternative to the teaching of document D11 in view of the well known effects of calcium levels on the aggregation of

casein micelles as described in document D4 and document D9, as well as document D13 itself.

IX. The arguments of the respondent-patent proprietor relevant to the present decision are summarised as follows:

(a) Admittance documents

Documents D14-D16 should not have been admitted by the opposition division, because these documents were late-filed and lacked *prima facie* relevance.

Documents A20 and A21, and the objections based on these documents, should have been filed during the first instance proceedings. Furthermore, these documents lacked *prima facie* relevance, because they did not disclose the effect of calcium depleted MPC on blood leucine levels.

(b) Sufficiency

No substantiated serious doubts had been raised to support an objection of insufficient disclosure of the claimed invention.

The argument that the claims defined the use to increase blood leucine levels and the rate of gastric emptying without specifying a baseline level concerned an objection of lack of clarity rather than an objection of insufficiency. The skilled person would in any case understand that the claimed invention involved the use of calcium depleted MPC to significantly increase blood leucine levels and enhance gastric emptying, in a

similar manner as whey protein, which allowed maximal stimulation of muscle protein synthesis.

The results reported in the examples of the patent demonstrated the suitability of calcium depleted MPC to increase blood leucine levels significantly higher and faster than standard MPC in a manner comparable to whey protein. The claims of the patent as granted did not require an improvement relative to sodium caseinate. Documents D15 and D16 confirmed that calcium depleted MPC provides similar benefits as whey protein, including elevated leucine levels, enhanced gastric emptying and increased muscle protein synthesis. Document D12 confirmed that whey protein acts as an advantageous "fast" source of protein in contrast to standard casein, which represented a "slow" source of protein. Document D14 confirmed the improved digestibility of calcium depleted MPC over standard MPC.

The effects of increased satiety and reduced satiation, as defined in claim 12, were not contradictory.

The patent provided sufficient guidance on the preparation of calcium depleted MPC as defined in the claims.

(c) Novelty

Micellar casein, as described in document D7, did not correspond to calcium depleted MPC as defined in the claims of the patent.

The use of calcium depleted MPC in cheese manufacturing to prevent nugget formation, as described in document D13, did not disclose the utility of calcium depleted MPC for increasing blood leucine levels and the rate of gastric emptying as defined in the claims of the patent.

The objection of lack of novelty based on document D10 represented an unjustified amendment to the opponent's case. The utility of calcium depleted MPC for increasing blood leucine levels and the rate of gastric emptying as defined in the claims of the patent remained in any case hidden in document D10.

(d) Inventive step

The examples of the patent demonstrated that calcium-depleted MPC effectively and rapidly increased blood leucine levels, in a manner comparable to whey protein and in contrast to the slower response observed with standard MPC. Documents D15 and D16 confirmed this effect. As indicated in document A19, the casein in standard MPC corresponded to micellar casein. The presented evidence therefore also demonstrated an effect relative to the micellar casein described in document D7.

The objective technical problem in view of document D7 or D12 was therefore the provision of an improved casein composition for increasing blood leucine levels in a similar fast manner to whey protein. Neither document D10 nor document D13 provided any suggestion that calcium depleted MPC

would offer a solution to this objective technical problem.

Documents D10 and D13 did not disclose the purpose of increasing blood leucine levels or the rate of gastric emptying as defined in the claims of the patent and were therefore not suitable starting points in the prior art.

Document D11 described the combination of coagulating casein with anti-coagulating pea or soy protein to promote gastric emptying and reduce coagulation in the stomach. Starting from document D11, the objective technical problem underlying the subject-matter of claim 2 concerned the provision of an alternative product for increasing the rate of gastric emptying and enhancing the digestibility of a protein composition. In the light of the prior art, it was not obvious to solve this problem by using the calcium depleted MPC described in documents D10 or D13.

X. The appellant-opponent requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

XI. The respondent-patent proprietor requested that the appeal be dismissed.

Insofar as relevant to the decision, the patent proprietor further requested that documents D14-D16 and A20-A21 not be admitted and that the objection of lack of novelty in view of document D10 not be admitted.

Reasons for the Decision

1. Admittance of evidence

1.1 Documents D14-D16

The opposition division admitted documents D14-D16 into the proceedings on the grounds that (i) the documents were filed by the opponent in response to the preliminary opinion issued by the opposition division within the time limit set under Rule 116 EPC; (ii) both parties relied on these documents to support their arguments concerning the issue of sufficiency; and (iii) the documents were considered helpful in understanding the claimed invention.

In its communication pursuant to Article 15(1) RPBA the Board indicated, with reference to Article 12(2) RPBA, that it did not recognize a basis for disregarding these documents in the appeal proceedings.

No substantive arguments were submitted by the patent proprietor in response to the preliminary opinion regarding documents D14-D16.

The Board has therefore confirmed that documents D14-D16 are part of the appeal proceedings.

1.2 Documents A20-A21

Documents A20 and A21 were filed by the opponent with the statement of grounds of appeal.

The admittance of documents A20 and A21 is therefore subject to the provisions of Article 12(4) and (6) RPBA. Under Article 12(6), second sentence, RPBA, the Board shall not admit evidence which should have been submitted in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

The opponent argued that the submission of documents A20 and A21 represented a justified response to the finding in the decision under appeal that the claimed subject matter was new over document D13. This finding was based on the assessment that document D13 disclosed the use of calcium-depleted milk protein concentrate (MPC) in cheese production but did not describe the consumption of the resulting cheese and could therefore not implicitly disclose any biological effects of the calcium depleted MPC. The filing of documents A20 and A21 with the statement of grounds of appeal was justified, because the issue that document D13 did not disclose the consumption was raised for the first time during the oral proceedings before the opposition division. In the opponent's view, documents A20 and A21 were *prima facie* relevant, because these documents explicitly disclosed the ingestion of products containing calcium-depleted milk protein concentrate, and should therefore be admitted.

However, given the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (Article 12(2) RPBA), it is the responsibility of the opponent to submit the evidence of the prior art supporting its case during the first-instance proceedings. In this context, it is established jurisprudence (see Case Law of the Boards of Appeal of the EPO, 11th edition, 2025, V.A.4.3.7.n)

that new objections or evidence against claims as granted or against claims filed with the reply to the notice of opposition should have already been filed in the opposition proceedings. The opponent relies on documents A20 and A21 as new evidence that the subject-matter of claims 1 and 2 as granted lack novelty. Accordingly, these documents should have been filed during the first-instance proceedings.

Notably, the patent proprietor contested the *prima facie* relevance of documents A20 and A21, because these documents failed to disclose the effect of calcium-depleted MPC on blood leucine levels. The Board does therefore not recognize any circumstances of the appeal case that would justify the admittance of documents A20 and A21.

Accordingly, the Board has decided not to admit documents A20 and A21 under Article 12(6) RPBA.

2. Sufficiency

2.1 Claims 1 and 15 define the non-therapeutic and therapeutic utility of a casein composition, which comprises or is in the form of calcium depleted milk concentration or isolate (MPC or MPI), for increasing the blood serum concentration of leucine. Claim 2 defines the non-therapeutic utility of such a casein composition for increasing the rate of gastric emptying, the digestibility of a protein composition, or the rate of delivery of amino acids to the blood.

Although claims 1, 2, and 15 do not specify a particular baseline level for the defined increase in blood leucine level, the rate gastric emptying, protein digestibility, or amino acid delivery, the person

skilled in the art would reasonably interpret these claims as requiring increases that significantly exceed an individual's physiological baseline.

This interpretation of the claims is consistent with the description of the invention in the patent, which explains that calcium depleted MPC can elevate blood leucine levels and enhance gastric emptying in a manner comparable to whey protein (see paragraph [0053]) and clarifies that increasing the blood serum concentration of leucine refers to maintaining and increasing blood leucine concentrations, preferably to adequate physiological concentrations to maximally stimulate muscle protein synthesis in the post-prandial period (see paragraph [0058]).

Therefore, the opponent’s contention that the claims lack a defined baseline level amounts to a clarity objection but does not effectively challenge the sufficiency of the patent’s disclosure of the claimed invention.

2.2 Example 1 of the patent compares changes in the blood leucine levels up to 180 minutes after consumption of equivalent amounts of leucine from (A) calcium-depleted MPC, (B) whey protein concentrate from cheddar cheese manufacture (WPC), (C) standard MPC, and (D) calcium caseinate. The results are presented in Figures 1-4, with Figure 1 reproduced below.

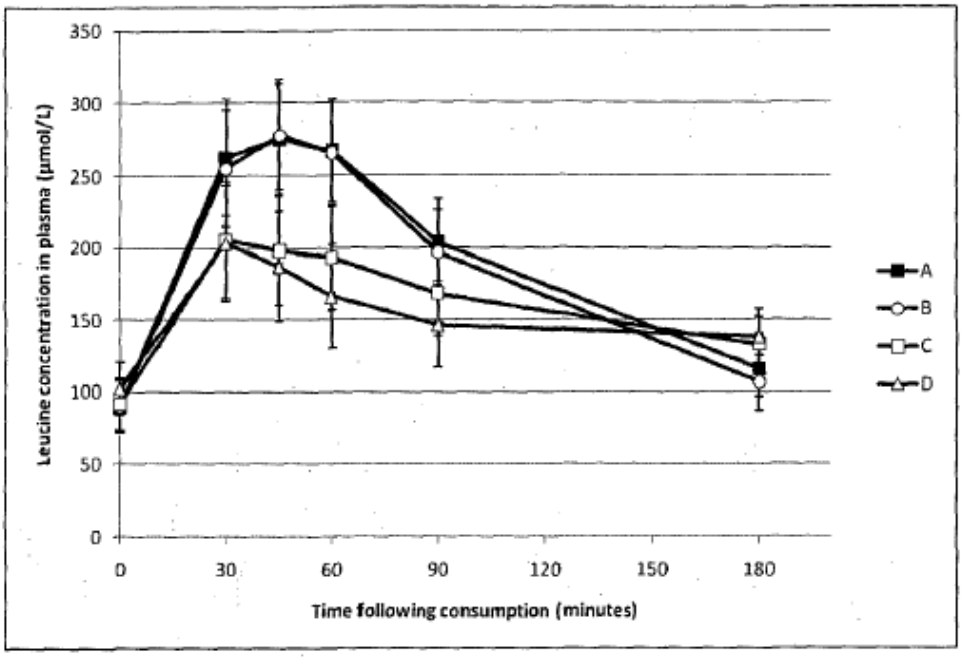

FIGURE 1

As noted in paragraph [0136] of the patent, the peak leucine concentrations and the amino acid availability within the first 60 minutes were significantly higher after consumption of calcium-depleted MPC and WPC compared to standard MPC or calcium caseinate.

Example 3 of the patent provides a further comparison of the changes in blood leucine levels after the consumption of equivalent amounts of leucine from (A) whey protein concentrate from cheddar cheese manufacture, (B) calcium-depleted milk protein concentrate, (C) standard milk protein concentrate, and (D) sodium caseinate. The results are presented in Figures 5-7, with Figure 5 shown below.

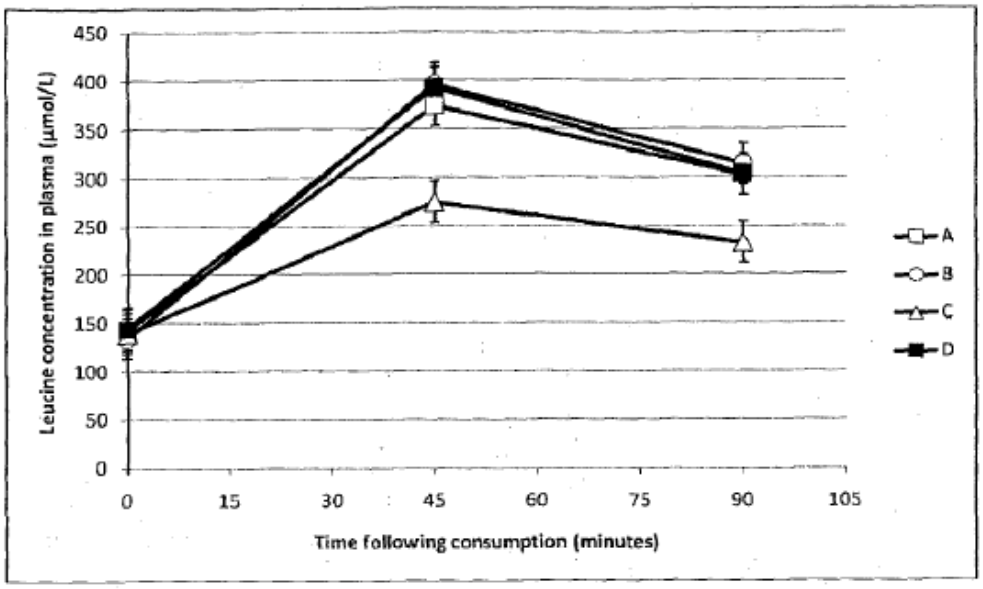

FIGURE 5

According to the patent (see paragraph [0148]) the results from Example 3 demonstrate that the maximum blood leucine levels following consumption of the calcium depleted MPC, sodium casein and WPC were significantly different to the maximum blood leucine level following consumption of standard MPC and that the availability of amino acids in the first 90 minutes was significantly greater following the consumption of calcium depleted MPC than following the consumption of standard MPC.

These conclusions are confirmed by document D15 (see page 1512, left column and page 1517, left column) and the declaration in document D16 (see D16, page 4, sections 13 and 14).

Document D14 further supports the enhanced gastric emptying associated with calcium-depleted MPC. Under simulated gastric conditions, standard MPC, which contains intact casein micelles, formed dense, cohesive curds within 10 minutes. In contrast, partially calcium-depleted MPC, which lacked an intact micellar

structure, produced curds only after 40 minutes, and these exhibited a loose, fragmented structure upon continued digestion (see D14, page 6842, Abstract).

In view of the evidence presented in the patent, the opponent's objection that the patent fails to demonstrate a significant increase in the levels of blood leucine from calcium depleted MPC relative to standard MPC and calcium caseinate and that claimed enhancement in gastric emptying is not credible, remains unsubstantiated. Moreover, the objection that the application does not plausibly demonstrate the ability of the defined composition to raise free leucine concentrations in blood serum to up to 400 µmol/L, as specified in granted claim 6, is equally unconvincing in light of the results from Examples 1 and 3.

2.3 The opponent argued that it was not plausible that the increase in blood leucine concentration could achieve the effect of an increase in muscle protein synthesis as defined in claims 12 and 15 of the patent.

However, the patent explains, with reference to relevant literature, that essential amino acids (EAAs) play a central role in regulating muscle protein synthesis, with leucine specifically recognized as particularly important for stimulating this process (see paragraphs [0004]-[0005]). Document D12, which is in this context cited in the patent, confirms that whey protein serves as a faster and more efficient source of leucine than caseinate and refers to multiple studies in which whey protein was found to be superior to casein in stimulating whole-body protein synthesis (see D12, page 7, right column to page 8, left column). Similarly, document D15 reports that whey protein may

provide superior post-exercise muscle protein synthesis (MPS) compared to casein (see page 1517, right column). Given the experimental results from Examples 1 and 3, which show that calcium-depleted MPC induces a rapid increase in blood leucine levels comparable to whey protein, it is therefore reasonable to conclude that the effect of enhanced muscle protein synthesis as underlying the use defined in claims 12 and 15 can be achieved with calcium-depleted MPC. This conclusion remains valid despite findings in documents D12 and D15 indicating that, under specific experimental conditions, the use of whey protein or calcium depleted MPC was not found to provide a higher anabolic response than casein or standard MPC.

2.4 As set out in the decision under appeal (see pages 8-9, bridging paragraph), satiety refers to the feelings of fullness between meals whereas satiation indicates feelings of fullness during ingestion. In view of these definitions of the terms satiety and satiation, no contradiction between the increased satiety and reduced satiation defined in claim 12 as effects of the use of calcium depleted MPC is apparent.

2.5 As further pointed out in the decision under appeal (see page 8), the patent provides with respect to the calcium depletion of the casein composition a definition in paragraph [0054] and instructions in paragraphs [0069]-[0072]. The opponent's argument regarding this feature amounts to an objection of lack of clarity rather than an objection of lack of sufficient disclosure.

2.6 Accordingly, the Board finds that the opponent has not raised any serious doubts as to whether a skilled person would be able to carry out the claimed invention

without undue burden and concludes that the patent as granted satisfies the requirement of sufficient disclosure (Articles 100(b), 83 EPC).

3. Novelty

3.1 Document D7

Document D7 investigates the amino acid absorption rates following dietary protein digestion and the subsequent postprandial response in muscle protein syntheses in young and elderly men. The document reports an increase in the blood leucine concentration and a subsequent muscle protein synthetic response following the ingestion of a single bolus of labelled micellar casein protein digestion in both groups of subjects (see D7, page 1710, Figure 2D and page 1712, right column).

The subject-matter of the claims of the patent differs from the teaching of document D7 in that it concerns the use of calcium depleted MPC instead of micellar casein.

The claims of the patent define a casein composition which comprises or is in the form of calcium depleted MPC or MPI. According to the textbook information presented in document A19, MPC is a spray dried powder manufactured from skim milk by ultrafiltration/ diafiltration (UF/DF), wherein casein is present in a similar, micellar, form as found in milk (see A19, pages 315-316, section 13.3.6). Document D8 indicates that the calcium content in MPC may be reduced by more than 10% with respect to skim milk powder (SMP). The claims of the patent require, however, a product in which the MPC or MPI itself has been modified by the

defined reduction of 10% or more of its calcium content. As confirmed by documents D14 and D15, the micellar structure of the casein in MPC is disrupted in calcium reduced MPC (see D14, page 6842, abstract and right column; D15, page 1512, left column and page 1513, left column). Accordingly, the micellar casein as described in document D7 cannot be equated to calcium depleted MPC as defined in the claims of the patent.

The description of the patent suggests in paragraph [0023]:

> "In various embodiments the casein composition comprises a calcium depleted casein composition; calcium depleted skim milk; calcium depleted skim milk powder; calcium depleted whole milk; calcium depleted whole milk powder; caseinate, sodium caseinate, potassium caseinate, zinc caseinate, magnesium caseinate; a milk protein concentrate or isolate that has been modified to dissociate casein micelles; non-micellar casein; a casein ingredient, such as an MPC or MPI, where at least a portion of the calcium or phosphate or both the calcium and phosphate has been replaced with sodium, potassium, zinc, magnesium and like, or a combination of any two or more thereof; an acid soluble casein; a non-micellar caseinate; chelated casein micelles; a charge-modified casein; a glycosylated casein; a casein modified to decrease its ability to form a coagulum at acid pH, preferably at a pH below pH 5, pH 4, or pH 3; a casein modified to speed its ability to be hydrolysed in the gastrointestinal tract; a casein ingredient with an altered ratio of casein to whey; a lactic acid casein; a mineral acid one or more casein fractions; an alpha-casein fraction; a beta-casein fraction; a kappa-casein

fraction; or any combination of any two or more thereof."

It is immediately evident that this list of embodiments, which is not limited to calcium depleted MPC or MPI, cannot be considered as a basis for the interpretation of the casein composition as defined in the claims of the patent, which explicitly refer to calcium depleted MPC or MPI. At the same time, insofar as this passage in the description mentions embodiments relating to MPC or MPI, it refers to modified forms thereof in which casein micelles are dissociated or at least a portion of the calcium or phosphate has been replaced with sodium, potassium, zinc, magnesium and like. Accordingly, paragraph [0023] of the patent cannot serve as a basis for an interpretation of the claims as encompassing the use of micellar casein as mentioned in document D7.

The Board therefore concludes that document D7 does not disclose the subject-matter of the claims of the patent as granted, which is thus novel over document D7 (Articles 100(a), 54 EPC).

3.2 Document D13

Document D13 discloses the use of calcium depleted MPC in the manufacture of cheese (see D13, page 2, lines 7–33). The stated purpose of this use is to improve processing properties, to provide cheese with a high protein content while avoiding nugget formation (see D13, page 5, lines 1-12). Document D13 does not address nutritional effects following consumption of the resulting cheese product.

As explained in section 2.1 above, independent claims 1, 2, and 15 of the patent define the use of calcium depleted MPC or MPI to achieve the physiological benefit of an increase in blood leucine level, gastric emptying, protein digestion or amino acid delivery which significantly exceeds an individual's physiological baseline.

The Enlarged Board of Appeal established in G 2/88 and G 6/88 that a claim directed to the use of a known composition for a new purpose is considered novel if the new purpose reflects a new technical effect. The claimed use of calcium depleted MPC to achieve the relevant physiological benefit as defined in the claims is neither explicitly nor implicitly disclosed in D13. The mere fact that cheese is intended for consumption does not render the claimed effect inherent. As emphasized in T 1523/07 (reasons 2.4), an implicit disclosure requires that the feature or effect be the inevitable result of what is explicitly disclosed in the prior art. Document D13 focuses on processing advantages and does not disclose the specific physiological benefits following ingestion as defined in the claims of the patent. Therefore, even if it is acknowledged that the consumption and digestion of cheese results in amino acid absorption, the specific technical effects defined in the claims remain undisclosed in D13 and cannot be regarded as an inevitable consequence of its teaching.

The claimed subject-matter is therefore new over document D13 (Articles 100(a), 54 EPC).

3.3 Document D10

In the notice of opposition, the opponent challenged the novelty of the claimed subject-matter based on documents D7 and D13. The objection relying on D13 was reiterated in the letter dated 14 July 2022, in which the opponent stated that an increase in blood serum concentration of free leucine is a known effect of ingesting a protein source. The letter also briefly asserted: "In that regard, the same applies to the calcium-depleted casein composition used in D10." However, during the oral proceedings before the opposition division (see minutes, sections 9–11), the opponent maintained its novelty objection solely on documents D7 and D13, without invoking document D10. In contrast, the patent proprietor argued that document D13 did not disclose the ingestion of the cheese necessary to achieve the use defined in claim 1 of the opposed patent. As a result, the opposition division's decision on novelty was based exclusively on documents D7 and D13.

In the appeal proceedings, the opponent has not demonstrated that the novelty objection based on document D10 was admissibly raised and maintained before the opposition division. Consequently, according to Article 12(4), first sentence, RPBA, the objection raised in the opponent's statement of grounds of appeal constitutes an amendment to its case. Its admittance is therefore subject to the Board's discretion under Article 12(4) and (6) RPBA.

Given the apparent focus of the debate during the oral proceedings before the opposition division on the issue of consumption in relation to document D13, there is no apparent justification for the opponent's failure to

argue, at that stage of the proceedings, that the claimed subject-matter lacked novelty over document D10 in view of its explicit disclosure of nutritional compositions comprising calcium depleted MPC intended for consumption.

Furthermore, during the appeal proceedings, the proprietor contested that D10 disclosed the effect of calcium-depleted MPC relevant to the claimed use. Notably, document D10 does not appear *prima facie* relevant to the issue of novelty, as it primarily addresses the use of calcium-depleted MPC to improve the viscosity of liquid nutritional compositions (see D10, page 5, lines 6–10), without discussing its effect on blood leucine levels or gastric emptying.

The Board has therefore decided not to admit the objection of lack of novelty based on document D10 into the appeal proceedings under Article 12(4) and (6) RPBA.

4. Inventive step

4.1 Closest prior art

4.1.1 Document D7 discloses the ingestion of micellar casein and reports an increase in blood leucine concentration and stimulation of muscle protein synthesis (see D7, page 1710, Figure 2D; page 1712, right column).

Document D12 describes the increase in blood leucine levels and muscle protein synthetic response following the intake of whey or caseinate before or immediately after exercise (see D12, page 8, left column).

It was not in dispute that documents D7 and D12 represent suitable starting points in the prior art, taking account of the purpose of the use defined in the claims and the effects of the protein compositions described in these documents.

4.1.2 Document D11 describes an increased rate of gastric emptying and reduced coagulation in the stomach resulting from the combination of coagulating casein with anti-coagulating pea or soy protein (see D11, claim 1 and paragraphs [0003] and [0009]).

It was undisputed that document D11 represented a suitable starting point with respect to the subject-matter of claim 2 of the patent.

4.1.3 In its communication pursuant Article 15(1) RPBA, the Board expressed the preliminary opinion that the difference of the claimed subject-matter with the teaching in documents D10 and D13 concerned in the first place the very purpose of the defined utility relating to an increase in blood leucine concentration and that, in line with the established jurisprudence, documents D10 and D13 did therefore not represent equally suitable starting points as document D7.

No substantive arguments were submitted by the opponent in response to the Boards's preliminary opinion on this issue.

The Board therefore confirms the preliminary opinion that documents D10 and D13 do not represent alternative suitable starting points in the assessment of inventive step.

4.2 Objective technical problem

4.2.1 The difference between the claimed invention and the teaching in documents D7 or D12 resides in the definition of the casein composition which comprises or is in the form of a calcium-depleted milk MPC or MPI instead of caseinate.

The subject-matter of claim 2 differs from the teaching in document D11 in that the defined use involves calcium-depleted MPC or MPI instead of the combination proposed in D11.

4.2.2 As explained in section 2.2 above, the patent demonstrates in Examples 1 and 3 that calcium-depleted MPC induces a significantly faster and higher increase in blood leucine levels compared to standard MPC and calcium caseinate, an effect comparable to the response observed with whey protein. This effect is corroborated by document D14, which shows that calcium depletion disrupts micellar structure, resulting in looser curds and improved gastric breakdown (see D14, page 6842, Abstract), and by documents D15 and D16, which confirm enhanced amino acid availability and gastric emptying from calcium depleted MPC (see D15, page 1512, left column and page 1517,left column; D16, page 4, sections 13 and 14).

The experiments reported in the patent do not provide a direct comparison with the micellar casein described in document D7 or the caseinate of document D12. However, since the patent demonstrates that calcium-depleted MPC performs better than standard MPC, which contains casein in micellar form, the Board considers this improvement to be equally representative of the performance relative to the micellar casein in

document D7. Notably, the micellar structure of casein in standard MPC is disrupted when the MPC undergoes partial calcium depletion (see D14, p. 6842, Abstract and right column; and A19, pp. 315–316, section 13.3.6). Furthermore, given the demonstrated comparable performance of calcium-depleted MPC to whey protein, which was known to serve as a faster and more efficient source of leucine than caseinate (see D12, page 7, right column to page 8, left column), the Board is also satisfied that calcium-depleted MPC provides an advantage over caseinate.

4.2.3 Accordingly, starting from documents D7 or D12, the objective technical problem may be formulated as the provision of an improved casein composition that achieves a higher and faster increase in blood leucine concentration and improved digestibility, comparable to whey protein.

Starting from document D11, the objective technical problem may be formulated as the provision of an alternative casein composition for increasing the rate of gastric emptying and improving digestibility.

4.3 Assessment of the solution

Neither document D7 nor document D12 provides any suggestion towards the use of calcium depleted MPC or MPI. Documents D7 and D12 describe the ingestion of micellar casein or caseinate and report postprandial responses but they do not hint at modifying the casein structure by calcium depletion to achieve higher blood leucine levels and faster digestion.

Document D11 proposes combining casein with anti-coagulating proteins to promote gastric emptying,

but does not suggest calcium depletion as an alternative approach.

Documents D10 and D13 disclose calcium depleted MPC in the field of food processing. Document D10 describes its use for improving viscosity in liquid nutritional compositions (see D10, page 5, lines 6-10), while document D13 describes its use for preventing nugget formation in cheese manufacture (see D13, page 5, lines 1-12). However, neither document D10 nor document D13 addresses or suggests the physiological effects underlying the formulated objective technical problem.

Document D4 explains that calcium influences micelle aggregation and that acidification can dissolve calcium phosphate, reducing colloidal stability (see D4, pages 153-152). While this represents general knowledge, it does not provide any indication that calcium depletion would result in higher blood leucine levels and faster digestion. Document D9 reports that low calcium MPC forms finer emulsions compared to higher calcium MPC (see D9, Abstract), but this observation relates to emulsion properties, not digestion kinetics or physiological effects. Document D13 reports that with 98% calcium depleted MPC no coagulum was formed until calcium was added (see page 10, lines 25-31); however, even when read with documents D4 and D9, document D13 focused on processing advantages and does not suggest any physiological benefit following ingestion.

The prior art therefore provides no motivation to use calcium-depleted MPC as a solution to the objective technical problem, whether formulated as an improvement starting from D7 or D12, or, for claim 2, as an alternative starting from D11.

4.4 Accordingly, the Board concludes that subject-matter as defined in the claims of the patent as granted involves an inventive step (Articles 100(a), 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Sánchez Chiquero A. Usuelli

Decision electronically authenticated