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**Datasheet for the decision
of 19 July 2018**

Case Number: T 2546/12 - 3.3.04

Application Number: 03705492.1

Publication Number: 1599215

IPC: A61K38/01, A23J3/34, A23L1/305,
C12P21/06, C12S3/24, A61P3/04

Language of the proceedings: EN

Title of invention:

Use of tryptophan rich peptides from whey protein hydrolysate
for treating overweight and obesity

Patent Proprietor:

Campina B.V.

Opponent:

Nestec S.A.

Headword:

Whey protein hydrolysate/CAMPINA

Relevant legal provisions:

EPC Art. 83

Keyword:

All requests: sufficiency of disclosure - (no)

Decisions cited:

T 0609/02

Catchword:

-



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Case Number: T 2546/12 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 19 July 2018

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
12 November 2012 concerning maintenance of the
European Patent No. 1599215 in amended form**

Composition of the Board:

Chairwoman R. Morawetz
Members: B. Claes
M. Blasi

Summary of Facts and Submissions

I. The appeal of the opponent (hereinafter "appellant") lies against the interlocutory decision of the opposition division that European patent No. 1 599 215, entitled "*Use of tryptophan rich peptides from whey protein hydrolysate for treating overweight and obesity*", could be maintained on the basis of a main request filed during the oral proceedings on 25 September 2012.

Claim 1 of the main request read:

"1. Use of peptides derived from a whey protein hydrolysate as active ingredient in the manufacture of a composition for preventing or treating overweight and/or obesity in a human."

II. The patent was opposed on the grounds in Article 100(a) EPC in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC) and on the ground in Article 100(b) EPC.

III. The appellant submitted with the statement of grounds of appeal, *inter alia*, that the patent in relation to the invention claimed in the main request lacked compliance with the requirements of Article 83 EPC. In support of its arguments, the appellant filed, *inter alia*, an expert declaration (document D22).

IV. With its reply to the statement of grounds of appeal, the patent proprietor (hereinafter "respondent") submitted claims of four auxiliary requests and arguments to the effect that the decision of the opposition division was correct in respect of the main

request and that the appellant's appeal should be dismissed. It also requested that document D22 not be admitted into the proceedings.

Claim 1 of auxiliary request 3 was based on claim 1 of the main request (see section I), in which, at the end, the method of isolation of the peptides was specified by the insertion of the following wording:

"wherein said peptides are obtained by an isolation method, said isolation method comprising:

- a) providing an aqueous whey protein hydrolysate,
- b) controlling the pH of said aqueous whey protein hydrolysate to 4.0 - 6.0, forming a peptide precipitate, and
- c) isolation of said precipitated peptides."

- V. In response to the reply of the respondent, the appellant submitted, *inter alia*, arguments to the effect that the patent did not meet the requirements of Article 83 EPC in relation to the invention as claimed in each of the auxiliary requests.
- VI. With a subsequent letter, the respondent submitted, *inter alia*, three further auxiliary requests.
- VII. The appellant addressed the last letter of the respondent in a further submission.
- VIII. During the oral proceedings the respondent withdrew all auxiliary requests filed during the written proceedings except auxiliary request 3. It further submitted auxiliary request 8. At the end of the oral proceedings, the chairwoman announced the decision.

Claim 1 of auxiliary request 8 read:

"1. Use of peptides derived from a whey protein hydrolysate as active ingredient in the manufacture of a composition for preventing or treating overweight and/or obesity in a human, wherein said peptides are prepared by enzymatic cleavage of whey protein by one or more acid proteases or cysteine proteases, preferably selected from the group consisting of pepsin, papain or bromelain, or a mixture of two or more thereof, and an isolation method, said isolation method comprising:

- a) providing an aqueous whey protein hydrolysate,
- b) controlling the pH of said aqueous whey protein hydrolysate to 4.0 - 6.0, forming a peptide precipitate, and
- c) isolation of said precipitated peptides."

IX. The following documents are referred to in the present decision:

D12: Backus *et al.* (1997), *Regulatory Peptides*, Vol. 72, pages 31 to 40.

D22: Declaration of Dr. D. Breuille of 21 March 2013.

X. The appellant's arguments, as far as they are relevant to the present decision, may be summarised as follows:

Main request

Claim 1 - sufficiency of disclosure

The claim was formulated in the second medical use format and the peptides used were defined in a product-by-process format, i.e. as being derived or derivable "from a whey protein hydrolysate". The therapeutic

effect achieved by the peptides used was based on the cholecystokinin (CCK) levels in the plasma. However, the invention was not enabled across the whole scope claimed.

The patent in suit provided only experimental evidence for a composition comprising peptides rich in tryptophan derived from an isolate highly enriched in α -lactalbumin, a tryptophan-rich whey protein. Indeed, Table 2 of the patent in suit demonstrated highest CCK levels in plasma after 30 minutes for the peptide mixture derived from the specific whey protein isolate disclosed in example 1, i.e. an isolate containing 75% α -lactalbumin (Davisco). The resulting product contained 8.5% tryptophan on powder and 10.4% on protein (see Table 1).

However, claim 1 was not limited to this peptide isolate and the patent lacked experimental evidence or guidance for peptides not containing tryptophan or extremely low levels thereof:

The patent contained an indication that not all peptides which were derivable from a whey protein hydrolysate were also suitable for preventing or treating overweight and/or obesity in human. Indeed, paragraph [0016] of the patent provided that cleavage of whey protein by acid proteases, especially pepsin as in example 1, generated peptides of a hydrophobic nature. This was consistent with what the skilled person knew from document D12, Table 1, i.e. the aromatic and hydrophobic amino acids (here tryptophan and phenylalanine in particular, but also leucine and isoleucine) which were particularly known in the art to cause significant elevation of CCK secretion. Paragraph [0016] of the patent also taught that it was from these

peptides of a hydrophobic nature that the "effective peptides could very efficiently be selectively isolated by controlling the pH". The patent therefore taught that the effective peptides of the invention had to be selectively isolated from a particular mixture of hydrophobic peptides derived by cleavage from a particular whey protein, as in example 1 (see paragraphs [0016], [0023] and [0024] of the patent) for instance. The patent, however, did not make plausible that non-hydrophilic peptides had an effect on CCK levels.

The disclosure did not allow the invention to be performed in the whole range claimed (Article 83 EPC).

Auxiliary request 3

Claim 1 - sufficiency of disclosure

The method of isolation of the peptides did not specifically result in peptides which had the required hydrophobicity or level of tryptophan content. The line of argument in relation to the invention defined in claim 1 of the main request thus applied equally here.

Auxiliary request 8

Admission into the proceedings

The claim request was late-filed, i.e. during the oral proceedings, and claim 1 *prima facie* did not remedy the issues under sufficiency of disclosure. The request should therefore not be admitted into the proceedings.

Claim 1 - sufficiency of disclosure

The claim was still not commensurate with the examples in the patent which derived the peptides from whey

protein isolates which were themselves highly enriched in α -lactalbumin. The claim did not however define the whey protein isolate on which the hydrolysis was conducted.

It was not the type of hydrolysis which guaranteed the resulting peptides to be rich in tryptophan and/or other hydrophobic amino acids but, rather, the whey protein isolate started from.

The line of argument in relation to the invention defined in claim 1 of the main request thus applied equally here.

- XI. The respondent's arguments, as far as they are relevant to the present decision, may be summarised as follows:

Sufficiency of disclosure (Article 83 EPC)

Main request - claim 1

Claim 1 was in the second medical use format.

The appellant had not established serious doubts based on verifiable facts that the invention could not be worked with any "peptides derived from a whey protein hydrolysate". It had therefore not discharged its burden of proof in this context.

The disclosure of aqueous peptide mixtures, i.e. the whey protein hydrolysate in paragraph [0016] of the patent, was described as being "preferably prepared by enzymatic cleavage of whey protein" and could not therefore limit the teaching of the patent.

The patent taught how to obtain the peptides derived from a whey protein hydrolysate (see paragraphs [0008]

and [0009]), and the compositions suitable for obtaining the claimed effect were amply disclosed in examples 1 to 5 of the patent.

The therapeutic effect was made plausible by a combination of the experiments in the patent and the knowledge in the prior art. In particular, example 6, Figure 1 and Table 2 demonstrated a clear increase in CCK levels in plasma 30 minutes after administration of the composition of the invention.

Document D12 was not pertinent for the claimed invention as it dealt with dietary amino acids rather than peptides. Moreover, on page 38, left-hand column, lines 39 to 41, document D12 taught that amino acids other than tryptophan could have the effect of elevating CCK secretion, i.e. phenylalanine, leucine and isoleucine. The skilled person, therefore, would not expect only tryptophan-rich peptides to be suitable for attaining the claimed effect. The patent just happened to focus on tryptophan since it was known as an appetite suppressant.

Auxiliary request 3 - claim 1

The claim now provided clear information, by means of the isolation method of the peptides, sufficient for the skilled person to reproduce the effect claimed without any undue burden.

The isolation method of the peptides, as now recited in the claims, did not result solely in hydrophobic peptides.

Auxiliary request 8
Admission into the proceedings

The new request was a direct reaction to the appellant's arguments first filed during the oral proceedings.

Claim 1 was a combination of claim 1 and claims 2 and 3 of auxiliary request 3 and was thus a simple combination of existing claims.

When following the steps indicated in the claim, the skilled person would arrive at a peptide mixture including an amount of hydrophobic residues. The mixture would accordingly provide the claimed effect.

Claim 1 - sufficiency of disclosure

Claim 1 now specified the method of obtaining the peptides with hydrophobic residues from a whey protein hydrolysate, which itself was obtained by enzymatic cleavage of whey protein by one or more acid proteases or cysteine proteases. Indeed, paragraph [0016] of the patent stated that when the whey protein hydrolysate was prepared by enzymatic cleavage of whey protein by one or more acid proteases or cysteine proteases, i.e. the ones specified in the claim, peptides having a hydrophobic nature were then generated, and, from these peptide mixtures, the effective peptides could very efficiently be selectively isolated by controlling the pH to 4.0-6.0.

The examples demonstrated that enzymatic cleavage, particularly by pepsin and bromelain, indeed resulted in peptides exhibiting the claimed affect.

XII. The appellant requested that the decision under appeal be set aside and the patent be revoked.

The respondent requested that the appeal be dismissed, i.e. that the patent be maintained in amended form as considered allowable by the opposition division (main request), or alternatively, that the patent be maintained on the basis of the set of claims of auxiliary request 3 filed with the respondent's reply to the statement of grounds of appeal, or further alternatively, on the basis of the set of claims of auxiliary request 8 filed during the oral proceedings.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 EPC and Rule 99 and is therefore admissible.

Admission of document D22 into the appeal proceedings

2. Before the parties were heard at the oral proceedings on the issue of sufficiency of disclosure (see below), the board dealt with the request of the respondent not to admit document D22 into the proceedings. After having considered the parties' arguments in this context, the board decided to reject the respondent's request that document D22 be held inadmissible.

3. However, for the decision on the present appeal, the board has not relied on document D22 or its content. Accordingly, in view of the fact that the outcome of this appeal does not hinge on document D22, the board sees no need to put the reasons for the decision in respect of its admission in writing.

Status of document D12 in the appeal proceedings

4. In the appeal proceedings, document D12 was relied upon for the first time at the oral proceedings before the board. The opposition division had stated in the decision under appeal that they did not take a decision on the admission of document D12 into the proceedings.
5. The board notes that, when presenting their arguments in the oral proceedings on the issue of sufficiency of disclosure (see below), both the appellant and the respondent relied on the disclosure in document D12. Furthermore, the respondent did not object against taking the document into consideration. The board, being in a position to deal with the parties' submissions, also saw no reason to object to the late submissions based on document D12 of its own motion.
6. Accordingly, document D12 was considered by the board to form part of the appeal proceedings.

Sufficiency of disclosure (Article 83 EPC)

Main request - claim 1

7. The invention shall be disclosed in the patent in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. According to the established case law of the boards of appeal, this requires, in general, that the patent as a whole and taking common general knowledge into account must disclose at least one way of performing the invention such that the skilled person is in a position to perform the claimed invention readily and without undue burden substantially across the whole range claimed

(see Case Law of the Boards of Appeal, 8th edition, 2016, "CLBA", II.C.4.4).

8. It has further been established in the case law of the boards of appeal that when assessing medical use claims, attaining the claimed therapeutic effect is a functional technical feature of the claims. Accordingly, unless this is already known to the skilled person at the priority date, the patent must disclose the suitability of the product to be manufactured for the claimed therapeutic application (see e.g. CLBA, II.C.6.2 and decision T 609/02 of 27 October 2004 cited therein).

9. In the case at hand, the product of the invention defined in the medical use claim is "peptides derived from a whey protein hydrolysate" as active ingredient in a composition for preventing or treating overweight or obesity.

10. Thus, the question to be assessed in the context of sufficiency of disclosure in the present case is whether or not the patent in suit or the prior art provides information disclosing the suitability of the compositions comprising peptides as recited in claim 1 for the claimed therapeutic application.

11. The patent in suit comprises the following pertinent disclosure in relation to the prior knowledge in the technical field and the claimed invention.
 - 11.1 It was known in the art that elevated cholecystokinin (CCK) levels mediated a satiety signal in animals and that CCK thus had an important role in the treatment and prevention of obesity and overweight in animals. The inventors had surprisingly found that "*peptides*

derived from a whey protein hydrolysate have a positive effect in elevating the CCK level in an animal, including humans, in particular in the blood" (see paragraph [0006]) and that, accordingly, these peptides could be used as an active ingredient in compositions for elevating the CCK levels and increasing the perception of satiety in the context of overweight and obesity (see paragraph [0007]).

- 11.2 Whey proteins were known to have a relatively high tryptophan content (about 1.8 w/w%) and the whey protein hydrolysates - from which the peptides of the invention are obtained - are stated to be preferably derived from known whey protein isolates enriched in α -lactalbumin, the latter having a high tryptophan content of about 5.8 w/w% (see paragraph [0011]), by hydrolysis, preferably by enzymatic cleavage; all known techniques in the art (see paragraph [0009]).
- 11.3 Examples 1 to 5 disclose the preparation of peptides from whey protein. The peptides prepared in examples 1 to 3 and 5 are derived from pepsin hydrolysates of particular whey protein isolates having enhanced levels of α -lactalbumin (examples 1 to 3) or having an unknown level of α -lactalbumin (example 5). The tryptophan concentration of the resulting peptides is indicated as being 10.4%; 9.3% and 9.5% on peptide in examples 1 (see also Table 1), 2 and 5 respectively. Example 4 similarly discloses the preparation of peptides from a bromelain hydrolysate of a whey protein isolate with enhanced level of α -lactalbumin, and the resulting tryptophan content of the peptides is indicated to be 8%.
- 11.4 Example 6 is the sole example assessing the suitability of compositions to influence CCK levels in healthy

human volunteers. It discloses, in particular, ingestion of compositions (on the basis of orange juice) comprising either the peptides as obtained by example 1 or control compositions by the volunteers and the subsequent analysis of the CCK levels in their blood. Table 2 demonstrates that ingestion of the composition comprising the tryptophan-rich peptides of example 1 leads to an observed increase of blood CCK levels after 30 minutes which is deemed sufficient for an increased perception of satiety and which is superior to the increase incurred by ingestion of the control (orange juice) composition. The board notes that CCK levels were also increased in the blood after ingestion of the control compositions, i.e. orange juice supplemented with the amino acid tryptophan as such, albeit inferior to the increase with the peptide of example 1.

- 11.5 The first half of paragraph [0016] of the patent states that *"As outlined above, the aqueous peptide mixture, i.e. the whey protein hydrolysate is preferably prepared by enzymatic cleavage of whey protein, and more preferably, the whey protein is cleaved at acidic pH **by one or more acid proteases or cysteine proteases**, especially by one or more enzymes, chosen from the group, consisting of pepsine, rennin, acid fungal proteases, chymosin, papain, bromelain, chymopapain or ficin or mixtures of two or more thereof. **By cleavage of whey protein by one or more of said acid proteases**, especially pepsin at a pH between 1,5 and 3,5, preferably between 2-3, **peptides having a hydrophobic nature are generated**. It was found that from these peptide mixtures, the effective peptides could very efficiently be selectively isolated by controlling the pH to 4,0-6,0, preferably to around 5,0" (emphasis added by the board).*

12. The appellant has additionally referred to the prior knowledge of the skilled person as documented in document D12, which teaches that the CCK-releasing potency of dietary (free) amino acids is related to their hydrophobicity (see title), whereby the (free) amino acids found to cause significant plasma CCK elevation upon ingestion are tryptophan, phenylalanine, leucine and isoleucine, i.e. four hydrophobic amino acids (see page 38, left-hand column, lines 39 to 42).
13. The board concludes from the above summary of the disclosure in the patent and of the prior knowledge of the skilled person that the patent in suit provides sufficient evidence demonstrating that a composition comprising peptides derived from a whey protein hydrolysate obtained from a whey protein isolate which is highly enriched in the tryptophan-rich whey protein α -lactalbumin and which peptides are rich in tryptophan, i.e. above 8%, are suitable to increase CCK levels in the blood of humans to levels deemed to increase the perception of satiety (see points 11.3 and 11.4).
14. Indeed, the experimental disclosure would seem, in particular, to confirm the teaching in document D12 (free amino acids, see point 12 above), albeit here for tryptophan-rich peptides. Accordingly, based on these corroborating experimental results, and in view of the statements made in paragraph [0016] (see point 11.5) the patent might be accepted to suggest that a composition comprising peptides that are particularly rich in hydrophobic amino acids and derived from a whey protein are suitable to increase CCK levels and would thus have the technical effect required by the claim.

15. The board notes, however, that the subject-matter as claimed is not limited to relate to such "peptides derived from a whey protein hydrolysate" which have a particular high tryptophan content or which have a particular hydrophobic nature, but reads equally on such peptides lacking any tryptophan and/or hydrophobic amino acids or containing a very limited number thereof. The board further notes that claim 1, in fact, is not even restricted to the total mixture of peptides derivable from the isolation procedure but also reads on the medical use of every individual peptide which is derivable from whey protein.
16. The respondent argued that document D12 did not indicate that non-hydrophobic peptides would not have a serum CCK elevating effect. Also in this respect, the board can agree with the respondent. On the other hand, however, the board is also satisfied that the appellant has discharged its burden of proof in this respect as it appears indeed not to have been known in the prior art - and the respondent has not argued differently - that every individual peptide derived from a whey protein hydrolysate, i.e. also such peptides which lack or comprise very low levels of tryptophan and/or hydrophobic amino acids, can induce plasma CCK levels sufficient to obtain the claimed effect. The board is accordingly satisfied that under these circumstances the burden of proof to show that the patent discloses the suitability of such peptides for the claimed therapeutic application is shifted to the respondent. Evidently, such disclosure of suitability is lacking in the patent (see points 11.1 to 11.5).
17. In view of the above considerations, the board judges that the patent as a whole and taking the common general knowledge of the skilled person into account

fails to put the skilled person in a position to perform the claimed invention readily and without undue burden substantially across the whole range claimed.

18. Accordingly, the board decides that the invention as defined in claim 1 of the main request is not sufficiently disclosed and, thus, the requirements of Article 83 EPC are not met.

Auxiliary request 3 - claim 1

19. The claimed invention is now defined in terms of peptides which are further defined by being obtained from the hydrolysate by an isolation method specified to comprise a) providing an aqueous whey protein hydrolysate, b) controlling the pH of said aqueous whey protein hydrolysate to 4.0-6.0, forming a peptide precipitate, and c) isolation of said precipitated peptides (see section IV).
20. The respondent submitted that the claim now provided sufficient information for the skilled person to reproduce the effect claimed without any undue burden and over the whole scope of the claim.
21. The board notes that step a) of the described isolation method merely refers to the provision of an aqueous whey protein *hydrolysate* without actually specifying the particular nature of the whey protein isolate started from to obtain this hydrolysate (e.g. enriched for tryptophan or not). Nor is the nature of the hydrolysis applied (i.e. chemical or enzymatic cleavage) specified, nor the conditions used defined. Also, steps b) and c) do not state that the resulting isolated peptides are limited to such peptides for

which an effect on plasma CCK levels could possibly be accepted (see points 14 and 15).

22. Furthermore, when asked during the oral proceedings, the respondent confirmed that it was not arguing that, based on the isolation method now specified in the claim, only hydrophobic peptides would be obtained.
23. Accordingly, the board considers that the isolation method for the peptides as recited in the claim does not restrict the claimed subject-matter to remedy the lack of sufficiency of disclosure noted in relation to the main request (see point 18).
24. For this reason, the board decides that the invention as defined in claim 1 is not sufficiently disclosed and that, therefore, auxiliary request 3 does not meet the requirements of Article 83 EPC.

Auxiliary request 8

Admission into the proceedings

25. This request was filed by the respondent in response to a line of argument relating to sufficiency of disclosure submitted for the first time by the appellant during the oral proceedings.
26. Amended claim 1 appeared to be a simple combination of claims 1 to 3 of auxiliary request 3 and a *bona fide* attempt to overcome the deficiency from which claim 1 of auxiliary request 3 alone suffered.
27. In view of the above considerations, the board decided to admit the request into the proceedings (Article 13 RPBA).

Claim 1 - sufficiency of disclosure

28. Compared with claim 1 of auxiliary request 3 (see section IV), the claim now further specifies that the peptides are prepared by enzymatic cleavage of whey protein by one or more acid proteases or cysteine proteases (see section VIII).

29. The respondent has submitted that the skilled person was taught in paragraph [0016] of the patent that enzymatic cleavage of whey protein by one or more acid proteases or cysteine proteases resulted in a hydrolysate comprising peptides of hydrophobic nature and that the examples demonstrated that such enzymatic cleavage, in particular by pepsin and bromelain, indeed resulted in peptides which exhibited the claimed effect.

30. The board agrees with the respondent that paragraph [0016] of the patent relates in particular to the enzymatic cleavage of whey protein at an acidic pH by one or more acid proteases or cysteine proteases, that it indeed also states that when the hydrolysates are prepared at an acidic pH by one or more acid proteases - especially pepsin at a pH between 1.5 and 3.5 - peptides of a hydrophobic nature are then generated, and that the subsequent paragraph then stipulates that "*from these peptide mixtures, the effective peptides could very efficiently be selectively isolated by controlling the pH to 4.0-6.0*". In the context of bromelain proteolysis paragraph [0016] of the patent further establishes that, when an enzyme having its pH optimum within the pH range of 4.5-6.0 is chosen, such as papain or bromelain, it will be possible to design the isolation method in such a way that cleavage of the

whey protein and precipitation of the peptides can occur simultaneously.

31. The board notes, however, that the method of obtaining the peptides as defined in the claim is not the same method as for obtaining the peptides referred to in paragraph [0016]. Furthermore, it is not evident that from each peptide hydrolysate generated by the method of preparation defined in the claim (i.e. "prepared by enzymatic cleavage by one or more acid proteases or cysteine proteases"), however again without defining the conditions of the hydrolysis or the particular nature of the whey protein isolate started from to obtain this hydrolysate (e.g. enriched for tryptophan or not), effective peptides can be isolated by controlling the pH to 4.0-6.0.
32. Furthermore, the board also notes that although it is stated in paragraph [0016] of the patent that peptide mixtures can be generated comprising peptides of a hydrophobic nature, this disclosure does not necessarily imply to the skilled person that the peptide hydrolysate solely consists of such peptides and that therefore any peptide isolated therefrom in accordance with the claimed method would be such a hydrophobic peptide. Moreover, as was submitted by the appellant, it was not the type of hydrolysis which guaranteed the resulting peptides to be rich in tryptophan and/or other hydrophobic amino acids but, rather, the whey protein isolate started from.
33. The consequence of the above considerations is that the invention as defined in claim 1 is not sufficiently disclosed and, therefore, auxiliary request 8 does not meet the requirements of Article 83 EPC.

Order

For these reasons it is decided that:

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

The Registrar:

The Chairwoman:



S. Lichtenvort

R. Morawetz

Decision electronically authenticated