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D E C I S I O N
of 2 December 1993

Case Number: T 0626/90 - 3.3.2

Application Number: 81105302.4

Publication Number: 0044032

IPC: A23J 3/00

Language of the proceedings: EN

Title of invention:
Process for producing a low-molecular weight peptide composition and nutrient agent containing the same

Patentee:
Terumo Corporation

Opponent:
OI) Krayer, Warner Dirk
OII) Unilever PLC / Unilever N.V.

Headword:
Production of peptides/TERUMO

Relevant legal norms:
EPC Art. 56

Keyword:
"Alternative claims submitted at oral proceedings; newly filed auxiliary requests; limitation to preferred embodiments; final decision possible; new requests accepted"
"Inventive step; main and first auxiliary request (no); second auxiliary request (yes); improvement not suggested by prior art"

Decisions cited:
T 0095/83, T 0153/85, T 0038/89, T 0131/87, T 0742/89, T 0741/91, T 0219/83

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0626/90 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 2 December 1993

Appellant: (Opponent 01)
Krayer, Warner Dirk
Volmerlaan 7
NL - GC Rijswijk (NL)

Representative:
Smulders, Theodorus A.H.J., Ir.
Vereenigde Octrooibureaux
Nieuwe Parklaan 97
NL - 2587 BN 's-Gravenhage (NL)

Appellant: (Opponent 02)
Unilever PLC /Unilever N.V.
Unilever House, Blackfriars / Burgmeesters' Jacobplein 1
London EC4 (GB)/NL - 3015 CA Rotterdam (NL)

Representative:
Hatzmann, Marinus Jan
Vereenigde Octrooibureaux
Nieuwe Parklaan 97
NL - 2587 BN 's-Gravenhage (NL)

Respondent: (Proprietor of the patent)
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku
Tokyo 151 (JP)

Representative:
Henkel, Feiler, Hänzel & Partner
Möhlstraße 37
D - 81675 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office dated 31 May 1990 concerning maintenance of European patent No. 0 044 032 in amended form.**

Composition of the Board:

Chairman: P.A.M. Lançon
Members: A.J. Nuss
S.C. Perryman

Summary of Facts and Submissions

I. European patent No. 0 044 032 was granted with five claims, i.e. two process claims together with three product claims, on European patent application No. 81 105 302.4 filed on 8 July 1981 and based on two Japanese priorities both dated 10 July 1980.

Claim 1 reads as follows:

"A process for producing a low-molecular weight peptide composition, characterized by the steps of dispersing protein raw material from any suitable source in water at a concentration of 5 to 20 w/v%, adjusting the pH of the dispersion in the range from 1 to 4 with an acid, adding at least two acid proteases to the dispersion simultaneously or sequentially, and permitting enzymatic proteolysis to take place for 8 to 72 hours at a temperature of 25 to 60°C, thereby producing a low-molecular weight peptide composition mainly based on dipeptides and tripeptides while suppressing the formation of free amino acids to 20% by weight or less."

II. Opposition was filed against the granted patent by the Appellants (Opponents). From the documents cited in support of the opposition only the following remained finally relevant in this appeal:

(2) Clinical Science (1971), 41, 409 to 417;
(7) FR-A-2 412 265;
(10) EP-A-0 022 019 (Art. 54(3) EPC document published on 7 January 1981);
(12) US-A-3 950 547;
(14) US-A-2 364 008;

(21) Eiyo to Shokuryo (J.Japan.Soc. Food & Nutrition) (1978), Vol. 31, No. 3, 247 to 253 [S. Arai].

III. In accordance with the interlocutory decision under appeal, the Opposition Division decided to maintain the patent in amended form, i.e. with the two process claims as granted.

The claimed invention was disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art as the Sephadex G-10® gel permeation method mentioned in the patent in suit could be found in the catalogue "gel filtration, theory and practice" under the heading "Chromatographic properties" together with the indication of a molecular range of 700 for peptides and other relevant additional information to be taken into account in practice in order to overcome interactions of certain compounds with the gel.

Furthermore, in its decision the Opposition Division took the view that the claimed process was novel and also involved an inventive step. This conclusion was in particular based on the uncontested figures of Table III contained in the patent in suit showing that, when administered to rats of the Wistar strain, the product obtained by the disputed process was able to reduce the cholesterol value in blood when compared to egg white protein, a corresponding mixture of free amino acids, or a peptide composition with an average molecular weight of 1400 and free amino acid content of 2% by weight. From none of the cited documents could there be derived any advice to change the process described in document (2), which used pancreatic hydrolysis for preparing a product, to achieve said beneficial effect. As document (10) was

an Article 54(3) EPC document, it could not even be used for assessing inventive step.

IV. Both Appellants (Opponents) lodged an appeal against this decision.

Oral proceedings were held on 2 December 1993.

(i) In their written submissions and at the oral proceedings before the Board, the Appellants argued in essence that the peptide product prepared from any suitable source in accordance with the claimed process could not be considered to be different from the hydrolysate disclosed in document (10) in view of a partial overlap in composition with that obtained in accordance with the claimed process. It was indeed commonly known in the art that the various peptides to be considered here had, on average, the following molecular weights: dipeptide about 260; tripeptide about 360; tetrapeptide about 510; pentapeptide about 630; hexapeptide about 750. Thus, the known hydrolysates necessarily had an average molecular weight lower than 700 as according to Claim 1 of (10) at least 50% of the peptides were required to contain merely 2 to 5 amino acids whereby the amount of free amino acids was less than 15%. The question of inventive step should therefore have been limited to the claimed process taken by itself, that is to say without considering the products to be obtained by the said process; it would then have come out that the process as such could not be regarded as inventive. The only important step in the claimed process appeared to be the moment of stopping the hydrolysis, namely when a certain maximum amount of free

amino acids had been formed. However, apart from being obvious in view of the teaching disclosed in (7), the said measure could not be regarded as critical as could be seen from the statement in the patent in suit that in the claimed process proteases were added in an amount sufficient to give a desired degree of proteolysis, that is, at least 1% by weight, preferably 2 to 5% by weight based on the substrate and that the reaction time depended on substrate concentration, protease amount, reaction temperature and the like, the reaction itself being terminated before the resulting peptide composition had been hydrolysed to amino acids. In addition, as could be derived from Table I contained in the patent in suit, the use of two acid proteases - in itself already known from (7) - could hardly be regarded as critical in respect of both the formation of a certain maximum amount of free amino acids and the average molecular weight of the resulting hydrolysates. Nothing inventive could be seen either in the cholesterol-reducing activity of the hydrolysates obtained in accordance with the claimed process as this effect had already been described in EP-A-0 033 694 (23) and Artherosclerosis (1977), 28(2), 187 to 195 [Huff et al], reported in Chemical Abstracts (24). The above objections would not be removed by limiting the starting material to solely egg white or by specifying, in addition to the latter, that the content of those peptides having a molecular weight of at least 700 in the enzymatic hydrolysis product should be 20% by weight or less, as it was already known from document (12) to prepare peptide mixtures having

an amino acid profile corresponding to that of egg albumin.

(ii) As far as the question of sufficiency of disclosure was concerned, the Appellants no longer maintained that the claimed invention could not be repeated by a person skilled in the art. They objected however that the patent in suit did not contain any information on how to determine the molecular weight of the peptides present in the hydrolysate obtained in accordance with the claimed process. Consequently, the person skilled in the art was not in a position to determine whether or not the resulting hydrolysate was a composition mainly based on dipeptides and tripeptides as required in the present claims. This was supported by the fact that, as could be seen in the patent in suit, peptides having a molecular weight of lower than 700 could not be identified by a gel filtration process using Sephadex G-10® gel permeation which merely allows fixing a cut-off point for substances having a molecular weight above 700 without exactly knowing which substances (peptides) passed the barrier.

(iii) The Appellants further objected to the filing of two alternative sets of claims at the oral proceedings before the Board. In their view, the Respondent had disposed of ample time, i.e. more than three years, to file amended claims.

V. The Respondent (Proprietor of the patent) argued as follows:

(i) Although at the oral proceedings before the Board, the Respondent conceded that the products

no longer claimed were not novel over those disclosed in document (10), as these were partly the same as those obtained by the claimed process, he maintained however that none of the cited documents including document (10) disclosed or foreshadowed the beneficial effects obtained by these products. In particular, the state of the art was silent on their property of reducing the cholesterol value in blood, the actual problem to be solved in the present case. Contrary to the opinion expressed by the Appellants, the claimed process differed from the known one by other features as well as by a longer duration of the enzymatic digestion. The latter should not be regarded as critical in comparison to other features of the claimed invention. In case the Board did not accept these arguments in connection with Claim 1 as granted, they should be considered to be sufficient to support inventive step of either a process limited to egg white as starting material or one containing the said limitation in addition to the further requirement that the content of peptides having a molecular weight of at least 700 in the enzymatic hydrolysate should be 20% by weight or less.

(ii) There were also no reasons to consider the disclosure to be insufficient. It was clearly stated in the patent in suit that gel filtration on Sephadex G-10® would lead to peptides with a molecular weight of about 300 to 550. This was not in contradiction with the requirement that the obtained peptides should be mainly di- and tripeptides. As the determination of their molecular weight would be nothing more than routine work involving the usual markers in that

field, the person skilled in the art required merely common general knowledge to carry out such determinations if wanted.

(iii) As to the filing of two alternative sets of claims during the oral proceedings, the Respondent argued in essence that both sets were far-reaching restrictions of what was claimed. The representative further declared that he was not in a position to file amended claims before having received corresponding instructions by the Patentee. Under these circumstances, the newly submitted alternative sets of claims should not be refused although filed at such a late stage of the proceedings.

VI. The two auxiliary requests read as follows, the amendments being emphasised:

Auxiliary request 1

"1. A process for producing a low-molecular weight peptide composition, characterized by the steps of dispersing protein raw material from **egg white** in water at a concentration of 5 to 20 w/v%, adjusting the pH of the dispersion in the range from 1 to 4 with an acid, adding at least two acid proteases to the dispersion simultaneously or sequentially, and permitting enzymatic proteolysis to take place for 8 to 72 hours at a temperature of 25 to 60°C, thereby producing a low-molecular weight peptide composition mainly based on dipeptides and tripeptides while suppressing the formation of free amino acids to 20% by weight or less.

2. A process for producing a low-molecular weight peptide composition according to claim 1, characterized in that the contents of free amino acids

and those peptides having a molecular weight of at least 700 in the enzymatic proteolysis product are individually 20% by weight or less."

Auxiliary request 2 (single claim)

"A process for producing a low-molecular weight peptide composition, characterized by the steps of dispersing protein raw material from **egg white** in water at a concentration of 5 to 20 w/v%, adjusting the pH of the dispersion in the range from 1 to 4 with an acid, adding at least two acid proteases to the dispersion simultaneously or sequentially, and permitting enzymatic proteolysis to take place for 8 to 72 hours at a temperature of 25 to 60°C, thereby producing a low-molecular weight peptide composition mainly based on dipeptides and tripeptides while suppressing the formation of free amino acids to 20% by weight or less, **the content of those peptides having a molecular weight of at least 700 in the enzymatic proteolysis product being 20% by weight or less.**"

VII. The Appellants requested that the decision under appeal be set aside and that the European patent No. 0 044 032 be revoked.

The Respondent requested as main request that the appeals be dismissed and that the patent be maintained, and as auxiliary requests that the decision under appeal be set aside and the patent be maintained on the basis of the first or second auxiliary request submitted during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

2. *Procedural matters: admissibility of auxiliary requests 1 and 2*

As is apparent from paragraphs IV(iii) and V(iii) above, two alternative sets of claims were submitted by the Respondent at the oral proceedings on 2 December 1993. In the present case, the Board decided to admit into consideration both sets of claims for the following reasons.

In decisions T 95/83 (OJ EPO 1985, 75, point 8 of the Reasons) and T 153/85 (OJ EPO 1988, 1, point 2.1 of the Reasons), it has been stated that Boards of Appeal **may** refuse late filed amendments, e.g. new claims presented at oral proceedings, if such claims are not clearly allowable or if the Proprietor of the patent can provide no justification for the late filing. As set out in decision T 38/89 of 21 August 1990, point 3 of the Reasons (not published in OJ EPO), it is quite clear that the Boards of Appeal have a general discretion to refuse all late-filed amendments depending in particular on any excuses put forward for the apparent lateness, and the inconvenience that would be caused if the amendments are admitted into the proceedings.

This jurisprudence is also in conformity with Article 11(3) of the Rules of Procedure of the Boards of Appeal which states that "if oral proceedings take place, the Board shall endeavour to ensure that each case is ready for decision at the conclusion of the oral proceedings, unless there are special reasons to

the contrary". In the present case the amendments were not such that the Board would have been prevented from taking a final decision at the end of the oral proceedings.

The lack of timely instructions from the Patentee put forward by their representative at the hearing could not in itself be regarded as justifying the late submission. The Board was, however, satisfied that the new versions of the claims were *bona fide* attempts to overcome the objections raised by the Appellants in connection with the question of inventive step of the claimed process, and that no question of the Appellants being taken unfairly by surprise arose, because in both requests the amendments were nothing more than a limitation of the claimed subject-matter to preferred embodiments of the invention as described in the patent in suit (see point V(iii) above).

3. *Allowability of amendments in auxiliary requests 1 and 2*

There are no formal objections on the basis of Articles 123(2) and (3) to the two sets of claims in the auxiliary requests (see point VI above) since these claims are adequately supported by the original description and do not extend the protection conferred when compared to the claims as granted. This was not contested by the Appellants.

4. *Patentability of main request and auxiliary request 1*

4.1 Sufficiency of disclosure

In the view of the Board, and for the same reasons as set out under point 5.1 below in connection with auxiliary request 2, the invention claimed in

accordance with the main and first auxiliary request must be regarded as satisfying the requirements of Article 83 EPC.

4.2 Novelty

None of the documents considered in the present proceedings discloses a **process** presenting all the features indicated in the claims in accordance with the main or first auxiliary request. This was not contested by the Appellants. The said claims must thus be regarded as novel.

4.3 Inventive step

4.3.1 In relation to the invention as claimed in all the requests, document (7) is regarded as constituting the closest prior art. It relates to a process for the treatment of a proteinaceous waste material such as blood, carcass waste, bone waste and meat waste by subjecting the said material to enzymatic hydrolysis with **at least one protease** whereby decomposition of the proteinaceous material is effected; and subsequently inactivating the said enzyme. The hydrolysis is effected in the pH range in which the enzymes display maximum proteolytic activity (i.e. pH between 2 to 7 in the case of **acid proteases**); the temperature is conveniently between room temperature (20°C) and 70°C, preferably between 25 and 50°C. A period of one to five hours is in general sufficient to effect enzymatic decomposition. By the use of suitable **enzyme mixtures** different protein hydrolysates can be prepared, which differ from one another in their degree of decomposition, i.e. the size of the molecules. Due to the combination of enzyme type and concentration, temperature and decomposition time, long-chain or medium-chain or

short-chain protein hydrolysates can be obtained. The hydrolysates thus obtained are products of high value which can be used for nutrition purposes (see claims; page 2, lines 12 to 34; page 3, line 1 to page 4, line 23; page 4, lines 33 to 37 and page 5, lines 5 to 17). In Example 4, chicken meat waste was hydrolysed at 50°C during five hours in the presence of fungal protease from Aspergillus oryzae and papain, the pH value of the hydrolysate being 4.1 whereas in Example 5 heavy blood is used at a hydrolysis temperature of 60°C and at a pH value of 5 in the presence of acid fungal protease from Aspergillus oryzae and papain. As stated in the latter, enzymes from Aspergillus saitoi, Aspergillus parasiticus, etc., can similarly be used instead of the acid enzymes from Aspergillus oryzae. This document does not mention any cholesterol-reducing property of the products obtained.

4.3.2 The Board does not agree with the submission by the Respondent that the technical problem underlying the patent in suit consisted in providing a process for producing a low-molecular peptide containing nutrient agent of high value capable of providing a reduced cholesterol value in blood.

When defining the technical problem an effect cannot be retained if it is not credible that the promised result is attainable throughout the entire range covered by a claim (see for example T 131/87 of 7 September 1989, point 8; T 742/89 of 2 November 1992, point 7.4 and T 741/91 of 22 September 1992, points 4.2 and 4.3).

Contrary to the submission of the Respondent, the problem as defined by him is not plausibly solved by

the process of the Claim 1 of the main or the first auxiliary request.

4.3.3 In Table III of the patent in suit, composition IV has not only been obtained in accordance with the claimed process, but also meets the widely drawn product definition mentioned in the claims; this composition leads to practically the same cholesterol/ serum values as composition I, i.e. egg white protein (unhydrolysed): 116 vs. 118 mg/dl. The claims put forward do not contain any product feature which would exclude a process leading to peptide compositions such as composition IV, i.e. with an average molecular weight of 1400 and a free amino acid content of 2% by weight, from their scope of protection. It is not sufficient that composition II, a peptide composition with an average molecular weight of 420 and a free amino acid content of 8% by weight, leads to a surprisingly low cholesterol/serum value of 95 mg/dl if the problem of providing a reduced cholesterol value in blood is not also solved by **all** other embodiments falling within the process claim of either the main request or the first auxiliary request.

4.3.4 Therefore, as far as the main and first auxiliary request is concerned, the underlying technical problem can only be seen in providing an alternative for the known process of producing peptide containing hydrolysates suitable for nutrition purposes. The Board accepts that this problem is solved by what is claimed.

However, when trying to solve the above problem, the person skilled in the art would realise that the process disclosed in document (7) offers the possibility of producing hydrolysates containing oligopeptides from a proteinaceous material by

enzymatic digestion which are suitable for use in nutrition. As a skilled person he will know that it has already been shown that the small intestine has a high capacity for absorption from mixtures of small peptides such as might be produced during protein digestion, especially those composed of two to six amino acid residues, and that mucosal uptake of intact oligopeptides is probably an important mode of protein absorption (see for example document (2), page 409, point 2 of the "Summary"). He would thus not only be aware that for **efficient nutrition**, the hydrolysates composed of low-molecular weight peptides were most advantageous but also that in view of the teaching contained in (7) (see point 4.3.1 above), it is merely a matter of routine to find out suitable process parameters in order to obtain such a high value nutrient. In connection with the latter it is indeed clear from the information contained in (7) that a suitable way to carry out the process consists in the combined use of two acid proteases of the type also used in the patent in suit (see page 3, lines 51 to 54) and that in the case of acid proteases the pH value may be as low as pH = 2, depending on the acid enzymes used for carrying out the degradation process. The same applies to the temperature, which in the known process is preferably between 25 and 50°C. Though in (7) the main purpose is to degrade the proteins contained in a proteinaceous waste material, the person skilled in the art would have no reason to believe that more valuable protein raw materials such as egg white could not be used in the same way. There is not only no evidence available to the Board which would show that with a particular protein raw material the known process could not be carried out but also no evidence that when allowing the acid enzymatic digestion to go on up to the point where a "short-chain protein hydrolysate" is obtained according to

(7), the composition necessarily contains more than the 20% by weight of free amino acids set as a limit in the claims now put forward. Although it is true that document (7) mentions urea and ammonium salts as additives in connection with enzyme preparations, it appears that such additives **may** be used with certain specific enzymes only (cf. page 4, second paragraph). Further, the present claims do not exclude such addition. Thus the claimed process is an obvious alternative to the process disclosed in (7) for obtaining short-chain protein hydrolysate suitable for nutrition purposes.

4.3.5 In view of the above, the Board holds that the process claimed in accordance with both the main and first auxiliary request does not involve an inventive step in the sense of Article 56 EPC.

5. *Patentability of auxiliary request 2*

5.1 Sufficiency of disclosure

It is well known that by gel filtration on Sephadex G-10® it is possible to fractionate peptide mixtures whereby those peptides having a molecular weight of 700 or lower are collected in one fraction. As this is no longer disputed by the Appellants, the only remaining question as regards sufficiency of disclosure is whether or not the patent in suit contains sufficient disclosure for the person skilled in the art to determine whether the product obtained by the claimed process corresponds indeed to a low-molecular weight peptide composition **mainly based on dipeptides and tripeptides** as indicated in the claim.

As can be seen from the "Production Example" contained in the patent in suit, the product obtained in

accordance with the claimed process is stated to have an average molecular weight of about 300 to 550, to contain about 5 to 20% by weight of free amino acids and 20% by weight or less of those peptides having a molecular weight of 700 or higher (see page 5, line 6 to page 6, line 3). In view of the known molecular weight averages for peptides cited by the Appellants themselves (see point IV(i) above), it is thus credible that the fraction obtained by Sephadex G-10® filtration is **mainly** composed of di- and tripeptides even if it is clear that other peptides with a higher molecular weight but well below 700 (e.g. tetra- or pentapeptides) must necessarily be present in an undefined amount as a consequence of the particular gel used in the patent in suit. As in the present case, all that is required, at least as far as the peptide composition as such is concerned, is a composition **mainly** based on di- and tripeptides, it is neither necessary nor relevant for the person skilled in the art to know the exact peptide composition in terms of molecular weight distribution. In the absence of adequate evidence in support, the Appellant's objection under Article 100(b) EPC therefore fails (cf. T 219/83, OJ EPO 1986, 211, in particular point 12 of the Reasons).

5.2 Novelty

The process claim of the second auxiliary request is not only limited to egg white as starting material, it also contains the further restriction that the content of those peptides having a molecular weight of at least 700 in the obtained enzymatic proteolysis product is 20% by weight or less, which considerably reduces the amount of peptides having an average molecular weight of 700 or higher tolerated in the final product. Thus, the **definition of the peptide**

composition is **far more precise** than in the process claim of the previous requests.

Consequently, not only is the claimed process novel over the cited state of the art but also its product is novel since none of the said features is disclosed in document (10) as can be seen from what has already been said under point 4.2 above.

5.3 Inventive step

5.3.1 Document (7) (see point 4.3.1 above) is considered as the closest prior art.

5.3.2 For this second auxiliary request, the Board does accept the Respondent's submission that the underlying problem consisted in providing a process for producing a low-molecular peptide containing nutrient agent of high value capable of providing a reduced cholesterol level in blood, and that this problem is solved by the process as now claimed.

5.3.3 In view of the present definition of the peptide composition already pointed out above, composition IV mentioned in Table III on page 6 of the patent in suit is not a composition resulting from the claimed process since a composition with an average molecular weight of 1400 and a free amino acid content of 2% cannot be **mainly** based on di- and tripeptides whereby, **in addition**, the content of those peptides having a molecular weight of at least 700 as well as that of free amino acid is at most 20% by weight. As can be seen in the patent in suit, such a product has only an average molecular weight of about 300 to 550 (see page 5, line 65 to page 6, line 3).

5.3.4 Having regard to the comparative data contained in Table II of the patent-in-suit, the Board is also satisfied that the problem stated above has indeed been solved by the process **as now claimed**. It appears from that table that the product obtained in accordance with the claimed process, i.e. composition II, leads to a much lower cholesterol/serum value (95 mg/dl) than composition IV, i.e. the product obtained in accordance with the closest state of the art (116 mg/dl). Moreover, when considering the fact that composition II leads to practically the same cholesterol/serum value as unhydrolysed egg white (118 mg/dl), the person skilled in the art will realise the importance of the cholesterol reducing effect achieved by composition II.

5.3.5 The only question which remains to be decided is thus whether the requirement for inventive step is met by the process as now claimed.

5.3.5.1 Although the person skilled in the art would certainly have taken note of document (7) for the reasons already set out in connection with the previous requests (see point 4.3.4 above), there is nothing pointing to this document as being relevant to solving the problem of providing a low-molecular peptidic nutrient showing reduced cholesterol level in blood. Neither document (7) nor document (2) deal with this property at all. The only documents mentioned in the whole proceedings which refer to the cholesterol level in connection with protein hydrolysates are documents (23) and (24). Neither is relevant to the question to be answered here for the following reasons:

- document (23) is an Article 54(3) EPC document published on 12 August 1981 and cannot therefore be used for dealing with the question of inventive

step under Article 56 EPC. Therefore, the mention on page 8, lines 11 to 21 of this document that both a quantitative and qualitative improvement of the total cholesterol and HDL cholesterol has been achieved must be ignored;

- document (24) is concerned with the effects of dietary proteins, protein hydrolysates and amino acid mixtures, and the following is stated therein: an enzymatic hydrolysate of casein or a mixture of L-amino acids equivalent to casein gave elevated plasma cholesterol levels similar to those obtained with the intact protein; plasma cholesterol levels remained low in rabbits fed an enzymatic digest of soy bean protein; a moderate, but not significant, increase in plasma cholesterol was observed when a mixture of L-amino acids equivalent to soy bean protein isolate was fed; evidently, the level of plasma cholesterol can be influenced by the amino acids supplied in the diet.

Although it is reasonable to admit that the person skilled in the art would certainly have noted with interest that an "enzymatic digest" of soy bean protein obviously keeps plasma cholesterol levels in rabbits low, he would not have missed the message that with hydrolysates from other starting materials (e.g. casein) elevated levels were observed. As for none of these hydrolysates the process of preparation or the composition had been described in any detail, the person skilled in the art was provided with no concrete teaching as regards the suitability or unsuitability of other protein materials as starting material, the exact enzymatic process to be followed or the minimal product characterisation to be met in order to

achieve the said effect. Document (24) thus in no way suggests the solution now claimed which, in particular, involves the selection of **egg white** as starting material in connection with a **specific process** (combined action of two acid proteases) whereby a **specific product** (mainly based on di- and tripeptides etc.) is obtained.

5.3.5.2 Document (12) not only is totally silent in respect of any possible cholesterol reducing property of the peptide mixture prepared there but also as regards the use of two acid proteases for obtaining them. There the only aim is to prepare a dry dietary food composition comprising a nutritionally balanced peptide mixture, or amino acid supplemented peptide mixture, with a total amino acid profile sufficient to support normal physiological functions whereby typically, and preferably, the peptide mixture will have an amino acid composition of **egg albumin**, which means that it will be primarily composed of peptides having a molecular weight between 400 to 1000 with a maximum molecular weight of 2000, and **typically the greatest distribution of peptides will have from four to eight amino acid residues**. It is also to be noted that such protein hydrolysates typically contain, in addition to peptides, about from 10 to 15% by weight, free amino acids (e.g. lysine, arginine, tyrosine, phenylalanine, and leucine) and can be prepared by known enzymatic or chemical hydrolysis of fish meal, oil seed proteins, leaf proteins, single cell proteins, or slaughterhouse animal scraps and blood. In "Preparation 1", an aqueous mixture of fish protein is digested in the presence of calcium hydroxide (pH controlled at about 7.7 ± 0.3) during almost 20 hours (see Claim 1, column 2, line 61 to column 3, line 46 and column 9, line 40 to 68). This information is sufficient to show that in (12) a different product is

prepared by a different process, and for a different purpose, so that (12) also does not suggest the claimed solution to the person skilled in the art.

5.3.5.3 Similar considerations must also apply to document (14) which concerns a process of making a nutrient material presented merely as being suitable for oral, rectal, and parenteral administration, comprising primarily polypeptides obtained by digesting a protein at a temperature between 37 and 70°C during several days in a medium having a pH between 4 to 5 with a (single) proteolytic enzyme (e.g. papain or those occurring in liver, kidney, and other animal tissue). The protein is desirably a natural protein such as casein, the protein from soy bean, or certain animal tissues (see claim; page 1, right-hand column, lines 9 to 11 and 29 to 36; Examples 1 and 2).

Document (21) is not relevant either as the only possibly relevant information is that "in the manufacture of enzymatically-hydrolysed products of protein, the substance containing large quantities of low-molecular peptides (roughly, peptides with not more than 500 molecular weight) such as di- and tripeptides is preferred **in terms of amino acid absorption and also of the balance in amino acids after the absorption**" (emphasis added by the Board) and that "further ..., it is also quite obvious that the less free amino acid content in hydrolysed protein, the better". It is not clear how the said enzymatic hydrolysis has been carried out, nor that the hydrolysate thus prepared can be regarded as a product with properties comparable to those of the product obtained in the patent in suit from egg white. Consequently, this document does not suggest the claimed solution to the person skilled in the art.

5.3.5.4 The other documents cited in the course of these proceedings were even less relevant than those discussed above.

5.3.6 The subject-matter of the single claim in accordance with the Respondent's second auxiliary request is thus not suggested by the cited state of the art as a solution to the stated problem, and the Board therefore holds that it involves an inventive step in the sense of Article 56 EPC.

6. Accordingly, there are no grounds which prejudice the maintenance of the patent in amended form on the basis of the claim of the second auxiliary request.

7. As the patent is to be maintained on the basis of a claim substantially restricted in comparison to the granted claims, the description needs to be carefully adapted to the new process claim. In accordance with Article 111 EPC, the case is remitted for that purpose to the Opposition Division.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent in amended form on the basis of the claim of the second auxiliary request

submitted at the oral proceedings on 2 December 1993, and a description to be adapted.

The Registrar: The Chairman:

P. Martorana P.A.M. Lançon