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**Datasheet for the decision
of 20 March 2007**

Case Number: T 0428/06 - 3.3.08

Application Number: 96904839.6

Publication Number: 0811056

IPC: C12N 5/02

Language of the proceedings: EN

Title of invention:

Peptides for tissue and cell culture media

Patentee:

Quest International Services B.V.

Opponent:

Campina Melkunie B.V.

Headword:

Glutamine culture media/QUEST

Relevant legal provisions:

EPC Art. 114(2)
RPBA Art. 10b(3)

Keyword:

"Admissibility of new documents"
"Admissibility of new main request (no)"

Decisions cited:

-

Catchword:

-



Case Number: T 0428/06 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 20 March 2007

Appellant I: Quest International Services B.V.
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Appellant II: Campina Melkunie B.V.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
23 December 2005 concerning maintenance of
European patent No. 0811056 in amended form.

Composition of the Board:

Chairman: L. Galligani
Members: P. Julià
B. Günzel

Summary of Facts and Submissions

- I. European patent No. 0 811 056 was granted on the basis of European patent application No. 96 904 839.6 (published as international application WO 96/26266) and was opposed on the grounds of Articles 100(a), (b) and (c) EPC.
- II. The opposition division, which regarded the opposition as admissible and allowed the request to correct the opponent's name under Rule 88 EPC, decided to maintain the patent in amended form on the basis of the first auxiliary request then on file. The main request (claims as granted) was considered to contravene Article 54 EPC because claim 7 thereof was found to lack novelty.
- III. Both the patentee (appellant I) and the opponent (appellant II) lodged an appeal against the interlocutory decision of the opposition division.
- IV. With letter of 28 April 2006, appellant I filed the statement setting out the grounds of appeal together with a main request and a first, second and third auxiliary request with an adapted description. Claim 1 of the **main request** read as follows:
- "1. A method for in vitro maintaining or growing **higher** eucaryotic cells by use of a culture medium comprising a glutamine containing protein hydrolysate, obtained by enzymatic hydrolysis of a protein material, wherein the protein hydrolysate has:

- a free amino acid level of less than 15% by weight of the total proteinaceous material,
- an average chain length of the peptides of less than 15 amino acids, **calculated according to formula (10)**

$$\begin{array}{rcl}
 & \text{TN/F - FAA} & \\
 \text{PCL}_{\text{pep}} & = & \frac{\text{-----}}{\text{AEN - EN - FAA}} \quad (10)
 \end{array}$$

in which TN, AN, AEN, EN and FAA are given in mmol per weight unit and the parameters in formula (10) have the following meanings:

- TN:** Total Nitrogen;
- EN:** Epsilon amino Nitrogen;
- AEN:** The sum of alpha and epsilon nitrogen;
- FAA:** Free amino acid level;
- F:** Average amount of Nitrogen per amino acid residue in a protein;
- PCL_{pep}:** Average peptide chain length for the peptide fraction;

- and wherein at least 90% by weight of the protein hydrolysate has molecular weight below 1000 D as determined by gel permeation chromatography."

(in bold-type character the differences in comparison with claim 1 as granted)

Claims 2 to 6 were directed to further embodiments of claim 1. Independent claim 7 related to a culture medium for in vitro maintaining or growing higher eucaryotic cells which comprised the glutamine containing hydrolysate as defined in claim 1, except

for the free amino acid level which was required to be less than 10% by weight of the total proteinaceous material. Claims 8 to 12 were directed to further embodiments of claim 7.

The **first, second and third auxiliary request** specified the type of higher eukaryotic cells (animal cells, preferably mammalian or insect). The third auxiliary request was the same as the request accepted by the opposition division.

- V. With letter of 1 May 2006, appellant II filed the statement setting out the grounds of appeal together with new documents D22 to D29.
- VI. Appellant I replied thereto with letter of 21 September 2006 and filed fourth, fifth and sixth auxiliary requests with corresponding adapted descriptions. New documents D30 to D34 were also filed in support of its arguments.

The said **fourth, fifth and sixth auxiliary requests** read as the first, second and third auxiliary requests except for further requiring the glutamine containing protein hydrolysate to have "*20% by weight or more of glutamine residues*".

- VII. With the summons to the oral proceedings, the Board sent a communication to the parties under Article 11(1) of the Rules of Procedure of the Boards of Appeal (RPBA). The parties were informed therein of the board's preliminary opinion on the relevant issues.

- VIII. With letters of 20 February 2007, both appellant I and appellant II replied to the communication of the Board. Appellant I requested that documents D22 to D29 be excluded from the proceedings under Article 114(2) EPC.
- IX. Oral proceedings took place on 20 March 2007. After a discussion on the admissibility of the documents filed on appeal and of issues of Articles 54 and 56 EPC, appellant I filed a further request, which - after a discussion on its admissibility into the proceedings - became the new main and sole request, all previous requests on file being withdrawn.
- X. Claim 1 of the **new main and sole request** filed during the oral proceedings read as the previous main request (cf. Section IV supra) except for the change of the term "*higher eucaryotic cells*" to "*animals cells, preferably animal or insect*" and the addition at the end of the claim of the sentence: "*wherein the protein material is selected from meat protein, soy protein, and rice or maize protein*". Corresponding amendments were introduced also in the independent product claim directed to the culture medium (former claim 7; cf. Section IV supra).
- XI. The following documents are referred to in the present decision:
- D6: J.M. Lacey and D.W. Wilmore, Nutrition Reviews, 1990, Vol. 48, No. 8, pages 297 to 309;
- D16: JP 02/049,579 (laid-open: 19 February 1990);
- D17: EP 0 220 379 (publication date: 6 May 1987);

D22: JP Kohyo Publication H6 245790 (publication date:
6 September 1994).

XII. The arguments of appellant I may be summarized as follows:

Admissibility of the documents filed in the appeal proceedings

The filing of new documents by appellant II was not occasioned by the amendments introduced into the auxiliary requests filed during the first instance proceedings. None of the new documents was highly relevant nor could prejudice the maintenance of the patent in suit. In particular, the teachings of document D22 concerned a technical field (nutrition) unrelated to that of the patent in suit (growth media).

Admissibility of the new main request filed during the oral proceedings

The new main request excluded only wheat from all the possible starting protein material explicitly indicated in the description of the patent in suit. The amendments made were aimed at overcoming the objection to patentability as neither document D22 nor document D16, which had affected the patentability of the previous requests, suggested a starting protein material other than wheat. The latter documents emphasized the high content of glutamine residues in wheat, thus they discouraged the use of other protein material, such as those now recited in the claims. In comparison with the requests previously on file, the

new main request was more limited, since specific subject-matter (wheat) was deleted and the claims recited only subject-matter that was already embraced by previous generic claims. There was technical information on file for at least one of the protein materials (soy) referred to in the new main request. The new main request did not create a new case, it was clearly allowable and thus it should be admitted into the proceedings.

XIII. The arguments of appellant II may be summarized as follows:

Admissibility of the documents filed in the appeal proceedings

Documents D22 to D29, filed with the statement setting out the grounds of appeal, were admissible into the appeal proceedings for three reasons. First, serious attempts to overcome the objections raised in the opposition proceedings were only made during the oral proceedings before the opposition division, when the patentee filed the auxiliary request allowed by the opposition division. Second, these documents addressed issues raised in the decision under appeal, such as that it had not been shown that low molecular weight protein hydrolysates could be suitable for growing animal cells. Their filing was thus prompted by the decision under appeal. Third, these documents, in particular document D22, were highly relevant and prejudiced the maintenance of the patent in suit.

Admissibility of the new main request filed during the oral proceedings

The deletion of the most preferred embodiment (wheat protein) and the introduction of starting protein material other than wheat into the claims represented a selection that had no formal support in the application as filed. Generic claims were not a valid support for specific embodiments that were not previously present in the claims. All the more so, since it was not clearly (and certainly not directly and unambiguously) derivable from the patent in suit that all material could be a suitable starting protein material for obtaining an appropriate protein hydrolysate. The teachings of document D22 were not limited to wheat protein but they were more general. Table 1 of document D6 showed that soy was a material with high content of glutamine and evidence was also on file showing that soy had already been used as protein hydrolysate for growth media. The new main request was not clearly allowable, it created a new case, and thus it was not admissible into the proceedings.

- XIV. Appellant I (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of its main and sole request filed during the oral proceedings ("New Main Request").

- XV. Appellant II (opponent) requested that the patent be revoked.

Reasons for the Decision

Admissibility of the opposition and request for correction of the opponent's name

1. The decision of the opposition division admitting the opposition and allowing the correction of the opponent's name has not been challenged by appellant I. The board has no reasons to question the findings of the opposition division.

Admissibility of the documents filed in the appeal proceedings

2. With the statement setting out the grounds of appeal, appellant II filed eight new documents (D22 to D29) which appellant I requested to exclude from the proceedings (cf. Sections V and VIII *supra*).
3. The board decided to admit into the proceedings only document D22 in view of its *prima facie* relevance. It discloses a glutamine-containing protein hydrolysate obtained by enzymatic hydrolysis of wheat protein. Said hydrolysate is characterized by the same structural properties as that of the patent in suit, in particular a high content of glutamine and of dipeptides and tripeptides. Although only its use as a protein source for nutritional purposes (for elderly people, nursing infants, etc.) is disclosed, reference is also made to the advantageous properties of the glutamine present in peptide form (stable with respect to heating and other treatment) and to the fact that it "*can be used for a wide range of applications*" (cf. page 2, line 5 from the bottom and page 20, lines 2 to 5).

4. None of the other documents filed by appellant II was considered to be *prima facie* sufficiently relevant, the protein hydrolysates disclosed therein not having all technical features that characterize the protein hydrolysate of the patent in suit. These documents were in fact not more relevant than those already on file. Also documents D30 to D33 filed by appellant I in direct reply to the filing of documents D23 to D29 were not admitted. The introduction of document D34 was not objected by appellant II and its introduction into the proceedings does not alter the board's conclusions in the case at issue.

Admissibility of the new main request filed during the oral proceedings

5. The "New Main Request" (sole request on file) was filed during oral proceedings - initially as a further auxiliary request - after the substantive discussion on the preceding requests (a main request and six auxiliary requests) had shown that none of them was patentable, especially in the light of the prior art documents D6, D16, D17 and D22. Following the discussion on its admissibility into the proceedings, appellant I decided to withdraw all previous requests and to maintain only the said request. However, for the reasons outlined hereinafter, this request cannot be admitted into the proceedings.
6. Amended sets of claims, when filed during the oral proceedings, can only be admitted into the proceedings if the amendments made are in direct response to the substantive discussion, and if they are manifestly allowable from a formal point of view (clarity, added

matter), can reasonably be dealt with in the oral proceedings by the other parties and by the board (Article 10b(3) RPBA), and do not extend the framework of the discussion.

7. Appellant I was of the view that the request in question here fulfilled the above conditions as it was filed to overcome the lack of inventive step objection which affected the previous requests by limiting the starting material for the preparation of the protein hydrolysate to material, other than wheat gluten, that was explicitly listed in the specification as a possible source (cf. paragraph 0017 of the description). Moreover, it submitted that, as the relevance of document D22 in the framework of the discussion on inventive step had become apparent only during oral proceedings, such a request could not be submitted before.
8. The board does not share this view for the following reasons:
 - 8.1 It is true that the protein material for the preparation of the protein hydrolysate was not specifically defined in the independent claims of the preceding requests (cf. claims 1 and 7) and that the patent specification explicitly indicates that it "*may be of plant or animal origin, such as milk protein (casein, albumin, etc.), meat protein, soy protein or cereal protein (wheat, rice, maize, etc).*" It is, however, a fact that the specification is centred on **wheat gluten** as a preferred embodiment (cf. page 3, lines 35 to 37 of the patent specification). This was reflected by the dependent claims (now deleted) wherein

the protein material was specified to be "*a cereal protein*" or "*a wheat gluten or a subfraction thereof*". No examples nor technical details are given in relation to other material of plant or animal origin.

8.2 The discussion at oral proceedings on the issue of inventive step in relation to the previous requests had indeed shown that the patentability of their subject-matter was seriously affected by the combination of the teachings of document D16 or D17 with those of document D22, both documents D16 and D22 being concerned with protein hydrolysates of **wheat gluten**.

8.3 Document D22, although not yet formally admitted by the board into the proceedings until the hearing, had been on file from the beginning of the appeal proceedings and had been referred to by appellant II in its submissions in respect of both novelty and inventive step, to which appellant I explicitly replied. Thus, although of a different opinion, appellant I must have been aware of the possible detrimental effect of this document. The fact that the document was officially admitted into the proceedings at oral proceedings, is no excuse for failing to file at an earlier stage a claim request aimed at avoiding said effect.

8.4 The new main request on file was indeed an attempt to overcome an inventive step objection by restricting the choice of the starting material for the preparation of the protein hydrolysate to specific protein materials listed in the specification **other than wheat**. This modification, however, opened a number of issues which would have required further careful consideration, namely e.g.:

a) Did the exclusion of wheat gluten from the list of possible sources for protein hydrolysates given in the specification result in the creation of new subject-matter?

b) In the absence of any example and/or further technical details in respect of the listed starting material, could the claims be considered to have the necessary support by the description?

c) In the absence of any example and/or further technical details (content of free amino acids, percentage of low molecular weight peptides, etc.), what could be considered to be the inventive merit of proposing as starting material for protein hydrolysate e.g. milk protein, meat protein, soy protein, maize, rice in the place of wheat gluten the use of which was already suggested in the prior art (cf. documents D16 and D22), also in consideration of the fact that some of the proposed materials (e.g. meat protein) have a low content in glutamine (cf. Table 1 of document D6)?

9. In the board's judgement, finding the proper answer to the above questions could not reasonably have been done in the oral proceedings and would have required an adjournment of these oral proceedings. Thus, in accordance with Article 10b(3) RPBA, the introduction of the new main (and sole) request could not be considered admissible.

10. As there is no other claim request pending, on the basis of which maintenance of the patent is requested, the patent is to be revoked, Article 113(2) 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 Chairman:

D. Magliano

L. Galligani