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Datasheet for the decision of 18 June 2008

Case Number: T 1010/05 - 3.3.04

Application Number: 96918707.9

Publication Number: 0833649

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Title of invention:
Methods of preventing or treating allergies

Patentee:
Valio Oy

Opponent:
Nestec S.A.
Friesland Brands B.V.

Headword:
Protein hydrolysate/VALIO

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Novelty, inventive step (yes)"

Decisions cited:
-

Catchword:
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Case Number: T 1010/05 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 18 June 2008

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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 10 June 2005 concerning maintenance of European patent No. 0833649 in amended form.

Composition of the Board:

Chairman: R. Moufang
Members: G. Alt
R. Gramaglia

Summary of facts and submissions

I. This is an appeal by opponent 01 (appellant) against the opposition division's decision that European patent No. 0 833 649, with the title "Methods of preventing or treating allergies", could be maintained in amended form pursuant to Article 102(3) EPC 1973.

II. The oppositions were based on Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC), lack of inventive step (Article 56 EPC) and exclusion from patentability (Article 52(4) EPC 1973), and on Article 100(b) EPC.

III. The opposition division decided that claims 1 to 9 of the proprietor's main request fulfilled the requirements of the EPC.

Independent claims 2, 3, 4 and 7 of this request read:

"2. A method of making a protein hydrolysate formula *in vitro* for downregulating hypersensitivity reactions and for promoting gut immune barrier, comprising the steps of hydrolysing proteins with pepsin and/or trypsin, and adding to the hydrolysate a bacterial preparation comprising the strain *Lactobacillus GG* (ATCC 53103).

3. An oral protein hydrolysate formula for downregulating hypersensitivity reactions and for promoting gut immune barrier, which hydrolysate is obtainable by the method as defined in claim 1 or 2.

4. Use of a protein hydrolysate formula according to claim 3 for the manufacture of a pharmaceutically

active formula to be administered orally for promoting tolerogenic immune responses to food antigens in a patient.

7. Use of a bacterial preparation comprising the strain *Lactobacillus GG* (ATCC 53103) together with a protein hydrolysate formula for the manufacture of a pharmaceutically active formula for promoting tolerogenic immune responses to food antigens in a patient."

IV. In the statement setting out the grounds of appeal the appellant stated inter alia that the appeal was restricted "[t]o the decision of the Opposition Division dated 10th June 2005 to the extent that it relates to Claims 7 to 9, Claims 3 to 5 when read as dependent on Claim 2 and Claim 2 itself."

V. The patent proprietor (respondent) and opponent 02 replied to the statement setting out the grounds of appeal.

VI. In one of its communications the board informed the parties of its preliminary view on some of the issues. With regard to the novelty of the subject-matter of claim 3 over the disclosure in document D1 or D11 (see section VIII below) the sequence-specific activity of pepsin and trypsin was noted.

VII. Oral proceedings were held on 18 June 2008, the appellant, the respondent and opponent 02 being present.

The appellant and opponent 02 requested that the decision under appeal be set aside to the extent that

it related to claims 7 to 9, claims 3 to 5 when read as dependent on claim 2, and claim 2 itself, and that those claims be revoked.

The respondent requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and the patent maintained in amended form on the basis of the first or the second auxiliary request, both filed with the letter dated 15 November 2006.

At the end of the oral proceedings the board pronounced its decision.

VIII. The following documents are mentioned in this decision:

D1: EP-A-0 199 535

D3: Fuller, R., Gut (1991), pages 439 to 442

D5: EP-A-0 629 350

D11: US-A-4,839,281

D17: Majamaa, H. et al., Allergiatutkimussäätiön Vuosikirja 1993, 1993, pages 10 to 16

D17a: English translation of document D17 (with the exception of the literature references on pages 15 and 16)

IX. The appellant's and opponent 02's arguments at the oral proceedings and in writing insofar as relevant to the present decision may be summarised as follows:

Novelty

Claim 3 when referring to claim 2 was directed to a protein hydrolysate formula containing "Lactobacillus GG (ATCC 53103)" (hereinafter referred to as LGG) and protein fragments obtainable by hydrolysis with pepsin and/or trypsin. It was stated on page 10 of document D1, a European patent application, and in column 5 of document D11, the US application corresponding to document D1, that "[L]. acidophilus strains [...] can be added to food products, particularly dairy products such as milk and yogurt ...". The hydrolysate according to claim 3 was not defined by any degree of hydrolysis. Conventional yoghurt such as the one referred to in document D1 or D11 inherently contained at least some hydrolysed proteins due to the activity of enzymes of the fermenting bacteria. Therefore, the disclosure in document D1 or in document D11 of yoghurt supplemented with Lactobacillus acidophilus, which was identical to the LGG as recited in claim 3, was novelty-destroying for the subject-matter of claim 3.

Inventive step

Document D5 could be regarded as the closest prior art document. It related to the treatment of milk allergy on the basis of a protein hydrolysate-based elimination diet. The hydrolysis process involved the proteolytic enzymes pepsin and trypsin. Immunological

tolerogenicity of the protein hydrolysate was improved by additional cleavage with elastase 2.

The problem to be solved in view of document D5 was the enhancement of the efficacy of an elimination diet.

The patent did not provide evidence that the solution as stated in the claims actually solved this problem since it was not certain that the hydrolysate used for the assays according to Example 2 was one obtainable by cleavage with pepsin and/or trypsin as required by the claims.

Moreover, it was also doubtful that the problem was solved because the claims did not mention any degree of hydrolysis or the patient group to be treated.

Document D17a disclosed events occurring during milk allergy, namely that immature intestinal epithelial cells unable to correctly process antigens allowed intact antigens to cross the intestinal mucosa, where contact with lymphoid tissue triggered a local hypersensitivity reaction which aggravated the permeability of the intestinal epithelium. Figure 2 of this document accordingly proposed three possible ways of intervention, namely elimination of the antigen, reduction of the permeability defect and correction of the immunological imbalance.

Hydrolysis of proteins was a well-known option for the elimination of antigen in the treatment of food allergy, see for example document D5.

Moreover, it was disclosed in document D17a that treatment with lactobacilli could prevent a permeability defect induced by an early antigen administration in suckling rats.

Thus, in view of the teachings in documents D5 and D17a the skilled person would add LGG to a protein hydrolysate in order to enhance the efficacy of an elimination diet and therefore arrive in an obvious way at the subject-matter of claims 7 to 9, claims 3 to 5 when read as dependent on claim 2 and claim 2 itself.

Document D17a could also be considered as the closest prior art document, the only difference between this disclosure and the claimed subject-matter being that the combination of nourishment in the form of a protein hydrolysate with LGG was not mentioned. However, it was common general knowledge that protein hydrolysates were the diet of choice for persons suffering from milk allergy (see for example document D5). It would therefore be obvious to administer a protein hydrolysate and LGG to such persons.

A further reason why the claimed simultaneous administration of the two compounds could not establish an inventive step was that, according to the case law, the combination of known features could be considered inventive only if it showed an effect beyond the sum of the individual effects. Such a synergy was however not demonstrated in the patent.

X. The respondent's arguments at the oral proceedings and in writing insofar as relevant to the present decision may be summarised as follows:

Novelty

Yoghurt was prepared by fermenting milk with particular lactic acid bacteria, however not LGG. These bacteria did not produce pepsin and/or trypsin. Consequently, yoghurt supplemented with LGG as disclosed in either of documents D1 and D11 did not destroy the novelty of the subject-matter of claim 3.

Inventive step

Document D5 could be regarded as the closest prior art document since its underlying problem was the same as that of the patent, i.e. the improvement of the efficacy of elimination diets.

The combination of an elimination diet with the treatment of the permeability defect was not suggested in document D17a.

The positive influence of LGG on the permeability of the gut mucosa had been observed in the presence of antigen. This teaching would therefore not suggest to the skilled person to use LGG in the framework of an elimination diet.

Reasons for the decision

1. In view of the appellant's statement made in the submission setting out the grounds for appeal (see section IV above), this appeal is restricted to a review of whether claims 7 to 9, claims 3 to 5 as far

as they refer to claim 2 and claim 2 itself fulfil the requirements of the EPC.

Novelty

2. The oral protein hydrolysate formula according to claim 3 is inter alia defined by a process feature, i.e. it "is obtainable by the method as defined in claim 1 or 2." According to the method defined in claim 2 proteins are hydrolysed with pepsin and/or trypsin, and a bacterial preparation comprising the strain Lactobacillus GG, having the ATCC number 53103 (hereinafter referred to as LGG), is added to the hydrolysate thus obtained (see section III above).

2.1 The appellant and opponent 02 maintain that the disclosure in either of documents D1 and D11 of the preparation of a composition comprising conventional yoghurt - which they submit inherently contains hydrolysed proteins - and a Lactobacillus acidophilus strain having a deposit number identical to LGG destroys the novelty of the subject-matter of claim 3.

2.2 If it is accepted for the sake of argument that conventional yoghurt falls under the term protein hydrolysate (see however point 3.2 below), the decisive question to be addressed is whether yoghurt is a hydrolysate obtainable by the method according to claim 2, i.e. whether it is obtainable by steps comprising hydrolysing proteins with pepsin and/or trypsin.

The board noted in its communication (see section VI above) that pepsin and trypsin, like other proteases,

cleave proteins at specific amino acid positions, thus generating protein fragments with characteristic amino acid residues at their N- and C-terminal ends - a fact which has not been disputed by the appellant and opponent 02. Therefore, in the present case the process feature is not merely illustrative, but contributes to the structural definition of the hydrolysate to which LGG is added.

2.3 There is no evidence before the board either that the lactic acid bacteria used for fermentation of milk for the production of yoghurt produce the enzymes pepsin and/or trypsin or that pepsin and trypsin per se or other bacteria which produce proteases cutting proteins with the same sequence specificity as pepsin or trypsin are added during the yoghurt production process.

2.4 The board therefore cannot come to the conclusion that the protein fragments present in conventional yoghurt would be the same as those present in a hydrolysate obtained according to the method in claim 2 and hence considers that yoghurt is not a hydrolysate as defined in claim 2. Consequently, the composition according to claim 3 insofar as it refers to the method according to claim 2 is novel over the composition disclosed in either of documents D1 and D11. Hence the subject-matter of claim 2 relating to the production and of claims 4 and 5 relating to the medical use of the composition according to claim 3 insofar as it refers to the method according to claim 2 is also novel.

3. The subject-matter of independent claim 7 (to which the appellant and opponent 02 have not raised an objection of lack of novelty) relates to the **use** of a bacterial

preparation comprising the strain LGG together with **any** protein hydrolysate formula for the manufacture of a pharmaceutically active formula for promoting tolerogenic immune responses to food antigens in a patient. Thus, since the hydrolysate according to this claim is not limited by the specific enzymatic production process, the reasons given in relation to the novelty of the composition according to claim 3 no longer apply.

3.1 However, documents D1 and D11, while disclosing the use of the compositions disclosed therein for combating side effects of antibiotic therapy, for treating ulcerative colitis and constipation, for supporting generation of normal intestinal flora and for reducing the excretion of cholesterol and oestrogen in faeces (see pages 11 ff of document D1; columns 5 to 9 of document D11), do not disclose their use for the treatment of allergies in general and the use recited in claim 7 in particular. Therefore, the subject-matter of claim 7 derives its novelty at least (see point 3.2 below) from the new use.

3.2 In addition, in the board's view, "yoghurt" cannot be considered a protein hydrolysate in the context of the description of the present patent, which has to be taken into account when construing the meaning of a patent claim. The patent in suit relates to making protein hydrolysate formulae for suppressing food-induced hypersensitivity reactions in patients suffering from food allergy (paragraph [0001]). Therefore, in the board's view, the term "hydrolysate" implies a certain level of hydrolysis, namely that the allergenic proteins in a food composition are

fragmented to such an extent that allergenic reactions in patients suffering from allergy against these proteins are appreciably reduced. However, there is no evidence before the board that the degree of hydrolysis in yoghurt reaches this threshold.

3.3 The board concludes that the subject-matter of claims 7 to 9 also complies with the requirements of Article 54 EPC.

Inventive step

4. Documents D5 and D17a are referred to by the parties as the closest prior art documents.

4.1 Document D5, a European patent application, relates to milk protein hydrolysate formulae for the treatment of cow's milk allergy in infants (page 3, lines 1 and 2). In particular, it is disclosed that whey protein, inter alia treated with pepsin, a mixture of porcine and bovine trypsin, bovine chymotrypsin and elastase 2, when administered, has the effect that the milk allergy disappears faster than would normally be expected for spontaneously acquired tolerance (page 3, lines 20 to 22; Example 1: 1.3 and 1.5; Example 2: 2.3 and 2.4).

Document D17a is the English translation of document D17, which is a report published in the yearbook of the Finnish foundation of allergy research. It deals inter alia with the mechanisms underlying the development of food allergy and proposes possible ways of treatment, amongst them the elimination of antigen from the patient's diet. Protein hydrolysis as a way of eliminating the antigen is not explicitly mentioned.

4.2 According to the case law the closest prior art is a document from which the invention could have been made most easily and which therefore constitutes the strongest basis for assessing inventive step. Accordingly, such a document typically discloses subject-matter relating to the same purpose as the invention and having the greatest concordance of features with the claimed subject-matter.

4.3 The board adheres to these criteria and therefore considers document D5 the closest prior art document.

5. The problem to be solved in view of this prior art may be formulated as the provision of alternative means for enhancing the efficacy of elimination diets based on protein hydrolysates.

6. The solution to this problem as proposed in claim 3, when read as referring to claim 2, consists in the provision of an oral protein hydrolysate formula consisting of a protein hydrolysate which is obtainable by a method comprising the steps of hydrolysing proteins with pepsin and/or trypsin and to which a bacterial preparation comprising the strain Lactobacillus GG (ATCC 53103) is added.

7. At the oral proceedings the appellant and the opponent 02 submitted that the whey hydrolysate used in assays according to Example 2 of the patent in suit, which is the only relevant example in this context, is merely characterised as an "extensively hydrolysed whey formula (Valio Ltd., Helsinki, Finland, EP-A-601802)" (paragraph [0038]). They argue that, given this

definition, it is not certain that the hydrolysate is one as referred to in claim 3, i.e. obtainable by a method comprising the steps of hydrolysing proteins with pepsin and/or trypsin, and that therefore the patent does not make it plausible that the solution as stated in claim 3 to the formulated problem actually solves this problem. Therefore, an inventive step should be denied.

7.1 Examples are not a requirement for patentability according to the EPC. Therefore, an example is not the only evidence in a patent to be taken into account for judging whether a patent makes it plausible that the claimed subject-matter "works". Instead, and independently of whether such an assessment is made in the context of the evaluation of inventive step or in the context of the evaluation of sufficiency of disclosure, it is the whole specification which is to be considered.

7.2 In the present case it is derivable from the explanations in paragraphs [0002] and [0003] of the patent that the invention is based on the finding that protein hydrolysate formulae used as nutrition for allergy patients - even hydrolysates which are prepared by extensive enzymatic hydrolysis - still contain trace amounts of original proteins. These proteins may induce allergenic reactions including increased intestinal permeability or dysfunction of the intestine's defence barrier. It is taught that the patient's tolerance to the hydrolysate formulae can be improved by administering a combination of the hydrolysate and LGG (paragraphs [0014], [0016] to [0018]).

7.3 The patent discloses two ways in which LGG improves the tolerance (paragraph [0015]). Firstly, viable LGG bacteria stabilize the gut mucosal barrier, thus enhancing the local defence, and secondly, the hydrolysing enzymes of the LGG bacteria are released in vivo and further hydrolyse the proteins in the hydrolysate. The board considers that, prima facie, neither of the two mechanisms is dependent on the nature of the hydrolysate, i.e. on which enzymes were used for hydrolysis. Therefore, it is plausible from the above-mentioned disclosure that the co-administration of LGG and **any** protein hydrolysate formula is a means for enhancing the efficiency of an elimination diet.

7.4 This is endorsed by Example 2, which demonstrates that infants with atopic eczema and supposed cow's milk allergy who received a given LGG-supplemented hydrolysate formula showed stronger improvement of dermatitis symptoms and higher reduction in the faecal concentration of antitrypsin and TNF-α than infants having received the same, non-supplemented hydrolysate formula (paragraph [0038]).

7.5 In the absence of evidence from the appellant and opponent 02 the board therefore considers in the light of its observations above (see in particular point 7.3) that prima facie the subject-matter of claim 3 and also that of claim 7 cannot be deemed purely speculative with regard to the disclosure in the patent.

8. The appellant and opponent 02 further argued that it is doubtful that the problem is solved over the whole breadth of the claim for the reason that claim 3 does

not indicate the degree of hydrolysis and that therefore the subject-matter of claim 3 encompasses formulae in which the proteins are hydrolysed to only a minimal extent.

8.1 However, as already stated above in point 3.2, the board considers that the term hydrolysate in the context of the present patent is to be interpreted as relating only to those hydrolysates which are capable of appreciably reducing allergenic reactions. Therefore, the question of whether formulae containing proteins with a minimal degree of hydrolysis solve the above formulated problem is not relevant.

8.2 Finally, the appellant and opponent 02 maintain that claim 3 does not contain any restriction as to the patient group to be treated and that therefore it is also doubtful that the problem is solved over the whole breadth of the claim, and in particular that the efficacy of an elimination diet is enhanced in relation to patients for whom the description does not contain experimental data. Since, however, these doubts have not been substantiated by verifiable facts, the board has to conclude that the problem is solved over the whole breadth.

9. As to the issue of obviousness the appellant and opponent 02 argue that the skilled person would have regarded it as obvious in view of document D17a to prepare a composition comprising a bacterial preparation which comprises the strain LGG and a protein hydrolysate formula in order to enhance the efficacy of the formula.

10. It was known at the priority date of the patent that certain Lactobacillus strains such as the LGG strain referred to in the present claims had probiotic characteristics. In other words, when ingested they do not get destroyed in the upper part of the gastro-intestinal tract, but reach the gut, where they have beneficial effects on the intestinal mucosa (see the introductory part of the patent, paragraph [0010]). Due to this property, probiotic organisms were used as supplements to conventional nutrition. Therefore, a definition proposed for probiotic organisms is: "A live microbial feed supplement which beneficially affects the host animal by improving its microbial balance" (see document D3, first column).

In the light of this knowledge and given the appellant's and opponent 02's argument (see point 9 above), the question thus arises whether or not the skilled person would have derived from document D17a the teaching that LGG is also suited as an additive in protein hydrolysate formulae-based allergy nutrition as for example disclosed in document D5.

11. Figure 2 of document D17a, subtitled "Development of milk allergy and target areas for treatment", schematically summarises the development of milk allergy, i.e. the antigen (by crossing the mucosa) causes an immunological inflammatory reaction resulting in a permeability defect of the mucosa, which in turn leads to an increase in the number of antigens crossing it. Accordingly, three target areas for treatment are identified in the figure, namely elimination of the antigen, immunotherapy, and stabilisation of the permeability defect.

11.1 In the text below Figure 2, entitled "Target areas for treatment in milk allergy", the possible treatment options set out in Figure 2 are dealt with in more detail.

The first paragraph relates to treatment by elimination of the antigen and reads:

"The most essential part of treatment in milk allergy is the elimination of cow's milk antigens from the patient's diet (Figure 2). The elimination must be complete and, at the same time, the adequate intake of nutrients must be ensured to provide for normal growth and development. In the prophylaxis of food allergies, attention has similarly been paid to the elimination of potential allergens from the diet."

Thus, in this paragraph the skilled person is mainly informed about possible problems involved with an elimination diet, namely that it is difficult to keep the balance between elimination of the antigen and sufficient nutritional status.

11.2 The immediately following first sentence of the second paragraph reads:

"It would be tempting to try to address the problem directly, i.e. by correcting the immunological imbalance and permeability defect, particularly where the elimination diet poses a threat to the nutritional status."

The board considers that, in the light of the stated drawbacks of an elimination diet as stated in the previous paragraph (see point 11.1 above), the skilled person would have understood this sentence as indicating that treatments based on immunotherapy/ stabilisation of the permeability defect have to be preferred at least theoretically over those relying on elimination diets because the former attack the problem at the roots ("directly"). Therefore, the skilled person would infer that the treatments mentioned in the first sentence of the second paragraph, i.e. immunotherapy/stabilisation of the permeability defect, are to be used as an **alternative** to those mentioned in the first paragraph, i.e. the elimination diet.

11.3 The last paragraph of document D17a presents a synopsis of the two foregoing ones. It states:

"At present, it is possible to influence the course of food allergy by breaking the vicious circle (Figure 2), i.e. by identifying the offending allergen and by totally eliminating it from the patient's diet. This approach aims to prevent the emergence of the varied symptoms of food allergy. In future, the treatment of food allergy may target specifically the immunological inflammatory reaction, by immunotherapy, and the stabilisation of the intestinal permeability defect."

From this statement, in the board's view, the skilled person would again have perceived that immunotherapy/ stabilisation of the permeability defect and elimination diet are two juxtaposed approaches, with the former being more advantageous because instead of

simply avoiding the symptoms, it specifically targets their cause.

11.4 Document D17a further discloses "that a permeability defect, induced by an early antigen administration to suckling rats, was preventable by the co-administration of the antigen and lactobacilli (Lactobacillus casei GG)" (page 6, second column). Thus, this teaching provides a link between one of the reasons for the allergic reaction, i.e. the defective gut mucosa, and a possible treatment of it, i.e. by LGG. Nevertheless, in the board's view, this teaching would not have motivated the skilled person to combine LGG and a protein hydrolysate formula because the above-mentioned observation was made in the presence of complete, non-hydrolysed antigen, i.e. in a situation different from that occurring during an elimination diet which is characterised by the substantial absence of complete antigen.

12. Since, for the reasons given above, the skilled person would have viewed the two approaches set out in document D17a as alternatives, the present case has to be distinguished from situations in which two well-known methods of treating a particular disease are combined and for which a synergistic effect is generally required in order to establish an inventive activity.

13. Thus, the board concludes that overall document D17a would not have taught the skilled person to supplement a protein hydrolysate formula used for nutrition of allergy patients with a bacterial preparation

comprising the strain LGG in order to enhance the efficacy of the hydrolysate during an elimination diet.

13.1 Therefore, neither the subject-matter of independent claim 3, when read as referring to claim 2, directed to a combination of a bacterial composition comprising LGG with a specific protein hydrolysate, nor that of independent claim 2 directed to a method of making this combination, nor that of independent claim 7 directed to a pharmaceutical use of a combination of a bacterial composition comprising LGG with an (unspecified) protein hydrolysate is rendered obvious by considering the teachings in documents D5 and D17a together. This finding also applies to the subject-matter of claims 4 and 5 as far as they are dependent on claim 3, when read as referring to claim 2, and to the subject-matter of claims 8 and 9 which depend on claim 7.

14. Thus, the board concludes that the subject-matter of the claims of the present patent insofar as they are under review in this appeal (see point 1 above) complies with the requirements of Article 56 EPC.

Articles 83 and 53(c) EPC

15. The objections under Articles 83 EPC and 53(c) EPC (corresponding to Article 52(4) EPC 1973) were not pursued by the appellant and opponent 02 in the appeal proceedings. In the absence of any new argument the board sees no reason to deviate from the opposition division's finding and concludes that the requirements of Articles 83 and 53(c) EPC are fulfilled.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

P. Cremona R. Moufang