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**Datasheet for the decision
of 7 June 2010**

Case Number: T 1758/07 - 3.3.09

Application Number: 97948938.2

Publication Number: 0946108

IPC: A23K 1/00

Language of the proceedings: EN

Title of invention:

A method for producing a food additive, food additive, and the use of it

Patentee:

Hankkija-Maatalous Oy

Opponent:

BIOTEC PHARMACON ASA

Headword:

-

Relevant legal provisions:

EPC Art. 56

Relevant legal provisions (EPC 1973):

EPC Art. 52(4), 54(5)

Keyword:

"First medical use: Novelty, Inventive step (yes)"

"First and second medical use claims in one set of claims (no)"

Decisions cited:

G 0001/83, T 0958/94

Catchword:

If the claimed subject-matter indeed relates to the first medical indication, G 1/83 provides no legal basis to additionally claim the same subject-matter in terms of a second medical indication (points 3.3 and 3.4)



Case Number: T 1758/07 - 3.3.09

DECISION
of the Technical Board of Appeal 3.3.09
of 7 June 2010

Appellant: BIOTEC PHARMACON ASA
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office
announced orally 20 June 2007 and posted
2 August 2007 concerning maintenance of
European patent No. 0946108 in amended form.

Composition of the Board:

Chairman: W. Sieber
Members: W. Ehrenreich
M.-B. Tardo-Dino

Summary of Facts and Submissions

I. Mention of the grant of European patent No. 0 946 108 in respect of European patent application No. 97 948 938.2 filed on 22 December 1997 as international application No. PCT/FI1997/000831 in the name of *Suomen Rehu OY*, now *Hankkija-Maatalous OY*, was announced on 21 July 2004 in Bulletin 2004/30. The patent was granted with fifteen claims, Claims 1, 2, 8, 9, 12 and 14 reading as follows:

"1. Procedure for preparing a feed additive, to be used for the prevention of gastric disorders and intestinal diseases and/or for the promotion of growth, **characterised in that** a yeast raw material is treated hydrolytically with an acid so that the cell wall structure is opened and the amount of free oligosaccharides and/or polysaccharides and/or the amount of oligosaccharides and/or polysaccharides on the surface of the cell wall are/is increased."

"2. Procedure as defined in claim 1, **characterised in that** the product obtained in the hydrolysis is used as such non-fractionated."

"8. Feed additive for the prevention of intestinal diseases and/or promotion of growth, **characterised in that** the additive has been prepared by hydrolytically treating a yeast raw material with an acid so that the cell wall structure is opened and the amount of free oligosaccharides and/or polysaccharides and/or the amount of oligosaccharides and/or polysaccharides on the surface of the cell wall are/is increased."

"9. Additive as defined in claim 8, **characterised in that** the additive comprises the non-fractionated product obtained as such."

"12. Feed additive as defined in any of claims 8-11 for use in conjunction with feed for animals for the prevention of gastric disorders and intestinal diseases and/or for the promotion of growth."

"14. Preparation containing a feed additive, designed for the prevention of intestinal diseases and/or for the promotion of growth and intended to be given to an animal to be fed, **characterised in that** the preparation contains a preparation according to any one of claims 8-11 in an amount of 0.01 - 0.6 g/kg, calculated from the daily ration of feed stuff as dry matter per kilogram of living weight."

II. An opposition against the patent was filed by

Biotec Pharmacon ASA

on 19 April 2005.

The opposition was based on grounds provided for in Article 100(a) EPC, i.e. that the subject-matter of the patent was neither new nor based on an inventive step. The opponent, *inter alia*, cited the following documents:

A6 WO-A 95/04467;
A7 WO-A 95/30022; and
A9 WO-A 92/06602.

Even though A9 was submitted after expiry of the opposition period in a letter dated 20 April 2007, it was admitted into the proceedings by the opposition division.

III. In its interlocutory decision announced orally on 20 June 2007 and issued in writing on 2 August 2007 the opposition division maintained the patent in amended form on the basis of the first auxiliary request submitted at the oral proceedings. The granted claims, which constituted the main request, were not allowed because the opposition division held that the subject-matter of Claims 8 and 12 was not novel over A9.

The set of claims according to the first auxiliary request essentially differed from the claims as granted in that

- the feature of Claim 9 according to which "*the additive comprises the non-fractionated product obtained as such*" was incorporated into Claim 8, and
- new use Claims 11 to 15 were introduced, Claim 11 reading as follows:

"11. Use of a yeast raw material treated hydrolytically with an acid so that the cell wall structure is opened and the amount of free oligosaccharides and/or polysaccharides and/or the amount of oligosaccharides and/or polysaccharides on the surface of the cell wall are/is increased for preparing a feed additive for the prevention of intestinal diseases and/or for the prevention of gastric disorders and/or promotion of growth."

The opposition division found that the feed additive of Claim 8 was novel, in particular over A9, because A9 only disclosed the use of a fractionated yeast product but not the non-fractionated product as such, as required by Claim 8. The process according to Claim 1 and the use according to new Claim 11 were also considered to be novel over A9, as these claims represented second medical use claims relating to therapeutic indications not disclosed in A9.

As to inventive step, the opposition division defined the problem to be solved as the provision of a feed additive acting on intestinal microbes so as to promote the health and/or growth of animals. In that respect, A6 was considered to represent the closest prior art as this document disclosed feed additives for enhancing animal growth. The opposition division argued that A6 proposed the provision of extracted yeast glucans obtained by centrifugation, filtration or decantation, i.e. via fractionation. By contrast, the yeast products according to the invention, obtained by acid hydrolysis, were used in their non-fractionated form and represented an alternative to the products of A6. Because the experimental evidence filed with the letter dated 27 September 2005 showed an improved prevention of pathogens in intestinal cells for the non-fractionated yeast hydrolysate, the claimed invention was considered to represent a non-obvious alternative.

IV. On 11 October 2007 the opponent (hereinafter: the appellant) lodged an appeal against the decision of the opposition division. The prescribed fee was paid on the same day.

The statement of the grounds of appeal was submitted on 12 December 2007. The appellant maintained the objections as to lack of novelty and lack of inventive step and cited new documents A10 to A16. From these citations the documents:

A12 US-A 4 962 094 and

A14 US-A 4 118 512

are relevant to this decision.

V. In its letter of response dated 13 June 2008 the patent proprietor (hereinafter: the respondent) defended the maintenance of the patent on the basis of the first auxiliary request as allowed by the opposition division. In response to a communication from the board dated 8 April 2010 in which, *inter alia*, the partial illegibility of the hand-written amendments in the claims of the first auxiliary request was criticised, the appellant filed on 5 May 2010 a fair copy of this request, which constituted the main request in the appeal proceedings. Furthermore, new sets of claims according to auxiliary requests 1 to 5 were filed with the same letter.

VI. Oral proceedings were held before the board on 7 June 2010, which the appellant, as announced in a letter dated 25 May 2010, did not attend. In the oral proceedings the respondent withdrew the main request and auxiliary requests 2 to 5 and filed new auxiliary requests 2 to 4.

The first auxiliary request corresponded to the withdrawn main request except for the essential

amendment that the use Claims 11 to 15 had been deleted. Consequently the claims of the first auxiliary request corresponded to the claims as granted except that the feature of granted Claim 9 stating that "*the additive comprises the non-fractionated product obtained as such*" had been incorporated into Claim 8, and that the remaining claims had been renumbered accordingly.

Claim 1 of the second auxiliary request was amended over granted Claim 1 (see point I) in that the passage "*to be used for the prevention of gastric disorders and intestinal diseases and/or for the promotion of growth*" was deleted.

The third auxiliary request consisted of five claims, Claims 1 and 4 reading as follows:

"1. Feed additive for the prevention of intestinal diseases and gastric disorders, **characterised in that** the additive has been prepared by hydrolytically treating a yeast raw material with an acid so that the cell wall structure is opened and the amount of free oligosaccharides and/or polysaccharides and/or the amount of oligosaccharides and/or polysaccharides on the surface of the cell wall are/is increased, and the additive comprises the non-fractionated product obtained as such."

"4. Feed additive as defined in any one of claims 1-3 for use in conjunctions [*sic*] with feed for animals in an amount of 0.01 - 0.6 g/kg, calculated from the daily ration of feed stuff as dry matter per kilogram of living weight."

Claims 2, 3 and 5 of the third auxiliary request were dependent claims.

Given the decision reached by the board in the present case, it is not necessary to quote the claims of the fourth auxiliary request.

VII. The appellant's written arguments relevant to this decision related to claims directed to the following subject-matter:

- "Procedure for preparing a feed additive, to be used for the prevention of gastric disorders and intestinal diseases and/or for the promotion of growth ..." - Claim 1 of the first auxiliary request;
- "Feed additive for the prevention of intestinal diseases and/or promotion of growth ..." - Claim 8 of the first auxiliary request and Claim 7 of the second auxiliary request; and
- "Feed additive for the prevention of intestinal diseases and gastric disorders ..." - Claim 1 of the third auxiliary request.

The arguments can be summarised as follows:

(a) Novelty

- Claim 1 of the first auxiliary request

The claim, which was directed to a procedure for preparing a feed additive, made reference to the medical uses to which the feed additive will eventually be put. Such a claim, which had similarities to a common second medical use claim,

did not use a defined product and should therefore be merely interpreted as a claim directed to a method of preparation.

In the context of this interpretation, document A14, disclosing a process for preparing a feed additive which involved the hydrolysis of yeast cells with an acid, would be novelty-destroying for such a method.

Even if the claim was to be interpreted as a second medical use claim, A14 would be of relevance as a novelty-destroying document because A14 disclosed the use of the feed additive described therein to improve the palatability of animal feed, which would result in the recipient animal ingesting more food and therefore displaying increased growth. This would be all the more so as it was pointed out in column 2, lines 20-29, of A14 that animal feed that did not have sufficient palatability resulted in an animal eating insufficient amounts of food.

- Claim 8 of the first auxiliary request, Claim 7 of the second auxiliary request and Claim 1 of the third auxiliary request

A14 described the use of the direct product of the acid hydrolysis of yeast cells as a coating on animal feed or in admixture with veterinary pharmaceuticals. This was a disclosure of the use of unfractionated products in the treatment of the human or animal body by therapy. Therefore, A14 deprived the first medical use claims of novelty.

(b) Inventive step - all above-mentioned claims

The available prior art showed that intact yeast cells, isolated components of yeast cell walls and crudely fractionated products from the acid hydrolysis of yeast cells could be used in the claimed medical treatments. Given the previous use of yeast preparations from across most of the fractionation spectrum of crude preparations to highly pure preparations, it could not be considered inventive to pick an alternative preparation from within the known spectrum and use it in the same medical uses. In particular, A14 showed that unfractionated materials had already been used as feed additives and there was therefore no prejudice against the use of unfractionated products from acid hydrolysed yeast. The data provided by the respondent/patentee in its submissions of 27 September 2005, which showed improved efficacy of an unfractionated product from the acid hydrolysis of yeast cells in the inhibition of microbial adhesion as compared to β -glucan, must be considered a bonus effect that could not render the claimed subject-matter inventive.

VIII. The respondent argued as follows:

(a) Novelty

The process for preparing a feed additive (Claim 1 of the first and second auxiliary requests) and the feed additive (Claim 8 of the first auxiliary request, Claim 7 of the second auxiliary request,

Claim 1 of the third auxiliary request) were novel over the cited prior art because none of the documents disclosed the preparation of the additive intended for the therapeutic treatment of preventing intestinal diseases, gastric disorders and promotion of growth via acid hydrolysis of a yeast raw material. Furthermore, there was no disclosure in the documents that the feed additive comprised the non-fractionated product as such when used for the above therapeutic purpose.

In particular the disclosure in A14 concerning an improvement in the palatability of food for dogs and cats through the use of acid-hydrolysed yeast materials could not be considered as a kind of promotion (stimulation) of growth within the meaning of the technical concept of the invention, since an improved palatability of animal food would not always result in stimulating the growth of the animal.

Moreover, the yeast hydrolysate obtained by acid hydrolysis according to A14 was concentrated (column 6, lines 10 to 12). Concentration, however, was tantamount to fractionation of the product. Thus, the additive according to A14 did not comprise the non-fractionated product as such, as required by the product claims of all requests.

(b) Inventive step

There was no hint in the cited prior art which would prompt a skilled person to use a yeast hydrolysate in non-fractionated form in order to obtain a positive influence in the prevention of

intestinal diseases or gastric disorders compared to the effects of isolated yeast components like glucans, as shown in the experiments filed with the letter dated 27 September 2005.

The appellant's allegation that the effect shown by the respondent's experiments was a bonus effect was unfounded because such a bonus effect was linked to a "one-way situation". Such a situation, however, did not exist here because the prior art offered several alternatives for the use of yeast components (e.g. such obtained by centrifugation or extraction) for therapeutic purposes.

- IX. The appellant had requested in writing that the appealed decision be set aside and the patent be revoked.

- X. The respondent requested that the patent be maintained on the basis of Claims 1-14 of the first auxiliary request as submitted with the letter of 5 May 2010, or alternatively on the basis of Claims 1-11 of the second auxiliary request, or of Claims 1-5 of the third auxiliary request, or of Claims 1-3 of the fourth auxiliary request, all filed during the oral proceedings (see point VI).

Reasons for the Decision

1. The appeal is admissible.
2. Admissibility of the requests
 - 2.1 First, third and fourth auxiliary requests

The amendments to the claims according to the first, third and fourth auxiliary requests are all derived from the claims as granted and consist in a deletion of claims or in a restriction of claims either by deletion of specific technical features (i.e. the promotion of growth in the third and fourth auxiliary requests) or by incorporation of embodiments of a dependent claim into an independent claim (combination of granted Claims 8 and 9 in the first, third and fourth auxiliary requests and of granted Claims 12 and 14 in the third auxiliary request).

These amendments simplify the case and do not raise issues which would have surprised the board or the appellant, which, on its own motion, did not attend the oral proceedings.

The board therefore exercised its discretion according to Article 13(1) of the Rules of Procedure of the Boards of Appeal (OJ EPO 11/2007, 536-547) and decided to admit the requests into the proceedings.

- 2.2 Second auxiliary request

In Claim 1 of the second auxiliary request, the therapeutic use of the feed additive, which was part of Claim 1 as granted, was deleted. This deletion, made at a very late stage in the appeal proceedings, namely at

the oral proceedings before the board, raised doubts as to whether or not Claim 1 of the second auxiliary request met the requirements of Article 123(3) EPC. For this reason alone, the board decided not to admit the second auxiliary request into the proceedings.

3. First auxiliary request - first and second medical uses

3.1 General remarks

The patent was granted before EPC 2000 entered into force. Therefore EPC 1973 applies for consideration of medical uses.

In the case of a first medical indication, it is permissible under Article 54(5) EPC 1973 to grant a patent with claims directed to a substance/composition for the treatment by therapy according to Article 52(4) EPC 1973, even if the additive as such belongs to the state of the art, provided that its use for the above therapy is not comprised in the state of the art.

Second and subsequent medical indications can be protected in accordance with decision G 1/83 (OJ EPO 1985, 60) by claims which are directed to the use of a substance/composition for the manufacture of a medicament for a specified new and inventive therapeutic application (Headnote II in conjunction with Reasons 19). Instead of use claims it is possible to formulate claims directed to a process for preparing the medicament which is characterised by the use of the substance/composition (e.g. T 958/94, OJ EPO 1997, 242, Headnote).

3.2 The claims of the first auxiliary request

The set of claims of the first auxiliary request contains a Claim 2 directed to a "*Procedure for preparing a feed additive, to be used for the prevention of gastric disorders and intestinal diseases ... and the product obtained in the hydrolysis is used as such non-fractionated*", which is, in accordance with G 1/83 and T 958/94 (*supra*), in the form of a second medical use. On the other hand, Claim 8 pertains to a "*Feed additive for the prevention of intestinal diseases ... and the additive comprises the non-fractionated product obtained as such*" by analogy with Article 54(5) EPC 1973.

Thus, in the first auxiliary request the same subject-matter is claimed **both** as a first medical use (Claim 8 as a purpose-related product claim) **and** as a second medical use (Claim 2 as a reformulated Swiss-type claim).

3.3 It is uncontested that the prevention of gastric disorders and intestinal diseases by using the feed additive according to Claims 1 and 8 represents a method for treatment of the human or animal body by therapy within the meaning of Article 52(4) EPC 1973.

G 1/83 only applies to second (and further) medical indications. From this it follows that the legal fiction behind G 1/83, namely that the therapeutic treatment according to Article 52(4) EPC 1973 is a limiting feature, is applicable only if a therapeutic treatment is indeed a second (or further) medical indication. If, however, the claimed subject-matter relates to the first medical indication, G 1/83

provides no legal basis for additionally claiming the same subject-matter as a second medical indication.

3.4 In the present case the question therefore arises whether Claim 8 has to be considered as representing a claim in accordance with Article 54(5) EPC 1973 (first medical use claim). In this context the following two questions have to be answered:

- (a) Is the feed additive as such (i.e. the additive resulting from hydrolytic treatment of a yeast raw material comprising the non-fractionated product obtained as such) comprised in the state of the art?
- (b) Is the use of the additive for the prevention of intestinal diseases and gastric disorders (i.e. the therapeutic treatment according to Article 52(4) EPC 1973) comprised in the state of the art?

3.4.1 Novelty of the additive - Question (a)

It is uncontested by the parties that A14 discloses a feed additive which has been prepared by hydrolytically treating a yeast raw material with an acid (Claim 1 in conjunction with column 6, lines 5 to 10). According to column 6, lines 10 to 12 the hydrolysate is dried and concentrated.

The board does not agree with the respondent's view as expressed at the oral proceedings (point VIII (a)) that concentration is tantamount to fractionation. According to the patent in suit (paragraph [0024] of the patent specification) the term "concentration" is mentioned besides "fractionation", from which it can be concluded

that "concentration" and "fractionation" are distinguishable technical features within the meaning of the invention. Therefore, there is no reason to assume that a concentrated yeast hydrolysate according to A14 is necessarily a fractionated product. Since there is no disclosure in A14 that the acid-hydrolysed yeast product is fractionated, it is reasonable to assume that the additive according to A14 comprises the non-fractionated yeast hydrolysate as such.

Thus, A14 anticipates the feed additive according to Claims 2 and 8 and question (a) has to be answered in the affirmative.

3.4.2 Therapeutic use of the additive - Question (b)

According to A14, the yeast hydrolysate is used for improving the palatability of oral ingesta for animals, e.g. animal feed (Claims 1 and 8; column 3, lines 39 to 49; column 11, lines 3 to 19 and Example 1). The improvement in the palatability of a feed has as its aim to induce an animal to eat more of the feed and not the treatment of an actual disease.

The second alternative for the additive according to A14 is the improvement in the palatability of medicaments (Claims 1 and 9 and column 7, line 34 to column 8, line 16). In this case, the active component for treating a disease is the medicament and not the additive, which serves only as an aid to ease administration of an oral medicament to animals by improving its palatability. This is clearly indicated in column 2, line 57 to column 3, line 13 of the document.

Thus, D14 does not disclose the use of the yeast hydrolysate as an active composition for therapy of a disease within the meaning of Article 52(4) EPC 1973.

Question (b) has therefore to be answered in the negative.

3.4.3 Conclusion

Since

- the feed additive as defined in Claims 2 and 8 belongs to the state of the art (question (a) to be answered in the affirmative); and
- its use for a therapeutic treatment within the meaning of Article 52(4) EPC 1973, i.e. for the prevention of intestinal diseases and gastric disorders, is not comprised in the state of the art (question (b) to be answered in the negative),

the first medical indication applies in accordance with Article 54(5) EPC 1973 and the feed additive can be protected by claims directed to a feed additive for the prevention of intestinal diseases and gastric disorders.

This means, however, that the legal fiction in G 1/83 relating to the second and further medical indications no longer applies. Consequently, there is no room to protect the feed additive once more by claims formulated as second medical use claims.

Therefore, the feature "to be used for the prevention of gastric disorders ..." in Claim 2 is not limiting, with the result that the subject-matter of Claim 2 is not novel because, as shown under point 3.4.1, the

preparation of a feed additive by hydrolysis of a yeast raw material with an acid and its use in non-fractionated form is anticipated by A14.

3.5 In consequence, the first auxiliary request is not allowable.

4. Third auxiliary request

4.1 Amendments

The set of claims according to the third auxiliary request consists of five claims with Claim 1 (point VI above) protecting the feed additive as a first medical indication according to Article 54(5) EPC 1973.

Claim 1 is based on granted Claims 8 and 9 ("non-fractionated product"), the reference to promotion of growth having been deleted and a reference to the prevention of gastric disorders (based on Claim 12 as granted) having been incorporated.

Claims 2 to 5 are dependent claims based on granted Claims 10, 11, 14 and 15.

4.2 Novelty

As set out above in points 3.4.1 and 3.4.2, the feed additive as such is not novel over A14 but its use in preventing intestinal diseases and gastric disorders according to Article 52(4) EPC 1973 is not comprised in the state of the art. Therefore, the additive of Claim 1 is novel in accordance with Article 54(5) EPC 1973.

4.3 Inventive step

4.3.1 A12 is considered to represent the closest prior art because it deals with the use of whole yeast β -glucans as a dietary additive to improve digestion or treat digestive disorders (column 2, lines 32 to 36). The whole β -glucan, which is obtained from yeast cell walls, is subjected to a purification process (e.g. an extraction - column 3, lines 8 to 14) and is very pure (column 3, lines 38/39). In other words, the hydrolysis product is not used as such (in non-fractionated form).

4.3.2 The problem underlying the patent in suit in the light of the closest prior art is to be seen in the provision of a feed additive providing improved prevention of intestinal diseases.

As a solution to this problem, Claim 1 proposes a feed additive comprising the non-fractionated hydrolysis product obtained as such.

4.3.3 In this connection, the respondent has submitted experimental evidence with the letter dated 27 September 2005. This report compares *inter alia* the results of an E-coli attachment inhibition test carried out on piglets fed with feed additives on the basis of the non-fractionated yeast acid-hydrolysate (in accordance with the invention) with the results obtained by feeding an extracted (i.e. fractionated) hydrolysate (outside the invention). The results clearly show a more efficient prevention of E-coli attachment to piglet ileal mucus for the non-fractionated yeast hydrolysate in comparison with the

centrifuged cell wall fraction (Example 1 and Figure 1). The concept of inhibiting the adherence of noxious microbes to the wall of the intestine is already foreshadowed in paragraph [0004] of the patent specification. Thus, the effect relied upon by the respondent not only demonstrates that the above identified problem is plausibly solved, but also that it has a sound basis in the patent in suit (and the application as filed, respectively).

- 4.3.4 There is no indication in A12 or any other cited document which would prompt a skilled person to use acid-hydrolysed raw yeast material in non-fractionated (non-purified) form in order to improve prevention of intestinal diseases and gastric disorders, in particular the prevention of E-coli attachment to ileal mucus.

The uncontested technical effect shown by the experimental evidence dated 27 September 2005 cannot, in the board's view, be considered as a bonus effect - contrary to the appellant's view. As convincingly argued by the respondent (point VIII (b)), a "one-way-situation" which would inevitably lead to the effect shown when the teaching of the prior art is implemented does not apply here, because the relevant prior art offers several alternatives to providing yeast material as an additive for stimulating the animal immune system, e.g. enzymatic or hydrolytic degradation followed by purification/fractionation via extraction or centrifugation (A6, A7, A12).

The subject-matter of the third auxiliary request is therefore based on an inventive step.

4.4 In summary, the third auxiliary request is allowable.

5. Under these circumstances, there is no need to consider the fourth auxiliary request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of Claims 1 to 5 of the third auxiliary request filed during the oral proceedings together with any necessary consequential amendments to the description and figure.

The Registrar

The Chairman

G. Röhn

W. Sieber