Datasheet for the decision of 10 September 2009

Case Number: T 1744/06 - 3.3.09
Application Number: 91911371.2
Publication Number: 0531437
IPC: A23K 1/00
Language of the proceedings: EN

Title of invention:
Hemicellulase supplement to improve the energy efficiency of hemicellulose-containing food and animal feed

Patentee:
CHEMGEN CORPORATION

Opponent:
Finnfeeds International Ltd

Headword:
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Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)

Relevant legal provisions (EPC 1973):
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Keyword:
"Art. 83: Not substantiated in opposition - not admitted"
"Art. 123(2): Amendments admissible"
"Art. 54, 56: Novelty, inventive step (yes)"

Decisions cited:
G 0010/91

Catchword:
-
Case Number: T 1744/06 - 3.3.09

DEcision
of the Technical Board of Appeal 3.3.09
of 10 September 2009

Appellant: Finnfeeds International Ltd
(Opponent)
Market House
Ailesbury Court
Marlborough
Wiltshire SN8 1AA (GB)

Representative: Alcock, David
D Young & Co
Briton House
Briton Street
Southampton SO14 3EB (GB)

Appellant: CHEMGEN CORPORATION
(Patent Proprietor)
16016 Industrial Drive
Gaithersburg
MD 20877 (US)

Representative: Mercer, Christopher Paul
Carpmaels & Ransford
43, Bloomsbury Square
London WC1A 2RA (GB)


Composition of the Board:
Chairman: P. Kitzmantel
Members: W. Ehrenreich
K. Garnett
Summary of Facts and Submissions

I. Mention of the grant of European patent No. EP-B 0 531 437 with respect of European patent application No. 91 911 371.2 filed on 29 May 1991 as International application PCT/US91/03754 in the name of Chemgen Corporation and published on 12 December 1991 as WO-A 91/18521, was announced on 29 December 1997 (Bulletin 1997/52).

The patent entitled "Hemicellulase Supplement to improve the Energy Efficiency of Hemicellulose-containing Food and Animal Feed" was granted with eight claims. Claim 1 read as follows:

"1. A feed composition comprising:

(A) protein, vitamins and minerals nutritionally suitable for a monogastric animal or human;

(B) a source of carbohydrates, comprising a mannan-containing hemicellulose selected from the group consisting of soybeans, corn, and alfalfa; and

(C) a mannanase that catalyzes the degradation of said mannan-containing hemicellulose, where the addition of said mannanase decreases the ratio of feed to gain, or increases weight gain, during growth of an animal fed said feed composition, relative to said animal fed an identical feed composition absent said mannanase".
Claims 2 to 6 were dependent on Claim 1. Claim 7, and Claim 8 dependent thereon, were directed to the use of a feed composition according to Claims 1 to 6 in the manufacture for the promotion of growth of monogastric animals or humans.

II. An opposition against the patent was filed by

Finnfeeds International Ltd.

on 28 September 1998.

The opposition was based on Article 100(a) EPC, in that the claimed subject-matter was not novel and inventive (point IV of the notice of opposition), 100(b) EPC, in that Claims 1 to 8 were not consistent with the description (point V of the notice of opposition) and 100(c) EPC, in that feature (C) relating to the enzyme "mannanase" had no basis in the application as filed.

The objections under Article 100(a) EPC were inter alia based on the following documents;


With the letter dated 24 May 2002 the document
D6 Declaration of Mr Anderson

was submitted.

III. With its decision orally announced 7 February 2005 and issued in writing 13 September 2006 the Opposition Division maintained the patent in amended form. The decision was based on the claims according to the main request submitted with the letter dated 13 December 2004 and the auxiliary requests 1 and 2, both filed in the oral proceedings. The patent was maintained on the basis of auxiliary request 2. Claim 1 of this request read as follows:

"1. "A feed composition comprising:

(A) protein, vitamins and minerals nutritionally suitable for a monogastric animal or human;

(B) a source of carbohydrates, comprising a mannan-containing hemicellulose selected from the group consisting of soybeans and alfalfa; and

(C) a mannanase that catalyzes the degradation of said mannan-containing hemicellulose, wherein the enzyme has a pH profile for its activity in catalysing said degradation that ranges from pH 4.5 to pH 11, where the addition of said mannanase decreases the ratio of feed to gain, or increases weight gain, during growth of an animal fed said feed composition, relative to said animal fed an identical feed composition absent said mannanase, provided that the composition does not
contain guar, locust bean gum, carob bean gum, cassava, copra or coconut residue".

Independent Claim 7 - in contrast to granted Claim 7 - was now directed to a process for the preparation of the feed composition claimed in Claim 1 and contained the same proviso as in Claim 1.

In its decision the Opposition Division considered the claims according to the main request not to be allowable under Article 123(2) and Rule 57a EPC 1973 and denied the novelty of the subject-matter of the claims according to auxiliary request 1 over D1.

The proviso in Claims 1 and 7 of auxiliary request 2 excluding certain carbohydrate sources, inter alia guar meal, originally disclosed as preferred components of the feed composition, was considered allowable under Article 123(2) EPC. As a consequence, novelty over D1 was acknowledged for the subject-matter of this request.

Concerning inventive step, the Opposition Division considered D1 the closest prior art and stated that D1 taught how mannanase could be used to partially offset the anti-nutritional effect of mannan-containing meals and gums, but that it failed to suggest the improved performance achieved by the specific mannanase used by the invention when added to a normal optimized diet comprising soy bean meal.

The Opponent's objections raised in the Notice of Opposition under the title "Insufficiency of Chemgen" were considered to be objections under Art. 84, not 83. As to the further argument brought forward in the oral
proceedings, namely that the claimed subject-matter was merely characterized by its objective, it was held that the invention specified in auxiliary request 2 could be carried out by a skilled person without undue burden.

IV. Appeal against the decision was filed:

by the Patent Proprietor (hereinafter: Appellant/Proprietor) - on 23 November 2006

and

by the Opponent (hereinafter: Appellant/Opponent) - on 8 November 2006.

The Statement of the Grounds of Appeal was filed:

by the Appellant/Proprietor on 23 January 2007

and

by the Appellant/Opponent on 22 January 2007.

V. With the grounds of appeal the Appellant/Proprietor filed sets of claims according to a new main request and auxiliary requests 1 to 4. Revised sets of claims as bases for auxiliary requests 1 to 4 replacing all former requests were filed with the letter dated 10 August 2009.

In the oral proceedings, which were held on 10 September 2009, the Appellant/Proprietor withdrew all former requests and filed a single set of Claims 1
to 8 and amended description pages 2 to 22 according to a new main request.

Claim 1 of this request reads as follows:

"1. A feed composition comprising:
   (A) protein, vitamins and minerals nutritionally suitable for a monogastric animal or human;
   (B) a source of carbohydrates comprising a mannan-containing hemicellulose selected from the group consisting of soybeans and alfalfa; and
   (C) a mannanase that catalyzes the degradation of said mannan-containing hemicellulose, wherein said mannanase has a pH profile for its activity in catalysing said degradation that ranges from pH 4.5 to pH 11,
   where the addition of said mannanase decreases the ratio of feed to gain, or increases weight gain, during growth of an animal fed said feed composition, relative to said animal fed an identical feed composition absent said mannanase."

VI. In its grounds of appeal the Appellant/Opponent raised various objections under Articles 123(2), as well as under Articles 84 and 83 EPC. Furthermore, in its view, the claimed compositions were not novel over D1 and/or lacked an inventive when starting from D1 as the closest prior art.

With the letter dated 1 July 2009 the Appellant/Opponent withdrew its request for oral proceedings and informed the Board that it would not be attending the oral hearing scheduled for 10 September 2009.
VII. The Appellant/Opponent's objections raised in its written submissions under Articles 123(2), 83, 84, 54 and 56 EPC partly apply to the claims according to the new main request submitted by the Appellant/Proprietor in the oral proceedings.

In the Appellant's view, the decrease of the ratio of feed to gain in Claims 1 and 7, the feature in Claim 3 that the mannanase is an endo-\( \beta \)-D-mannanase and the process steps recited in Claim 7 were not disclosed in the application as filed, contrary to Article 123(2) EPC.

As regards Article 83 EPC the Appellant/Opponent's respective objections were in particular directed to the mere result-orientation of the functional feature in Claim 1 that the addition of mannanase "decreases the ratio of feed to gain, or increases weight gain, during growth of an animal ...", the undue burden involved in its accomplishment and the lack of an enabling disclosure of the bacillus strain used for the mannanase preparation.

Furthermore, novelty of the claimed compositions vis-à-vis the control compositions described in D1 - not containing guar meal but containing soybean, alfalfa and a hemicellulase - was denied. It was argued that these compositions already exhibited an improved feed to gain ratio.

As to inventive step, D1 was considered the closest prior art because it addressed the same technical problem, namely the provision of feedstuff for
livestock which was nutritionally valuable. In the Appellant/Opponent's view the solution of this problem as presented by the features in Claim 1 was also disclosed in D1.

VIII. The Appellant/Proprietor argued as follows:

Article 123(2) EPC

Redefinition of the term "hemicellulase" by "mannanase" in Claims 1 and 7 was justified by the fact that the whole application as filed pertained to compositions comprising as carbohydrate source a mannann-containing hemicellulose. The use of enzymes other than mannanase that do not degrade mannan in mannann-containing carbohydrates would therefore make no sense. The ability of mannanase to effect hydrolysis of mannans in hemicelluloses, like glucomannan or galactan, furthermore clearly emerged from page 1 of the WO-publication representing the application as filed. In this context, the disclosure of an endo-β-D-mannanase disclosed at page 17 of the WO-publication and being the subject of Claim 3 had to be considered a more specific mannanase falling under the general term "mannanase" in the sense of the application.

Furthermore, the aim of decreasing the ratio of feed to gain of the claimed composition relative to a feed absent the enzyme mannanase according to Claim 1, and the preparation of the composition according to Claim 7 by incorporating the enzyme mannanase into the source of proteins, vitamins and minerals and the source of carbohydrates in order to reach this aim, emerged clearly from the application in its whole context. A
violation of Article 123(2) EPC could not, therefore, be seen.

Article 83 EPC

The Appellant/Opponent's objections under Article 83 EPC raised in its grounds of appeal introduced a new opposition ground because the insufficiency case brought forward under point V of its notice of opposition before the Opposition Division was unsubstantiated and could not therefore be regarded as a validly invoked opposition ground under Article 100(b) EPC.

Novelty

The claimed composition was novel over the composition disclosed in the control examples of D1 in that D1 did not explicitly disclose that the hemicellulase enzyme CE-100,000 used according to this document had the specific pH profile for its activity as claimed in Claim 1.

Inventive step

When considering D1 as the closest prior art, it should be noted that the problem underlying this document was to counter the anti-nutritive effects of guar meal, which was a relatively inexpensive ingredient in common animal food compositions. For this purpose the effects of autoclaving and/or digesting the high protein guar meal with hemicellulase were studied with the aim of increasing the bioavailability of the polysaccharide components in the largely indigestible guar component
and to make the food composition more nutritionally valuable.

This problem was entirely different from that of the patent in suit which seeks to render guar-free food compositions containing soybean or alfalfa more nutritionally valuable by the addition of mannanase.

Even if the skilled person was aware of the slight numerical improvement in the body weight of chickens fed with hemicellulase-containing guar-free control compositions over those containing no hemicellulose as depicted in Tables 3 and 4 of D1, he would not consider the improvement statistically significant. The reason is that all these values were marked with the same significance index "a" which indicated, according to the footnotes below Tables 3 and 4, that the values did not differ statistically significantly. This view was corroborated when comparing the values for the chicken body weight resulting from feeding a composition according to the teaching of D1 containing 15% autoclaved guar meal (last sample in Table 3). Although the corresponding values relating to a composition without and with hemicellulase differed by 13 grammes, they were both indexed with "c" which meant that this difference - being even greater than the numerical difference of 10g between the body weight of the control sample without hemicellulase and that with hemicellulase according to Table 3 - was not significant.

In contrast, the gain/feed values for chicken fed with guar-containing compositions without and with hemicellulase were marked with different indices. The skilled person would conclude therefrom that the
addition of hemicellulase to compositions containing guar meal (raw and autoclaved) significantly improves the gain/feed ratios for chicken relative to hemicellulose-free compositions.

It was conspicuous therefore that for the skilled person what was important was not the numerical magnitude of the weight difference but its statistic significance. Therefore he would not, in the light of the results depicted in the Tables of D1, deduce any significant improvement in body weight or feed/gain for chicken fed with guar-free food compositions containing hemicellulase.

Although Claim 1 of the main request did not quantify the ratio of feed to gain or increase of weight gain during growth of the animals, it clearly emerged from Table X in the patent specification by way of the different significance-indices "A" and "B" that the values in body weight and feed/gain of the enzyme-containing feed composition marked with "A" were significantly improved over those representing the enzyme-free control compositions being marked with index "B".

IX. In its written submissions, the Appellant/Opponent requested that the appealed decision be set aside and the patent be revoked.

X. The Appellant/Proprietor requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request filed during the oral proceedings.
Reasons for the Decision

1. The appeals are admissible.

2. The following considerations all relate to the main request submitted by the Appellant/Proprietor in the oral proceedings, which is the sole operative request.

3. Article 123(2) EPC

The Board shares the Appellant/Proprietor's view that the amendment of the enzyme designation "hemicellulase" to "mannanase" in Claims 1 and 7 has a basis in the application as filed, as represented by the WO publication.

According to Claim 1 of the WO document the source of carbohydrates has to be a mannan-containing hemicellulose (feature (B)) and the enzyme (C) has to catalyse the degradation of this mannan-containing hemicellulose. Furthermore, it unambiguously follows from the first paragraph on page 1 of the description that the hydrolysis of heteropolysaccharides composed inter alia of mannans is catalysed by mannanase. This is confirmed by the sequence correspondence of the lists of the hemicellulases "glucanase, xylanase, mannanase" and their heteropolysaccharide substrates "glucan, xylan, mannan" in the same paragraph. It is further mentioned there that mannanases are produced by certain microorganisms, for instance a Bacillus, as exemplified in original Claim 3.
A basis for the disclosure of the subject-matter of Claim 3 can also be found in the last paragraph on page 17 of the WO-document, where it is specified that endo-β-D-mannanase is a particularly preferred hemicellulase; this feature is thus an admissible limitation of the more general term "mannanase".

It also follows from the WO-document in its whole context (cf. for instance page 4, paragraph 2 in combination with pages 26 and 27 and Claim 1) that it is the aim of the invention to increase the nutritional value of food compositions by enzymatic digestion of hemicellulose, thereby decreasing the ratio of feed to gain, and to provide such a composition by incorporating the enzyme into a composition containing a source of protein, vitamins and minerals and a source of carbohydrates.

Consequently, the amendments to the claims meet the requirements of Article 123(2) EPC.

4. Article 83 EPC

The Board shares the opinion of the Appellant/Proprietor that the opposition ground under Article 83 EPC was not substantiated in the opposition proceedings. The Appellant/Opponent's objections under Article 83 EPC raised in its grounds of appeal therefore constitute the introduction of a fresh opposition ground. Because the Appellant/Proprietor did not agree to its consideration, this ground is not admitted into the appeal proceedings (G 10/91, Headnote 3.)
5. Novelty

Claims 1 and 7 contain the feature that the mannanase that catalyzes the degradation of the hemicellulose "has a pH profile for its activity in catalysing said degradation that ranges from pH 4.5 to pH 11".

This feature can be interpreted according to its literal wording to mean that the enzyme has a biologically relevant enzyme-activity over the whole pH range of 4.5 to 11. The Board sees no reason to adopt a different interpretation.

The pertinent document for considering novelty is D1, which discloses in the control examples a feed composition comprising proteins, vitamins and minerals, a carbohydrate source comprising a mannan-containing hemicellulose selected from soybean and alfalfa and the enzyme hemicellulase which is specified as "CE-100,000" (Tables 3 and 4 in conjunction with Table 1 and page 1149, right column, first paragraph).

Although it can be assumed that the enzyme CE-100,000 according to D1 contains a mannanase, there is no unambiguous disclosure in this document about its enzymatic activity, let alone the pH range within which it is biologically active. Convincing evidence that CE-100,000 is active over the claimed pH range has also not been provided by the Appellant/Opponent.

Furthermore, in the Board's judgment, the wording of feature (B) in Claim 1 "a source of carbohydrates comprising a mannan-containing hemicellulose selected
from the group consisting of soybeans and alfalfa ...
" excludes other mannan-containing hemicelluloses including guar meal, which was investigated in D1 for its nutritional value in combination with other food-type carbohydrates like corn, soybean and alfalfa. There is thus no need for the proviso considered necessary by the Opposition Division in order to clarify this aspect.

Since the other citations do not comprise any disclosure relevant to cast light on the activity of CE-100,000 or other mannanase enzymes, the claimed pH profile for the activity of the mannanase represents a distinguishing feature over the guar-free compositions of D1.

The claimed subject-matter is therefore novel over D1.

6.  Inventive step

6.1  The subject-matter of the patent in suit

The patent is concerned with feed compositions for monogastric animals. The compositions are based on vitamins, proteins and minerals and a vegetable carbohydrate source comprising a mannan-containing hemicellulase selected from soybeans and alfalfa and should have an enhanced energy content when consumed. For this purpose it is the aim of the invention to transfer the indigestible mannan-containing hemicellulose contained in the carbohydrate source into lower molecular weight carbohydrates which can be metabolized by monogastric animals (patent
specification, page 3, lines 1 to 13 and page 4, lines 11 to 13).

According to Claim 1 this aim is achieved by the addition of a mannanase having a specific pH profile for its activity.

6.2 The closest prior art

The Board agrees with the Parties that D1 represents the closest prior art.

D1 is concerned with the improvement of the nutritional value of guar meal in poultry feed compositions and starts from the observation that guar meal as ingredient in poultry feed caused loss of body weight and depressed feed consumption (page 1148, right column to page 1149 first paragraph of the left column). In order to overcome this problem, effects of autoclaving time, temperature and graded levels of hemicellulase supplementation on performance of chicks and laying hens fed guar meal-containing diets were studied (page 1149, second paragraph of the left column).

In Tables 3 and 4 the effect of raw and autoclaved guar meal in diet compositions containing corn, soybean meal and alfalfa as vegetable carbohydrate source in the absence or presence of the enzyme hemicellulase, as regards the growth of chickens fed the diet, are depicted. In the section "Results" at page 1152 it is stated with respect to Experiments 1 and 2 that:

(a) autoclaving or enzyme supplementation of guar meal increased body weight and feed efficiency (i.e.
gain/feed) of chicks fed the diet containing either 10 or 15% guar meal;
(b) hemicellulase addition to diets containing autoclaved guar meal produced a further significant improvement on body weight only with the 10% meal diets;
(c) addition of 15% raw guar meal to the control diet (i.e a composition which was guar-free marked with "0% guar meal" in Tables 3 and 4) significantly decreased body weight and feed efficiency.

Observations (b) and (c) correspond to the diagram on the right-hand side of page 2 of the declaration D6 representing the prior art and comparing it with the claimed invention depicted on the left-hand diagram.

Furthermore, it is concluded in the section "Discussion" on pages 1154 and 1155 that the improvements obtained from enzyme treatment of guar meal or the addition of enzymes to diets containing guar meal were probably due to enzyme action on the guar gum.

D1, however, contains no text passage from which the skilled person could conclude that hemicellulase action on the guar-free control diet provides an improvement over a corresponding control diet in which hemicellulase is absent.

6.3 Problem/solution

The composition according to the claimed invention differs from the diet composition according to the teaching of D1 in that it is guar-free and contains a
mannanase that has a pH profile for its activity in the range of from 4.5 to 11.

It follows from the experimental evidence according to example 18 of the patent, in particular the statistical analysis depicted in Table X, that the addition of mannanase to guar-free feed compositions containing soybean meal leads to an increase in average chicken body weight and a decrease in feed/gain both of which are statistically significant. This significance is expressed by the different indices "A" marking the results for the composition according to the invention and "B" characterizing the results of the control samples.

Therefore, the problem to be solved is seen in providing a feed composition for monogastric animals which is guar-free and which leads to an increased ratio of feed to gain or increases weight gain during growth of an animal which is statistically significant.

6.4 Obviousness

In Tables 3 and 4 of D1 results in chicken body weight and gain/feed (the reciprocal of feed/gain according to Claim 1) of guar-free control feed compositions containing hemicellulase are listed. Although slight numerical "improvements" in comparison with the corresponding hemicellulase-free control compositions can be observed, the skilled person would not, as the Appellant/Proprietary convincingly argued (point VIII), consider the results significant because the corresponding results are marked with the same index "a" which means according to the footnote at pages 1152.
and 1153 that the differences are not statistically significant.

A skilled person considering D1 would therefore not expect that the addition of hemicellulase to guar-free feed compositions would significantly improve gain to feed (i.e. decrease the reciprocal feed to gain ratio as claimed) or increase chicken body weight relative to a hemicellulose-free composition. A combination of D1 with any other document of the prior art does not change this conclusion.

Therefore, the claimed composition is based on an inventive step.

7. In conclusion, the claims according to the main request are allowable.
Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division with the order to maintain the patent on the basis of:

   (a) Claims 1 to 8 according to the Main Request filed during the oral proceedings;
   (b) Pages numbered 2 to 22 of the amended description filed during the oral proceedings;
   (c) Figures 1 to 5 as granted.

The Registrar

The Chairman

L. Fernández Gómez

P. Kitzmantel