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

Case Number: T 0417/05 - 3.3.09

Application Number: 94102243.6

Publication Number: 0610957

IPC: A23K 1/16

Language of the proceedings: EN

Title of invention:

Method for supplementing amino acid levels in ruminant animals

Patentee:

Ajinomoto Co., Inc.

Opponent:

Evonik Degussa GmbH
Cargill, Inc.

Headword:

-

Relevant legal provisions:

EPC Art. 56

Relevant legal provisions (EPC 1973):

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Keyword:

"Inventive step (no)"

"Solution of the problem not over the whole breadth of the claim"

Decisions cited:

-

Catchword:

-



Case Number: T 0417/05 - 3.3.09

D E C I S I O N
of the Technical Board of Appeal 3.3.09
of 20 December 2007

Appellant:
(Patent Proprietor)

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-

Respondent:
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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office orally announced
10 November 2004 and posted 26 January 2005
revoking European patent No. 0610957 pursuant
to Article 102(1) EPC.**

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. 0 610 957 in respect of European patent application No. 94 102 243.6, filed on 14 February 1994 in the name of *Ajinomoto Co., Inc.*, was announced on 6 November 2002 (Bulletin 2002/45).

The patent, entitled "*Method for supplementing amino acid levels in ruminant animals*", was granted with four claims. Claims 1, 2 and 4 were independent claims which were directed to a method for increasing milk production in ruminant animals. Claim 3 was dependent on Claims 1 or 2.

Claim 1 read as follows:

"1. A method for increasing milk production in ruminant animals comprising feeding said animals a rumen-protected feed additive comprising lysine, methionine or a mixture thereof each day beginning at any time from 60 to 5 days prior to the parturition date of said ruminant animal and continuing said feeding at most 5 months into the lactation period of said animal."

- II. Notice of opposition was filed by

I *Degussa AG, now Evonik-Degussa GmbH,* on
24 July 2003

and

II *Cargill Inc.* on 6 August 2003.

The Opponents based their opposition on Articles 100(a), (b) and (c) EPC and requested that the patent be revoked because the claimed invention lacked novelty and inventive step, was insufficiently disclosed and the amendments made violated Article 123(2) EPC.

As regards the issue of novelty and inventive step the Opponent cited, *inter alia*, the following documents:

D1 C.E. Polan et al: "*Responses of Dairy Cows to Supplemental Rumen-Protected Forms of Methionine and Lysine*" in J. Dairy Sci., 74 (1991), pp. 2997-3013;

D2 J. Leibetseder und H.P. Ertl: "*Über den Einfluß von Ketionin auf die Milchleistung von Kühen*" in Wien. tierärztl. Mschr. 71 (1984), pp. 94-98.

III. With the letter dated 5 March 2004 the Patent Proprietor filed three sets of claims according to a new main request and auxiliary requests 1 and 2.

Claim 1 according to the main request differed from Claim 1 as granted by the deletion of the wording "*methionine or a mixture thereof*", and additionally, in Claim 1 according to auxiliary request 1, the feature "at any time from 60 to 5 days ..." was replaced by the feature "*at 60, 30, 10 or 5 days...*".

Claim 1 according to auxiliary request 2, which was identical with Claim 2 as granted, read as follows:

"1. A method for increasing milk production in ruminant animals comprising feeding said animals a rumen-

protected feed additive comprising lysine, methionine or a mixture thereof each day beginning approximately 1 day after parturition and continuing said feeding at most 5 months into the lactation period of said animal".

IV. With its decision orally announced on 10 November 2004 and issued in writing on 26 January 2005 the Opposition Division revoked the patent.

The main request and auxiliary request 1 were considered not allowable under the provisions of Article 123(2) EPC.

In the decision it was held that the features in Claims 1 (i) "at any time from 60 to 5 days" (main request) / "at 60, 30, 10 or 5 days" (auxiliary request 1) and (ii) "lysine" were selected from two different lists, ie (i) a list of beginning dates disclosed on page 5, lines 19 to 21 of the application as filed and (ii) a list of three amino acids disclosed on page 6, line 7 of the application as filed. Such a combination from two lists constituted added subject-matter.

In the Opposition Division's view, the subject-matter of Claim 1 according to auxiliary request 2 was not inventive vis à vis D2. It was held that the claimed method for increasing milk production differed from the method according to D2 only in that the feeding period of the rumen-protected additive began 1 day after parturition instead of 20 days prior to parturition according to D2. However, no specific effect resulting from this difference was shown. The effect of increased milk production, which according to D2 continued after removal of the amino acid, could also be observed in example 4 of the patent in suit where the supple-

mentation began only at day 29 postpartum. The beginning date of the feeding period for the rumen protected additive was therefore arbitrary and did not involve an inventive step.

V. On 5 April 2005 the Patent Proprietor (hereinafter "the Appellant") lodged an appeal against the decision of the Opposition Division.

With the Statement of the Grounds of Appeal filed on 6 June 2005 two sets of amended claims as bases for a new main request and an auxiliary request were submitted. Each set consisted of two claims, which were based on Claims 1 and 3 as granted. The amendments to Claims 1 corresponded to the amendments made in Claims 1 according to the main request and the auxiliary request 2 submitted in the opposition proceedings (see point III).

Claim 1 of each request reads as follows:

Main Request

"1. A method for increasing milk production in ruminant animals comprising feeding said animals a rumen-protected feed additive comprising lysine each day beginning at any time from 60 to 5 days prior to the parturition date of said ruminant animal and continuing said feeding at most 5 months into the lactation period of said animal."

Auxiliary Request

"1. A method for increasing milk production in ruminant animals comprising feeding said animals a rumen-

protected feed additive comprising lysine each day beginning at 60, 30, 10 or 5 days prior to the parturition date of said ruminant animal and continuing said feeding at most 5 months into the lactation period of said animal."

VI. The Respondents (Opponents I and II) maintained their objections as to added subject-matter and lack of inventive step raised in the first instance opposition proceedings. With its letter dated 22 December 2005 the Respondent/Opponent II filed further documents to support its allegations as to lack of inventive step.

VII. In the oral proceedings held on 20 December 2007 the issues of added subject-matter and inventive step were discussed. As to the alleged added subject matter the Board expressed its provisional view that the amendments to Claims 1 of the main and auxiliary requests resulted from an admissible selection from several lists of features. The Board, however, refrained from taking a final decision on that point because - as will be seen below - the subject-matter according to both requests lacked an inventive step. The following considerations therefore refer to the issue of inventive step only.

VIII. The Appellant's arguments concerning inventive step can be summarized as follows:

It was shown in example 5 of the patent that the feeding of a rumen-protected additive containing lysine alone (emphasis by the Board) as amino acid led to an increased milk production. Although it was disclosed in D1 that lysine was one of the limiting amino acids in

milk production, reference was also made to methionine as the other first limiting amino acid, and lysine was always used in combination with methionine. The importance of methionine as a limiting amino acid emerged in particular from D2, which exclusively indicated the use of rumen protected methionine as feed additive for increasing milk production.

It was therefore not rendered obvious that lysine alone was suitable for increasing milk production when applied in the form of a rumen-protected additive.

IX. The Respondents' counter arguments were as follows:

The wording in Claims 1 of the main and auxiliary requests "feed additive comprising lysine" (emphasis by the Board) did not exclude the presence of methionine. Therefore, rumen-protected additives in accordance with D1 and comprising a combination of lysine with methionine were also embraced by the claims.

It was furthermore known to a skilled person that milk production depends to a considerable extent on the feeding circumstances, in particular the feed composition. This was stated in the patent specification itself, which pointed out in paragraphs [0034] to [0036] that the supplementation of the feed by rumen-protected amino acids depended on the content of metabolizable proteins in the feed. It was furthermore disclosed in paragraphs [0035] and [0036] that the Cornell Carbohydrate and Protein System was known in the prior art, which allowed the metabolizable protein for e.g. dairy cattle to be calculated. The model also provided animal responses to given diets based upon

feed composition, digestion rates and digestible protein and therefore enabled, dependent on the amount of metabolizable protein, deficient amino acids to be supplemented by rumen protected feed additives to the required levels.

A skilled person would therefore not add any rumen protected amino acid to the feed without considering its composition.

The Appellant's allegation that an increased milk production could be achieved by the addition of rumen protected lysine to any feed, in the sense of the claimed invention, was therefore not realistic and, hence, not convincing. This was all the more so as the increased milk production with rumen-protected lysine was not demonstrated in general but was shown in example 5 only for a specific feed composition. When starting from D2, which disclosed feeding dairy animals with rumen protected methionine within the claimed feeding period, a skilled person seeking increased milk production would therefore consider the addition of rumen protected lysine as one of the limiting amino acids for milk production in accordance with D1, if this was required by the composition of the feed.

X. The Appellant (Patent Proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main, alternatively the auxiliary request, both filed with the letter of 6 June 2005.

XI. The Respondents (Opponents) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.
2. *Inventive step of the subject-matter according to the main and auxiliary requests*
 - 2.1 The objective underlying the patent in suit is the increase of the milk production of ruminant animals by increasing the digestible amino acids (methionine and/or lysine) in the feed for the ruminants (paragraph [0001]).

According to Claims 1 of the main and auxiliary requests this objective is allegedly attained by feeding the animals a rumen-protected feed additive comprising lysine as rumen-protected amino acid

- each day beginning at any time from 60 to 5 days prior to the partition of the ruminant animal (main request) or beginning at 60, 30, 10 or 5 days prior to the parturition of the ruminant animal (auxiliary request); and
- continuing the feeding for at most 5 months into the lactation period of the animal.

- 2.2 In the light of the above objective, it follows from these definitions that the specified methods should lead to an increase of the milk production by feeding the ruminant animal with a rumen-protected additive comprising lysine alone (point VIII) to any

conventional ruminant feed, irrespective of its composition.

According to the established jurisprudence of the boards of appeal, acknowledgement of an inventive step depends on the successful solution of the problem underlying the claimed invention (ie attainment of the set objective) over the whole breadth of the claim.

- 2.3 The experimental evidence presented in example 5 of the patent specification shows that a rumen-protected feed additive comprising as amino acid lysine alone (ie rumen protected amino acid, RPAA, according to example 1) provides an increased milk production in the early, middle and late lactation periods for Group A and Group B cows fed with rumen-protected lysine over Group C cows fed without the additive (Table 4).

This effect, however, is only shown for a certain feed composition, mainly one based on corn/corn silage which was fed according to a feeding regimen comprising feeding first low protein feed CP14 (ie 14% crude protein) plus RPAA each day 3 weeks prior to parturition until parturition, followed by feeding high protein feed CP19 (ie 19% crude protein) plus RPAA from the day of parturition for 70 days.

- 2.4 As compared thereto, it is shown by the prior art represented by D1 that rumen-protected lysine alone does not lead to an increased milk production for any feed composition.

D1 discloses (page 2998, right column) that among the nutritive amino acids methionine and lysine are the

first limiting amino acids for milk production in ruminant animals. In the section "Discussion" (page 3010 to page 3011 right column), D1 examines the relationship between the feed composition and the deficient amino acids with which the feed is to be supplemented.

In line with the experimental results set out in Table 7 it is stated there that animal feed based on corn gluten meal (CGM) supplied insufficient amounts of digestible lysine for milk production and that dairy cows which consumed CGM-based diets supplemented with rumen-protected lysine (RPLys) responded positively by increased milk yields (page 3012, right column).

While these results confirm the experimental results in the present patent specification, it is also made clear in this "Discussion" that ruminant feed based on soy bean meal (SBM) provides by itself (without supplementation with RPLys) sufficient post-ruminally available lysine for a milk yield which is superior to the one achieved by supplementing a CGM based diet with RPLys (page 3011, right column, lines 5 to 9; page 3012, last paragraph). In conclusion it is set out on page 2998, right column, lines 23 to 29: "Yields of both milk and milk protein were improved by various combinations of RPLys and RPMet when cows consumed a diet containing corn silage, shelled corn, corn gluten meal (CGM), and urea, but not when they consumed diets in which soy bean meal (SBM) replaced CGM". (emphasis by the Board)

It is noted that the above observations are consistent with the explanations in paragraphs [0034-36] of the

patent specification itself (which the Respondents referred to in the oral proceedings, point IX) dealing with the situation that the supplementation of animal feed with deficient amino acids - either methionine or lysine - in rumen-protected form depends on the composition of the feed.

- 2.5 The Board therefore concludes that the claimed solution to the problem posed, ie the increase of milk production of ruminant animals by feeding rumen-protected lysine in general, is not solved across the entire scope claimed because RPLys alone is not able to increase the milk yield of ruminant animals in all feeds, particularly not in feeds based on soy bean meal SBM.

The process claimed according to the main and auxiliary requests therefore lacks an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar

The Chairman

G. Röhn

P. Kitzmantel