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Bezeichnung der Erfindung: Ruminant lactation improvement

Title of invention:

Titre de l'invention :

Klassifikation / Classification / Classement : A23K 1/17

### ENTSCHEIDUNG / DECISION

vom / of / du 17 May 1990

Anmelder / Applicant / Demandeur :

Patentinhaber / Proprietor of the patent /

Titulaire du brevet :

Eli Lilly and Company

Einsprechender / Opponent / Opposant :

Smith Kline Beecham Corporation

Stichwort / Headword / Référence :

EPÜ / EPC / CBE Articles 83, 54 and 56

Schlagwort / Keyword / Mot clé :

"Sufficiency (yes)"

"Novelty (yes) - second non-medical use"

"Inventive step - broad claim (no)"

"Remittal"

Leitsatz / Headnote / Sommaire

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European Patent  
Office

Boards of Appeal

Office européen  
des brevets

Chambres de recours



Case Number : T 582/88 - 3.3.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 17 May 1990

Appellant :  
(Opponent)

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Decision under appeal :

Decision of Opposition Division of the European  
Patent Office dated 23 September 1988 rejecting  
the opposition filed against European patent  
No. 0 063 491 pursuant to Article 102(2) EPC.

Composition of the Board :

Chairman : P. Lançon

Members : U. Kinkeldey

C. Holtz

## Summary of Facts and Submissions

- I. The mention of the grant of European patent No. 0 063 491 in respect of European patent application No. 82 301 996.3, filed on 19 April 1982, was announced on 15 January 1986 (cf. Bulletin 86/03).

Claims 1, 2 and 8 read as follows:

"1. The non-therapeutic treatment of dairy cows for the purpose of improving the milk-production thereof which comprises orally administering a propionate increasing amount of a glycopeptide antibiotic to said ruminant.

2. A method according to Claim 1 wherein the glycopeptide employed is selected from actaplanin, avoparcin, A35512, A477, AM374, ristocetin, vancomycin, and K288.

8. The non-therapeutic use of a propionate-increasing amount of a glycopeptide antibiotic in improving milk production in a lactating ruminant having a developed rumen function."

- II. On 9 October 1986 the Appellants (Opponents) filed notice of opposition against the European patent requesting revocation of the patent on the grounds of Article 100 EPC and cited 15 documents of which the following remained relevant during the appeal procedure:

- (1) US-PS-3 928 571
- (3) Pankhurst et al., Ann. Rep. 1977, Ellinbank Dairy Research Institute
- (4) Pankhurst et al., Ann. Rep. 1978, Ellinbank Dairy Research Institute (cited during examination).
- (5) Ruffo et al., Arch. Vet. ital. 27, 100-105 (1976)
- (6) Ruffo et al., Folia vet. lat. 7, 341-357 (1977)

- (7) Lassiter et al., Michigan Q. Bull. 43(1), 105-116 (1960).
- (8) Gulia et al., Indian J. Dairy Sci. 31, 99-103 (1978).
- (9) Rangnekar et al., Indian Vet. J. 48(9), 934-938, 1971.
- (10) Dzingaite, Chem. Abstr. 64, 11729h (1966).
- (14) Lemenarger et al., J. Anim. Sci. 47, 247-253 (1978).
- (15) GB-2 137 087.

III. The Opposition Division maintained the patent as granted by decision of 23 September 1988.

IV. On 25 November 1988 the Appellants filed a notice of appeal against this decision, paying the appeal fee at the same time and filing a statement of grounds on 1 February 1989.

The main arguments submitted by the Appellants were as follows:

The claimed process, including the effect obtained, was an inevitable result of the teaching of document (1).

The process, in any event, did not involve an inventive step having regard to the prior art teachings that glycopeptide antibiotics could increase propionate production without significantly decreasing acetate and butyrate production and also improved feed utilisation efficiency.

The claims were unduly broad so that the specification did not enable the full scope of the invention to be carried out by a person skilled in the art. The claimed invention did not supply a solution to the problem of

increasing milk yield without decreasing fat content. It was clear that not all glycopeptide antibiotics at dosage levels likely to be selected by the skilled addressee had the desired effect. If proprietor had made a selection invention in the discovery that at certain doses certain glycopeptides improved milk yield without decreasing fat content, then the claims should be commensurate with the enabling disclosure of the application. An interpretation of the requirements of Article 83 EPC of that kind was expressed in the Decision T 226/85 (OJ EPO 1988, 336) by a Board of Appeal.

- V. In reply the Respondents submitted further documents and the following arguments:

The use of the antibiotics described in document (1), which are the same as the ones used in the patent in suit, was clearly for the treatment of a certain disease in dairy animals and there was not the slightest hint that these antibiotics could have been administered to dairy animals for the purpose of increasing milk yield while not decreasing fat content. Having regard to document (1), therefore, the claimed use of glycopeptide antibiotics undoubtedly was novel. No other document taught the claimed use either.

An inventive step of the teaching of Claim 1 had to be acknowledged because the values shown in document (1) for a certain increase in propionate in the rumen of dairy animals when treating these animals with various glycopeptide antibiotics showed at the same time a decrease of acetate and butyrate which was contrasted with the teaching of the patent in suit at page 2, line 22, which said "...in order to increase milk production in lactating ruminants, it is necessary to increase propionate production, but not at a large expense of

acetate and butyrate production" (emphasis added). Therefore one could not agree with the Appellants' argument that document (1) indicated that certain glycopeptide antibiotics can be effective in altering rumen fermentation so as to increase production of propionates without significantly decreasing production of acetates and butyrates.

Documents (5) to (10) and (14) in particular further showed that actually there was a prejudice against administering expensive growth promoters e.g. certain antibiotics because none of the cited documents showed that growth promoters had any significant and consistent effect on milk production.

Further pioneering nature of the invention was alleged on the basis of the facts that most of the trials reported in the mentioned prior art documents were unsuccessful. There was, thus, no logical reason to feed a growth promoter to a dairy cow to achieve an improvement in milk production and there was considerable negative teaching against so doing.

Objections raised by the Appellants with regard to insufficiency (Article 83 EPC) were answered by the Respondents, relying on the decision T 292/85 (OJ EPO 1989, 275) and pointing out that clearly there is one example in the description of the patent in suit which can be repeated by the skilled worker. The two glycopeptide antibiotics extensively tested, namely actaplanin and A35512, had both been demonstrated to be effective. The determination of the correct dosage level for any particular glycopeptide antibiotic was simply a matter of routine trial well within the scope of any dairy scientist's normal skill. This argument was supported by Prof. Emery's affidavit (document (22)). The non-

biological case T 226/85 (see above paragraph IV) upon which the Appellants relied was far less relevant than the decision T 292/85 (see above).

VI. With letter of 24 April 1990 the Appellants withdrew their objections against novelty of Claim 1 because of the decision of the Enlarged Board of Appeal G 2/88 - "Friction reducing additive - MOBIL OIL III of 11 December 1989 (to be published in the OJ EPO). In a further letter dated 15 May 1990 the Appellants submitted two further documents out of which the following remained relevant:

(24) M.M. Abubaker and P. Rowlinson, Animal Production, 49, 323-325 (1989).

Further a set of restricted claims was submitted in respect of which, if accepted by the Respondents, the Appellants would not pursue the appeal further. Claims 1 and 7 of this set of claims read as follows:

"1. The non-therapeutic treatment of dairy cows for the purpose of improving the milk-production thereof which comprises orally administering a propionate-increasing amount of a glycopeptide antibiotic to said ruminant wherein the glycopeptide employed is selected from actaplanin, avoparcin, A35512, A477, AM374, ristocetin, vancomycin, and K288.

7. The non-therapeutic use of a propionate-increasing amount of actaplanin in improving milk production in a dairy cow."

VII. During oral proceedings which took place on 17 May 1990 both parties confirmed their positions as already submitted. Further questioned by the Board, the Appellants confirmed that the rates of increase of

propionate and decrease of acetate and butyrate in document (14) wherein the antibiotic monensin was administered to dairy animals, were the same as given in a table in document (1) for the glycopeptide antibiotics used there which in turn are identical to those used in the patent in suit.

The set of claims submitted by the Appellants with letter of 15 May 1990 was made subject-matter of auxiliary requests by both parties.

The Appellants requested that the decision under appeal be set aside and that the patent be revoked, or, as an auxiliary request, that the patent be maintained in an amended form with Claims 1 to 7 as proposed in letter of 15 May 1990, submitted by the Appellants.

The Respondents requested that the appeal be dismissed and that the patent be maintained, or, as an auxiliary request, that the patent be maintained in an amended form with Claims 1 to 7 as proposed in letter of 15 May 1990, submitted by the Appellant. Finally, the Respondent requested apportionment of costs under Article 104 EPC.

At the conclusion of the oral hearing the Board's decision was announced in accordance with the order set out below.

#### **Reasons for the Decision**

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.
2. **Amendments (Article 123(2) and (3) EPC)**

Claims 1 to 9 of the main request are the same as granted. The main claim of the auxiliary request represents a mere



combination of Claims 1 and 2 as granted. Claims 3 to 7 according to the auxiliary request correspond to Claims 4 to 7 and 9 respectively of the granted set of claims. There are, therefore, no objections with respect to Article 123(2) and (3) EPC.

3. Sufficiency of disclosure (Article 83 EPC)

3.1 From the facts of the present case the Board finds it apparent that the description of the patent in suit only provides two particular glycopeptide antibiotics, namely actaplanin and A35512, for detailed information as to how to produce and use them, whereas the broad claim covers all glycopeptide antibiotics. In particular in Example 5 very specific and detailed data are presented wherein the amount of actaplanin administered to a special kind of cow is given and the corresponding milk production (kg/day), milk fat (%), milk protein (%) and weight gain (kg) is noted. Further, in Example 5 the feeding conditions are described. Also the duration of the treatment is precisely mentioned (page 10, lines 5 to 65 of the patent specification). Additional experiments had been carried out for testing further parameters which might influence the effect of the administration of actaplanin (e.g. the time of milking, the kind of feed and the duration of the treatment with actaplanin). Finally, comparative data are presented making use of a further glycopeptide antibiotic, namely A35512B, which in fact provides an increase in the milk production compared to a control, but seems to be associated with a decrease of fat and milk solids. The data thus generated demonstrate that two particular glycopeptide antibiotics, namely actaplanin and A35512B, administered to lactating ruminants under definite conditions significantly increased the amount of milk without adversely affecting the levels of milk fat and milk protein.

- 3.2 The Appellants relied on documents which were published only after the priority date of the patent in suit but nevertheless proved in their opinion that the described examples did not meet the requirements of Article 83 EPC. In this respect the most relevant document seems to be document (24) which was published in 1989 and describes the administering of the glycopeptide antibiotic actaplanin under certain conditions. The authors of document (24) observed a non-significant trend towards higher daily milk yields which was believed to be insufficient to persuade dairy farmers to incorporate this antibiotic in their dairy cow diets. When now comparing the detailed experimental conditions described in document (24) with those disclosed in the examples of the patent in suit it is evident that the experimental parameters differ from each other. Therefore, the facts of the patent in suit differ from those on which the decision T 226/85 (see above paragraph IV) was based.
- 3.3 All further evidence provided by the Appellants in support of their allegation that the description of the patent in suit does not meet the requirements of Article 83 EPC are less relevant.
- 3.4 The facts of the patent in suit now before the Board resemble those upon which the decision T 292/85 (see above paragraph V) was based. There was no convincing evidence in the case T 292/85 that the single example would not work or that variants of single parameters of the whole procedure were not available or would possibly not lead to the desired result. Likewise in the patent in suit there is no convincing evidence that Example 5, which describes the administering of actaplanin to cows and the respective effect on milk production is not repeatable as such, nor that using variants of certain parameters like the amount of administered actaplanin, climate, feed or age of the

cows would not lead to the desired result. The conditions described in Example 5 are of a kind which show the skilled person that some trial and error may be necessary.

Thus, the Board cannot see that in the present case there is an insufficient disclosure within the meaning of Article 83 EPC.

4. Novelty (Article 54 EPC)

After issuance of the decision G 2/88 (to be published in the OJ EPO) the Appellants withdraw their request to revoke the patent because of lack of novelty of Claim 1. The teaching of the decision G 2/88 is that a claim to the use of a known compound for a particular purpose, which is based on a technical effect which is described in the patent application, should be interpreted to include that technical effect as a functional technical feature and is to be judged as novel provided that such technical feature has not previously been made available to the public. In the patent in suit the main claim is directed to the use of known glycopeptide antibiotics for the non-therapeutic treatment of dairy cows for the novel purpose of improving milk production. The teaching of the said decision is thus applicable to the present case.

5. Inventive step (Article 56 EPC)

5.1 In the Board's opinion document (14) represents the closest state of the art. During the proceedings both parties had considered that the closest state of the art was represented by document (1) but, as is made clear by the detailed discussion below, document (14) contains more features of the invention as claimed in the patent in suit.

5.2 Document (14) relates to the effects of monensin, an antibiotic, on forage intake and lactation of cows grazing low quality dry winter range grass, which was examined in two trials. The purpose of this study was to evaluate the effect of monensin on forage and supplement intake, weight change and milk production and milk composition of range beef cows (emphasis added). It is stated in document (14) ("introduction" page 247) that it was known that monensin increases the metabolizable energy content from feed theoretically by increasing the ratio of propionate to acetate and butyrate produced in the rumen and thereby diverting energy from methane to propionate. Lipids in the milk of ruminants contain a substantial quantity of short and medium chain length fatty acids. This is the result of active *de novo* synthesis from the simple metabolites, acetate and B-hydroxybutyrate, which are supplied to the mammary gland. Milk fat levels typically decrease as the ruminal acetate to propionate ratio decreases. The state of the art knowledge was in this context that monensin had little effect on milk production or levels of butter fat, solids and protein. This knowledge was confirmed by the study carried out in document (14). However, a detailed analysis was carried out to investigate the percentage of the volatile fatty acids propionate, acetate and butyrate and the respective ratios as well (Table 3 and Table 6).

5.3 Bearing in mind the closest prior art as represented by document (14), the technical problem to be solved can be defined as to provide a method for improving ruminant lactation such that the volume of milk produced is increased without a concomitant decrease in milk fat content.

In order to solve this problem, the main claim of the patent in suit suggests treating dairy cows by orally administering a propionate-increasing amount of a glycopeptide antibiotic. As already discussed in detail above under paragraph 3 (sufficiency of disclosure according to Article 83 EPC) the Board believes that Example 5 of the description of the patent in suit provides sufficient information to prove that the problem identified above has actually been solved, at least by two representatives of the general term "glycopeptide antibiotics".

- 5.4 Document (14) as well as the process presently claimed describes the treatment of dairy cows by orally administering a propionate-increasing amount of an antibiotic. The only difference is that the patent in suit claims that this treatment is "for the purpose of improving the milk production", whereas document (14) states that the investigations had been carried out for the purpose of evaluating the effect of monensin on milk production and milk composition.
- 5.5 In document (1) it is demonstrated that ruminant animals having a developed rumen function and animals which ferment fibrous vegetable matter in the cecum convert their feed more efficiently to energy when orally treated with an antibiotic chosen from among A477, A4696, vancomycin and ristocetin. This document discloses that the efficiency of carbohydrate utilisation, (carbohydrates being the major nutritive portion of ruminant animals' feed), can be increased by treatments which encourage the animal to produce propionate rather than acetate from the carbohydrates. If the animal is making more propionates, it will be found to be using its feed more efficiently (column 1, lines 50 to 59). In a table (column 15, line 60 bridging column 16, line 11) the values of the increase of

propionate and the corresponding values for acetate and butyrate are given. The two glycopeptide antibiotics expressly mentioned in the table are covered by the more general term "glycopeptide antibiotic" of Claim 1 of the patent in suit and are identical with substances claimed in sub-Claims 2 and 3.

The patent in suit contains no specific analysis of the increase or decrease of said volatile fatty acids but rather restricts itself to the statement that it is decisive for the invention that there is an increase of propionate without a significant decrease of acetate and butyrate to achieve the claimed result, namely to increase milk production. Therefore, one has to assume that the values given in document (1) for the three fatty acids would be the same as when administering the identical compounds to cows according to the patent in suit, which should then be comparable in their effect on milk production. The data for the amounts and ratio of the three volatile fatty acids in document (14) and in document (1) are the same. This was confirmed by the Appellants upon questioning by the Board. If it is true that it is decisive for the object of invention that an increase of propionate in the rumen of a cow after the administering of an antibiotic must not cause a corresponding decrease of acetate and butyrate to provide the inventive effect, this effect should appear whenever the important ratio of the volatile fatty acids is present.

The question now is, whether, for the skilled person knowing the effect of the feeding of monensin to cows to the ratio of propionate, acetate and butyrate as described in document (14) as well as the effect of the glycopeptide antibiotics on the efficiency of feed utilisation as described in document (1) which are identical with some

glycopeptide antibiotics as claimed in the patent in suit, it would be obvious to attempt the process as claimed in Claim 1 of the patent in suit. In the Board's opinion the combined knowledge from documents (14) and (1) would indeed make it obvious for a skilled person to try glycopeptide antibiotics for an increase of propionate, with a reasonable expectation of success.

5.6 The fact that document (14) does not describe a considerable effect on milk yield is, in the Board's opinion, no prejudice against the use of glycopeptide antibiotics in general. Rather, based on the disclosure of all further documents (4) to (10), which describe the administering of various antibiotics to cows and their effects, and furthermore based on all those documents which were submitted by the parties to prove the efficiency or non-efficiency of the administration of antibiotics to cows with respect to milk yield, it is a normal technical step to try glycopeptide antibiotics for the claimed purpose.

5.7 Already document (3) which, like document (14) describes the administering of monensin to cows and its effect on milk composition and yield, states that monensin treatment causes the ruminal proportion of acetic and butyric acids to decrease and propionic acid to increase. As a result feed intake was reduced by monensin, thereby increasing the efficiency of milk production. Also the teaching of this document, combined with that of document (1), would have led the skilled person to try the glycopeptide antibiotics of document (1) to increase milk production, since the ratio of propionate, acetate and butyrate is the same as in the case of administering the glycopeptide antibiotics as already discussed in detail above under paragraph 5.5.

5.8 Thus, the process of the main claim of the main request, namely orally administering the propionate-increasing amount of glycopeptide antibiotics to ruminants for the purpose of improving the milk production thereof lacks an inventive step over the combined knowledge of documents (14) or (3) and (1).

5.9 The Board makes use of its power according to Article 111(1) EPC to remit the case to the Opposition Division for further prosecution on the basis of the auxiliary request submitted by the Appellants with letter of 15 May 1990, which is in fact the subject-matter of the auxiliary requests of both parties.

#### 6. Costs (Article 104)

The Respondents had requested apportionment of costs. According to Article 104 EPC each party to the proceedings shall meet the costs he has incurred unless, for reasons of equity, a different apportionment of costs is ordered. The Board cannot agree to the Respondents arguments that the Appellants should have submitted all necessary arguments already before the first instance. It is clear from the file that the Appellants/Opponents had argued in writing before the Opposition Division which then announced in a communication of 9 May 1988 that it intended to maintain the patent and even further informed the Appellants (Opponents) that they had to expect an apportionment of costs, if they insisted on their request for oral proceedings. In this situation it was to await the final decision of the Opposition Division and to appeal against this decision. In the established case law of the European Patent Office only special circumstances, such as improper behaviour, make it equitable to award costs against one of the parties (see e.g. T 170/83, OJ



EPO 1984, 605 and T 305/86 of 22 November 1988, unpublished). These circumstances differ from those of the present case.

**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 for further prosecution on the basis of the claims as proposed by the Appellants with letter of 15 May 1990.
3. The request for apportionment of costs is rejected.

The Registrar:

The Chairman:

M. Beer

P. Lançon

28.6.90  
Whey