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D E C I S I O N
of 27 November 1996

Case Number: T 0667/92 - 3.3.4

Application Number: 82301996.3

Publication Number: 0063491

IPC: A23K 1/17

Language of the proceedings: EN

Title of invention:
Ruminant lactation improvement

Patentee:
ELI LILLY AND COMPANY

Opponent:
SmithKline Beecham Corporation et al.

Headword:
Lactation/ELI LILLY

Relevant legal provisions:
EPC Art. 123(2) & (3), 115, 56

Keyword:
"Res judicata (no)"
"Observations by third parties in appeal proceedings disregarded"
"Inventive step (yes) - no reasonable expectation of success"

Decisions cited:
T 0582/88; G 0009/91; G 0010/91; G 0004/92; G 0007/91;
G 0008/91; G 0004/88

Catchword:

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Case Number: T 0667/92 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 27 November 1996

Appellant: ELI LILLY AND COMPANY
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Respondent: SmithKline Beecham Corporation
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Philadelphia, Pennsylvania 19101 (US)

and

Pfizer Ltd
Sandwich
Kent CT13 9NJ (GB)

Representative: Wood, D.J.
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office dated 22 May 1992 rejecting the opposition filed against European patent No. 0 063 491 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairperson: U. M. Kinkeldey

Members: L. Galligani

C. Holtz

Summary of Facts and Submissions

I. The appellants (proprietors of the patent) lodged an appeal against the decision of the opposition division issued on 22 May 1992 whereby the European patent No. 063 491 was revoked pursuant to Article 102(1) EPC. The opposition division, to which the case had been remitted by the Board of Appeal with decision T 582/88 of 17 May 1990 for further prosecution on the basis of the auxiliary request, held that, since the facts in respect of the claims on file were the same as in respect of the claims as granted, the ratio decidendi of the said decision applied. In the latter decision, claim 1 as granted had been considered to lack an inventive step having regard to the following documents:

- (1) US-A-3 928 571;
- (3) I. Pankhurst et al., "Effect of monensin, cobalt and hien on milk composition and yield" in the Annual Report of the Ellinbank Dairy Research Institute, 1977;
- (14) Lemenager et al., J. Anim. Sci., 1978, Vol. 47, 247-253.

Claim 1 as granted read as follows:

"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."

Claim 1 of the auxiliary request as remitted for further prosecution by the Board read as follows:

"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."

- II. In the present appeal, the appellants requested inter alia the reconsideration by the Board of the earlier decision T 582/88 (supra).
- III. As the statement of grounds was not filed within the prescribed time limits, the appellants applied for re-establishment of rights under Article 122 EPC. With the interlocutory decision T 667/92 dated 10 March 1994, the request for re-establishment was allowed.
- IV. On 10 January 1995, third party's observations were filed under Article 115 EPC together with experiments allegedly establishing the inoperability of avoparcin in the claimed method.
- V. In a communication dated 26 May 1995, the Board pointed out that issues resolved by decision T 582/88 (supra) were res judicata which was not open to appeal. Furthermore, the Board expressed its preliminary opinion on the issues of the case.

- VI. In reply thereto, the appellants submitted on 27 October 1995 a new main and an auxiliary request (claims 1 to 6) together with affidavit evidence in rebuttal of the third party's observations.
- VII. With letter dated 6 November 1995, the respondents informed the Board that their interests were not affected by the maintaining of the claims as set out in either the main or auxiliary request on file and that they would not attend oral proceedings.
- VIII. On 29 November 1995, the Board sent a further communication with a preliminary opinion on the new requests on file. The appellants replied thereto on 5 August 1996.
- IX. Oral proceedings took place on 27 November 1996. The appellants filed claims 1 to 3 as a new and only request in substitution of all previous requests. Also amended description pages 2 to 4, 9 and 13 were filed in substitution of the corresponding pages of the patent as granted. Claim 1 of the new request reads as follows:

"The non-therapeutic treatment of dairy cows for the purpose of providing an increase in milk volume thereof without a concomitant increase in food consumption and without a concomitant decrease in milk fat content which comprises orally administering a propionate increasing amount of a glycopeptide antibiotic to said dairy cow, wherein the antibiotic is a glycopeptide antibiotic selected from the group consisting of actaplanin, avoparcin and A35512."

Dependent claims 2 and 3 relate to embodiments of the method according to claim 1 wherein, respectively, actaplanin and avoparcin are used.

X. During oral proceedings, in particular the following document - already cited in the opposition phase - was discussed:

(4) I. Pankhurst and A. McGowan, "Monensin administration to cows in early lactation" in the Annual Report of the Ellinbank Dairy Research Institute, 1978.

XI. The appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 3 and pages 2 to 4, 9 and 13 of the description as submitted in the oral proceedings on 27 November 1996, and the remainder of the description as granted.

Reasons for the Decision

1. The appeal is admissible.

Res judicata

2. As only the subject-matter of the claims as granted was decided in T 582/88 (supra) and the claims now on file differ therefrom, the request on file is not res judicata.

Observations by third parties (Article 115 EPC)

3. As regards the observations filed by a third party under Article 115 EPC, the Board notes that they were made at the appeal stage. The Enlarged Board of Appeal both in decision G 9/91 (OJ EPO 1993, 408, see in particular points 16 to 18) and in opinion G 10/91 (OJ EPO 1993, 420) concluded that in an inter partes appeal procedure, in consideration of its purpose and with reference to decisions G 7/91 and G 8/91 (OJ EPO 1993, 356 and 346, respectively), the provisions of Article 114(1) EPC had to be interpreted in a more restrictive manner than in an opposition procedure and that, accordingly, fresh grounds for opposition raised by an opponent or referred to by a third party under Article 115 EPC after expiry of the time limit laid down in Article 99(1) EPC may in principle not be introduced at the appeal stage, unless the patentee has agreed therewith. Thus, in the present case, the Board disregards the observations made by this third party under Article 115 EPC.

The respondents

4. The original opponents announced during the appeal proceedings that they had sold all their interests within the area of Animal Health to Pfizer Inc. (see letter dated 1 June 1995). However, no evidence followed to enable the Board to establish whether the opposition would be an accessory part of the assets sold, as required by decision G 4/88 (OJ EPO 1989, 480). However, as the patent proprietors are the appellants, the appeal has to be examined regardless

of the details of the sales agreement. Therefore, the Board has noted both as respondents.

5. The respondents, as stated above (see section VII), informed the Board that their interests were not affected by the granting of the claims as set out in either the main or auxiliary requests filed by the appellants on 27 October 1995 and that they did not intend to make further observations or attend oral proceedings. The opposition was not withdrawn. According to decision G 4/92 (OJ EPO 1994, 149), a decision against a party who has been duly summoned but who fails to appear at oral proceedings may not be based on facts put forward for the first time during those oral proceedings. In the Board's judgement, a decision based on the claims submitted in these proceedings is not in conflict with the quoted decision of the Enlarged Board of Appeal for the following reasons:

- The submission of a request introducing a feature which has always been part of the process specifically described, does not amount to introducing a new fact;
- Moreover, the claims have a more limited scope than those of the main request filed by the appellants on 27 October 1995 about which the respondents had indicated that they did not affect their interests.

*Admissibility of the request under Article 123(2) and (3)
EPC*

6. The new claims on file have a more limited scope than the claims as granted of which claim 1 was directed generally to a treatment of dairy cows for improving the milk production by administering a glycopeptide antibiotic. Thus, the requirements of Article 123(3) EPC are satisfied.

7. The amended claims find formal support in the application as filed (see on page 6, lines 17 to 21 the feature "an increase in milk volume produced without a concomitant increase in food consumption and without a reduction in the quality of the milk produced (i.e. milk fat content)". The amendments introduced in the new description pages constitute a mere adaptation to the more restricted claims and do not result in any additional subject-matter in comparison with the application as filed. Thus, no objection under Article 123(2) EPC is seen.

Inventive step (Article 56 EPC)

8. The most appropriate starting point for evaluating inventive step in the present case is represented by documents dealing with the problem of increasing the milk yield in dairy cows. At the priority date of the present case, a whole series of prior art documents dealt with the question of milk production in lactating ruminants consequent to the supplementation of their feed with antibiotics. The reported results were controversial and thus no definite, general conclusion could be drawn by the skilled person. Among the many citations, reference is made eg to document (3), which was concerned with the effect of

feeding monensin to dairy cows **in late lactation** and reported a decrease in the ruminal proportion of acetic and butyric acid and an increase of propionic acid. Milk yield was not increased as it would have been expected based on the increased propionic acid level. This, however, was explained as being due to some other, non-nutritional limitation to production in late lactation. Milk fat content was decreased. Further document (4), which related to a study of the effect of monensin in dairy cows **in early lactation**, reported an **increased milk yield**, but **reduced fat content**. Feed intake was not affected.

9. In the light in particular of document (4), the problem to be solved by the patent in suit is seen in the provision of an alternative method for increasing milk volume in dairy cows without a concomitant decrease in milk fat content. As shown by the examples in the patent in suit, this problem is convincingly solved by the method claimed which consists in the administration of a propionate-increasing amount of a glycopeptide antibiotic selected from the group consisting of actaplanin, avoparcin and A35512.

10. When faced with the above technical problem, the skilled person, being aware of the fact that increases in the propionate level are usually associated with increased milk yield and protein content (see eg document (3)), would have readily turned his or her attention to document (1). In fact, this document reported that the administration of a glycopeptide antibiotic such as A477, A-4696 (=

actaplanin cf. patent in suit page 2, line 65 to page 3, line 1), vancomycin and ristocetin to ruminants resulted in a beneficial alteration in the production of propionate relative to the production of acetates in the rumen. This was stated to produce a more efficient feed utilisation in the animals and in the prevention and treatment of ketosis. The document suggested in particular the administration of the said antibiotic compounds to animals in conditions of stress such as the **onset of high lactation** (see column 2, lines 27 to 28).

11. In view of the teaching of document (1), for the skilled person it would have been **obvious to try** to supplement the feed of dairy cows with a propionate-increasing amount of one of the cited antibiotics, eg A-4696 (=actaplanin). The relevant question here is whether the skilled person would have thereby reasonably expected an increase in milk volume without concomitant increase in food consumption and without a concomitant decrease in milk fat content.

12. In the Board's judgement, having regard to the general technical knowledge, the skilled person would have reasonably expected an **increase in milk volume without concomitant increase in food consumption**.
This is because:

- firstly, as already stated (see point 10 above) the skilled person was aware of the direct connection between the level of propionate and milk yield; and
- secondly, the skilled person knew that in ruminants, in particular in lactating dairy cows, a better feed utilisation was not necessarily linked to a higher consumption of feed and, thus, live weight gain (see eg documents (3) and (4)).

13. It remains thus to be decided whether the skilled person would have reasonably expected the increased milk yield consequent to the administration to dairy cows of a propionate-increasing amount of a glycopeptide antibiotic compound, to occur **without a concomitant decrease in milk fat content.**

14. It was common wisdom in this technical area that changes in the ratio of the three main volatile fatty acids (propionic, acetic and butyric acids) were associated with changes in the composition of the milk subsequently produced. In particular, as acetic and butyric acids are the main precursors of synthesized fat, changes in their levels are usually reflected in changes in the fat content of the milk (see eg document (3)). The results reported eg in documents (3) and (4) (see point 7 above) constituted for the skilled person a further confirmation of the validity of this belief. Consequently, the Board is of the opinion that the skilled person **would not** have expected the increased milk yield consequent to the

administration of a propionate-increasing amount of a glycopeptide antibiotic compound, to occur **without a concomitant decrease in milk fat content**. For this reason, the subject-matter of claims 1 to 3 involves an inventive step and the request is allowable.

Order

for these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of claims 1 to 3 and pages 2 to 4, 9 and 13 of the description as submitted in the oral proceedings on 27 November 1996, and the remainder of the description as granted.

The Registrar:

The Chairperson:

L. McGarry

U. M. Kinkeldey