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Chambres de recours



Case Number : T 48/85



Correction Order of 3 April 1987
to the D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 18 November 1986

Appellant : National Research Development Corporation
P.O. Box 236, Kingsgate House
66-74 Victoria Street
London SW1E 6SL

Representative : Percy, Richard Keith
National Research Development Corporation
Patent Department
P.O. Box 236, Kingsgate House
66-74 Victoria Street
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Composition of the Board:

Chairman : P. Lançon
Member : G. Szabo
Member : F. Benussi

In accordance with Rule 89 EPC, the Decision is amended as follows:

Page 6, line 5, delete "opposition".

The Registrar:



F. Klein

The Chairman:



P. Lançon

Veröffentlichung im Amtsblatt	Ja/Nein
Publication in the Official Journal	Yes/No
Publication au Journal Officiel	Oui/Non



Aktenzeichen / Case Number / N^o du recours : T 48/85
Anmeldenummer / Filing No / N^o de la demande : 81 304 084.7
Veröffentlichungs-Nr. / Publication No / N^o de la publication : 47 662

Bezeichnung der Erfindung: Coccidiosis vaccines
Title of invention:
Titre de l'invention :

Klassifikation / Classification / Classement : C 12 N 1/36

ENTSCHEIDUNG / DECISION

vom / of / du

18 November 1986

Anmelder / Applicant / Demandeur : National Research Development Corporation

Patentinhaber / Proprietor of the patent /
Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence :

EPO / EPC / CBE Articles 83, 111(1) and Rule 67 EPC

Kennwort / Keyword / Mot clé : "Sufficiency of disclosure"
"Prejudice against reproducibility of cited art"

Leitsatz / Headnote / Sommaire

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Decision under appeal : Decision of Examining Division of the
European Patent Office dated 18.09.84
refusing European patent application
No. 81 304 084.7 pursuant to
Article 97(1) EPC

Composition of the Board :

Chairman : P. Lançon
Member : G. Szabo
Member : F. Benussi

Summary of Facts and Submissions

I. European patent application 81 304 084.7 filed on 7 September 1981 and published on 17 March 1982 with publication number 47 662, claiming priority of the prior application on 5 September 1980 (GB-8 028 676) was refused by the decision of the Examining Division of the European Patent Office dated 18 September 1984. The decision was based on Claims 1 to 13. The main claim was worded as follows:

1. A process for the production of an attenuated strain of *Eimeria necatrix* which comprises passaging pathogenic *Eimeria necatrix* in embryonated eggs, in each passage embryonated eggs being inoculated with sporozoites of *Eimeria necatrix* and oocysts being subsequently recovered from the eggs, for a total of from 20 to 60 egg passages.

II. The ground for the refusal was that the disclosure was insufficient under Article 83. The decision explained that the article of Shibalova, T.A., *Acta Protozoologica*, 1972, 9, 299-303(1), for the cultivation of *E. necatrix* organisms in chicken embryos, had been cited but the Applicant referred to Long, who had failed to reproduce the results of Shibalova (*Proceedings of the Symposium on Coccidia and Related Organisms*, Guelph, Ontario, p. 57-82, at p. 63 (3)). Since the Applicant used no other methodology than that attributed to Long, the claimed process must also be suffering from the same deficiency. Unless the Applicant disclosed how he could be successful in such circumstances the main claim was incomplete and unallowable.

III. The Applicant filed an appeal against the decision on 3 November 1984 with the payment of the fee and submitted a Statement of Grounds on 14 January 1985. A Communication from the Board expressed doubts about the alleged irreproducibility of Shibalova's results and pointed out that if this emerged as an enabling disclosure, this could also raise again the question of obviousness. The Appellant thereafter submitted further arguments and evidence. An oral hearing took place on 18 November 1986.

IV. During these proceedings the Appellant submitted substantially the following arguments:

- a) It was long known that some species of *Eimeria* could be attenuated but *E. necatrix* had been an unsolved problem in this respect. Dr. Long, a leading expert in the field, had reported in 1966 (*Parasitology*, 56, 569 at p. 572 (4)), and 1973 (3) that he had failed to get beyond the asexual stage of development. The second paper of Long referred only to Shibalova's preliminary report alleging success in this respect (*Parasitology*, 1970, 56, 315 (2)). In view of this, nobody believed that proper cultivation of this particular organism was possible.
- b) The second, more detailed Shibalova paper (1) was so poorly drafted that the skilled practitioner would have seriously doubted the authenticity of her statements. There was no real evidence as to the correctness of the results. Since *E. tenella* and *E. necatrix* were morphologically indistinguishable at the development stages, the oocysts could have been those of the former. That the author wrongly interpreted microscopic

pictures could be seen from erroneous statements about other organisms in the article. Furthermore, what should have been identified as 2nd generation schizonts were stated to be 1st generation schizonts.

- c) As to why Dr. Long had not obtained satisfactory results with *E. necatrix* before and after the Shibalova disclosures, one could only speculate. Perhaps his strain had changed in some way during the course of 4-5 years to make it less infective to embryonated eggs (cf. Doran's affidavit, page 4). Alternatively he might have simply missed the oocysts which only appeared in a low yield. (cf. Shirley's Declaration dated 1 October 1982). Whilst it was at the oral hearing admitted that the Shibalova method was repeatable, her disclosure rather acted as a deterrent to do this.
- d) The inventor acted against the prejudice created by the background situation and succeeded in overcoming the same. The objection as to insufficiency of disclosure could only be raised against the application on the basis of some irreproducibility of the Examples. There was no evidence to that effect. On the contrary, the claimed process was repeated even with different strains and other workers also succeeded in attenuating the strain substantially following the method of the application (cf. Shirley affidavit dated 7 January 1985 and in particular Gore, T.C., Long, P.L. et.al., *Avian Diseases*, 1983, 27, 569-576, (5)). There could be no doubt about the reproducibility of the claimed process.
- e) The Examining Division, however, ignored the Gore paper, representing independent evidence as to the question at issue, by referring to the fact that this was published after the priority date of the

application. In doing so the Division committed a substantial procedural violation, since the argument about the dates was completely irrelevant and the evidence was decisively in favour of the Applicant showing the reproducibility of his process.

- V. The Appellant requests that the decision under appeal be set aside and that the patent be granted on the basis of the claims which were under consideration by the decision under appeal. As an auxiliary request he requested that the patent be granted on the basis of amended Claim 1 submitted during the oral proceedings to be followed by Claim 2 and by Claims 5 to 13 renumbered 3 to 11. Additionally, the Appellant requests the reimbursement of the appeal fee.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is, therefore, admissible.
2. The matter under appeal concerns the sufficiency of the disclosure under Article 83 EPC. As far as the refusal by the Examining Division referred to Claims 1 to 13 in this respect, this is interpreted as expressing the view that the claims cover embodiments which are irreproducible and that this may be due to the fact that certain features essential for success are not specified in the claims.
3. Whilst it is necessary that claims should contain all the essential features of the invention and define the subject-matter for which protection is sought, it need not state **expressis verbis** those features and conditions which

are known to the skilled person as necessary for such subject-matter to be carried out in practice. The Board follows the decision in case of "Vinylchloride resins/SUMITOMO, T 14/83, OJ 7/1984, 105).

It can be noted that use claims for instance often omit a number of essential features since the skilled person would know exactly what other components, reagents or conditions to apply in order to obtain the specified result.

4. The sufficiency of the disclosure in the present case was doubted only on account of the Applicant's own statements about the irreproducibility of the Shibalova (2) disclosure on the basis of Long's unsuccessful work. It seemed that the absence of detailed instructions in the Shibalova reference as well as Long's failure, could be an indication of a situation whereby the broad claim may cover embodiments which could not be performed with success in the absence of some essential feature which Shibalova, Long and the claim in question failed to specify.
5. In view of the above quoted decision of the Board, such deficiency would only arise if the skilled person could not recognize the necessary conditions and steps, as a matter of general knowledge, which might be needed to bring about the desired result. There was no suggestion so far that the examples in the specification would not be reproducible themselves because someone trying to repeat them had been unsuccessful without any hope of rectifying the position. To the contrary, the successful repetition of the simple methodology of the application by other workers in the field demonstrates that the disclosure was not insufficient from this point of view (cf. in particular the Gore-Long reference in 1983 (4)).

As to whether the claims were properly supported and embraced all expressed or implied essential features, irrespective of sufficiency of description, this is a matter under Article 84 EPC which cannot be an issue in the present opposition proceedings.

6. The argument that the controversy in the state of the art about the reproducibility of the Shibalova disclosure casts doubts on the sufficiency of the application under appeal, cannot be followed. It was finally conceded by the Appellant that (2) was an enabling disclosure if one is not distracted from repeating it in view of other unsatisfactory features in the publication. Indeed, no example in a publication or in a patent becomes unrepeatable for the reason only that the product was not specifically tested for its identity, provided the alleged product can indeed be obtained on the basis of instructions.

7. The possible errors in the paper or wrong interpretations of observations need not affect the question of reproducibility but could, of course, be relevant to the evaluation of the paper from other points of view. Whether or not the strains were pure or mixed has no bearing on the question either (Long's admitted mistake might have been caused by using an unsuitable weakened *E. necatrix* strain according to the Doran affidavit, cf. answer to Questions 2 and 3), as long as the correct result is necessarily obtained with the correct starting strain and under proper conditions later on. The actual outcome of even foolish-looking instructions are in the public domain and cannot be removed from the state of the art, and the same applies to other publications irrespective of their geographical location or the alleged reputation of the periodical.

8. It is relevant in this respect that a Board stated in another case (cf. "Herbicides/ICI" T 206/83, pages 6 and 7, 26 March 1986 to be reported) the "need for enabling disclosure not only applies to documents cited under Article 54(2) and (3) EPC but is also in conformity with the principle expressed in Article 83 EPC for patent applications ...". In addition to such identity of standard for sufficiency of disclosure, the same Board also suggested that "an error in the description is immaterial to insufficiency of disclosure if the skilled person could recognize and rectify it using his common general knowledge ..." (cf. "Redox catalyst/AIR PRODUCTS, T 171/84, OJ 4/1986, 95). None of the deficiencies in the Shibalova papers could be seen as disabling the skilled person or rendering the instructions irreproducible, let alone to cast any doubt on the disclosure in the present application.
9. The Appellant also suggested that the Examining Division made a substantial procedural error by disregarding the above-mentioned paper (4) for the stated reasons. The Board recognizes the error in the reasoning of the decision since there is no doubt that the date of publication is irrelevant when it comes to the confirmation of the reproducibility of the disclosure of the application. Otherwise the Office could never ask for evidence in order to resolve problems of sufficiency in case of objection. The consequences of such error were serious since they resulted in the complete disregard of the evidence in circumstances when its contents could have led to reverse the attitude of the Division. After all this was not only the only independent confirmation of the repeatability of the attenuation method but included, as a co-author, Dr. Long from whom the earlier controversy originated. Refusing to consider such evidence in the

first place is a substantial violation of procedural rules under Rule 67 EPC (in agreement with the Guidelines for Examination in the EPO, E. XI-8) which justifies the reimbursement of the appeal fee.

10. The Board has indicated to the Appellant at the oral hearing that it would not wish to consider the question of inventive step since that matter had not been fully examined by the first instance in view of the emergence of the insufficiency issue. Indeed, it has now been established that the most relevant state of the art to be considered is the Shibalova reference (1). Although the Appellant's representative was willing to accept a decision on the issue of the inventive step in any case, it was the considered view of the Board that it should prefer not to allow a loss of instance in case of doubt, and consequently not to consider or even listen to any further argument on submission on the subject lest the position of the Appellant be prejudiced before the Examining Division in the future proceedings. Whilst it is possible that the Appellant would have preferred certainty, even if this is unfavourable, to further delay, but the possibility of continuation in writing was in any case very likely in the circumstances. Notwithstanding, such preference on the part of the Appellant, it is more important and in the interest of the public that the full investigation of a new situation, which could have only arisen after the insufficiency issue is cleared with all its consequences, go through all proper stages, utilizing the special technical expertise of the Examining Division (Article 111(1) EPC).

Order

For these reasons,

it is decided that:

1. The decision of the Examining Division of 18 September 1984 is set aside.
2. The case is remitted to the Examining Division for further prosecution.
3. The appeal fee is reimbursed.

The Registrar

Rückerl

The Chairman

Lançon