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

*0000879*

Aktenzeichen / Case Number / N° du recours : T 19/86

Anmeldenummer / Filing No / N° de la demande : 82 200 705.0

Veröffentlichungs-Nr. / Publication No / N° de la publication : 0 069 407

Bezeichnung der Erfindung:
Title of invention:
Titre de l'invention : Method of immunizing pigs against Aujeszky's disease

Klassifikation / Classification / Classement : A 61 K 39/245

## ENTSCHEIDUNG / DECISION

vom / of / du 15 October 1987

Anmelder / Applicant / Demandeur : DUPHAR INTERNATIONAL RESEARCH B.V.

Patentinhaber / Proprietor of the patent /
Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence : Pigs II/Duphar

EPÜ / EPC / CBE Article 52(1) and (4)

Kennwort / Keyword / Mot clé : Known therapeutic treatment - application to new class of animals - further medical use

### Leitsatz / Headnote / Sommaire

I. Both prophylactic and curative treatments of disease are within the meaning of the word "therapy" as used in Article 52(4) EPC.

II. The therapeutic application of a vaccine, which is known for treatment of a particular class of animal (here sero-negative pigs), to a new and different class of the same animal (here sero-positive pigs), is a second medical use within the principle set out in Decision Gr 05/83, and is therefore patentable if such new use is inventive.

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Case Number : T 19/86

# D E C I S I O N
## of the Technical Board of Appeal 3.3.1
## of 15 October 1987

Appellant : DUPHAR INTERNATIONAL RESEARCH B.V.
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Decision under appeal : Decision of Examining Division 001 of the European Patent Office dated 21.08.1985 refusing European patent application No. 82 200 705.0 pursuant to Article 97(1) EPC

Composition of the Board :

Chairman : K. Jahn
Members : J. Arbouw
G. D. Paterson

Summary of Facts and Submissions

I. European patent application No. 82 200 705.0, filed on 9 June 1982 claiming a Dutch priority of 10 June 1981, and published on 12 January 1983 under publication No. 0 069 407, was refused by a decision of the Examining Division 001 dated 21 August 1985. The decision was based on Claims 1 to 5 filed on 11 March 1985 which read:

(1) Use of live attenuated Aujeszky-virus for the manufacture of a vaccine for intranasally protecting maternally immune pigs against Aujeszky's disease.

(2) Use according to Claim 1, characterised in that the virus of the Bartha-strain is brought into form suitable for intranasal administration.

(3) Use according to Claim 2, characterised in that virus cultivated in secondary porcine kidney cells or in a porcine kidney continuous cell line is brought into a form suitable for intranasal administration.

(4) Use according to Claim 3, characterised in that an amount of $10^4$ - $10^7$ $TCID_{50}$ of virus is brought into a form suitable for intranasal administration.

(5) Use according to Claim 4, characterised in that an amount of $10^6$ $TCID_{50}$ is brought into a form suitable for intranasal administration.

II. The reasons for the above decision were essentially as follows:

(i) The live attenuated Aujeszky-virus used for the manufacture of a vaccine for intranasal administration to maternally-immune (i.e. sero -

positive) piglets according to the invention does not differ from the live attenuated Aujeszky-virus used in the prior art to protect by intranasal administration sero-negative piglets.

(ii) The aim of a vaccine (therapeutic application) is to elicit a state of immunisation thus conferring protection against a certain disease (Aujeszky's disease in the present case). This aim is reached in the same way by both the vaccines according to the prior art and to those of the present invention. The therapeutic application is therefore not regarded as novel.

(iii) Whether the application of a known medicament for the treatment of the same disease in an immunologically different population of animals of the same species is to be regarded as a novel and inventive therapeutic application, was not stated by the Enlarged Board of Appeal in the above-mentioned Decision.

Thus Claims 1 and 2 were regarded as not novel, and Claims 3, 4 and 5 were not regarded as involving any feature which could provide patentability.

III. On 18 October 1985 the Appellant filed a notice of appeal against the above decision, paying the prescribed fee at the same time. A statement of grounds of appeal was filed on 21 December 1985, in which the Appellant submitted that it had surprisingly been found that vaccination by intranasal administration to young sero-positive piglets, i.e. when they are still maternally immune, results in good protection against Aujeszky's disease. This finding was contrary to what could be expected from experience with

injection vaccines, and is new and inventive. The question was how to protect this invention by acceptable claims.

The Appellant requested the grant of a patent on the basis of Claims 1-5 filed on 11 March 1985, in view of the Decision of the Enlarged Board of Appeal Gr 05/83, which the Appellant submitted was not restricted in a way which prevented the patentability of the claimed invention.

Alternatively, as a first auxiliary request, he requested the reconsideration of Claims 1 to 6 as originally filed, which were directed to a method of immunizing pigs; and, as a second auxiliary request he filed two claims directed to a kit containing a vaccine for protecting pigs against Aujeszky's disease, and instructions indicating that young sero-positive animals can be vaccinated by intranasal administration.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 54 EPC and is therefore admissible.

2. There is no formal objection to the version of Claims 1 to 5 of the main request, since they correspond to the originally filed method claims, reworded in the light of the Second Medical Indication decision Gr 05/83.

3. The background to the subject-matter of this application is set out in pages 1 and 2 of the application and is as follows:

An article by J.B. McFerran and C. Dow in "Research in Veterinary Science" (1975), 19, pages 17 to 22, (document (1)) states that sero negative piglets, i.e. piglets without maternal antibodies (see particularly

page 17, right-hand column, first paragraph), can be protected against subsequent challenge with virulent virus both by means of intramuscular injection and by intranasal administration of an Aujeszky virus (Bartha strain or K-strain) grown in Vero cells. The authors, however, came to the conclusion that intranasal innoculation with the K-strain proved to be a disappointment. Since Aujeszky virus first of all multiplies in the upper part of the respiratory tract, it was expected that the local immunity after intranasal administration would be stimulated and in this manner colonisation of the upper respiratory tract by pathogenic strains would be prevented. Although a slight decrease in the degree of clinical symptoms following challenge with virulent virus could be observed after intranasal administration, these minimum advantages did not outweigh the disadvantages associated with an intranasal administration.

Good results are also shown by Howarth (Proceedings of the 74th Annual Meeting of the United States Animal Health Association (1972) pages 371 to 384) after intranasal administration of Aujeszky-virus of the BUK strain passaged in porcine kidney cell line. These experiments were also carried out with sero-negative animals (see page 371, chapter "Materials and Methods").

The disadvantage of such injection vaccines, which give good results in sero-negative animals, is that they are not active in sero-positive piglets as long as they are maternally immune: this was demonstrated by the Appellant in the experiment III at page 6 of the description of the present application (the vaccine is neutralized by the maternal antibodies). This problem particularly occurs in areas where one strives after a high titer of maternal antibodies in young animals through a good vaccination scheme of the breeding sows.

4. The technical problem underlying the present invention is therefore to provide a method of immunization applicable to sero-positive piglets. In order to solve this problem, the Appellant proposes the vaccination of such piglets against Aujeszky's disease as early as possible, i.e. at an age at which they usually are still maternally immune, by vaccinating them intranasally with a living attenuated Aujeszky virus vaccine.

5. Claims 1 to 5 of the main request are in line with the formulation adopted by the Enlarged Board of Appeal in its Decision GR 05/83 (OJ EPO, 3/1985, page 64) and the six related Decisions. The Enlarged Board of Appeal held that claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application are allowable, even in cases in which the medicament is not in any way different from a known medicament.

In each of the cases with which the Enlarged Board were concerned, the specified new therapeutic application of the medicament was the treatment of a different ailment from that previously disclosed. As the Board recognised, the claims in such cases did not conflict with Articles 52(4) and 57 EPC, but having regard to the provision in the last sentence of Article 54(5) EPC ("... provided that its use for any method" within Article 52(4) EPC "is not comprised in the state of the art"), such claims could be considered as lacking novelty.

However, in spite of the fact that a prior therapeutic use of the medicament was comprised in the state of the art, the Enlarged Board held that it was justifiable to derive the novelty for the manufacture of the medicament from the

new therapeutic use of the medicament; on this basis, claims with the particular formulation were patentable.

The Enlarged Board emphasized that "the application of this special approach to the derivation of novelty can only be applied to claims to the use of substances or compositions included for use in a method referred to in Article 52(4) EPC.

6. In the present case, there is no suggestion that the known medicament - the vaccine - can be used for the treatment of a different ailment from what has previously been disclosed. It is the same disease that is treated, namely Aujeszky's disease. Thus, in the present case there has been no new therapeutic application of the vaccine of the kind that was before the Enlarged Board - namely an application to a different ailment. What has been taught is that the known vaccine is effective on a new class of pigs - sero-positive pigs - that are maternally immune. The question is whether the application of the vaccine to this new class of pigs can be considered a new therapeutic application from which novelty for the claims can be derived in accordance with the principles of the Enlarged Board's Decision.

7. As mentioned at the end of paragraph 5 above, the special approach to the derivation of novelty can only be applied in connection with claims where the application is within Article 52(4) EPC. The treatment of the pigs in the present case is prophylactic rather than curative. In the Board's view both prophylactic and curative treatments of disease should be regarded as falling within the meaning of the word "therapy" in the sense that that word is used in Article 52(4) EPC since both are directed to the same objective, i.e. the maintenance or restoration of health.

Such a construction of Article 52(4) EPC is in accordance with the principles which underlie Article 52(4) EPC - as to which see Decision T 116/85 dated 14 October 1987. Such a construction is also in accordance with a judgment of the UK Patents Court in Unilever Limited (Davis') Application, 1983 RPC 219, where the proper construction in this respect of the wording of Section 4(2) of the Patents Act 1977, which is based upon and intended to have the same effect as Article 52(4) EPC, was exhaustively discussed. Such an interpretation is also in accordance with the comment by Bruchhausen paragraph 5, note 11 in Benkard's Patentgesetz und Gebrauchssmustergesetz, 7. Auflage, München 1981. A similar view is taken in the "Guidelines for Examination in the EPO", CIV, 4.3.

8. The concept of patentability of the use of a substance or composition for the manufacture of a medicament for a new and inventive therapeutic application in accordance with the decision of the Enlarged Board of Appeal (Gr 05/83) even for a substance or composition, the use of which in therapy is known, should be broadly construed.

Such a new use is not only valuable in cases where a novel area of therapeutic use, i.e. a novel medical indication, is provided but also in those cases where a novel class of animals, which previously did not respond to a medicament, is cured or protected against a disease.

The question whether a new therapeutic use is in accordance with the decision GR 05/83 should not be answered exclusively on the basis of the ailment to be cured but also on the basis of the subject (in the present case the new group of pigs) to be treated. A medical indication is incomplete if the subject to be treated is not identified; only a disclosure from which both the disease and the

subject to be treated are clear represent a complete technical teaching.

As already pointed out above, the Applicant has shown that sero-positive piglets could hitherto not be protected against Aujeszky disease. The proposal according to the application to protect such piglets against this disease by intranasally administering a known serum to this particular group of animals was not disclosed in the prior art and, therefore, constitutes a novel therapeutic application in accordance with the above-mentioned decision.

9. It is not in dispute that the particular application of the vaccine for intranasally protecting maternally immune pigs is novel. In relation to the question of inventiveness of this particular application, document (1) can be considered as the closest prior art. This document discloses that the intranasal administration of this vaccine to sero-negative piglets is disappointing, although the degree of clinical illness following challenge is lower than with intramuscular vaccination. The authors state that this minimal advantage must be weighed against potential excretion of vaccine virus from the intranasally vaccinated group, and also the increased difficulty of administration by the intranasal route. Particularly, in the Board's view, the presence of the first drawback would not have suggested to the skilled man to use intranasal vaccination with sero-positive piglets, because of the risk of contamination just after the vaccination within a population with different maternal antibodies titers. It appears also that with intranasal vaccination of sero-positive piglets, a very gradual build-up of immunity takes place, which brings an optimal protection against the disease (compare Tables A and B on page 4 of the present application), and that the intranasal vaccination of sero-positive piglets is more

complete, (compare Table C, where an animal remained sero-negative even after vaccination, with Table D on page 4 of the present application).

10. Following paragraph 21 of the Enlarged Board's Decision, the Board recognises that Article 52(1) EPC expresses a general principle of patentability for inventions which are industrially applicable, new and inventive, and that in accordance with that principle, in all fields of industrial activity other than those of making products for use in surgery, therapy and diagnostic methods (as to which Article 52(4) EPC applies), a new use for a known product can be fully protected by claims directed to that use - provided that such use is new and inventive.

In the Board's view as set out in paragraph 9 above the intranasal administration of the vaccine to sero-positive pigs provides a surprisingly effective solution to the problem set out in paragraph 4 above, and should be considered as involving an inventive step.

11. In the present case, as discussed above, the Board considers that the claimed use of vaccine of live attenuated Aujeszky-virus is new and inventive. Accordingly, Claim 1 of the main request, together with the dependent Claims 2 to 5 are patentable.

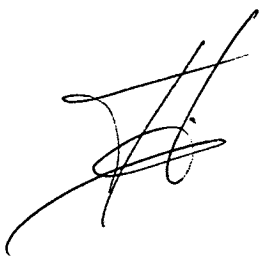
**Order**

**For these reasons, it is decided that:**

1. The impugned Decision of the Examining Division is set aside.

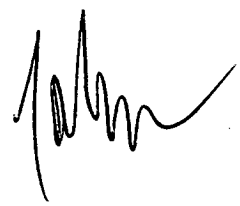
2. The case is remitted to the Examining Division with the order to grant a patent on the basis of Claims 1 to 5 filed on 11 March 1985, with a description to be adapted accordingly.

The Registrar



F.Klein

The Chairman



K.Jahn