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D E C I S I O N
of 16 June 2004

Case Number: T 1147/01 - 3.3.4

Application Number: 92920950.0

Publication Number: 0610250

IPC: A61K 39/12

Language of the proceedings: EN

Title of invention:
Porcine reproductive respiratory syndrome (PRRS) vaccine and diagnostic

Patentee:
Akzo Nobel N.V.

Opponents:
Boehringer Ingelheim GmbH
Cyanamid Iberica
Stichting Dienst Landbouwkundig Onderzoek (SDLO)

Headword:
PRRS Vaccine/AKZO NOBEL N.V.

Relevant legal provisions:
EPC Art. 107, 123(2), 83, 56
EPC R. 28

Keyword:
"Main request to 4th Auxiliary request - Inventive step (no)"
"5th Auxiliary Request: added subject-matter (no), sufficiency of disclosure (yes) - Inventive step (yes)"

Decisions cited:
T 0073/88, T 0224/96, T 0084/02, T 0118/87

Catchword:
-

Case Number: T 1147/01 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 16 June 2004

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 31 August 2001 revoking European patent No. 0610250 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairwoman: U. M. Kinkeldey
Members: R. E. Gramaglia
R. Moufang

Summary of Facts and Submissions

I. European Patent No. 0 610 250 (application No. 92 920 950.0) was filed on 9 October 1992. The patent relates to porcine reproductive respiratory syndrome (PRRS) vaccine and diagnostic and was granted on the basis of 14 claims for the Contracting States AT, BE, CH, DE, DK, FR, GB, IT, LI, LU, NL and SE and 13 claims for the Contracting States ES and GR.

II. Notices of opposition were filed by opponents 01, 02 and 03 all requesting the revocation of the European patent on the grounds of Article 100(a), (b) and (c) EPC. The opposition division concluded that the subject matter of the claims of the main request and of auxiliary requests I to III then on file lacked an inventive step over document

(D5) Wensvoort G. et al., Terpstra C. et al., Pol J.M.A. et al., The Veterinary Quartely, Vol. 13, No. 3, pages 121-143 (July 1991)

and revoked the patent.

III. Appellant I (patentee) and appellant II (opponent 03) filed appeals against the decision of the opposition division. With telefax of 8 June 2004 appellant I submitted a main request and auxiliary requests I to IV.

Claims 1, 4, 8 and 9 of the **Main Request** for the non-ES/GR Contracting States read as follows:

"1. A vaccine for the protection of pigs against Porcine Reproductive Respiratory Syndrome (PRRS)

comprising viral antigen derived from a PRRS virus deposited at the CNCM under accession no. I-1140 or a PRRS virus isolate immunologically related thereto, wherein the viral antigen is inactivated PRRS virus and the vaccine comprises:
a. an adjuvant selected from the group consisting of vitamin-E acetate o/w-emulsion, aluminium phosphate, -oxide, an oil-emulsion provided that the oil-emulsion is not Freund's adjuvant, and saponins, or
b. the PRRS virus deposited at the CNCM under accession no. I-1140.

4. A PRRS virus deposited at the CNCM under accession no. I-1140 or a PRRS virus isolate immunologically related thereto, which virus can be propagated in cell culture to a titre of at least $10^{6.0}$ $TCID_{50}$/ml provided that the PRRS virus is not the virus as deposited at the ATCC under no. VR-2332.

8. A method for the preparation of a viral antigen derived from a PRRS virus deposited at the CNCM under accession no. I-1140 or a PRRS virus isolate immunologically related thereto, comprising the steps of:
a. inoculating susceptible tissue cells with the virus,
b. cultivating the cells, and
c. harvesting the viral antigen from the culture, wherein the pre-harvest titer is at least $10^{6.0}$ $TCID_{50}$/ml.

9. A method for the detection of antibodies to PRRS virus comprising the steps of:

a. incubating a test sample suspected of containing anti-PRRS virus antibodies with PRRS viral antigen reagent derived from a PRRS virus deposited at the CNCM under accession no. I-1140 or a PRRS virus isolate immunologically related thereto, under conditions which allow the formation of an antibody-antigen complex, and
b. detecting the antibody-antigen complex involving the use of a labelled antibody, the label being selected from the group consisting of fluorescent labels, chemoluminescent labels, radioactive labels, dye molecule labels and enzyme labels provided that the enzyme label is not used in an immunoperoxidase monolayer assay (IPMA)."

Claims 1 and 2 of **Auxiliary Request I** for the non-ES/GR Contracting States were identical to claims 4 and 5 of the main request.

The claims of **Auxiliary Request II** for the non-ES/GR Contracting States were identical, but for the deletion of claims 4 and 5, to those of the main request.

Claim 1 of the **Auxiliary Request III** for all the designated Contracting States was identical to claim 9 of the main request.

Claim 1 of the **Auxiliary Request IV** for all the designated Contracting States read as follows:

"1. A method for the detection of antibodies to PRRS virus comprising the steps of:

a: incubating a test sample suspected of containing anti-PRRS virus antibodies with PRRS viral antigen reagent derived from a PRRS virus deposited at the CNCM under accession number I-1140 or a PRRS virus isolate immunologically related thereto, said viral antigen reagent being a viral polypeptide selected from the group of viral polypeptides having a molecular weight of 14 kD, 21 kD, 46 kD, 49 kD and 55 kD as determined by SDS-PAGE, under conditions which allow the formation of an antibody-antigen complex, and
b: detecting the antibody antigen complex involving the use of a labelled antibody, the label being selected from the group consisting of fluorescent labels, chemoluminescent labels, radioactive labels, dye molecule labels and enzyme labels provided that the enzyme label is not used in an immunoperoxidase monolayer assay (IPMA)."

IV. Oral proceedings were held on 15 and 16 June 2004, during which appellant I filed **Auxiliary Request V**, the sole claim of which for all the designated Contracting States read as follows:

"1. A method for the detection of antibodies to PRRS virus, which method is an enzyme-linked immune sorbent assay (ELISA) or a Western blot immunoassay, comprising the steps of
a: incubating a test sample suspected of containing anti PRRS virus antibodies with PRRS viral antigen reagent derived from a PRRS virus deposited at the CNCM under accession number I-1140 or a PRRS virus isolate immunologically related thereto, said viral antigen reagent being a viral polypeptide selected from the

group of viral polypeptides having a molecular weight of 14 kD or 21 kD as determined by SDS-PAGE, under conditions which allow the formation of an antibody-antigen complex, and
b: detecting the antibody-antigen complex involving the use of a labelled antibody, the label being selected from the group consisting of fluorescent labels, chemoluminescent labels, radioactive labels, dye molecule labels and enzyme labels."

V. The following further documents are cited in the present decision:

(D1) WO-A-93/03760;

(D2) EP-A-0529584;

(D3) WO-A-92/21375;

(D4) Collins J.E. et al., Proceedings of the Minnesota Conference for Veterinarians, pages 200-205 (15 to 17 September 1991);

(D16) Ohlinger V.F. et al., Tierärztl. Umschau, Vol. 46, pages 703-708 (1991);

(D19) Lennette E.H. et al. Editors, Laboratory Diagnosis of Infectious Diseases, Springer-Verlag, Vol. II, pages 76-101 (1988);

(D21) Diagnostic Methods in Clinical Virology, Second Edition, Grist N.R. et al. Editors, Blackwell Scientific Publications, Oxford (1974);

(D22) General Virology, Luria S.E. et al Editors, Third Edition, John Wiley & Sons, New York, pages 1-20 (1978);

(D23) Declaration of Dr. G. Wenswoort dated 1 September 1996 (submitted by appellant I);

(D32) Declarations of P.A.M. van Woensel dated 20 October 1997 (submitted by appellant I);

(D39) GB-A-2,282,811;

(D40) Ahl R. in "The new pig disease", Chapter 7 (pages 32-35) of the Report on the Seminar/Workshop held in Brussels on 29-30 April 1991;

(D41) Terpstra C. et al. in "The new pig disease", Chapter 8 (pages 36-45) of the Report on the Seminar/Workshop held in Brussels on 29-30 April 1991;

(D42) EP-A-0541418;

(D43) Test Report by A.U. Hostench (submitted by opponent 02).

VI. The submissions by appellant I (patentee), insofar as they are relevant to the present decision, can be summarized as follows:

Admissibility of the appeal by opponent 03

- The appeal by opponent 03 was inadmissible as the opponent was not adversely affected by the decision of the opposition division revoking the patent in suit. Opponent 03 could take part in the proceedings as a party as of right, not as an appellant.

Main request (claim 4), Auxiliary Request I (claim 1) and Auxiliary Request II (claim 6, after renumbering) Inventive step (Article 56 EPC)

- The preliminary and incomplete disclosure by document (D5) of the Lelystad Virus (LV), another name for the claimed PRRS virus, represented the closest prior art. This document did not provide sufficient information for the skilled person to arrive at the PRRS virus of claim 4 in an obvious manner.

- In particular, the method described in document (D5) for isolation of the "right" virus used a tool (ie the LV postinfection monospecific sera c-829 and b-822) which was not available to the public. The isolated virus itself had also not been made available to the public.

- Documents (D40) and (D41) demonstrated that other teams applying very similar methods of isolating viruses as described in document (D5), did not obtain the virus as described in document (D5) in a predictable manner. Document (D42) was a further example of a failed attempt to isolate the

causative agent of Mystery Swine Disease (MSD) ending with the isolation of a myxo-like virus not related to LV.

- The claimed PRRS virus had the advantageous and unexpected property (cf the feature "which virus can be propagated in cell culture to a titre of at least $10^{6.0}$ $TCID_{50}$/ml") that it could grow to 10-100 times higher titres than the prior art PRRS viruses which grew poorly in cell cultures and reached maximum titres of about $10^{5.3}$ $TCID_{50}$/ml.

Auxiliary Request III (claim 1)
Inventive step (Article 56 EPC)

- Document (D5) provided no information with regard to any part of the virus, e.g. nucleic acid, polysaccharide, protein etc, or to which family or genus this virus belonged. No indication was given that antigens derived from a PRRS virus could be used as the reagent in a reliable immunoassay to detect the presence of PRRS antibodies in a sample.

Auxiliary Request IV (claim 1)
Inventive step (Article 56 EPC)

- Document (D5) merely disclosed the isolation of LV but left the skilled person totally in the dark as to the question of which antigen(s) could be used as the reagent in a reliable immunoassay to detect the presence of LV/PRRS antibodies in a sample. The useful viral polypeptides having a mw of 14 kD, 21 kD, 46 kD, 49 kD and 55 kD mentioned in claim 1 that display an appropriate affinity to the PRRSV

serum are provided in this patent for the first time. The prior art did not suggest their existence nor their usefulness as a diagnostic reagent in an immunoassay.

Auxiliary Request V
Article 123(2) EPC

- The claimed immunoassays involving the specific combination of the viral polypeptides 14 kD and 21 kD and fluorescent, chemoluminescent, radioactive, enzyme and dye molecule labels had a basis on page 14, last paragraph taken in combination with page 12, end of the first paragraph of the application as filed.

Article 83 *EPC*

- The discordant molecular weights (mw's) reported in document (D3) (see page 26, line 27) for the LV/PRRS viral polypeptides (15 kD, 16 kD, 19 kD, 26 kD, 35 kD, 39 kD and 65 kD) had not been obtained by SDS-PAGE.

Inventive step (Article 56 EPC)

- Example 4 and Figure 1 (new copy enclosed to the Grounds of Appeal) of the patent in suit showed the unexpectedly high antigenicity of the 14 kD and 21 kD PRRSV polypeptides that made them especially suited as antigens in a diagnostic assay endowed with very high sensitivity.

VII. The submissions by appellant II (opponent 03) and the respondent (opponent 02), insofar as they are relevant to the present decision, can be summarized as follows:

Admissibility of the appeal by opponent 03

- Although the patent in suit had been revoked, opponent 03 was still adversely affected in that a number of grounds of opposition (eg novelty of claim 4) had been decided in favour of the patentee.

Main request (claim 4), Auxiliary Request I (claim 1) and Auxiliary Request II (claim 6, after renumbering) Inventive step (Article 56 EPC)

- The problem solved by the patent in suit was the provision of a further PRRSV isolate using the method disclosed in document (D5).

- The skilled person would have had no problem to repeat the method described in document (D5) and to isolate with a reasonable expectation of success a PRRS virus which was immunologically related to the claimed deposited virus.

- Further, not all experiments described in document (D5) would have to be repeated, as only those cells which were known to be susceptible to viral growth would have to be used for propagation of the virus (alveolar lung macrophages) and the experimental reproduction of the disease would allow a very easy control of the isolated viruses.

- The experiments of document (D5) had been successfully repeated by others.

- One of the technical experts of appellant I acknowledged that viral strains which were immunologically related to the claimed deposited virus could be passaged to the required high titre.

- Test Report (D43) showed the inability of the claimed deposited virus to grow to a higher titre than the prior art viruses.

Auxiliary Request III (claim 1)
Inventive step (Article 56 EPC)

- The claimed immunoassay was obvious in view of document (D5) taken in combination with document (D19).

Auxiliary Request IV (claim 1)
Inventive step (Article 56 EPC)

- No unexpected effects or advantages could be attributed to the various polypeptides listed in claim 1. The said polypeptides were detected in a standard Western blot and it was considered to be a routine procedure to analyse and detect PRRS specific polypeptides, once a PRRS virus had been isolated.

Auxiliary Request V

Article 123(2) EPC

- There was no basis in the application as filed for the immunoassays as claimed involving the specific combination of the viral polypeptides 14 kD and 21 kD and fluorescent, chemoluminescent, radioactive, enzyme and dye molecule labels.

Article 83 *EPC*

- According to document (D3) (see page 26, line 27), the LV/PRRS viral polypeptides had molecular weights (mw's) of 15 kD, 16 kD, 19 kD, 26 kD, 35 kD, 39 kD and 65 kD. Therefore, a skilled person could not perform any reliable immunoassay based on the incorrect mw's of 14 kD and 21 kD referred to in the claim.

Article 56 *EPC*

- The polypeptides having mw's of 14 kD and 21 kD referred to in the claim were detected in a standard Western Blot and it was considered to be a routine procedure to analyse and detect PRRS specific polypeptides, once a PRRS virus had been isolated.

- Example 4 and Fig. 1 of the patent in suit related to the suitability as antigens of the 14 kD and 21 kD PRRSV polypeptides in a Western Blot. However, in the absence of evidence that they would also achieve high sensitivity in an ELISA,

no unexpected effects or advantages could be attributed to these polypeptides.

VIII. Appellant I (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request or auxiliary requests I to IV, all filed with telefax of 8 June 2004, or on the basis of the sole claim of auxiliary request V filed during oral proceedings. He further requested that the appeal of appellant II be rejected as inadmissible.

Appellant II (opponent 03) requested that the decision under appeal be set aside and the patent be revoked again in whole, also based on grounds not considered.

The respondent (opponent 02) requested that the appeal of appellant I be dismissed.

Reasons for the Decision

Opponent status of Stichting Dienst Landbouwkundig Onderzoek (SDLO)

1. The original opponent 03 was the Instituut voor Dierhouderij en Diergezondheid (ID-DLO). On 15 June 2004, Stichting Dienst Landbouwkundig Onderzoek (SDLO) submitted a statement by Freerk Volders, deputy civil-law notary in Rotterdam, according to which ID-DLO was merged into SDLO on 4 September 1998, and requested to record the transfer. The statement submitted proves to the satisfaction of the board that SDLO is the legal successor of ID-DLO and has thus

acquired the status of opponent 03 in the present proceedings.

Admissibility of the appeal by appellant II (opponent 03)

2. Pursuant to Article 107 EPC any party to proceedings adversely affected may appeal. Appellant II (opponent 03) argued that, although the first instance revoked the patent in suit, he was still adversely affected in that a number of grounds of opposition had been decided in favour of the patentee. However, for a party to be adversely affected within the meaning of Article 107 EPC, the first instance must have refused some request of the party appealing. Here, opponent 03 had requested that the patent be revoked, and this was the order made by the opposition division. Accordingly, no request of opponent 03 was refused, so he was not adversely affected. The appeal by SDLO is therefore inadmissible (see decision T 73/88 OJ EPO 1992, 557, point 1.3; T 224/96 of 19 December 2001, point 2; T 84/02 of 27 September 2002, point 1.3). However, opponent 03 remains a party as of right to the present proceedings under Article 107 EPC.

Inventive step (Article 56 EPC)

3. The first two claim requests before the board comprise a claim to a PRRS virus. Therefore, the board first turns to the question of whether or not the skilled person, departing from the closest prior art, would arrive at the claimed PRRS virus in an obvious manner, bearing in mind that answering this decisive question has deep implications on the allowability of all the successive claim requests including claims to the viral

antigen and to immunoassays involving said viral antigen or viral polypeptides. Thus, in order to streamline the reasons for the decision, the discussion of the claim requests will be confined to the inventive step of claims directed to the virus, the viral antigen and immunoassays involving said viral antigen or viral polypeptides. Reasons for any other claim of the requests being regarded as allowable/not allowable under other EPC Articles need not be given, despite the pro/contra arguments of the parties, if these claim requests already fail on the requirements of Article 56 EPC. Detailed reasons for claim(s) being regarded as allowable under other EPC Articles will be given in relation to the request on which the board sees no objections to (any of) the claim(s).

Main Request (claim 4) and Auxiliary Request I (claim 1)

4. The above claims, which are identical, relate to the deposited PRRS virus or to a PRRS virus isolate immunologically related to the deposited strain (see paragraph III supra). The parties and the board agree that document (D5) represents the closest prior art, as it deals with the isolation of the Lelystad Agent/Virus (LV), ie a virus isolate that the parties do not dispute to be immunologically related to the deposited PRRS strain CNCM I-1140 referred to in these claims (see eg document (D23), under "Immunological relatedness"). The controversial "high titre" feature as contained in the above claims is dealt with in more detail under point 9 infra.

5. Appellant I maintains that this document does not provide sufficient information for the skilled person

to arrive in an obvious manner at a LV immunologically related to the deposited PRRS virus referred to in the claims. It is argued in particular that document (D5) does not make available to the public a crucial element for isolation of the "right" virus, namely the postinfection LV monospecific sera "c-829" and "b-822" (see ibidem, page 125), let alone the virus itself.

6. The board accepts that LV monospecific post infection sera "c-829" and "b-822" might have been a decisive tool in the hands of the authors of document (D5), when they isolated the LV for the first time. However, if a viral agent has been isolated once, it becomes much easier to isolate the same again. This is because the skilled person need neither repeat all experiments described in document (D5), nor use the same LV monospecific post infection sera "c-829" and "b-822", so long as a (great) number of specific characteristics of the virus looked for are revealed by the document. This is indeed the case for document (D5), which teaches the skilled person exactly what virus he/she has to look for: the virus can be cultivated in porcine alveolar macrophages (to which it is cytopathic) but not in other known cell types; it is sensitive to chloroform; it exhibits a buoyant density of 1.19 g/cm^3 in CsCl,(ibidem, page 125, under "Virus isolation"); it is not neutralized by any known virus-specific antiserum (ibidem, page 124, 4th full paragraph); it does not hemagglutinate red blood cells of chickens, guinea pigs, pigs, sheep, or humans (red blood cell type 0) and does not react in the immunoperoxidase monolayer assay (IPMA) with specific antisera against known animal viruses (page 126, last paragraph); it passes through a 0.2 µm filter (ibidem). Moreover,

document (D5) also discloses how to carry out experimental infections of other animals to confirm that the isolated virus is actually LV (see page 132, first paragraph).

7. Appellant I relies on documents (D40), (D41) and (D42) for arguing that other teams applying very similar methods of isolating viruses as described in document (D5), did not obtain LV. However, these documents have to be balanced with documents (D1), (D2), (D3), (D4), (D16) and (D39), illustrating the successful isolation of the virus by relying on the information provided by document (D5). For instance the authors of documents (D4) (see page 201, last paragraph) and (D16) (see page 707, end of the central column) compare the buoyant density of 1.19 g/cm^3 in CsCl and sensitivity to chloroform treatment of their virus with that reported in document (D5) (see page 125) to establish identity.

8. In view of the foregoing, the board must conclude that the skilled person departing from document (D5) would arrive in an obvious manner at a LV isolate, ie a PRRS virus immunologically related to the deposited strain referred to in claim 4 of the Main Request and in claim 1 of Auxiliary Request I.

9. The claimed PRRS virus, in the appellant I's view, has the advantageous and unexpected property (cf the feature "which virus can be propagated in cell culture to a titre of at least $10^{6.0}$ $TCID_{50}$/ml") that it can grow to 10-100 times higher titres than the prior art PRRS viruses which grow poorly in cell cultures and reach maximum titres of about $10^{5.3}$ $TCID_{50}$/ml only (see document (D5), page 126, last line).

10. As emphasized in point 8 supra, arriving at a LV/PRRS virus isolate in the light of the prior art, was obvious for the skilled person. Therefore, the only question left is whether a LV/PRRS isolate having the feature "which virus can be propagated in cell culture to a titre of at least $10^{6.0}$ $TCID_{50}$/ml" could be arrived at in an obvious manner or not.

11. The board accepts that the ability of growing to high titres may reflect genetical changes (eg mutations and/or deletions) in a virus. The deposited virus of present claim 4 of the Main Request and claim 1 of the Auxiliary Request I is "isolate No. 10" deposited under the number CNCM I-1140 (see patent in suit, page 9, lines 21-22). Table 1 on page 9 of the patent also shows that the deposited virus is a "passage level 3" yielding a maximum $TCID_{50}$/ml (titre) of $10^{6.0}$ upon one further propagation in a cell culture (see also the table on page 2 of document (D32)).

As for the LV/PRRS virus disclosed in document (D5), the statement on page 124 of this document, under the heading "Further identification of Lelystad agent", that a third passage of Lelystad agent had a $TCID_{50}$/ml of $10^{5.05}$ ($10^{5.3}$ after filtration: see page 126, last line) suggests that the virus at a "passage level 2" could be propagated in cell culture to that titre ($10^{5.05}$), which is lower than $10^{6.0}$, ie the virus grew more slowly.

For the sake of reasoning, the board assumes that the passaging conditions (inter alia, the cells and the MOI (multiplicity order of infection)), are the same for

both the CNCM I-1140 virus and the Lelystad virus of document (D5), otherwise the above comparison between the achievable maximum titres would not be meaningful.

12. However, it can be derived from appellant I's own declaration (D32) (see the table on page 2) that "lazy" virus strains such as "Cob" and "DK" (see eg passage levels 0 and 1), which admittedly are strains immunologically related to the deposited virus "I10" (Isolate No. 10), and thus within the reach of the skilled person (see supra), can easily be turned, after a few passages, into "clever" viruses achieving titres higher than $10^{6.0}$. This finding is in line with page 16, lines 18-20 of document (D22), according to which further passaging a virus often enhances its virulence, and with document (D21)(see page 118, last lines and page 120, first lines), teaching that rapid virus growth is obtained by further passaging. Therefore, in the board's view, no case has been made out that a LV/PRRS virus having the feature "which virus can be propagated in cell culture to a titre of at least $10^{6.0}$ $TCID_{50}$/ml" was not within the reach of the skilled person applying the technique disclosed by document (D5) and taking obvious measures to increase virulence.

13. In conclusion, claim 4 of the Main Request and claim 1 of the Auxiliary Request I do not fulfil the requirements of Article 56 EPC. These requests must thus be refused.

Auxiliary Request II (claim 6, after renumbering)
Inventive step (Article 56 EPC)

14. Claim 6, after renumbering, of this request is identical to claim 8 of the main request and relates to a method for the preparation of a viral antigen comprising the steps of inoculating susceptible tissue cells with the PRRS virus, cultivating the cells and harvesting the viral antigen from the culture, wherein the pre-harvest titre is at least $10^{6.0}$ $TCID_{50}$/ml, the "viral antigen" being eg virus particles or disrupted virus (see page 7, lines 37-38 of the patent in suit). However, it is obvious for the skilled person looking for a viral antigen to arrive, in the light of the prior art, at a PRRS virus or virus particles (disrupted or not), wherein the pre-harvest titre is at least $10^{6.0}$ $TCID_{50}$/ml,(see paragraph 12 supra). The board must conclude that claim 6 does not fulfil the requirements of Article 56 EPC and that Auxiliary Request II must also be refused.

Auxiliary Request III (claim 1)
Inventive step (Article 56 EPC)

15. Claim 1 of this request is identical to claim 9 of the main request and relates to an immunoassay for the detection of antibodies against the PRRS virus involving the viral antigen reagent derived from a PRRS virus. The immunoassay is conventional (see eg document (D19), page 80, Table I: "Available tests") and the viral antigen involved in the immunoassay is obvious (see point 14 supra). The board must conclude that the claim does not fulfil the requirements of Article 56 EPC and that this request must also be refused.

Auxiliary Request IV
Inventive step (Article 56 EPC)

16. Claim 1 of this request differs from claim 1 of Auxiliary Request III in that the viral antigen reagent is specified to be a viral polypeptide having a mw of 14 kD, 21 kD, 46 kD, 49 kD and 55 kD. Appellant I maintains that these viral polypeptides display an appropriate affinity to the PRRSV serum and that they can be used in a sensitive and reliable immunoassay to detect the presence of LV/PRRS antibodies in a sample. However, insofar as polypeptides with a mw of 46 kD, 49 kD and 55 kD are concerned, this proposition is not supported by Figure 1 of the patent in suit (see new copy enclosed to appellant I's Grounds of Appeal), showing only two bands at 14 kD and 21 kD and nothing else. The description on page 8, line 19 ("two or three") also suggests that not all of 14 kD, 21 kD, 46 kD, 49 kD and 55 kD polypeptides listed in claim 1 are suited for carrying out an immunoassay, so that no proof is given that the technical problem of providing a reliable and sensitive immunoassay is indeed solved by polypeptides other than the 14 kD and 21 kD. Consequently, claim 1 of this request is considered to lack an inventive step (Article 56 EPC) and Auxiliary Request IV has to be refused.

Auxiliary Request V
Article 123(2) EPC

17. The sole claim of this request satisfies the requirements of Article 123(2) EPC. The immunoassays now claimed are limited to Western Blot (see Example 4) and ELISA (page 12, second paragraph, of the

application as filed). Immunoassays involving the specific combination of the viral polypeptides 14 kD and 21 kD and fluorescent, chemoluminescent, radioactive, enzyme and dye molecule labels have a basis on page 14, last paragraph, taken in combination with page 12, end of the first paragraph of the application as filed. A Western Blot is an assay according to page 12, end of the first paragraph, requiring a solid support and wherein any of the listed labels can be used for detecting the antigen-antibody complex.

The sole claim of the request also satisfies the requirements of Article 123(3) EPC since it does not extend the protection conferred by claim 9 (for the non-ES/GR Contracting States) and claim 8 (for the Contracting ES and GR) of the patent as granted.

Article 83 EPC

18. Appellant II relies on document (D3) disclosing LV/PRRS viral polypeptides having a mw of 15 kD, 16 kD, 19 kD, 26 kD, 35 kD, 39 kD and 65 kD (see page 26, line 27) for arguing insufficiency on the grounds that the mw's of 14 kD and 21 kD in the claim are not correct. However, there is no evidence before the board that the discordant mw's reported in document (D3) have been obtained by SDS-PAGE, as required by the present claim. These mw's are moreover not supported by experimental evidence. Therefore, in the board's judgement, no case of insufficiency of disclosure has been made out.

Rule 28 EPC

19. The board notes that claim 1 refers to a microorganism, the deposit of which had not been made by appellant I, as shown by the deposit receipt in the file. However, appellant I declared that the depositor Intervet International B.V. was a 100% subsidiary of appellant I, which was not contested by the other parties. The board therefore considers that the principles laid down in decision T 118/87 (OJ EPO 1991, 474 point 7), according to which non-identity between applicant and depositor is not detrimental in such a case to the validity of the deposit under Rule 28 EPC in its version not yet amended by decision of the Administrative Council of 14 Juni 1996, also apply to the present situation.

Inventive step (Article 56 EPC)

20. In the sole claim of this request it is specified that the viral antigen reagent is a viral polypeptide having a mw of 14 kD and/or 21 kD as determined by SDS-PAGE. Example 4 of the patent in suit and the new copy of Figure 1 enclosed to appellant I's Grounds of Appeal show the high antigenicity of the 14 kD and 21 kD PRRSV polypeptides that renders them especially suited as antigens in a diagnostic assay endowed with high sensitivity. Moreover, according to page 8, lines 18-24 and 31-34 of the patent, the major immune reactivity/specificity of PRRS sera is directed against these 14 kD and 21 kD polypeptides. In the board's view, this technical effect is surprising and could not be derived from the prior art in an obvious manner. Therefore, the sole claim of this request also satisfies the requirements of Article 56 EPC.

21. Appellant II denies that the 14 kD and 21 kD PRRSV polypeptides achieve high sensitivity in an ELISA (enzyme-linked immune sorbent assay), which thus lacks an inventive step.

The board accepts that Example 4 and Fig. 1 of the patent in suit are confined to a highly sensitive Western Blotting involving the 14 kD and 21 kD PRRSV polypeptides. If these polypeptides are used in immunoassays other than a Western Blotting (eg ELISA), a less sensitive immunoassay may result, although no evidence is before the board to this effect. Yet, even assuming that it is the case, this would rather depend on the (weaker) signal (label), not on the technical effect mentioned above that polypeptides 14 kD and 21 kD "capture" the major immune response of PRRS sera, on the basis of which technical effect (and not the signal strength) the board acknowledges the presence of an inventive step. The board has no reason to assume that this technical effect will not turn up in any immunoassay involving the 14 kD and 21 kD PRRSV polypeptides and PRRS sera, including the claimed ELISA, which thus involves an inventive step, too.

Order

For these reasons it is decided that:

1. The appeal of appellant II is rejected as inadmissible.

2. The decision under appeal is set aside.

3. The case is remitted to the first instance with the order to maintain the patent on the basis of the sole claim for all designated countries of auxiliary request V filed during oral proceedings and a description to be adapted.

The Registrar:	The Chairwoman:
P. Cremona	U. M. Kinkeldey