Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 9 January 2024

Case Number: T 1346/22 - 3.3.04

Application Number: 14805617.9

Publication Number: 3076996

IPC: A61K39/02, A61K39/12, A61P31/20, A61P31/04

Language of the proceedings: EN

Title of invention:
Vaccine against porcine circo virus type 2

Patent Proprietor:
Intervet International B.V.

Opponents:
Laboratorios Hipra, S.A.
Elanco US Inc.

Headword:
PCV2 vaccine/INTERVET

Relevant legal provisions:
EPC Art. 100(a), 56
RPBA 2020 Art. 12(2), 12(4)

Keyword:

Inventive step - main request (no) - auxiliary requests 1 to 9 (no)

Amendment to appeal case - amendment overcomes issues raised - auxiliary requests 10 to 19 (no)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1346/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 9 January 2024

Appellant: (Patent Proprietor)	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Representative:	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Respondent: (Opponent 1)	Laboratorios Hipra, S.A. Avda. La Selva, 135 17170 Amer (ES)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Respondent: (Opponent 2)	Elanco US Inc. 2500 Innovation Way Greenfield, IN 46140 (US)
Representative:	Potter Clarkson Chapel Quarter Mount Street Nottingham NG1 6HQ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 30 March 2022 revoking European patent No. 3 076 996 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	B. Rutz
	A. Bacchin

Summary of Facts and Submissions

I. The appeal by the patent proprietor (appellant) lies from the decision of the opposition division to revoke European patent No. 3 076 996 (the patent), entitled "*Vaccine against porcine circo virus type 2*".

II. The opposition proceedings were based on the grounds of Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and of Article 100(b) and (c) EPC.

III. In the decision under appeal, the opposition division decided that the subject-matter of claim 1 of the patent as granted (main request) lacked an inventive step over the disclosure of document D7, D30 or D44 in combination with the disclosure of document D25. The same applied to the subject-matter of claim 1 of auxiliary requests 1 to 9.

IV. With its statement of grounds of appeal, the appellant re-filed auxiliary requests 1 to 9 as had been dealt with in the decision under appeal. It also filed new auxiliary requests 10 to 19 and documents D52 to D56.

V. Opponent 1 and opponent 2 (respondent I and respondent II, respectively) both replied to the appeal.

VI. The board summoned the parties to oral proceedings, as requested, and informed them of its preliminary opinion in a communication under Article 15(1) RPBA 2020.

VII. In this communication, the board indicated that it was also prepared to hear the parties on inventive step starting from document D16, which disclosed single-dose

intradermal administration of inactivated PCV2 virus into pigs with maternal antibodies (see Example 4). The board also raised the question of whether the skilled person would have been motivated to replace the whole inactivated PCV2 by a recombinant PCV2 ORF2 protein, which was already known to be effective even in single-dose regimens (see, for example, D7 or D30), and whether the skilled person would have had a reasonable expectation of success that such a recombinant vaccine would be effective when administered as a single shot intradermally.

VIII. Claim 1 of the main request reads as follows:

"1. Vaccine comprising recombinantly expressed ORF2 protein of porcine circo virus type 2 for use in prophylactically treating an animal that has circulating antibodies directed against porcine circo virus type 2, against an infection with pathogenic porcine circo virus type 2 by a single dose administration of the vaccine into the dermis of the animal."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that it specifies the ORF2 protein as being a "capsid" protein.

Claim 1 of auxiliary request 2 differs from claim 1 of auxiliary request 1 in that it specifies the vaccine as comprising the protein "as a subunit immunogen".

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 2 in that it specifies the circulating antibodies as being "maternally derived".

Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 3 in that "the vaccine comprises non-live immunogen of *Mycoplasma hyopneumoniae* to treat the animal against an infection with pathogenic *Mycoplasma hyopneumoniae* bacteria".

Claim 1 of auxiliary request 5 differs from claim 1 of the main request in that it specifies the administration as being "intradermal" instead of "into the dermis".

Claim 1 of auxiliary request 6 differs from claim 1 of auxiliary request 5 in that it specifies the ORF2 protein as being a "capsid" protein.

Claim 1 of auxiliary request 7 differs from claim 1 of auxiliary request 6 in that it specifies the vaccine as comprising the protein "as a subunit immunogen".

Claim 1 of auxiliary request 8 differs from claim 1 of auxiliary request 7 in that it specifies the circulating antibodies as being "maternally derived".

Claim 1 of auxiliary request 9 differs from claim 1 of auxiliary request 8 in that "the vaccine comprises non-live immunogen of *Mycoplasma hyopneumoniae* to treat the animal against an infection with pathogenic *Mycoplasma hyopneumoniae* bacteria".

Claim 1 of auxiliary requests 10 to 19 corresponds to claim 1 of the main request and auxiliary requests 1 to 9, respectively, with the addition that the protein is "baculo virus" expressed.

IX. Oral proceedings were held by videoconference. The parties did not object to the format. At the end of the

oral proceedings the chairwoman announced the board's decision.

X. The following documents are referred to in this decision:

D4 A. Evans, "*Intra-dermal vaccination series. Part 3. Skin immune system*", Pig Progress 22(5), 2006, 24-25

D7 P. Martelli et al., "*One dose of a porcine circovirus 2 subunit vaccine induces humoral and cell-mediated immunity and protects against porcine circovirus-associated disease under field conditions*", Vet. Microbiol. 149, 2011, 339-351

D9 B. Heißenberger et al., "*Efficacy of vaccination of 3-week-old piglets with Circovac® against porcine circovirus diseases (PCVD)*", Trials in Vaccinology 2, 2013, 1-9

D14 A. Silva Junior et al., "*Development and evaluation of a recombinant DNA vaccine candidate expressing porcine circovirus 2 structural protein*", Pesq. Vet. Bras. 29(1), 2009, 76-82

D15 K. A. McIntosh, "*MOLECULAR TECHNIQUES IN THE STUDY AND CONTROL OF PORCINE CIRCOVIRUS TYPE 2*", PhD thesis, 2011, 173 pages

D16 WO 2006/113373 A2

D20 T. Opriessnig et al., "*Effect of porcine circovirus type 2 (PCV2) vaccination on porcine reproductive and respiratory syndrome virus (PRRSV) and PCV2 coinfection*", Veterinary Microbiology 131, 2008, 103-114

D23 P. H. Lambert and P. E. Laurent, "*Intradermal vaccine delivery: Will new delivery systems transform vaccine administration?*", Vaccine 26, 2008, 3197-3208

D24 EP 1 958 644 A1

D30 M. Haake et al, "*Influence of age on the effectiveness of PCV2 vaccination in piglets with high levels of maternally derived antibodies*", Vet. Microbiol. 168, 2014, 272-280

D35 P. Nawagitgul et al., "*Open reading frame 2 of porcine circovirus type 2 encodes a major capsid protein*" J. Gen. Virol. 81, 2000, 2281-2287

D36 Expert declaration of Prof. Francois Meurens

D43 E. Crisci et al., "*Virus-like particle-based vaccines for animal viral infections*", Inmunología 32(2), 2013, 102-116

D44 WO 2009/127684 A1

XI. The appellant's submissions, as far as relevant to the present decision, are summarised as follows:

Main request - claim 1
Inventive step (Articles 100(a) and 56 EPC)

Document D16 was not a realistic starting point for an analysis of the inventive step of the claimed invention and could only have been selected in hindsight. It was conceived for a different purpose, namely the provision of new oil-in-water emulsions. Example 4 was only intended to test a serological response and did not show a protective effect of the vaccination because no challenge with PCV2 virus was performed. Under "real world circumstances", the skilled person aiming to develop a vaccine would never start with a document disclosing a different vaccine format (whole inactivated virus vs. recombinantly expressed protein) simply because it disclosed one-shot intradermal administration.

Even if the skilled person had started from the disclosure of document D16 and in particular from Example 4 therein, there would have been no reasonable expectation of success, i.e. they would not have expected to arrive at a vaccine which provided effective protection over a long duration, e.g. 23 weeks as shown in the patent. Document D16 disclosed only inactivated PCV2 virus as the vaccine format for PCV2 (see page 20, penultimate paragraph). The skilled person knew that changing the vaccine format was fraught with uncertainty (see document D4, page 25, left-hand column; D23, page 3198, right-hand column, penultimate paragraph). Although intradermal injection devices had been known for several years before the

priority date, nobody had used them to administer recombinantly expressed PCV2 ORF2 protein as a vaccine (see D4, published in 2006, Figure 1). The intradermal injection of PCV1-2 chimeric virus in D20 was not comparable because it related to seronegative animals. The results in the patent in animals with a high maternal antibody background were therefore surprising.

Auxiliary requests 1 to 9
Inventive step (Article 56 EPC)

The restriction of the first auxiliary request to the antigen being the capsid protein of PCV2 and the restriction of the second auxiliary request to the antigen being a subunit immunogen were intended to overcome potential novelty and inventive-step problems with respect to prior art disclosing whole virus vaccines, for example.

The further restriction of auxiliary request 3 to the circulating antibodies being maternally derived antibodies was intended to set the invention apart from the use in animals having antibodies as a result of an infection (see D24).

The incorporation of the subject-matter of claim 6 as granted into claim 1 of auxiliary request 6 overcame potential novelty objections with respect to prior art that did not disclose these combination vaccines.

The replacement of "into the dermis" with "intradermal" was intended to overcome a potential inventive-step objection in line with the preliminary opinion of the opposition division.

Auxiliary requests 10 to 19
Admission (Article 12(4) and (6) RPBA 2020)

The additional new auxiliary requests 10 to 19 restricted the antigen in the vaccine to baculovirus-expressed protein in claim 1 of each of the requests. This was to overcome the new objection raised in the decision under appeal that the claims were not inventive beyond the product Porcilis® PCV.

XII. The respondents' submissions, as far as relevant to the present decision, are summarised as follows:

Main request - claim 1
Inventive step (Articles 100(a) and 56 EPC)

Document D16 used a killed virus (inactivated whole PCV2 virus comprising the ORF2 capsid protein) in a single administration (by the intradermal route) with success, imparting protection over a long duration of up to 180 days after vaccination (see the table of Example 4) even in the presence of maternal antibodies at the time of the vaccination (see Results, Example 4).

The only difference between the subject-matter of claim 1 and the disclosure of D16 was that claim 1 specified that the ORF2 protein was recombinant, whereas D16 used a killed whole PCV2 virus. No surprising effect was achieved by means of this difference. The technical problem was to provide an alternative immunogen. Using a recombinant antigen instead of a whole, killed, virus was obvious because D16 itself stated, on page 6, first complete paragraph, that the immunogen could be a "*subunit or portion of an organism*", and in the first complete paragraph on

page 16 that "*The immunogen or antigen suitable for use in the present invention may be … immunogenic subunits (e.g. proteins, polypeptides, peptides, epitopes, haptens), or recombinant expression vectors, including plasmids having immunogenic inserts*".

The only PCV2 capsid protein is ORF2, which meant that the antigen in a whole, killed, vaccine was the same as in a vaccine based on a recombinant ORF2 protein.

This was also apparent from documents D15, D35 and D36, which showed that recombinantly expressed PCV2 ORF2 protein self-assembled into virus-like particles which corresponded immunologically to the PCV2 virus.

There was a general trend in the vaccine art to use recombinant antigens, particularly if it was hard to obtain enough whole virus (see, for example, D14, first paragraph of the discussion on page 80).

Many different teams in the PCV2 vaccine art had already used recombinant ORF2 as the immunogen, often in a single-dose regimen (see D7, title; D18, abstract; D24, paragraphs [0044] to [0046]; D30, abstract, third sentence; and D33, paragraph [0013]).

Furthermore, given the knowledge of the successful intradermal administration in D20 and the apparent need for the skilled person to increase the spectrum of commercial vaccines that were also suitable for intradermal vaccination, the skilled person only had to try the obvious and had a reasonable expectation of success even in the presence of maternally derived PCV2 antibodies.

Auxiliary requests 1 to 9
Inventive step (Article 56 EPC)

It was obvious to use recombinant ORF2 (rORF2), also as defined in claim 1 of auxiliary requests 1 and 2 ("capsid", "as a subunit immunogen"), instead of the killed virus of D16. As shown by D7 and D30, this was usually the whole ORF2 protein.

The pigs in D16 had high maternally derived antibodies (MDA, see Example 4, page 24).

Examples 3 and 4 of D16 already disclosed vaccines that combined a PCV2 immunogen and an *M. hyo.* immunogen in a single vaccine. There was no difference between "into the dermis" and "intradermal" as in auxiliary requests 5 to 9.

Auxiliary requests 10 to 19
Admission (Article 12(4) and (6) RPBA 2020)

The only amendment was to specify that the ORF2 protein was "baculo virus expressed". There were no comparative data to show that such a protein was a better immunogen than rORF2 expressed any other way. Moreover, it was well known to make proteins in general, and ORF2 in particular, in the baculovirus expression system (see, for example, D7, D15, D18, D24 and D44). It was therefore obvious to use that system to make the ORF2 protein of the opposed patent.

XIII. The appellant requests that the decision under appeal be set aside and that the patent be maintained as granted, or, alternatively that the patent be maintained in amended form based on the set of claims

of one of auxiliary requests 1 to 19. The appellant further requests that documents D52 to D56 be admitted into the proceedings.

The respondents request that the appeal be dismissed and that new auxiliary requests 10 to 19 not be admitted into the proceedings. The respondents further request that documents D52 to D54 not be admitted into the proceedings.

Reasons for the Decision

Admission of documents D52 to D54 into the appeal proceedings

1. Since none of these documents were required for the present decision and none of the parties relied on them in their submissions, it is not necessary to decide on the admission thereof.

Main request (patent as granted) – claim 1
Inventive step (Articles 100(a) and 56 EPC)
Closest prior art

2. The problem-solution approach represents a well-established tool for analysing inventive step in an efficient and objective manner. However, this analysis always remains within the framework of Article 56 EPC, i.e. it includes addressing whether, "*having regard to the state of the art, it* [the subject-matter claimed] *is not obvious to a person skilled in the art*". State of the art which clearly belongs to the field of the invention, in the present case PCV2 vaccines for pigs, cannot therefore be excluded as a starting point for an inventive-step analysis merely because documents exist which in the view of a party are allegedly "closer" or more similar in purpose to the claimed subject-matter.

3. Document D16 discloses PCV2 vaccines. This is apparent from the use of the words "*vaccine*", "*vaccine composition*" and "*vaccinated*" in Example 4, but also from the presence of claims directed to compositions comprising PCV2 as the vaccine antigen (see claims 19 and 20 on page 42 of document D16). The purpose of Example 4 in document D16 is thus to test whether an adequate immune response is achieved in the context of a PCV2 vaccine.

4. In Example 4, piglets with pre-existing high maternal antibodies are "*vaccinated*" with a single dose of a "*vaccine composition*" comprising "*inactivated Mycoplasma hyopneumoniae"* and "*inactivated porcine circovirus 2*" "*by intradermal route with a needle free injector*". In the Results of Example 4, it is concluded that "*the vaccinates showed a significant anti-PCV-2 ORF2 antibody response from 7 to 180 days after vaccination*". By analysing the antibody response against the PCV2 ORF2 protein, document D16 thus also implicitly discloses the antigenic nature of the ORF2 protein within the inactivated PCV2 virus vaccine.

5. The appellant argued that choosing document D16 and Example 4 therein as a starting point for an inventive-step analysis would involve "hindsight", because the overall purpose of document D16 was to develop novel oil-in-water emulsions and not to develop new protective vaccination methods (see page 1, "*FIELD OF THE INVENTION*", and page 2, "*SUMMARY OF THE INVENTION*"). The purpose of Example 4 in document D16 was also different from that of the claimed invention because it did not relate to protection by vaccination; rather, it related to a serological analysis of the PCV2 vaccine (see the title on page 24: "*Example 4:*

Serological results after administration of one dose of PCV-2 vaccine adjuvanted with LR4 emulsion"). Since Example 4 in document D16 did not involve any challenge with virus, in contrast to other examples therein, e.g. Example 7, the skilled person would not recognise this example as representing a valid starting point for the development of a vaccine with a protective effect.

6. The board does not agree. Document D16 relates to the field of animal vaccines, and in particular swine vaccines (see the paragraph bridging pages 16 and 17). This is also apparent from the examples in which all *in vivo* tests are carried out in pigs (see Examples 4 and 7 to 11). Even if the overall focus of the patent application D16 is different from the purpose of the subject-matter of claim 1, this overall focus does not override or render invisible to the skilled person the disclosure in document D16, namely the intradermal one-shot vaccination with inactivated PCV2 virus of piglets with pre-existing high maternal antibodies. It therefore cannot be concluded that the disclosure of document D16 is limited to a mere serological experiment.

Differences, technical effects and objective technical problem

7. The appellant considered that achieving the claimed prophylactic treatment of "*an animal that has circulating antibodies directed against porcine virus type 2, against an infection with pathogenic porcine virus type 2 by a single dose administration of the vaccine into the dermis of the animal*" represented a difference to the disclosure of document D16. The appellant argued that in contrast to the patent, which contained data which showed long-term (at least 23 weeks) "*almost sterile*" protection for vaccinated pigs,

Example 4 of document D16 only showed an antibody response to PCV2, which in fact even slightly decreased over the course of the study (see the table in Example 4 on page 24). It was common general knowledge in the field of vaccines that a serological response to a virus antigen could not be equated with protection against the pathogenic virus. The appellant cited document D4 in this regard, which states on page 25, left-hand column, that "*it is not guaranteed that always a protective immunity is mounted when an antigen is given by the intra-dermal route*", and document D23, page 3198, right-hand column, penultimate paragraph, which states "[t]*he way in which a vaccine is delivered can have considerable bearing on these factors through its influence on the efficiency of the procedure, the dose required, compliance, and safety*".

8. The respondents counter-argued that the antigen used in document D16 was the same as in the commercial PCV2 vaccine Circovac® from the company Merial, i.e. the applicant of the patent application document D16, which had been approved for use in pigs and thus had already been shown to be protective. The appellant, while not disputing this, insisted that the prior art mainly related to intramuscular administration and that the protective effect in the prior art was not as long-lasting as shown in the patent. In the absence of a viral challenge in Example 4, the skilled person reading document D16 could thus not directly infer that a protective effect was also achieved when the PCV2 inactivated virus was given as a one-shot vaccine intradermally to piglets with high maternal PCV2 antibodies. The board agrees, and notes that the registered recommendation for the Circovac® vaccine was one shot intramuscularly (see document D9, page 2,

left-hand column, penultimate paragraph, and page 5, right-hand column, last paragraph).

9. Claim 1 is formulated as a purpose-limited product claim, which means that achieving the therapeutic or prophylactic effect, i.e. protection against PCV2 infection, represents a functional feature of the claim. Since the protective effect is not directly shown in Example 4 of document D16, the board has come to the conclusion that achieving this effect represents a first difference.

10. It is undisputed that the ORF2 protein of PCV2 is defined in claim 1 as "*recombinantly expressed*", while it is part of an inactivated PCV virus in Example 4 of document D16. This represents a further difference.

11. ORF2 capsid protein is the only structural protein of the virus and self-assembles into virus-like particles which immunologically correspond to the whole PCV2 virus (see documents D15, D35, D36 and the patent).

12. Document D15 states on page 94, second paragraph, that "*Sf9 cells cultured in spinner flasks were infected with recombinant baculovirus expressing the complete ORF2 gene of PCV2 [...] The cell culture was centrifuged [...] and VLPs extracted from the resulting cell pellet.*"

13. Document D35 states in the abstract that "*The recombinant ORF2 protein self-assembled to form capsid-like particles when viewed by electron microscopy.*"

14. Document D36, an expert declaration initiated by the appellant-patent proprietor in different proceedings, states on page 2, third bullet-point, that "*PCV-2 Open*

reading frame 2 (ORF-2) protein assembles into Virus Like Particles (VLPs) that immunologically correspond to the whole PCV-2 virus". Reference is also made therein to the findings of document D35 (see document D36, page 3, fourth full paragraph).

15. This is also recognised, as part of the common general knowledge at the relevant time, in the patent in paragraph [0003] of the "*BACKGROUND ART*" section: "*this subunit* [the ORF2 encoded capsid protein]*, in a circulatory system, shows up the same way as the virus itself, essentially differing in the fact that the DNA and non-structural proteins are not present inside the capsid.*"

16. Thus, no different immunological effects are expected to result from the use of a recombinantly expressed PCV2 ORF2 protein instead of an inactivated PCV2 virus. The patent also contains no experimental data to compare these two types of antigens. The first difference is therefore not linked to a technical effect.

17. The objective technical problem can thus be formulated as the provision of an alternative PCV2 vaccine composition which provides protection against PCV2.

Obviousness

18. First, the question to be asked is whether the skilled person would have had a reasonable expectation of success on the basis of the disclosure of Example 4 in document D16 in obtaining a protective effect against PCV2 when replacing the inactivated PCV2 virus with recombinantly expressed ORF2.

19. The results of Example 4 show "*a significant anti-PCV-2 ORF2 antibody response from 7 to 180 days after vaccination even in presence of maternal antibodies at the time of vaccination*". The significance of this long-lasting response is apparent from the comparison with the control (unvaccinated) group which, from day 63 to day 180, shows about one $\log_{10}$ unit fewer antibodies than the vaccinated piglets (cf. Group 1 and Group 2 in the table of Example 4).

20. The skilled person knew that Circovac®, which uses the same antigen as Example 4 in document D16 (see point 8. above), is protective when administered as a single shot intramuscularly in the presence of maternally derived antibodies (see document D9, page 7, right-hand column, last sentence of penultimate paragraph).

21. The skilled person was further aware of other PCV2 vaccines which contain PCV2 ORF2 as the antigen. Suvaxyn® is a killed chimeric PCV1-2 virus containing the PCV2 ORF2 protein as a capsid of the viral particles. In document D20, Suvaxyn® is administered intradermally as a one-shot vaccine and is found to be effective in "*significantly reducing PCV2-associated lesions and PCV2 viremia*" while "[d]*ifferences between intradermal and intramuscular routes of administration were not observed*" (see the abstract, last sentence). With its capsid comprised entirely of PCV2 ORF2 protein, the Suvaxyn® chimeric virus corresponds immunologically to the VLPs self-assembled from recombinant PCV2 ORF2 protein (see points 11. to 16. above) as well as to the inactivated PCV2 virus used in document D16. The skilled person would therefore have considered the findings in document D20 to be relevant for interpreting the serological results obtained in

document D16 and for judging whether a recombinantly expressed ORF2 could be expected to be effective.

22. The overall antibody response increase shown in document D16 indicates to the skilled person that even "*preexisting high maternal antibodies*" as reported in Example 4 did not interfere with the immune response and that a protective effect similar to that reported in document D20, which was shown in the absence of maternally derived antibodies, could be expected. The appellant, in any case, stated that pre-existing immunity (maternal) "*plays no role in PCV2 vaccination: at the priority date of the present invention it was consistently accepted that pre-existing (in particular maternal) immunity played no negative effect on the take of the vaccine*" (see the statement of grounds of appeal, page 10, last two paragraphs, citing document D30 as evidence).

23. In conclusion, based on the results of Example 4 in document D16 the skilled person would have had a reasonable expectation of success that a protective effect could be obtained. This protection could be expected not only with whole inactivated PCV2 but also with recombinant vaccines based on the same immunogen, i.e. PCV2 ORF2, the sole capsid protein of the virus (see documents D7, D20, D30, D44).

24. With regard to the second difference, i.e. the vaccine comprising recombinantly expressed ORF2 protein, document D16 itself states on page 16, first full paragraph, that recombinant subunits might also be used as vaccines ("immunogenic subunits (e.g. proteins, polypeptides, epitopes, haptens)"). It was therefore obvious for the skilled person to replace the inactivated PCV2 virus with the ORF2 protein, which is

the only capsid protein and was recognised as such in document D16 when measuring the antibody response thereto. Moreover, the skilled person knew from documents D7, D24, D30, D43 and D44 that recombinantly expressed PCV2 ORF2 was commercially available and protective, at least when given intramuscularly (e.g. Porcilis® PCV in documents D7, D30 and D44, Ingelvac CircoFlex® in documents D24 and D43, see also the summary in Table 1.1 of document D15, page 18).

25. The advantages of recombinant expression were generally known in the field (see, for example, document D14, page 80, right-hand column, last paragraph: "*Because of difficulties in obtaining high PCV2 titers in vitro, potential recombinant vaccines would be particularly useful in this viral system*") and no particular hurdles for replacing the inactivated virus with recombinantly expressed ORF2 protein have been invoked by the appellant.

26. The subject-matter of claim 1 therefore lacks an inventive step (Article 56 EPC).

Auxiliary requests 1 to 9
Inventive step (Article 56 EPC)

27. The appellant has not indicated why and how the amendments "capsid" (auxiliary requests 1 to 4 and 6 to 9), "as a subunit immunogen" (auxiliary requests 2 to 4 and 7 to 9), "maternally derived" (auxiliary requests 3, 4, 8 and 9), "intradermal" (auxiliary requests 5 to 9) and combination with a "non-live immunogen of *Mycoplasma hyopneumoniae*" (auxiliary requests 4 and 9) would contribute an inventive step to the subject-matter of claim 1 of auxiliary requests 1 to 9 starting from the disclosure of document D16 as

the closest prior art, which already discloses one-dose intradermal vaccination of piglets with high pre-existing maternal antibodies in combination with inactivated *Mycoplasma hyopneumoniae*.

28. The subject-matter of claim 1 of auxiliary requests 1 to 9 therefore lacks an inventive step for the same reasons as those given with respect to the subject-matter of claim 1 of the main request.

Auxiliary requests 10 to 19
Admission (Article 12(2) and (4) RPBA)

29. Auxiliary requests 10 to 19 were first filed with the statement of grounds of appeal and therefore represent an amendment within the meaning of Articles 12(2) and (4) RPBA, the admittance of which is subject to the discretion of the board. The appellant indicated in its statement of grounds of appeal that the amendment in claim 1 of auxiliary requests 10 to 19, i.e. that the ORF2 protein was "baculo virus expressed", was made to overcome the allegedly new objection raised in the decision that the subject-matter of the claims was not inventive beyond the specific product Porcilis® PCV. This objection, however, was not upheld by the respondents on appeal, and was clearly not relevant for the board when deciding on the inventive step of the main request and auxiliary requests 1 to 9. Most importantly, the appellant has not substantiated how this amendment would overcome the objections against inventive step, as required by Article 12(4) RPBA. The board therefore holds that the amendment in auxiliary requests 10 to 19 is not suited to overcome the objections raised.

30. Auxiliary requests 10 to 19 are therefore not admitted into the appeal.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated