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Datasheet for the decision of 11 September 2025

Case Number: T 1524/23 - 3.3.04

Application Number: 17208901.3

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Language of the proceedings: EN

Title of invention:
Multivalent PCV2 immunogenic compositions and methods of producing such compositions

Patent Proprietor:
Boehringer Ingelheim Animal Health USA Inc.

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

Headword:
Multivalent PCV2 composition/BOEHRINGER INGELHEIM

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 12(4), 12(6)

Keyword:
Inventive step - (no)
Amendment to appeal case - taken into account (no)

Decisions cited:
T 1862/15, T 1179/16, T 2410/19, T 0860/21

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Case Number: T 1524/23 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 11 September 2025

Appellant: (Patent Proprietor)	Boehringer Ingelheim Animal Health USA Inc. 3239 Satellite Blvd Duluth, GA 30096 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent I: (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 II: (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 22 June 2023 revoking European patent No. 3320919 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	A. Chakravarty
	M. Blasi

Summary of Facts and Submissions

I. European patent 3 320 919, with the title "*Multivalent PCV2 immunogenic compositions and methods of producing such compositions*" was granted on application EP 17 208 901.3. This application was a divisional application of earlier (parent) application EP 06 848 471.6, which was filed as an international application, published as WO 2007/076520. European patent 1 968 630 was granted on said parent application, which was subject to both opposition and appeal proceedings, with the final outcome being decision T 860/21 by which the patent was revoked.

II. The patent in suit was opposed by two opponents and was revoked by the opposition division. An appeal was filed by the patent proprietor (appellant) against the opposition division's decision to revoke the patent. Opponent 1 and 2 replied to the appeal and are respondent I and II in the appeal proceedings.

III. In the decision under appeal, the opposition division considered objections under Article 83 EPC made by the respondents against the main request (filed on 24 September 2021) and held that the claimed invention was not disclosed in the application as filed in a manner sufficiently clear and complete for it to be carried out by the skilled person. This finding was held to apply equally to the subject-matter of auxiliary claim requests 1 to 22. The set of claims of auxiliary request 23, submitted during the oral proceedings before the opposition division, was not admitted into the proceedings. The opposition division also provided *obiter dicta* on Articles 123(2)/ 76(1) EPC, Article 54 and Article 56 EPC.

IV. With its statement of grounds of appeal, the appellant resubmitted sets of claims of a main request and of auxiliary requests 1 to 23, previously submitted in the proceedings before the opposition division, and the sets of claims of auxiliary requests 24 to 27 for the first time.

V. The appellant submitted a corrected set of claims of auxiliary request 10 with a letter dated 3 May 2024.

VI. With letters dated 11 March 2025 respondent I submitted further arguments. Respondent II submitted letters dated 13 June 2024, 1 August 2024 and 21 March 2025. containing further arguments.

VII. The board issued a communication pursuant to Article 15(1) RPBA *inter alia* setting out its preliminary construction of claim 1 of the main request according to which, the feature that one dose of the vaccine is to be administered intramuscularly to the subject and the feature that therapeutic effect is obtained by a single administration of the vaccine, means that the therapeutic effect defined in the claim is achieved with the administration of one dose of the combination vaccine. In other words, in a regimen falling within the ambit of the claim, the subjects (piglets) receive only one dose of the vaccine defined the claim. However, the wording of the claim did not exclude that other immunogens or immunogenic compositions which are not the "A multivalent combination vaccine" defined in the claim, can contribute to achieving the therapeutic aim defined in the claim. Moreover, the claim did not define the vaccination status of the subjects.

The communication went on to explain that the board was of the preliminary view that the subject-matter of claim 1 of the main request considered by the board in the parent case T 860/21 was encompassed by claim 1 of the main request and that in view of this it was inclined to hear the parties on inventive step at the oral proceedings, and decide on this issue first, under its power pursuant to Article 111(1) EPC. It further informed the parties that it was of the preliminary view that the same considerations on inventive step as those reached in case T 860/21 applied to the subject-matter of present claim 1.

VIII. The appellant and respondent I replied to the board's communication, with letters dated 8 August 2025 (appellant), 14 July 2025 and 3 September 2025 (respondent I).

IX. All parties submitted documents for the first time in the appeal proceedings.

X. Oral proceedings before the board were held as scheduled. During the oral proceedings, the appellant withdrew auxiliary requests 1 to 23. Auxiliary requests 24 to 27 became auxiliary requests 1 to 4. At the end of the oral proceedings, the Chairwoman announced the decision of the board.

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

"1. A multivalent combination vaccine for use in a method for
(i) the prevention of an infection with PCV2, or re-infection with PCV2 or
(ii) the reduction or elimination of clinical symptoms caused by PCV2

in a subject, wherein one dose of the vaccine is to be administered intramuscularly to the subject and wherein

(i) said prevention of an infection with PCV2, or re-infection with PCV2 or
(ii)said reduction or elimination of clinical symptoms caused by PCV2,
is obtained by a single administration of the vaccine,

and wherein the vaccine includes
- an antigenic composition obtainable by a method comprising:
i) preparing and recovering recombinant PCV2 ORF2 protein, and
ii) admixing this with a suitable adjuvant

and
- at least one immunogenic active component against another disease-causing organism in swine".

Auxiliary request 1 (submitted as auxiliary request 24 with the statement of grounds of appeal)

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that it includes the additional feature "and wherein said vaccine comprises 2 µg to 50 µg recombinant PCV2 ORF2 protein per dose".

Auxiliary requests 2 to 4 (submitted as auxiliary requests 25 to 27 with the statement of grounds of appeal)

Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that it includes the additional feature "and wherein said vaccine comprises 4 µg to 16 µg recombinant PCV2 ORF2 protein per dose".

Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that "subject" has been replaced by "pig or piglet" and in that it includes the additional features "wherein the administration of the combination vaccine is performed when the animals are 2 to 8 weeks of age,
and wherein said vaccine comprises 2 µg to 50 µg recombinant PCV2 ORF2 protein per dose".

Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 3 in that the dose is "4 µg to 16 µg" instead of "2 µg to 50 µg".

XII. The following document is referred to in this decision.

D9: Blanchard P. *et al.*, "*Protection of swine against post-weaning multisystemic wasting syndrome (PMWS) by porcine circovirus type 2 (PCV2) proteins*", Vaccine, 2003, 21, 4565-4575.

XIII. The appellant's submissions relevant to the decision are summarised as follows:

Main request - claim 1

Claim construction

The claim was a purpose-limited product claim and was directed to a multivalent combination vaccine comprising recombinant PCV2 ORF2 protein and at least one immunogenic active component against another swine pathogen, wherein the vaccine was administered in a single dose intramuscularly to confer protection against PCV2 infection or reduce/eliminate associated clinical symptoms. The claimed vaccine achieved protection against PCV2 infection in "one-shot". The

subjects received no other treatment of PCV2 infection or of its symptoms.

The only therapeutic effects required by the claim were (i) the prevention of an infection with PCV2, or re-infection with PCV2 or (ii) the reduction or elimination of clinical symptoms caused by PCV2. No therapeutic efficacy against the "at least one immunogenic active component against another disease-causing organism in swine" (further immunogen) was required by the claim. It was sufficient that the further immunogen elicited an immune response.

Remittal (Article 111(1) EPC and Article 11 RPBA)

Remittal to the opposition division was appropriate to allow the case to be heard by two instances. The decision under appeal only dealt with some aspects under Article 83 EPC, while inventive step was not considered. Moreover, the objection of lack inventive step based on a claim construction now pursued by the respondents had been only one of many objections initially raised. It would have been in keeping with procedural economy to file auxiliary requests to take all such objections into account. Furthermore, it had only become clear that the board was unlikely to adopt the appellant's claim construction in relation to the 'one shot' feature as decisions in related cases were issued. In particular, the decision in the parent case, T 860/21 was the first case to deal with a combination vaccine. Although the board had adopted a similar claim construction in decision T 2410/19, the opposition division had in its *obiter dictum* expressed doubts that this construction would stand.

Thus, remittal was appropriate to allow the parties to put their arguments on inventive step to the opposition division in the light of decisions T 2410/19 and T 860/21. The findings in these decisions represented special reasons for remittal within the meaning of Article 11 RPBA.

Inventive step (Article 56 EPC)

None of the cited prior art documents disclosed or rendered obvious the claimed one-shot administration of a recombinant PCV2 ORF2 protein-based vaccine for achieving the recited medical effects.

D9 disclosed prime-boost vaccination regimens involving multiple administrations, including DNA priming and protein boosting, and did not suggest that a single administration of recombinant PCV2 ORF2 protein alone could confer protective immunity. The authors of D9 themselves had recommended further studies using prime-boost approaches.

The claimed invention provided a surprising technical effect, namely that a single administration of recombinant PCV2 ORF2 protein was sufficient to confer protective immunity against PCV2 infection. This was supported by experimental data in the patent (Examples 4 and 5), which showed efficacy across multiple clinical parameters. The prior art did not provide a reasonable expectation of success for achieving such an effect with a one-shot subunit vaccine.

Regarding the inclusion of a second immunogenic active component, such as PRRSV or *M. hyo* antigens, the prior art did not disclose or suggest that such components

could be combined with PCV2 ORF2 protein in a single-dose vaccine without compromising efficacy.

Even when adopting the claim construction given in the board's communication under Article 15(1) RPBA, the claimed subject-matter still differed from that disclosed in D9 in the addition of the further antigen. Should the skilled person have considered including another antigen in a vaccination scheme disclosed in D9, there were three options of how the second antigen could be included in the vaccination regime disclosed in D9: i) together with the first injection (DNA), ii) together with the second injection (DNA), or iii) together with the third injection (protein subunit).

If anything, the skilled person would have added the further antigen to the first injection because this took place when the pigs were 25 days old, while the second injection and the third (protein) injection were administered at an age of 39 days. In general, it would be desirable to have any effect of the further component (even if not required in itself to lead to protection, but merely to aid in the generation of the immune response as a further immunogenic component) as early as possible. Thus, even if the skilled person had decided to include a further antigen, they would not have arrived at the claimed subject matter.

Respondent II had submitted that the skilled person would not have administered a PRRS vaccine along with the PCV DNA vaccine. This was not correct. Firstly, the second antigen in the claim was not limited to PRRS vaccines. Secondly, even D9 itself in trial 1 taught that DNA and protein vaccines can be administered at the same time, in form of the second and third shot two weeks after first DNA shot (point 2.4.1). There was no

teaching in the art that suggested that DNA and protein vaccines cannot be administered together, whether they are mixed prior to administration or not.

Auxiliary requests 1 to 4
Admittance (Article 12(4) RPBA)

These auxiliary requests should be admitted because they met the requirements for admittance set out in Article 12(4) RPBA. They had been filed with the statement of grounds of appeal, which was the earliest suitable moment. Their filing was triggered *inter alia* by the fact that in decision T 2410/19 on a related case, a different claim interpretation on the "one shot" feature was adopted, compared to that in earlier decision T 1021/11. The decision under appeal did not deal with claim construction because it dealt only with an aspect of the requirements of Article 83 EPC which did not depend on claim construction. Moreover, in an *obiter dictum* the opposition division had indicated doubts about whether the claim construction in T 2410/19 would be followed.

Thus the auxiliary requests were filed at the earliest opportunity and the amendments made further supported inventive step even under the claim construction adopted T 2410/19 and T 860/21.
The amendments made were straightforward and overcame the respondents' inventive step objections even under the changed claim construction, while not adding any further complexity or raising new issues. The concept of a dose for the recombinant ORF2 protein was already present within the claim set of the main request. Auxiliary requests 1 to 4 merely restricted this feature in a more narrow way in the independent claims. The claims of these auxiliary requests recited a

significantly smaller dose than that used in D9 and there was no indication or any teaching in D9 or in any other document cited by the respondents that a small dose as recited in the claims would be effective in a one dose vaccine as claimed. Reducing the dose in a vaccine could lead to a reduction of effects, and the present patent showed that the ORF2 protein was a stronger antigen than e.g. inactivated whole virus or isolated viral ORF2 antigen, see paragraph [0116] and example 4.

Accordingly, the claimed invention provided substantial benefits over D9, as it allowed vaccination with much lower amounts of protein, allowing e.g. for more economic vaccination schemes. Starting from D9, the skilled person had no teaching towards the claimed invention, and clearly had no reasonable expectation that a significantly lower dose could obtain the beneficial effects.

XIV. The respondents' submissions relevant to the decision are summarised as follows:

Main request - claim 1

Claim construction

Claim 1 was drafted in the format of a purpose-limited product claim under Article 54(5) EPC and, as such, had to be interpreted as open, in that it did not exclude the administration of other agents prior to or following the administration of the claimed multivalent combination vaccine. Nor did it exclude that the subjects (e.g. pigs) had previously received or would subsequently receive other treatments. The terms 'one dose' and 'single administration' were to be understood

as applying solely to the administration of the claimed vaccine and did not preclude additional administrations of other substances.

This approach to claim construction had been applied by the boards in related cases, in particular in decisions T 2410/19 and T 860/21. In these cases, the board had held that the therapeutic effect recited in a purpose-limited product claim did not need to be achieved exclusively by the claimed product and that the claim format did not impose further restrictions on the treatment regimen or patient population.

Remittal (Article 111(1) EPC and Article 11 RPBA)

The case should not be remitted to the opposition division just because the board announced its intention to deal with inventive step before sufficiency of disclosure. There were several reasons for not remitting the case to the opposition division, including the age of the case and the need for legal certainty. Remitting the case would only prolong uncertainty. Moreover, the claim construction now adopted by the board had been put forward by the respondents since the very beginning of the opposition and was no surprise to the appellant. The appellant had presented its case based on a preferred claim construction without preparing fall back positions in case this was not adopted. Furthermore, there were no special reasons for remittal under Article 11 RPBA, for instance there had been no deficiencies in the proceedings before the opposition division. In any case, parties did not have a right to have all issues in a case dealt with by the opposition division and the board of appeal.

Inventive step (Article 56 EPC)

Regarding inventive step, the preliminary conclusion set out in the board's communication pursuant to Article 15(1) RPBA was correct. The findings reached in case T 860/21 applied equally to the subject-matter of present claim 1, thus the subject-matter of claim 1 lacked an inventive step over several prior art documents, particularly D9 (trial 1).

D9 in trial 1 disclosed a single administration of PCV2 protein in combination with prior or simultaneous DNA injections. The only distinguishing feature of claim 1 was the presence of a second antigen. The patent did not disclose any unexpected technical effect of administering an additional immunogenic active component against another disease causing organism in swine in the context of vaccination against PCV2. Thus, the objective technical problem was merely to provide an alternative vaccine for the same purpose as the one disclosed in D9, i.e. preventing or treating PCV2 infection in piglets.

For the skilled person, the combination of known antigens in a multivalent vaccine was routine and motivated by known advantages such as cost reduction, ease of administration and animal welfare. The purpose of adding one or more further immunogenic active components against another disease-causing organism in swine would normally be to provide protection against the further disease-causing organism(s). It was completely obvious to the skilled person to want to produce combination vaccines for the sake of convenience and no unexpected technical effect of doing so could be derived from the patent.

The appellant had further argued that the claimed invention was not obvious starting from D9, trial 1, on the basis that the skilled person would have combined the second antigen, namely PRRS, with the DNA injection of D9, trial 1, rather than with the PCV2 protein injection. According to the appellant, this would have led the skilled person away from the claimed subject-matter.

However, the skilled person would have been motivated to combine the second antigen with the PCV2 protein, rather than with the DNA encoding ORF2, for several reasons:
a) From a technical perspective, the skilled person would have considered the stability and compatibility of the components, which would have favoured combining the second antigen with the protein rather than with the DNA.
b) In terms of timing, the skilled person would have been inclined to administer additional immunogen, such as *Mycoplasma hyopneumoniae* (Mhyo), PRRS, or *Lawsonia intracellularis,* at the time of the protein administration in trial 1 of D9, which occurred at approximately 5.5 weeks of age. This timing corresponded well with standard vaccination schedules for these pathogens, typically administered between 4 and 7 weeks of age.
c) In any case, the claimed multivalent combination vaccine did not exhibit any surprising technical effect compared to the use of two separate monovalent vaccines. In the absence of a demonstrated synergistic effect or other unexpected benefit arising from the combination of the two immunogens in a single formulation, the claimed subject-matter represented a mere obvious alternative lacking inventive step.

Auxiliary requests 1 to 4
Admittance (Article 12(4) RPBA)

Auxiliary requests 1 to 4 had been filed too late in the proceedings to be admitted. They had not been submitted during the proceedings before the opposition division despite the fact that the objections they aimed to address (particularly those under Article 56 EPC) had been raised by the respondents from the beginning of the opposition proceedings. The 'open' claim construction had also been presented since the beginning of the opposition proceedings. Admitting these claim requests would disadvantage the respondents, who had not had the opportunity to respond to these new claim sets during the opposition proceedings. The appeal proceedings were in principle a review process, and admittance of the auxiliary requests would not be in keeping with this but instead restart the opposition proceedings with claim sets directed to an invention whose subject-matter was not in the focus of the opposition proceedings until now.

In any case, the appellant had had ample opportunity to respond to the respondents' objections earlier, including after receiving the summons to oral proceedings and the preliminary opinion of the opposition division.

These claim requests were therefore not to be admitted under Article 12(4) RPBA. They moreover lacked *prima facie* allowability under multiple EPC provisions. In particular, they did not contribute to inventive step, the claimed invention did not meet the requirements of Article 83 EPC and the claimed subject-matter contravened Article 123(2) EPC.

In relation to the late filing of these claim requests, the appellant had not explained why these requests were not filed earlier or how they overcame the objections raised.

Relevant requests of the parties

XV. The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form based on the set of claims of the main request as filed on 24 September 2021, or alternatively, of auxiliary requests 1 to 4, filed as auxiliary requests 24 to 27 with the statement of grounds of appeal.

It further requested that:

- in case the board considered that any claim request meets the requirements of Article 83 EPC, the case be remitted to the opposition division for further prosecution.

XVI. Both respondents requested that the appeal be dismissed and that none of auxiliary requests 1 to 4 (filed as auxiliary requests 24 to 27 with the statement of grounds of appeal) be admitted into the proceedings.

XVII. The parties also maintained requests for the admittance and non-admittance of various documents and lines of argument, which are not relevant to this decision. They are recorded in the minutes of the oral proceedings before the board. In relation to the issue of inventive step, the board took into account the appellant's substantive submissions and evidence relied upon irrespective of whether the admittance of these submissions was in dispute.

Reasons for the Decision

Main request - claim 1

Claim construction

1. The claim is a purpose-limited product claim under Article 54(5) EPC. The product is a multivalent combination vaccine comprising recombinant PCV2 ORF2 protein and at least one immunogenic active component against another disease-causing organism in swine and an adjuvant. The therapeutic purpose is either (i) the prevention of infection with PCV2, or re-infection with PCV2 or (ii) the reduction or elimination of clinical symptoms caused by PCV2. The claim also specifies that "one dose of the vaccine is to be administered intramuscularly to the subject" and that the therapeutic effect "is obtained by a single administration of the vaccine".

2. There are two contentious points on claim construction. The first concerns whether the therapeutic effect defined in the claim is brought about solely by the administration of one dose of the vaccine. The second concerns whether the expression "a multivalent combination vaccine" means that a therapeutic effect against the non-PCV2 immunogen is a feature of the claim.

3. Regarding the first point, the appellant submitted in writing that the claim requires that the therapeutic effect defined in the claim is brought about solely by the administration of one dose of the vaccine, in particular by the PCV2 ORF2 protein that is comprised therein. The respondents disagreed, arguing that as

long as the piglets receive only a single dose of the claimed combination vaccine, and this contributes to achieving the therapeutic effect, other agents which also contribute to achieving the therapeutic effect may be administered to the piglets, either before, after or at the same time as the claimed vaccine.

4. The board considers that the disputed features

"(i) said prevention of an infection with PCV2, or re-infection with PCV2 or
(ii)said reduction or elimination of clinical symptoms caused by PCV2,
is obtained by a single administration of the vaccine"

mean that the therapeutic effect defined in the claim is achieved by a single administration of the combination vaccine. In other words, in a regimen falling within the ambit of the claim, the subject receives only one dose of the vaccine defined in the claim. However, the wording of the claim does not exclude that compositions that are not the combination vaccine defined in the claim, can contribute to achieving the therapeutic aim defined in the claim. This is reinforced by the fact that the patient group (e.g. piglets) mentioned in the claim is not limited in any way.

This reading of the claim aligns with that adopted in decisions T 2410/19 and T 860/21, which both dealt with a similar issue on claim construction.

5. In relation to the second point, it is noted that Article 54(5) EPC refers to the patentability of any substance or composition referred to Article 54(4) EPC "for any specific use" in a method referred to in

Article 53(c) EPC, provided that such use is not comprised in the state of the art. The subject-matter of a claim under Article 54(5) EPC is therefore a substance or composition for a specific use. Only the specific therapeutic use or therapeutic purpose defined in the claim is a functional feature of the claim. Since the claim includes the wording "for use in a method for (i) the prevention of an infection with PCV2, or re-infection with PCV2 or (ii) the reduction or elimination of clinical symptoms caused by PCV2", only these features are the specific use within the meaning of Article 54(5) EPC and are functional features of the claim. The expression "multivalent combination vaccine" is therefore considered as a reference to the structure, not the function, in the sense of the "specific use" of the claimed composition.

6. In view of these considerations, a therapeutic effect due to the "at least one immunogenic active component against another disease-causing organism in swine" is not a functional feature of the claim. This is not to say that the claim language excludes the possibility that such a therapeutic activity may exist.

Remittal (Article 111(1) EPC, Article 11 RPBA)

7. The appellant requested that if the board were to hold that any claim request meets the requirements of Article 83 EPC, the case be remitted to the opposition division for further prosecution. At the oral proceedings before the board, the topic of Article 83 EPC was not discussed because the board decided to deal with the respondents' objections of lack of inventive step under Article 56 EPC first, thus the condition for remittal did not arise.

8. The board considered whether to remit the case to the opposition division in spite of the above procedural situation and decided not to remit the case to the opposition division for further prosecution. The factors taken into consideration were *inter alia* developments in parallel cases relating to patents owned by the appellant, the possibility to plead the case before two instances, the term of the patent expiring in 2026, considerations of legal certainty and the lack of special reasons for remitting the case.

9. The board further considered that the parties had had ample opportunity in the appeal proceedings to present their respective cases on inventive step, since they had been informed of the board's intention to deal with inventive step in the communication pursuant to Article 15(1) RPBA. The appellant made relevant submissions in its letter dated 8 August 2025.

Inventive step (Article 56 EPC)

10. In view of the above claim construction, the appellant's arguments in favour of inventive step that rely on a claim construction under which the therapeutic effect defined in the claim is brought about solely by the administration of one dose of the vaccine, in particular by the PCV2 ORF2 protein, do not succeed.

11. The appellant also submitted that the claimed subject-matter involves an inventive step even under the claim construction adopted by the board, due to the presence of the "at least one immunogenic active component against another disease-causing organism in swine" (see Section XIII.).

The closest prior art, difference thereto and technical effect

12. The parties agree that document D9 can represent the closest prior art for the claimed subject-matter. It discloses a trial in which "*35 25-day-old SPF piglets were divided into five groups of seven piglets randomized according to sex and weight in our facilities under strictly controlled conditions [...] Piglets from four groups received a first intramuscular injection of DNA plasmid preparation on one side of the neck, followed by a second injection, 2 weeks later on the same side, completed by a third injection of recombinant protein emulsion on the opposite side*" (see page 4566, section 2.4.1). Table 1 on page 4567, concerns a "*Trial no. 1*", where an "*ORF2-vaccine group*" of piglets received:
- an injection 1 at 25 days, comprising DNA encoding PCV2 ORF2 and GM-CSF,
- followed at 39 days by an injection 2 of the same DNA vaccine and of
- a third comprising recombinant PCV ORF2 protein (ORF2 subunit vaccine or protein vaccine).

13. The vaccines in D9 were prepared according to the protocol on page 4566, "*2.4. Vaccination protocol*", which reads "*For 2 ml of emulsion to be prepared, 500 µl of crude lysate from each recombinant baculoviruses (BacOrf1, BacOrf2), alone or in association, were completed to 1 ml of PBS pH 7.2 and mixed with 1 ml of a water-in-oil adjuvant (Montanide IMS 1313 PR provided by Seppic). For the control, 1 ml of crude lysate from wild-type AcNPV was mixed under the same conditions. The preparations were emulsified and stored on ice until inoculation of the pigs*".

14. Ten days after receiving the vaccinations, the pigs were challenged with PCV2 and then monitored for symptoms of PCV2 disease. Table 3 reports the "*Clinical protection of vaccinated groups after PCV2 challenge in trial no. 1*". In the "*Discussion*" section (see paragraph bridging page 4572 and 4573) it is reported that "*vaccination significantly reduced the duration of the pyrexic phase, more efficiently in the Orf2 and Orf1&Orf2-vaccine groups than in the Orf1-vaccine group. Moreover, during the third-week post-infection, only the Orf2 and Orf1 &Orf2 groups showed a significantly reduced growth retardation compared to the CC [challenge control] group, which was more pronounced in the Orf2 group*".

15. In summary, D9 discloses a vaccine comprising recombinant PCV2 ORF2 protein, and a vaccination regimen in which a composition comprising the PCV2 ORF2 protein is administered once to 42 day old pigs (as part of a prime/boost regimen with a DNA vaccine being administered by injection to the pigs at 28 days of age), where the therapeutic effects i) and ii) recited in the claim are achieved and are disclosed in Table 3, as clinical protection against PCV2 challenge, with the ORF2-vaccine group showing no clinical symptoms of post-weaning multisystemic wasting syndrome (PMWS).

16. The difference between the claimed subject-matter and the vaccine/vaccination regimen disclosed in D9 is therefore that the claimed vaccine additionally includes at least one immunogenic active component against another disease-causing organism in swine.

The objective technical problem

17. In its construction of the claim, the board held that a therapeutic effect against the second antigen is not a feature of the claim. No technical effect can be attributed to said difference beyond that the second component, being immunogenic, elicits an immune response. In view of the above difference between the the PCV2 ORF2 protein subunit containing vaccine disclosed in document D9 and the claimed one, the claimed subject-matter can be said to solve the objective technical problem of providing an alternative vaccine for the treatment and prophylaxis of PCV2 infection (i.e. for the therapeutic use defined in the claim).

Obviousness

18. The skilled person, starting from the disclosure in document D9 and seeking a solution to the above problem, would have provided the claimed combination vaccine. In particular, the skilled person would have modified the ORF2 protein vaccine disclosed in D9 (see page 4566, "2.4. Vaccination protocol") and used in trial 1 (see Table 1) to include at least one immunogenic active component against another disease-causing organism in swine. In view of the fact that the skilled person had the aim of merely providing an alternative vaccine to the one disclosed in D9, any solution they chose only had to avoid that the addition of a second immunogenic component significantly impaired the already effective ORF2 vaccine composition. The skilled person, using common general knowledge, could and would have chosen any known immunogenic active component against another disease-causing organism in swine (the common general knowledge

about known immunogenic active components is reflected in paragraph [0131] of the patent) to add to the ORF2 subunit vaccine disclosed in D9 as a solution to the objective technical problem. Since the objective technical problem to be solved was the provision of an alternative vaccine for the treatment and prophylaxis of PCV2 infection, the skilled person needed no incentive or pointer to the claimed solution in the prior art (see also e.g. T 1862/15, Reasons 7.6 and 8.4 and T 1179/16, Reasons 3.4.4).

19. The appellant argued that, when seeking a solution to the objective technical problem, the skilled person would have added the further antigen to the first injection (DNA vaccine) in the prime and boost protocol disclosed in D9. The board is not convinced by this argument. The starting point in the present assessment of inventive step is the PCV2 ORF2 protein subunit vaccine disclosed in D9, not the whole of D9 in general. The problem facing the skilled person was providing an alternative to this ORF2 subunit vaccine, not to the DNA vaccine. Seeking an alternative to the PCV2 ORF2 protein subunit vaccine, and aiming merely to maintain the existing therapeutic effect, the skilled person would have considered adding any known immunogenic active component against other disease-causing organisms in swine to this vaccine, i.e. the ORF2 subunit vaccine. The fact that adding a second immunogenic component to the DNA vaccine disclosed in D9 might also have been obvious does not detract from this conclusion.

20. In view of the above considerations, the subject-matter of claim 1 of the main request lacks an inventive step and the main request is not allowable.

Auxiliary requests 1 to 4, filed as auxiliary requests 24 to 27 with the statement of grounds of appeal

Admittance (Article 12(4) RPBA)

21. Auxiliary requests 1 to 4 were first filed as auxiliary requests 24 to 27 with the statement of grounds of appeal and therefore the decision under appeal was not based on them within the meaning of Article 12(2) RPBA. They thus represent an amendment to the appellant's case.

In accordance with Article 12(4) RPBA, such amendments may be admitted at the discretion of the board in view of *inter alia* the complexity of the amendment, the suitability to address the issues which led to the decision under appeal and the need for procedural economy. In addition, Article 12(6) RPBA provides that the board shall not admit requests which should have been submitted in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

22. In the board's view, the claim requests should have been submitted in the proceedings before the opposition division as the amendments aim to overcome objections raised in the opposition proceedings which the appellant had opportunity to address before the opposition division.

23. More specifically, the amendments introduce a dosage feature into claim 1 with the aim of addressing an objection of lack of inventive step based on document D9, where said objection was successful on appeal *inter alia* because the board adopted a different claim construction from the one argued for by the appellant

(see point 4. above). However, both the claim construction adopted by board and the related objection of lack of inventive step based on document D9 had been made by both respondents already in their notices of opposition (see notice of opposition of respondent I, Section A, 2.3 and Section G, 1.4 and 5, and of respondent II, 5.3 to 5.3.1). The appellant could, in response to these submissions and in the proceedings before the opposition division, have reasonably been expected to submit appropriately amended claim requests and arguments in their favour.

23.1 The fact that the respondents had made the relevant objections in their notices of opposition is also a reason why the board is not persuaded by the argument that the issuance of T 2410/19 and T 860/21 can serve as a justification for not submitting the auxiliary requests in the proceedings before the opposition division.

24. The appellant's further arguments in favour of admittance were:

i) that the decision under appeal dealt only with an aspect of the requirements of Article 83 EPC which did not depend on claim construction. It did not deal with claim construction, which affected the approach taken on inventive step.

ii) the amendments made were straightforward and overcame the respondents' inventive step objections even under the changed claim construction, while not adding any further complexity or raising new issues.

25. These arguments did not persuade the board. The admittance of the auxiliary requests would have

required consideration of new issues on appeal. Specifically, the amendment to include a dosage feature would change the focus of the considerations of inventive step and the admittance of the requests would have resulted in the board having to consider issues that played no role in the proceedings before the opposition division, i.e there would be a fresh case on appeal.

26. In light of the above considerations, the board decided not to admit auxiliary requests 1 to 4 into the appeal proceedings.

Admittance of documents and lines of argument

27. The board did not need to decide on the admittance or otherwise of any document or line of argument whose admittance was disputed. In relation to the issue of inventive step, the board took into account the appellant's substantive submissions and evidence relied upon irrespective of whether the admittance of these submissions was in dispute. By considering these submissions on substance the board also admitted them in the proceedings.

28. Thus, the main request is not allowable and auxiliary requests 1 to 4 were not admitted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated