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Datasheet for the decision of 16 March 2023

Case Number: T 2410/19 - 3.3.04

Application Number: 06850366.3

Publication Number: 1976558

IPC: A61K39/12

Language of the proceedings: EN

Title of invention:
PCV2 immunogenic composition for lessening clinical symptoms in pigs

Patent Proprietor:
Boehringer Ingelheim Animal Health USA Inc.

Opponent:
Eli Lilly and Company

Headword:
PCV2 composition/BOEHRINGER INGELHEIM

Relevant legal provisions:
EPC Art. 54(5), 56

Keyword:
Admissibility of opposition - (yes)
Inventive step - (no)

Decisions cited:
T 0516/89, T 0609/02, T 1021/11, T 1845/14

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Case Number: T 2410/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 16 March 2023

Appellant I: (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)
Appellant II: (Opponent)	Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285 (US)
Representative:	Potter Clarkson Chapel Quarter Chapel Bar Nottingham NG1 6HQ (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 1 July 2019 concerning maintenance of the European Patent No. 1976558 in amended form.**

Composition of the Board:

Chairman	B. Rutz
Members:	A. Chakravarty
	L. Bühler

Summary of Facts and Submissions

I. Both the patent proprietor (appellant I) and the opponent (appellant II) filed appeals against the opposition division's decision that the European patent No. 1 976 558, with the title "*PCV2 immunogenic composition for lessening clinical symptoms in pigs*", amended according to auxiliary request 1 met the requirements of the EPC.

II. In its decision, the opposition division held that the subject-matter of claims 1 and 8 of the patent as granted lacked an inventive step. It dismissed objections under Article 100(a) together with Article 54 EPC and Article 100(c) together with Article 123(2) EPC raised against the patent as granted. It considered and dismissed objections raised under Articles 123(2), 84, 54, 56 and 83 EPC against auxiliary request 1.

III. With its statement of grounds of appeal, appellant I requested as a main request, that the patent be maintained as granted. It further maintained auxiliary requests 1 and 2 filed in the proceedings before the opposition division. With a letter dated 11 November 2020, it filed sets of claims of auxiliary requests 3 to 5.

IV. The following document is referred to in this decision:

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

V. Claim 1 of the patent as granted (main request) reads:

"1. An immunogenic composition for use in a method of preventing lymphadenopathy associated with PCV2 infection in swine, wherein the composition is to be administered once in swine, said composition comprising 4 µg to 200 µg of recombinant PCV2 ORF2 protein as the antigenic component and 100 µg to 10 mg adjuvant per dose, wherein said recombinant PCV2 ORF2 protein has been obtained in that (a) susceptible cells are infected with a recombinant baculovirus vector containing PCV2 ORF2 DNA coding sequences, (b) PCV2 ORF2 polypeptide is expressed by said recombinant baculovirus, and (c) the expressed PCV2 ORF2 polypeptide is recovered from the supernate by filtration and the baculovirus vector inactivated".

Claim 1 of auxiliary request 1 differs from claim 1 as granted in that it includes the text "wherein said composition, by a one dose intramuscular administration, is effective for the prevention of lymphadenopathy associated with PCV2 infection in swine", after the word 'inactivated'.

Claim 1 of auxiliary request 2 differs from claim 1 as granted in that it includes the text "wherein the prevention of lymphadenopathy associated with PCV2 infection is obtained by a single administration of the immunogenic composition", after the word 'inactivated'.

Claim 1 of auxiliary request 3 is identical to claim 1 of the patent as granted. Claim 1 of auxiliary request 4 is identical to claim 1 of auxiliary request 2. Claim 1 of auxiliary request 5 is identical to claim 1 of auxiliary request 1.

VI. A number of requests concerning the admittance and/or non-admittance of documents were filed in writing by both parties and maintained at the oral proceedings before the board. However, these requests are not relevant to the board's decision and are therefore not reproduced here.

VII. The arguments of appellant I, relevant to the decision, are summarised as follows.

Admissibility of the opposition

The opposition was inadmissible under Rule 77(1) EPC and Rule 76(2)(c) EPC, due to a lack of substantiation. Each page of the grounds of opposition filed on 14 December 2017 by the opponent was expressly marked as "Privileged and confidential, Attorney-client communication".

The opposition division had been wrong to take the document indicating the facts and evidence into account. The correct procedure was set out in decision T 516/89, the headnote of which read:
"*Papers marked 'confidential' which do not belong to classes of documents to be excluded from file inspection (Rule 93 EPC; decision of the President of the EPO, OJ EPO 1985, 316) are returned to the party concerned, without taking note of their contents*" (emphasis added)

Following this principle, as the entire substantiation of the grounds of opposition was marked as "confidential", it should have been returned to the opponent, and the grounds of opposition contained therein should have been considered as not having been

filed. The opposition was therefore inadmissible under Rule 77(1) EPC and Rule 76(2)(c) EPC.

Main request - claim 1
Claim construction

The claimed subject-matter was a purpose limited product, i.e. a second medical use. The claimed medical use, however, did not include embodiments in which the recited effect was brought about by the recited features in combination with other features, such as previous vaccination steps, not given in the claim. This construction was a logical consequence of the fact that a medical use claim imparted a causative link between the recited effect and the recited technical features.

In the present case, the single administration of the vaccine was a dosage regime feature under the legal standard established in G 2/08. The claim linked the technical features (the compound and the administration, i.e. the one dose administration) to the recited medical effect. The legal situation was also explained in the Guidelines for examination, 2022, Part G, Chapter VI-6, point 7.1.2. The claim at hand was similar to one specifying that a substance be administered three times daily. Such a claim did not include administration 1x or 4x daily. It would be inconsistent with the above case law to read the animals mentioned in the claim as potentially having been "pre-treated animals" (either with protein or with DNA). Indeed, the pre-treatment would not be possible if the claim were (correctly) understood to require that the effect was achieved by the recited technical features only.

The board's preliminary view on claim construction and novelty with regard to document D9 expressed in its communication under Article 15(1) RPBA was inconsistent with the board's (in another composition) decision in case T 1021/11, which concerned the same case and the same claims, in examination appeal proceedings.

Novelty (Article 54 EPC)

In view of the claim construction above, a relevant prior art document had to disclose that administering a single dose PCV2 ORF2 protein alone was suitable for preventing lymphadenopathy associated with PCV2 infection in swine. No such teaching was to be found in any of the cited documents. For instance, document D9 described a two (or multiple)-shot vaccination regime that comprised one dose of the ORF2 protein and at least one dose of another vaccination compound, such as a DNA vaccine. It did not disclose that above mentioned therapeutic the effect could be achieved with one dose of ORF2 protein.

Finally, even if the board's preliminary claim construction was adopted and the only difference between the claimed subject-matter and that in document D9 was the specified amount of adjuvant per dose, the claimed subject-matter was not obvious. The amount of adjuvant specified in the claim was significantly lower than that used in document D9 so that the skilled person would not have considered using it. This could be calculated from the disclosure in document D9, that 1 ml of a water-in-oil adjuvant (Montanide) was mixed with 1 ml of protein in solution (see page 4566, right-hand column, section 2.4). Based on a density of slightly less than 1 g/ml, it was apparent that about

1 g adjuvant per dose had been used, as compared to 100 µg to 10 mg adjuvant per dose in the claim.

Auxiliary request 1

The amendment to claims 1 and 8 further codified that the technical effect resulted from a single administration of the composition comprising 4 µg to 200 µg of recombinant PCV2 ORF2 protein as the antigenic component.

The opposition division's findings in respect of auxiliary request 1 regarding the inventiveness of the single-shot vaccination protocol were also in complete agreement with the conclusions of the present board in a different composition in decision T 1021/11, wherein the subject matter of claims 1 and 8 was held to be inventive over the same prior art document.

Auxiliary request 2

In case the board were to decide that neither the main request nor auxiliary request 1 were allowable, then the patent should be maintained on the basis of the set of claims of auxiliary request 2.

Auxiliary requests 3 to 5

The opponent had argued that the repercussive effect of claim 6 meant that claim 1 encompassed a vaccine comprising baculoviral vector that had not been inactivated, i.e. that can replicate within the host and produce antigen following injection.

While, this view was incorrect, auxiliary requests 3 to 5 were submitted in direct response to this objection.

They corresponded exactly to the main request and to auxiliary requests 1 and 2 respectively, except that claim 6 as granted has been deleted.

VIII. The arguments of appellant II, relevant to the decision, are summarised as follows.

Admissibility of the opposition

The situation considered in decision T 516/89 and the present one differed. In the case underlying T 516/89, the board's registrar twice asked the appellants whether the papers marked 'CONFIDENTIAL' should be returned or transmitted to the respondent. In response, the appellants requested the President of the European Patent Office to order under Rule 93(d) EPC that the respective documents should be excluded from public file inspection.

In the present case, the opposition division made no inquiry of the opponent as to how to treat the notice of opposition. If it had, the opposition division would have been informed that the document was not confidential. Presumably no such inquiry was made because it was so clear that the grounds of opposition were not confidential.

In any event, the intentions of the party that submits a document are paramount. If those intentions are not clear, then inquiries are made.

Rule 76(2)(c) EPC said nothing about any confidentiality marking. It simply required there to be some grounds of opposition. The opposition contained grounds of opposition that complied with all the requirements of Rule 76(2)(c) EPC.

Main request (patent as granted) - claim 1
Claim construction

It was common ground that the claim was for a purpose-limited product under Article 54(5) EPC. However, contrary to appellant I's view, the claimed medical use could include the administration of other antigenic compositions to the swine either before, after or at the same time as the composition defined in the claim. In other words, the swine defined in the claim were not necessarily naïve in relation to PCV2 vaccination or infection, as long as they did not receive more than one dose of the composition defined in the claim as part of the "method of preventing lymphadenopathy associated with PCV2 infection in swine". Thus, the claim was not directed to a true "one shot" vaccination but was for an immunogenic composition for use 'in' a method of preventing lymphadenopathy associated with PCV2 infection in swine, which was to be administered once to pigs where said method could include vaccinating swine with e.g. a DNA vaccine but no more than a single administration of PCV2 ORF2 protein.

Under G 2/08, novelty could reside in a dosage regimen, however, the claim did not define a dosage regimen. In particular, the claim did not specify anything about
- whether the pig had previously received a dose of a different composition (e.g. one containing plasmids),
- whether the pig would subsequently receive a dose of a different composition (e.g. containing immune stimulants or a subclinical dose of live virus, as in the patent itself),
- whether the pig had previously been exposed to PCV2
- the specific pig in which the symptoms were prevented e.g. if it was a sow, vaccinated to prevent symptoms in the piglet.

In summary, claim 1 as granted did not state that the technical effect of preventing lymphadenopathy was achieved solely as a result of the administration of the ORF2-containing composition because it did not state that the medical use consisted of a single administration of the claimed composition.

This reading of the claim was not in contradiction to the case law on second medical use. For instance decision T 1319/04, cited by appellant I, dealt with a composition "for use in the treatment by oral administration once per day prior to sleep". In contrast the claim at issue just stated that the composition was to be administered once. It did not say that the effective treatment was achieved solely by said single administration.

Inventive step (Article 56 EPC)

Assuming that the subject-matter of claim 1 was novel over the disclosure in document D9 because said document did not unambiguously disclose an amount of adjuvant in the range of 100 µg to 10 mg, it lacked an inventive step. Firstly, the claim did not specify any particular adjuvant. Secondly, the patent did not contain any comparative data showing a technical effect attributable to the claimed (and very broad) range of 100 µg to 10 mg of adjuvant. The problem was therefore just to provide an alternative to the amount of adjuvant that was used in document D9.

The use of an adjuvant was standard in the art of vaccine composition, (see for example the list in document D5, column 27, lines 19 to 25). The amount of the adjuvant would be chosen on the basis of routine optimisation, the manufacturer's directions, and/or on

the basis of the amounts of known adjuvants that had been found to be effective for other antigens. The claimed subject-matter thus lacked an inventive step over the disclosure in document D9 alone, in the light of common general knowledge or in combination with the disclosure in document D5.

Auxiliary request 1 - claim 1

Claim construction

The amendment compared to claim 1 as granted was to state at the end of the claim that the prevention of lymphadenopathy associated with PCV2 infection was obtained by a single administration of the immunogenic composition. Appellant I's view that this meant that the prevention of lymphadenopathy was obtained as a result of a single administration of the defined composition, even though the vaccination regimen might not consist of the administration of the defined composition, was not correct and not reflected by the wording of the claim.

Inventive step (Article 56 EPC)

In view of the above considerations, the conclusion on inventive step given for claim 1 as granted applied equally to claim 1 of auxiliary request 1.

Auxiliary requests 2 to 5

The arguments on claim construction and inventive step above applied equally to claim 1 of these requests.

IX. Appellant I requested:

- that the opposition be rejected as inadmissible under Rule 77(1) EPC;
- that the decision under appeal be set aside and that the patent be maintained as granted;
- alternatively, that the patent be maintained on the basis of any of the sets of claims of auxiliary requests 1 to 5, where auxiliary requests 1 and 2 were filed in the proceedings before the opposition division and auxiliary requests 3 to 5 were filed with the letter dated 11 November 2020.

X. Appellant II requested that the decision under appeal be set aside and that European patent No. 1976558 be revoked.

Reasons for the Decision

Admissibility of the opposition

1. The board decided that the opposition was admissible. As noted by the opposition division in the decision under appeal, the notice of opposition must be taken into account even though it was marked 'confidential', because a notice of opposition is by its nature, not confidential.

2. No correction of the notice of opposition under Rule 139 EPC was needed because the opposition division correctly understood from the context of its filing that the notice of opposition was not confidential.

3. The present case also differs from that dealt with in decision T 516/89, referred to by the parties. In that case, the emphasis lay on whether or not to exclude

certain documents, marked as confidential and also accompanied by a letter requesting them to be treated as such and excluded from file inspection - "*With two letters the registrar of the Board made inquiries whether these papers should be returned to the Appellants or should be transmitted to the Respondents. In reply, on 27 December 1989 the Appellants requested the President of the European Patent Office to order under Rule 93(d) EPC that the respective documents should be excluded from public file inspection*" (see decision T 516/89, Facts and Submissions, section V.). The President of the EPO decided that the documents could not be so excluded. After this decision of the President of the EPO, the Board returned the documents marked 'CONFIDENTIAL' to the Appellants, informing them *inter alia* that no member of the Board had taken note of these documents.

4. This procedure was not remarked on or dealt with in the reasons for the decision.

5. In contrast to the situation in T 516/89, in the present case there was no request to exclude the document in question (the Grounds for Opposition) from file inspection, nor was there any complaint by the affected party that exclusion from file inspection had not occurred. In view of these differences, the procedure followed in the above mentioned decision is not applicable to the present case.

Main request - claim 1

Claim construction

6. Appellant I is of the view that the claim relates to an immunogenic composition comprising recombinant PCV2

ORF2 protein for use in a method for preventing lymphadenopathy associated with PCV2 infection in swine, where the therapeutic effect is achieved solely by single administration of the immunogen PCV2 ORF2. In other words, it considers that the only antigenic component responsible for achieving the therapeutic aim of preventing lymphadenopathy in swine, is the PCV2 ORF2 protein and that the method in which the composition is used and which achieves the therapeutic aim cannot comprise vaccinating the swine with any other immunogen, in particular before they receive the single dose of PCV2 ORF2 protein defined in the claim.

7. As is common ground, the board considers that the claim is for a purpose-limited product under Article 54(5) EPC (i.e. a second medical use). The product is a composition comprising PCV2 ORF2 protein, characterised by the process of its production, and an adjuvant, where the adjuvant can be any adjuvant. The therapeutic aim defined in the claim is preventing lymphadenopathy associated with PCV2 infection in swine. The claimed composition comprises 4 µg to 200 µg of recombinant PCV2 ORF2 protein as the antigenic component and 100 µg to 10 mg adjuvant per dose and is to be administered once in swine .

8. The feature "wherein the composition is to be administered once in swine" means that the animals treated receive only a single administration of the composition defined in the claim. However, in agreement with appellant II, the board considers that the term "swine" mentioned in the claim includes any swine, regardless of its vaccination status. Furthermore, the term "once" does not exclude that the method of preventing lymphadenopathy, defined in the claim, includes the administration to the animal of other

immunogens or immunogenic compositions which do not comprise PCV2 ORF2 protein.

9. Appellant I argues that the claim does not allow for the therapeutic effect to be brought about by the recited features in combination with other features not recited in the claim, such as previous vaccination steps, as this is, in its view, a logical consequence of acknowledging that a medical use claim imparts a causative link between the recited effect and the recited technical features.

10. Appellant II on the other hand, is of the view that the claim is not for a 'one-shot' regimen, schedule or protocol but, as reflected in the claim language, for an immunogenic composition for use "in" a method of preventing lymphadenopathy associated with PCV2 infection in swine, which composition is to be administered once to pigs.

11. In construing the claim, the board follows the well established rule of giving the terms used their ordinary meaning and ruling out illogical interpretations or interpretations that are technically not sensible, while giving the parameters used their broadest technically sensible meaning as seen by the skilled reader (c.f. T 1845/14, reasons 11). The board is not convinced by appellant I's argument above because the wording of the claim does not support this reading. In particular, the only requirement imparted by the expression "wherein the composition is to be administered once in swine" is that the composition defined in the claim is administered only once in the course of the method defined in the claim. The skilled person reading the claim could derive no additional limitations or features from this phrase, other than

the above mentioned one, which is unambiguously supplied by the wording of the claim.

12. Appellant I also argues that the purpose-limited product format establishes a causal link between the technical features in the claim and the recited effect, meaning that the only possible reading of the claim is one in which the one dose administration of the recited compound on its own achieves the recited effect when administered once to pigs.

13. The board is of the view that appellant I has misunderstood the effects of the claim format established by Article 54(5) EPC. Article 54(5) EPC establishes a special concept of novelty for substances or compositions for which a first medical use is already known (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, I.C. 7.2.1), together with a corresponding purpose-limited product claim format. In such claims, the claimed therapeutic effect is a functional technical feature of the claim (see e.g. T 609/02, reasons 9).

14. In the present case "use in a method of preventing lymphadenopathy associated with PCV2 infection in swine" is a feature of the claim. However, the claim format does not establish any further special rules on claim construction. Thus, although the claimed product must have an effect in the recited therapeutic method, the format does not impose any further restrictions, such as a requirement that the therapeutic purpose (here, preventing lymphadenopathy associated with PCV2 infection in swine) must be achieved **only** by the claimed product. Indeed, imposing such a limitation would go against the above mentioned, established rules of claim construction.

15. In relation to appellant I's submission that the board's view on novelty with regard to the distinction over document D9 is inconsistent with its decision in T 1021/11 (by this board in a different composition), it can be noted that in both cases the board adopts the same claim construction. However, the present board, in contrast to that in T 1021/11, has taken into account that document D9 *inter alia* discloses a vaccination regime in which swine receive a single dose/shot of an immunogenic composition comprising recombinant PCV2 ORF2 protein in combination with a DNA plasmid injection (see Table 1, "Orf2-vaccine group"). Finally, as a matter of law, the board is not bound by its decision in the examination appeal (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, V.A.10.3)

16. In conclusion, appellant I's arguments do not persuade the board that the claim should be construed as requiring that the therapeutic effect is brought about solely and entirely by a single administration of the composition defined in the claim.

Inventive step (Article 56 EPC)

17. Document D9 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; emphasis by the

board). As can also be taken from Table 1 on page 4567, the "*ORF2-vaccine group*" received injection 1 at 25 days, comprising DNA encoding PCV2 ORF2 and GM-CSF, followed by an additional DNA vaccine and a composition comprising recombinant ORF2 protein as injection 2.

18. The opposition division held that the claimed subject-matter differs from the vaccination protocol disclosed in document D9 only in that a specific amount of adjuvant was used, as compared to an unknown amount in document D9.

19. In its appeal, appellant I contests the opposition division's decision that the subject-matter of claim 1 lacks inventive step with respect to the disclosure in document D9. In the written appeal proceedings, its only rebuttal was that the opposition division had construed the claim incorrectly, in particular, that it had erred in determining that the claim did not impart a limitation on the administration of other compositions in the method, as long as the composition comprising PCV2 ORF2, defined in the claim, was administered only once.

20. The board has, above, explained why it agrees with the opposition division's claim construction. Thus, appellant I's argument on inventive step fails.

21. During the oral proceedings before the board, appellant I also argued that, even if the claim were construed as done by the board and the difference between the disclosure in document D9 and the claimed subject-matter lay in the presence of 100 µg to 10 mg adjuvant per dose, the claimed subject-matter was not obvious over the disclosure in document D9 because the amount of adjuvant used in the claim composition would

not have been obvious to the skilled person starting from the amount of adjuvant used in the immunisation done in document D9.

22. Notwithstanding that this was a late argument, it is not persuasive. Firstly, the calculation on the amount of adjuvant used in document D9 presented by appellant I at the oral proceedings is not convincing. Document D9 specifies that for the protein vaccine, 1 ml of water-in-oil adjuvant (Montanide) was mixed with one millilitre of lysate (see page 4566, right-hand column, section 2.4). This disclosure allows no direct comparison with the adjuvant amount specified in the claim (100 µg to 10 mg adjuvant per dose) because the proportion of adjuvant in the water-in-oil emulsion is not known. Thus, the weight of adjuvant used in document D9 is not known. In terms of the amount of adjuvant, the difference between document D9 and the claim is that in the former it is not known and in the latter it is specified. The appellant's view that the amount of adjuvant specified in the claim is significantly lower than that used in document D9 cannot be endorsed.

23. Secondly, the claim does not specify a particular type of adjuvant but only specifies an amount of 100 µg to 10 mg of adjuvant per dose. As the board understands it, this range is large enough to accommodate the standard, commonly used amounts of adjuvant, regardless of type (see also paragraphs [0043] to [0046] of the patent). Appellant II suggests that the skilled person would follow the manufacturer's instructions when deciding on the amount of adjuvant to use per dose and that in doing so they would arrive at a dose as defined in the claim. In the absence of a convincing rebuttal, the board is persuaded that this is correct.

24. Finally, no technical effect has been shown or suggested to be associated with any difference in the amount of adjuvant used, which must therefore be regarded as arbitrary. An arbitrary choice from a host of possible solutions cannot be considered inventive if not justified by a new technical effect that distinguishes the claimed solution from the other solutions (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, I.D.9.21.9a))

25. In view of the considerations set out above, the board concludes that the subject-matter of claim 1 lacks an inventive step.

Auxiliary request 1 - claim 1

Inventive step (Article 56 EPC)

26. Claim 1 differs from claim 1 of the main request in that it includes the additional wording "wherein said composition, by a one dose intramuscular administration, is effective for the prevention of lymphadenopathy associated with PCV2 infection in swine".

27. In the decision under appeal, the opposition division, when considering the clarity of the claim, held that "*The scope of the claim is unambiguous in its requirement that a single administration of the composition defined according to the claim must yield the claimed effect*" (emphasis added by the board). In view of this claim construction, the opposition division then decided that the claimed subject-matter involved an inventive step over the disclosure in document D9. Appellant I relied on the claim

construction of the opposition division in its submissions on inventive step.

28. The board, however, is of the view that the additional wording "wherein said composition, by a one dose intramuscular administration, is effective for the prevention of lymphadenopathy associated with PCV2 infection in swine" does not alter the meaning of the claim compared to claim 1 as granted. The reason for this is that the features imparted by this wording are already features of claim 1 as granted. Specifically, there is nothing in the additional wording to limit the swine to naive animals (e.g. ones that have not been previously vaccinated against PCV2 with a different composition). Nor does the wording exclude that 'effective prevention' by intramuscular administration of 'one dose' of the composition defined in the claim is part of a 'method' which achieves this aim but also comprises administering other, different immunogens to the swine.

29. In view of this claim construction, the only difference between the subject-matter of claim 1 as granted and claim 1 of auxiliary request 1 is the "intramuscular administration". However, the route of administration used for injecting the PCV2 ORF2 protein in document D9 was also intramuscular (see page 4566, right hand column, section 2.4.1). Thus, this feature does not distinguish the claimed subject-matter from that in document D9 and therefore cannot contribute to the inventive step of the claimed subject-matter, which therefore lacks an inventive step for the reasons given for the subject-matter of claim 1 of the main request above.

Auxiliary request 2 - claim 1

30. This claim differs from claim 1 of the patent as granted in that it has the additional wording "wherein the prevention of lymphadenopathy associated with PCV2 infection is obtained by a single administration of the immunogenic composition". As for claim 1 of auxiliary request 1, this amendment was intended to emphasise that the therapeutic effect is brought about solely by the immunogenic composition defined in the claim. The board, however, considers that it does not achieve this aim and that the subject-matter claimed is identical to that of claim 1 of the main request - the added features are merely a repetition of features already present in claim 1 as granted. The claimed subject-matter lacks an inventive step for the same reasons as given for the subject-matter of claim 1 of the main request.

Auxiliary requests 3 to 5 - claim 1

31. Auxiliary requests 3 to 5 correspond exactly to the main request and auxiliary requests 1 and 2 respectively, except that claim 6 as granted has been deleted. Thus, claim 1 of these requests is identical to claim 1 as granted and claim 1 of auxiliary requests 1 and 2, respectively. The finding of lack of inventive step for the main request and auxiliary requests 1 and 2 therefore applies to these requests equally.

32. In view of the above considerations, no claim request is allowable. Thus, the patent must be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

I. Aperribay B. Rutz

Decision electronically authenticated