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Datasheet for the decision of 20 February 2024

Case Number: T 0860/21 - 3.3.04

Application Number: 06848471.6

Publication Number: 1968630

IPC: A61K39/295, A61K39/04, A61K39/12

Language of the proceedings: EN

Title of invention:
Multivalent PCV2 immunogenic compositions

Patent Proprietor:
Boehringer Ingelheim Animal Health USA Inc.

Opponents:
Elanco US Inc.
Intervet International B.V. (opposition withdrawn)
Laboratorios Hipra, S.A.

Headword:
Multivalent PCV2 composition/BOEHRINGER INGELHEIM

Relevant legal provisions:
EPC Art. 56, 111(1)
RPBA 2020 Art. 13(2)

Keyword:
Inventive step - (no)
Amendment to appeal case - justification by party (no)
Remittal - (no)

Decisions cited:
T 1319/04, T 1020/11, T 2410/19

Catchword:

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European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0860/21 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 20 February 2024

Appellant I: (Patent Proprietor)	Boehringer Ingelheim Animal Health USA Inc. 3239 Satellite Boulevard, Bldg. 500 Duluth, GA 30096 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Appellant II: (Opponent 1)	Elanco US Inc. 2500 Innovation Way Greenfield, IN 46140 (US)
Representative:	Potter Clarkson Chapel Quarter Mount Street Nottingham NG1 6HQ (GB)
Appellant III: (Opponent 3)	Laboratorios Hipra, S.A. Avda. La Selva, 135 17170 Amer (ES)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 28 April 2021 concerning maintenance of the European Patent No. 1968630 in amended form.**

Composition of the Board:

Chairwoman	D. Luis Alves
Members:	A. Chakravarty
	M. Blasi

Summary of Facts and Submissions

I. European patent 1 968 630, with the title "*Multivalent PCV2 immunogenic compositions*", was opposed by three opponents. In an interlocutory decision, the opposition division decided that the patent, as amended in the form of auxiliary request 1, met the requirements of the EPC.

II. The patent proprietor (appellant I; Boehringer Ingelheim Animal Health USA Inc.) and opponents 1 (appellant II; Elanco US Inc.) and 3 (appellant III; Laboratorios Hipra, S.A.) all filed appeals against the opposition division's decision. Opponent 2 had withdrawn its opposition during the proceedings before the opposition division.

III. In this decision the parties will be referred to by their roles in the opposition proceedings.

IV. In the decision under appeal, the opposition division considered grounds for opposition under Article 100(a) EPC for lack of novelty and lack of inventive step (Articles 52(1), 54 and 56 EPC), Article 100(b) EPC, and Article 100(c) EPC. It held that the subject-matter of the set of claims of the main request, filed with the letter dated 3 April 2020, did not meet the requirements of Article 83 EPC.

V. With its statement of grounds of appeal, the patent proprietor re-filed sets of claims of the main request (identical to the main request considered by the opposition division) and auxiliary requests 1 to 15, where requests 1 to 8 were filed in the proceedings

before the opposition division. Auxiliary requests 9 to 15 were filed for the first time in appeal.

VI. The patent proprietor and opponents 1 and 3 filed statements of grounds of appeal. The patent proprietor filed a reply to the opponents' statements of grounds of appeal (dated 24 January 2022) and opponents 1 and 3 replied to the patent proprietor's statement of grounds of appeal (with letters dated 21 December 2021 and 24 January 2022). The patent proprietor submitted a further letter dated 23 December 2022. Opponent 1 submitted further letters dated 25 November 2022, 31 March 2023, 23 June 2023, 7 August 2023, 20 October 2023. Opponent 3 submitted further letters dated 15 September 2022, 26 April 2023, 29 August 2023, 31 October 2023.

VII. The parties had request oral proceedings and consequently, the board issued a summons to oral proceedings. It subsequently issued a communication under Article 15(1) RPBA, dated 10 January 2024, setting out its preliminary opinion on various matters of the appeal case.

VIII. After the issue of the board's communication pursuant to Article 15(1) RPBA, the parties made the following submissions:

The patent proprietor submitted letters dated 12 February 2024 and 19 February 2024.

Opponent 1 submitted letters dated 16 February 2024 and 19 February 2024.

Opponent 3 submitted a letter dated 15 February 2024.

IX. With the letter dated 12 February 2024, the patent proprietor withdrew the main request and auxiliary requests 1 to 6 and 8 to 14. It maintained former auxiliary request 7, filed on 3 April 2020, as the main request and former auxiliary request 15, filed on 8 September 2021, as auxiliary request 1. In the letter it also stated "*Both pending requests recite that the vaccine comprises a carbomer adjuvant. The application as filed demonstrates the use of carbomer, specifically Carbopol, in the examples and notes that compared to the IMS1314 adjuvant, it does not have any adverse events, such as injection site reactions, see application as filed page 140, first paragraph and page 135, last paragraph. The commercial product based on the patent, CircoFLEX, is equally formulated with carbomer (see e.g. D83). None of the cited art discloses or renders obvious the subject matter of new MR or new AR1*".

X. In their letters dated 16 February 2024 and 15 February 2024, opponents 1 and 3 respectively replied to the patent proprietor's submission dated 12 February 2024. Both raised objections to the patent proprietor's latest submissions on inventive step in view of the effect of the carbomer adjuvant.

XI. Oral proceedings were held as scheduled. During the oral proceedings, the patent proprietor withdrew auxiliary request 1. At the end of the proceedings, the Chair announced the decision of the board.

XII. The following documents are 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.

D159: Hoogland MJ *et al., "Effects of adjuvants on porcine circovirus type 2-associated lesions*". J. Swine Health Prod., 2006, 14(3), 133-139.

XIII. Claim 1 of the main request (former auxiliary request 7) reads:

"1. A combination vaccine for use in a method for

(i) lessening the severity of clinical symptoms associated with PCV2 infection, and/or
(ii) preventing PCV2 infection,

in piglets by administration of one dose of said vaccine, the vaccine comprising:

1.6 µg to 400 µg/dose recombinant PCV2 ORF2 protein, a PRRS antigen, and an adjuvant, wherein the adjuvant is carbomer".

XIV. The patent proprietor's submissions, relevant to the decision are summarised as follows.

Main request

Admittance

The claim request had been filed during the proceedings before the opposition division in response to objections under Article 123(2) EPC and was refiled with the statement of grounds of appeal. The request thus met the requirements of Rule 80 EPC. It had been admissibly raised and maintained in the proceedings

leading to the decision under appeal within the meaning of Article 12(4) RPBA. Article 12(4) RPBA established that a claim request which had been admissibly raised and maintained in the proceedings leading to the decision under appeal was not to be regarded as an amendment to the case. Its admission was therefore not subject to the conditions set out in Article 12(3) RPBA and the board did not have discretion not to admit it. In any case, the request had been substantiated in regard of Article 123(2) EPC.

It was also requested that opponent 1's request not to admit the main request, itself not be admitted because it was submitted with the letter dated 16 February 2024 and as such represented an amendment to its case, which was prohibited under Article 13(2) RPBA unless there were cogent reasons to justify its admittance. There were no such reasons.

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

If the main request were admitted, the case should be remitted to the opposition division for further prosecution. Remittal of the case would make it possible for the opposition division as well as the board to decide on inventive step in view of the carbomer feature.

Remittal would also be beneficial to the other parties. With the delivery of decisions T 1020/11 and T 2410/19, the framework for interpretation of claim 1 had changed during the appeal proceedings.

Claim 1

Claim construction

The claim was a purpose-limited product claim, i.e. it related to a second medical use of that product. The medical effect recited in the claim was the lessening of the severity of clinical symptoms associated with PCV2 infection and/or preventing PCV2 infection. The claim further recited that the effect is obtained by a single administration of the vaccine. It was of note that the medical effects recited in claim 1 were directed towards treating PCV2 infection only but did not require that the vaccine had efficacy against PRRS.

The opposition division had correctly noted that the second medical use format established a link between the administration of one dose of the claimed vaccine and the attainment of the medical effect. This effect could not be brought about by the recited features in combination with other features not mentioned in the claim, such as previous vaccination steps, as these were not recited in the claim. This reading of the claim was a logical consequence of the fact that a medical use claim imparted a causal 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 claim at hand was similar to one specifying that a substance be administered once a day (as dealt with in decision

T 1319/04). Such a claim did not include administration e.g. twice daily.

Inventive step (Article 56 EPC)

Non-obviousness based on the "one shot" feature

Document D9 disclosed a multiple shot vaccination, a so-called "prime and boost approach". This was fundamentally different from the claimed one-shot protein vaccination, where the immune system had to launch a full response, including humoral and cellular aspects of the immune response, in response to the first and only encounter with the antigen. The requirements in both approaches were thus significantly different.

Nothing in document D9 indicated to the skilled person that an efficacious one shot PCV2 vaccine could be provided to prevent PCV2 infection. Instead, based on the data of document D9, the authors suggested that a prime-boost approach might be successful.

Non-obviousness based on the "PRRS antigen" and "carbomer" features

The claim also recited that the vaccine comprised a carbomer adjuvant. The application as filed demonstrated the use of carbomer, specifically Carbopol, in the examples and disclosed that it had no adverse events, such as injection site reactions, compared to the IMS1314 adjuvant (see application as filed page 140, first paragraph and page 135, last paragraph). CircoFLEX, the commercial product based on the patent, was also formulated with carbomer. None of the cited art disclosed or rendered this subject-matter

obvious. The carbomer feature was an additional difference over the vaccine disclosed in document D9. A further effect of this difference was increased immunogenicity (see paragraph [0112] of the patent). The skilled person starting from the disclosure in document D9 and seeking a vaccine with increased immunogenicity would not have expected that a carbomer adjuvant would solve this problem.

In the event that the effect of increased immunogenicity was not taken into account, then the vaccine including the feature carbomer represented a non-obvious alternative to other adjuvants.

It was further noted that document D9 did not suggest the addition of a further antigen, such as PRRS, but instead suggested a prime boost approach with a PCV2 subunit vaccine.

Admittance of arguments relating to the carbomer feature (Article 13(2) RPBA)

The submissions made at oral proceedings and set out in the letter dated 12 February 2024, in support of inventive step that the use of carbomer, specifically Carbopol adjuvant was not associated with adverse events, did not represent a change of case and were admissible. The carbomer feature was taken from the granted claims and had been present in an independent claim of auxiliary request 7 in the opposition proceedings. Relying on the benefits of this feature in the oral submissions on inventive step was not a change of case, nor did these submissions take the opponents by surprise because this technical effect (lack of adverse effects) was disclosed in the application as filed. An extensive discussion amongst the parties on

the carbomer feature had already taken place in the written proceedings, albeit under a different heading.

Even if there was an amendment of the appeal case (which was denied), this was a legitimate reaction to the board's preliminary opinion set out in the communication under Article 15(1) RPBA and to the developments which related to parallel cases: while *ex parte* decision T 1020/11 had found claims to a one shot composition allowable, in decision T 2410/19 and the related preliminary opinion, the competent board had adopted a claim construction deviating from the patent proprietor's interpretation. This second decision was issued in 2023, after the present appeal had already been filed and it fundamentally changed the case. It was legitimate to await this board's preliminary opinion in these exceptional circumstances.

The line of argument that vaccines comprising a carbomer adjuvant had improved immunogenicity and therefore represented a non-obvious alternative, had been made in the written opposition and appeal proceedings. It was accepted that the sections relied upon had been presented in the context of Article 123(2) EPC and Article 83 EPC and not of inventive step, but immunogenicity had been discussed and thus the arguments were not new. As the technical effect was described in the application as filed, relying on this effect was not a change of the appeal case.

In summary, the claimed subject-matter was not obvious over the prior art firstly because of the "one-shot" feature and secondly because of the carbomer adjuvant feature and the technical effects of these features.

XV. The arguments of the opponents are summarised as follows:

Main request

Admittance

With its letter of 12 February 2024, the patent proprietor withdrew the previous main request and previous auxiliary requests 1 to 6 and 8 to 14, making previous auxiliary request 7, the main request.

The admittance of the main request was contested because the main request had not been substantiated. Although it had been filed as auxiliary request 7 with the patent proprietor's statement of grounds of appeal, no explanation had been provided either in the statement of grounds of appeal or in the reply to the opponents' appeals as to why the amendments made overcame any objections raised by the opponents, especially those of lack of inventive step.

Article 12(3) RPBA applied and required that the statement of grounds of appeal and the reply contained the party's complete appeal case, i.e. that they set out clearly and concisely the reasons why it was requested that the decision under appeal be reversed, amended or upheld, and that they specify expressly all the requests, facts, objections, arguments and evidence relied on. This explanation was lacking for former auxiliary request 7.

This meant that the board had discretion over admittance of the claim request under Article 12(5) RPBA, even though it was not contested

that the claim request had been admissibly raised and maintained within the meaning of Article 12(4) RPBA.

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

The patent proprietor's request for remittal to the opposition division should not be allowed. Instead, the board should decide on inventive step itself. The reasons for this were that the patent term was about to expire and legal uncertainty should not be prolonged.

Moreover, the patent proprietor had requested remittal only at the oral proceedings before the board. The patent proprietor should not be rewarded for having submitted late arguments in relation to inventive step. The request for remittal, submitted at the oral proceedings, was submitted too late and therefore represented an amendment of the patent proprietor's appeal case.

Claim construction

The claim was a purpose-limited product claim and was drafted in the further medical use format of Article 54(5) EPC. Although the feature "by administration" linked the technical effect of lessening the severity of clinical symptoms and/or preventing PCV2 infection to the administration of one dose of the vaccine, other steps could take place. In other words, as long as the administration of one (first) dose of the vaccine produced a lessening of the severity of clinical symptoms the claim permitted further steps, e.g. one or more further administrations of the vaccine and/or of other substances (before or after the "one dose" of the PCV2 vaccine was administered), whether or not such further steps

provided a further lessening of the severity of clinical symptoms or an improved (e.g. longer-lasting or more effective) prevention of PCV2 infection.

This interpretation was consistent with the statement in the patent at the end of paragraph [0179]:

"*Depending on the desired duration and effectiveness of the treatment, the compositions according to the invention may be administered once or several times, also intermittently, for instance on a daily basis for several days, weeks or months, and in different dosages*".

The above construction was in line with the interpretation in Board of Appeal decisions in parallel cases. The cases in question were T 2353/19, T 1045/19, T 1025/19, T 1026/19 and T 2410/19. These decisions without exception were strong evidence that the claims of all requests on file could not be distinguished from the prior art by the feature of a one-time administration of the combination vaccine of claim 1 and that as a consequence, an inventive step could not be acknowledged.

In view of the decisions in these cases, which dealt with the same or similar wording to the present one, the administration regimen recited in the present claims was not suitable to disclaim or exclude further administration steps or regimens of active agents different from the "combination vaccine" defined in present claim 1.

Similarly, the group of patients ("piglets") included ones that had previously received other active agents.

Inventive step (Article 56 EPC)

Non-obviousness based on the "one shot" feature

Document D9 disclosed a regimen for vaccinating piglets against PCV2 infection by administration of a single dose of recombinant PCV2 ORF2 protein (e.g. in trial 1). The only differences between the claimed subject-matter and the disclosure in document D9 was the administration of the PRRS antigen component of the combination vaccine and the use of a carbomer adjuvant. The patent proprietor had made no argument that these features were non-obvious. Indeed, no technical effect at all was attributed to the PRRS antigen.

Non-obviousness based on the "PRRS antigen" and "carbomer" features

In the decision under appeal, the opposition division had correctly concluded that the presence of the PRRS antigen does not confer an inventive step. The addition of a PRRS antigen was obvious over a combination of the disclosure in D9 with that in document D159. The inclusion of a Carbopol adjuvant was also obvious to the skilled person. Document D159 (see page 135, left-hand column, "*Vaccines and adjuvants*") showed that carbomer-type adjuvants were known and had been used in commercial pig vaccines. Moreover, there was no comparative data in the patent to show that carbomers or Carbopol were surprisingly better than other adjuvants.

Admittance of arguments relating to the carbomer feature (Article 13(2) RPBA)

The patent proprietor had, in its submission of 12 February 2024, made former auxiliary request 7 the main request and argued for the first time that the claimed subject-matter was not obvious over the prior art based on the adjuvant carbomer not leading to any adverse events, such as injection site reactions. At the oral proceedings before the board the patent proprietor expanded on these arguments and then presented a further new line of argument based on further technical effects of the carbomer feature, in particular increased immunogenicity.

Both of these lines of argument represented amendments to the patent proprietor's appeal case and should not be admitted under Article 13(2) RPBA. There were no exceptional circumstances which justified their late submission. In particular, the claim construction given by the board in its communication under Article 15(1) RPBA and the claim construction applied by Boards in related cases did not constitute exceptional circumstances for the late submission of a defence of inventive step based on the carbomer feature. The construction of the claim in relation to whether nor not it required the therapeutic effect against PCV2 infection to be brought about solely by a single shot, adopted by the board in its communication under Article 15(1) RPBA (which was the same as that adopted in the related appeal cases T 2353/19, T 1045/19, T 1025/19, T 1026/19 and T 2410/19, referred to above), had been present in the opponents' statements of grounds of appeal and replies to the patent proprietor's appeal and indeed had already been made in the proceedings before the opposition division.

Thus, the patent proprietor had ample opportunity to make any defence it wished much earlier in the proceedings.

The fact that the board had found in the patent proprietor's favour in the *ex parte* appeal decision (T 1020/11) in relation to the application on which the patent in suit was granted was not a legitimate reason to refrain from presenting a full case in reply to the opposing parties' appeals.

The patent proprietor had also submitted that the arguments, presented at oral proceedings before the board, according to which the claimed subject-matter was inventive because vaccines comprising a carbomer adjuvant had improved immunogenicity and therefore represented a non-obvious alternative, were not submitted for the first time at the oral proceedings but had been made in writing. This was not correct. No such arguments in favour of inventive step had been made in the written proceedings. This line of argument was also an amendment to the patent proprietor's case that was not to be admitted under Article 13(2) RPBA. Moreover, there were no exceptional circumstances which justified the admittance the late submissions. The arguments as to why the inclusion of the carbomer adjuvant, Carbopol, was obvious to the skilled person had been presented in the statement of grounds of appeal of opponent 1 (see point 12.4). The patent proprietor could have replied to these submissions much earlier in the appeal proceedings.

XVI. The requests of the patent proprietor, relevant to the present decision:

- that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the set of claims of the main request, filed as auxiliary request 7 on 3 April 2020 during the proceedings before the opposition division and resubmitted with the statement of grounds of appeal;

- that, if the main request were admitted, the case be remitted to the opposition division for further prosecution;

- that none of documents D191, D27, D57, D58, D59, D63, D76a, D85, D90, D112, D114, D116, D117, D118, D134, D142, D144, D185, D200, D201 and D202, D210 to D215, and the new versions of D199 and D199a, filed by opponent 1 on 25 November 2022, be admitted into the proceedings;

- that none of the documents D217, D218, D219, D221 to D227 as defined in the consolidated list be admitted into the proceedings;

- that documents D122, D186 to D199, D205 to D209 and D216 be admitted into the proceedings

XVII. The requests of opponent 1, relevant to the present decision are:

- that the decision under appeal be set aside and that the patent be revoked.

- that the patent proprietor's presentation of former auxiliary request 7 as the new main request not be admitted into the proceedings;

- that, in the event that the main or auxiliary request 1 were admitted, the case not be remitted to the opposition division.

- that the patent proprietor's submissions in its letter dated 12 February 2024 relating to the carbomer adjuvant in support of inventive step not be admitted into the proceedings;

- that document D191, filed by opponent 2 in the proceedings before the opposition division, be admitted into the proceedings

- that documents D56, D60, D61, D62, D64, D65, D66, D67, D68, D69, D70, D71, D72, D127, D196 to D199, D205, D206, D207, D122, D208, D209, D186 and D187 not be admitted into the proceedings

- that documents D27, D57 to D59, D63, D76a, D85, D90, D112, D115 to D118, D134, D142, D144 and D200 to D202, filed with the statement of grounds of appeal, and documents D199a and D212 to D215, submitted with the letter of 25 November 2022 be admitted into the proceedings, as well as documents D217, D220, D221 to D225, D226 and D227 be admitted into the proceedings.

XVIII. The requests of opponent 3, relevant to the present decision are:

- that the decision under appeal be set aside and that the patent be revoked;

- that the patent proprietor's submissions in its letter dated 12 February 2024 relating to the carbomer adjuvant in support of inventive step of the subject-matter claimed in the new main request not be admitted into the proceedings;

- that documents D210 and D211, filed with the letter dated 15 September 2022 and documents D218 and D219, filed with the letter dated 26 April 2023, be admitted into the proceedings;

- that the case not be remitted to the opposition division.

Reasons for the Decision

Admittance of documents

1. The board did not decide on the admittance/non-admittance of any documents. Since the arguments that these documents were filed to support are moot for the present decision, their admission did not need to be decided on.

2. In more detail, the patent proprietor requested that documents D122, D186 to D199, D205 to D209 and D216 be admitted into the proceedings. Documents D122 and D186 to D199 were filed by the patent proprietor during the proceedings before the opposition division, with the aim of supporting arguments under Article 83 EPC or Article 123(2) EPC, that are not dealt with in this decision. Similarly, documents D205 to D207 were filed in support of lines of argument on the valid transfer

of priority. Documents D208 and D209 were filed in support of lines of argument under Article 83 EPC. Document D216 was filed to show that the skilled person would not have assumed "*that a prime-and-boost regime can be converted to a one shot with any reasonable expectation of success*" (see patent proprietor's letter dated 23 December 2022, page 29, paragraph 2). None of these lines of argument are dealt with in the decision.

3. Similar considerations apply for the documents which the opponents requested the admittance of. Moreover, in view of the board's decision (see point 39.), the opponents are not adversely affected by the fact that they were not taken into account.

Main request

Admittance

4. The set of claims of the main request was filed as auxiliary request 7 with the patent proprietor's statement of grounds of appeal. It had also already been filed in the proceedings before the opposition division.

5. The board decided to admit this claim request although the opponents had objected to its admittance. However, in view of the board's decision on the merits, see point 38. below, no reason for its admittance need be given here.

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

6. As the requests considered in the decision under appeal had been withdrawn in the course of the appeal proceedings, and the new main request was admitted by

the board, the decision under appeal had to be set aside and the issue of remittal to be considered and decided upon by the board. The patent proprietor requested that the case be remitted to the opposition division if the board saw fit to admit the main request. The opponents were against this course of action. They submitted that the patent term was about to expire and that the patent proprietor should not be rewarded for having submitted late arguments in relation to inventive step. They also requested that the patent proprietor's request for remittal, submitted at the oral proceedings before the board, not be admitted as it was submitted late in the appeal proceedings.

7. The decision on whether to deal with a case itself or to remit it to the opposition division under Article 111(1) EPC is at the board's discretion. Pursuant to Article 11 RPBA, a board does not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. As a request on the question of remittal was put forward to the board by a party, the board saw it fit to take an explicit decision on this issue. Moreover, due to the fact that the decision under appeal had to be set aside, the board, had in any case to decide, implicitly or explicitly, on the further course of action. The opponents' request not to admit the patent proprietor's request for remittal of the case to the opposition division into the proceedings was thus not allowable. However, the positions of the parties on the issue of remittal, including their reasoning, and the point in time at which the position was presented to the board, were included in the board's considerations on remittal.

8. In the present case, the board decided not to remit the case to the opposition division for further prosecution. The main request had been filed as auxiliary request 7 with the patent proprietor's statement of grounds of appeal and was already submitted in the proceedings before the opposition division. Thus the parties had ample opportunity to present their case on the claim request. Moreover, the patent proprietor's request for remittal was submitted at the oral proceedings before the board, i.e. at the latest possible stage of the appeal proceedings and after the board, in its communication under Article 15(1) RPBA, had already implicitly considered not remitting the case by addressing the auxiliary requests in substance. Remitting the case to the opposition division would thus have been counter to procedural economy and would also have further prolonged legal uncertainty, especially given that the patent is due to expire soon, since the date of filing of the patent (application) was 28 December 2006.

9. The patent proprietor submitted that it was in favour of remittal so that the case, especially inventive step in view of on the carbomer feature, could be considered by two instances which would also be beneficial to the other parties. Furthermore, in its view, the framework of the proceedings had been changed by the decision T 2410/19 on a related case.

10. However, it is settled case law and confirmed by Article 11 RPBA that parties do not have a fundamental right to have their case heard by an administrative department of the EPO (e.g. an examining division or an opposition division) and at a judicial level by a board of appeal; otherwise all cases where lower ranking requests not considered by the opposition division need

to be considered by the board, would have to be remitted. Furthermore, the board does not agree that the framework of the case was changed by decision T 2410/19, even though the issue of claim construction was similar and played a key role in both cases. In the present case the board has adopted a claim construction presented by the opponents in their statements of grounds of appeal and in their replies to the patent proprietor's appeal. Thus, the framework of the appeal case was set by the parties' submissions and was not changed by the delivery of decision T 2410/19. The board therefore saw no special circumstances which would have warranted a remittal of the case to the opposition division.

Claim 1

Claim construction

11. The claim is a purpose-limited product claim under Article 54(5) EPC. The product is the combination vaccine comprising 1.6 µg to 400 µg/dose recombinant PCV2 ORF2 protein, a PRRS antigen, and an adjuvant, wherein the adjuvant is carbomer. The therapeutic use is lessening the severity of clinical symptoms associated with PCV2 infection, and/or (ii) preventing PCV2 infection.

12. The patent proprietor is of the view 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 opponents disagree, being of the view 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.

13. The board considers that the feature "administration of one dose of said 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 piglets receive only one dose of the vaccine defined the claim. However, the wording of the claim does not exclude that other immunogens or immunogenic compositions which are not the combination vaccine defined in the claim, i.e. ones that do not comprise PCV2 ORF2 protein and a PRRS antigen, can contribute to achieving the therapeutic aim defined in the claim. Moreover, the piglets mentioned in the claim can be any piglets. This reading of the claim is in line with decision T 2410/19 which dealt with a similar issue on claim construction (see Reasons 6 to 16).

14. In decision T 2410/19 the competent board held that the phrase "wherein the composition is to be administered once in swine" did not require that the therapeutic effect was brought about solely and entirely by a single administration of the composition defined in the claim. Analogously in the present case, "by administration of one dose of said vaccine" means that the piglets treated receive only one dose of the vaccine defined in the claim. The claim construction in point 13. above is in line with this.

15. The board also sees no contradiction with decision T 1319/04, as suggested by the patent proprietor. In said decision the competent board implicitly

interpreted a claim to the use of an agent for administration "once per day" as excluding administration of that agent more than once per day. The present board is in agreement with this view. However, the analogy drawn by the patent proprietor is not the right one; the wording of the present claim does exclude the administration of the claimed combination vaccine more than once. Similarly, there is nothing the wording of the claim in T 1319/04 that excludes the use of compounds other than the ones specified for achieving the therapeutic aim.

Inventive step (Article 56 EPC)

The closest prior art, difference and technical effect

16. 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). It can also be taken from Table 1 on page 4567, that 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 an injection. In summary, and as noted in the decision under appeal (see point 7.3), "*D9* [---] *discloses a vaccine comprising recombinant PCV2 ORF2 within the dose range of 1.6 µg to 400 µg/dose where the protein is administered once, (despite the prime/boost regime with DNA), where the*

effect [recited in the claim] *is disclosed in Table 3* [with piglets] *showing no clinical symptoms of PMWS and Table 4 as clinical protection against PCV2 challenge*."

17. The patent proprietor has not challenged the opposition division's reading of document D9. Its main line of argument on inventive step was rather that document D9, representing the closest prior art, disclosed a prime and boost approach to vaccination, from which the claimed vaccine was distinguished in that it was a true "one-shot" vaccine. The success of this line of argument is therefore dependent on the claim being construed as relating to a true "one-shot" vaccine. Since this construction is not the one adopted by the board, this defence cannot succeed.

18. There remain two differences between the vaccine disclosed in document D9 and the claimed one. The first is that the latter is a combination including both a recombinant PCV2 ORF2 protein and a PRRS antigen, while the former does not include a PRRS antigen. The second is the inclusion in the latter of a carbomer adjuvant, since a different adjuvant (Montanide IMS 1313 PR, an oil-in-water adjuvant) was used in the vaccine disclosed in document D9 (see page 4566, section 2.4).

The objective technical problem

19. In view of the above two differences between the vaccine disclosed in document D9 and the claimed one, and the technical effects thereof, the claimed subject-matter can be said to solve the problem of provision of a vaccine for the treatment and prophylaxis of PCV2 infection (i.e. the therapeutic use defined in the claim) and of PRRS infection in piglets.

Obviousness

20. The skilled person, starting from the disclosure in document D9 would have provided the claimed combination vaccine. In particular, the skilled person would have modified the "*ORF2-vaccine*" disclosed in document D9 to include a PRRS antigen and a carbomer adjuvant for the following reasons.

The Carbomer adjuvant

21. The skilled person seeking a solution to the objective technical problem formulated above would have substituted a carbomer adjuvant for the Montanide adjuvant used in document D9. Carbopol in particular was known to be suitable in the context of a vaccine for pigs against PCV2 (see document D159, page 133, "Summary"). Furthermore, the patent proprietor has made no admissible submissions which the board could consider on substance that substitution of a Montanide adjuvant for a carbomer adjuvant is linked to any further technical effect.

The PRRS antigen

22. The further modification of the "*ORF2-vaccine*" of document D9 by inclusion of a PRRS antigen allows treatment or prophylaxis of Porcine Reproductive and Respiratory Syndrome (see paragraph [0007] of the patent).

23. Indeed, the patent proprietor has not made the case that the inclusion of a PRRS antigen is a feature that contributes to a non-obvious technical effect and the board considers that the inclusion of a PRRS antigen would have been a routine measure for the skilled

person seeking to address the problem of PRRS infection in piglets. This view is supported by the fact that the patent application and the claim refer to a generic PRRS antigen, which indicates that, at least in the view of the author of the patent, the skilled person knew how to select an effective antigen.

Admittance of the patent proprietor's submissions presented in the letter dated 12 February 2024 relating to the carbomer feature in support of inventive step

24. By letter dated 12 February 2024, the patent proprietor made previous auxiliary request 7 the main request by withdrawing all higher ranking requests. Claim 1 of this request includes the feature that the vaccine comprises a carbomer adjuvant. In that letter the patent proprietor also submitted that the "*application as filed demonstrates the use of carbomer, specifically Carbopol, in the examples and notes that compared to the IMS1314 adjuvant, it does not have any adverse events, such as injection site reactions, see application as filed page 140, first paragraph and page 135, last paragraph. The commercial product based on the patent, CircoFLEX, is equally formulated with carbomer (see e.g. D83)*".

25. At the oral proceedings, the admittance of the submissions presented in the patent proprietor's letter was discussed in light of Article 13(2) RPBA, in force since 1 January 2024 (see OJ EPO 2023, A103). Under this provision, any amendment to a party's appeal case made after notification of a communication under Article 15(1) RPBA shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

26. The patent proprietor submitted that relying on additional benefits/technical effects of the carbomer feature, namely reduced side effects, was not an amendment of its case. This feature had been present in the granted claims and had already been present in an independent claim in the proceedings before the opposition division. Discussing the benefits of this feature was therefore not a change of case.

27. The board was not persuaded by this argument. Although claims having the carbomer feature were indeed present in the granted patent, the feature and the technical effect thereof was not relied on in the appeal proceedings to justify an inventive step before the patent proprietor's submission in its letter dated 12 February 2024.

28. The patent proprietor argued that the feature "carbomer" had been discussed at length in the written proceedings and in the proceedings before the opposition division, although it could not direct the board to any evidence that a technical effect associated with this feature had been addressed/ discussed previously. As stated by the opponents, a distinction has to be made between the carbomer feature itself and the arguments presented in relation to that feature. The arguments in the letter dated 12 February 2024 were new. Until that date, the patent proprietor's case was that it did not matter which adjuvant was used, as is clear from page 6, third paragraph, of the patent proprietor's statement of grounds of appeal. The patent proprietor's appeal case for the main request, i.e. former auxiliary request 7, remained confined to the submissions on page 39 of its statement of grounds of appeal and page 104 of its reply to the opponents' appeals, according to which

this claim request met the requirements of the EPC for the same reasons as the then main request; the technical effect of reduced side effects due to the carbomer feature were however not relied upon in support of an inventive step.

29. Thus, the patent proprietor's submissions in the letter dated 12 February 2024 represented an amendment to its appeal case and the board thus had discretion over whether or not to admit this amendment.

30. As to whether exceptional circumstances were present that justified the late submissions, the patent proprietor argued that relying on the technical effect of the carbomer was a legitimate reaction to the board's preliminary opinion set out in the communication under Article 15(1) RPBA and to the developments in related, parallel cases.

31. However, as set out in Point 10. above, the board does not agree with the patent proprietor that the framework of the case was changed by the delivery of decision T 2410/19, even though the issue of claim construction was similar and played a key role in both cases.

32. The patent proprietor further argued that the opponents could not be surprised since this technical effect was also disclosed in the application as filed and an extensive discussion amongst the parties on the carbomer feature had already taken place before the opposition division. However, a lack of surprise of another party does not equate to the presence of exceptional circumstances which may justify the presentation of such submissions at such a late stage of the appeal proceedings.

33. The patent proprietor could not persuade the board that there were exceptional circumstances for the late submission of its arguments. Thus, the line of argument on inventive step relying on a technical effect due to the carbomer feature was not taken into account in accordance with Article 13(2) RPBA.

Admittance of the patent proprietor's submissions relating to the technical effect of increased immunogenicity due to the carbomer feature and any technical effects relating to the submission that the composition was a non-obvious alternative

34. At the oral proceedings before the board, the patent proprietor presented a further line of argument based on the carbomer feature, according to which the claimed subject-matter involved an inventive step because it either was not obvious in view of the technical effect of improved immunogenicity brought about by said feature, or, if improved immunogenicity was not deemed credible, then the vaccine including said feature was a non-obvious alternative to the disclosure in document D9. In the patent proprietor's view these arguments did not represent a change of case within the meaning of Article 13(2) RPBA because immunogenicity had been discussed in the opposition proceedings and in the written appeal proceedings. The arguments in relation to it were therefore not new and the argument relating to a non-obvious alternative did not rely on this effect. The patent proprietor accepted that immunogenicity had been discussed in the appeal proceedings, although in a different context. Also, since the technical effect was described in the application as filed, relying on this effect could not be a new case.

35. The board notes that, contrary to the patent proprietor's position, no line of argument on inventive step identical or even similar the above was made in the written appeal proceedings. The fact that the technical effect of immunogenicity was described in the application as filed or raised in relation to other Articles of the EPC cannot be considered as a line of argument on inventive step. Similarly, the line of argument concerning the claimed subject-matter representing a non-obvious alternative due to the carbomer feature was not submitted on appeal. Hence, the patent proprietor's submissions made at the oral proceedings before the board were an amendment to its appeal case.

36. No cogent reason was given by the patent proprietor to explain why these lines of argument were submitted only at the oral proceedings before the board. Receipt of the communication under Article 15(1) RPBA and the board's preliminary opinion on the case does not constitute a cogent reason justifying the patent proprietor's amendment of its appeal case, let alone justifying an amendment made only at the oral proceedings before the board. It is also noted that the board did not raise any objections for the first time in its communication under Article 15(1) RPBA, which might have justified the timing of the patent proprietor's submissions. Moreover, opponent 1 had already made submissions in relation to the carbomer feature in the context of inventive step in the statement of grounds of appeal (see statement of grounds of appeal, point 12.4) to which the patent proprietor could have been responded earlier.

37. Thus, the patent proprietor's submissions made at the oral proceedings relating to the technical effects

attributed to the feature "carbomer adjuvant", namely increased immunogenicity and any technical effects relating to the submission that the composition was a non-obvious alternative to that disclosed in document D9 were not admitted in accordance with Article 13(2) RPBA.

38. In view of the above considerations claim 1 does not meet the requirements of Article 56 EPC and the main request is not allowable.

39. Since no allowable claim request is on file, 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 Chairwoman:

I. Aperribay D. Luis Alves

Decision electronically authenticated