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**Datasheet for the decision
of 10 February 2026**

Case Number: T 0330/24 - 3.3.04

Application Number: 16185663.8

Publication Number: 3127551

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.

Opponents:

Laboratorios Hipra, S.A.
Ceva Sante Animale
Elanco US Inc.

Headword:

PCV2 immunogenic composition/BOEHRINGER INGELHEIM

Relevant legal provisions:

EPC Art. 76(1)

Keyword:

Divisional application - subject-matter extends beyond content of earlier application (yes)

Decisions cited:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 0330/24 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 10 February 2026

Appellant: Boehringer Ingelheim Animal Health USA Inc.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 2 January 2024
revoking European patent No. 3127551 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman L. Bühler
Members: A. Chakravarty
 O. Lechner

Summary of Facts and Submissions

- I. European patent 3 127 551, with the title "*PCV2 immunogenic compositions for lessening clinical symptoms in pigs*" was granted on European patent application EP 16 185 663.8, which was filed as a divisional application of earlier European patent application, EP 06 850 366.3. This had been filed as an international application and published under the PCT as WO 2007/094893 (the earlier application as filed, P3).
- II. The opposition division issued a decision revoking the patent. It considered sets of claims of a main request and auxiliary requests 1 to 18, all amended compared to the set of claims of the patent as granted.
- III. It held that the main request did not meet the requirements of Article 76(1) EPC. Auxiliary requests 1 to 15 did not meet the requirements of Article 76(1) EPC either. For auxiliary requests 16 to 18 the opposition division concluded that "*[t]he requirements of Article 76(1) EPC, therefore, do not appear to be met*" and considered it "*not necessary to reach a conclusion on admissibility of auxiliary requests 16 to 18*".
- IV. The patent proprietor (appellant) filed an appeal against the opposition division's decision and is the appellant in the appeal proceedings. Opponents 1 to 3 are respondents I to III in the appeal proceedings.
- V. With its statement of grounds of appeal, the appellant submitted sets of claims of a main request and auxiliary requests 1 to 18, identical to the requests

in opposition proceedings. All three respondents replied to the statement of grounds of appeal.

- VI. The appellant submitted a letter dated 4 December 2024 in which it withdrew the main request and auxiliary requests 1 to 16. It requested that the patent be maintained on the basis of auxiliary requests 17 or 18, first filed 20 September 2023. These requests were renumbered as main request and auxiliary request 1, respectively.
- VII. All three respondents replied to this letter. The appellant submitted further letters dated 28 August 2025 and 31 October 2025. Respondent II submitted further letters dated 2 October 2025 and 27 November 2025.
- VIII. The board issued a summons to oral proceedings and subsequently a communication pursuant to Article 15(1) RPBA *inter alia* setting out its preliminary opinion on compliance of the main request and auxiliary request 1 with Article 76(1) EPC. It stated in point 23 that *"none of the passages relied on by the patent proprietor, either alone or in combination disclose the claimed subject-matter. In particular, the board can see no disclosure of a vaccine having the particular therapeutic aim (reducing mortality and/or nasal shedding) in combination with 'single administration' feature and with the age of the pigs"*.
- IX. Claim 1 of the main request reads:

"1. A vaccine for use in reducing one or more of the following symptoms associated with PCV2 infection:

nasal shedding, increased mortality rate,

wherein the vaccine comprises recombinant protein expressed by ORF2 of PCV2 and is capable of eliciting or enhancing an immune response against PCV2, and wherein the reduction in symptoms is obtained by a single administration of the vaccine to pigs not older than 3 weeks of age".

The claim differs from claim 1 of the main request considered by the opposition division in that the expression "immunogenic composition" has been replaced by "vaccine", the word "recombinant" has been inserted before the word "protein" and the age of the pigs is "3 weeks" instead of "6 weeks".

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the expression "increased mortality rate" is deleted.

- X. The appellant's arguments, relevant to this decision are summarised as follows:

Claim construction

The subject-matter of claim 1 was a purpose-limited product, directed to a further medical application of the PCV2 ORF2 protein. The claim was directed to a one shot vaccine, where the effect is obtained by a single administration of the Open Reading Frame 2 (ORF2) encoded protein based vaccine.

Main request - claim 1

Divisional applications (Article 76(1) EPC)

The opposition division's decision on added subject-matter under Article 76(1) EPC was wrong. It did not take the general description and P3 as a whole into

account properly. The general description disclosed the use of a single administration of a recombinant protein expressed by ORF2 ('rORF2') of Porcine Circovirus Type 2 (PCV2) based vaccine as claimed to treat clinical symptoms of Post-weaning Multisystemic Wasting Syndrome (PMWS).

The examples showed this for specific symptoms, including nasal shedding and mortality, which did not mean that the disclosure of the specification was limited to the examples.

In addition, the question of an intermediate generalisation did not arise with regard to symptoms associated with PCV2 infection. Firstly, the symptoms nasal shedding and mortality were specifically mentioned as general aspects in the description. It was also well known that nasal shedding and mortality were symptoms of PCV2 infection.

Secondly, a symptom or sign of a disease was not dependent on how it was measured in an example and was technically independent of the test parameters applied in the example.

There was in any case a general teaching in the specification to use the compositions of the invention to reduce symptoms associated with PCV2. The specification further disclosed that increased mortality and nasal shedding were such symptoms. The claim did not present the skilled person with any new information irrespective of which of the tested symptoms are recited in the claim.

The disclosure of P3 was not limited to the specific embodiments disclosed in the examples, such as the use of caesarean derived colostrum deprived (CDCD) piglets,

their age, etc. The entire application mentioned pigs and piglets, without a restriction to e.g. CDCD piglets. The application as a whole aimed to address issues that arise in normal herds and stables, namely PMWS infections. The general description also disclosed a single administration of the vaccine combination in general, and the age of the piglets.

The concept of a single administration was clearly disclosed in P3. On page 25, last line, there was a statement that the composition may be administered once or several times. The section was entitled "*Administration of the immunogenic composition*" and thus applied to all compositions described in the application. Page 26 then continued to describe particular embodiments of such a one dose or two dose administration, noting e.g. that the at least one dose can be administered intramuscularly. The examples further supported this teaching, as Example 4 demonstrated the one dose efficacy of the recombinant antigen, while Example 5 related to a two shot approach. Thus, a one shot approach was demonstrated to work in the experimental section of P3. The efficacy against the specifically recited clinical symptoms was also demonstrated in the experiments.

In relation to the specific symptoms associated with PCV2 infection that are recited in claim 1, namely nasal shedding and mortality, both were discussed and assessed in detail in P3. Here it was disclosed that vaccination with PCV2 ORF2 protein leads to the prevention, reduction or lessening of PCV2 associated symptoms, including nasal shedding and mortality. Basis for these features was for example, page 62, paragraph 3 of P3, which contained a general statement with regard to an aspect of the invention:

"In still another aspect of the present invention, nasal shedding of PCV2 was assessed as an efficacy parameter and the previous PCV2 efficacy parameters from previous studies were reconfirmed."

Mortality was also discussed as a PMWS clinical symptom, and page 2, lines 19-20 noted that: *"Mortality rates for swine infected with PCV2 can approach 80%."* Nasal shedding and mortality were further tested as efficacy parameters in Example 4. However, Example 4 was not the sole basis for the claimed subject-matter.

Auxiliary request 1

The above submissions on compliance with Article 76(1) EPC applied *mutatis mutandis* to the subject-matter of auxiliary request 1.

- XI. The respondents' arguments, relevant to this decision are summarised as follows:

Main request - claim 1

Claim construction

In relation to the feature in claim 1 "...wherein the reduction in symptoms **is obtained by a single administration** of the composition to pigs...", the Board had been consistent in its interpretation, all language discussing one dose or a single administration had been interpreted to be open language, permitting other steps or administrations (provided they were not the same protein/vaccine) to contribute to the technical effect.

Divisional applications (Article 76(1) EPC)

The opposition division had correctly found that there was no direct and unambiguous basis for the combination of features present in the claim. In particular P3 did not disclose the combination of single administration, pigs not older than six weeks of age, and the medical applications (reducing nasal shedding and/or increased mortality rate).

Single administration of the composition feature

The only passage in P3 referring to a single administration was the one on page 25, line 23 up to the end of the second paragraph on page 26. In these two paragraphs, there was no teaching at all that an immunogenic composition as claimed can be administered by a single administration to achieve the medical application recited in the claim requests. Rather, it was stated that, "*depending on the desired duration and effectiveness of the treatment, the composition 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.*" (see page 25, lines 23 to page 26, line 2).

According to this sentence, the skilled person would understand that, to obtain effective and durable effects, the composition should rather be administered repeatedly ("*on a daily basis for several days, weeks or months*").

Furthermore, P3 did not disclose subject-matter in which the features an immunogenic composition for use in reducing one or more of the following symptoms

associated with PCV2 infection: nasal shedding, increased mortality rate, were present in combination.

In P3, the general description of the invention did not explicitly disclose the claimed vaccine for achieving the specific technical effects claimed, namely reduced nasal shedding or reduced mortality rate associated with PCV2 infection. In the "*Disclosure of the Invention*" section, starting halfway down page 3, P3 disclosed:

- "*a medicinal use(s) of immunogenic composition(s) comprising PCV2 antigen*" (page 3, lines 16-17);
- "*the immunogenic compositions used herein appear to be safe when administered to young pigs*" (page 3, lines 19-20); and
- "*the therapeutic use of the immunogenic compositions described below, is effective for lessening the severity of various clinical symptoms in swine*" (page 4, lines 4-5).

The next passage from page 5, line 21 to page 7 line 23 related to additional symptoms (not present in the granted claims) in combination with lymphadenopathy. The passage from page 7, line 24 to page 9 line 2 further related to the reduction or lessening of Pia-like lesions. However, the only clinical symptoms actually mentioned in these sections were lymphadenopathy, lymphoid depletion, and multinucleated/giant histiocytes in swine infected with PCV2. Other discussed symptoms also related only to lymphadenopathy or to reducing Pia-like lesions, not to nasal shedding or mortality.

The Opposition Division correctly noted that

- Nasal shedding was mentioned only in Example 4, and

- Mortality rate was mentioned only in Examples 4 and 5. Moreover, the selection of these two particular consequences of PCV2 infection gave them a significance which was not imparted by P3.

The experimental examples in P3 did not provide a direct and unambiguous basis for linking a single administration of the PCV2 ORF2 protein with a reduction in nasal shedding or a reduction in mortality rate either. Thus, a skilled reader would not understand from the examples that administering the ORF2 protein could be expected to reduce nasal shedding or mortality.

Furthermore, choosing nasal shedding and mortality rate as the technical effects in claim 1 added subject-matter, because neither effect appeared in the list of potential technical effects in the description (pages 3-7).

Example 4 of P3

The reduction of nasal shedding and increased mortality rate in pigs by the administration of a single dose of immunogenic composition comprising recombinant protein expressed by ORF2 of PCV2 was only envisioned in the experimental part of the application, particularly in Example 4. However, Example 4 included many specific experimental conditions which were not present in the claims, such as: the age of the piglets between 9 and 14 days (i.e., pigs not older than 2 weeks of age); the immunologic status of the piglets (i.e. caesarean derived colostrum deprived (CDCD) piglets); specific doses of rORF2 (4 µg, 8 µg, 16µg); a specific adjuvant (Carbopol); administration of a strong immune stimulant

(KLH/ICF) twice; administration of antibiotic (NAXCEL®) and so on.

All of these conditions contributed to the effects reported in Example 4. In other words, there was a technical interdependence between the claimed symptoms and the above listed parameters. The skilled person would have understood that the doses as well as the presence of an adjuvant and two separate shots of a specific PCV2-immune stimulant had a functional relationship with the antigen (ORF2 of PCV2), its dosage and the age of the animals and their immunologic status.

Auxiliary request 1

The above submissions on compliance with Article 76(1) EPC applied *mutatis mutandis* to the subject-matter of auxiliary request 1.

Requests of the parties

XII. The appellant requested that

- the decision under appeal be set aside and that the patent be maintained on the basis of the main request or of auxiliary request 1 (first filed as auxiliary requests 17 and 18 on 20 September 2023 in the proceedings before the opposition division);
- the main request and auxiliary request 1 be admitted;
- or alternatively, the main request and auxiliary request 1 be considered as having been implicitly admitted by the opposition division;
- if the board were to set the opposition division's decision aside, then the case be remitted to the opposition division for further prosecution.

XIII. The respondents requested that the appeal be dismissed. Respondents I and III further requested that the case not be remitted to the opposition division, but that the board makes a final decision on the case and no further claim requests be admitted.

Respondent II further requested that the case be remitted to the opposition division to discuss sufficiency of disclosure, novelty and inventive step of any of the requests on file, should the board set aside the decision under appeal with respect to Articles 123(2) or 76(1) EPC.

All three respondents withdrew their requests not to admit the main request and auxiliary request 1.

Reasons for the Decision

Admittance (Article 12(4) RPBA)

1. The main request and auxiliary request 1 were filed in the proceedings before the opposition division, on the final date for making written submissions under Rule 116 EPC, in reply to the opposition division's communication issued with the summons to oral proceedings. They were re-submitted with the statement of grounds of appeal.
2. At the oral proceedings, the opponents withdrew their objections to the admittance of there requests. The board decided to admit then for reasons of procedural economy.

Main request - claim 1

Claim construction

3. The claimed subject-matter is a purpose-limited product under Article 54(5) EPC. The product is a vaccine comprising recombinant protein expressed by the Open Reading Frame 2 (ORF2) of Porcine Circovirus Type 2 (PCV2). The vaccine is further defined by the functional feature that it "is capable of eliciting or enhancing an immune response against PCV2".

4. The therapeutic purpose is the reduction of nasal shedding and/or increased mortality rate, as a symptom associated with PCV2 infection. This includes embodiments where only nasal shedding or only increased mortality rate is reduced, embodiments where both nasal shedding and increased mortality rate are reduced and embodiments (not explicitly mentioned but not excluded by the wording) where other symptoms of PCV2 infection are also reduced.
 - 4.1 Claim 1 also specifies that "the reduction in symptoms is obtained by a single administration of the vaccine to pigs not older than 3 weeks of age". This is understood to mean that after a single administration of the vaccine to any pigs not older than 3 weeks of age, said pigs exhibit a measurable reduction in nasal shedding of the PCV2 virus and/or increased mortality rate compared to unvaccinated pigs. This includes embodiments in which the entire therapeutic effect is attained by a single administration of the vaccine and also embodiments in which a different vaccine is administered to the pigs either before or after the claimed one, which contributes to the therapeutic effect.

European divisional application - amendments (Article 76(1) EPC)

5. Under Article 76(1) EPC subject-matter of a divisional application must be directly and unambiguously disclosed in the earlier application as filed, as determined by the totality of its claims, description and figures when read in context (see Case Law of the Boards of Appeal of the European Patent Office 11th edition 2025, II.F.2.1.2).

6. In relation to claim 1 of the main request before it (identical to claim 1 of the patent as granted), the opposition division held that the earlier application as filed (P3) did not disclose the subject-matter having the combination of features claimed, even though each individual feature appeared in the text of said application. In particular, it did not disclose the specific combination of following features:
 - (a) clinical symptoms,
 - (b) single administration,
 - (c1) (not necessarily caesarean derived colostrum deprived (CDCD)) pigs not older than 6 weeks not infected with PCV2,
 - (c2) (not necessarily CDCD) pigs not older than 6 weeks infected with PCV2.

7. The board considers that this objection still holds, *mutatis mutandis*, for the subject-matter of claim 1 of the present main request. In particular, the earlier application (P3) does not directly and unambiguously disclose a vaccine as defined in the claim wherein the reduction in symptoms of nasal shedding and/or increased mortality rate is obtained by a single administration of the vaccine.

8. It is noted that the claim differs from that considered by the opposition division in some aspects (see point IX.), however these differences do not materially affect the board's considerations under Article 76(1) EPC because these relate to subject-matter and wording that was unchanged.

9. In relation to the "is obtained by a single administration of the vaccine" feature, the earlier application from page 25, in the section headed "*Administration of the immunogenic composition*" contains the following passage "*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*".
 - 9.1 This passage discloses that the immunogenic composition may be administered once or several times depending on the desired effectiveness. However, this passage does not link the number of administrations of the vaccine to any particular therapeutic effect. Thus, it does not disclose that administration of a single dose of the vaccine, regardless of the specific regimen, can bring about the claimed therapeutic effect on its own (which as noted above, is an embodiment of the subject-matter of claim 1).

 - 9.2 Furthermore, as also noted in the decision under appeal (see page 13, paragraph 2), P3 (page 25, last line) mentions 'compositions' in the plural, meaning that this passage does not refer to a specific composition.

10. The appellant further relied on the disclosure in the examples as further supporting the teaching on page 24 as a pointer to preferred embodiments. However, the disclosure in the examples is limited to particular embodiments and cannot provide a basis for the present, more general claim language for the following reasons.

10.1 Example 4 of P3 was said to demonstrate the one dose efficacy of the recombinant antigen, while Example 5 demonstrated a two shot approach. However, the single administration feature in Example 4 is disclosed in a specific context which cannot be taken as a general disclosure. While Example 4 does show results from experiments where a single dose of the recombinant antigen PCV2 ORF2 antigen was administered and was effective, the disclosure is limited to specific embodiments as follows:

The piglets in groups 4 to 6 in Table 4 received a single dose of rORF2 of 4, 8 or 24 µg, i.e. particular doses are used. Moreover, the patient group (pigs) is narrower than that defined in the claim, being *"cesarean deprived colostrum deprived (CDCD) piglets, 9-14 days of age"*. In addition, the treatment regimen includes the use of a particular adjuvant (Carbopol), which is not mentioned in claim 1 either. Since all of the features of the embodiment in Example 4 may have contributed to its success, attaining effective treatment with a single dose of vaccine (one shot vaccination), the example cannot serve as a basis for the present more general claim.

11. Similarly, P3 does not disclose that a vaccine as claimed can achieve a reduction in nasal shedding alone or a reduction in increased mortality rate alone, i.e. in isolation from a reduction in other symptoms of PCV2 infection. Both of these are key embodiments of the

claimed subject-matter. Instead, it is apparent from P3 that nasal shedding serves as an efficacy parameter (P3, page 62, lines 14 and 15) for the vaccination and not as therapeutic aim in itself. There is no disclosure in P3 that suggests that only nasal shedding or only increased mortality rate can be reduced while other symptoms are not.

12. In view of the above considerations, it is concluded that the subject-matter of claim 1 cannot be directly and unambiguously derived from P3. Consequently the requirements of Article 76(1) EPC are not met.

Auxiliary request 1

13. The above conclusions apply equally to auxiliary request 1, claim 1 of which differs from claim 1 of the main request only in the deletion of "increased mortality rate" which does not affect the considerations under Article 76(1) EPC made above.
14. No claim request is allowable, thus the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



I. Aperribay

L. Bühler

Decision electronically authenticated