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Datasheet for the decision of 10 March 2026

Case Number: T 0106/24 - 3.3.04

Application Number: 10174464.7

Publication Number: 2275132

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

Language of the proceedings: EN

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

Patent Proprietor:
Boehringer Ingelheim Animal Health USA Inc.

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

Headword:
Multivalent PCV2 immunogenic compositions/BOEHRINGER

Relevant legal provisions:
EPC Art. 76(1)

Keyword:
Divisional application - extension beyond the content of the earlier application as filed (yes)

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Case Number: T 0106/24 - 3.3.04

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

Appellant: (Patent Proprietor)	Boehringer Ingelheim Animal Health USA Inc. 3239 Satellite Blvd Duluth, GA 30096 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent I: (Opponent 1)	Laboratorios Hipra, S.A. Avda. La Selva, 135 17170 Amer (ES)
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Respondent II: (Opponent 2)	Elanco US Inc. 2500 Innovation Way Greenfield, IN 46140 (US)
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Respondent III: (Opponent 3)	Ceva Sante Animale 10, avenue de la Ballastière 33500 Libourne (FR)
Representative:	Cabinet Becker et Associés 25, rue Louis le Grand 75002 Paris (FR)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted/electronically transmitted on 23 November 2023 revoking European patent No. 2275132 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

I. European patent 2 275 132, with the title "*Multivalent PCV2 immunogenic compositions and methods of producing them*" was granted on European patent application EP 10 174 464.7, which is a divisional application of earlier application EP 06 848 471.6, which was filed as an international application, published as WO 2007/076520.

II. The patent proprietor (appellant) filed an appeal against the opposition division's decision to revoke the patent. The patent had been opposed by three opponents 1 to 3, who are respondents I to III to the patent proprietor's appeal.

III. In the decision under appeal, the opposition division considered sets of claims of a main request and of 19 auxiliary requests, all amended compared to the claims of the patent as granted. It held that claim 1 of the main request and of auxiliary requests 1 to 7 did not meet the requirements of Article 83 EPC. Auxiliary Requests 8 to 15 were held not to satisfy the requirements of Articles 123(2) and 76(1) EPC. Auxiliary Requests 16 to 19 were not admitted into the procedure because they *prima facie* did not overcome the objections of added subject-matter.

IV. With its statement of grounds of appeal, the appellant re-submitted a set of claims of a main request, which was the same as the main request considered by the opposition division in the decision under appeal. It further re-submitted sets of claims of auxiliary requests 1 to 19 and filed sets of claims of auxiliary requests 20 to 23 for the first time.

V. The respondents all replied to the appellant's statement of grounds of appeal. All parties submitted further letters, after which the board issued a communication pursuant to Article 15(1) RPBA in preparation for the oral proceedings scheduled for 10 March 2026, setting out its preliminary opinion on the appeal case.

VI. Further substantive submissions were made by the parties. In particular, with a letter dated 10 February 2026, the appellant withdrew the main request and auxiliary requests 1 to 15. Auxiliary requests 16 to 23 were renumbered as the main request and as auxiliary requests 1 to 7. Respondent I replied to the appellant's letter dated 10 February 2026.

VII. Oral proceedings were held as scheduled. At the oral proceedings the appellant withdrew all claim requests other than the main request (former auxiliary request 16). At the end of the oral proceedings, the Chairwoman announced the decision of the board.

VIII. Claim 1 of the main request reads:

"1. A multivalent 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 a pig, the vaccine comprising 2 µg to 50 µg recombinant PCV2 ORF2 protein per dose and at least one immunogenic active component against another disease-causing organism in swine,
and wherein the lessening of the severity of clinical symptoms associated with PCV2 infection, and/or the

prevention of PCV2 infection, is obtained by a single administration of the vaccine to the pig, and wherein the administration of the combination vaccine is performed when the pig is 2 to 8 weeks of age".

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

Main request - claim 1
Divisional application - extension beyond content of the earlier application as filed (Article 76(1) EPC)

With regard to the feature that the administration of the combination vaccine is performed when the pig is 2 to 8 weeks of age, the opposition division erroneously came to the conclusion that this feature adds subject-matter.

In fact, the feature was directly and unambiguously disclosed on page 79 of the application as filed. The section '*Dosage and administration*', provided a general basis for dosage and administration regimens for the vaccines disclosed in the application as filed. Lines 7 to 11 of said page provided a general disclosure regarding the age at which the vaccine should be administered. Said paragraph read:

"*According to a further embodiment, the combination vaccine is administered to pigs in one or two doses at an interval of about 2 to 4 weeks. For example, the first administration is performed when the animal is about 2 to 3 weeks to about 8 weeks of age. The second administration is performed about 1 to about 4 weeks after the first administration of the first vaccination*".

The paragraph thus referred to administration in one or two doses and specified that the first (i.e. in case of a one dose administration, the only) administration is performed when the animal is about 2 to 3 weeks to about 8 weeks of age. The paragraph was a direct and unambiguous disclosure for the feature that the administration of the combination vaccine is performed when the pig is 2 to 8 weeks of age.

The opposition division had concluded that this paragraph should be read as referring to either the administration in one dose without a specified administration age or to two doses, where the age of the piglets is further defined. Moreover, the reference to a "first" vaccination was seen as not applying to a single administration.

It was however nonsensical to consider that a disclosure relating to a single administration could not be combined with any of the disclosed ages of piglets. The paragraph disclosed particular ages at which administration can be performed, including administration of one dose (which was then necessarily and unambiguously the first dose) and of two doses (in which case different ages for the first and second administration were taught).

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

Main request - claim 1
Divisional application - extension beyond content of the earlier application as filed(Article 76(1) EPC)

The only passage cited by the appellant as a basis for subject-matter including the feature "and wherein the administration of the combination vaccine is performed when the pig is 2 to 8 weeks of age" was on page 79, lines 7 to 11 of the earlier application. It described a two dose (prime-boost) regimen, introduced by the phrase "*According to a further embodiment*", followed by the explanation that the first administration may be performed when the animal is about 2 to 3 weeks to about 8 weeks of age, and a second administration is to follow 1 to 4 weeks later.

This passage clearly related only to a multi-dose protocol and therefore could not provide a basis for a single-shot vaccination being performed at 2 to 8 weeks. The skilled person would not have equated the timing of a first dose of a multi-administration schedule with the timing appropriate for a single-administration schedule, because vaccination ages differed depending on whether the animal receives just one dose or a priming and boosting sequence.

The appellant's remark that "first administration" included one-shot administration was contradictory to both technical reality and to the disclosure in the earlier application. Age recommendations were known to differ between single-dose and two-dose regimens

Accordingly, the claim including the feature "when the pig is 2 to 8 weeks of age" extended beyond the content of the earlier application as filed contrary to Article 76(1) EPC.

XI. The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form based on the set of claims of the main request, filed as auxiliary request 16 with the statement of grounds of appeal.

XII. Respondents I to III all requested that the appeal be dismissed.

Reasons for the Decision

Admittance of the main request (Article 12(4) RPBA)

1. The board dealt with the claim request on the merits. Thus, it was admitted into the proceedings for reasons of procedural economy, regardless of its status in the proceedings before the opposition division.

Divisional application - extension beyond content of the earlier application as filed (Article 76(1) EPC)

2. Under Article 76(1) EPC a divisional application may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed. Accordingly, 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 also G 2/10, OJ EPO 2012, 376 and Case Law of the Boards of Appeal of

the European Patent Office 11th edition 2025, II.F. 2.1.2).

3. In relation to claim 1 of auxiliary request 8 before it (which differs from present claim 1 only in amount of recombinant PCV2 ORF2 protein per dose), the opposition division held that "*the overall combination of features of the purpose limited combination therapy ... in combination with the limitation of 2 to 8 weeks ...* [was not]*, clearly and unambiguously derivable from the application as originally filed, contrary to the requirements of Article 123(2) and 76(1) EPC*" (see point 7.9 of the decision under appeal).

4. The board confirms the opposition division's decision in this regard and was not persuaded by the appellant's submissions on this topic.

5. The key question is whether or not the earlier application directly and unambiguously discloses a vaccination regimen wherein the pigs receive only a single shot of the claimed combination vaccine and wherein the administration of the combination vaccine is performed when the pig is 2 to 8 weeks of age.

6. The relevant passage in the earlier application is at page 79, lines 7 to 11. It reads: "*According to a further embodiment, the combination vaccine is administered to pigs in one or two doses at an interval of about 2 to 4 weeks. For example, the first administration is performed when the animal is about 2 to 3 weeks to about 8 weeks of age. The second administration is performed about 1 to about 4 weeks after the first administration of for first vaccination. According to a further embodiment, revaccination is performed in an interval of 3 to 12*

month after administration of the second dose. Administration of subsequent vaccine doses is preferably done on a 6 month to an annual basis. In another preferred embodiment, animals vaccinated before the age of about 2 to 3 weeks should be revaccinated. Administration of subsequent vaccine doses is preferably done on an annual basis".

7. The board is, in agreement with the opposition division and the respondents, of the view that in the above cited passage, the disclosure of "*2 to 8 weeks*" is made strictly in the context of a two dose regimen. Said passage clearly refers to a "*first*" and "*second*" administration. The terms "*first*" and "*second*" given their ordinary meanings, denote the earliest and the next item in a sequence. In the context of the timing of the administration of doses in a vaccination regimen, the phrase "*the first administration is performed when the animal is about 2 to 3 weeks to about 8 weeks of age*" would be understood by the skilled reader to refer to the age of an animal when it receives the first dose in the previously mentioned two dose regimen. This understanding is reinforced by the following sentence, which gives examples of the age of the animal when the second administration occurs. The animal's ages are therefore only disclosed in the context of a two dose regimen. As correctly noted by the opposition division, there is mention of a one dose regimen but no direct and unambiguous disclosure of the age of the animal when it receives this one dose. The skilled person might, on the basis of the disclosure on page 79, be able to make speculations about a suitable age for the administration of a single dose of vaccine, but this would go beyond what is directly and unambiguously disclosed.

8. In view of the above considerations, claim 1 of the main request includes subject-matter which extends beyond the content of the earlier application as filed contrary to Article 76(1) EPC.

9. Since the main (sole) request is not allowable, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated