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Datasheet for the decision of 7 April 2016

Case Number: T 1020/11 - 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 and methods of producing such compositions

Applicant:
Boehringer Ingelheim Vetmedica, Inc.

Headword:
PCV2 combination vaccine/BOEHRINGER INGELHEIM

Relevant legal provisions:
EPC Art. 83, 84, 111(1), 123(2)

Keyword:
Main request
Amendments - allowable (yes)
Sufficiency of disclosure - (yes)
Claims - clarity (yes)

Decisions cited:
T 1021/11

Catchword:

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Case Number: T 1020/11 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 7 April 2016

Appellant: (Applicant)	Boehringer Ingelheim Vetmedica, Inc. 2621 North Belt Highway St. Joseph MO 64506-2002 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 2 December 2010 refusing European patent application No. 06848471.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	G. Alt
Members:	A. Chakravarty
	M. Blasi

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division refusing European patent application No. 06848471 entitled "*Multivalent PCV2 immunogenic compositions and methods of producing such compositions*". The application was filed as international application which was published as WO 2007/076520 (the "application as filed").

II. The examining division considered a main request and an auxiliary request and found that neither request met the requirements of Article 123(2) EPC or Article 83 EPC.

III. In a section headed "*Further Remarks*", the Examining Division, as *obiter dictum*, stated its view that the application contained no evidence that the "*concomitant administration of PRRS leads to a double protection (against PCV2 and PRRSV)*". In view of this and of the skilled person's general knowledge that vaccination by co-administration of two or more antigens was not always successful due to immune interference, the claimed subject-matter did not meet the requirements of Article 84 EPC for support by the description. Moreover, the phrase "*for lessening the severity of clinical symptoms associated with PCV2 infection*" was unclear as it covered both prevention and treatment of an existing infection, while the examples provided support only for preventative administration. Finally, the examining division commented that "*if claims 1 and 8 were construed as relating to a composition suitable for lessening the severity of PCV2 symptoms (and not as second medical uses)*", this subject-matter would an lack inventive step.

IV. With the statement setting out the grounds of appeal, the appellant submitted a main request and seven auxiliary requests.

V. The board appointed oral proceedings and, in a communication pursuant to Article 15(1) RPBA, informed the appellant that it had doubts about whether the subject-matter of claim 1 of main request met the requirements of Article 123(2) EPC. In relation to the disclosure of the invention (Article 83 EPC), the board indicated that it was inclined to disagree with the position taken in the decision under appeal.

VI. The appellant replied to the board's communication and submitted a new main request and auxiliary requests 1 to 5. The previously pending main request and auxiliary requests 1 to 7 were maintained as auxiliary requests 6 to 13.

VII. In response to a telephone consultation with the rapporteur of the board, the appellant submitted a set of 24 claims as a new main request and maintained the previously pending claim requests as auxiliary requests 1 to 14.

VIII. Independent claims 1 and 13 of the main request read:

"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, and a PRRS antigen.

13. The use of recombinant PCV2 ORF2 protein in the manufacture of a combination vaccine for

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

(ii) preventing PCV2 infection

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

1.6 µg to 400 µg/dose recombinant PCV2 ORF2 protein, and a PRRS antigen".

Claims 2 to 12 are dependent on claim 1, while claims 14 to 24 are dependent on claim 13.

IX. Oral proceedings before the board were held on 7 April 2016. At the end of the oral proceedings, the chairwoman announced the decision of the board.

X. The arguments of the appellant relevant for the present decision are summarised as follows:

Article 123(2) EPC

The application as filed disclosed the immunogenic compositions comprising recombinant PCV2 ORF2 protein of claim 1 on page 45, lines 22 to 24. Their use as a vaccine against PCV2 was disclosed on page 60, lines 14 to 19. The therapeutic purpose of the compositions and pigs as the subject was disclosed on page 60, lines 20 to 25, as was the administration in one dose.

Combination therapy together with PRRS antigen was to be found on page 61, lines 20 to 21, while the doses referred to in the claims came from page 52, line 23 to page 53, line 7. Page 52, line 25, in combination Example 4 (Table 14 on page 110, group 6) disclosed the subject-matter of claim 2, with the subject-matter of claim 3 to be found on page 80, line 8. Claim 4 derived from page 80, lines 14 to 16 and claim 5 from page 66, lines 3 to 5. The basis for the subject-matter of claim 6 was on page 79 at lines 8 to 9, while that of claim 7 was to be found on page 42, lines 7 to 10, which described the preparation of a composition comprising PCV2 ORF2 protein and an adjuvant. Claim 8 specified that the adjuvant belonged to the class of polymers of acrylic or methacrylic acid which are cross-linked which was disclosed on page 41, lines 4 to 5 of the application as filed. Claim 9 related to the vaccine in which the adjuvant was carbomer as disclosed on page 41, line 6 of the application as filed. The basis for the subject-matter of claim 10 was to be found on page 53, line 22 to page 54, line 2, for claim 11 on page 66, lines 3 to 4, first half of the sentence and for claim 12 on page 80, lines 18 to 19.

Claims 13 was the equivalent of claim 1 but drafted in the "Swiss-type" format. Thus, the basis for claims 13 to 24 was the same as that for claims 1 to 12.

Article 83 EPC

The examining division was mistaken in finding that claims 1 to 9 related to an invention not disclosed in the application in a manner that allowed the skilled person to carry it out. In fact the description taught that a combination of PCV2 and PRRS worked as a

vaccine, including disclosure of the dosages of both components to be used.

Furthermore, the documents (re-)submitted with the statement of grounds of appeal entitled "*Efficacy of PRRS antigen in a combination vaccine*" (Exhibit G) and "*Efficacy of PCV-2 Antigen in a combination vaccine*" (Exhibit J), as well as Eichmeyer *et al.* "*Evaluation of Ingelvac® 3FLEX: Demonstration of efficacy for the mixture of Ingelvac® PRRS MLV when rehydrated with Ingelvac CircoFLEX® and Ingelvac MycoFLEX®*" (Exhibit K) all contained evidence that the compositions claimed were able to successfully lessen the severity of clinical symptoms associated with PCV2 infection in piglets.

Article 84 EPC

The examining division was wrong to consider the phrase "*for lessening the severity of clinical symptoms associated with PCV2 infection*" used in claim 1 of the main request pending before it, as unclear, as it could mean either the prevention of an infection or the treatment of an existing infection. The skilled person would have understood that, in reality, pigs were held in huge stables and the time of PCV2 infection was hardly under control. Thus, prevention and treatment could not be readily distinguished in veterinary practice and did not exclude each other. If the time of infection in the veterinary practice were under control, as in the challenge experiment provided in the application, infection would be avoidable altogether. Thus, unlike in the experimental section of the present application, a useful vaccine should not only be useful for treating naive piglets that have never seen a single PCV2 virus. The vaccine should also have the

potential to evoke an immune response such that the clinical signs of a PCV2 infection that might be already developing prior to vaccination are overridden. However, this effect in already infected pigs was only a side aspect. The main effect was that a powerful immunogenic composition was provided that was primarily aimed at preventing lymphadenopathy associated with PCV2 in swine, whether or not these pigs had already received a certain dose of the PCV2 virus, e.g. in the course of infection as it may occur in day to day veterinary practice.

XI. The appellant requested that the decision under appeal be set aside and the case be remitted to the examining division for further prosecution on the basis of the set of claims of the new main request filed together with the letter of 6 April 2016. The other claim requests (previous main request and auxiliary requests) were maintained and renumbered as auxiliary requests 1 to 14.

Reasons for the Decision

Main request

Article 123(2) EPC - Amendments

1. The examining division held that the feature (f) of claim 1 of the two requests before it, i.e. "*10^4 to 10^8 $TCID_{50}$ of a Porcine Reproductive and Respiratory Syndrome modified live virus*", related to subject-matter which extended beyond the content of the application as filed.

2. This feature is not present in claim 1 of the main request. The objection that led to the refusal of the

application therefore does not apply to the main request.

3. The subject-matter of present claim 1 is the medical use of PCV2 ORF2 protein in combination with a PRRS antigen. This is disclosed in the application as filed as follows: Immunogenic compositions comprising recombinant PCV2 ORF2 protein are disclosed on page 45, lines 22 to 24. The use of these compositions as a vaccine against PCV2 is disclosed on page 60, lines 14 to 19. On the same page, lines 20 to 25 "*a method for (i) the prevention of an infection, or reinfection with PCV2 or (ii) the reduction or elimination of clinical symptoms caused by PCV2 in a subject, comprising administering any of the immunogenic compositions provided herewith to a subject in need thereof*" is disclosed. Piglets as subject of the vaccination are disclosed on page 60, line 19, while administration in one dose is disclosed at page 60, line 24. Co-administration with PRRS antigen is found on page 61, lines 20 to 21. Turning to the dosage of the ORF2 protein, this is disclosed at page 52, line 23 to page 53, line 7.

3.1 The subject-matter of claim 2 finds a basis on page 52, line 25 (400 µg/dose PCV2 ORF2 protein) and in Example 4 (4 µg/dose PCV2 ORF2 protein). The dosage range of 2 µg to 150 µg/dose ORF2 protein set out in claim 3 is found on page 80, line 8 of the application as filed. A composition of claim 1 comprising 3 to 10 logs of PRRS virus (claim 4) is disclosed on page 80, lines 14 to 16, whilst the embodiment of the PRRS antigen as a modified life virus (claim 5) is found on page 66, lines 3 to 5. The subject-matter of claim 6 can be found on page 79, lines 8 to 9. Page 42, lines 7 to 10 discloses the preparation of a composition

comprising PCV2 ORF2 protein and an adjuvant (claim 7). Claim 8 specifies that the adjuvant belongs to the class of polymers of acrylic or methacrylic acid which are cross-linked, as disclosed on page 41, lines 4 to 5 of the application as filed. Claim 9 relates to a vaccine in which the adjuvant is carbomer, as disclosed on page 41, line 6. The subject-matter of claim 10 derives from page 53, line 22 to page 54, line 2, that of claim 11 from page 66, lines 3 to 4 and finally, that of claim 12 from page 80, lines 18 to 19.

3.2 Claims 13 to 24 are equivalent to claims 1 to 12 but are in the "Swiss-type" format. The board has no objections to the presence of claims drafted in the "Swiss-type" format and according to the provisions of Article 54(5) EPC in a single set of claims (see decision T 1021/11, points 34 to 49 of the reasons). The basis in the application as filed set out above for the subject-matter of claims 1 to 12 is also basis for the subject-matter of claims 13 to 24.

4. Thus, the board is satisfied that the main request meets the requirements of Article 123(2) EPC.

Article 83 EPC - Disclosure of the invention
Article 84 EPC - Support in the description

5. In its decision, the examining division held that claims 1 to 9 of both the main and auxiliary request related to an invention which the patent application did not disclose sufficiently clearly or completely for it to be carried out by a person skilled in the art. The reason given for this finding was the absence of information about "*how and how much* [of the PRRS antigen] *to give so that it works*". This information

was "*crucial because success in vaccine development is unpredictable [...] the co-administration of two or more antigens is not always successful, even when it is known that the two antigens by themselves are efficient ("interference"). The phenomenon of interference has been recognized for decades and belongs to the common general knowledge of the skilled artisan, and the technical field is riddled with suitable examples of interference*". In the section "*Further Remarks*", this reasoning was held to apply *mutatis mutandis* as an objection of lack of support in the description (Article 84 EPC).

6. The established case law of the boards of appeal is that a finding of lack of sufficient disclosure should be based on serious doubts, substantiated by verifiable facts (Case Law of the Boards of Appeal of the European Patent Office, 7th edition 2013, II.C. 4.3, 6.1.4 and 8.). The facts put forward by the examining division to justify a finding of lack of sufficient disclosure are based on the potential problem of immune interference between the PCV2 ORF2 protein and the PRRS antigen. As noted by the examining division, interference does not occur in every case and it is not predictable between which antigens it will occur. There is no evidence on file that interference occurs in the present case. Thus, the objection is based on a potential problem which might occur between different antigens in combination. There are however no verifiable facts on file that demonstrate that interference is a problem in the present, specific case. In the absence of such verifiable facts relevant to the specific case, the board cannot find the objection of lack of sufficient disclosure persuasive.

7. It follows that the board concludes that claims 1 to 24 of the main request meet the requirements of Article 83 EPC and by the same token, the requirements of Article 84 EPC for support in the description.

Article 84 EPC - Clarity

8. As an *obiter dictum*, the examining division remarked that the phrase "*for lessening the severity of clinical symptoms associated with PCV2 infection*" was unclear as it covered both prevention and treatment of an existing infection.

9. The board notes that, although the objection was raised under the heading lack of clarity, the reasoning provided (see Section III.) shows that the examining division did not in fact question the skilled person's ability to understand the claim.

9.1 The board is of the view that, as submitted by the appellant (see Section X.), the skilled person would realise that pigs may be held together in very large units and therefore the time of PCV2 infection will not be controlled. Thus, in veterinary practice, prevention and treatment cannot be readily distinguished and are not mutually exclusive. As a consequence, the board considers that, in the context of infection of pigs with PCV2, the skilled person would consider the expression "(i) lessening the severity of clinical symptoms associated with PCV2 infection, and/or (ii) preventing PCV2 infection, in piglets" to be clear.

9.2 The clarity of claims 2 to 24 was not questioned in the decision under appeal. The board see no reason to raise such objections of its own motion.

9.3 Accordingly, claims 1 to 24 of the main request are considered to meet the requirements of Article 84 EPC for clarity.

10. In summary, the board finds that the claims of the main request meet the requirements of Article 123(2) EPC, Article 83 and Article 84 EPC.

Article 111(1) EPC - Remittal

11. In view of the appellant's request (see Section XI) and also considering that, beyond a brief negative comment as *obiter dictum*, the question of inventive step was not addressed in the contested decision, the board considers it appropriate to make use of its discretion under Article 111(1) EPC and remits the case to the examining division for further prosecution on the basis of the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution on the basis of the claims of the main request filed on 6 April 2016.

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated