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Datasheet for the decision of 2 June 2015

Case Number: T 1021/11 - 3.3.04

Application Number: 06850366.3

Publication Number: 1976558

IPC: A61K39/12

Language of the proceedings: EN

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

Applicant:
Boehringer Ingelheim Vetmedica, Inc.

Headword:
PCV2 composition/BOEHRINGER INGELHEIM

Relevant legal provisions:
EPC 1973 Art. 54(1), 54(2), 54(4), 56, 83, 84, 111(1)
EPC Art. 54(3), 54(5), 123(3)

Keyword:
Main request: Two independent claims for the same medical use; one claim under the provisions of EPC 1973 invoking legal fiction in G 5/83 and other claim under the provisions of Article 54(5) EPC 2000 (yes)
Main request: allowable (yes)

Decisions cited:
G 0005/83, G 0002/08, T 0396/09, T 1570/09, T 1869/11, T 0879/12, T 1780/12

Catchword:
see points 34 to 49

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Case Number: T 1021/11 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 2 June 2015

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 29 November 2010 refusing European patent application No. 06850366.3 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 to refuse European patent application No. 06 850 366 which was filed as an international application and published as WO 2007/094893 (the application as filed).

II. The decision under appeal dealt with a main and three auxiliary requests.

III. The examining division took the view that claim 5 of the main request related to subject-matter which extended beyond the content of the application as filed, while claim 1 of the main request lacked clarity in view of the phrase "*for reducing or lessening the severity of clinical symptoms associated with PCV2 infection in pigs*" which was considered not to unambiguously define whether the claim related to a treatment **before or after infection** with the virus, and thus whether the claim was directed to a composition for prophylaxis or for the treatment of an existing infection.

IV. All claimed subject-matter of the main request was deemed not supported by the description, as required by Article 84 EPC and deemed not to be disclosed in the application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, as required by Article 83 EPC because there was "*no evidence whatsoever that the composition is effective in reducing the same symptoms if it is administered once the piglets have already been infected [and that] therefore, in this respect, the application fatally lacks disclosure.*"

V. The three auxiliary requests were found to suffer from the same deficiencies under Articles 83 and 84 EPC as the main request.

VI. At the end of the decision, the examining division, by way of *obiter dicta* made some comments on the relevance of document D3 to the novelty of the subject-matter of potentially amended claims should these be directed to compositions for use in a preventative rather than a curative role. It stated that "*any subject-matter actually supported by and disclosed in the application* [...] *would inevitably* [*be*] *something already disclosed in D3, and therefore encounter an objection under Article 54(3)* [*EPC*]".

VII. The board set out its preliminary appreciation of the substantive and legal matters concerning the appeal in a communication according to Article 15(1) RPBA.

VIII. In reply to the board's communication, the appellant submitted a letter dated 9 December 2014. This submission was accompanied by a new main request and five auxiliary claim requests, auxiliary requests 1a, 1b, 1c, 2 and 3.

IX. In a telephone conversation with the rapporteur on 16 December 2014, the appellant's representative was informed of issues of clarity and inventive step concerning the main request and was invited to comment on the presence of two independent claims for the same medical use in the same set of claims in this request.

X. With a letter dated 18 December 2014, the appellant submitted a new main request and provided comments on its allowability. The board then cancelled the oral

proceedings scheduled for 9 January 2015 and indicated its intention to issue a decision in writing.

XI. The appellant's requests were that the decision under appeal be set aside and that a patent be granted on the basis of the main request filed with the letter dated 18 December 2014, or alternatively on the basis of one of the five auxiliary claim requests, 1a, 1b, 1c, 2 and 3 filed with the letter dated 9 December 2014.

XII. Claims 1 to 9 of the main request read:

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

2. The immunogenic composition according to claim 1, wherein the adjuvant is chosen from the class of polymers of acrylic or methacrylic acid, which are cross-linked.

3. The immunogenic composition according to claim 1, wherein the adjuvant is Carbopol and wherein the immunogenic composition comprises 500 µg to 5 mg Carbopol per dose.

4. The immunogenic composition according to any one of claims 1 to 3, wherein the composition comprises 8 µg to 200 µg of recombinant PCV2 ORF2 protein.

5. The immunogenic composition of any one of claims 1 to 4, wherein the immunogenic composition is to be administered to pigs not older than 6 weeks.

6. The immunogenic composition according to any one of claims 1 to 5, wherein said composition further comprises a recombinant baculovirus expressing the PCV2 ORF2 protein and cell culture supernate.

7. The immunogenic composition according to any one of claims 1 to 6, wherein said immunogenic composition is stable over a period of 24 months.

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

9. The use according to claim 8, wherein said administration is to be done intramuscularly."

XIII. The following documents are referred to in this decision:

D1: Blanchard P. *et al.*, Vaccine 21:4565-4575 (2003)

D3: W02006/072065

XIV. The appellant's arguments relevant to the decision can be summarised as follows:

Main request

Clarity (Article 84 EPC 1973)

The examining division was wrong to consider the phrase "*for reducing or lessening the severity of clinical symptoms associated with PCV2 infection in pigs*" 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. 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. Moreover, the new set of claims defined the claimed subject matter more clearly with respect to the primary objective of the claimed immunogenic composition being prevention.

Article 83 EPC 1973 (Disclosure of the invention); Article 84 EPC 1973 (Support in the description)

The examining division's objection that the claimed subject-matter lacked support and disclosure because of a lack of evidence that the composition could effectively reduce the symptoms of PCV2 infection when administered after the piglets had already been infected was moot because the claims should be construed as concerning the medical use of a recombinant ORF2 (rORF2) composition for vaccination, i.e. prophylaxis.

Novelty (Article 54(1),(2) and (4) EPC 1973 and Article 54(3) EPC)

With respect to the disclosure of document D3

The examining division considered that the disclosure of document D3 was novelty destroying for the claimed subject-matter under Article 54(3) EPC. However, the claimed subject-matter relating to an immunogenic composition to be administered **in one dose** for the prevention of lymphadenopathy associated with PCV2

infections in swine, was entitled to the first priority date established by US 60/755016 filed on 29 December 2005, whereas document D3 was not entitled to the priority dates of either of its two priority application, namely 30 December 2004 or 13 January 2005 for the subject-matter presently claimed. The third application from which document D3 claimed priority had the same filing date as the document D3 itself, namely 29 December 2005. Neither of these dates was earlier than the effective date of the present application for the claimed subject-matter.

Consequently, the subject-matter of claim 1 of the main request was novel over the disclosure of document D3. The same applied *mutatis mutandis* for the independent second medical use claim in the Swiss-type format and for all dependent claims.

With respect to the disclosure of document D1

Document D1 described the treatment of piglets with different immunogenic compositions including with baculovirus-expressed PCV2 ORF1 and PCV2 ORF2 proteins in non-quantified amounts. Each of the vaccines described in Tables 1 and 2 were administered at least twice and no information was provided regarding the effect of vaccination of swine on the prevention of lymphadenopathy associated with a PCV2 infection. Thus, the claimed subject-matter differed from that of document D1 in the features of i) single-administration ii) prevention of lymphadenopathy and iii) the absence of ORF1 protein within the subunit vaccine.

Inventive step (Article 56 EPC 1973)

In view of the differences between the subject-matter of document D1 and the claimed subject-matter, the problem to be solved by the claimed invention was "*the provision of a vaccine that allows convenient administration within its defined indication*".

The vaccine disclosed in document D1 did not solve this problem. The document did not teach or suggest that a vaccine comprising PCV2 ORF2 protein could prevent swine from developing lymphadenopathy associated with a PCV2 infection by only one administration of such vaccine. The disclosure of document D1 also raised some questions about the overall performance of the subunit vaccine which included PCV2 ORF2 protein in a two-shot prime and boost administration regimen, since it was disclosed that, while the ORF2 subunit vaccine provided significant protection, the group receiving this vaccine still presented a significant growth retardation compared to the control group at the third and fourth-week post infection.

A person skilled in the art starting from document D1 would not have considered reducing the stimulation of the immune system by administering the PCV2 ORF2 protein in merely a one-shot administration regimen.

Second medical indication - allowability of "Swiss-type" and "Article 54(5) EPC-type" claims

Both a purpose-limited product claim and a claim in the Swiss-type format for the same medical indication were allowable in the present set of claims.

The Swiss-type format was allowable for applications having a filing date before 28 January 2011, in accordance with the "Notice from the European Patent Office dated 20 September 2010 concerning the non-acceptance of Swiss-type claims for second or further medical use following decision G 2/08 of the Enlarged Board of Appeal". The Enlarged Board of Appeal had in decision G 2/08 intentionally introduced a transitional period during which Swiss-type claims could still be pursued while the revised EPC was already in force. This clearly indicated that the Enlarged Board of Appeal saw no "*contradictory legal situation*" between the provisions of Article 54 EPC 1973, which led to the allowability of Swiss-type claims as the exceptional solution provided in decision G 5/83 and the provisions in Article 54 EPC.

Furthermore, an applicant had a legitimate interest to pursue both claim types in one set because determining the scope of those claims in potential infringement proceedings was a matter for national courts. Which exact scope would in future be attributed to each of these claim types by any specific national court was yet to be determined, as confirmed in decision G 02/08 of the Enlarged Board of Appeal which stated that "*It appears that the rights conferred on the patentee by the claim category under Article 54(5) EPC are likely broader, and could, in particular, lead to possible restrictions on the freedom of medical practitioners to prescribe or administer generics. However, in view of the clear provisions of Articles 53(c), second sentence, and 54(5) EPC and the intention of the legislator, the Enlarged Board has no power to broaden or reduce in a praetorian way the scope of these provisions. If deemed necessary, the freedom of medical*

practitioners may be protected by other means on the national level".

Reasons for the Decision

Applicability of EPC 1973 and the revised EPC

1. The present application has a filing date of 28 December 2006. Thus, on 13 December 2007, the date of entry into force of the revised version of the European Patent Convention, the present application was pending.

2. Pursuant to Article 7(1), second sentence, of the Act revising the EPC of 29 November 2000, the revised version of the Convention does not apply to such applications, unless otherwise decided by the Administrative Council of the European Patent Organisation. By the decision of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November 2000 (see special edition No. 1, OJ EPO 2007, 197) the revised version of the EPC was ordered to be applicable to pending patent applications with regard to a number of provisions.

3. In the following, "EPC" and "EPC 1973" will be used in order to specify whether reference is made to the revised EPC or to its previous version.

Main request

Clarity (Article 84 EPC 1973)

Claim 1

4. The board notes that the phrase "*for reducing or lessening the severity of clinical symptoms associated with PCV2 infection in pigs*" objected to in the decision under appeal is no longer present in the claim. The examining division had found that in view of this definition, it was unclear whether the claim related to treatment **before or after infection** with the virus and it was therefore unclear if the claim was directed to a composition for prophylaxis or for the treatment of an existing infection.

5. The present claim 1 is directed to the medical indication "*preventing lymphadenopathy associated with PCV2 infection in swine*". This indication is not dependent on the moment of exposure of the pigs to the virus because it relates to the prevention of symptoms, which may be achieved both in infected and uninfected pigs. The board considers that the medical indication "*preventing lymphadenopathy associated with PCV2 infection in swine*" is clear.

Article 83 EPC 1973 (Disclosure of the invention);
Article 84 EPC 1973 (Support in the description)

6. The examining division considered that there was "*no evidence whatsoever that the composition is effective in reducing the same symptoms if it is administered once the piglets have already been infected [and that] therefore, in this respect, the application fatally lacks disclosure*".

7. As set out in point 4. above, "*preventing lymphadenopathy associated with PCV2 infection in swine*" relates only to the prevention of symptoms of PCV2 infection in swine regardless of when this occurs. The board considers that the application provides convincing evidence that this effect can be achieved by the claimed subject-matter. Specifically, the application provides evidence that the technical feature "*preventing lymphadenopathy associated with PCV2 infections in swine, wherein the composition is to be administered once*" is achieved over the scope claimed, including at the minimum dosage of 4 µg of recombinant PCV2 ORF2 protein. This is demonstrated in Example 4, where the results of a study of the efficacy of PCV2 candidate vaccines are presented. Table 9, headed "*Summary of Group Overall Incidence of Clinical Symptoms*" shows that Group 6 which consisted of pigs vaccinated with a 4 µg dose of recombinant PCV2 ORF2 protein (rORF2) had a 9.1% incidence of pigs showing clinical symptoms (1/11 pigs), while Group 5 which consisted of pigs vaccinated with an 8 µg dose of rORF2 had an 8.3% incidence of pigs showing clinical symptoms (1/12 pigs). Group 4 (16 µg rORF2 in 1 dose) had a 36.4% incidence rate while the challenge control group (i.e. the group that was infected with PCV2 without vaccination) had an incidence rate of around 40%. The tests included in the results of Table 9 include immuno-histochemistry (IHC) testing which encompasses a check for lymphadenopathy (see page 55, paragraph 1 of the application as published).

8. The board therefore considers that the invention of claim 1 is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and by the same token, the subject-matter of claim 1 is supported by the description.

9. In view of the conclusions reached above, the claims of the main request overcome the examining division's reasons for refusing the application. The appeal is therefore allowable.

Remittal (Article 111(1) EPC 1973)

10. Under Article 111(1) EPC 1973, following the examination as to the allowability of the appeal, the board may exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department.

11. The board has assessed the appropriateness of a remittal in the present case. The subject-matter of the pending requests is similar to that considered by the examining division and the examination as to the allowability of the claims is made in respect of the same documents as those taken into consideration by the division. The board therefore does not consider it appropriate to remit the case and exercises its discretionary power under Article 111(1) EPC 1973 to take a final decision in the interest of overall procedural economy and effectiveness.

Amendments (Article 123(2) EPC)

12. The application as filed discloses "*a medicinal use(s) of immunogenic composition(s) comprising PCV2 antigen*" at page 3, lines 15 to 17. That this medicament is "*for the prevention of lymphadenopathy associated with PCV2 infection in swine*" can be taken from page 4, lines 14-25. That "*the medicament is to be administered once in swine*" is disclosed at page 25, line 24 of the application as filed. The dosage of 4 µg of the recombinant PCV2 ORF2 protein can be found *i.a.* in

Table 13 (Group 6), while a dosage range end-point of 200 µg of rOFRF2 is disclosed on page 18, lines 1 to 4, which reads "*According to a further aspect, the ORF2 antigen inclusion level is [...] preferably from about 0.3 to about 200 µg/dose*". On page 22, line 15 of the application as filed it is disclosed that "*the adjuvant is added in an amount of about 100 µg to about 10 mg per dose*". Finally, that the recombinant PCV2 ORF2 protein is obtained through infection of susceptible cells with a "*recombinant viral vector containing PCV2 ORF2 DNA coding sequences [and that] PCV2 ORF2 polypeptide is expressed by the recombinant virus [...] the expressed PCV2 ORF2 polypeptide [being] recovered from the supernate by filtration and inactivated*" can be taken from page 18, paragraph 2 of the application as filed.

13. The subject-matter of claim 2 is supported by the disclosure at page 21, final paragraph: "*Advantageous adjuvant compounds are the polymers of acrylic or methacrylic acid which are cross-linked*". The subject-matter of claim 3 is supported by the disclosure at page 22, paragraph 1: "*most preferred is use of Carbopol [...] in amounts of about 500 µg to about 5 mg per dose*". The subject-matter of claim 4 is supported by the disclosure at page 39, lines 4 to 5 "*Group 6 was designed to administer 11 ml of rORF2 containing 8 µg rORF2/ml*" together with page 18, paragraph 1: "*the ORF2 antigen inclusion level is [...] preferably from about 0.3 to about 200 µg/dose*". The subject-matter of claim 5 reflects the disclosure of the second paragraph of page 4 of the application as filed. The subject-matter of claim 6 can be derived from the disclosure of page 18, lines 24 to page 19, line 3 of the application as filed which reads: "*the immunogenic composition can comprise i) any of the PCV2 ORF2 proteins described*

above, preferably in concentrations described above, ii} at least a portion of the viral vector expressing said PCV2 ORF2 protein, preferably of a recombinant baculovirus and iii) a portion of the cell culture supernate". The subject-matter of claim 7 is based on the application as filed at page 24, lines 20 to 21.

14. It follows from the above that the subject-matter of the claims has a basis in the application as filed and therefore meets the requirements of Article 123(2) EPC.

Clarity (Article 84 EPC 1973)

15. Concerning the clarity of claim 1 beyond the issues raised in the decision under appeal already addressed in paragraphs 4. and 5. above, the board notes with regard to the medical indication "*lymphadenopathy associated with PCV2 infection in swine*", that the condition of lymphadenopathy is well known to the skilled person and its progression can be measured by the skilled person using known methods of immuno-histochemistry (see application as published, page 45, paragraph 1). Furthermore, the board concurs with the appellant's statement in the letter of 9 December 2014 (page 5, paragraph 4) that "*lymphadenopathy is one of the hallmark symptoms of PMWS*" [post-weaning multisystemic wasting syndrome].

16. The board has no objections to the clarity of claims 2 to 9 and therefore concludes that the claims of the main request comply with the requirements of Article 84 EPC.

Novelty (Article 54(1),(2) and (4) EPC 1973 and Article 54(3) EPC)

With respect to the disclosure of document D3

17. The examining division at the end of their decision, made some remarks by way of *obiter dicta* on the relevance of document D3 to the novelty of the subject-matter of potentially amended claims should these be directed to compositions for use in a preventative rather than a curative role. The examining division stated that "*any subject-matter actually supported by and disclosed in the application [...] would inevitably [be] something already disclosed in D3, and therefore encounter an objection under Article 54(3) [EPC]*".

18. Indeed, document D3 is a Euro-PCT application which meets the requirements of Article 54(4) EPC 1973 and Article 153(3) to (5) and Rule 165 EPC and discloses immunogenic compositions comprising ORF2 of PCV2 (*inter alia* on page 2, paragraph 2) to be administered once in swine (page 78, paragraph 2) which corresponds to the subject-matter of claim 1 of the main request.

19. A key feature of the claimed composition is that they are **to be administered once** in swine. This feature is common to all claims of the main request. It can also be found in the earliest application from which the present application claims priority (US 60/755016, filed on 29 December 2005) at page 25, lines 1 to 6. The board is therefore satisfied that the claimed subject-matter is entitled to an effective date of 29 December 2005.

20. Document D3 has a filing date of 29 December 2005 and was published on 6 July 2006. Priority is claimed from

three US applications, dated 30 December 2004, 13 January 2005 and 29 December 2005, this latter date being identical to the filing date of document D3. Hence, in view of its first two priority claims – i.e. those having an earlier filing date than the effective date of the present application – document D3 could be conflicting prior art pursuant to the provisions of Article 54(3) EPC.

21. However, the subject-matter corresponding to that of present claim 1, in particular that relating to a composition that **is to be administered once** in swine, is not disclosed in either of these two earliest applications from which document D3 claims priority. Hence, the effective date of the relevant disclosure remains the filing date of document D3, 29 December 2005. As this is the same date as the effective date of the claimed invention, document D3 is not prior art under Article 54(3) EPC.

With respect to the disclosure of document D1

22. Of the remaining cited documents on file, document D1 is the most relevant with regard to the novelty of subject-matter of the present claims. Document D1 discloses a trial in which piglets were vaccinated with a PCV2 ORF2 subunit vaccine and which shows that PCV2 replication is completely inhibited in these subjects (see document D1, abstract). The vaccination was done according to a prime and boost protocol, that is to say that the vaccination involved administration of two or more doses of the vaccine (see document D1, point 2.4.1). Document D1 therefore discloses an immunogenic composition for use in a method of protecting swine against post-weaning multisystemic wasting syndrome (PMWS) which syndrome is caused by PCV2 and includes

lymphadenopathy as a key symptom (see also point 15. above).

23. However, the composition of claim 1 differs from the composition disclosed in document D1 in that it is to be administered as a single shot, as opposed to being administered in a prime and boost protocol.

24. The subject-matter of claim 1 and by the same token that of dependent claims 2 to 7 and of Swiss-type medical use claim 8 and dependent claim 9 is therefore novel over the disclosure of document D1. Hence the requirements of Article 54(1) EPC 1973 are fulfilled.

Inventive step (Article 56 EPC 1973)

Closest prior art

25. Considering that, as set out in points 22. to 23. above, both the subject-matter of present claim 1 and the disclosure of document D1 concern vaccination of swine against the symptoms of the same disease with the same antigen, the board concludes that document D1 discloses subject-matter conceived for the same purpose which moreover is structurally close and represents the closest state of the art for the purpose of the assessment of inventive step of the subject-matter of claim 1 (c.f. Case Law of the Boards of Appeal of the European Patent Office, 7th edition 2013, I.D. 3.1).

Technical problem and solution

26. The technical effect of the difference between the claimed subject-matter and that of document D1 is that the claimed vaccine composition achieves the purpose of preventing lymphadenopathy associated with PCV2

infection in swine in a manner that is less stressful for the pigs by avoidance of injection site reaction risks, injection site injury from the actual injection and from hazards such as broken needles, abscesses, general injury risk to the animals from the acts of administering vaccines and from the animals reactions to such attempts.

27. In view of the closest prior art, document D1, the difference thereto and the technical effect of this difference and further considering the disclosure of the application, the problem to be solved by the claimed subject-matter is formulated as the provision of a vaccine against PCV2 with reduced risks associated with the vaccination procedure.

Obviousness

28. In the board's view, the skilled person starting from the closest prior art document D1 and seeking to solve the problem formulated in point 27. above would have considered it obvious that a single shot vaccine would be very desirable. This has not been contested by the appellant, who stated that "*...the general knowledge and common sense in the art would support the assertion that reducing the number of vaccine administrations for animals is highly desirable because each such administration subjects the animals to stress that is detrimental to their health, injection site reaction risks, injection site injury from the actual injection and from hazards such as broken needles, abscesses, general injury risk to the animals from the acts of administering vaccines and from the animals reactions to such attempts, and, ultimately, their value at market*" (see letter of 9 December 2014, paragraph 2).

29. It is established case law of the boards of appeal that in assessing inventive step, it is asked whether the teaching in the prior art as a whole **would** have prompted the skilled person, faced with the objective technical problem, to modify or adapt the closest prior art to arrive at something falling within the terms of the claims. A skilled person could be prompted to take a particular course of action if, for example, there was reason to expect that by following such a course, the problem could be successfully solved. The question of whether the skilled person **could** have modified or adapted the closest prior art to arrive at the claimed subject-matter is not relevant to the assessment of inventive step (see Case Law of the Boards of Appeal of the EPO, 7th edition, I.D.5).

30. In the present case, the board concurs with the appellant's assessment that the skilled person aware of the teaching of document D1, would have considered that a prime and boost vaccination protocol comprising two (or more) shots was necessary to achieve protection against PCV2 infection, including prevention of the symptom of lymphadenopathy associated with PCV2 infection in swine. Document D1 discloses two trials of a number of vaccine compositions including an ORF2 protein subunit vaccine. In all of these trials the pigs were challenged with virus at the earliest after the second vaccination.

31. In view of this, the board considers that the skilled person reading document D1 would have expected that protection could only be achieved after at least a second "booster" injection. The skilled person would not have considered that omission of this second "booster" vaccination would have been associated with a

reasonable expectation of successfully solving the technical problem.

32. In summary, the skilled person faced with the objective technical problem and starting from the closest prior art compositions disclosed in document D1, would not have been prompted to modify or adapt this closest prior art to arrive at something falling within the terms of the claims. This reasoning applies also to the subject-matter of dependent claims 2 to 7 and to the subject-matter of Swiss-type claim 8 and dependent claim 9.

33. The subject-matter of claims 1 to 9 meets requirements of Article 56 EPC 1973.

Second medical indication - allowability of "Swiss-type" and "Article 54(5) EPC-type" claims

34. The main request comprises two independent claims (claim 1 and claim 8) for the same medical indication of the same substance, one claim drafted in the Swiss-type format (use of substance X for the manufacture of a medicament for the treatment of disease Y) and the other claim following the provisions in Article 54(5) EPC (substance X for use in the treatment of disease Y).

35. In decision G 2/08 (OJ EPO 2010, 456), the Enlarged Board of Appeal considered the consequence of the revised EPC on claims in the Swiss-type format. The Enlarged Board decided that since *"Article 54(5) EPC now permits purpose-related product protection for any further specific use of a known medicament in a method of therapy the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament,*

such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83" (see Reasons 7.1.3). In view of the fact that patents had been granted and many applications were still pending seeking patent protection for claims of this (Swiss) type, the Enlarged Board considered that a transitional arrangement was necessary to ensure legal certainty and to protect the legitimate expectations of applicants. It therefore set a time limit of three months after publication of its decision in the Official Journal of the EPO for **future** applications to comply with the new situation. In this respect the relevant date for future applications was ordered to be their date of filing or, if priority has been claimed, their priority date (see Reasons 7.1.4).

36. Hence, in applications not covered by the transitional arrangement, protection for second medical indications may no longer be sought in the Swiss-type format where the claimed subject-matter is rendered novel only by a new therapeutic use of a medicament. However, for applications covered by the transitional arrangement, no restriction has been set by the Enlarged Board for the use of Swiss-type claims.

37. The present application was pending when the decision G 2/08 (*supra*) was issued and it therefore belongs to the category of applications in which the Swiss-type format may, as a general rule, still be used. Thus, it follows that the Swiss-type format may be used in the present application.

38. At the same time, pursuant to the transitional provisions concerning the revised Convention Article 54(5) EPC applies to the present application

(cf. Article 1 point 3 of the decision of the Administrative Council of 28 June 2001, *loc. cit.*).

39. As both claim formats - Swiss-type and the format according to Article 54(5) EPC - are available for the present application and claims of both formats are present in the main request, the question arises whether both claim types may be present in a single set of claims.

40. Decision G 2/08 (*supra*) does not deal with this question. This board therefore concurs with the conclusion reached in decision T 1570/09 of 16 May 2014 that decision G 2/08 (*supra*) did not give applicants an absolute right to draft two independent claims in one single set of claims for one and the same medical indication of one and the same substance, one claim in the Swiss-type format and the other claim in the format in accordance with Article 54(5) EPC (see decision T 1570/09, reasons 4.4, last paragraph). However, it appears to this board that no prohibition of the coexistence of such claims in one claim set can be deduced from G 2/08 (*supra*) either, as it is silent in this respect.

41. In decision T 1570/09 (*supra*), the competent board did not consider a set of claims comprising the two claim formats to be allowable. Against the background that an allowable claim pursuant to Article 54(5) EPC could be formulated and was present in the claim set and that the Swiss-type form was conceived as an exception under the EPC 1973, the board held that there was no longer an objective reason which justified the simultaneous presence of both claims in the set of claims to be proposed for grant. "*Allowing such a set of claims would cause the contradictory legal situation that the*

old provisions in Article 54 EPC 1973 together with Article 52(4) EPC 1973, and the new provisions in Article 54 EPC 2000 together with Article 53(c) EPC 2000 would apply simultaneously to one and the same set of claims" (see T 1570/09, reasons 4.4, paragraph 4).

42. The present board, having carefully examined the reasoning given in decision T 1570/09 (*supra*), has several considerations which prevent it from raising an objection against the presence of claims in the two formats in one single set of claims in the present case.

43. Firstly, it is noted that a single set of claims may be governed by provisions of the EPC 1973 and the revised EPC at the same time. This is the result of the transitional provisions adopted by the Administrative Council and can be seen, for instance, from the application of provisions from both versions of the EPC to the present case (see in particular Article 1 points 1 and 3 of the decision of the Administrative Council of 28 June 2001, *loc. cit.*). A specific provision does not apply in both versions at the same time, with either the old version or the new version of the provision applying.

44. Secondly, there might no longer be a need for patent protection for second or further medical indications to be sought in the form of Swiss-type claims from the time of entry into force of the revised EPC since the new format is at an applicant's disposal. However, in the board's view the continued existence of the Swiss-type format, in parallel to the provisions of Article 54(5) EPC, is a direct consequence of the transitional arrangement provided for by the Enlarged Board in decision G 2/08 (*supra*). The gap in the EPC 1973

regarding patent protection of second or further medical indications was closed in a praetorian way by the Enlarged Board by the introduction of Swiss-type claims and the special approach for assessing the novelty of such claims. As the cause of this praetorian ruling ceased to exist with the creation of a legal provision in the revised EPC by the legislator, the Enlarged Board decided to abandon the special approach on novelty for Swiss-type claims. However, in order to avoid a retroactive effect on pending applications or granted patents, the Enlarged Board ordered that the Swiss-type claim format may no longer be used as of the specified cut-off date. It thereby created a time period in which both the old and the new format for claims for second and further medical indications could be used.

45. Thirdly, the board sees no reason to prevent an applicant from choosing both available formats during the interim period and considers it justified to do so in one set of claims. Even though the claims in both formats provide patent protection for the same medical indication, there is a difference in the subject-matter of the claims due to their category, in combination with their technical features: The Swiss-type claim is a purpose-limited process claim whereas the claim pursuant to Article 54(5) EPC is a purpose-limited product claim. Moreover, in addition to the definition of the compound and the therapeutic use present in both claim formats, the Swiss-type claim comprises the feature of manufacturing a medicament and therefore differs also in this respect from a claim formulated according to the provisions of Article 54(5) EPC (see T 1780/12 of 30 January 2014, reasons 11 to 17; T 879/12 of 27 August 2014, reasons 7 to 11). It is because of this difference in subject-matter that, in a

situation in which a patent was granted with (only) a Swiss-type claim and protection is then sought using a purpose-limited product claim pursuant to Article 54(5) EPC for the same medical indication, in a patent application of the same applicant, designating the same contracting states and having the same effective date, the issue of double-patenting does not arise (see also decision T 1780/12 (*supra*), reasons 25 and 26 and T 879/12 (*supra*), reasons 15 and 16).

46. Thus, by filing two patent applications having the same effective date (two parallel applications or parent/ divisional or priority/subsequent application) it is possible for an applicant to obtain patent protection for the same second or further medical indication in both available claim formats.

47. Allowing the coexistence of two patents from the same applicant, having the same effective date, one including a claim in the Swiss-type format and the other including a claim for a purpose-limited product, does not seem to be materially different from accepting the two claims in one set of claims. The result is that in both cases, patent protection is available for the same second or further medical indication in both available formats.

48. The board therefore does not object to the presence of both formats in a single set of claims, as both formats are applicable to the present application. The board notes that no objections were raised in similar previous cases (see e.g. decision T 396/09 of 27 February 2013 and decision T 1869/11 of 22 March 2013), even if the issue was not discussed in these decisions.

49. Thus, for the reasons set out above, the present board is of the opinion that independent claim 1, drafted following Article 54(5) EPC and independent claim 8, drafted as a Swiss-type claim, as instituted by decision G 5/83 (OJ EPO 1985, 64), are both allowable in the same set of claims.

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 with the order to grant a patent on the basis of claims 1 to 9 of the main request filed with the letter dated 18 December 2014, with a description and figures to be adapted thereto.

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated