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Datasheet for the decision of 23 May 2017

Case Number: T 1415/16 - 3.3.04

Application Number: 06793347.3

Publication Number: 1926496

IPC: A61K39/12, A61P31/20

Language of the proceedings: EN

Title of invention:
PCV-2 Vaccine

Patent Proprietor:
Intervet International B.V.

Opponents:
01 Merial Limited
02 Boehringer Ingelheim Vetmedica GmbH

Headword:
PCV-2 Vaccine/INTERVET

Relevant legal provisions:
EPC Art. 56, 84
RPBA Art. 13(1), 13(3)

This datasheet is not part of the Decision.
It can be changed at any time and without notice.

Keyword:
Main request - inventive step - (no)
Auxiliary requests 1 and 2 - clarity - (no)
Auxiliary request 3 - admission into proceedings - (no)

Decisions cited:
G 0002/04, G 0001/13, T 0009/00, T 0015/01, T 0006/05

Catchword:
-

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Case Number: T 1415/16 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 23 May 2017

Appellant I: (Opponent 01)	Merial Limited 3239 Satellite Blvd Duluth, GA 30096-4640 (US)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Appellant II: (Opponent 02)	Boehringer Ingelheim Vetmedica GmbH Binger Strasse 173 55216 Ingelheim am Rhein (DE)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Patent Proprietor)	Intervet International B.V. P.O. Box 31 Wim De Körverstraat 35 5830 AA Boxmeer (NL)
Representative:	van Gent, Marieke Merck Sharp & Dohme Ltd. Hertford Road Hoddesdon, Hertfordshire EN11 9BU (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 April 2016 rejecting the opposition filed against European patent No. 1926496 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairwoman	G. Alt
Members:	B. Claes
	M. Blasi

Summary of Facts and Submissions

I. Both opponents (opponents 01 and 02 are hereinafter referred to as "appellant I" and "appellant II", respectively) filed appeals against the decision of the opposition division to reject the oppositions filed against the European patent No. 1 926 496.
The patent is based on European patent application No. 06 793 347.3 which was filed as international patent application and published as WO2007/028823. The patent has the title "*PCV-2 vaccine*".

II. Claim 1 of the patent read:

"1. Use of ORF-2 protein of Porcine Circovirus type 2 (PCV-2) for the manufacture of a vaccine that comprises at least 20 microgram/dose of said ORF-2 protein, for the protection of PCV-2-Maternally Derived Antibody-positive (PCV-2-MDA-positive) piglets against PCV-2 infection."

III. The patent was opposed on the grounds for opposition in Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and Article 100(b) and 100(c) EPC.

IV. This decision refers to the content of the following documents:

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

D3: Charreyre *et al.* (2004), "*Vaccination concepts in controlling PCV2-associated diseases*", in Proceedings of the 18th IPVS, Hamburg (Germany), pages 95-107.

D13: Siegrist (2003), Vaccine 21, pages 3406-3412.

D14: Siegrist *et al.* (1998), Eur. J. Immunol., Vol. 28, pages 4138-4148.

D31: Eisele (2009), PhD Dissertation, Veterinary Faculty, Ludwig-Maximilian-Univertsity, Munich, Germany.

D53: Kamstrup *et al.* (2004), Vaccine 22, pages 1358-1361.

D55: Opriessing *et al.* (2004), Journal of Swine Health and Production, Vol. 32, No. 4, pages 186-191.

D66: Prof. Gordon Allan, expert opinion, 23 February 2017.

V. In their statements of grounds of appeal the appellants reiterated arguments to the effect that the invoked grounds for opposition justified revocation of the patent in suit. They furthermore submitted thirteen new documents (referred to as documents D53 to D65). It was requested that these documents, as well document D47, a document, not admitted in the opposition proceedings, be admitted into the proceedings.

VI. With its reply to the appeals, dated 23 December 2016, the respondent requested to dismiss the appeals, filed claims of auxiliary requests 1 to 7 and requested to not admit document D47 and documents D53 to D65 into the proceedings.

VII. The board summoned the parties to oral proceedings.

VIII. The respondent filed two expert opinions, documents D66 and D67, and requested these to be admitted into the proceedings if the board were to admit documents D56 to D58, document D60 and document D65 into the proceedings.

IX. Both appellants filed further submissions. Appellant II filed *inter alia* further eight new documents (referred to as documents D68 to D75) and objections against auxiliary requests 1 to 7. Appellant I similarly filed *inter alia* two further declarations (referred to as documents D76 and D77) and objections against auxiliary requests 1 to 7. Appellant I requested furthermore to not admit the auxiliary requests into the proceedings.

X. The respondent submitted in writing claims of a further auxiliary request 8.

XI. At the onset of the oral proceedings the respondent requested to hold the appeal of appellant I inadmissible. After having heard the parties on this issue the board decided that appellant I's appeal was admissible.

The appellants declared that they had no objections to the admission of documents filed by the respondent in the appeal proceedings. The respondent declared to object to the admission of all documents filed by the appellants in the appeal proceedings (document D47, documents D53 to D65 and documents D68 to D77).

The respondent maintained auxiliary request 1, filed with its reply to the appeals (see section V); renumbered auxiliary request 7, filed with the same submission (see section V), as auxiliary request 2 and renumbered an auxiliary request 9 which was filed

during the oral proceedings, as auxiliary request 3 and withdrew all other auxiliary requests.

Hence, claims 1 of the auxiliary claim requests read respectively:

Auxiliary request 1

"1. Use of ORF-2 protein of Porcine Circovirus type 2 (PCV-2) for the manufacture of a vaccine that comprises at least 20 microgram/dose of said ORF-2 protein, for the protection of PCV-2-Maternally Derived Antibody-positive (PCV-2-MDA-positive) piglets against PCV-2 infection to efficiently protect a herd against the consequences of PCV-2 infection." (emphasis added by the board)

Auxiliary request 2:

"1. Use of ORF-2 protein of Porcine Circovirus type 2 (PCV-2) for the manufacture of a vaccine that comprises at least 20 microgram/dose of said ORF-2 protein, for the protection of PCV-2 Maternally Derived Antibody-positive (PCV-2-MDA-positive) piglets against PCV-2 infection, wherein the MDA level is such that in a prime-boost vaccination regimen, between 0 and 100% of the piglets have a PCV2 specific antibody titre at 1 week post booster vaccination, 3 weeks after primary vaccination, that is equal to or higher than the PCV-2 specific titre at primary vaccination, using a vaccine comprising 20-80 µg ORF2 protein per dose." (emphasis added by the board)

Auxiliary request 3:

"1. Use of ORF-2 protein of Porcine Circovirus type 2 (PCV-2) for the manufacture of a vaccine that comprises at least 20 microgram/dose of said ORF-2 protein, for the protection of PCV 2-Maternally Derived Antibody-positive (PCV- 2-MDA-positive) piglets against PCV-2 infection to protect a group of piglets against PCV-2 infection, the group having a distribution of MDA titers including a titer providing protection against infection." (emphasis added by the board)

At the end of the oral proceedings the chairwoman announced the decision of the board.

XII. The arguments of the respondent in relation to the admissibility of the appeal of appellant I and its status as party and opponent can be summarised as follows:

A change in the organisation of the companies of both appellants had taken place in the first quarter of 2017. Merial Limited (here opponent 01/appellant I) had become part of Boehringer Ingelheim (here opponent 02/ appellant II) and a universal succession had occurred whereby appellant II had acquired all business assets of appellant I. Thus, the circumstances were such as described on page 960 ff. of the Case Law of the Boards of Appeal of the EPO, 8th Edition (CLBA), in particular decisions T 2357/12 and T 9/00.

Documents were available demonstrating that universal succession had been agreed upon (see CLBA, IV.C.2.2.6). They did however not prove that the universal succession had already taken place.

The respondent had become aware of these facts only very recently and they could therefore only be presented at the onset of the oral proceedings. It was established in decision T 1178/04 (OJ EPO 2008, 80; see reasons point 27) that the issue of the opponent status might be raised at all times.

It was not contested that appellant I, as such, further existed as a legal entity. By the acquisition of its business assets, however, appellant II had gained control over appellant I. It was unfair that, under these circumstances, the number of opponents was not reduced to one because now one party (appellant II) was in a position to control two oppositions. Accordingly, the appeal of appellant I should be held inadmissible.

XIII. The arguments of the appellants in relation to the admissibility of the appeal of appellant I and its status as party and opponent can be summarised as follows:

The objection should have been raised earlier by the respondent. Only raising the objection at the onset of the oral proceedings was too late.

Merial Limited (appellant I) had remained and still existed as a separate legal entity and had its own employees.

As long as a party existed as a legal entity it had the right to oppose a patent.

XIV. The further arguments of the appellants, in as far as they are relevant for the present decision, can be summarised as follows:

Admission into the proceedings of documents D44, D47, D56 to D58, D60, D61 and D65

These documents should be admitted into the proceedings.

The patent as granted - claim 1 - inventive step (Article 56 EPC)

The claim did not relate to herd protection, but rather to the vaccination of individual PCV-2-MDA (maternally derived antibody)-positive piglets. The claim furthermore did not define a particular lower limit for the PCV-2-MDA titer present in the piglets to be protected and accordingly also covered the vaccination of piglets having very low PCV-2-MDA titers.

Table 2 of the patent made reference to piglets with PCV-2 specific MDA titers as low as equal to or less than 4 log2 and such piglets where were still considered also "MDA-positive". The prior art did not teach the skilled person that MDAs reactive with PCV-2 posed a problem for PCV-2 vaccination.

Document D1 represented the closest prior art and disclosed PCV-2 vaccine candidates for protecting 28 days old piglets against post-weaning multisystemic wasting syndrome (PMWS) caused by PCV-2 infection. The PCV-2 ORF-2 subunit protein was capable of inducing a protective immune response in piglets and protecting them against PCV-2 infection. Document D1 thus had the same objective as the claimed invention to provide a vaccine for (early) vaccination of piglets against PCV-2 infection.

The disclosure in document D3 was more remote than that in document D1 as it hypothesised that vaccination of the breeder herd (sows), rather than of piglets, and with "inactivated" PCV-2, rather than the ORF-2 protein, would allow a decrease of PCV-2 infection in the herd. Furthermore, document D3 did not disclose whether or not piglets born from the vaccinated sows were actually protected against PCV-2 infection.

The difference between the disclosure in document D1 and the claimed invention was that in document D1, not MDA-positive piglets were vaccinated, but rather specific pathogen free (SPF) piglets in which PCV-2 MDAs were not expected to be present.

The problem to be solved was thus the provision of a PCV-2 ORF-2 subunit vaccine for protection of PCV-2-MDA-positive piglets, with any titer of PCV-2 MDAs, against PCV-2 infection.

Document D1 disclosed on page 4565 (right-hand column, lines 6 to 8) that "*PMWS still remains a major problem in the swine population, as the mortality is still considerable in some farms*". Accordingly, the disclosure in document D1 related to the real life situation in swine herds. It disclosed an experimental model to examine the problem by using SPF piglets which provided controlled conditions rather than to mimic a real life situation. Nevertheless, the aim of the document was to develop a real life vaccine. It was reported that protection induced by a subunit vaccine completely inhibited PCV-2 replication (abstract, last sentence).

On page 4574, left-hand column, in the final sentence, document D1 stated that "... *on the basis of the*

results obtained with our subunit vaccine in terms of seroconversion and clearance of virus following PCV2 challenge, we can predict a good efficacy of our subunit vaccine in a prime-boost approach, that would induce both antibodies and cell-mediated immunity."
This prediction was for PCV-2-MDA-positive piglets.

The skilled person was thus motivated to use the prime-boost approach with a subunit vaccine according to document D1 in the field, i.e. also in PCV-2-MDA positive piglets, by the final conclusion in document D1 (page 4574, left hand column, last sentence). This motivation was further fostered by the general knowledge of infant T-cell responses elicited in the presence of maternal antibodies (see document D13, title of chapter 3.1. and page 3410, right-hand column, last full sentence).

Furthermore, it was common general knowledge that piglets on conventional farms had varying level of MDA titers, as the case may be, against PCV-2 and that these titers declined with age and that thus older piglets were easier to vaccinate (see e.g. document D55, Figures 2 and 4, respectively).

Starting from the disclosure in document D1, the skilled person would thus, as a matter of course, try the PCV-2 ORF-2 protein vaccine as disclosed in document D1, with a reasonable expectation of success, in PCV-2-MDA-positive piglets.

He would routinely undertake dose titration, first in mice and ultimately, in the target group of animals, to determine the appropriate dose of the PCV-2 ORF-2 protein for protecting such piglets from PCV-2 infection.

Document D14 disclosed in the context of measles vaccination in mice that "*High levels (> 5 log10) of maternal anti-HA antibodies totally inhibited antibody responses to each of the vaccine constructs, whereas normal antibody responses were elicited in presence of lower titers of maternal antibodies*" (see abstract, lines 10 to 13). Similar statements could be taken from document D31 in relation to piglets and PCV-2 (see e.g. page 16, lines 15 to 21).

It was thus obvious to use any dose of or above 20ug in the prime-boost protocol of document D1 to vaccinate and prevent PCV-2 infection in MDA-positive piglets **with at least low titers of MDA**.

Document D13 listed a number of mechanisms by which maternal antibodies influenced infant vaccine responses and reviewed the various hypothesises and defined the main determinants. On page 3410, right-hand-column, under the heading "Conclusions" document D13 states that "*Understanding that the influence of MatAb on infant responses does not result from neutralization of in vivo vaccine replication or from FcγR-mediated inhibition of infant B cell activation, but essentially depends upon the MatAb:vaccine antigen ratio at the time of immunization, allows better definition of the potential influence of immunization strategies resulting in enhanced MatAb titers in infants*." Figure 3 shows this concept. Accordingly, the skilled person was taught that the concentration of the antigen was important.

Table 2 of the patent demonstrated that at low levels of MDA 100% "protection" could be attained, whereas in the high level of MDAs no "protection" could be attained by the vaccination. This was exactly what

could be expected from the prior art (see e.g. documents D13 and D14).

Document D66, a declaration submitted by the respondent, concluded in point 7 that based on the teachings in document D3 and D13 (see Figure 3, sentence bridging the columns on page 3409) the skilled person would not expect antibody formation following immunisation of piglets with high levels of MDAs. Accordingly, the expert did not expect interference with vaccination in piglets with normal or low levels of MDAs.

Auxiliary request 1

Admission into the proceedings

The request had not been presented in the proceedings before the opposition division and was therefore late filed. In addition, the auxiliary requests were not convergent with one another. Also, the claims of auxiliary request 1, *inter alia*, *prima facie* lacked clarity and therefore created problems rather than solving them. Accordingly, this request should not be admitted into the proceedings.

Claim 1 - clarity (Article 84 EPC)

The notion "to efficiently protect a herd against the consequences of PCV-2 infection" was unclear in various aspects. In particular the term "efficiently" in relation to "protect" was a relative term which had no established meaning in the art. The term could, for example, refer to protection which was of rapid onset or of long duration or was strong.

The patent in suit did not provide a definition for the notion of "herd" nor did it provide guidance as to when a protection of such a herd was "efficient against the consequences of PCV-2 protection".

Whereas a person skilled in the art defined a herd as a group of animals of the same genus/species in the same geographical location, the piglets in the studies of the patent in suit, in particular example 5, were sampled from "*various countries across Europe*".

Auxiliary request 2

Admission into the proceedings

The request *prima facie* lacked clarity and therefore created problems rather than solving them. Accordingly this request should not be admitted into the proceedings.

Claim 1 - clarity (Article 84 EPC)

The amendment to the claim as compared to claim 1 as granted was convoluted, not concise and extremely unclear.

Non-conciseness arose, in particular, by the placements of commas (e.g. "... at 1 week post booster vaccination, 3 weeks after primary vaccination, that is equal to... ") rendering it unclear whether certain features are additional or merely optional.

The claim simultaneously recited a "MDA level" and a "PCV-2 specific titre" without being clear what each of these terms was intended to mean. It was unclear whether a "level" and "titre" were the same or

different things. Furthermore, the recitation of the dose "20-80 µg ORF2 protein" conflicted with the "at least 20 microgram/dose of said ORF-2 protein" in the preamble of the claim.

Auxiliary request 3

Admission into the proceedings

The request had been filed late, during the oral proceedings before the board, and should not be admitted into the proceedings. The request was *prima facie* not allowable and did not contribute to procedural expediency.

The notion "a group of piglets" lacked equally to the term "a herd" in claim 1 of auxiliary request 1 clarity. The reference to MDA titers in the second part of claim 1 was not qualified as to constitute the PCV-2-MDA or the total MDA level and was therefore unclear. The claim still covered groups of piglets with low MDA titer levels for which claim 1 of the main request was found to lack inventive step.

The oral proceedings had been prepared on the basis of the requests on file. It would be unfair to require that the appellants familiarised and dealt with this completely new request at such a late stage of the proceedings.

XV. The arguments of the respondent, in as far as they are relevant for the present decision, can be summarised as follows:

Admission into the proceedings of documents D44, D47, D56 to D58, D60, D61 and D65

The respondent requested during the oral proceedings that these documents should not be admitted into the proceedings.

The patent as granted - claim 1 - inventive step (Article 56 EPC)

Rather than that of document D1, the disclosure in document D3 represented the closest prior art since it aimed at the same purpose, namely to protect a herd of piglets, through vaccination, wherein these piglets were positive for MDAs against PCV-2. The solution proposed in document D3 was to vaccinate the sows in the herd and accordingly passively protect the piglets. Document D1 did not aim at protecting MDA-positive piglets through vaccination and was thus not conceived for the same purpose as the claimed invention.

Document Dl only disclosed vaccines for piglets which were clearly negative for MDAs against PCV-2. Indeed, since it was known in the art that MDA's interfered with vaccination and document Dl specifically qualified the pigs as substantially pathogen free ("SPF"), the person skilled in the art would infer that these animals were (at least) negative with regard to anti-PCV-2 antibodies. Figure 3 of document D1 in fact showed that the animals were seronegative for PCV-2 specific antibodies at the time of vaccination (see also page 4567, right hand column, paragraph 2.5.1, first three lines). Accordingly, document D1 did not contemplate the use of the ORF-2 protein in PCV-2 MDA positive piglets and was furthermore silent on the amount of the protein in the subunit vaccine doses.

Contrary to the allegations of the appellants, document D13 explicitly disclosed, prior to the relevant date of the patent, that the skilled person was not in a position to predict whether or not a given vaccine might prove capable of escaping from the inhibitory influence of MDAs. Accordingly, MDAs were commonly known to have an inhibitory effect on vaccines. It could be taken from document D59 that European regulatory law required that the influence of MDAs was tested for veterinary medicinal products, which demonstrated, in line with document D13, that it was not obvious that any vaccine that worked in MDA-negative animals would not be inhibited in MDA-positive animals. Moreover, document D3 stated that, since prior art vaccination strategies could not have taken MDAs into account, it was easier to target the breeder herd (page 102, lines 24 to 26). Also document D53 recognised the problem of MDAs for vaccination as well and proposed a DNA vaccine.

Document D1 contemplated farm conditions but did not demonstrate effects under such conditions.

"MDA-positive" was a common concept in serology which was clear to the skilled person. The concept was about a certain threshold of maternally derived antibodies which, admittedly, could be low.

The skilled person, starting from the disclosure in document D1, would start from a vaccine based on the ORF-2 protein which was effective in protection of MDA-negative piglets against PCV-2 infection. When looking for a solution to the problem of protecting MDA-positive piglets by vaccination, the skilled person would turn to other art to find the solution and would not find the current solution - use of more than 20µg

of ORF-2 protein per dose - in any of the documents D2, D3, D4, D13, D14 or D55. In fact, only document D3 provided a solution for protecting MDA-positive animals, i.e. by vaccinating the sows instead of the piglets.

The question was whether it was obvious per se to expect the subunit vaccine to work in animals (piglets) with low levels of MDAs. In fact, neither of documents D13 and D14 mentioned PCV-2 nor did the skilled person differentiate between animals with high or low amounts of MDA.

Document D13 did not disclose that MDA would pose a problem only in high-MDA-titer piglets, in fact, even minute levels could form a problem (see page 3410, left hand column, line 9 to 11): "*It is important to recognize that even modest changes in MatAb titers at the time of immunization may significantly impact on infant responses*").

Also document D59 on page 57 did not exclude low MDA levels from the required evaluation. Similarly, document D3 warned on page 102, lines 24 to 26: "*Done with seronegative or SPF pigs, these studies could not take into account pre-existing maternal responses. Thus it appears easier and more economical to target the breeder herd*."

Also document D53, e.g. in the abstract, did not refer to high MDA levels. There were thus no documents on file dealing with low level/low titer MDA piglets and the suggestion that such low levels would not interfere with vaccination.

Auxiliary request 1

Admission into the proceedings

The board should allow a bona fide attempt to overcome the deficiencies in the main request into the proceedings. Since the animals within a herd have varying levels of MDA, the subject-matter of claim 1 now addressed the problem of providing herd protection against PCV-2 protection.

Claim 1 - clarity (Article 84 EPC)

The notion "herd" was known and clear to the skilled person and was a group of animals in a natural setting on farms.

Auxiliary request 2

Admission into the proceedings

The amendment over claim 1 of the main request intended to exclude cluster 1 in Table 2 of the patent, i.e. those piglets having low PCV-2 MDAs as referred to in the claim by the 100% of the piglets, from the scope of the claim. It therefore excluded the group of piglets from the scope for which the subject-matter of claim 1 of the main request was found not inventive.

Claim 1 - clarity (Article 84 EPC)

The claim was clear to the skilled person.

Auxiliary request 3

Admission into the proceedings

The respondent should, in view of the opinions expressed by the board on the higher ranking requests, be allowed a further bona fide attempt to react to these. The claim should therefore be admitted into the proceedings.

The amendment had no literal counterpart in the description of the application as filed, but found ample basis in examples 1 and 5 of the same and in particular in table 2 which referred to a "Group 1" and "Group 2" of piglets.

The claim should be read with a mind willing to understand. The notion "distribution of MDA titers" referred to the natural distribution of such titers in swine populations and such providing PCV-2 protection.

XVI. The final requests of the parties were the following:

The appellants requested that the decision under appeal be set aside and the patent be revoked.

The respondent requested that the appeals be dismissed, or alternatively, that the patent be maintained in amended form on the basis of the claims of auxiliary requests 1 or 2, filed as auxiliary requests 1 and 7 with letter dated 23 December 2016, or further alternatively, on the basis of the claims of auxiliary request 3 filed as auxiliary request 9 during the oral proceedings.

Reasons for the Decision

Admissibility of the appeals and appellant I's status as party and opponent

1. The appeal of opponent 02 (appellant II) is admissible since it complies with the requirements of Articles 107 and 108 and Rule 99 EPC. Admissibility of this appeal had also not been contested by the respondent.

2. The respondent contested, however, the admissibility of the appeal of opponent 01 (appellant I). Even though the objection had been raised very late, namely at the beginning of the oral proceedings before the board, the board considered this issue since this is one which can and has to be examined *ex officio* at every stage of the appeal proceedings (see e.g. decision T 15/01, OJ EPO 2006, 153, point 1 of the reasons). The appellants' objection against the late introduction of this issue could therefore not succeed.

3. The requirements of Articles 107 and 108 and Rule 99 EPC for the filing an admissible appeal were met by appellant I upon expiry of the relevant time limits. This had not been questioned by the respondent.

4. In order for the board to consider on the merits an appeal that had been duly filed by a party, it is, however, a procedural pre-condition that the party has capacity to be a party to the proceedings when the decision terminating the appeal proceedings is taken. It is a generally recognised principle of national law and also under the EPC that legal entities which do not exist cannot bring or take part in proceedings (see decision G 1/13 of the Enlarged Board of Appeal, OJ EPO 2015, A42, point 5.2 of the reasons).

5. In the present case, while it was argued that a transfer of all business assets was agreed upon between appellants I and II, the respondent confirmed that the continued existence of appellant I as a legal entity on the date of the oral proceedings was not denied. According to the respondent's own submissions, the evidence available to it proved the conclusion of a contractual agreement on a transfer of business assets but did not prove that the transfer, or a universal succession, had already taken place. The representative of appellant II likewise confirmed the existence of appellant II as a legal person and stated in this context that appellant II also continued to have employees.

6. In view of these concordant statements of the parties, the board had no doubt that appellant I existed as a legal entity at the date of the oral proceedings, *i.e.* on the date on which the board intended to take a final decision on the appeals. There was thus no need for the board to make further investigations on its own on the issue of the existence of appellant I.

7. The respondent had argued that appellant I's appeal should be held inadmissible because appellant II had gained control over appellant I and, thus, could pursue two oppositions. The further question therefore arose whether appellant I had lost its status as opponent.

8. Article 99 EPC provides that a notice of opposition can be filed by "any" person. No particular interest in instituting opposition proceedings has to be demonstrated by an opponent. With the filing of a notice of opposition the person acquires the status as opponent.

9. It is established case law that the status as an opponent cannot be freely transferred (see decision G 2/04 of the Enlarged Board of Appeal, OJ EPO 2005, 549, Order I.(a)). Apart from the case of universal succession, in which case the opponent status would be automatically acquired from the date of the effective succession (see T 6/05, point 1.7 of the reasons), the procedural status as opponent may only be transferred together with the opponent's business assets in the interests of which the opposition had been filed (see also decision G 2/04, *supra*, point 2.2.1).

10. This does, however, not imply that a legal person that has the status of an opponent would automatically loose this position or would, contrary to its intention, be obliged to give up this position if the business assets, in the interest of which the initial opposition had been filed, are transferred to a different legal entity. To the contrary, the original opponent may continue the opposition proceedings (see also decision T 6/05, point 1.6.4 of the reasons). Accordingly, a transfer of the status as opponent, together with the transfer of business assets, from one legal entity to another to be valid in the proceedings before the EPO requires an explicit request to the EPO to this effect. Such a request is not on file for the present case.

11. Is is true that a person is not allowed to pursue two or more oppositions. This was also confirmed in decision T 9/00 (OJ EPO 2002, 275), cited by the respondent, in which the second filing of an opposition by the same legal person, after a first admissible opposition, was considered inadmissible for lack of a general legitimate interest (see point 2(c) of the reasons). According to this decision, a legitimate

interest can also not be inferred from the fact that the later opposition has been filed on behalf of a different department of the company without legal personality, having its own economic interest and being subsequently transferred to a third party.

12. The circumstances of the present case are, however, quite different because the two oppositions had actually been filed by separate legal persons and these legal persons were still in existence when the appeal case was about to be decided by the board at the oral proceedings.

13. Moreover, from the mere circumstance that a transfer of all business assets from appellant I to appellant II, or a universal succession, was contractually agreed upon, the board could not derive that appellant II had control over appellant I at the date of the oral proceedings. The documents referred to by the respondent allegedly proved that a transfer between the two companies had been agreed upon. The board had not to evaluate evidence as to whether or not appellant I was under control of appellant II or whether the transfer was already effective.

14. In view of the above considerations, the board decided that the appeal of appellant I is admissible, and that the appeal proceedings were continued with appellant I as a party to the proceedings.

Admission into the proceedings of documents D44, D47, D56 to D58, D60, D61 and D65

15. The board decided during the oral proceedings to take documents D44, D56 to D58, D60, D61 and D65, which were relied upon by the appellants but to the consideration

of which the respondent had objected, into account in the appeal proceedings. The board further decided to not overturn the opposition division's decision to not admit document D47 filed by appellant I during opposition. The board's decision on the merits, however, did not rely on these documents' content (see further). Accordingly, the board sees no need for reasoning its procedural decisions in this respect.

The patent as granted - claim 1

Inventive step - Article 100(a) and Article 56 EPC

Construction of the claim

16. Claim 1 (see section II) is for the "Use of **ORF-2 protein** of Porcine Circovirus type 2 **(PCV-2)** for the manufacture of a vaccine comprising at least 20 microgram/dose of said ORF-2 protein, for the protection of PCV-2-Maternally Derived Antibody-positive (PCV-2-MDA-positive) piglets against PCV-2 infection." (emphasis added by the board).

17. The board considers it appropriate, in order to allow for a proper appreciation of the assessment of inventive step, to emphasise that the claim relates to the protection of PCV-2-MDA-positive piglets as such without thereby specifying certain further features of these piglets on which certain arguments of the appellant relied or related to.

18. Indeed, as correctly argued by the appellants, neither the claim nor the patent in suit provides a definition of the minimum titer MDAs required to be present in a piglet for it to be denominated "PCV-2-MDA-positive" and referred to in the claim. In particular, the claim

does not require the piglets to have PCV-2-MDA levels which may be too low to provide protection against PCV-2 infection while still high enough to interfere with vaccination (see paragraph [0018] of the patent). The board, for the purpose of construing claim 1, thus notes that the PCV-2-MDA-positive piglets as referred to in the claim also read on such piglets which have an extremely low titer of PCV-2-MDAs, but which are nevertheless detectable.

19. The claim further does not require the piglets to be vaccinated and protected to belong to a particular group of animals such as a particular breeding herd or another particular group of animals wherein each piglet has a different individual PCV-2-MDA titer. The claim also does not refer to the provision of a so-called "herd protection" as referred to e.g. in paragraph [0071] of the patent, i.e. when about 80% or more of a herd of piglets are protected, e.g. with a MDA distribution as in table 1 and example 5 of the patent.

20. Similarly, the claim does not define for instance a minimum or maximum, age of the piglets to be vaccinated and in particular does not require that the ORF-2 protein vaccine allows protecting PCV-2-MDA-positive piglets as early as of weaning onwards by a priming vaccination in the first week(s) of age and booster vaccination round the time of weaning (see e.g. paragraph [0014] of the patent).

21. In view of the above considerations, the board judges that the claim relates *inter alia* to the protection of piglets against PCV-2 infection by the vaccination of particular piglets, i.e. those with extremely low, but nevertheless detectable titers of PCV-2-MDA. Therefore, in order for the claimed subject-matter to involve an

inventive step, also the subject-matter relating to such particular piglets needs to comply with this requirement.

Closest prior art

22. To assess whether or not a claimed invention meets the requirements of Article 56 EPC, the boards of appeal apply the "problem and solution" approach, which requires as a first step the identification of the closest prior art. In accordance with the established case law of the boards of appeal, the closest prior art is a teaching in a document conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant features in common (Case Law of the Boards of Appeal of the European Patent Office, 8th edition 2016, I.D.3.1).

23. Document D1 recognises the major problem of PVC-2 infection in swine breeding and discloses the development of a specific PCV-2 vaccine candidate for application to piglets to control PCV-2. The PCV-2 ORF-2 protein, i.e. the capsid protein of PCV-2 as expressed in a baculovirus based system in insect cells, was found to be a major immunogen inducing protection of 28 days old piglets in a prime-boost protocol. The vaccine protected the vaccinated piglets against a subsequent PVC-2 challenge and completely inhibited PVC-2 replication (see e.g. abstract).

24. Whereas the respondent considered the disclosure in document D3 to represent the closest prior art for the assessment of inventive step of the claimed subject-matter, the board considers this rather to apply to the disclosure in document D1. Indeed, where document D3 suggests that piglets can be passively immunised

against early infections with PCV-2 through the colostrum by vaccination of the sows in, typically chronically infected, breeder herds with an inactivated PCV-2 vaccine (see page 97 under the heading "Vaccination of the breeder herds can protect the piglets" and page 104, "Conclusion), document D1 discloses experiments on the active vaccination of piglets, to protect them against PCV-2 infection, as in the claimed invention, with *inter alia* vaccines based on the PCV-2 ORF-2 protein in a prime-boost protocol.

25. The board accordingly concludes that the disclosure of the use of an ORF-2 protein based vaccine in piglets in document D1 represents the closest prior art for the assessment of inventive step of the claimed subject-matter.

The problem to be solved

26. The board can concur with the respondent that the relevant technical difference between the disclosure in document Dl and the claimed subject-matter (see section II) is that the latter applies the ORF-2 protein vaccine as disclosed in document D1 to piglets which are defined in the claim as being "PCV-2-MDA-positive" whereas the experiments in document D1 were conducted with so-called "specific pathogen free" (SPF) piglets (see document D1, page 4566, right-hand column, lines 31 to 34). The technical effect of this difference is that the vaccine also allows protection of PCV-2-MDA-positive piglets, in particular of such piglets with extremely low, but nevertheless detectable titers of PCV-2-MDA.

27. A further difference between the disclosure in document D1 and the claimed subject-matter is the

reference in the claim to a particular ORF-2 protein content in the vaccine (i.e. at least 20 microgram/ dose). It has, however, not been argued by the respondent that this definition of the minimum ORF-2 constituted the crucial feature on which inventive step was to be based.

28. In this respect the board notes that from Table 2 of the patent it can be derived that there is minimal difference in the percentage of vaccine "take" between the group of piglets which obtained 1 to 14 µg/dose and the group receiving equal or more than 20 µg/dose, when these piglets belong to the so-called cluster 1 and have MDA titres lower or equal than 7 log2 (see also paragraph [0069] of the patent), i.e. the vaccine take is 90% and 100% respectively. This difference is, however, not observed for piglets having MDA titres lower than 6 log2 where the vaccine takes at 100% in both cases.

29. The board therefore concludes that, at least for the piglets with extremely low, but nevertheless detectable titers of PCV-2-MDA, the indication of a minimum ORF-2 protein content in the claim has no essential role in the technical effect achieved by the claimed subject-matter over the disclosure in the prior art.

30. Starting from the disclosure in document D1 as the closest prior art the problem to be solved is therefore to provide a vaccine formulation to protect PCV-2-MDA-positive piglets against PCV-2 infection.

31. In this context reference is made to point 22 above where the board concluded that for the purpose of assessing the claimed subject-matter the term "PCV-2-

MDA-positive piglets" also reads on individual piglets with extremely low, but detectable PCV-2-MDA titers.

32. The board is satisfied that example 5 of the patent in suit discloses at least the suitability of the PCV-2 ORF-2 subunit vaccine, in a concentration of as low as 1 µg/dose, in piglets having PCV-2 specific MDA titers of smaller than 6 log2 (see table 2), i.e. having such titers which are extremely low but still detectable.

Obviousness

33. The respondent has submitted in particular that it was known in the prior art that the existence of maternally derived antibodies (MDAs) in young piglets had deleterious effects on vaccination regimes. In support reference was in particular made to the disclosures in documents D13, D14 and D53. Therefore, it was argued, the skilled person would not consider the prime-boost protocols as disclosed in document D1 to be applicable to piglets as defined in the claim.

34. The board can concur with the respondent that, in general, it was known to the skilled person that the presence of MDAs potentially mediated an inhibitory influence of infant vaccine responses, and that possibly the skilled person would expect a certain degree of interference when applying the ORF-2 prime-boost protocol as disclosed in document D1. However, it needs to be established in the present case whether the skilled person would also expect, in the case of MDA-positive piglets having an extremely low PCV-2-MDA titer, such a substantial inhibitory effect on vaccination that the skilled person would dismiss applying the ORF-2 prime-boost protocol as disclosed in document D1 to such piglets with a reasonable

expectation to successfully vaccinate them against PVC-2 infection.

35. In this respect the board notes that neither document D13 nor document D14 as such make particular reference to vaccination strategies to protect piglets against PCV-2 infection. Nevertheless, the board considers that both documents, in fact, make statements which would support the development of a reasonable expectation of the skilled person that similar vaccination results would be obtained for piglets with extremely low but detectable MDAs against PCV-2 when applying the vaccination strategy as disclosed in document D1.

36. Indeed, document D13 which deals with mechanisms by which MDA influence infant vaccine responses, determines that the main determinant of infant antibody response was the MDA/vaccine antigen ratio (see point 3.2. starting on page 3408) and thereby states that "*Identifying the MatAb:vaccine antigen ratio and the lack of inhibition of T cell priming as the main determinants of the influence of MatAb on infant antibody responses explains the contradictory clinical observations reported using infant vaccines at various doses, with various immunization schedules, in populations characterized by distinct levels of MatAb. Conditions of MatAb excess or use of a low vaccine dose results in inhibition of antibody responses, which are in contrast preserved when MatAb decline or when the vaccine dose increases above certain thresholds (Fig. 3). At conditions of equivalence, partial masking of B cell epitopes occurs and may result in distinct outcomes in terms of infant antibody titers and epitope-specificity, depending upon the distribution of MatAb concentrations and the relative vaccine*

immunogenicity in a given population" (see page 3409, right-hand column, lines 20 to 34; emphasis added by the board) whereby the title of the Figure 3 is "*Expected influence of maternal antibodies on infant antibody responses to subunit vaccines*".

Accordingly, this passage teaches the skilled person in fact that no inhibition of the antibody responses to subunit vaccines will hamper the success of subunit vaccines in particular at waning MDA titers.

37. Document D14 similarly deals with the influence of maternal antibodies in vaccine responses and discloses in the context of measles vaccines in mouse pups to BALB/c mothers that "*High levels (>5 log10) of maternal anti-HA antibodies totally inhibited antibody responses to each of the vaccine constructs, whereas normal antibody responses were elicited in presence of lower titers of maternal antibodies*" (see abstract lines 10 to 13, and point 2.1 starting on page 4139) and on page 4144, left-hand column, line 42 to 53, that "*Indeed, DNA vaccines were often shown to induce normal Ab responses under conditions associated with relatively moderate levels of pre-existing Ab. This is the case in pups of mothers immunized with DNA vaccines, which frequently generate lower Ab responses than conventional vaccines, and in pups immunized at <3 days of life, when Ab transfer through suckling is not yet completed. Thus, it is not the vaccine type, whether live, inactivated or DNA, which emerges as the main determinant of the influence of maternal immunity on Ab responses, but rather the relative amount of maternal antibodies to vaccine antigen*".

Accordingly, also document D14 teaches the skilled person that rather than expecting inhibition of the

antibody responses to vaccines as in mice with high levels of MDA, such an inhibition was not observed in the context of measles vaccination in mice pups with low(er) titers of MDA.

38. Finally, the other document referred to by the respondent in this context, document D53, actually relates to the development of vaccination methods at a pre-weaning age of piglets, typically before the age of 3 to 5 weeks where the piglets still have access to MDA-containing colostrum, and not of piglets with extremely low but detectable PCV-2-MDA titers (see abstract, line 1 to 4, page 1360, right-hand column, lines 4 to 8 and 30 to 36).

39. In view of the above considerations on the disclosure in documents D13, D14 and D53 and in view of the formulated problem to be solved of vaccination of piglets with extremely low but detectable levels of PCV-2-MDA titers, the board cannot infer from these publications a warning or discouragement for the skilled person which would influence his reasonable expectation that the vaccine disclosed in document D1 would successfully vaccinate such low MDA titer piglets.

40. The board furthermore notes that also the respondent's expert in declaration D66 (see under point 7), when addressing the question whether the skilled person would not expect active immunisation of MDA-positive piglets with high titers (>13 log2) of PCV-2-MDAs (see example 5 of the patent in suit), states that: "*To address the question of EXPECTED active immunisation in Example 5 of EP 496* [note by the board: the patent in suit] *we should consider the teachings of SIEGRIST and CHARREYRE* [note by the board: document D14 and D3,

respectively, in these appeal proceedings]. *SIEGRIST (Fig 1) demonstrates that immunization of mice that had high titre MDA against measles virus with a live attenuated measles vaccine, an inactivated measles vaccine, a TT vaccine and/or a canary-pox vectored measles virus failed to demonstrate an active immune response, as defined by continued decline in serum antibody levels post vaccination. Clearly, SIEGRIST demonstrates an absence of "antibody formation in the body" in this study, following vaccination in the face of high MDAs.*

CHARREYRE furthers the teachings of SIEGRIST and moves the debate to PCV2 infections of swine. She reports the results of studies that demonstrate the protective effects of high PCV2 MDA (Table 2 and Fig 5), noting that pigs with high PCV2 MDAs did not show an active immunization response (antibody formation) when challenged with live PCV2 virus and were protected from PCV2 infection. Decreased levels of PCV2 virus in lymphoid tissues in high MDA animals compared to low MDA animals demonstrated this protection.

These teachings, and the general knowledge at the time that MDAs negated successful vaccination of neonates, would lead an expert in the field of PCV2 not to expect antibody formation following immunization of piglets with high MDAs."

41. The appellants have argued in this context that the conclusion of the expert expressly only referred to the skilled person's absence of expectation that high MDA levels would allow seroconversion, i.e. antibody formation upon immunisation of piglets, but was silent on such expectation in piglets with low MDA levels. Accordingly, such a lack of expectation was not

inferable from the prior art for piglets with low MDA levels.

42. The respondent has counter-argued that the reference to only high MDA titer piglets in the conclusion of the expert was merely made in the context of the formulated question which referred to MDA-positive piglets with high titers (>13 log2) of PCV-2-MDAs.

43. The board notes that the expert of document D66 refers explicitly to the content of document D3 in relation to the results of studies that demonstrate the protective effects of high PCV-2 MDA as depicted in Figure 5 of document D3 (with the title: "Serological profiles in 2 groups of pigs with initially high or low amounts of maternal antibodies and submitted to PCV2 challenge") which are commented on in the paragraph bridging pages 99 and 100 of that document reading "*Not surprisingly, antibody levels decreased up to challenge.* ***After challenge, while antibodies continued to decrease in pigs with initially high maternal antibodies, in the low antibody group a significant rise was seen with IFA titers, while ELISA titers remained stable and VNA titers were decreasing,*** *maybe because they were depleted or not generated in this group (Fig 5). (Pigs that had PMWS failed to seroconvert in the 3 tests). Absence of PCV2 active seroconversion in the group with high maternal antibodies emphasized the protective effect of maternal immunity on PCV2 circulation*" (emphasis added by the board).

44. Consultation of the disclosure in document D3 therefore reveals that the expert in document D66 appropriately had referred only to the conclusion in relation to an absence of seroconversion of high-titer MDA piglets (see "*High maternal antibody group*" in Figure 5) as

opposed to the positive observation of seroconversion in the "Low maternal antibody group" in Figure 5.

45. In view of these considerations, the board judges that the subject-matter of claim 1 of the patent as granted is obvious to the skilled person in the light of document D1 alone. Accordingly, the ground for opposition of lack of inventive step prejudices the maintenance of the patent as granted (Article 100(a) and Article 56 EPC).

Auxiliary request 1

Admission into the proceedings

46. Auxiliary request 1 was filed by the respondent in reply to the statements of grounds of appeal (see section VI). According to Article 12(1) RPBA, the request is therefore, as a rule, part of the appeal proceedings. In the present case, the board had no reason to hold auxiliary request 1 inadmissible pursuant to Article 12(4) RPBA. Having regard to the outcome of the first-instance proceedings terminating with the rejection of the oppositions, the board cannot identify a procedural situation in which the respondent would have been expected to file this auxiliary request before the opposition division.

47. That, as argued by the appellants, auxiliary requests 1 to 7 as filed by the respondent with its reply to the appeals are not convergent with one another, is, in the board's view an aspect which may be relevant in the context of the admission of auxiliary requests 2 and the following, but not for assessing admission of auxiliary request 1.

48. Auxiliary request 1 addresses objections under Article 56 EPC raised by the appellants in their statement of grounds of appeal. Whether or not these objections are overcome and other requirements as to patentability are fulfilled is, in the circumstances of the present case, a matter of consideration of this request in substance and not a question of its admission into the proceedings.

Claim 1 - clarity (Article 84 EPC)

49. As compared to claim 1 as granted (see section II), claim 1 (see section XI) now specifies that the vaccine that comprises the ORF-2 protein is to "to efficiently protect a herd against the consequences of PCV-2 infection". Accordingly, the wording now comprises the terms "herd", "efficiently protect a herd" and "consequences of PCV-2 infection".

50. The board considers that the term "herd" in the context of the claim is unclear. Indeed, whereas the board can accept that the term has some general meaning and relates, here, to e.g. a group of pigs kept in close proximity to each other, it appears that the term has no exact meaning in terms of e.g. the minimum or maximum number of animals required for a group of animals to be considered as a "herd" or the age distribution of the animals in such a group.

51. In the absence of an exact technical meaning of the term "herd" and in the absence of a definition of the term in the patent, the claim is not only unclear in this respect, but also in respect of the whole feature "to efficiently protect a herd against the consequences of PCV-2 infection".

52. Accordingly, claim 1 lacks clarity within the meaning of Article 84 EPC.

Auxiliary request 2

Admission into the proceedings

53. Auxiliary request 2, similar to auxiliary request 1, is aimed at addressing objections under Article 56 EPC raised by the appellants in their statement of grounds of appeal and during the oral proceedings which eventually convinced the board to hold the subject-matter of claim 1 of the main request to lack inventive step.

54. Also this request was already filed by the respondent in reply to the statements of grounds of appeal, as auxiliary request 7 (see section XI). According to Article 12(1) RPBA, the request is therefore, as a rule, part of the appeal proceedings and similar considerations apply as in relation to auxiliary request 1. As regards the aspect of an alleged lack of convergence with auxiliary request 1, the board considered this aspect outweighed by the respondent's attempt to address the appellants' objections already at the initial stage of the appeal proceedings.

Claim 1 - clarity (Article 84 EPC)

55. As compared to claim 1 as granted (see section II), claim 1 (see section XI) now specifies that the MDA level in the PCV-2-MDA-positive piglets is such that "in a prime-boost vaccination regimen, between 0 and 100% of the piglets have a PCV2 specific antibody titre at 1 week post booster vaccination, 3 weeks after primary vaccination, that is equal to or higher than

the PCV-2 specific titre at primary vaccination, using a vaccine comprising 20-80 µg ORF2 protein per dose".

56. The board considers that the added feature does not define the required MDA level in the PCV-2-MDA-positive piglets in an unambiguous manner. Indeed, whereas the claim, on the one hand, is directed to the vaccination of PCV-2-MDA-positive individual piglets, the added feature relates, on the other hand, to particular PCV2-specific MDA levels after vaccination in a group of piglets, i.e. in particular in an undefined percentage of that group of piglets. Due to this discrepancy the wording of the claim is unclear (Article 84 EPC).

Auxiliary request 3

Admission into the proceedings

57. This claim request was filed during the oral proceedings, after the board had given its opinion that the subject-matter of claim 1 of the main request lacked inventive step and that claim 1 of both auxiliary requests 1 and 2 lacked clarity. The filing of this request amounts thus to an amendment to the respondent's case and its admission is at the board's discretion (Article 13(1) and (3) RPBA).

58. The respondent has argued that the request should be admitted into the proceedings because it constituted a bona fide attempt to overcome the board's opinions expressed in relation to the higher ranking requests.

59. However, those arguments by the appellants which persuaded the board to arrive at its respective decisions during the oral proceedings in relation to

the higher ranking requests had been on file prior to the oral proceedings.

60. Hence, the board considers that, objectively, the respondent has not put forward arguments to the effect that unforeseeable developments had occurred in the oral proceedings that would justify admitting amended claims at this late stage of the appeal proceedings. In these circumstances the fact as such that the board found against the respondent at the oral proceedings cannot be qualified as "unforeseeable".

61. Rather, the new request was unforeseeable for the appellants and the board since none of these claim requests on file prior to the oral proceedings was for subject-matter as now claimed since it was not the result of a simple contraction of the subject-matter of a dependent claim with that of an independent claim. For reasons of procedural fairness, admission of this claim request into the appeal proceedings would have required an adjournment of the oral proceedings. This would, however, have been contrary to procedural economy.

62. Therefore, the board decided not to admit auxiliary request 3 into the proceedings (Article 13(1) and (3) RPBA).

Conclusion

63. The board concludes that none of the claim requests considered by the board meets the requirements of the EPC. Accordingly, the patent cannot be maintained on the basis of any of these claim requests and, in the absence of any other allowable claim request, must be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated