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Datasheet for the decision of 27 April 2016

Case Number: T 0619/12 - 3.3.04

Application Number: 02735755.7

Publication Number: 1474067

IPC: A61K39/00, A61P31/00

Language of the proceedings: EN

Title of invention:
One dose vaccination with Mycoplasma hyopneumoniae

Patent Proprietor:
Zoetis Services LLC

Opponents:
Intervet International B.V.
Boehringer Ingelheim Vetmedica GmbH
Merial Limited

Headword:
One dose vaccination/ZOETIS

Relevant legal provisions:
EPC Art. 123(2), 56

Keyword:
Main request - requirements of the EPC met (yes)

Decisions cited:

Catchword:

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Case Number: T 0619/12 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 27 April 2016

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Appellant IV: (Opponent 3)	Merial Limited 3239 Satellite Blvd Duluth, GA 30096-4640 (US)

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 26 January 2012 concerning maintenance of the European Patent No. 1474067 in amended form.**

Composition of the Board:

Chairwoman G. Alt
Members: R. Morawetz
M. Blasi

Summary of Facts and Submissions

I. The appeals by the proprietor ("appellant I") and by opponents 1, 2 and 3 ("appellants II, III and IV") lie against the decision of the opposition division maintaining European patent No. 1 474 067 in amended form on the basis of auxiliary request IV.

II. The patent at issue has the title "*One dose vaccination with Mycoplasma hyopneumoniae*". It was granted in respect of European patent application No. 02735755.7, which originated from international patent application No. PCT/IB2002/002121, published as WO 03/003941 ("application as filed" or "application").

III. The patent was opposed under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Article 100(b) and (c) EPC. The opposition division held that the main request and auxiliary request II failed to meet the requirements of Article 54 EPC, while the subject-matter of claim 1 of auxiliary request I lacked inventive step and claim 1 of auxiliary request III lacked clarity. The subject-matter of the claims of auxiliary request IV was held to meet the requirements of the EPC.

IV. With its statement of grounds of appeal, appellant I submitted a main request and auxiliary requests I to V. Auxiliary request V corresponded essentially to auxiliary request IV before the opposition division, except that in claim 1 the phrase "*pigs serologically negative*" had been replaced with the phrase "*pigs seronegative*".

V. The board summoned the parties to oral proceedings and issued a communication pursuant to Article 15(1) RPBA.

VI. Oral proceedings before the board took place on 26 and 27 April 2016. In the course of the oral proceedings appellant I filed an amended auxiliary request V comprising 9 claims with dependent claim 8 amended to read "*pigs*" instead of "*swine*". Subsequently, it withdrew the pending main request and auxiliary requests I to IV and made amended auxiliary request V its new main (and sole) request. Appellant II withdrew its objection under Article 83 EPC.

Claims 1 and 8 of the new main request read:

"1. Use of a *Mycoplasma hyopneumoniae* bacterin for the manufacture of a vaccine for treating or preventing, in pigs seronegative for *Mycoplasma hyopneumoniae*, a disease or disorder caused by infection with *Mycoplasma hyopneumoniae* for administration to the pigs at from 3 to 10 days of age, an effective amount of a single dose of the *Mycoplasma hyopneumoniae* vaccine.

8. The use according to claim 1, wherein said pigs are protected up to 25 weeks following vaccination."

Claims 2 to 9 of the new main request are dependent on claim 1.

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

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

D1 Truchan L. *et al.*, American Association of Swine Practitioners (2000), page 125

D3 WO 91/18627

D4 WO 94/07531

D5 WO 02/10343

D6 Miller, S.K. *et al.*, The 16th International Pig Veterinary Society Congress, Melbourne, Australia, 17 to 10 September 2000, page 498

D9 WO 92/03157

D21 Schwager J. and J. Schulze, Veterinary Immunology and Immunopathology (1997), vol. 57, pages 105 to 119

D29 Hammerberg, C. *et al.*, Am. J. Vet. Res. (1989), vol. 50, pages 868 to 874

D31 Okada M. *et al.*, J. Vet. Med. Sci. (1999), vol. 61, pages 1131 to 1135

D46 Kim Y.B., *et al.*, The Journal of Immunology (1966), vol. 97, pages 52 to 63

D47 Bilic V. *et al.*, Acta Veterinaria Hungarica (1996), vol. 44, pages 287 to 293

D61 RespiSure® product information, Pfizer

VIII. The arguments of appellant I relevant for the present decision may be summarised as follows:

New main (sole) request

Article 123(2) EPC

The application taught that the *Mycoplasma hyopneumoniae (M. hyo)* vaccine might be administered to either seronegative or seropositive pigs. Since a pig could not be both seronegative and seropositive for *M. hyo*, then - implicitly - the application as filed had to have envisaged, separately, the vaccination of pigs of either serostatus (see also examples of the application). To restrict the claims to pigs of one serostatus (seronegative) rather than another (seropositive) could therefore not be held to add subject-matter.

The treatment of seronegative pigs in combination with the other features of claim 1 was disclosed in the application on page 3, lines 2 and 8 and on page 10, lines 14 to 15. A basis for limiting the use of the *M. hyo* vaccine to "*pigs seronegative for M. hyo*" could also be found in examples 4 and 5 of the application.

The omission of the feature "*against challenge with virulent M. hyo*" disclosed on page 3, line 9, and of the feature "*provide protective immunity*" disclosed on page 10, line 14, did not result in added subject-matter. The skilled person would understand that the reference to the use of a vaccine for treating or preventing a disease was synonymous with providing protective immunity or protection against challenge.

Article 56 EPC

Closest prior art

Document D3 referred to a two-dose vaccination regimen with *M. hyo* and any reference to a single dose in document D3 was without reference to the age of the pig when vaccinated (i.e. page 14, lines 7 to 9).

Document D4 was mainly concerned with the treatment of seropositive pigs. Table 1 showed no effect in seronegative pigs (group 3) over the controls (group 1).

All efficacy studies described in document D6 had been carried out with pigs that were seropositive for *M. hyo*.

Document D9 was not a suitable starting point, as it did not disclose single dose administration of an *M. hyo* vaccine.

Document D1 was the closest prior art. It disclosed a single dose vaccine regime against *M. hyo* using RespiSure®. This was an *M. hyo* bacterin, which was licensed as a two dose product for use in pigs of approximately one week of age, followed by a booster two weeks later. In document D1, RespiSure® was given to pigs seronegative for *M. hyo* at 3 or 8 weeks of age.

Technical problem and its solution

Piglets at the age of 3 to 10 days were easier to handle than those at 3 to 8 weeks. Moreover, while in document D1 the piglets were protected for 18 weeks against challenge with *M. hyo*, they were shown to be

protected much longer by the claimed regime, i.e. for 25 weeks or longer (see examples 4 and 5). Accordingly, the technical problem to be solved was the provision of a vaccination regime against *M. hyo* in seronegative pigs that was more convenient and provided longer protection. The solution to this problem was provided by the subject-matter of claim 1.

Obviousness

The claimed solution was neither taught nor suggested in document D1, which showed that pigs vaccinated with one dose of RespiSure® at the age of 3 or 8 weeks - but not younger - were protected against challenge with *M. hyo*. Vaccination at one week of age was disclosed, but only in combination with a booster two weeks later.

A person skilled in the art would have taken the results of document D1 to indicate that a single dose of the two-dose regimen at one week of age was ineffective unless given much later, when the pig's immune system was more mature. There was no evidence, or indication based on the teaching of document D1, that one dose of RespiSure® given at one week of age was efficacious, because the second dose at 3 weeks was all that was shown to be required for efficacy. Thus, in view of this teaching, a veterinarian would not have considered vaccinating only at one week of age. Nor, from the teaching of document D1, would a veterinarian have expected such a vaccine regimen to work at one week of age.

One week old pigs had a rather immature immune system compared to pigs at 3 to 8 weeks of age. There were numerous factors that governed immune system maturation, as recognised in the art, all of which

suggested that the immune system of a piglet at 3 to 10 days of age was not able to mount a proper antigen response (see e.g. documents D21, D29, and D31).

Document D4 disclosed the vaccination of seronegative pigs at one week of age (see Tables I and II). Document D46 reported a study involving colostrum-deprived piglets. In both cases, no protective immune response was shown.

According to document D9 local secretory antibodies and/or cell-mediated immunity were important for immuno-protection against infection by *M. hyo* (see page 32, last paragraph).

Document D5 was an Article 54(3) EPC document and thus not available for the assessment of inventive step.

The pigs vaccinated in document D6 at 1 week of age received two doses of the *M. hyo* vaccine. Document D47 used two doses of RespiSure® at 12 and 14 weeks of age. The label claim for RespiSure® was for administration at 1 and 3 weeks of age (i.e. two doses), not for administration at 1 to 3 weeks of age, as incorrectly stated in document D47. This was evidenced by documents D1 and D61.

Document D31 reported (see Table 1) that 4 weeks after the first vaccination with an inactivated *M. hyo* vaccine, no antibody response was seen.

IX. The arguments of appellants II, III and IV relevant for the present decision may be summarised as follows:

New main (sole) request

Article 123(2) EPC

The passages in the application as filed on page 3, lines 7 to 9 and page 10, lines 14 to 17 emphasised that the invention related to a method of vaccinating both seronegative and seropositive pigs. Vaccination of only seronegative pigs, as now claimed, was a selection which was not envisaged in the application. The examples too referred to both populations.

Omission from claim 1 of the feature "*against challenge with virulent M. hyo*" disclosed on page 3, line 9, and of the feature "*provide protective immunity*", disclosed on page 10, line 14, resulted in subject-matter not disclosed in the application.

Article 56 EPC

Closest prior art

Appellants II, III and IV considered that document D1 was the closest prior art because it related to the same purpose as the claimed invention, namely the immunisation of seronegative pigs. The pigs were vaccinated at 3 weeks of age with RespiSure®, "*a liquid inactivated, whole cell, M. hyopneumoniae bacterin*" (see D1, first paragraph), to protect them from chronic pneumonia caused by *M. hyo*. According to document D1 the immunity lasted 18 weeks.

Appellant III further submitted that documents D3, D4, D6 or D9 could also be considered to represent the closest prior art.

Technical problem and its solution

The difference between the teaching of document D1 and the claimed subject-matter was that the pigs were vaccinated at 10 days of age rather than at 3 weeks. No technical effect was attributed in the application to the point in time at which the single dose was administered. Also, prolonged protection was not a feature of claim 1. Finally, pigs were just as easy to handle at 3 weeks of age as at 3 to 10 days of age. Therefore the claimed subject-matter had to be seen as providing an alternative to the regime taught in document D1.

Obviousness

Based on the teaching of document D1, the next obvious step that the skilled person would take was to prime earlier and to omit the booster vaccination from the known RespiSure® scheme, thus arriving at a single dose vaccination in pigs of one week of age. Moreover, document D1 taught the person skilled in the art that long-lasting immunity could be achieved by one injection of RespiSure® and also that there was no difference in the protective effect achieved by vaccination at 3 or 8 weeks of age. The skilled person thus had a reasonable expectation of success.

The skilled person was motivated to vaccinate at an earlier age for reasons of convenience and to provide protection as early as possible. Because of the licensed dosage regimen of RespiSure® illustrated in

e.g. document D61, and also because of the data in document D4, the skilled person would reasonably expect vaccination at 1 week of age to be successful.

It was true that the immune system of pigs was fully mature only after 4 weeks of age. Document D46 disclosed however that pigs were already fully immunocompetent at birth with regard to an antibody response. In keeping with this, document D1 disclosed that a prime vaccination with RespiSure® at one week of age was adequate. There was thus a reasonable expectation of success in obtaining an adequate immune response when omitting the booster vaccination from the RespiSure® scheme.

The present invention was merely a routine modification of the timing of the dosing. Vaccination with an *M. hyo* vaccine at one week of age was known to be effective (see documents D4, D5, D6 and D47).

X. Appellant I requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the claims of the new main request filed during the oral proceedings before the board.

XI. Appellants II, III and IV requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

Introduction

1. The present invention relates to the vaccination of pigs against *Mycoplasma hyopneumoniae* (*M. hyo*), a bacterial antigen that causes enzootic pneumonia in swine. Enzootic pneumonia is a chronic disease that results in poor feed conversion, stunted growth and predisposition to secondary pulmonary infections. Piglets may be seropositive or seronegative for antibodies against *M. hyo*. Seropositive piglets are piglets which have antibodies against *M. hyo* in their serum. If nursed by a seropositive sow, a piglet can become seropositive, since in pigs passive transfer of antibodies from mother to offspring occurs through the colostrum. Seronegative piglets are those piglets which do not have detectable levels of antibodies against *M. hyo* in their serum.

New main (sole) request

2. The only points at issue amongst the parties in relation to the claims of the new main request were whether they contained subject-matter extending beyond the content of the application as originally filed and whether the claimed subject-matter involved an inventive step. The board is satisfied that the other requirements of the EPC are met.

Article 123(2) EPC

3. Claim 1 relates to the use of an *M. hyo* bacterin for the manufacture of a vaccine for treating or preventing, in pigs seronegative for *M. hyo*, a disease or disorder caused by infection with *M. hyo* for

administration to the pigs at from 3 to 10 days of age, an effective amount of a single dose of the *M. hyo* vaccine.

4. The application as filed discloses on page 3, lines 2 to 5 that "*the present invention provides a method of treating or preventing a disease or disorder in an animal caused by infection with Mycoplasma hyopneumoniae comprising administering to the animal at from about 3 to about 10 days of age, an effective amount of a single dose of a Mycoplasma hyopneumoniae vaccine*". This passage thus discloses all the features of the subject-matter of claim 1, except for the feature "*in pigs seronegative for Mycoplasma hyopneumoniae*".

5. A basis for this feature is provided by page 3, lines 8 to 9, which discloses that "*the present method of single (one) dose vaccination provides protection to both seronegative and seronegative pigs against challenge with virulent M. hyo*" and by page 10, lines 14 to 15, which discloses that "*the present vaccination methods provide protective immunity for both piglets seropositive and piglets seronegative for M. hyo.*" Also examples 4 and 5 disclose protection against challenge with virulent *M. hyo* in seronegative pigs vaccinated with a single dose of *M. hyo* bacterin.

6. The board notes that protection against challenge with virulent *M. hyo* or provision of protective immunity is the very purpose of vaccination and that therefore the omission of these features from the subject-matter of claim 1 does not result in subject-matter which extends beyond the content of the application as filed.

7. Moreover, the application explicitly teaches that the *M. hyo* vaccine can be administered to either seropositive pigs (example 3) or seronegative pigs (examples 4 and 5). Therefore, the restriction of the claimed subject-matter to seronegative pigs does not result in added subject-matter.

8. The subject-matter of claims 1 to 9 fulfils the requirements of Article 123(2) EPC.

Article 56 EPC

Closest prior art

9. In accordance with established jurisprudence, the closest prior art for assessing inventive step is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications (see Case Law of the Boards of Appeal of the EPO, 7th edition 2013, section I.D.3.1).

10. The purpose of the claimed invention is the protection of pigs seronegative for *M. hyo* from a disease or disorder caused by infection with *M. hyo*.

11. While all parties agreed that document D1 could be considered as the closest prior art, appellant III further submitted that, alternatively, documents D3, D4, D6 or D9 could also represent the closest prior art.

12. Document D1 discloses vaccination of pigs seronegative for *M. hyo* with a single dose of an *M. hyo* bacterin

(RespiSure®) at 3 or 8 weeks of age. The pigs are shown to be protected against experimental challenge with *M. hyo* 18 weeks later. Document D1 thus relates to the same purpose as the claimed invention.

13. Document D3 refers to a two-dose vaccination regime of pigs with an *M. hyo* vaccine. It discloses that primary immunisation of piglets should be initiated at approximately one week of age with a booster dose two weeks later (see page 13, lines 10 to 12). The board notes that document D3 is however silent about the serostatus of the vaccinated pigs.

14. Document D4 concerns a method which involves vaccinating pregnant sows with an *M. hyo* vaccine and then administering the same vaccine to their newborn piglets at between one and three weeks of age (see e.g. example 1). It was undisputed that the newborn piglets were seropositive due to being nursed by vaccinated mothers. Thus, the document discloses a single dose *M. hyo* vaccination regime for pigs seropositive for *M. hyo*. It is correct that in document D4 experiments using seronegative pigs were also conducted. However, firstly, these experiments were not aimed at showing any immune effect or protection against *M. hyo* challenge. Secondly, no difference was seen between control and seronegative pigs in the effect of primary vaccination on the T cell profiles in peripheral blood lymphocytes of the piglets (see example 1, Table I, groups 1 and 3).

15. Document D6 relates to safety and efficacy studies of a single dose *M. hyo* bacterin. In the safety studies, the pigs were seronegative, while the efficacy studies were done with pigs from herds that were seropositive for *M. hyo* (see page 498, left hand column, last

paragraph). Thus, while in document D6 experiments with seronegative pigs were carried out, these experiments were conducted to evaluate the safety of the vaccine but not any immune effect or protection against *M. hyo* challenge.

16. Document D9 relates to vaccination with an *M. hyo* bacterin, wherein the bacterin is preferably administered twice to the pigs, once at about one week of age and once at about three weeks of age (see page 12, lines 23 to 25). The serostatus of the vaccinated pigs is only disclosed for the pigs of example 2, which were seropositive (see page 32, lines 11 to 12).

17. The board concludes from the above that documents D3, D4, D6 and D9 do not aim at the protection of pigs seronegative for *M. hyo* from infection with *M. hyo*. Therefore, these documents do not relate to the same purpose as the present invention and are thus not an appropriate starting point for the assessment of inventive step. Only document D1 discloses subject-matter conceived for the same purpose as the claimed invention. Therefore the board takes the view that document D1 represents the closest state of the art for the purpose of the assessment of inventive step of the subject-matter of claim 1.

Technical problem and its solution

18. The subject-matter of claim 1 differs from the teaching of document D1 in that the seronegative pigs are vaccinated at 3 to 10 days of age instead of at 3 or 8 weeks of age. The technical effect associated with this difference is the same as in the prior art, namely effective protection from infection with *M. hyo*. The problem to be solved can thus be formulated as the

provision of an alternative effective single dose vaccine for treating or preventing, in pigs seronegative for *M. hyo*, a disease or disorder caused by infection with *M. hyo*. Based on the data provided in the patent in suit, in particular in examples 4 and 5, the board is satisfied that the problem is solved by the claimed subject-matter.

19. Appellant I submitted that not only were piglets easier to handle at the age of 3 to 10 days than at 3 to 8 weeks, but also that the claimed regime provided 25 weeks of protection against challenge with *M. hyo* while the prior art regime disclosed in document D1 provided only 18 weeks of protection. Accordingly, in its view, the problem to be solved was the provision of a vaccination regime for vaccination against *M. hyo* in seronegative pigs that was more convenient and that provided prolonged protection.

20. The board is not convinced by these arguments. In the absence of any feature relating to the length of protection, the subject-matter of claim 1 covers any period of protection, including periods that are substantially shorter than 25 or even 18 weeks. There is also no adequate evidence before the board to persuade it that pigs are significantly easier to handle at 10 days of age than at 21 days of age. Accordingly, longer protection than under the regime of document D1 or convenience of handling are both effects that cannot be taken into account for determining the problem to be solved by the subject-matter of claim 1.

Obviousness

21. The question which remains to be answered is whether the skilled person, aware of the teaching of

document D1 and faced with the technical problem defined in point 18 above, would have modified the teaching of the closest prior art document D1 - possibly in the light of other prior art teachings - so as to arrive at the claimed invention in an obvious manner.

22. As set out above (see point 12), document D1 discloses vaccination of pigs seronegative for *M. hyo* with a single dose of an *M. hyo* bacterin (RespiSure®) at 3 or 8 weeks of age. It also discloses vaccination of piglets at one week of age, but only in combination with a booster two weeks later. Thus, document D1 mentions that RespiSure®, an *M. hyo* bacterin, is licensed as a two dose product for use in pigs of approximately one week of age followed by a booster two weeks later (see page 125, left hand column, first paragraph).

23. In the board's judgement, the fact that RespiSure® was licensed for a treatment regime including a prime vaccination at 1 week of age, and the observation in document D1 that there was no difference in effect of a single vaccination at 3 or at 8 weeks of age, would not in themselves prompt the skilled person to vaccinate seronegative pigs with a single dose of an *M. hyo* vaccine at 1 week of age.

24. This is so, firstly, because according to document D1 (see page 125, left hand column, first paragraph) - and also according to document D61 (see page 1, point 2 under Directions) - vaccination with an *M. hyo* vaccine at 1 week of age does require a booster 2 weeks later.

25. Secondly, at the priority date of the patent in suit, it was assumed that the immune system of pigs matured

over time and that the immune system of a piglet at 1 week of age was not able to mount a proper immune response. Thus, document D21 discloses that there is a "*clear deficit in specific cellular immune mechanisms over the first 3-4 weeks after birth*" in neonatal piglets (see page 106, third paragraph). Document D29 discloses that "*immunodeficiency that extended from birth up to 4 weeks, was observed in serum antibody concentration and in vitro proliferative responses of blood mononuclear cells from young pigs exposed to a low antigen dose of a T-cell dependent antigen (...)*" (page 868, left hand column, lines 5 to 10). Therefore, the skilled person had no reason to conclude from the teaching of document D1 that a single vaccination at 1 week of age provided protection against infection with *M. hyo*, simply because a single vaccination at 3 weeks of age did.

26. The teaching of document D46 would not convince the skilled person otherwise. At the priority date of the patent *in suit* it was assumed that for the protection against *M. hyo* local secretory antibodies and/or cell-mediated immunity were required (see document D9, page 32, last paragraph). And while document D46 reports that colostrum-deprived "*immunologically virgin*" piglets, obtained by hysterectomy, produce detectable antibodies after a single injection of antigen within 5 hours after hysterectomy, it is silent as to any cell-mediated immune response to the antigen (see page 57, left hand column, last paragraph - page 58, left hand column, first paragraph). Thus, from the fact that an antibody response can be induced in piglets under the particular conditions studied in document D46, no

conclusion can be drawn as regards the efficacy of a single dose of a *M. hyo* bacterin given to piglets at one week of age.

27. The board considers that the skilled person faced with the problem formulated above is also aware of the teaching of document D31. This document reports on the evaluation of an inactivated *M. hyo* vaccine under field conditions. A first vaccination was given at 3 to 7 weeks of age and then repeated 4 weeks later (see paragraph bridging pages 1131 and 1132). Only 4 weeks after the second vaccination an antibody response was seen, while 4 weeks after the first vaccination no antibody response was seen (see abstract and Table 1). In other words, no antibody response was seen in document D31 after a single vaccination of pigs with the relevant antigen, *M. hyo*. Based on these results, the skilled person has no reason to consider that a single dose of an *M. hyo* bacterin given at the age of 1 week is efficacious in seronegative pigs.

28. Documents D4, D5, D6 and D47 were relied on by appellants II, III and IV to argue that vaccination with an *M. hyo* vaccine at one week of age was known to be effective.

29. In example 1 of document D4, phenotypic analyses of lymphoid cells by flow cytometry were used to assess the effects of vaccination on piglets at one week of age (see page 15, lines 19 to 24). From Table I, which summarises the effects of primary vaccination on the T cell profiles in peripheral blood lymphocytes of piglets, it can be seen that vaccinated piglets nursed by non-vaccinated sows, i.e. seronegative piglets, had the same T cell profiles as non-vaccinated piglets (see Table I, compare groups 1 and 3). In other words, no

effect on T cell profiles was seen after a single vaccination of seronegative pigs at one week of age. Also, post-primary *in vitro* proliferation responses of lymphoid cells from piglets born to and nursed by non-vaccinated sows after vaccination with RespiSure® at 1 week of age were very low compared to post-primary vaccination responses of T cells from piglets born to vaccinated pigs, i.e. seropositive pigs, which "*were comparable to the responses typically expected from a second vaccination in a piglet*" (see page 18, lines 1 to 4; page 19, lines 20 to 24; Table II). The board concludes that the skilled person does not receive any reassurance, from the teaching of document D4, that a single vaccination of seronegative pigs at the age of 1 week against *M. hyo* is efficacious.

30. It is uncontested between the parties that document D5 is state of the art under Article 54(3) EPC for the claimed subject-matter. As an Article 54(3) EPC document, it is not to be considered for the assessment of inventive step.

31. Document D6 does not disclose the age of the piglets vaccinated with a single dose of the vaccine, while the piglets vaccinated at 1 week of age received a second dose (see Tables 1 and 2).

32. Document D47 discloses a two-dose vaccination regimen according to which pigs are immunised with RespiSure® at 12 and 14 weeks of age. In addition, document D47 also mentions that the producer of the vaccine "*suggested that the optimal age for vaccination was 1 to 3 weeks*" (see page 289, third paragraph and page 292, third paragraph). The reference to "*1 to 3 weeks*" is however incorrect, as evidenced e.g. by document D1 (see page 125, left hand column, first paragraph) and

document D61 (see page 1, point 2 under Directions). In fact, RespiSure® is licensed for administration to pigs at 1 week of age with a booster dose 2 weeks later, i.e. for vaccination at 1 week and 3 weeks of age.

33. The board concludes that neither document D4 nor documents D6 or D47 show that vaccination with an *M. hyo* vaccine at one week of age is effective.

34. To summarise, in view of what was known at the priority date of the patent *in suit* about the maturation of the pig's immune system (see point 25), about the type of immune response required for protection against *M. hyo* (see point 26), and in view of the results from earlier *M. hyo* vaccination trials (see points 22, 27 and 29), there was no reason for the skilled person to suppose that a single dose of an *M. hyo* bacterin given to seronegative pigs at 1 week of age was efficacious. The board accepts that the skilled person is aware that seronegative pigs need protection against infection with *M. hyo* as early as possible after birth. That in itself however is not enough to prompt him to vaccinate seronegative pigs with a single dose at 1 week of age in the absence of any indication that this regimen is also efficacious. Accordingly, the skilled person faced with the technical problem defined in point 18 above would not vaccinate seronegative pigs with a single dose of *M. hyo* bacterin at 1 week of age.

35. The board concludes from the above that the skilled person would not have arrived in an obvious manner at the subject-matter of claim 1 or of dependent claims 2 to 9. The new main request meets the requirements of Article 56 EPC.

Adaptation of the description

36. The subject-matter of the claims of the new main request corresponds in essence to the subject-matter of the claims of auxiliary request IV that was found by the opposition division to meet the requirements of the EPC (see sections III and IV above). The description of the patent in suit was adapted to that request during the proceedings before the opposition division. No further adaptation is considered necessary by the board.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of claims 1 to 9 of the new main request filed during the oral proceedings before the board and a description in the following version:
   - pages 4,5,7 and 9 of the patent specification
   - pages 2,3,6,8 and 10 as filed during the oral proceedings before the opposition division on 4 November 2011.

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated