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Datasheet for the decision of 28 February 2023

Case Number: T 1589/21 - 3.3.08

Application Number: 13169835.9

Publication Number: 2633867

IPC: A61K39/295, A61K39/106, A61P31/04, A61P31/12, A61K39/02

Language of the proceedings: EN

Title of invention:
Vaccine for protection against Lawsonia intracellularis, Mycoplasma hyopneumoniae and Porcine circo virus

Patent Proprietor:
Intervet International B.V.

Opponent:
Ceva Santé Animale

Headword:
Vaccine comprising non-live antigens/INTERVET

Relevant legal provisions:
EPC Art. 76(1), 100(c), 123(2)
RPBA 2020 Art. 12(4), 12(6), 13(2)

Keyword:

Grounds for opposition - subject-matter extends beyond content of earlier application and application as filed (yes)
Late-filed request - circumstances of appeal case justify admittance (no)
Amendment after summons - exceptional circumstances (no) - cogent reasons (no) - admitted (no)

Decisions cited:

G 0001/03, G 0002/10, T 0085/93, T 1859/08, T 2593/11, T 0239/16

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Case Number: T 1589/21 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 28 February 2023

Appellant: (Patent Proprietor)	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)
Representative:	Intervet International B.V. Hertford Road Hoddesdon, Hertfordshire EN11 9BU (GB)
Respondent: (Opponent 1)	Ceva Santé Animale 10, avenue de la Ballastière 33500 Libourne (FR)
Representative:	Cabinet Becker et Associés 25, rue Louis le Grand 75002 Paris (FR)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 26 July 2021 revoking European patent No. 2633867 pursuant to Article 101(2) and Article 101(3)(b) EPC**

Composition of the Board:

Chair	T. Sommerfeld
Members:	A. Schmitt
	M. Blasi

Summary of Facts and Submissions

I. The patent proprietor's (appellant's) appeal lies from the opposition division's decision to revoke European patent No. 2 633 867 (hereinafter "the patent").

Claim 1 of the patent as granted reads as follows:

"1. A vaccine comprising in combination non-live antigens of *Lawsonia intracellularis*, *Mycoplasma hyopneumoniae* and Porcine circo virus, and a carrier, the antigen of *Lawsonia intracellularis* is inactivated whole cell *Lawsonia intracellularis*, the antigen of *Mycoplasma hyopneumoniae* is inactivated *Mycoplasma hyopneumoniae* and the antigen of Porcine circo virus is ORF2 encoded protein of PCV-2, for use in protection against *Lawsonia intracellularis*, *Mycoplasma hyopneumoniae* and porcine [sic] circo virus by intramuscular administration of the vaccine only once."

II. The patent, entitled "*Vaccine for protection against Lawsonia intracellularis, Mycoplasma hyopneumoniae and Porcine circo virus*", was granted on European patent application No. 13 169 835.9 (hereinafter "the application"), which is a divisional application in respect of European patent application No. 09 732 113.7, which had been filed as an international patent application published as WO 2009/127684 (hereinafter "the earlier application").

III. Two oppositions were filed against the patent. 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.

IV. The opposition division held *inter alia* that the sole claim of the patent as granted (claim 1) did not contain subject-matter which extended beyond the content of the application and the earlier application (Article 100(c) EPC). However, the invention as defined in claim 1 of the patent as granted was not sufficiently disclosed (Article 100(b) EPC). The same applied to the invention as defined in claim 1 of each of auxiliary requests 1 and 2 (Article 83 EPC). Auxiliary requests 3 and 4 were not admitted.

Claim 1 of auxiliary request 1 is identical to claim 1 of the patent as granted except for the additional features that the vaccine is for use in the protection "of a pig" against the three pathogens recited in the claim by intramuscular administration of the vaccine "to the pig".

Claim 1 of auxiliary request 2 is identical to claim 1 of the patent as granted except that the vaccine further comprises "an adjuvant".

Claim 1 of auxiliary request 3 is identical to claim 1 of the patent as granted except that the vaccine further comprises "an oil in water adjuvant".

Claim 1 of auxiliary request 4 is identical to claim 1 of the patent as granted except that the vaccine further comprises "an oil in water adjuvant containing oil droplets of sub-micrometer size".

V. With the statement of grounds of appeal the appellant submitted claims of auxiliary requests 1 to 4, which are identical to the claims of auxiliary requests 1 to 4 submitted during opposition (see section IV.).

VI. Opponent 1 (respondent) replied to the appeal and submitted, *inter alia*, arguments supporting its view that claim 1 as granted and claim 1 of each of auxiliary requests 1 and 2 contained subject-matter that extended beyond the content of the application and the earlier application, and that auxiliary requests 3 and 4 should not be admitted into the appeal proceedings. Opponent 2, having withdrawn the opposition during the opposition proceedings, had ceased to be a party to the opposition proceedings and thus was never a party to the appeal proceedings.

VII. The board summoned the parties to oral proceedings in accordance with their requests and, in a communication pursuant to Article 15(1) RPBA, expressed its preliminary opinion *inter alia* that claim 1 of the patent as granted and claim 1 of each of auxiliary requests 1 and 2 contained subject-matter which extended beyond the content of the application and the earlier application, and that the board did not intend to admit auxiliary requests 3 and 4 pursuant to Article 12(6) RPBA.

VIII. On 12 January 2023, the appellant submitted two documents (D54 and D55) and a set of claims of auxiliary request 5.

Claim 1 of auxiliary request 5 is identical to claim 1 of the patent as granted except for the additional features that the vaccine is for use in the protection "of a pig" against the three pathogens recited in the claim by intramuscular administration of the vaccine "to the pig", and that the vaccine also comprises "an adjuvant".

IX. The oral proceedings took place as scheduled. At the end of the oral proceedings, the chair announced the board's decision.

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

D54 "Veterinary Vaccinology", ed. by P.-P. Pastoret et al., Elsevier Science B.V. 1997, pages 175, 177, 178

D55 "Infectious Diseases of Livestock", 2nd Ed., Vol. 3, Oxford University Press Southern Africa 2004, ed. by J.A.W. Coetzer and R.C. Tustin, page 2043

XI. The appellant's arguments, in so far as relevant to the decision, are summarised as follows.

Admittance of documents D54 and D55
(Article 13(2) RPBA)

Documents D54 and D55 were filed in response to objections submitted by the respondent in the reply to the appeal. Since the opposition division had considered that the grounds in Article 100(c) EPC did not prejudice the maintenance of the patent, the appellant did not have any reason to submit documents D54 and D55 with the statement of grounds of appeal. The respondent's objections presented in its reply to the statement of grounds of appeal with respect to added subject-matter could not have been known beforehand, and the appellant must be allowed to respond to them. At any stage of the proceedings a party must be able to rely on common general knowledge and provide proof, such as documents D54 and D55, for that.

Main request (patent as granted)
Amendments (Article 100(c) EPC)

Claim 1 had a basis in the vaccination of the animals in Group 2 of Example 3 of the application and the earlier application. The purpose of vaccinating – and hence protecting – the animals of Group 2 against the three pathogens recited in the claim was disclosed in lines 2 to 4 of page 14 and the sentence bridging pages 14 and 15, and therefore no issue of added subject-matter could arise with respect to this feature. Page 4, lines 4 to 8 of the application and the earlier application was a further basis for this purpose since it disclosed that the object of the invention was providing a vaccine that comprised in combination non-live antigens against the three pathogens recited in the claim. Therefore, the claim did not contain any new technical information in this respect. The question of whether or not this purpose was actually achieved by the claimed vaccine when administered intramuscularly only once was a matter not of added subject-matter but of sufficiency of disclosure (see decision T 2593/11, Reasons 3.4 and 3.5).

Auxiliary requests 1 and 2
Amendments (Article 123(2) EPC and Article 76(1) EPC)

Claim 1 of auxiliary request 1 specified that the vaccine was used in pigs, a feature which had a basis in Example 3 of the application and the earlier application.

Claim 1 of auxiliary request 2 specified that the vaccine comprised an adjuvant, like the vaccine

disclosed in Example 3. This feature thus had a basis in Example 3 of the application and the earlier application.

Auxiliary requests 3 and 4
Admittance (Article 12(4) and (6) RPBA, Article 13(2) RPBA)

Since the board expressed in its preliminary opinion that the subject-matter of claim 1 resulted from an unallowable intermediate generalisation, the appellant was in a different situation from that in the opposition proceedings. Auxiliary requests 3 and 4 addressed this issue by further specifying the nature of the adjuvant and should therefore be admitted into the proceedings.

Auxiliary request 5
Admittance (Article 13(2) RPBA)

A new situation arose from the board's preliminary opinion because, according to the board, one reason for not allowing claim 1 of the main request was that a specific combination of features had been omitted. In contrast, the respondent's arguments had been directed to omitted features individually. Auxiliary request 5 should therefore be admitted into the proceedings.

XII. The respondent's arguments, in so far as relevant to the decision, are summarised as follows.

Admittance of documents D54 and D55
(Article 13(2) RPBA)

Documents D54 and D55 could and should have been submitted earlier because it had already been argued in

the notice of opposition that omitting the target animal and the precise nature and dosage of the recited antigens in the claim resulted in an unallowable intermediate generalisation of the disclosure in Example 3 of the application and the earlier application. It was not true that documents allegedly illustrating common general knowledge could be submitted at any stage during the proceedings, as confirmed in the Case Law of the Boards of Appeal, 9th edition 2019, V.A.4.13.1(c)). Doing so would introduce new facts, thereby changing the factual framework.

Main request (patent as granted)
Amendments (Article 100(c) EPC)

Claim 1 was a second medical use claim defined by three characterising features, namely a vaccine product, an administration route and scheme, and a specific therapeutic purpose. The claimed vaccine product and the intramuscular administration of the vaccine only once, as recited in the claim, were disclosed only in the context of the vaccination experiment of the "Group 2" animals in Example 3. However, Example 3 did not disclose the purpose recited in the claim (protection against *Lawsonia intracellularis*, *Mycoplasma hyopneumoniae* (Mhyo) and Porcine circo virus (PCV)) in combination with this intramuscular administration of the vaccine only once, since the same negative results on Mhyo antibody titres were reported for both "Group 2" and control "Group 5" (see Table 5). Thus, according to Example 3, no protection against Mhyo could be obtained when the claimed vaccine was administered intramuscularly only once.

The claimed therapeutic purpose could not be derived from the experimental vaccination design described in Example 3 either, because the purpose of this vaccination experiment was merely to test an experimental combination vaccine using two different administration schemes. The results of these test vaccinations dictated what therapeutic purpose was disclosed for each of the two administration schemes tested.

The fact that Example 3 disclosed effective protection against Mhyo only in the context of a "booster" vaccination scheme was acknowledged on page 16, lines 6 to 8 and in the section entitled "Conclusions of Example 3" on page 17, line 20 to page 18, line 6 of the application and the earlier application. Obtaining protection against Mhyo by a single intramuscular vaccination was hence ruled out. Consequently, in combination with the single intramuscular vaccination of Group 2 as disclosed in Example 3, the purpose recited in the claim was neither literally nor implicitly disclosed. The general reference to a combination vaccine on page 4, lines 4 to 8 of the application and earlier application could not remedy this deficiency because this passage disclosed neither the specific antigens of the vaccine nor an administration route and scheme, so it was not a basis for claim 1.

Auxiliary requests 1 and 2
Amendments (Article 123(2) EPC and Article 76(1) EPC)

Claim 1 of each of auxiliary requests 1 and 2 contained subject-matter that extended beyond the content of the application and the earlier application for the same reasons as claim 1 of the main request. Defining the

animal type, as in claim 1 of auxiliary request 1, or including an adjuvant in the claimed vaccine, as in claim 1 of auxiliary request 2, did not address the added-matter objection raised against claim 1 of the main request with respect to the purpose recited in the claim.

Auxiliary requests 3 and 4
Admittance (Article 12(4) and (6) RPBA, Article 13(2) RPBA)

Auxiliary requests 3 and 4 had been filed late in the opposition proceedings and were not admitted by the opposition division. On appeal, the appellant indicated that these auxiliary requests were being submitted to address the lack of sufficiency of disclosure raised with respect to the invention defined in claim 1 of the main request and auxiliary requests 1 and 2, but it did not comment on added subject-matter. No new situation arose from the board's preliminary opinion because the issue of the non-allowability of the intermediate generalisation, *inter alia* for want of a definition of the adjuvant, had already been an issue throughout the opposition proceedings. Auxiliary requests 3 and 4 thus could and should have been filed during the written proceedings in opposition. Furthermore, these requests were neither convergent with auxiliary requests 1 and 2 nor suitable to overcome the unallowable amendments present in those claim requests. They should therefore not be admitted into the appeal proceedings.

Auxiliary request 5
Admittance (Article 13(2) RPBA)

The relevance of multiple features omitted in the claim compared with the disclosure in Example 3 of the

application and the earlier application for achieving the effect recited in the claim had been an issue from the outset of the opposition proceedings. The appellant was not presented with any new information in the board's preliminary opinion that could justify filing auxiliary request 5 at this late stage of the appeal proceedings. Auxiliary request 5, which combined the amendments present in claim 1 of each of auxiliary requests 1 and 2, could and should have been filed in the opposition proceedings together with these auxiliary requests. It should not be admitted into the appeal proceedings.

XIII. The parties' requests relevant for the decision were as follows.

The appellant requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution in relation to novelty and inventive step, and that auxiliary requests 3, 4 and 5 and documents D54 and D55 be admitted into the proceedings.

The respondent requested that the appeal be dismissed and that auxiliary requests 3 and 4 submitted with the statement of grounds of appeal, auxiliary request 5 submitted by letter received on 12 January 2023, and documents D54 and D55 not be admitted into the proceedings.

Reasons for the Decision

Admittance of documents D54 and D55 (Article 13(2) RPBA)

1. Documents D54 and D55 were submitted after the board had issued a summons to oral proceedings and a communication in preparation for the oral proceedings setting out its preliminary opinion.

   Admittance of documents D54 and D55 into the proceedings is governed by the provisions set out in Article 13(2) RPBA, in force since 1 January 2020 and applicable pursuant to Article 24 RPBA.

   Under Article 13(2) RPBA, any amendment to a party's appeal case made after notification of a summons to oral proceedings is, in principle, not to be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

2. According to the appellant, document D54 was submitted as proof that a dose-effect relationship existed for any vaccine, and document D55 was submitted as proof that *Mycoplasma hyopneumoniae* (Mhyo) only affected pigs. These documents did not need to be filed earlier because Article 123(2) and Article 76(1) EPC were not part of the appeal, the opposition division having decided that Article 100(c) EPC did not prejudice the maintenance of the patent.

3. This argument is, however, not persuasive because the opponent had already argued in opposition that omitting the target animal and the precise nature and dosage of the recited antigens in the claim was an unallowable intermediate generalisation, as evident, for example,

from point 2.2.2 of the decision under appeal. Documents D54 and D55 thus could have been submitted in opposition proceedings in response to these objections, irrespective of the fact that the opposition division came to the conclusion that the claims as granted complied with Article 123(2) and Article 76(1) EPC.

4. Moreover, neither the respondent in the reply to the statement of grounds of appeal nor the board in its communication issued in preparation for the oral proceedings had disputed that Mhyo only affected pigs and that a dose-effect relationship existed for vaccines. The appellant's argument that documents D54 and D55 were filed in response to new objections raised in the respondent's reply to the appeal is therefore not persuasive either.

5. In a further line of reasoning, the appellant submitted that a party must be able to rely, at any stage of the proceedings, on common general knowledge and provide proof for that. This argument implies that a board does not have discretion to disregard documents (allegedly) supporting common general knowledge. However, the board cannot derive any such limitation from the EPC or the RPBA. The documents are evidence supporting allegations of fact which, under Article 114(2) EPC, may be disregarded if not submitted in due time by the party concerned. Article 12(3) and (5) RPBA confirms the board's discretionary power in this respect. The board therefore sees no reason for any preferential treatment of evidence for alleged common general knowledge. This is also in line with e.g. decision T 85/93, OJ EPO 1998, 183 (see also Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, V.A.5.13.1(c)).

6. In view of the above considerations, none of the reasons submitted by the appellant justified submitting documents D54 and D55 at this late stage of the proceedings. The board therefore decided not to take them into account under Article 13(2) RPBA.

Main request (patent as granted) - claim 1
Amendments (Article 100(c) EPC)

7. For the purpose of assessing whether or not the claim contained subject-matter that extended beyond the content of the application and the earlier application, reference is made only to the application since the relevant disclosures in the descriptions of the application and the earlier application are identical.

8. One of the issues with respect to the amendments was whether or not the application and the earlier application disclosed the purpose recited in the claim, i.e. protection against *Lawsonia intracellularis*, Mhyo and Porcine circo virus (PCV), in combination with the claimed vaccine and the administration route and scheme recited in the claim (intramuscular administration of the vaccine only once).

9. Example 3 is the only passage in the application that discloses the administration of a composition of the three non-live antigens of the pathogens *Lawsonia intracellularis*, Mhyo and PCV as defined in the claim to subjects (pigs) intramuscularly and only once. However, as also disclosed in Example 3, after a single intramuscular injection, no Mhyo antibodies could be detected (see page 16, lines 6 to 8 and Table 5 of the application). Mhyo antibodies were only detected when a second ("booster") vaccination was given (ibid.).

10. In the application, however, the suitability of the combination vaccine for protecting against the three pathogens is linked to achieving particular Mhyo and PCV antibody titres. This is evident from page 18, lines 1 to 6 of the application, which discloses that "*given the fact that the combination vaccine provided titres for Mhyo and PCV antibodies to a level comparable with the levels obtainable with available single vaccines that are adequate to combat these micro-organisms, it has been demonstrated that a combination vaccine comprising non-live Lawsonia intracellularis antigens in combination with Mhyo and PCV antigens is suitable to combat* [the three pathogens]". This passage thus links the effectiveness of the combination vaccine against Mhyo to Mhyo antibody titres comparable with those achieved with prior-art vaccines. As set out in point 9. above, however, such Mhyo antibody titres were only obtained when the vaccine was administered twice (see Table 5 of the application).

11. Thus, the information conveyed to the skilled person by Example 3 of the application is that the claimed vaccine does not confer protection against Mhyo when administered intramuscularly only once, yet the contrary is claimed, i.e. that it does confer such protection (see section I.). The claimed subject-matter hence relates to new technical information which is not directly and unambiguously derivable from the application.

12. The opposition division held that achieving the purpose recited in the claim was only a matter of sufficiency of disclosure, not of added subject-matter. In line with decision T 2593/11 (Reasons 3.4), it was sufficient that the inventors had "thought of"

protection against *Lawsonia intracellularis*, Mhyo and PCV by intramuscular administration of the claimed vaccine only once. This was evident from the purpose of Example 3 described in lines 2 to 4 of page 14 of the application and from the vaccination experiment carried out for Group 2 of Example 3 (see the sentence bridging pages 14 and 15 of the application).

13. Line 2 of page 14 of the application discloses that the purpose of Example 3 was "to test" a combination vaccine comprising killed whole cells of *Lawsonia intracellularis* and antigens of Mhyo and PCV. However, a mere statement that a vaccine test experiment was conducted, without disclosing any results, does not amount to a disclosure of the tested vaccine for a specific therapeutic purpose. As such, lines 2 to 4 on page 14 of the application do not disclose protection against the three pathogens by the test vaccine. The same is true for the sentence that bridges pages 14 and 15 of the application. This sentence merely describes that "*Group 2 was vaccinated intramuscularly once with 2 ml combi vaccine at 25 days of age*" but does not disclose any results of the vaccination. Hence it also fails to provide a direct and unambiguous disclosure of effective protection against the three pathogens recited in the claim by the claimed vaccine.

14. The board considers that this conclusion is in line with the established case law on novelty of second medical use claims. By way of example, mere statements that a particular therapy is being explored do not amount to a novelty-destroying disclosure of a second medical use claim which includes the achievement of this therapy as a technical feature (T 1859/08, Reasons 13), and a document that describes the administration of a compound to diseased subjects but

neither explicitly nor implicitly discloses an effective treatment of the disease by this compound does not directly and unambiguously disclose this treatment (T 239/16, Reasons 5.2 and 5.3). Although this case law is on novelty and not on added subject-matter, the concept of disclosure must be the same for the purposes of Articles 54 and 123 EPC (G 2/10, OJ EPO 2012, 376, Reasons 4.6, citing G 1/03, OJ EPO 2004, 413, Reasons 2.2.2).

15. In line with this case law, the disclosure in the application that pigs were vaccinated with a combination vaccine comprising antigens of the three pathogens by intramuscular administration of the vaccine only once does not *per se* amount to a disclosure of protection against these three pathogens by this vaccine via this administration route and scheme. Moreover, as set out above (see point 9.), Example 3 in fact discloses that no protection against Mhyo could be obtained by an intramuscular administration of the combination vaccine only once. Therefore, Example 3 of the application does not directly and unambiguously disclose a vaccine comprising in combination non-live antigens of *Lawsonia intracellularis*, Mhyo and PCV for use in protection against *Lawsonia intracellularis*, Mhyo and PCV by intramuscular administration of the vaccine only once.

16. As an additional basis for the purpose recited in the claim, the appellant referred to the general disclosure of the object of the invention on page 4, lines 4 to 8 of the application. However, page 4 of the application merely discloses that it was "*an object of the present invention to provide a vaccine to combat Lawsonia intracellularis, and at the same time combat one or more other swine pathogens*" and that "[t]*o this end a*

vaccine has been devised that comprises in combination non-live antigens of Lawsonia intracellularis, Mycoplasma hyopneumoniae and Porcine circo virus, and a pharmaceutically acceptable carrier".

17. Hence, this passage neither discloses any details on the composition of the vaccines nor contains any teaching on administration schemes, so it is not a basis for the claimed subject-matter whether read alone or in combination with the disclosure in Example 3. The case in hand is therefore different from that underlying decision T 2593/11, in which the deciding board held that a particular feature recited in the claim was disclosed in the general part of the description as an equally suitable option to that exemplified in the application's examples. It was this literal disclosure of the particular feature that was considered sufficient for complying with the requirements of Article 123(2) EPC (see T 2593/11, Reasons 3.3). Since, in the case in hand, the application does not contain any general disclosure of administering a vaccine intramuscularly only once, decision T 2593/11 is irrelevant.

18. In view of the above consideration, claim 1 contains subject-matter that extends beyond the application (and the earlier application). The ground for opposition under Article 100(c) EPC thus prejudices the maintenance of the patent as granted.

Auxiliary requests 1 and 2
Amendments (Article 123(2) EPC and Article 76(1) EPC)

19. Compared with claim 1 of the patent as granted, claim 1 of auxiliary request 1 comprises the additional feature that the vaccine is administered to a pig, and claim 1

of auxiliary request 2 specifies that the vaccine comprises an adjuvant (see section IV.). Claim 1 of each of auxiliary requests 1 and 2 is thus directed to a vaccine comprising in combination non-live antigens of *Lawsonia intracellularis*, Mhyo and PCV, for use in protection against *Lawsonia intracellularis*, Mhyo and PCV by intramuscular administration of the vaccine only once.

20. The same considerations on added subject-matter as for the claim of the patent as granted apply to the claim of each of auxiliary requests 1 and 2 with respect to the combination of the purpose and the administration route and scheme recited in the claim (see points 7. to 18. above). Claim 1 of each of auxiliary requests 1 and 2 therefore contains subject-matter that extends beyond the content of the earlier application and the application for the same reasons as claim 1 of the patent as granted. It thus does not meet the requirements of Article 76(1) EPC and Article 123(2) EPC.

Auxiliary requests 3 and 4
Admittance (Article 12(4) and (6) RPBA, Article 13(2) RPBA)

21. Auxiliary requests 3 and 4, resubmitted with the statement of grounds of appeal, had first been filed by the appellant during the oral proceedings before the opposition division. The opposition division decided not to admit these requests into the proceedings because they were filed after the final date for making written submissions set under Rule 116 EPC and did not *prima facie* overcome the lack of sufficiency of disclosure found to be present for the invention defined in the claim of auxiliary request 2.

22. Pursuant to Article 12(6) RPBA, the board does not admit requests, facts, objections or evidence which were not admitted in the proceedings leading to the decision under appeal, unless the decision not to admit them suffered from an error in the use of discretion or unless the circumstances of the appeal case justify their admittance.

23. The appellant did not argue that the opposition division's decision not to admit auxiliary requests 3 and 4 into the proceedings suffered from an error in the exercise of the division's discretion, nor can the board recognise any such error.

24. However, the appellant argued that since the board had a different opinion on added subject-matter from the opposition division, the appellant's situation had changed. The board understands this to mean that in the appellant's view admitting auxiliary requests 3 and 4 was justified by particular circumstances of the appeal case under Article 12(6) RPBA or owing to exceptional circumstances under Article 13(2) RPBA which would justify resorting to these auxiliary requests at a subsequent stage of the appeal proceedings.

25. This argument is, however, not persuasive. The respondent had already argued in opposition that the lack of the definition (and presence) of the adjuvant resulted in an unallowable amendment (see section 2.2 on pages 6 to 8 of the respondent's notice of opposition), so auxiliary requests dealing with this objection could already have been filed during the written proceedings before the opposition division. Furthermore, the respondent had repeated this objection in the reply to the appeal (see the last paragraph of section 3.1.3 on page 7 of the reply). In its

preliminary opinion, contained in the communication issued in preparation for the oral proceedings, the board merely agreed with the respondent on this issue. The appellant's situation on appeal had therefore not changed compared with that in opposition, nor had this issue been raised for the first time by the board in its communication issued in preparation for the oral proceedings.

26. In view of the above considerations, the opposition division's decision not to admit auxiliary requests 3 and 4 did not suffer from an error in the use of the division's discretion, nor did the circumstances of the appeal case justify admitting and considering these auxiliary requests under Article 12(4) and (6) RPBA. There were no exceptional circumstances within the meaning of Article 13(2) RPBA either. The board thus decided not to admit auxiliary requests 3 and 4 into the appeal proceedings.

Auxiliary request 5
Admittance (Article 13(2) RPBA)

27. Auxiliary request 5 was submitted after the board had issued a summons to oral proceedings and the communication in preparation for the oral proceedings setting out its preliminary opinion. Admittance of auxiliary request 5 is subject to the provisions set out in Article 13(2) RPBA (see point 1. above).

28. Claim 1 of auxiliary request 5 has been amended compared with claim 1 of the patent as granted in that the claimed vaccine comprises an adjuvant and is administered to a pig (see section VIII.). It was, however, already argued in opposition that the claim lacked several features of Example 3's vaccination

protocol necessary for achieving the therapeutic effect recited in claim 1 of the patent as granted. These features included *inter alia* the definition of the vaccinated animal and the presence of an adjuvant. An auxiliary request in which the animal type was defined and the claimed vaccine comprised an adjuvant could thus have already been filed in the opposition proceedings in response to these objections.

29. In its preliminary opinion, the board had indicated that the (successful) vaccination of an animal appeared to depend on each of several parameters of Example 3 not present in the claim. The board, however, did not point to a specific new combination of missing parameters, as argued by the appellant, but merely provisionally agreed with the respondent's opinion, expressed in the reply to the appeal (see sections 3.1, 3.1.1, 3.1.2 and 3.1.3 on pages 3 to 8 of the reply), that several parameters, including the animal and the presence of an adjuvant, appeared to be necessary for achieving the purpose recited in the claim. The board's communication thus did not raise any new objections, so no new situation arose which could justify filing the claims of auxiliary request 5 at this late stage of the appeal proceedings.

30. The board therefore could not discern any exceptional circumstances that would have justified taking auxiliary request 5 into account at this stage of the proceedings, so it decided not to admit auxiliary request 5 pursuant to Article 13(2) RPBA.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

L. Malécot-Grob T. Sommerfeld

Decision electronically authenticated