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Datasheet for the decision of 22 March 2022

Case Number: T 0394/20 - 3.3.04

Application Number: 08853123.1

Publication Number: 2222335

IPC: A61K39/15

Language of the proceedings: EN

Title of invention:
Bluetongue virus vaccine and immunogenic compositions, methods of use and methods of producing same

Patent Proprietor:
Zoetis Belgium S.A.

Opponent:
Boehringer Ingelheim Animal Health USA Inc.

Headword:
Bluetongue virus vaccine/ZOETIS

Relevant legal provisions:
EPC Art. 56, 100(a), 111(1)
RPBA 2020 Art. 13(2)

Keyword:
Inventive step - obvious alternative
Amendment after summons - exceptional circumstances (no) - taken into account (no) - cogent reasons (no)
Remittal to the department of first instance (no)

Decisions cited:
T 0197/86

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Case Number: T 0394/20 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 22 March 2022

Appellant: (Opponent)	Boehringer Ingelheim Animal Health USA Inc. 3239 Satellite Blvd. Bldg. 500 Duluth GA 30096 (US)
Representative:	D Young & Co LLP 120 Holborn London EC1N 2DY (GB)
Respondent: (Patent Proprietor)	Zoetis Belgium S.A. 1, Rue Laid Burniat 1348 Louvain-la-Neuve (BE)
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Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 17 December 2019 rejecting the opposition filed against European patent No. 2222335 pursuant to Article 101(2) EPC**

Composition of the Board:

Chair	R. Morawetz
Members:	A. Schmitt
	P. de Heij

Summary of Facts and Submissions

I. The appeal of the opponent ("appellant") lies from the opposition division's decision rejecting the opposition to European patent No. 2 222 335 ("patent").

II. The patent, entitled "*Bluetongue virus vaccine and immunogenic compositions, methods of use and methods of producing same*", was granted on European patent application No. 08 853 123.1, which had been filed as an international application under the PCT published as WO 2009/065930 ("application").

Claim 1 of the patent as granted reads as follows:

"1. A vaccine composition for use in preventing or ameliorating an outbreak of Bluetongue virus (BTV), the composition comprising
(i) at least one strain of a twice inactivated BTV,
(ii) aluminium hydroxide and
(iii) Quil-A,
wherein the BTV is inactivated a first time with binary ethyleneimine (BEI) at a concentration of 10 mM for 24 hours and inactivated a second time with BEI at a concentration of 5 mM for 48 hours."

III. An opposition was filed against the patent in its entirety, based, *inter alia*, on the ground of lack of inventive step (Article 56 EPC) in Article 100(a) EPC.

IV. In the decision under appeal, the opposition division considered that the vaccine composition recited in claim 1 as granted differed from that disclosed in the closest prior art, document D1, in that it comprised the adjuvant "Quil-A" instead of "saponin". The

technical effect of this difference was deemed to be a reduced viraemia duration, and the objective technical problem was formulated as providing an "*improved vaccine composition against BTV*". Since the skilled person knew at least three different saponins that could have been used as the adjuvant, and the prior art lacked a pointer towards Quil-A, selecting Quil-A involved an inventive step. The same reasoning applied if the problem was formulated as providing an alternative.

V. In the statement of grounds of appeal the appellant argued, *inter alia*, that the studies set out in document D1 and Example 4 of the patent were not comparable since their experimental protocols differed in many aspects, including the point in time at which viraemia was measured in the vaccinated animals after viral challenge (hereinafter "the line of argument"). No alleged technical effect could therefore be attributed to using Quil-A as the adjuvant instead of saponin. The objective technical problem was therefore providing an alternative BTV vaccine composition. Since Quil-A was the main form of saponin used as the adjuvant in veterinary vaccines, using Quil-A as an alternative saponin adjuvant in the vaccine composition disclosed in document D1 did not involve an inventive step.

VI. In reply to the statement of grounds of appeal, the patent proprietor ("respondent") kept the patent as granted as its main request and kept the set of claims submitted on 5 July 2018 as auxiliary request 1. It submitted, *inter alia*, arguments to the effect that using Quil-A as the adjuvant instead of saponin was the only relevant difference between the experimental protocols in document D1 and Example 4 of the patent

since none of the alleged further differences listed by the appellant influenced the outcomes of the studies. Documents D29 and D30, *inter alia*, were submitted in support of these arguments. Furthermore, in footnote 11 of the reply, the respondent noted that during the opposition proceedings the appellant had not argued that the differences between the results of the studies set out in document D1 and Example 4 of the patent were not due to using Quil-A rather than saponin. However, the respondent did not request that this line of argument not be admitted into the proceedings.

Claim 1 of auxiliary request 1 is identical to claim 1 of the patent as granted (see section II.) except for the additional feature whereby the vaccine is for use "in an animal".

VII. The board summoned the parties to oral proceedings, as requested by each party, and issued a communication pursuant to Article 15(1) RPBA setting out its preliminary opinion that, *inter alia*, the subject-matter of claim 1 of the main request and auxiliary request 1 did not involve an inventive step. Furthermore, the parties were invited to inform the board if their requests had not been summarised correctly in the preliminary opinion. This summary of requests did not include any request by the respondent that the appellant's line of argument not be admitted into the appeal proceedings.

VIII. In response to the board's communication, the respondent submitted, *inter alia*, sets of claims of auxiliary requests 2 and 3.

Claim 1 of auxiliary request 2 is identical to claim 1 of auxiliary request 1 (see section VI.) except for the

additional feature "wherein the composition is administered by subcutaneous injection".

Claim 1 of auxiliary request 3 is identical to claim 1 of auxiliary request 1 (see section VI.) except for the additional feature "wherein the composition is administered by subcutaneous injection, and wherein the strain is serotype 4".

IX. In a further letter, the appellant submitted, *inter alia*, comments on the admittance of the sets of claims of auxiliary requests 2 and 3.

X. During the oral proceedings, the appellant requested that documents D29 and D30 not be admitted into the proceedings. However, the board did admit them. At the end of the oral proceedings, the Chair announced the board's decision.

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

D1 Ramakrishnan et al., Vet Res Comm 30, 2006, 873-880

D8 Barr et al., Adv Drug Deliv Rev 32, 1998, 247-271

D9 Oda et al., Biol. Chem. 381, 2000, 67-74

D10 Rajput et al., J Zhejiang Univ Sci B 8(3), 2007, 153-161

D11 Kensil et al., J. Immunol. 146, 1991, 431-437

D13 Dalsgaard, Vet Immunol Immunopathol 17, 1987, 145-152

D14 Spickler and Roth, J Vet Intern Med 17, 2003, 273-281

D29 Jiménez-Clavero et al., J Vet Diagn Invest 18, 2006, 7-17

D30 Declaration of Paul J. Dominowski (August 2020)

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

Admittance of the respondent's request that the appellant's line of argument not be admitted and the respondent's conditional request for remittal (Article 13(2) RPBA 2020)

The line of argument had not been raised for the first time in the appeal proceedings. In the proceedings before the opposition division, the appellant had already argued that the patent did not specify the point in time at which the animals were screened for viraemia and that this made it impossible to compare the data in Table 15 with the data in document D1. At no point had the respondent stated that it needed more time to perform further experiments. Remittal of the case was in any event not expedient.

Main request (patent as granted)
Inventive step (Article 100(a) and Article 56 EPC) - claim 1

Document D1 constituted the closest prior art. The claimed subject-matter differed from the vaccine composition disclosed in document D1 only in that it contained Quil-A instead of saponin. No technical

effect could be associated with this difference. The patent did not disclose any comparison between a Bluetongue virus (BTV) vaccine composition comprising, as adjuvants, a combination of Quil-A and aluminium hydroxide, and a BTV vaccine composition comprising, as adjuvants, a combination of saponin and aluminium hydroxide.

Furthermore, the results of the study described in Example 4 of the patent (Table 15) and those of the study described in document D1 could not be compared because the two studies differed in many aspects other than just the adjuvants of the BTV vaccine compositions; the patent did not disclose all the experimental parameters of the study in Example 4.

For example, the patent did not disclose the point in time at which viraemia was analysed in the vaccinated animals after viral challenge (see Table 15). However, the time was relevant since document D1 disclosed that from day eight after viral challenge viraemia could no longer be detected in animals which had been injected with a vaccine adjuvanted with aluminium hydroxide and saponin (see document D1, Table 1, Group 3). Detection of viraemia was therefore dependent on the point in time at which the animals were examined, so viraemia could have been missed in Example 4 of the patent.

It therefore did not follow from a comparison of the results disclosed in document D1 and Example 4 of the patent that using Quil-A instead of saponin as the adjuvant in the vaccine led to a reduction in viraemia.

The statement in item 11 of document D30 that viraemia had been measured in Example 4 of the patent on particular days after challenging the vaccinated

animals with the virus could not remedy the deficiency in the patent because document D30 simply provided the opinion of a technical expert without any supporting evidence. It was therefore simply an unsubstantiated assertion that did not require any counter-evidence in reply. Document D29 did not contain any information in this particular context and was therefore irrelevant.

Since no technical effect could be attributed to using Quil-A instead of saponin, the objective technical problem was providing an alternative vaccine for BTV.

Quil-A was widely used as a saponin adjuvant in veterinary vaccines and was known to be well tolerated in sheep and cattle, i.e. the animals susceptible to infection with BTV.

This was evident from, for example, review articles D8 (abstract; paragraph bridging pages 248 and 249; page 260, right-hand column, second half of the first paragraph), D10 (page 156, left-hand column, last paragraph), D13 (page 149, fourth paragraph) and D14 (page 276, right-hand column, last paragraph; page 277, left-hand column, first paragraph).

Furthermore, there were no concerns regarding the toxicity of Quil-A for sheep and cattle; see e.g. document D8 (see page 260, right-hand column, first paragraph) and document D14 (last paragraph on page 276 and first paragraph on page 277). Documents D8, D9, D10, D11 and D14 did mention toxicity of Quil-A but only in relation to mice, cats or humans, which was irrelevant for a BTV vaccine intended for use in sheep and cattle. Consequently, documents D8, D9, D10, D11 and D14 could not discourage the skilled person from using Quil-A in a BTV vaccine composition.

Moreover, contrary to the respondent's assertion, document D1 did not teach away from using a BTV vaccine adjuvanted with both saponin and aluminium hydroxide. Using saponin as the sole adjuvant was considered to be the most suitable option only when the costs for aluminium hydroxide were taken into account (see document D1, page 879, last paragraph).

Starting from the BTV vaccine administered to sheep in document D1, the skilled person would deem it obvious to replace saponin with Quil-A. Hence, the subject-matter of claim 1 did not involve an inventive step (Article 56 EPC).

Auxiliary request 1
Inventive step (Article 56 EPC) - claim 1

The same reasoning as for the subject-matter of claim 1 of the main request also applied to the subject-matter of claim 1 of auxiliary request 1, so this request did not involve an inventive step either.

Auxiliary requests 2 and 3
Admittance (Article 13(2) RPBA 2020)

Auxiliary requests 2 and 3 should not be admitted into the appeal proceedings because they were an amendment to the respondent's appeal case made after the summons to oral proceedings and there were no exceptional circumstances or cogent reasons. The board had not raised any new objection. The fact that the board had expressed a preliminary opinion was not an "exceptional circumstance".

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

Admittance of the respondent's request that the appellant's line of argument not be admitted and the respondent's conditional request for remittal (Article 13(2) RPBA 2020)

In the statement of grounds of appeal, the appellant had raised the new line of argument that the results of the studies described in the patent and document D1 were not comparable and that, therefore, the reduction in viraemia duration observed in the patent for the claimed vaccine composition could not be associated with Quil-A. This new line of argument should not be admitted into the appeal proceedings.

The respondent was justified in not submitting this request until the oral proceedings before the board because the respondent had been taken by surprise by the fact that the board had in its preliminary opinion found this new line of argument to be credible despite the appellant not having provided any evidence for its assertion or any evidence to counter the respondent's submissions filed in response, in particular documents D29 and D30.

If the board decided to admit the line of argument and found it convincing despite the disclosure in documents D29 and D30 and the lack of any counter-evidence submitted by the appellant, the case should be remitted to the opposition division to give the respondent a fair chance to conduct further experiments to demonstrate its position and so that the EPO could decide on this issue at two instances.

Main request (patent as granted)
Inventive step (Article 100(a) and Article 56 EPC) - claim 1

The claimed vaccine composition differed from the vaccine composition disclosed in the closest prior art, document D1, in that it contained the saponin "Quil-A". The technical effect of the difference was a reduction to almost zero in the occurrence of viraemia in vaccinated animals after viral challenge. This was evident from Example 4 and Table 15 of the patent, which demonstrated that none of the vaccinated animals developed viraemia. In the study in document D1, however, all the vaccinated animals did. The appellant had not demonstrated that there was any difference between the experimental protocols in D1 and the patent that would have influenced this outcome.

In particular, for acknowledging this technical effect it was irrelevant that the patent did not disclose the points in time at which the animals had been examined for viraemia. First of all, the points in time were disclosed in item 11 of document D30 – this document constituted evidence that had to be believed because it contained statements from a technical expert in the field and the appellant had failed to provide any counter-evidence. Moreover, since viraemia was not present at any point after the vaccinated animal had been challenged with the virus, the point in time at which viraemia was measured was irrelevant.

The objective technical problem was thus providing an improved vaccine composition for use in preventing or ameliorating a BTV outbreak. What remained to be assessed, therefore, was not whether the skilled person could have used Quil-A instead of saponin in the BTV

vaccine composition of document D1 to provide an improved BTV vaccine composition but whether they would have done so ("could/would approach").

In document D1, three BTV vaccine compositions comprising different adjuvants (saponin, aluminium hydroxide, and a combination of saponin and aluminium hydroxide) were compared with respect to their effects on viraemia in vaccinated animals after viral challenge. Document D1 taught away from using the combination adjuvant, as evident from the last paragraph on page 879, in which the saponin adjuvant was identified as "the most suitable one". In light of the teaching of document D1, it was therefore not obvious to use Quil-A.

Furthermore, none of the prior-art documents contained a pointer towards using Quil-A. Document D8 disclosed that the skilled person had at least three saponins at their disposal – Quil-A, QS21 and ISCOMs – and that Quil-A was the most toxic one (see page 260, right-hand column, first paragraph). Document D10 disclosed more than 23 different saponins. It warned that Quil-A was toxic and described QS-21 as being less toxic than Quil-A (see page 156, left-hand column, last paragraph and right-hand column, first full paragraph). Document D10 therefore pointed towards using QS-21 as the saponin adjuvant, not Quil-A. Document D11 (see paragraph bridging pages 434 and 435) and document D14 (see page 277, left-hand column, first paragraph) also disclosed that Quil-A was toxic and even lethal. Document D9 disclosed that at least 47 saponins from many different sources were available and did not specifically point towards using Quil-A either.

Consequently, using Quil-A in a BTV vaccine was not obvious to the skilled person in view of the disclosure of document D1 alone or in combination with any of the other cited documents. The subject-matter of the claim therefore involved an inventive step.

Auxiliary request 1
Inventive step (Article 56 EPC) - claim 1

The respondent did not submit any arguments in this context.

Auxiliary requests 2 and 3
Admittance (Article 13(2) RPBA 2020)

Auxiliary requests 2 and 3 were submitted in response to point 28 of the board's preliminary opinion, in which the board considered that Quil-A was not the only relevant difference between the vaccination protocol disclosed in document D1 and that described in Example 4 of the patent. This preliminary opinion had taken the respondent by surprise. In claim 1 of auxiliary requests 2 and 3, some of these alleged additional differences were eliminated. Since auxiliary requests 2 and 3 had been submitted in direct response to point 28 of the board's preliminary opinion and dealt with the objection raised in that point, they should be admitted into the appeal proceedings.

XIV. The appellant's requests, in so far as relevant to the decision, were that the decision under appeal be set aside and the patent be revoked in its entirety, and that documents D29 and D30 and auxiliary requests 2 and 3 not be admitted into the appeal proceedings.

The respondent's requests, as far as relevant to the decision, were:
- that the appeal be dismissed and the patent be maintained as granted (main request) or, alternatively, that the patent be maintained in amended form on the basis of the set of claims of auxiliary request 1, filed with the letter dated 5 July 2018, or further alternatively, that the patent be maintained in amended form on the basis of the set of claims of one of auxiliary requests 2 and 3, filed with letter dated 24 January 2022;
- that documents D29 and D30 and auxiliary requests 2 and 3 be admitted into the appeal proceedings;
- that the appellant's new line of argument not be admitted into the appeal proceedings and that, if the board were to admit the appellant's line of argument and found it convincing despite the counter-evidence submitted by the respondent in documents D29 and D30, the case be remitted to the opposition division for further consideration.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

Admittance of the respondent's request that the appellant's line of argument not be admitted and the respondent's conditional request for remittal (Article 13(2) RPBA 2020)

2. The respondent requested during the oral proceedings before the board that a line of argument raised in the appellant's statement of grounds of appeal (see section V.) not be admitted into the appeal proceedings.

3. In the course of the written proceedings, the respondent had asserted that this line of argument was new but had not requested that it not be admitted (see sections VI. and VII.). On the contrary, it had addressed the argument by submitting documents D29 and D30 as well as counter-arguments based on those documents (see sections VI. and VII.).

4. The respondent's request that the appellant's line of argument not be admitted into the appeal proceedings therefore constitutes an amendment to the respondent's appeal case made after notification of a summons to oral proceedings; pursuant to Article 13(2) RPBA 2020, this will, "*in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned*".

5. The respondent argued that it had been taken by surprise by the fact that the board had in its preliminary opinion found the appellant's line of argument to be credible despite the appellant not having provided any evidence for its assertion or any evidence to counter the respondent's submissions filed in response, in particular documents D29 and D30.

6. However, the board did not raise any new issues in its communication. The fact that the board endorsed some of the arguments put forward by the appellant in the statement of grounds of appeal, i.e. was not persuaded by the respondent's counter-arguments, does not give rise to "exceptional circumstances" within the meaning of Article 13(2) RPBA 2020.

7. Consequently, in the case in hand, there were no "exceptional circumstances" which could justify

admitting the respondent's request (which was not submitted until the oral proceedings before the board) that the appellant's line of argument not be admitted. The board therefore decided not to admit this request into the appeal proceedings.

8. The respondent furthermore submitted a conditional request for the case to be remitted to the opposition division in the event that the board admitted the appellant's line of argument and found it convincing despite the counter-evidence (documents D29 and D30) submitted by the respondent. In the circumstances of the case in hand, this means that the board was requested to remit the case if it were to accept the appellant's view that the claimed subject-matter did not involve an inventive step.

9. The legal basis for remitting a case to the department responsible for the decision under appeal is set out in Article 111(1) EPC, which stipulates that a board "may either exercise any power within the competence of the department which was responsible for the decision or remit the case to that department for further prosecution". Thus, if the board examines inventive step and finds the appellant's line of argument convincing, there is no scope for it to also remit the case to the opposition division for further consideration of inventive step (see Article 111(1) EPC: "*may either exercise ... or remit*").

10. The board therefore decided to reject the conditional request for the case to be remitted to the opposition division for want of a legal basis in the EPC.

Admittance of documents D29 and D30

11. The appellant objected to the admittance of documents D29 and D30. The board decided to admit documents D29 and D30 into the appeal proceedings (see section X.), but in view of the board's negative decision regarding inventive step it is not necessary to provide reasons for this decision.

Main request (patent as granted)
Inventive step (Article 100(a) and Article 56 EPC) - claim 1

Closest prior art and objective technical problem

12. Both parties agreed that document D1 constituted a suitable starting point for assessing the inventive step of the subject-matter of claim 1 and that the vaccine composition recited in the claim differed from that disclosed in document D1 only in that it comprised the adjuvant "Quil-A" instead of "saponin" (see document D1, Table 1, Group 3). The board sees no reason to deviate from this view.

13. In the decision under appeal, this difference was considered to be associated with a technical effect, so the objective technical problem was considered to be providing an improved BTV vaccine composition (see section IV.).

14. However, in order to acknowledge an improvement, an appropriate comparison with the closest prior art must be available which convincingly shows that the alleged technical effect has its origin in the distinguishing feature of the claimed invention compared with the closest prior art (see e.g. decision T 197/86, OJ EPO 1989, 371; Reasons, point 6.1.3).

15. The patent itself does not disclose appropriate comparative tests because the study disclosed in Example 4 of the patent compares Quil-A (and aluminium hydroxide) with Montanide™, not saponin (and aluminium hydroxide) (see e.g. Table 15 of the patent).

16. The board agrees with the appellant that the results of the study described in Example 4 of the patent and those of the study disclosed in document D1 cannot be compared either, because the experimental protocols of these studies differ in more aspects than just using Quil-A as the adjuvant instead of saponin and do not disclose all the parameters which would be necessary to allow for a direct comparison. *Inter alia*, Example 4 of the patent fails to indicate at which point(s) in time after viral challenge the vaccinated animals were examined for the presence or absence of viraemia (see Table 15).

17. As for the respondent's reliance on document D30, the board notes that, according to the principle of free evaluation of evidence, each piece of evidence is given an appropriate weighting in accordance with its probative value. Document D30 is a declaration drawn up by one of the respondent's employees. The employee indicates that he was asked to analyse whether the experiments disclosed in the patent were directly comparable with those disclosed in document D1 (see document D30, point 2). He then addresses the differences identified by the appellant between the disclosure in document D1 and the patent (ibid.; see points 3 to 12).

In point 11 he states "[t]*he time points of measuring post-challenge viremia in the patent were days 0, 3, 5,*

7, 10, 13, 18, 21, 24 and 27. This complies with standard procedures" (see document D30). This statement is not supported by any references or evidence. Since the patent does not disclose these points in time, state that standard procedures were used or indicate what these were, this information cannot be derived from analysing the patent. Nor is it stated that the employee was involved in the tests reported in the patent. It is therefore unclear on what evidence the statement is based. The statement in point 11 of document D30 thus amounts to nothing more than an unsubstantiated and unsupported assertion.

18. Therefore, the board does not accept that document D30 constitutes evidence that would prove the point(s) in time at which viraemia was assessed in the study disclosed in Example 4 of the patent. Accordingly, the appellant did not need to submit any evidence to counter the unsupported assertions made in document D30.

19. The respondent also cited document D29 in response to the appellant's argument that the studies in Example 4 of the patent and document D1 were not comparable. However, the respondent referred to document D29 only in the context of the viraemia detection method used in the patent, not as evidence for the points in time at which viraemia was detected in the patent. Document D29 therefore does not help the respondent's case.

20. The respondent furthermore argued that since no viraemia was detected in the animals examined in Example 4 of the patent, viraemia had not occurred at all, meaning that the precise point in time at which viraemia was assessed was irrelevant. However, it does not follow from the data disclosed in the patent that

no viraemia had occurred at all because even in non-vaccinated animals viraemia is detected only for a limited number of days (see e.g. first paragraph on page 878 of document D1). If the animals were bled too late in Example 4 of the patent, viraemia might have simply been missed. This argument therefore also fails to persuade the board.

21. Consequently, for want of any indication in the patent of the precise point(s) in time at which the vaccinated animals were examined for viraemia, no conclusions can be drawn on the occurrence and/or duration of viraemia in these animals. Thus, no appropriate comparison with the closest prior art is available to convincingly show that using Quil-A instead of saponin in the BTV vaccine composition of document D1 resulted in a reduced occurrence of viraemia. For this reason alone, the technical effect of reduced viraemia duration cannot be attributed to using Quil-A instead of saponin as an adjuvant in a BTV vaccine composition.

22. The objective technical problem to be solved therefore cannot be formulated as in the decision under appeal or as proposed by the respondent (see point 13. above). On the contrary, it has to be formulated as providing an alternative vaccine composition for use in preventing or ameliorating a BTV outbreak.

Obviousness

23. Quil-A is a well-known saponin adjuvant that has been used for decades as an adjuvant in veterinary vaccines, including those for sheep and cattle, i.e. animals susceptible to infection with BTV (see e.g. document D8 (paragraph bridging pages 248 and 249), document D10 (page 156, left-hand column, last paragraph),

document D13 (page 149, fourth paragraph) and document D14 (paragraph bridging pages 276 and 277). The skilled person therefore would have considered Quil-A to be a suitable alternative adjuvant for a BTV vaccine composition as described in document D1. Consequently, starting from the BTV vaccine composition disclosed in document D1, it was obvious to the skilled person seeking to provide an alternative vaccine composition for use in preventing or ameliorating a BTV outbreak to replace saponin with Quil-A.

24. In a first line of reasoning, the respondent argued that document D1 taught away from adding an adjuvant comprising both saponin and aluminium hydroxide since it disclosed that only saponin should be used as the adjuvant.

25. However, as correctly noted by the appellant, document D1 presents the saponin adjuvant as the most suitable one only when "[c]*onsidering the cost-benefit factor*" because of the "*lower cost of saponin compared to* $Al(OH)_3$ *gel adjuvant*" (see last paragraph of page 879). Recommending a substance on the sole basis of its cost and not its efficacy does not teach away from a more expensive but equally efficacious substance. Table 1 of document D1 demonstrates that the average duration of viraemia was even slightly shorter in animals vaccinated with a combination of saponin and aluminium hydroxide as adjuvants (see Group 3) compared with vaccines comprising either adjuvant alone (see Groups 1 and 2). This argument therefore fails to persuade the board.

26. In a second line of reasoning, the respondent argued, with reference to documents D8, D9, D10, D11 and D14, that the state of the art did not contain any pointer

towards Quil-A and that the skilled person had multiple different saponins at their disposal which they could also have chosen.

27. However, since the problem to be solved is providing an alternative and not an improved BTV vaccine composition (see point 22. above), no pointer towards Quil-A is required for the skilled person to select Quil-A as the adjuvant. It is sufficient for the prior art to indicate that Quil-A can be used as a suitable alternative to saponin in a vaccine composition.

28. Moreover, it is irrelevant that the skilled person had several saponins at their disposal (at least three according to document D8, more than 23 according to document D10 and at least 47 from different sources according to document D9) since, under the circumstances in hand, all known saponin adjuvants are possible solutions available to the skilled person and hence obvious. Selecting one of these obvious solutions, i.e. Quil-A, is considered arbitrary (see the decisions cited in Case Law of the Boards of Appeal of the European Patent Office, 9th edition, 2019, I.D.9.19.8).

29. In this context, the respondent also argued, with reference to documents D8, D10, D11 and D14, that Quil-A was known to be toxic whereas other saponin preparations from the same source were not. The skilled person would therefore have opted for a less toxic saponin than Quil-A.

30. However, the passages relied on by the respondent in documents D8 (page 260, right-hand column, first paragraph), D10 (page 156, last paragraph of the left-hand column and first full paragraph of the right-hand

column), D11 (paragraph bridging pages 434 and 435) and D14 (page 277, left-hand column, first paragraph) mention toxicity of Quil-A only in relation to mice, cats or humans. Moreover, documents D8 and D14 (ibid.) report that Quil-A has little toxicity and is well tolerated in sheep and cattle, i.e. in animals infected with BTV. Furthermore, the review articles D10 (ibid.), D13 (paragraph in the middle of page 149) and D14 (page 276, last paragraph of the right-hand column) report that Quil-A is widely used in veterinary vaccines.

31. Therefore, on the basis of the evidence provided by the respondent, the board is not persuaded that the skilled person was discouraged from using Quil-A as an alternative saponin adjuvant in the BTV vaccine composition of document D1.

32. In view of the above, the subject-matter of claim 1 of the main request does not involve an inventive step (Article 56 EPC).

Auxiliary request 1
Inventive step (Article 56 EPC) - claim 1

33. The only difference between claim 1 of auxiliary request 1 and claim 1 as granted is the addition of the feature "in an animal" to claim 1 of auxiliary request 1. This feature addresses an objection of added subject-matter and has no bearing on the assessment of the inventive step of the claimed subject-matter.

34. Consequently, the subject-matter of claim 1 of auxiliary request 1 does not involve an inventive step for the same reasons as for the subject-matter of claim 1 of the main request (Article 56 EPC).

Auxiliary requests 2 and 3
Admittance (Article 13(2) RPBA 2020)

35. Auxiliary requests 2 and 3 were submitted after the board had issued a summons to oral proceedings and a communication setting out its preliminary opinion. Claim 1 of each of these auxiliary requests was amended to contain, *inter alia*, a feature relating to the administration route of the vaccine (see section VIII.). However, the respondent had not pursued this subject-matter previously during the appeal proceedings. Furthermore, the respondent was aware of the appellant's line of argument when filing its reply and had chosen to address it by filing counter-arguments and documents D29 and D30 (see also point 3. above). Therefore, auxiliary requests 2 and 3 are an amendment to the respondent's appeal case pursuant to Article 13(2) RPBA 2020 (see point 4. above).

36. As set out above, the line of argument that the experimental conditions of the vaccination studies disclosed in document D1 and Example 4 of the patent differed in too many aspects to be comparable was part of the appellant's reasoning in the statement of grounds of appeal (see section V.), which the board endorsed in its preliminary opinion.

37. Therefore, this line of argument was not an issue that the board had newly raised in its preliminary opinion. Furthermore, the fact that the board's preliminary opinion was not in the respondent's favour in this respect does not qualify as "exceptional circumstances" justified by cogent reasons (see also point 6. above).

38. Consequently, there were no "exceptional circumstances" which would have justified admitting auxiliary requests 2 and 3. The board therefore decided not to admit auxiliary requests 2 and 3 into the appeal proceedings (Article 13(2) RPBA 2020).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

I. Aperribay R. Morawetz

Decision electronically authenticated