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Datasheet for the decision of 18 June 2024

Case Number: T 0271/22 - 3.3.08

Application Number: 13713195.9

Publication Number: 2831246

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Language of the proceedings: EN

Title of invention:
Multivalent recombinant avian herpes viruses and vaccines for immunizing avian species

Patent Proprietor:
Ceva Santé Animale

Opponent:
Boehringer Ingelheim Animal Health USA Inc.

Headword:
Recombinant avian herpes virus/CEVA

Relevant legal provisions:
EPC Art. 54, 56, 83, 123(2)
RPBA 2020 Art. 12(2), 12(3), 12(4), 12(5), 12(6)

Keyword:
Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)
Amendments - allowable (yes)
Amendment to case - requirements of Art. 12(2) RPBA 2020 met (no) - reasons for submitting amendment in appeal proceedings (no) - amendment within meaning of Art. 12(4) RPBA 2020 - admissibly raised and maintained (no)
Discretion not to admit submission - requirements of Art. 12(3) RPBA 2020 met (no)

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Case Number: T 0271/22 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 18 June 2024

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)	Ceva Santé Animale 10 Avenue de La Ballastière 33500 Libourne Cedex (FR)
Representative:	Cabinet Becker et Associés 25, rue Louis le Grand 75002 Paris (FR)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 2 December 2021 concerning maintenance of the European Patent No. 2831246 in amended form**

Composition of the Board:

Chair	T. Sommerfeld
Members:	A. Schmitt
	D. Rogers

Summary of Facts and Submissions

I. The appeal lodged by the opponent (appellant) lies from the opposition division's interlocutory decision that European patent No. 2 831 246 (the patent) as amended in the form of auxiliary request 1 filed on 22 October 2021 and the invention to which it relates meet the requirements of the EPC. The patent proprietor (respondent) withdrew its appeal on 18 March 2022.

II. The patent, entitled "*Multivalent recombinant avian herpes viruses and vaccines for immunizing avian species*", was granted on the basis of European patent application No. 13 713 195.9 which had been filed as an international application published as WO 2013/144355 (the application).

III. The opposition proceedings were based on the grounds for opposition in Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and those in Article 100(b) and (c) EPC.

IV. In the reply to the appeal, the respondent submitted sets of claims of a main request and auxiliary requests 1 to 6. The set of claims of the main request contains 15 claims and is identical to the set of claims of auxiliary request 1 dealt with in the decision under appeal. Claims 1, 12, 13, 14 and 15 of this request are independent claims and read as follows:

"1. A recombinant avian herpes virus, which comprises at least two recombinant nucleotide sequences, each recombinant nucleotide sequence encoding a distinct

antigenic peptide from an avian pathogen, wherein each of said at least two recombinant nucleotide sequences is inserted into a distinct non-coding region of the viral genome chosen among the region located between UL44 and UL45, the region located between UL45 and UL46, the region located between US10 and SORF3, and the region located between SORF3 and US2, wherein a first recombinant nucleotide sequence encoding a first antigenic peptide is inserted into the non-coding region located between UL45 and UL46, and a second recombinant nucleotide sequence encoding a second antigenic peptide is inserted into the non-coding region located between UL44 and UL45, or between US10 and SORF3, or between SORF3 and US2."

"12. A multivalent vaccine which comprises an effective immunizing amount of recombinant avian herpes virus of any one of the preceding claims.

13. A recombinant avian herpes virus of any one of claims 1 to 11, for use for immunizing an avian, such as poultry, against a pathogen.

14. A multivalent vaccine of claim 12 for use in a method for vaccinating an avian simultaneously against at least two pathogens.

15. A vaccination kit for immunizing avian species which comprises the following components:
a. an effective amount of the vaccine of claim 12, and
b. a means for administering said components to said species."

V. 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 on the appeal. It concluded that the appeal was likely to be dismissed.

VI. On 8 February 2024, the appellant informed the board in writing that they would not attend the oral proceedings.

VII. The board then cancelled the oral proceedings.

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

D3 WO 2010/119112 A1
D9 EP 1 026 246 A1
D19 US 5,965,138

IX. The arguments of the parties relevant to the board's decision are summarised in the reasons for the decision.

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

XI. The respondent requested that the appeal be dismissed (main request) or that the patent be maintained on the basis of the set of claims of one of auxiliary requests 1 to 6, all submitted with the reply to the appeal, and that the objections summarised in Annex 2 submitted with the statement of grounds of appeal not be considered in the appeal proceedings.

Reasons for the Decision

Consideration of the objections summarised in Annex 2 submitted with the statement of grounds of appeal (Article 12 RPBA)

1. Together with the statement of grounds of appeal, the appellant submitted an annex called "Annex 2" and entitled "FURTHER ARGUMENTS MAINTAINED AGAINST '246". The appellant asserted that "*Auxiliary Request 1 as maintained by the Decision ... does not meet the requirements of Arts. 54, 56, 83 or 123(2) EPC*" (see the penultimate paragraph on page 4 of the statement of grounds of appeal) and provided reasons in support of this opinion (sections 3., 4., 5., 6. and 7. on pages 5 to 19 of the statement of grounds of appeal).

2. In addition to these specific reasons, the appellant indicated that their "*complete case against '246* [the patent] *is maintained in fullness, including all facts, arguments and reasoning submitted during the Opposition at first instance*", that "[s]*ome of the facts and arguments forming part of this case are further included as Annex 2*" (penultimate paragraph on page 3 of the statement of grounds of appeal), and that "*specifically in respect of lack of novelty, the objections in Annex 2 are those which may become more relevant depending on the arguments of the respondent in these proceedings*" (last paragraph on page 3 of the statement of grounds of appeal). The appellant also stated that the patent "*contravenes the requirements of the EPC for the further reasons discussed in Annex 2*" (final bullet point on page 20 of the statement of grounds of appeal).

3. However, in Annex 2, the appellant neither provided any reasons why the opposition division might have erred in

their assessment with respect to the claims of former auxiliary request 1 nor referred to the decision under appeal at all. Instead, Annex 2 appears to be a compilation of previously raised and new objections against the claims of the patent as granted (see also points 8. to 12. below).

4. The primary object of the appeal proceedings is, however, to review the decision under appeal in a judicial manner and hence, a party's appeal case must be directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based (Article 12(2) RPBA). The statement of grounds of appeal must set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed (Article 12(3) RPBA).

5. The mere reiteration of previous objections or the submission of new objections without any reference to the reasons provided in the decision under appeal, as is the case for the submissions set forth in Annex 2 (see point 3. above), hence meet neither the requirements set forth in Article 12(2) RPBA nor those of Article 12(3) RPBA.

6. Under Article 12(4) RPBA, any part of a party's appeal case which does not meet the requirements in Article 12(2) RPBA is to be regarded as an amendment, unless the party demonstrates that this part was admissibly raised and maintained in the proceedings leading to the decision under appeal. Any such amendment may be admitted only at the discretion of the board. Under Article 12(5) RPBA, the board has discretion not to admit any part of a submission by a party which does not meet the requirements in Article 12(3) RPBA. Requests, facts, objections or

evidence which should have been submitted, or which were no longer maintained, in the proceedings leading to the decision under appeal, should not be admitted by the board, unless the circumstances of the appeal case justify their admittance (Article 12(6) RPBA).

7. Since the submissions in Annex 2 do not meet the requirements set forth in Article 12(2) and/or Article 12(3) RPBA (see point 5. above), they were not admitted into the appeal proceedings under Article 12(5) or Article 12(6) RPBA. In particular, the following submissions in Annex 2 were not considered.

8. In sections A2-4.1 and A2-4.2 on page 58 of Annex 2, objections under Article 123(2) EPC are raised concerning the feature "antigenic fragment" used in claims 2, 3, 8, 9 and 10 and against claim 7. However, these observations neither refer to the decision under appeal nor indicate why the opposition division might have erred in its opinion that this feature (points 2.8 and 2.9 of the decision under appeal) and the subject-matter of all claims of former auxiliary request 1 (point 4.6 of the decision under appeal) have a basis in the application. The appellant therefore failed to set out why it was requested that the decision under appeal be reversed in these aspects, contrary to the requirements of Article 12(3) RPBA, and the board decided not to admit these objections into the appeal proceedings under Article 12(5) RPBA.

9. The objections as to novelty summarised on pages 24 to 32 of Annex 2 merely consist of reiterating arguments that *"formed part of the case against '246* [the patent] *at first instance*" (see first paragraph on page 24 of Annex 2) and refer to "*claim 1 of '246*" (header of chapter A2-1.1 on page 24 of Annex 2), i.e.

concern the claims as granted and do not refer to the decision under appeal. The objections as to novelty summarised in Annex 2 therefore do not meet the requirements of Article 12(3) RPBA. The board therefore decided not to admit them into the appeal proceedings under Article 12(5) RPBA.

10. In addition to documents D3 and D9, the appellant proposed document D19 as suitable closest prior art and referred to Annex 2 for further arguments (first paragraph on page 10 of the statement of grounds of appeal). Moreover, Annex 2 proposed a number of further documents as closest prior art (section A2-2.3 with subsections A2-2.3.1 to A2-2.3.6 on pages 40 to 46 of Annex 2). However, as evident from point 3.36 of the decision under appeal, only problem-solution approaches starting from either document D3 or document D9 as closest prior art were raised or maintained by the opponent in the opposition proceedings.

11. Hence, each of the additional objections summarised in Annex 2, including the problem-solution approach starting from document D19 as closest prior art, is either new to the proceedings or was not maintained during the opposition proceedings and therefore does not meet the requirements of Article 12(2) RPBA (see point 4. above). The appellant did not provide any justification for raising these objections only on appeal. In the absence of any special circumstances justifying their admittance, the board decided not to admit them into the appeal proceedings under Article 12(6) RPBA (see point 6. above).

12. In sections A2-3 and A2-3.1 to A2-3.5 on pages 52 to 57 of Annex 2, the appellant raised further objections under Article 83 EPC, but did not make any reference to

the appealed decision. Indeed, as stated by the board in point 36. of its communication under Article 15(1) RPBA (see section V.) and as undisputed by the appellant, these objections appear to be new to the proceedings and were not dealt with by the opposition division. The appellant did not submit any reasons for submitting these objections only on appeal. In accordance with Article 12(6) RPBA (see point 6. above), the board therefore decided not to admit these objections into the appeal proceedings.

Main request
Amendments (Article 123(2) EPC) - claim 1

13. Claim 1 of the main request concerns a recombinant avian herpes virus which comprises at least two recombinant nucleotide sequences, each recombinant nucleotide sequence encoding a distinct antigenic peptide, wherein "each of said at least two recombinant nucleotide sequences is inserted into a distinct non-coding region of the viral genome" chosen among four different insertion sites (see section IV. for the full wording of the claim).

14. Hence, according to the claim, two, three or four different recombinant nucleotide sequences are inserted into the viral genome. If three different recombinant nucleotide sequences are inserted, they must be inserted into three different non-coding regions of the viral genome, and if four different recombinant nucleotide sequences are inserted, they must be inserted into four different non-coding regions of the viral genome.

15. The appellant asserted that these two embodiments of the claim were the result of an unallowable

intermediate generalisation from the recombinant avian herpes virus defined in claim 1 of the application, which only required the use of two different insertion sites, even if three or four different recombinant nucleotide sequences were inserted, and the application's specific examples, which only concerned a recombinant virus where two different recombinant nucleotide sequences were inserted into two distinct insertion sites.

16. Indeed, in contrast to the definition in claim 1 of the main request cited in point 13. above, claim 1 of the application defines that "said at least two recombinant nucleotide sequences are inserted into distinct non-coding regions" and therefore does not clearly indicate that *each* of the at least two recombinant nucleotide sequences is inserted into a distinct non-coding region of the viral genome.

17. However, this feature is disclosed in lines 23 to 26 on page 14 of the application, which describe, as an object of the invention, "*multivalent recombinant herpes viruses which present at least two foreign nucleotide sequences each being inserted in a particular insertion site*". Hence, according to this sentence, *each* foreign nucleotide sequence is inserted into a different insertion site, in agreement with the preferred embodiments of the application, in which two different recombinant nucleotide sequences are inserted into two distinct insertion sites (see e.g. lines 1 to 4 on page 3 of the application).

18. The application therefore encompasses, in lines 23 to 26 on page 14, the teaching that *each* foreign nucleotide sequence is inserted into a different insertion site, even if more than two foreign

nucleotides are inserted into the recombinant avian herpes virus. The subject-matter of claim 1 of the main request is therefore not the result of an intermediate generalisation. The appellant's objection under Article 123(2) EPC against this claim is therefore without merit.

19. The further objections under Article 123(2) EPC raised in Annex 2 against claims 2, 3, 7, 8, 9 and 10 were not admitted into the appeal proceedings (see point 8. above).

20. The requirements of Article 123(2) EPC are met.

Novelty (Article 54 EPC) - claim 1

21. Although, in the decision under appeal, the opposition division considered a number of documents in the context of novelty (points 3.11 to 3.19 and 3.22 to 3.33 on pages 7 to 9 of the decision under appeal), in the statement of grounds of appeal, the appellant submitted arguments only with respect to the opposition division's conclusions on the disclosure in document D9 (section 4 on page 7 of the statement of grounds of appeal) and did not challenge the decision under appeal with respect to novelty vis-à-vis any of the other documents. Objections under Article 54 EPC that were mentioned only in Annex 2 were not admitted into the appeal proceedings (see point 9. above).

22. The only objection under Article 54 EPC which is considered to be part of the appeal's framework is therefore lack of novelty over the disclosure in document D9.

23. Document D9 concerns a recombinant avian herpes virus, in which a foreign gene is integrated into an untranslated region of the herpes virus genome (e.g. paragraphs [0011] and [0012]). Document D9 teaches in paragraph [0013] that "[a] *specifically preferred insertion site for a foreign gene is at least one insertion site selected from the group consisting of sites in (1) between UL44 and UL45, (2) between UL45 and UL46, (3) between UL41 and UL42, (4) between UL40 and UL41, (5) a region located downstream of the gB gene, (6) between UL53 and 10 UL54, and (7) between UL36 and UL37*". It discloses a series of monovalent herpes virus constructs, in which a single foreign gene is inserted into the viral genome, and two bivalent herpes virus constructs, in which two foreign genes are inserted into a single cloning site (see table 1 and paragraph [0087] of D9). Document D9 therefore concerns recombinant avian herpes virus constructs, in which different foreign gene(s) are inserted into a single cloning site.

24. The appellant asserted that claim 1 was not novel over the disclosure in paragraph [0035] of document D9. This paragraph discloses that "[i]*nsertion sites for foreign gene are not limited as long as they are within the untranslated region. Specific examples include sites in (1) between UL44 and UL45 and between UL45 and UL46, (2) between UL41 and UL42, (3) between UL40 and UL41, (4) a region located downstream of the gB gene, (5) between UL53 and UL54, (6) between UL36 and UL37, and the like.*"

25. Hence, contrary to the disclosure of the same preferred insertion sites in paragraph [0013] (see point 23. above), paragraph [0035] mentions two of the sites within a single bullet point ("(1) *between UL44 and*

UL45 and between UL45 and UL46"). However, paragraph [0035] discloses these insertion sites for "*foreign gene*" (see the citation in point 24. above), i.e. uses the singular form. This sentence in paragraph [0035] of document D9 is therefore ambiguous and for this reason alone does not *unambiguously* disclose a construct where *two* distinct foreign genes are inserted into *two* distinct insertion sites.

26. The claimed subject-matter is novel (Article 54 EPC).

Inventive step (Article 56 EPC)

27. According to point 3.36 of the decision under appeal, the opponent proposed document D3 or document D9, but no other document, as a suitable starting point for the assessment of inventive step in the opposition proceedings. In the statement of grounds of appeal, the appellant asserted that document D19 was also suitable as closest prior art and referred to Annex 2 (see the first paragraph on page 10 of the statement of grounds of appeal). However, none of the problem-solution attacks developed only in Annex 2, including that starting from the disclosure in document D19, were admitted into the appeal proceedings (see points 10. and 11. above).

Document D3 or document D9 as closest prior art

28. Documents D3 and D9 both disclose recombinant avian herpes virus constructs comprising two recombinant nucleotide sequences encoding a distinct antigenic peptide from an avian pathogen inserted into a single insertion site, including a site between the UL45 and UL46 loci (see Examples 16 and 17 of D3; see constructs HF006 and HF007 in Tables 1 to 3 of D9). Document D9

furthermore discloses data on expression of the foreign genes (Example 16 and Table 2) and vaccination efficiency against the pathogen NDV (Example 17 and Table 3), but does not disclose any data on stability of expression of these genes. Document D3 does not disclose any data on efficiency of vaccination or expression (stability) of the foreign genes in the recited constructs.

29. The claimed recombinant avian herpes virus differs from those of documents D3 and D9 in that the at least two distinct recombinant nucleotide sequences are each inserted into a distinct non-coding region of the viral genome chosen among the region located between UL44 and UL45, the region located between UL45 and UL46, the region located between US10 and SORF3, and the region located between SORF3 and US2, wherein a first recombinant nucleotide sequence encoding a first antigenic peptide is inserted into the non-coding region located between UL45 and UL46, and a second recombinant nucleotide sequence encoding a second antigenic peptide is inserted into the non-coding region located between UL44 and UL45, or between US10 and SORF3, or between SORF3 and US2.

Technical effect and objective technical problem

30. The patent discloses the construction of a series of recombinant herpes virus of turkey (HVT) constructs containing two foreign genes ("VP2" and "F") under different promoters and at different insertion sites (see e.g. Figures 2A and 2B and paragraph [0096] of the patent). Some of these constructs were assessed with respect to stability of gene expression and vaccination efficacy in comparison to an HVT construct in which both foreign genes were inserted into the same

insertion site (UL45/UL46: "FW137"; see Experiments 5 to 10 of the patent).

31. The patent demonstrates that various different recombinant HVT constructs containing the first foreign gene inserted into the UL45/UL46 site and the second foreign gene inserted into the UL44/UL45 site or the SORF3/US2 site are able to stably express both foreign genes after multiple passages of infected cells *in vitro* (see paragraph [0112] of the patent) and in vaccinated chickens *in vivo* (Experiment 6 and Figures 8A and 8B), contrary to the FW137 construct (see also section 4.4 on pages 7 to 9 of the reply to the appeal).

32. Furthermore, additional data were submitted in the opposition proceedings that demonstrate that recombinant HVT constructs in which the first foreign gene is inserted into the UL45/UL46 site and the second foreign gene is inserted into the US10/SORF3 site also stably express both foreign genes after multiple passages of infected cells *in vitro* (see pages 9 to 11 of the reply to the appeal, where the additional data are discussed).

33. In view of these data, a technical effect associated with the claimed recombinant HVT constructs is that they stably express several foreign genes. The claimed constructs are therefore not arbitrary recombinant HVT constructs without any technical effects as asserted by the appellant.

34. The appellant also asserted that the claimed HVT constructs were mere alternatives to those provided in documents D3 and D9. The reason therefor was that the concept of expressing foreign genes from more than one

insertion site in HVT was known from document D19 (see Examples 16A and 17C), as were all insertion sites recited in the claim.

35. However, the two constructs described in document D19 to which the appellant refers (S-HVT-123 in Example 16A and S-HVT-143 in Example 17C) employ insertion sites that differ from those recited in the claim and have not been tested in any transfection experiments. It is therefore not known whether these constructs could stably express the foreign genes. Since stable expression of multiple foreign genes was not demonstrated for any of the prior art herpes virus constructs and cannot necessarily be expected, it can be acknowledged as a technical effect of the claimed HVT constructs (see point 33. above).

36. The objective technical problem may therefore be formulated, as proposed by the respondent, as the provision of stable multivalent recombinant avian herpes virus vectors that allow the co-expression of foreign genes in infected cells.

Obviousness

37. None of documents D3, D9 and D19 suggest that stable multivalent recombinant avian herpes virus vectors that allow the co-expression of foreign genes in infected cells could be provided by inserting a first recombinant nucleotide sequence encoding a first antigenic peptide into the non-coding region located between UL45 and UL46, and a second recombinant nucleotide sequence encoding a second antigenic peptide into the non-coding region located between UL44 and UL45, or between US10 and SORF3, or between SORF3 and US2. Documents D3 and D9 only disclose constructs where

the foreign genes are inserted into a single genomic site and do not provide any data on expression stability (see point 28. above). Document D19 proposes inserting the foreign genes into insertion sites different from those recited in the claim and does not provide any data on stability or vaccination efficacy of these constructs (see point 35. above).

38. The recombinant avian herpes virus defined in claim 1 was therefore not obvious to the skilled person from the teaching in any of these documents. Claims 2 to 15 are either dependent on claim 1 or refer to the (use of the) recombinant avian herpes virus of claim 1 (see section IV.). The same considerations regarding inventive step therefore apply to the subject-matter of these claims.

39. The claimed subject-matter involves an inventive step (Article 56 EPC).

Sufficiency of disclosure (Article 83 EPC)

40. With respect to sufficiency of disclosure of the claimed invention, the appellant submitted that "*if any functional feature was considered to be present in claim 1 of '246, this would only result in an issue of insufficiency of disclosure. This would arise because '246 does not make it plausible at the priority date that the combinations of insertion sites which are mere paper disclosures could be used to obtain stable and efficacious expression of an inserted recombinant nucleotide sequence*" (see section 6. on page 15 of the statement of grounds of appeal).

41. Claim 1 of the main request concerns a recombinant avian herpes virus which comprises at least two

distinct recombinant nucleotide sequences inserted into two different non-coding regions of the viral genome, as defined in the claim (see section IV.). No functional features are present in this claim. The appellant's considerations under Article 83 EPC (see point 40. above) are therefore not relevant to the claimed subject-matter, as admitted by the appellant itself.

42. The further objections raised under Article 83 EPC in Annex 2 were not admitted into the appeal proceedings (see point 12. above).

43. The requirements of Article 83 EPC are met.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

L. Malécot-Grob T. Sommerfeld

Decision electronically authenticated