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Datasheet for the decision of 9 April 2024

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Title of invention:
Recombinant non-pathogenic Marek's Disease Virus constructs encoding Infectious Laryngotracheitis Virus and Newcastle Disease Virus antigens

Patent Proprietor:
Intervet International B.V.

Opponent:
Boehringer Ingelheim Animal Health USA Inc.

Headword:
Multivalent avian vaccines/INTERVET

Relevant legal provisions:
EPC Art. 54
RPBA 2020 Art. 12(4), 12(6), 13(1)

Keyword:
Novelty - Main request and auxilary request 1 - no

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Case Number: T 0939/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 9 April 2024

Appellant: (Patent Proprietor)	Intervet International B.V. Wim de Körverstraat 35 5831 AN Boxmeer (NL)
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Respondent: (Opponent)	Boehringer Ingelheim Animal Health USA Inc. 3239 Satellite Blvd., Bldg. 500 Duluth, GA 30096 (US)
Representative:	D Young & Co LLP 3 Noble Street London EC2V 7BQ (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 3 February 2022 revoking European patent No. 2768964 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman M. Pregetter
Members: O. Lechner
L. Bühler

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies from the decision of the opposition division to revoke the patent.

II. The patent is based upon European patent application No. 12 775 246.7. The application was filed as an international patent application and published as WO2013/057236.

III. In its decision, the opposition division held that the set of claims according to the claims as granted (main request) lacked novelty under Articles 100(a) and 54 EPC.
The sets of claims according to auxiliary requests 1 and 13 were, like auxiliary requests 7 to 11, found to not comply with Article 123(2) EPC. Auxiliary request 4 was found to lack novelty under Article 54 EPC.
Auxiliary requests 2, 3, 5, 6 and 12 were not admitted into the proceedings.

IV. With its statement of grounds of appeal, the appellant (patent proprietor) resubmitted sets of claims according to a main request (claims as granted) and auxiliary request 1 (corresponding to auxiliary request 4 in the decision under appeal and auxiliary request 3 as filed with the patent proprietor's observations on the notice of opposition) and also filed new auxiliary request 2.

V. The opponent (respondent) replied to the statement of grounds of appeal. By letter dated 19 February 2024, the appellant filed two new sets of claims according to

auxiliary requests 3 and 4. The opponent replied to this submission.

VI. The board provided its preliminary opinion in a communication under Article 15(1) RPBA.

VII. The oral proceedings before the board took place as scheduled.

During the oral proceedings, the appellant withdrew the main request (claims as granted) and renumbered its auxiliary requests 1 to 4 to become its main request and auxiliary requests 1 to 3, respectively.

VIII. Claim 1 of the main request reads:

"1. A vaccine comprising a recombinant nonpathogenic Marek's Disease Virus (rMDVnp) comprising a first nucleic acid inserted in a first nonessential site in the rMDVnp genome and a second nucleic acid inserted in a second nonessential site in the rMDVnp genome; wherein the first nucleic acid comprises both a nucleotide sequence that encodes an Infectious Laryngotracheitis Virus (ILTV) gD protein and a nucleotide sequence that encodes an ILTV gI protein; wherein the second nucleic acid comprises a nucleotide sequence that encodes a Newcastle Disease Virus fusion protein (NDV F); wherein the first nonessential site and the second nonessential site are are both the US2 site, or both the UL54.5 site, or alternatively the first nonessential site is the US2 site and the second nonessential site is in between the UL7 and UL8 genes; and wherein the rMDVnp is a recombinant herpesvirus of turkeys (rHVT)."

Claim 1 of auxiliary request 1 reads (amendments compared to the main request highlighted by the board):

"1. A vaccine comprising a recombinant nonpathogenic Marek's Disease Virus (rMDVnp) comprising a first nucleic acid inserted in a first nonessential site in the rMDVnp genome and a second nucleic acid inserted in a second nonessential site in the rMDVnp genome; wherein the first nucleic acid comprises both a nucleotide sequence that encodes an Infectious Laryngotracheitis Virus (ILTV) gD protein and a nucleotide sequence that encodes an ILTV gI protein; wherein the second nucleic acid comprises a nucleotide sequence that encodes a Newcastle Disease Virus fusion protein (NDV F); wherein the first nonessential site and the second nonessential site are are both the US2 site, ~~or both the UL54.5 site, or alternatively the first nonessential site is the US2 site and the second nonessential site is in between the UL7 and UL8 genes;~~ and wherein the rMDVnp is a recombinant herpesvirus of turkeys (rHVT)."

Claim 1 of auxiliary requests 2 and 3 is identical to claim 1 of auxiliary request 1 but incorporates the subject-matter of dependent claims 5 and 6 from the claims as granted, which define technical features on the promoters used for the nucleic acid sequences to be inserted.

IX. Reference is made to the following documents:

D2: Declaration under 37 C.F.R §1.132 of Stephanie M. Cook, dated 27 January 2014, 4 pages including Table 1

D8: US 6,913,751 B2

D10: R. Heckert et al., Avian Diseases 40, 1996, 770-7

X. The appellant's arguments relevant to the decision can be summarised as follows.

(a) Claim construction

Vaccine

The term vaccine related to a composition with a therapeutic purpose able to induce *in vivo* an active and protective immune response. In the current case, this required a genetically stable virus construct capable of stably expressing over a couple of days to ensure continuous replication.

Recombinant virus - Chimeric virus

A "recombinant virus", e.g. a recombinant herpesvirus of turkey (rHVT), related to a virus that has undergone modifications but remains classified as a herpesvirus of turkey (HVT), i.e. retained its characteristics. The patent in suit (page 7, lines 14 to 17) defined that an rHVT does not include viral constructs in which a specific region of the genome of one Marek's disease virus (MDV) serotype is replaced by the corresponding region of a different MDV serotype to form a chimeric virus, such as the novel avian herpesvirus (NAHV). Thus, the patent in suit clarified that the term was not to be interpreted as encompassing a chimeric virus as described in document D8.

A "chimeric virus" was constructed by combining genome sections of two or more different virus types (e.g. MDV and HVT), resulting in a novel and artificial virus

construct (e.g. NAHV) which is not a version or variant of either of its parents.
The constructs according to claim 18 of document D8 were clearly chimeric, while the constructs according to claim 1 were recombinant but not chimeric. Replacement of about 15% of the HVT genome with MDV sequences resulted in a NAHV with different properties compared to HVT such as decreased stability.

(a) Main request

Admittance - Article 12(2) and (3) RPBA

The main request, originally filed as auxiliary request 3 along with the patent proprietor's observations on the notice of opposition and dealt with in the decision under appeal as auxiliary request 4, was resubmitted as auxiliary request 1.

Novelty - Article 54 EPC - claim 1

Document D8 did not anticipate the subject-matter of claim 1, which refers to a vaccine composition implying a therapeutic purpose and a protective effect against all the viruses incorporated in the recombinant HVT, specifically MDV, Newcastle disease virus (NDV), and infectious laryngotracheitis virus (ILTV). Unlike the chimeric constructs tested in documents D8 and D2, the recombinant HVT in claim 1 was not chimeric and retained the characteristics of an HVT virus.

The subject-matter of claim 18 of document D8 was not supported by the description. Examples 1 to 3 in document D8 test the constructs for stability prior to their use as vaccines. While Examples 2 and 3 show effective vaccines based on a chimeric NAHV construct

with single inserts from NDV or ILTV, they do not describe or test constructs combining both NDV and ILTV sequences. Neither the examples, the description nor the figures in document D8 suggested that such a combination had been constructed or tested, even prophetically.

Furthermore, document D8 was not enabling because no simultaneous protective effect against MDV, NDV and ILTV for the trivalent vaccine according to claim 18 was shown. The theoretical constructs of this claim required replacing approximately 15% of the HVT genome with other viral sequences, this resulted in an inherently unstable chimeric construct, as evidenced by Table 1 (last row) of document D2. This table showed instability of a chimeric NAHV with two inserts encoding NDV and ILTV proteins in the MDV-U2 region. As a result, these constructs could not be stably expressed for several days and failed to induce a protective immune response against MDV, NDV and ILTV.

Additionally, if the NAHV vector according to claim 18 of document D8 lost one of its NDV or ILTV inserts, it would fall outside of the scope of claim 1 since it could not provide a protective affect against all mentioned pathogens.

(b) Auxiliary request 1

Admittance

Auxiliary request 1 further narrowed the claimed subject-matter compared to the main request and addressed the opposition division's objections against novelty.

Novelty - Article 54 EPC

Auxiliary request 1 was novel, essentially for the reasons as outlined above for the main request. None of the cited prior-art documents disclosed, directly and unambiguously, and in an enabling manner, a vaccine of an rHVT having all three genes for NDV fusion protein (F), ILTV glycoprotein D (gD) and ILTV glycoprotein I (gI) inserted into the US2 site according to claim 1 of auxiliary request 1. Document D8 did not provide, as also admitted by the opposition division, any proof of making and testing a vaccine based on such a trivalent construct. In addition, the term rHVT did not cover one of the chimeric constructs of document D8.

(c) Auxiliary requests 2 and 3

Admittance - Article 13(1) RPBA

Auxiliary requests 2 and 3 were convergent and comprised further limitations compared to the subject-matter of the main request and auxiliary request 1. Although not submitted with the statement of grounds of appeal, these requests were submitted well in advance of the oral proceedings. They addressed all objections raised, including those in the opposition division's preliminary opinion and the respondent's arguments in its reply to the statement of grounds of appeal.

XI. The respondent's arguments relevant to the decision can be summarised as follows.

(a) Claim construction

Vaccine

A "vaccine" claim was a product claim that merely required the specified composition to be suitable for formulation as a vaccine. However, it was not to be construed as a medical use claim within the meaning of Article 54(4) or (5) EPC and thus did not imply the claimed therapeutic effect to be a limiting functional technical feature.

Recombinant virus - Chimeric virus

The term "recombinant virus" merely referred to a virus comprising one or more recombinant modifications. In line with the definition provided in the patent in suit (page 7, lines 13 to 20, especially lines 19 to 20), a "recombinant virus" encompassed any virus that has been genetically modified to encode a heterologous sequence.

A "chimeric virus" was a specific form of a recombinant virus, in the current case, formed by replacing a specific region of the genome of one MDV serotype with the corresponding region of another serotype. The NAHV was an example of a chimeric virus since it involves specific modifications to the MDV genome by replacing portions of it with sequences from another MDV serotype. A chimeric HVT was a specific form of an HVT virus.

(b) Main request

Admittance - Article 12(2) and (3) RPBA

The main request is identical to auxiliary request 4 in the decision under appeal and to auxiliary request 3 as filed with the patent proprietor's observations on the notice of opposition. In response to the opposition division's findings on novelty in its preliminary opinion, the appellant filed auxiliary requests 6 to 13. Following the opposition division's decision during oral proceedings, which confirmed that the main request lacked novelty, auxiliary requests 6 and 13 were promoted to auxiliary request 1, one after the other. However, the appellant had not chosen to elevate or further discuss auxiliary request 3, which is identical to the current main request. Thus, this claim request could not be considered a reaction to the decision under appeal.

Novelty - Article 54 EPC - claim 1

The subject-matter of claim 1 lacked novelty over the vaccine defined in claim 18 of document D8.

Contrary to the appellant's allegations, the description of document D8 also provided, e.g. in column 3, lines 25 to 29 or column 7, lines 4 to 13, a vaccine against Marek's disease, Newcastle disease and infectious laryngotracheitis.

Since document D8 showed in Examples 2 and 3 that vaccines comprising NAHV and either NDV F-protein or ILTV gD and gI proteins were stable and provided a protective effect against MDV and NDV or MDV and ILTV *in vivo*, it was credible that inserting a combination

of NDV and ILTV proteins into the same MDV-derived U2 insertion site of the NAHV construct would also result in a stable and protective vaccine. There was an expectation from the prior art that a construct according to claim 18 of document D8 was stable. Document D10 reports that a recombinant HVT-based vaccine comprising four inserts encoding foreign genes was stable and able to produce protective immunity (page 774, right-hand column, first full paragraph). The appellant had not provided evidence to the contrary.

The data in Table 1 of document D2 were not conclusive. While they reported that the trivalent HVY-198 (NAHV) vaccine would not be stable, it was not clear what the stability criteria were. This was, however, important since e.g. the HVT 079 construct was reported to be not stable but at the same time to provide protection against ILTV. The HVT 078 and HVT 106 constructs comprised identical inserts, nevertheless, they showed different stability.
Thus, the meaning of stable/unstable was not clear and had no correlation to practice.

Even if the vaccine of claim 18 was considered to imply a certain protective effect, it would be sufficient if such an effect were provided for at least one of the encoded pathogens. Given that the NAHV vector itself was reported to confer protection against very virulent strains of MDV (document D8, column 4, lines 20 ff), it was secondary whether the heterologous inserts were stable.

(b) Auxiliary request 1

Admittance

Auxiliary request 1 was not *prima facie* relevant and could not be considered a genuine attempt to overcome the novelty objections. The appellant did not provide reasoning as to why this request should be admitted into the proceedings.

Novelty - Article 54 EPC

Compared to claim 1 of the main request, claim 1 of auxiliary request 1 had merely been further restricted to specify the use of the US2 site as the sole insertion site. However, this feature was already disclosed in the same passages of document D8, which were discussed during the opposition proceedings, over which the patent was found to lack novelty.

(c) Auxiliary requests 2 and 3

Admittance - Article 13(1) RPBA

Auxiliary requests 2 and 3 were not admissible as they were unsubstantiated and late filed. These requests could and should have been filed at the latest with the statement of grounds of appeal. Moreover, neither of the two auxiliary requests resolved the existing novelty objections.

XII. The parties' requests relevant to the decision were as follows.

(a) The appellant requested that:

- the decision under appeal be set aside and that the claims of the main request, filed as auxiliary request 1 with the statement of grounds of appeal, or, alternatively, the claims of one of auxiliary request 1, filed as auxiliary request 2 with the statement of grounds of appeal, and auxiliary requests 2 and 3, filed as auxiliary requests 3 and 4 with a letter dated 19 February 2024, be found to be novel
- the opposition division's decision on sufficiency and added matter be confirmed in respect of a set of claims found to be novel
- the case be remitted to the opposition division for the assessment of inventive step
- the main request and auxiliary requests 1 to 3 (as renumbered) be admitted into the proceedings

(b) The respondent requested that:

- the patent proprietor's appeal be dismissed
- the case be remitted to the opposition division in case the board would find the claims of any of the main request or of auxiliary requests 1 to 3 (as renumbered) to be novel
- the main request and auxiliary requests 1 to 3 (as renumbered) not be admitted into the proceedings

Reasons for the Decision

Main request

Admittance - Article 12(2) and (3) RPBA

1. The main request is identical to auxiliary request 4 of the decision under appeal (and to auxiliary request 3 as filed with the reply to the notice of opposition). This claim request was part of the opposition proceedings, considered in the decision under appal and also substantiated in the statement of grounds of appeal. It thus forms part of the appeal proceedings (Article 12(2) and (3) RPBA).

Claim construction - claim 1

Vaccine

2. The term "vaccine" imparts a functional limitation and requires that the claimed composition be suitable for eliciting an immune response against one of the comprised or encoded antigens in a manner providing protection against a particular disease, either by preventing or curing it or reducing its severity. In the current invention, a vaccine comprising/encoding antigens from Marek's disease virus (MDV), Newcastle disease virus (NDV) and infectious laryngotracheitis virus (ILTV) is required to be suitable to elicit an immune response against (at least) one of the encoded antigens in a manner that will provide some level of protection.

Recombinant virus - chimeric virus

3. In virology, "recombinant" broadly refers to a virus that has been genetically modified through recombination. This process involves incorporating one or more modifications, such as foreign nucleic acid sequences that encode (a) foreign gene(s), into the virus's genome.

Consequently, in claim 1, the terms recombinant non-pathogenic MDV (rMDVnp) and recombinant herpesvirus of turkey (rHVT) define a class of viral vectors by reference to their viral genome stemming from non-pathogenic MDV strains of different serotypes but are not to be understood as being equated to the final viral construct which consists of the genome of the viral vector plus all heterologous nucleotide inserts as required by claim 1.

4. The definition of rMDVnp in the description on page 7, lines 19 to 20 of the patent in suit states that the term rMDVnp refers to a rMDVnp that includes heterologous nucleotide sequences (i.e. sequences from pathogens other than MDV). In other words, the definition in the description equates the term rMDVnp to a specific recombinant vector with inserts of nucleotide sequences encoding proteins from other pathogens.

However, this definition cannot change the common understanding of the terms of art rMDVnp and rHVT as used in claim 1, as set out above, nor is this definition consistent with how a skilled person would understand the claim.

Indeed, the skilled person would understand the terms rMDVnp and rHVT as used in claim 1 to refer to the genome of a viral vector stemming from a non-pathogenic strain of an MDV serotype. No further limitations are implied by the terms rMDVnp and rHVT. The skilled person would not understand the term rHVT to exclude viral vectors in which a specific region of the genome of HVT (which is MDV serotype 3, i.e. MDV3) have been replaced by the corresponding region of a different MDV serotype, as is the case for novel avian herpesvirus (NAHV). Of course, claim 1 further requires that nucleotide sequences of at least two specified pathogens other than MDV, i.e. NDV and ILTV, be inserted into the rMDVnp/rHVT vector. Hence, the claim is directed to a construct formed by the rMDVnp/rHVT vector and inserts of nucleotide sequences from other pathogens.

5. The exclusion of viral constructs comprising nucleotide sequences from different MDV serotypes from the term MDVnp (see page 7, lines 14 to 17 of the patent in suit) is in line with how the skilled person would understand the term MDVnp as it does not include recombinant viral constructs but refers only to the naturally occurring viruses. Claim 1 is specifically directed to a vaccine comprising a recombinant non-pathogenic MDV (rMDVnp), specifically rHVT. Even if the definition of MDVnp in the description were intended to include rMDVnp in a way that excludes chimeric viruses, this cannot change the skilled person's understanding of the terms rMDVnp and rHVT, as set out above.

Moreover, excluding chimeric viruses from the claimed subject-matter appears contradictory for the following reasons.

The term chimeric virus, as understood by the skilled person, relates to a specific type of recombinant virus that contains genetic material from different viruses within a single viral genome construct. This typically implies that the resulting viral construct exhibits characteristics derived from each of the parental viruses. Accordingly, inserting nucleotide sequences of NDV and ILTV into the rHVT vector as claimed results in a chimeric virus.
Therefore, chimeric viruses cannot be excluded from the subject-matter of claim 1, let alone a (recombinant) NAHV that includes nucleotide sequences from NDV and ILTV.

6. Due to the comprising language, claim 1 does not exclude that the rMDVnp may be engineered to comprise additional nucleic acid inserts encoding antigens of pathogens other than NDV and ILTV.

Novelty - Article 54 EPC - claim 1

7. Document D8 discloses a recombinant novel avian herpesvirus (NAHV) composed of the long repeat region (LR) and the unique long regions (UL) of herpesvirus of turkey (HVT) and the unique short region (US) and short repeat regions (SR) of the MDV (see Figure 1). MDV (MDV1) is described to be a virulent strain of herpesvirus in chicken and HVT (MDV3) to be a non-pathogenic HVT (see column 2, paragraph 1).

Claim 3 of document D8 discloses a NAHV in which the MDV US region comprises a US2 gene into which the "at least one" foreign DNA sequence is inserted. Claims 4, 9 and 11 directly depend on claim 3. Claim 4 specifies that the foreign DNA sequence (in the singular) to be

inserted be selected from the group consisting of NDV-F, an ILTV gD gene and an ILTV gI gene. Claim 9 specifies that the foreign DNA sequences (in the plural) are the ILTV gD and gI genes. Claim 11 specifies that the foreign DNA sequences (in the plural) are the NDV-F gene, the ILTV gD gene and ILTV gI gene.

The combination of different foreign DNA sequences in one viral construct follows also from claim 18 which relates to a multivalent vaccine for protecting against Marek's disease, infectious laryngotracheitis and Newcastle disease using the recombinant avian herpesvirus of claim 11 in a suitable carrier.

Claim 19 covers, as an alternative option, a multivalent vaccine comprising two different chimeric viruses each expressing one foreign antigen.

Lastly, claim 25 claims a method of immunising an avian species against Marek's disease, infectious laryngotracheitis and Newcastle disease comprising administering to the avian species an effective immunising amount of the vaccine of claim 18.

8. The appellant argued that the disclosure of document D8 did not meet the "directly and unambiguously" standard for novelty, did not enable a vaccine according to claim 18 and was contradicted by evidence provided in document D2.

Document D8 - direct and unambiguous disclosure

9. It is clear from the wording and structure of claims 3, 4, 9 and 11 that the inventors of document D8 envisaged both (i) a multivalent vaccine that was a mixture of

different NAHV constructs, each encoding a separate foreign gene (as covered by claim 19), and (ii) a multivalent vaccine based on a single NAHV construct encoding a plurality of foreign genes (as specified in claim 11, to which vaccine claim 18 refers).

9.1 A multivalent vaccine encoding more than one heterologous antigen is furthermore addressed in several passages of the description of document D8. For example, column 3, lines 25 to 27 describes that the invention is directed to a vaccine against Marek's disease (caused by serotype 1 MDV, i.e. MDV1), Newcastle disease (caused by NDV) and/or infectious laryngotracheitis (caused by ILTV). Column 6, lines 15 to 24 specifically refers to a multivalent vaccine useful for immunising against (i) MDV1 and (ii) NDV or ILTV. Column 7, first full paragraph also discloses a multivalent vaccine for immunising against (i) MDV1 and (ii) NDV or ILTV, followed by the disclosure of a multivalent vaccine against (i) MDV1, (ii) NDV and (iii) ILTV.

Furthermore, a multivalent vaccine against MDV1, NDV, and ILTV cannot be considered merely an artefact of the claim drafting process, especially in view of the alternative vaccines defined in claim 19 and the disclosure of multivalent vaccines against MDV and NDV or MDV and ILTV in Examples 2 and 3.

10. The board considers that document D8 directly and unambiguously discloses a multivalent vaccine against MDV, NDV and ILTV.

Document D8 - enabling disclosure

11. The appellant argued that document D8 was not enabling because the trivalent vaccine according to claim 18 had not been tested for its protective effect against all three encoded pathogens.

12. In accordance with established case law, the board considers that subject-matter described in a document can be regarded as having been made available to the public if the information given is sufficient to enable the skilled person, at the relevant date of the document, to practise the technical teaching which is the subject of the document, taking into account also the general knowledge at that time in the field.

13. Document D8 provides in columns 7 to 16 detailed instructions on how to prepare the recombinant chimeric virus and in Examples 1 to 3 clear protocols on how to test them for their suitability as vaccines. Thus, sufficient information is provided to enable the skilled person to produce and test a composition suitable as a multivalent vaccine as defined in claim 18 of document D8.

Assessment of alleged counter-evidence

14. The appellant cited document D2, particularly the last row of Table 1, as evidence that the multivalent recombinant virus construct according to claim 11 of document D8 was unstable. The demonstration of genetic and expression stability of a recombinant viral construct was, however, necessary for providing an effective vaccine.

15. Document D2 is inconclusive for several reasons. The first part of document D2 describes criteria and methods for determining stability and protection, but it does not provide information on how the recombinant viruses mentioned in Table 1 were constructed and tested. For example, the text on page 2, points 6 and 7, describes testing for genetic and phenotypic stability, yet it does not specify whether the observed (in)stability reported in Table 1 refers to the replicability (genetic stability) of the recombinant virus (after a certain number of passages) and/or to the expression of one or more encoded antigens (phenotypic stability) or something else. Furthermore, a protective effect of the HVY-198 (NAHV) construct was not tested for any of the included antigens.

This is in stark contrast to what has been done for the double recombinant viral construct "HVT 079", which includes MDV1 gA, gB, gD and ILTV gB and gD inserted at the US2 site. The row describing results for HVT 079 shows that despite being reported as unstable, this recombinant construct was still able to provide 71 to 100% protection against ILTV. Protection against MDV1 was not tested.

16. Contrary to the inconclusive evidence of document D2, document D10 teaches that a viral HVT vector can accommodate up to four foreign genes (two genes from each of two different heterologous viruses). The resulting recombinant viral construct remains stable enough to produce protective immunity against challenges from NDV and MDV1 (see page 774, right-hand column, first full paragraph).

17. Document D8 shows that the multivalent MDV and NDV or MDV and ILTV recombinant viruses are genetically stable

over 12 passages in tissue culture and able to induce a protective immune response against (i) MDV1 and (ii) NDV or ILTV (see Examples 1 to 3).

18. From the foregoing, it is therefore credible that a recombinant MDV comprising more than one insert from two different heterologous viruses in the non-essential US2 site, encoding thus one additional foreign antigen to those tested in Examples 1 to 3 of document D8, can be prepared and will provide protection by preventing or reducing the severity of a disease caused by at least one of the viruses whose antigens are encoded by the recombinant MDV construct.

19. Therefore, the board considers the multivalent recombinant vaccine for protecting against the diseases caused by MDV1, ILTV and NDV according to claim 18 of document D8 to be enabled and to anticipate the subject-matter of claim 1 within the meaning of Article 54 EPC.

Auxiliary requests 1

Admittance - Article 12 (4) and (6) RPBA

20. Since the novelty objections discussed for claim 1 of the main request apply *mutatis mutandis* to claim 1 of auxiliary request 1 (see points 21. and 22. below), no reasons for the admittance of auxiliary request 1 need to be provided.

Novelty - Article 54 EPC - claim 1

21. Claim 1 of auxiliary request 1 differs from claim 1 of the main request only in that it has been limited to specify the US2 site as the sole non-essential site for

insertion of the nucleic acids encoding the ILTV and NDV proteins.

22. Since document D8 identifies in claim 3 that the US2 gene is the insertion site for the foreign DNA sequence(s), and claim 18 indirectly refers to the US2 gene via its reference to claim 11, which is dependent on claim 3, the subject-matter of claim 1 of auxiliary request 1 is anticipated by the subject-matter of claim 18 of document D8 for the same reasons as provided for claim 1 of the main request (see points 8. to 18. above).

Auxiliary requests 2 and 3

Admittance - Article 13(1) RPBA

23. Auxiliary requests 2 and 3 were filed by the appellant by letter of 19 February 2024.

Novelty objections in view of document D8 were raised in the notice of opposition. The opposition division's preliminary opinion clearly stated that the subject-matter of claims 5 and 6 of the claims as granted would be considered novel over the disclosure of document D8 (see point 9.4.4.2). In response, the patent proprietor filed several auxiliary requests, but none identical to the current auxiliary requests 2 and 3.

24. Consequently, auxiliary requests 2 and 3 could and should have been filed during the opposition proceedings. Auxiliary requests 2 and 3 are not admitted into the proceedings (Article 13(1) RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated