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# Datasheet for the decision of 23 September 2022

**Case Number:** T 0974/20 - 3.3.08

**Application Number:** 15817860.8

**Publication Number:** 3185899

**IPC:** A61K39/12, A61K39/17, A61K39/295, C07K14/005, C12N15/86, A61K39/00

**Language of the proceedings:** EN

**Title of invention:**
Improved HVT-vectored ND-IBD vaccine

**Patent Proprietor:**
Intervet International B.V.

**Opponent:**
Boehringer Ingelheim Animal Health USA Inc.

**Headword:**
HVT-vectored ND-IBD vaccine/INTERVET

**Relevant legal provisions:**

EPC Art. 54, 56, 83, 123(2)
RPBA 2020 Art. 13(1), 13(2)

**Keyword:**

Amendment after summons - exceptional circumstances (yes)
Amendments - extension beyond the content of the application as filed (no)
Novelty - (yes)
Inventive step - (yes)
Sufficiency of disclosure - (yes)

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**Case Number: T 0974/20 - 3.3.08**

# D E C I S I O N
# of Technical Board of Appeal 3.3.08
# of 23 September 2022

| | |
|---|---|
| **Appellant:** (Opponent) | Boehringer Ingelheim Animal Health USA Inc.<br>3239 Satellite Blvd., Bldg. 500<br>Duluth, GA 30096 (US) |
| **Representative:** | D Young & Co LLP<br>120 Holborn<br>London EC1N 2DY (GB) |
| **Respondent:** (Patent Proprietor) | Intervet International B.V.<br>Wim de Körverstraat 35<br>5831 AN Boxmeer (NL) |
| **Representative:** | Intervet International B.V.<br>Hertford Road<br>Hoddesdon, Hertfordshire EN11 9BU (GB) |
| **Decision under appeal:** | **Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 February 2020 concerning maintenance of the European Patent No. 3185899 in amended form** |

**Composition of the Board:**

| | |
|---|---|
| **Chair** | B. Claes |
| **Members:** | A. Schmitt |
| | L. Bühler |

## Summary of Facts and Submissions

I. The appeal lodged by the opponent (appellant) lies from the interlocutory decision of the opposition division that European patent No. 3 185 899 (patent), as amended in the form of auxiliary request 1, and the invention to which it relates meet the requirements of the EPC. The title of the patent is "*Improved HVT-vectored ND-IBD vaccine*".

The patent was granted with 14 claims. Claims 1 and 9 of the patent as granted read as follows:

"1. Recombinant DNA expression cassette comprising in 5' to 3' direction and in this order:
a. a murine cytomegalovirus immediate early 1 gene (mCMV-IE1) promoter,
b. an infectious bursal disease virus (IBDV) viral protein 2 (VP2) gene,
c. a transcription terminator,
d. a human cytomegalovirus immediate early 1 gene (hCMV-IE1) promoter,
e. a Newcastle disease virus (NDV) fusion (F) protein gene.

9. Ex vivo method for the preparation of a vaccine according to claim 7, said method comprising the steps of:
- infecting host cells with a recombinant HVT according to claim 4,
- harvesting the infected host cells, and
- admixing the harvested infected host cells with a pharmaceutically acceptable carrier."

II. The patent was granted on European patent application No. 15 817 860.8, which had been filed as an international application (application) published as WO 2016/102647.

Claims 1, 4 and 9 of the application as filed read as follows:

"1. Recombinant DNA expression cassette comprising in 5' to 3' direction and in this order:
a. a murine cytomegalovirus immediate early 1 gene (mCMV-IE1) promoter,
b. an infectious bursal disease virus (IBDV) viral protein 2 (VP2) gene,
c. a transcription terminator,
d. a human cytomegalovirus immediate early 1 gene (hCMV-IE1) promoter,
e. a Newcastle disease virus (NDV) fusion (F) protein gene.

4. A recombinant herpes virus of turkeys (HVT), comprising a recombinant DNA expression cassette according to any one of claims 1 or 2, whereby the expression cassette is inserted in the Us region of the genome of the recombinant HVT.

9. Method for the preparation of a vaccine according to claim 7, said method comprising the steps of:
- infecting host cells with a recombinant HVT according to claim 4,
- harvesting the infected host cells, and
- admixing the harvested infected host cells with a pharmaceutically acceptable carrier."

III. The opposition proceedings were based on the grounds for opposition in Article 100(a) EPC, for exceptions to

patentability (Article 53(c) EPC), novelty (Article 54 EPC) and inventive step (Article 56 EPC), and in Article 100(b) and (c) EPC.

IV. In the decision under appeal, the opposition division considered, *inter alia*, that the claims of auxiliary request 1 met the requirements of the EPC.

The set of claims of auxiliary request 1 was amended compared to the set of claims of the patent as granted (see section I.) in that in claim 9, the expression "Ex vivo" was replaced with "In vitro", claim 11 was deleted and claims 12 to 14 were renumbered accordingly.

V. With the statement of grounds of appeal, the appellant submitted five documents (D27 to D31) and arguments supporting its view that claim 9 of auxiliary request 1 contained subject-matter that extended beyond the disclosure of the application as filed; the subject-matter of claim 1 of this request was not new and lacked an inventive step when, *inter alia*, document D3 was selected as the closest prior art; and the invention as defined in the claims of this request was not sufficiently disclosed in the patent in so far as it required the provision of an effective vaccine.

VI. With the reply to the statement of grounds of appeal, the patent proprietor (respondent) submitted sets of claims of a main request and auxiliary request 1 to 7 and four documents (D32 to D35), the main request being identical to auxiliary request 1 underlying the decision under appeal (see section IV.). It requested, *inter alia*, that the appellant's line of attack on inventive step using document D3 as the closest prior art and documents D27 to D31 not be admitted.

VII. In a further letter, the appellant submitted, *inter alia*, arguments on the admittance of documents D27 to D31.

VIII. The board summoned the parties to oral proceedings in accordance with their requests and issued a communication pursuant to Article 15(1) RPBA, in which it, *inter alia*, provided its preliminary opinion that the subject-matter of claim 1 of the main request did not involve an inventive step (Article 56 EPC).

IX. By letter dated 21 June 2022, received on 22 June 2022, the respondent filed a set of claims of a new main request, which, if admitted into the proceedings by the board, was to replace all other claim requests. If the board did not admit the new main request, auxiliary request 1 submitted with the statement of grounds of appeal would be the "alternative" main request.

The main request filed by letter dated 21 June 2022 consists of claims 1 to 7 which read as follows:

"1. A recombinant herpes virus of turkeys (HVT), comprising a recombinant DNA expression cassette inserted in the Us region of the genome of the recombinant HVT, the recombinant DNA expression cassette comprising in 5’ to 3’ direction and in this order:
a. a murine cytomegalovirus immediate early 1 gene (mCMV-IE1) promoter,
b. an infectious bursal disease virus (IBDV) viral protein 2 (VP2) gene,
c. a transcription terminator,
d. a human cytomegalovirus immediate early 1 gene (hCMV-IE1) promoter,

e. a Newcastle disease virus (NDV) fusion (F) protein gene,
characterised in that the recombinant DNA expression cassette is the region of nucleotides 630 - 6127 of SEQ ID NO: 1, and in that the recombinant DNA expression cassette is inserted in the Us2 gene of the genome of the recombinant HVT.

2. Host cell comprising a recombinant HVT according to claim 1.

3. Vaccine for poultry comprising a recombinant HVT according to claim 1, and/or a host cell according to claim 2, and a pharmaceutically acceptable carrier.

4. A vaccine according to claim 3, comprising at least one additional immunoactive component.

5. In vitro method for the preparation of a vaccine according to claim 3, said method comprising the steps of:
- infecting host cells with a recombinant HVT according to claim 1,
- harvesting the infected host cells, and
- admixing the harvested infected host cells with a pharmaceutically acceptable carrier.

6. A vaccine according to anyone of claims 3 or 4 for use in a method for preventing or reducing infection by IBDV and/or NDV, or associated signs of disease, wherein said method comprises the administration of said vaccine to poultry.

7. A vaccine according to any one of claims 3 or 4 for use in a method of vaccination of poultry comprising

the step of inoculating said poultry with said vaccine."

X. The appellant submitted objections to the admittance and allowability of the new main request. It also raised, *inter alia*, an objection under Article 123(3) EPC against claim 5 of this request.

XI. During the oral proceedings, the board admitted the new main request filed by letter dated 21 June 2022 in the proceedings. The board furthermore admitted the line of attack on inventive step starting from document D3 as the closest prior art and documents D27 to D35 into the proceedings. At the end of the oral proceedings, the Chair announced the board's decision.

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

D1 EP 0 719 864 A2 (3 July 1996)

D1a US 6,045,803 (4 April 2000)

D3 US 2014/0147457 A1

D6 WO 2013/057235 Al

D7 WO 2013/144355

D8 EP 1 026 246 A1

D22 First declaration by R.M. Nordgren

D23 CA 2 626 498 A1

D24 M. Bublot et al., J Comp Path 137, 2007, S81-S84

D27 Second declaration by R.M. Nordgren

XIII. The appellant's arguments relevant to the decision on the main request are summarised as follows.

*Admittance (Article 13(2) RPBA 2020)*

Admitting the main request would be contrary to procedural economy, *inter alia,* because the amendments would give rise to new objections under Article 84 EPC, Article 123(2) EPC and Rule 80 EPC.

The amendments did not *prima facie* overcome the objection of the board that the promoters and genes of the DNA expression cassette in claim 1 of the request commented on by the board (i.e. auxiliary request 1 considered by the opposition division) were not operably linked.

Submitting a "conditional" main request and an "alternative" main request created an unacceptable procedural situation, aggravated by the fact that these claim requests were not convergent.

No new objections had been presented in the board's communication under Article 15(1) RPBA (the board's communication).

The objection on the lack of linkage of all elements of the DNA expression cassette had been part of the opponent's case in opposition (see section A.3.2 of Annex A submitted with the statement of grounds of appeal and point 18.1 of the decision under appeal).

There was no contradiction between the claim interpretation on page 12 of the statement of grounds of appeal and that in section A.3.2 of Annex A because both had to be understood in the context of the missing second transcription terminator. The claim construction provided on page 10 of the statement of grounds of appeal, pointing out that the proximity of the elements in the expression cassette was not a feature of the claim, confirmed this.

The argument that the DNA expression cassette's insertion site into the viral vector was relevant for the inserted gene's expression levels was not new either (see section A.3.5 of Annex A). Consequently, the respondent could and should have filed the new main request at an earlier stage of the proceedings. There were hence no exceptional circumstances justified by cogent reasons why this claim request was only submitted after the board had issued its communication. It should therefore not be admitted into the appeal proceedings under Article 13(2) RPBA.

*Rule 80 EPC*

The deletion of claims 10 to 12 compared to the claims as granted was not occasioned by a ground for opposition, contrary to the requirements of Rule 80 EPC.

*Clarity (Article 84 EPC) and claim construction - claim 1*

It was not clear whether the expression "is the region of nucleotides 630 - 6127 of SEQ ID NO: 1" limited the sequence of the DNA expression cassette recited in claim 1 to nucleotides 630 to 6127 of SEQ ID NO: 1. The

expression "in the region of" was used for estimates of a given value, and therefore the language of the claim gave the impression that the DNA expression cassette did not have a precise nucleotide sequence. Moreover, Table 1 of the patent showed that the DNA expression cassette contained unaccounted sequence gaps between the different elements of the cassette as defined in points a. to e. of the claim. Thus, these elements were not required to be linked in a particular manner. As a consequence, the promoters and genes recited in the claim were not necessarily operatively linked.

Paragraphs [0061], [0066] and [0067] of the patent supported this claim construction. They defined the DNA expression cassette as "is the region of nucleotides 630 - 6127 of SEQ ID NO: 1", "comprises the region of nucleotides 630 - 6127 of SEQ ID NO: 1" and "comprises the DNA molecule as presented in SEQ ID NO: 1", respectively. This meant that each of these expressions must have a different meaning.

*Amendments (Article 123(2) EPC)*
*Claim 1*

The feature that "the recombinant DNA cassette is the region of nucleotides 630 - 6127 of SEQ ID NO: 1" was disclosed on page 14, lines 15 to 16 of the application as a separate embodiment which could not be combined with the embodiment on page 16, lines 8 to 10 of the application that the recombinant herpes virus of turkeys (HVT) insertion site could be in the Us2 gene. The application thus did not disclose that a DNA expression cassette which "is the region of nucleotides 630 - 6127 of SEQ ID NO: 1" could be inserted anywhere in the Us2 gene of HVT.

Table 1 in the application could not serve as basis for the claimed recombinant HVT either because the DNA expression cassette of Table 1 was inserted in a specific site of the HVT Us2 gene. The subject-matter of claim 1 was an unallowable intermediate generalisation of this example.

*Claim 5*

The expression "In vitro" inserted in claim 5 did not have a basis in the application. The passages on page 17, lines 34 to 35 and page 20, lines 37 to 39 of the application did not concern methods for the preparation of a vaccine. It was furthermore incorrect that the only two ways of characterising the method of claim 9 was as an "in vivo" or "in vitro" method because, for example, an "ex vivo" method was another possibility.

*Admittance of the objection under Article 123(3) EPC (Article 13(2) RPBA 2020)*

For the method of claim 5, the term "ex vivo" was narrower than the term "in vitro". It was therefore immediately apparent that the replacement of the term "ex vivo" with the term "in vitro" in claim 5 of the main request compared to claim 9 of the patent extended the protection conferred by the patent and did not comply with the requirements of Article 123(3) EPC. This objection was straightforward and should therefore be admitted into the appeal proceedings.

*Novelty (Article 54 EPC) - claim 1*

Paragraph [0079] of the patent disclosed that the nucleotide sequence of the DNA expression cassette

recited in the claim could have only 95% nucleotide sequence identity to nucleotides 630 to 6127 of SEQ ID NO: 1. In view of this disclosure, the DNA expression cassette in the recombinant HVT disclosed in paragraph [0117] of document D3 was also covered. In this recombinant HVT, a mouse cytomegalovirus immediate early 1 gene (mCMV-IE1) promoter, an infectious bursal disease virus (IBDV) viral protein 2 (VP2) gene and a transcription terminator were inserted in the HVT intergenic region 1 (IG1) site, and a human CMV (hCMV) promoter and the Newcastle disease virus (NDV) fusion protein (F) gene were inserted into the Us region (see document D3, paragraphs [0104] and [0117] and Tables 6.1 and 12). The claimed subject-matter was thus not novel over the recombinant HVT disclosed in document D3.

*Sufficiency of disclosure (Article 83 EPC)*

Since, the DNA expression cassette recited in the claims could have only 95% nucleotide sequence identity to nucleotides 630 to 6127 of SEQ ID NO: 1 (see paragraph [0079] of the patent), it could comprise an ineffective form of the hCMV-IE1 promoter or a codon-optimised nucleotide sequence of the NDV F or the IBDV VP2 gene. Neither of these variant constructs allowed stably expressing the genes, and hence neither was suitable as a vaccine (see document D6, page 9, lines 39 to 42; document D3, paragraph [0117]). The claims directed to vaccines thus encompassed non-working embodiments, and the invention was hence not sufficiently disclosed in the patent.

The claims did not specify the insertion site of the DNA expression cassette in the Us2 gene. Since the insertion site influenced the expression and stability

of the expression cassette (see page 3, lines 3 to 8 of the patent and the paragraph bridging pages 2 and 3 of document D6), not every insertion within the Us2 gene would necessarily result in a recombinant HVT suitable as a vaccine.

*Inventive step (Article 56 EPC)*

The disclosure in any of documents D1a, D3, D6, D8 and D23 were all equally suitable starting points for the assessment of inventive step. They all concerned HVT constructs achieving excellent levels of recombinant gene expression and protection.

*Document D6 as the closest prior art*

The recombinant HVT HVP309 disclosed in document D6 (see section 1.6 bridging pages 25 to 26) provided a strong and stable expression of both NDV F and IBDV VP2 genes in vivo and in vitro and generated an efficacious immune response providing 100% protection to viral challenge (see page 15, lines 21 to 27; page 26, lines 1 to 3; page 28, lines 34 to 36; page 29, lines 22 to 24; page 30, lines 18 to 21; page 34, lines 7 to 9; Tables 1, 2 and 3).

Improved genetic stability should not be taken into account when formulating the technical effect of the differences because for a vaccine, only protection from viral challenge was relevant, on which the stability of viral expression had no bearing. This was evident from, *inter alia*, the fact that HVP309 provided better protection from viral challenge than the claimed construct (see Table 3 of the patent compared to Tables 2 and 3 of document D6).

The patent did not compare the stability of the claimed HVT construct and HVP309 in side-by-side experiments. The allegation in paragraph [0013] of the patent that HVP309 did not display adequate genetic stability was not supported by experimental evidence and contradicted the teaching in document D6 that HVP309 was stable (see page 29, lines 22 to 24 and page 34, lines 7 to 9). In fact, the genetic stability of HVP309 had been assessed in document D6 for five consecutive animal passages (see page 34, lines 7 to 9), whereas the patent only contained results for a single in vivo passage (see paragraph [0016] of the patent; points 19 to 22 of document D27).

A virus having better than 95% genetic stability was suitable for vaccine production (see document D6, page 16, lines 1 to 3).

In the absence of any relevant technical effects of the claimed construct compared to that of document D6, the objective technical problem was the provision of an alternative recombinant HVT construct.

The order of two individually expressed antigen genes inserted into an HVT vector influenced neither the stability of expression nor the protection provided by the construct and was therefore arbitrary and obvious to the skilled person (see document D22, points 11 and 12 and document D8, Examples 13 to 16).

The mCMV-IE1 promoter had been used to drive the expression of the IBDV VP2 gene in HVT constructs which provided 100% protection when used as a vaccine, including commercial products (see document D1a: Example 9, column 14, lines 18, 54 to 55 and 63; document D3: footnote to Table 12 and paragraph [0104];

document D7: page 18, lines 5 to 10; page 19, lines 1 to 7; page 19, lines 23 to 28; passage spanning pages 19 to 20; page 23, lines 28 and 31; document D24: page S82, left-hand column, Table 2, pages S83 and S84).

The selection of the mCMV-IE1 promoter for expressing the IBDV VP2 gene was therefore also obvious to the skilled person.

*Documents D1a, D3, D8 or D23 as the closest prior art*

Starting from the recombinant HVT disclosed in document D1a (see column 2, line 65 to column 3, line 4; column 3, lines 28 to 32 and lines 56 to 63), the objective technical problem was the provision of a vaccine against IBDV and NDV. It was obvious to the skilled person to select the NDV F gene. Moreover, a "CMV-IE promoter" meant, in document D1a, the promoters disclosed in the examples (see column 2, lines 65 to 67), which were, for IBDV VP2, the mCMV-IE promoter (see Examples 9 and 18), and for NDV F, a hCMV-IE promoter (see Example 12). Thus, it was obvious to the skilled person to use these promoters in a recombinant viral vector of D1a expressing IBDV VP2 and NDV F.

The only difference of the recombinant HVT disclosed in document D3 (see paragraph [0117]) to the claimed HVT construct was the use of one as opposed to two insertion sites in the HVT vector. The separation of unrelated genetic elements in an expression cassette by genomic HVT DNA did not have any effect on genetic stability of the genetic elements or on viral protection by the HVT construct (see document D27, paragraphs 23 to 26). The stability data disclosed in document D3 had been assessed under different

experimental conditions and could thus not be compared to the data disclosed in the patent. Therefore, the use of one instead of two insertion sites was merely an arbitrary variation in the positioning of the recombinant genetic elements. The claimed subject-matter was hence obvious to the skilled person.

The difference of the recombinant HVT disclosed in document D8 (HF007, see Example 13) to the claimed HVT was that the CMV promoter driving IBDV VP2 gene expression was mCMV-IE and that the antigen order was not specified. This construct provided stable expression of both antigens (see Table 2, paragraph [0106]) and 100% protection against NDV challenge (see Example 7, Table 3, paragraph [0112]). The objective technical problem was therefore the provision of an alternative vaccine against IBDV and NDV. Since the order of the antigens was arbitrary and the modification of an existing construct by using an mCMV promoter to drive IBDV VP2 gene expression obvious, the claimed HVT construct lacked an inventive step.

The difference of the recombinant HVT designated S-HVT-143 disclosed in document D23 (see page 129 and Example 17C) to the claimed HVT was that the IBDV VP2 gene was linked to an mCMV promoter. S-HVT-143 was useful as a vaccine in poultry against IBDV, MD and NDV (see page 129, lines 26 to 29). The technical problem was thus the provision of an alternative vaccine against IBDV and NDV. The use of an mCMV promoter to drive IBDV VP2 expression was obvious.

XIV. The respondent's arguments relevant to the decision on the main request are summarised as follows.

*Admittance (Article 13(2) RPBA 2020)*

The main request was submitted in direct response to the board's communication, which raised new objections against the former main request filed with the reply to the appeal (identical to auxiliary request 1 considered by the opposition division).

In its communication, the board had considered that in claim 1 of the former main request, none of the elements a. to e. of the DNA expression cassette were operatively linked; the claim construction was not only relevant under Article 84 EPC, as deemed by the opposition division, but also for the assessment of novelty and inventive step; and the insertion site in the HVT vector was relevant for the assessment of inventive step.

Not all arguments raised during the opposition proceedings were maintained in appeal. This was for example evident from the discrepancy between the definition of the expression cassette provided on pages 12 and 13 and in Figure 1 of the statement of grounds of appeal and that expressed on page 74 of Annex A to the statement of grounds of appeal which summarised the objections made during the opposition proceedings but not those presented in appeal. This discrepancy also showed that the objection of a lack of linkage between the first three elements of the expression cassette was not maintained in appeal.

The amendments in the new main request made in reply to new objections raised by the board further limited the

claimed subject-matter, could not come as a surprise since they concerned the exemplified expression cassette, overcame all outstanding objections and were presented sufficiently early in advance of the oral proceedings. The new main request hence improved procedural efficiency and economy, especially as all other claim requests were withdrawn subject to its admittance. It was procedurally acceptable that the new main request was filed conditional on its admittance and that previous auxiliary request 1 was maintained as the alternative main claim request if the new main request was not admitted. This corresponded to maintaining an auxiliary request to which the respondent was entitled.

*Rule 80 EPC*

The deletion of claims 10 to 12 of the patent as granted was occasioned by a ground for opposition since all claims had been attacked by the appellant for lack of inventive step and lack of sufficiency of disclosure.

*Clarity (Article 84 EPC) and claim construction - claim 1*

The expression "region of nucleotides 630 - 6127 of SEQ ID NO: 1" related to the nucleotide sequence defined by nucleotides 630 to 6127 of SEQ ID NO: 1. The linkage of the elements of the cassette was an implicit feature of this nucleotide sequence. The alleged gaps in the sequence as presented in Table 1 of the application concerned additional elements required for cloning. These elements were, however, also defined within the nucleotide sequence of SEQ ID NO: 1. Paragraphs [0061], [0066] and [0067] related to three

different DNA expression cassettes which all had clearly defined but different nucleotide sequences. Hence, no lack of clarity arose from the definition of the DNA expression cassette in claim 1.

*Amendments (Article 123(2) EPC)*
*Claim 1*

Basis for the claim was to be found in claims 1 and 4; page 13; page 14, lines 15 to 16; page 15, lines 10 to 12, 27 to 32 and 34 to 37; page 16, lines 1 to 10; Table 1; and SEQ ID NO: 1 of the application. Both the definition of the DNA expression cassette and its insertion into the Us2 gene in HVT were disclosed as separate preferred embodiments such that no selection of embodiments from different lists was required to arrive at the combination of these two features. The construct disclosed in Table 1, Figure 1 and SEQ ID NO: 1 of the application represented an embodiment of this general disclosure. The claimed HVT thus had a basis in the cited passages of the application.

*Claim 5*

The expression "In vitro" in claim 5 had a basis on page 17, lines 34 to 35 and page 20, lines 37 to 39 of the application.

*Admittance of the objection under Article 123(3) EPC (Article 13(2) RPBA 2020)*

The objection that the replacement of the expression "Ex vivo" with the expression "In vitro" in claim 5 as compared to claim 9 of the patent extended the scope of protection of the patent was raised for the first time

in appeal proceedings. Since the expression "Ex vivo" had been present in claim 9 of the patent and the term "In vitro" in claim 9 of auxiliary request 1 considered by the opposition division, this objection could and should have been raised during the opposition proceedings. The objection should not be admitted into the appeal proceedings under Article 13(2) RPBA 2020.

*Novelty (Article 54 EPC) - claim 1*

The disclosure in paragraph [0079] of the patent had no bearing on the definition of the nucleotide sequence recited in the claim. Document D3 did not disclose a recombinant HVT comprising a DNA expression cassette having the nucleotide sequence recited in the claim.

*Sufficiency of disclosure (Article 83 EPC)*

Since the nucleic acid sequence of the DNA expression cassette was precisely defined in the claims, neither an hCMV-IE promoter nor IBDV VP2 or NDV F gene sequences other than those precisely defined by SEQ ID NO: 1 were encompassed by the claims.

The expression cassette was inserted in the HVT vector within a single gene, Us2, and the patent demonstrated that by inserting the DNA expression cassette in this gene, particular stable and effective recombinant HVT vectors were obtained (see paragraphs [0075] to [0077]). The exact insertion site within the Us2 gene was not relevant for the expression levels and stability of the IBDV VP2 or NDV F genes because in any case the same single gene was affected.

The appellant had not provided any serious doubts supported by verifiable facts that the precise

insertion site of the expression cassette within this single gene was relevant for genetic stability.

*Inventive step (Article 56 EPC)*

The recombinant HVT construct HVP309 disclosed in document D6 constituted the most suitable starting point for the assessment of inventive step because it had more features in common with the claimed recombinant HVT than those disclosed in documents D1a, D3, D8 and D23.

The claimed recombinant HVT differed from HVP309, *inter alia,* in the order of the two genes IBDV VP2 and NDV F and the promoter used to drive IBDV VP2 gene expression. The technical effect of these differences was, *inter alia*, improved genetic stability as evident from paragraphs [0013] and [0016] and Example 3 of the patent. Document D6 disclosed that HVP309 was not 100% genetically stable (see page 16, lines 1 to 3).

Examples 4, 5 and 6 of the patent showed that the claimed HVT construct provided excellent protection in viral challenge experiments. In the absence of appropriate side-by-side experiments, it could therefore not be concluded that the claimed construct was less effective in protecting against viral infection than HVP309.

The appellant's argument that HVT constructs inserted at a different site within the Us2 gene might not be genetically stable was neither supported by evidence nor credible because in each HVT construct, the same gene was disrupted.

The objective technical problem was the provision of a recombinant HVT with improved genetic stability.

The claimed solution was not obvious to the skilled person in view of the large number of choices for regulatory elements and the different options for placing the genes in the expression cassette. The cited prior-art documents did not disclose any guidance on improving genetic stability of a dual gene recombinant HVT. This was not trivial due to possible interference between the two promoters and genes. It was therefore not predictable for the skilled person how each possible variation would influence the stability of gene expression.

The same considerations applied if any of the HVT constructs disclosed in document D1a, D3, D8 or D23 were considered to represent the closest prior art, which differed in even more aspects from the claimed HVT construct and were either demonstrated to be genetically unstable (see document D3) or had not been actually produced or tested for genetic stability (see documents D1a, D8 and D23).

XV. The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims of the main request filed by letter dated 21 June 2022.

## Reasons for the Decision

1. The appeal is admissible.

*Main request*
*Admittance (Article 13(2) RPBA 2020)*

2. The main request submitted by letter dated 21 June 2022 constitutes an amendment of the respondent's appeal case to which Article 13(2) RPBA 2020 applies. Any such amendment must, in principle, not be taken into account unless there are exceptional circumstances justified with cogent reasons by the party concerned.

3. New objections raised by the board in a communication may qualify as such "exceptional circumstances" (see Case Law of the Boards of Appeal of the European Patent Office, 10th edn. 2022, V.A.4.5.4.a), second paragraph and the decisions cited there).

4. In its communication, the board had considered, *inter alia*, that, contrary to the claim construction underlying the decision under appeal, claim 1 of the former main request (see section IV.) did not require that in the recombinant DNA expression cassette, the mouse cytomegalovirus immediate early 1 gene (mCMV-IE1) promoter be necessarily operably linked to the infectious bursal disease virus (IBDV) viral protein 2 (VP2) gene and the human cytomegalovirus immediate early 1 gene (hCMV-IE1) promoter be necessarily linked to the Newcastle disease virus (NDV) fusion protein (F) gene. The board further considered that this claim construction and the insertion site in the HVT vector were both relevant for inventive step. Objections to the same effect were not present in the statement of grounds of appeal.

5. Instead, the appellant stated that "*the broadest technically sensible interpretation of claim 1 of '899* [the patent] *is an 'expression cassette' intended for the expression of an **IBDV VP2 gene** (via elements **a-c**), which merely further comprises the stated elements **d-e** ...*" (see page 12 of the statement of grounds of appeal). Thus, in the appellant's claim construction in the statement of grounds of appeal, elements a to c of the expression cassette are operably linked.

6. According to the appellant, the above-cited sentence had to be understood in line with the argument on page 10 of the statement of grounds of appeal that "*the proximity of the elements is **not** a feature of the claim" and that "[p]articularly, the proximity of elements **a-c** and elements **d-e** is not specified*". The sentence on page 12 therefore could only relate to the missing second transcription terminator after elements d and e and could hence not be understood as acknowledging that elements a to c were operatively linked.

7. However, the sentence on page 12 represents the appellant's conclusion drawn from the claim construction on pages 10 to 13 of the statement of grounds of appeal. Here, the sentence from page 10 precedes the interpretation of the term "expression cassette", which ends with the conclusion cited in point 5. above that in the "*broadest technically sensible interpretation*", elements a. to c. form an expression cassette intended for the expression of an IBDV VP2 gene. Since this is the conclusion from the entire claim construction provided on pages 10 to 13 of the statement of grounds of appeal, the sentence on

page 10 cited by the appellant (see point 6.) cannot be used to interpret this conclusion differently.

8. This interpretation of the appellant's claim construction is furthermore confirmed in the legend of Figure 1 and on page 13 of the statement of grounds of appeal, where it is stated that the elements a to c of the expression cassette are considered to be operatively linked in an "IBDV VP2 expression cassette" (see Figure 1), that is, "*intended for expressing IBDV VP2 via the claimed elements* ***a-c***".

9. Consequently, the statement of grounds of appeal did not contain the objection that elements a. to c. of the expression cassette were not linked. Moreover, while it is stated that the nature of the HVT insertion site(s) is not specified in the claim (see fourth paragraph from the bottom of page 10), it is not argued anywhere in the statement of grounds of appeal that this might have consequences for inventive step. The board concludes therefore that the objections were new to the appeal proceedings.

10. The board is not persuaded by the appellant's argument that both objections were part of the appeal proceedings because they had been raised during opposition proceedings and were maintained in appeal in sections A.2.4.1 and A.3.2 of Annex A to the statement of grounds of appeal. Annex A entitled "*Consolidated arguments from Opposition proceedings*" may well summarise the objections made during the opposition proceedings by the opponent. However, the arguments in this annex are not automatically part of the opponent's appeal case. An appellant must present its complete case in the statement of grounds of appeal.

11. Therefore, the mere compilation of objections raised during opposition proceedings in an annex to and a mere statement in the statement of grounds of appeal that it is intended to rely on all facts, evidence and objections presented during the opposition proceedings collated in such an annex (see page 4 of the statement of grounds of appeal) do not constitute an indication of the reasons for setting aside a decision under appeal required under Rule 99(2) EPC.

12. Moreover, in the case at hand, the discrepancy between the definition of the expression cassette provided on pages 12 and 13 and Figure 1 of the statement of grounds of appeal (see points 5., 7. and 8. above) and the definition in section A.3.2 of Annex A confirm that not all arguments raised during the opposition proceedings were indeed maintained in appeal. The objections compiled in Annex A hence do not form part of the statement of grounds of appeal.

13. Consequently, in view of the above considerations, new objections were raised in the board's communication which, in accordance with established case law (see point 3. above), are considered to qualify as exceptional circumstances justified by cogent reasons.

14. Additionally, when deciding on the request for admittance, the board considered aspects set out in Article 13(1) RPBA 2020 for guidance. While the state of proceedings at which the new main request was filed was in the phase after issuance of the communication under Article 15(1) RPBA 2020, the board holds that they had been filed sufficiently early, namely three months ahead of the oral proceeding, such that the appellant and the board were in a position to consider

the amended claims. This was not contested by the appellant.

15. Furthermore, by defining the nucleotide sequence of the DNA expression cassette and the HVT insertion site in claim 1 of the main request, the amendments overcome the new objections raised in the board's communication and did not *prima facie* give rise to new objections.

16. The appellant also objected to the unusual procedural situation arising from the submission of the main request conditional on its admittance. However, the conditional nature of the main request is understood by the board to be acceptable given that it entails the simultaneous withdrawal of all other claim requests on file. As the respondent was not submitting a new main request while maintaining other auxiliary requests, it was clear that it wished to discuss only the new main request, provided it was admitted in the proceedings. In view of this context, the board is satisfied that submitting the new main request conditional to its admittance was not detrimental to procedural economy.

17. The board therefore decided to admit the main request into the appeal proceedings (Article 13(2) RPBA 2020).

*Rule 80 EPC*

18. Under Rule 80 EPC, the description, claims and drawings of a patent may be amended, provided that the amendments are occasioned by a ground for opposition under Article 100 EPC, even if that ground has not been invoked by the opponent. Objections under any ground for opposition in Article 100 EPC may be raised against each claim in the patent. The deletion of entire claims

of a patent is hence always occasioned by a ground for opposition, whether or not the ground was invoked.

19. For this reason, the deletion of claims 10 to 12 as granted complies with the requirements of Rule 80 EPC.

*Clarity (Article 84 EPC) and claim construction - claim 1*

20. In the feature "characterised in that the recombinant DNA expression cassette is the region of nucleotides 630 - 6127 of SEQ ID NO: 1" contained in the claim (see section IX.), the expression "the region of" refers to a region of SEQ ID NO: 1 defined by nucleotides 630 to 6127 of this sequence. This phrase therefore means that the DNA expression cassette consists of nucleotides 630 to 6127 of SEQ ID NO: 1.

21. The appellant argued that the nucleotide sequence of the DNA expression cassette was not limited to the recited nucleotide sequence because the phrase "in the region of" denominated an approximation. However, the phrase "*in* the region of" is clearly different from the phrase "the region of" recited in the claim. This argument therefore does not persuade the board.

22. Moreover, by defining that the DNA expression cassette is the region of nucleotides 630 to 6127 of SEQ ID NO: 1, every consecutive nucleotide of this DNA expression cassette is defined, and hence no unaccounted gaps are allowed for in the cassette. The mCMV-IE1 promoter is therefore operably linked to a specific IBDV VP2 gene, and the hCMV-IE1 gene core promoter is operatively linked to a specific NDV F gene, each of these elements being defined by precise nucleotides as recited in SEQ ID NO: 1. The recombinant

DNA expression cassette hence does not encompass promoters and genes not operatively linked.

23. This interpretation is not in contradiction to Table 1 and paragraphs [0061], [0066] and [0067] of the patent. Table 1 merely discloses which nucleotides encode a particular element of SEQ ID NO: 1. Some nucleotides of SEQ ID NO: 1 do not belong to one of these elements but are nonetheless precisely defined in SEQ ID NO: 1. In paragraphs [0061], [0066] and [0067] of the patent, the DNA expression cassette is defined in that it "is" or "comprises" the region of nucleotides 630 to 6127 of SEQ ID NO: 1 or that it comprises the DNA molecule as presented in SEQ ID NO: 1. These embodiments therefore define three different embodiments where, in the first embodiment, the DNA expression cassette consists of nucleotides 630 to 6127 of SEQ ID NO: 1, in the second, the DNA expression cassette comprises these nucleotides and in the third, the DNA expression cassette comprises the entire sequence of SEQ ID NO: 1, i.e. including parts of the Us2 insertion site.

24. Consequently, the claim relates to a recombinant HVT comprising a recombinant DNA expression cassette inserted in the Us2 gene of the genome of the recombinant HVT and defined by a precise nucleotide sequence. Hence, claim 1 is clear (Article 84 EPC).

*Amendments (Article 123(2) EPC)*
*Claim 1*

25. Claim 1 is based on a combination of claims 1 and 4 of the application (see section II.), where the recombinant DNA expression cassette is further characterised in that it "is the region of nucleotides 630 - 6127 of SEQ ID NO: 1" and where the insertion

site in the HVT Us region is further defined as the Us2 gene. Literal basis for the recited DNA expression cassette is found on page 14, lines 15 and 16 of the application, which read: "*In an embodiment, the recombinant DNA expression cassette is the region of nucleotides 630 - 6127 of SEQ ID NO: 1*". Nucleotides 630 to 6127 of SEQ ID NO: 1 form the nucleotide sequence of the only embodiment of elements a. to e. of claim 1 exemplified in the application (see Table 1 of the application).

26. Furthermore, the insertion site is disclosed on page 16, lines 5 to 10, which read: "[p]*articularly stable and effective recombinant HVT vectors for the invention could be made by employing the Us2 gene of the HVT genome as the single genetic insertion locus for the invention. Therefore, in an embodiment of the recombinant HVT according to the invention, the recombinant DNA expression cassette according to the invention is inserted in the Us2 gene of the genome of the recombinant HVT*".

27. Consequently, the only exemplified, and thus also preferred, embodiment of elements a. to e. of claim 1 of the application is combined with the preferred HVT insertion site in the claim. Claim 1 therefore comprises a combination of two preferred embodiments singled out in the application which does not result in subject-matter extending beyond the content of the application as filed. Claim 1 therefore meets the requirements of Article 123(2) EPC.

*Claim 5*

28. Claim 5 differs from claim 9 of the application in the addition of the expression "In vitro" (see sections II.

and IX.). The definition of a method as "in vitro" means, in this board's understanding, that neither of the method steps is carried out "in vivo", i.e. in or on a living human or animal body.

29. Claim 5 concerns a method for the preparation of a vaccine comprising the three steps of infecting host cells with a recombinant HVT, harvesting the infected host cells and admixing the harvested infected host cells with a pharmaceutically acceptable carrier. In this method, the infection of the host cells and the subsequent harvesting of these infected cells could be carried out in vivo, if host cells within a living organism are infected, or in vitro, if host cells outside of a living organism are infected, such as in a cell culture dish.

30. This claim construction is supported by the teaching on page 20, lines 34 to 41 of the application, which, contrary to the appellant's assertion, is on a method for the preparation of a vaccine and discloses that "[t]*he vaccine according to the invention is prepared from a recombinant HVT ... as described herein...*" and that the amplification of the recombinant HVT in infected cells is carried out "*preferably in in vitro cell cultures*".

31. The application therefore discloses that a method for the preparation of the vaccine can be carried out "in vitro". Moreover, in this board's opinion, defining the method of claim 9 as "in vitro" excludes one of two options encompassed within the ambit of claim 9 of the application, and this would not add subject-matter even if no literal basis for the term "in vitro" was present in the application. The board is therefore not persuaded by the appellant's argument that more options

than "in vivo" or "in vitro" for carrying out the method of claim 9 existed.

32. An "ex vivo" method as defined by the appellant, i.e. a method carried out on cells extracted from a living organism, would, for example, be encompassed by "in vitro" methods. The appellant presented neither any other way of interpreting the meaning of an "ex vivo" method nor any further way the method of claim 5 could be carried out which would not be considered as either "in vivo" or "in vitro" according to the above definition. The board is therefore not persuaded that further options for carrying out the method of claim 5 exist.

33. Claim 5 therefore meets the requirements of Article 123(2) EPC.

*Admittance of the objection under Article 123(3) EPC (Article 13(2) RPBA 2020)*

34. The objection that the protection conferred by the patent was extended by claim 5 of the main request was submitted for the first time in the appellant's letter dated 4 August 2022, i.e. after the parties had been summoned to oral proceedings and the board had issued a communication under Article 15(1) RPBA setting out its preliminary opinion (see section X.). This objection therefore constitutes an amendment of the appellant's appeal case, which, under Article 13(2) RPBA 2020, must, in principle, not be taken into account unless there are exceptional circumstances justified with cogent reasons by the party concerned.

35. Claim 9 of the patent refers to an "Ex vivo" method for the preparation of a vaccine (see section I.). In

response to an objection under Article 123(2) EPC against the term "Ex vivo", the respondent submitted during opposition an amended set of claims in which this term was replaced with the term "In vitro" (see auxiliary request 4 submitted on 2 October 2019, renumbered as auxiliary request 1 during the oral proceedings before the opposition division; see also section IV.). The amendment of the term "In vivo" to the term "In vitro" was therefore made during the opposition proceedings and was present in the set of claims which the opposition division considered to meet the requirements of the EPC. Consequently, the appellant could and should have raised the objection under Article 123(3) EPC arising from this amendment during the opposition proceedings.

36. The appellant has not submitted any reason why this objection could not have been raised earlier. It only argued that it was immediately apparent that the protection conferred by the patent was extended by this amendment. However, an objection possibly having merits is not a reason for submitting it late. If anything, it instead underlines that it could indeed have been raised earlier.

37. Consequently, the board could not identify any exceptional circumstances justified by cogent reasons for submitting this objection at this late stage in appeal proceedings. The board therefore decided not to admit the appellant's objection under Article 123(3) EPC into the proceedings.

*Novelty (Article 54 EPC) - claim 1*

38. The appellant's objection that the claimed recombinant HVT is not novel over the recombinant HVT disclosed in

document D3 is based on an interpretation of the claim in light of paragraph [0079] of the patent which discloses that "[i]*n an embodiment, the recombinant HVT according to the invention comprises a DNA molecule ... comprising a nucleotide sequence that has at least 95 % nucleotide sequence identity to the full length of the region of nucleotides 630 - 6127 of SEQ ID NO: 1*". The appellant argued that due to this disclosure in the patent, the expression cassette recited in the claim did not necessarily consist of nucleotides 630 to 6127 of SEQ ID NO: 1.

39. However, the claimed subject-matter is, in itself, clear (Article 84 EPC) and relates to a recombinant HVT comprising an expression cassette of which the nucleotide sequence is exactly defined by nucleotides 630 to 6127 of SEQ ID NO: 1 (see points 20. to 24. above). The corresponding paragraph in the patent is paragraph [0061]. Consequently, paragraph [0079] concerns a recombinant HVT not encompassed by the claim.

40. Since document D3 neither discloses a DNA expression cassette comprising or consisting of nucleotides 630 to 6127 of SEQ ID NO: 1 nor an HVT construct comprising a single DNA expression cassette inserted into the Us2 gene, the claimed subject-matter is novel over the HVT constructs disclosed in document D3.

*Sufficiency of disclosure (Article 83 EPC)*

41. The definition of the DNA expression cassette recited in claim 1 has the consequence that the nucleic acid sequences of the genes IBDV VP2 and NDV F, the mCMV-IE1 and hCMV-IE1 promoters, and the transcription terminators within this DNA expression cassette are

precisely defined and that the respective promoters, genes and transcription terminators are operatively linked (see also points 20. to 24. above). Consequently, the appellant's objections that the elements of the expression cassette were not operably linked and that optimised gene sequences fell within the ambit of the claim that could not be stably expressed are not applicable to the set of claims of the main request.

42. The appellant further argued that insertion of the DNA expression cassette into each and every site within the Us2 gene would not necessarily result in a recombinant HVT suitable as a vaccine. However, the appellant has not submitted any evidence or explanation for this assertion. While the replication of the virus and/or the expression levels and stability of the inserted gene(s) could be differently affected depending on the HVT gene interrupted by insertion of the DNA expression cassette, it is the board's view that the skilled person would not expect that different insertion sites within the same gene also had such effects. Consequently, in the absence of any evidence that different insertion sites within a single gene affected the suitability of the recombinant HVT as a vaccine in a significant manner, this argument does not convince the board.

43. The patent with the claims of the main request therefore meets the requirements of Article 83 EPC.

*Admittance of documents D27 to D35 and the appellant's line of attack on inventive step starting from document D3 (Rule 12(4) RPBA 2007)*

44. The board decided, against the respondent's requests, to admit documents D27 to D31 and the line of attack on inventive step starting from document D3 as the closest prior art submitted by the appellant with the statement of grounds of appeal (see section VI.) in the proceedings (see section XI.). However, in view of the board's decision on inventive step in favour of the respondent, it is not necessary to provide reasons for the admittance of documents D27 to D31 and the objection of lack of inventive step starting from document D3.

45. The board furthermore decided to admit documents D32 to D35 submitted by the respondent into the proceedings (see section XI.). However, since these documents are not relevant for the board's decision, it is not necessary to provide reasons for their admittance.

*Inventive step (Article 56 EPC)*

46. Each of the documents D1/D1a, D3, D6, D8 and D23 disclose recombinant HVT construct(s) comprising DNA expression cassette(s) for the expression of the IBDV VP2 gene and the NDV F gene. Consequently, each of these documents constitutes a suitable starting point for the assessment of inventive step.

47. The HVT constructs disclosed in these documents differ from the claimed construct, *inter alia,* in the choice of the promoters, the order of the genes, and/or the number and identity of the insertion sites in the HVT genome.

48. The recombinant HVT disclosed in document D6 (HVP309) differs from the claimed HVT in the order of the genes NDV F and IBDV VP2 in the DNA expression cassette and in the promoter used for expressing the IBDV VP2 gene (core chicken beta-actin promoter; see page 6, lines 14 to 21 and section 1.6 bridging pages 25 to 26 of document D6).

49. The patent discloses that the claimed HVT has improved genetic stability compared to the construct of document D6. No non-expressing virus plaques were found for the claimed HVT after 15 consecutive passages in cell culture and one passage in birds (see paragraphs [0016] and [0166]). In contrast, between 1 and 3% of replicated HVP309 did not express one or both of the heterologous genes (see paragraph [0013] of the patent).

50. The board is not persuaded by the appellant's arguments that this technical effect could not be acknowledged and taken into account. In fact, document D6 discloses that the HVP309 construct is not 100% genetically stable since up to 0.3% of non-expressing plaques were detected after 16 cell culture passages (see page 29, lines 22 to 24) and the patent reports that subsequent "prolonged" studies showed that for HVP309, the number of non-expressing plaques was considerably higher and hence did not display adequate genetic stability (see paragraph [0013] of the patent). The appellant has not submitted any evidence that this teaching in the patent is not correct, and the board sees no reason to doubt it. Furthermore, since the claimed construct did not display any genetic instability at all (see paragraphs [0016] and [0166] of the patent), the board sees no reason, either, to disregard this technical

effect for the sole reason that the patent reports on these results without explicitly disclosing results of a side-by-side comparison of the claimed construct and HVP309.

51. The stable expression of the inserted antigens is an important property of any recombinant vector construct used as a vaccine in terms of safety and long-term reliability, and the protection from viral challenge is therefore not the only relevant property of a viral vector-based vaccine.

52. Moreover, as assessed for sufficiency of disclosure (see point 42. above), the skilled person would not expect that insertion of a DNA expression cassette at different positions within the same HVT gene (here Us2) influenced the expression of the inserted genes. Therefore, without any evidence to the contrary, the board considers that improved genetic stability can be acknowledged for insertion in each position in the Us2 gene.

53. It can also not be concluded from the results on viral challenge experiments disclosed in Tables 2 and 3 of document D6 and Table 3 of the patent that the HVT construct of document D6 provided for better protection than the claimed construct since these results did not arise from comparative experiments carried out under identical experimental conditions, a prerequisite for comparing results obtained from experiments with living animals.

54. Consequently, the objective technical problem may be formulated as the provision of a recombinant HVT that more stably expresses the heterologous genes IBDV VP2 and NDV F.

55. The skilled person had no guidance on how to improve the genetic stability of a known HVT construct. In fact, document D3 discloses that, in the context of a recombinant HVT expressing both IBDV VP2 and NDV F, the hCMV promoter, which is successfully used in the claimed HVT construct, "*is not an ideal promoter for the generation of stable HVT recombinants expressing NDV-F protein*" (see paragraph [0117] of document D3). The effects of a particular promoter, the order of the genes in the expression cassette, the insertion site(s) in the HVT genome and combinations of these variables on the genetic stability of the inserted DNA expression cassette were therefore unpredictable. It was consequently not obvious to the skilled person to change the order of the two genes or replace the promoter for the expression of the IBDV VP2 gene with an mCMV-IE1 promoter in the expression cassette of document D6 for obtaining a more genetically stable recombinant HVT for the expression of the IBDV VP2 and the NDV F genes.

56. Furthermore, since the mCMV-IE1 promoter was not the only alternative promoter available in the art for the expression of the IBDV VP2 gene, the appellant's argument that this promoter was an established tool in the art to express the IBDV VP2 gene in other HVT constructs, including the commercially available vHVT13, and was therefore an obvious choice, does not persuade the board. Moreover, the board also fails to see how the mere fact that HVT constructs comprising the IBDV VP2 and NDV F genes in an alternative order were known in the art (see constructs HF007 and HF007 of document D8) would prompt the skilled person to change the order of the genes in the HVT construct of document D6 with the aim of improving the genetic

stability of the HVT construct. In fact, the appellant argued in a similar context that the skilled person would not have expected the order of the genes to have any effect on the HVT construct (see points 11 and 12 of document D22).

57. Consequently, in the absence of any guidance in the art on how the stability of a HVT construct could be improved, the subject-matter of claim 1 was not obvious to the skilled person when using the recombinant HVT disclosed in document D6 as the starting point in a problem-solution analysis.

58. The same considerations on obviousness as above apply when the HVT construct known from any of documents D1a, D3, D8 or D23 is considered to represent the closest prior art in the assessment of inventive step. In fact, Documents D1a, D8 and D23 do not disclose data on the genetic stability of the respective HVT constructs. The HVT constructs of documents D1a and D23 had not been tested at all. The HVT constructs of D8 expressed the genes (see Table 2) and were effective in NDV challenge experiments (see Table 3) but had not been assessed for genetic stability. The HVT constructs of document D3 are not genetically stable (see point 55. above). Hence, in either case the objective technical problem can be formulated as the provision of a recombinant HVT that stably expresses both the IBDV VP2 gene and the NDV F gene. The solution to this problem provided in claim 1 was not obvious to the skilled person, *mutatis mutandis*, for the same reasons provided in points 55. to 57. above.

59. Consequently, the subject-matter of claim 1 involves an inventive step (Article 56 EPC).

60. Claim 2 relates to a host cell comprising the recombinant HVT according to claim 1; claims 3, 4, 6 and 7 relate to a vaccine comprising the recombinant HVT of claim 1 or the host cell of claim 2; and claim 5 relates to an in vitro method for the preparation of a vaccine of claim 3 (see section IX.). Each of these claims therefore involves an inventive step for at least the same reasons as claim 1 (Article 56 EPC).

## Order

## For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of claims 1 to 7 of the main request filed by letter dated 21 June 2022, received on 22 June 2022, and a description and drawings to be adapted thereto.

The Registrar: The Chair:

L. Malécot-Grob B. Claes

Decision electronically authenticated