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Datasheet for the decision of 16 November 2021

Case Number: T 0531/19 - 3.3.04

Application Number: 13157573.0

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Language of the proceedings: EN

Title of invention:
Norovirus vaccine formulations

Patent Proprietor:
Takeda Vaccines, Inc.

Opponent:
Lederer & Keller Patentanwälte Partnerschaft mbB

Headword:
Norovirus combination vaccine/TAKEDA VACCINES

Relevant legal provisions:
EPC Art. 56, 123(2)
RPBA Art. 12(2), 12(4)
RPBA 2020 Art. 13(2)

Keyword:

Main request and auxiliary requests B5a, B5b and B5c - amendments - allowable (no);
auxiliary request B6 - inventive step - (no);
auxiliary request B6d - admitted (no)

Decisions cited:

T 1621/16

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Beschwerdekammern

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Case Number: T 0531/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 16 November 2021

Appellant: (Opponent)	Lederer & Keller Patentanwälte Partnerschaft mbB Unsöldstr. 2 80538 München (DE)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstraße 4 81675 München (DE)
Respondent: (Patent Proprietor)	Takeda Vaccines, Inc. One Takeda Parkway Deerfield, IL 60015 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 December 2018 concerning maintenance of the European Patent No. 2601970 in amended form.**

Composition of the Board:

Chair	A. Chakravarty
Members:	R. Morawetz
	E. Mille

Summary of Facts and Submissions

I. An appeal was filed by the sole opponent ("appellant") against the interlocutory decision of the opposition division that European patent No. 2 601 970 (the "patent") as amended in the form of the main request, and the invention to which it relates, meet the requirements of the EPC. The patent proprietor is respondent in this appeal.

II. The patent, entitled "*Norovirus vaccine formulations*", was granted for European patent application No. 13 157 573.0 ("the application"), which was filed as a divisional application of European patent application No. 07 853 688.5, with a date of filing of 28 September 2007.

III. In its decision, the opposition division considered grounds for opposition under Article 100(a) EPC together with Articles 54 and 56 EPC, Article 100(b) EPC and Article 100(c) EPC.

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

D2 LoBue A.D. et al., Vaccine (18 April 2006), vol. 24, pages 5220 to 5234

D3 Nicollier-Jamot B. et al., Vaccine (2004), vol. 22, pages 1079 to 1086

D4 Ball J.M. et al., Gastroenterology (1999), vol. 117, pages 40 to 48

D5 Nakata S. Nippon Rinsho (2002), vol. 60, pages 1222 to 1227

D6 Midthun K. and A.Z. Kapikian, Clinical Microbiology Reviews (1996), vol. 9, pages 423 to 434

D7 WO 2003/077942

D9 WO 2007/081447

D15 Harrington P.R. et al., Journal of Virology (2002), vol. 76, pages 730 to 742

V. The decision under appeal dealt with a single set of claims, the main request. The opposition division held, *inter alia*, that the subject-matter of claim 1 of this request did not extend beyond the content of the application as filed. As regards the requirements of Article 56 EPC, it noted that the "*opponent alleged lack of inventive step on the basis of D2, D3, D4, D5, D9 taken as closest prior art*". The opposition division held that document D4 represented the closest prior art and that the claimed subject-matter involved an inventive step in the light of this document alone.

VI. In their statement setting out the grounds of appeal, the appellant submitted, *inter alia*, arguments to the effect that the subject-matter of claim 1 of the main request extended beyond the content of the application as filed (Article 123(2) EPC) and that claim 1 and its dependent claims lacked inventive step (Article 56 EPC) over the disclosure in document D3, taken to represent the closest prior art in combination with the disclosure in document D2 (see points A.IV.3.3, A.IV.6.1 to A.IV.6.6 and A.IV.6.8 of the statement of

grounds of appeal). With respect to auxiliary request B6, filed during the opposition proceedings, the appellant submitted (see point H. of the statement of grounds of appeal) that claim 1 "*recites wherein said monovalent Norovirus VLPs are derived from genotypes I.1 and II.4. This feature was recited in claim 2 of the MR. It was known that Norwalk virus (I.1) and Bristol-like viruses (II.4) were circulating viruses. Consistently, vaccines targeting such a combination are disclosed, e.g. in D2. Thus, such a combination is at the latest obvious over the prior art assessed above.*"

VII. The respondent submitted in their reply to the appeal sets of claims of, *inter alia*, a main request and of auxiliary requests B5a, B5b, B5c, B6 and B6d. The set of claims of the main request was identical to the set of claims of the main request considered by the opposition division. Auxiliary requests B5a, B5b, and B6 were identical to the corresponding sets of claims filed during the opposition proceedings while auxiliary requests B5c and B6d were newly filed. With respect to auxiliary request B6d, the respondent explained that it was filed in response to the appellant's objection under Article 100(c) EPC to the feature "*combination of two or more monovalent Norovirus virus-like particles (VLPs)*" and that it included the further amendment that the claimed vaccine comprised a combination "of no more than two" monovalent Norovirus VLPs (see reply to the statement of grounds of appeal, point 9.11.1). As regards inventive step, auxiliary requests B6 and B6d were said to be limited to VLPs derived from genotypes I.1 and II.4 which separated the claimed subject-matter from the cited prior art (see reply to the statement of grounds of appeal, point 9.1).

Claims 1 and 2 of the main request read:

"1. A vaccine comprising a combination of two or more monovalent Norovirus virus-like particles (VLPs) for use in a method of generating an immune response such that the combined VLP composition is able to elicit immunity against infection by each Norovirus genotype represented in the vaccine, wherein the immune response against a given VLP in the combination is at least 50% of the immune response of that same VLP when measured individually, wherein said monovalent Norovirus VLPs are derived from genogroup I and genogroup II viral sequences.

2. A vaccine comprising a combination of at least two monovalent Norovirus VLPs according to claim 1 for the use according to claim 1, wherein said monovalent Norovirus VLPs are derived from genotypes 1.1 [sic] and II.4."

Claim 1 of auxiliary request B5a differs from clam 1 of the main request in that the expression "is able to elicit" is replaced by the word "elicits".

Claim 1 of auxiliary request B5b differs from clam 1 of auxiliary request B5a in that the expression "and wherein the VLP is comprised of predominantly VP 1 proteins" is inserted after the expression "genogroup II viral sequences".

Claim 1 of auxiliary request B5c differs from clam 1 of auxiliary request B5b in that the expression "two or more" is replaced by the expression "no more than two".

Claim 1 of auxiliary request B6 reads:

"1. A vaccine comprising a combination of two or more monovalent Norovirus virus-like particles (VLPs) for use in a method of generating an immune response such that the combined VLP composition is able to elicit immunity against infection by each Norovirus genotype represented in the vaccine, wherein the immune response against a given VLP in the combination is at least 50% of the immune response of that same VLP when measured individually, wherein said monovalent Norovirus VLPs are derived from genotypes 1.1 [sic] and II.4."

Claim 1 of auxiliary request B6d reads:

"1. A vaccine comprising a combination of no more than two monovalent Norovirus virus like particles (VLPs) for use as a vaccine in a method of generating an immune response such that the combined VLP composition elicits immunity against infection by each Norovirus genotype represented in the vaccine, wherein the immune response against a given VLP in the combination is at least 50% of the immune response of that same VLP when measured individually, wherein said monovalent Norovirus VLPs are genotype 1.1 [sic] and II.4 VLPs, and wherein the VLP is comprised of predominantly VP1 proteins."

VIII. In its response to the respondent's reply, the appellant maintained the inventive step objections set out in the grounds of appeal. The appellant further submitted that claim 1 of auxiliary request B5c extended beyond the content of the application as filed (Articles 123(2) EPC).

IX. In its response to the appellant's submissions mentioned in the previous point, the respondent submitted arguments in support of an inventive step for the subject-matter of the main request and in support of claim 1 of auxiliary request B5c meeting the requirements of Article 123(2) EPC.

X. The board appointed oral proceedings in view of corresponding requests of the parties and informed the parties of its preliminary appreciation of certain substantive and legal matters concerning the appeal. The board was, *inter alia*, of the opinion that the appellant's submissions filed with the statement of grounds of appeal did not raise a fresh case compared to the case made in the opposition proceedings and should be admitted into the appeal proceedings. The board noted that it intended to hear the parties on, *inter alia*, the identification of a suitable starting point for the assessment of inventive step.

XI. In response to the board's communication, the appellant maintained that there were several prior art disclosures that could serve as a suitable starting point and re-iterated that claim 1 of the main request lacked inventive step in view of the teaching of document D3 alone or in combination with the disclosure in document D2. Furthermore it submitted that claim 1 of auxiliary request B6 was obvious in view of document D3 for the same reasons as the main request (see point 5.2.10).

XII. The respondent filed a copy of decision T 1621/16 and indicated the sections of this decision that it intended to rely on during the oral proceedings.

XIII. Oral proceedings before the board took place as scheduled. At the end of the oral proceedings, the Chair announced the board's decision.

XIV. The arguments of the appellant, as far as relevant for the decision, are summarised below.

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

The application disclosed a composition of monovalent virus-like particles VLPs from Norovirus genogroup I and Norovirus genogroup II "*purely by way of example*" and not as a preferred embodiment (see page 10, lines 13 to 25).

The passage on page 11, lines 6 to 14, of the application did not disclose a combination of monovalent VLPs derived from Norovirus genogroup I and Norovirus genogroup II viral sequences. Furthermore, this passage disclosed that "*no interference*" between Norovirus VLPs was preferred, which was missing from the claim. The feature "*at least 50% of the immune response*" was not equivalent to "*no interference*" as it allowed for interference between the VLPs.

Example 12 used VLPs based on specific Norovirus genotypes, and therefore did not point to monovalent VLPs of genogroup I and II but to VLPs based on Houston virus and Norwalk virus as being preferred. The same disclosure could be derived from page 8, lines 20 to 23, of the application. Furthermore, Example 12 concerned the absence of cross-reactivity (see page 30, lines 23 to 25) and was silent about interference.

Decision T 1621/16 concerned lists of converging alternatives and required that there be a pointer supporting the combination resulting from multiple selections from such lists. In the case at hand, there were no lists of converging alternatives and a pointer to the claimed combination was missing. In contrast, the claimed combination of monovalent Norovirus VLPs was a patchwork of different disclosures resulting in subject-matter that was not directly and unambiguously derivable from the application as filed.

Auxiliary requests B5a and B5b
Amendments (Article 123(2) EPC) - claim 1

The subject-matter of claim 1 of these claim requests extended beyond the content of the application as filed for the same reasons as the subject-matter of claim 1 of the main request.

Auxiliary request 5c
Admittance (Article 12(4) RPBA 2007)

The feature "*two or more*" had been objected to in the opposition proceedings (see e.g. section 39 of the decision under appeal). Thus, this claim request could have been filed earlier.

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

The combination of features recited in claim 1 added subject-matter for the same reasons as set out for claim 1 of the main request.

Auxiliary request B6
Admission into the appeal proceedings of the objections under Article 56 EPC with respect to claim 1 of auxiliary request B6 (Article 12(4) RPBA 2007, in conjunction with Article 13(2) RPBA 2020)

The starting points in the assessment of inventive step set out in the statement of grounds of appeal, including document D3, were the same as in the opposition proceedings (see the decision under appeal, points 22 and 23 and notice of opposition points 8.1 to 8.4.2). The objection set out in the statement of grounds of appeal was based on the same arguments, facts and evidence as relied on in the proceedings before the opposition division, while further arguments were included to address issues raised in the decision under appeal.

As the objection under Article 56 EPC based on document D3 as closest prior art had been raised in the statement of grounds of appeal (see sections A.IV.6 and H), pursuing this objection in the oral proceedings was neither an amendment of the case nor late.

Claim construction - claim 1

The "*at least 50% of the immune response*"-feature did not mean that there was no interference, it allowed for up to 50% interference.

Inventive step (Article 56 EPC) - claim 1
Closest prior art

The disclosure in any of documents D1, D2, D3, D4 and D9 could serve as a suitable starting point for the assessment of inventive step.

Document D3 concerned monovalent Norovirus VLPs derived from Dijon171/96 virus. Dijon171/96 was a genotype II.4 virus (see document D2, page 5222, left hand column, first paragraph and page 5223, right hand column, last paragraph). Document D3 also disclosed monovalent Norovirus VLPs derived from Norwalk virus (NV) and provided references for the work done with NV VLPs in mice and in humans (see page 1079, left hand column, line 4 from the bottom to right hand column, line 7; page 1084, last paragraph; page 1085, left hand column, last paragraph). NV was a genotype I.1 virus (see document D2, page 5223, right hand column, last paragraph). Document D3 furthermore disclosed that these VLPs induced specific immune responses in mice (see title; page 1084, left hand column, last paragraph; page 1085, left hand column, last paragraph) and suggested including different VLPs in a vaccine preparation to induce a broader immune response (see page 1079, right hand column, lines 3 to 7). Thus, document D3 was concerned with the technical problem of providing broad protection.

Objective technical problem

The difference between the subject-matter of claim 1 and the disclosure of a vaccine comprising monovalent VLPs from Norovirus of genotype II.4 in document D3 was that additional VLPs of genotype I.1 were comprised in the vaccine of claim 1.

The technical effect resulting from this difference was that it was possible to raise a protective immune response against more than one Norovirus genotype.

The objective technical problem to be solved was the provision of a vaccine against a broad panel of

noroviruses.

Obviousness

Document D3 already prompted the skilled person to combine different VLPs to induce a broader immune response (see page 1079, right hand column, lines 5 to 7). The skilled person would have included VLPs derived from genotype I.1 since candidate vaccines comprising VLPs of NV (genotype I.1) were available (see page 1079, left hand column, line 4 from the bottom to right hand column, line 7). The skilled person would have combined the monovalent Dijon171/96 VLPs and NV VLPs in the expectation of achieving a broad immune response such that the "50% feature" was met.

There was no evidence on file that the skilled person was *a priori* worried about interference between Norovirus VLPs of different genogroups/genotypes or that there existed a technical prejudice in the art based on interference: Document D3 did not mention interference. Document D2 demonstrated that a cocktail of VRPs expressing VLPs derived from different viruses from genogroup I and II elicited immunity against each virus without any significant interference (see page 5228, left hand column, second paragraph, lines 15 to 28, and Fig. 6A of document D2).

The skilled person would have taken document D2 into account since it related to a combination vaccine for noroviruses. Document D2 (page 5222, second paragraph) and document D15 (referenced as [29] in document D2, see page 733, right hand column, full paragraph, lines 12 to 13 and sentence bridging pages 738 and 739) taught that the VRPs express the encoded VLPs in

mammalian cells, i.e. that the *in vivo* immunogenic entity was the VLP. Document D3 confirmed that the skilled person knew that VLPs produced by VRPs were identical to VLPs produced by e.g. the baculovirus system (see page 1079, left hand column, lines 7 to 12). The assay used in document D2 to determine the immune response used intact VLPs as coating material (see page 5222, right hand column, section 2.5 and Fig. 6).

Document D6 merely indicated that it was controversial in the art whether interference between a specific rotavirus vaccine and a poliovirus vaccine existed. It did not constitute a prejudice in the art which would have prevented the skilled person from combining an effective Norovirus genotype I.1 VLP with an effective Norovirus genotype II.4 VLP.

Document D7 only showed that "no interference" was preferred (see page 4, last paragraph) but not that the skilled person was worried about interference. More relevant than the hypothetical possibility that interference between VLPs might occur, was the fact that in document D7 interference was checked for and not found (see page 22, last sentence).

Auxiliary request B6d
Admittance (Article 12(4) RPBA 2007)

This claim request could have been filed during opposition proceedings and should not be admitted into the appeal proceedings.

XV. The arguments of the respondent, as far as relevant for the decision, are summarised below.

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

The claimed subject-matter resulted from the combination of a preferred embodiment disclosed on page 10, lines 22 to 24 of the application with a more preferred embodiment disclosed on page 11, lines 6 to 14 of the application.

Examples could provide a pointer to a combination of features resulting from multiple selections (see also decision T 1621/16, Reasons, points 1.7.3 and 1.8.2). In the case at hand, Example 12 provided an indication that the combination disclosed on page 10, lines 22 to 24, "purely by way of example" was actually preferred. Example 12 did not articulate "no interference" but showed a robust immune response without one immune reaction interfering with the other (see Fig. 12). Example 12 therefore provided a pointer to the claimed combination of features.

The most preferred embodiment disclosed on page 10 of the application was the VLP mixture composed of Norwalk and Houston Noroviruses. This embodiment was fully encompassed by the less preferred embodiment of the mixture containing monovalent VLPs from genogroup I and genogroup II. The same considerations applied to the disclosure on page 11 of the application. The more preferred embodiment of "*no interference*" was encompassed by the broader embodiment of "*at least 50% of the immune response*". Accordingly, the findings of decision T 1621/16 as regards converging alternatives applied (see Catchword and Reasons, point 1.7.2;

page 9, second paragraph) and Example 12 provided the necessary pointer.

Auxiliary requests B5a, B5b and B5c
Amendments (Article 123(2) EPC) - claim 1

The same line of argument as given for the subject-matter of claim 1 of the main request applied, *mutatis mutandis*.

Auxiliary request B6
Admission into the appeal proceedings of the objections under Article 56 EPC with respect to claim 1 of auxiliary request B6 (Article 12(4) RPBA 2007, in conjunction with Article 13(2) RPBA 2020)

The objection based on document D3 raised in the statement of grounds of appeal with respect to the claims of the main request in combination with the objection raised against claim 1 of auxiliary request B6 should not be admitted. In the statement of grounds of appeal, reference was made, in the context of auxiliary request B6, to "prior art assessed above" generically and not to a specific combination of documents. The objection in the statement of grounds of appeal based on document D3 had not been raised in the opposition proceedings.

Claim construction - claim 1

The expression "*at least 50% of the immune response*"-feature meant that the VLPs derived from genotypes I.1 and II.4 each contributed 50% of the immune response so that the immune response was 100%, i.e. there was no interference.

Inventive step (Article 56 EPC) - claim 1
Closest prior art

Document D4 was the closest prior art for the claimed invention. It concerned a human study using Norovirus VLPs specific for the Norwalk virus and provided positive results. In contrast, document D3 was a scientific document which focused on the comparison of different routes of administration and the use of different adjuvants for the use of single VLPs in mice.

In any case, the claimed subject-matter was inventive even when starting from the disclosure in document D3 as the closest prior art.

Objective technical problem

The claimed subject-matter differed from the disclosure in document D3 in that the vaccine comprised monovalent Norovirus VLPs derived from genotypes I.1 and II.4.

The technical effect associated with this difference was a broad spectrum protection with no interference.

The objective technical problem was the problem defined in the decision under appeal, namely to provide a broad-spectrum vaccine against Norovirus, in which the components did not interfere with each other.

Obviousness

From document D3, the skilled person did not know that interference was not a problem. Although document D3 suggested using different VLPs, this amounted to a proposition for a research program. The skilled person,

worried about interference, had no incentive to combine different VLPs because testing was required and the outcome of such tests was unpredictable. The skilled person would have adopted a conservative attitude and would not have gone against an established prejudice, nor ventured into unpredictable areas, nor taken incalculable risks. Even if the skilled person had had an incentive to use a combination of VLPs, they had no reasonable expectation of success that the combination of Norovirus VLPs derived from Dijon171/96 and NV would result in no interference as claimed.

The prior art warned about interference as a possibility, see document D6 (see page 427, left hand column, last paragraph; the concluding paragraph on page 431) and document D7 (see page 4, last paragraph).

"Thus, in general, when considering combination treatment of multiple vaccines, the skilled person "*was a priori worried about the possibility of interference*" and would perform the required assays to ensure that interference was not an issue" (emphasis in the original, see reply to the statement of grounds of appeal, page 58, third paragraph). The skilled person did not know whether interference would occur or not, therefore they had to test the combination. The opposition division correctly considered that under these circumstances the skilled person would have had no incentive to embark on a combination approach.

Document D2 concerned Venezuelan equine encephalitis virus (VEE) replicon particles (VRPs) expressing antigens of Norovirus and did not concern VLP vaccines. VRPs were an engineered recombinant expression system, maintaining replication ability. This was different to VLPs which were a set of capsid proteins self-assembled

into a non-infectious molecule resembling a virus. While VRPs express capsid proteins there was no evidence whether VLPs were formed *in vivo*.

The skilled person would not have combined the teaching of document D3 with the disclosure in document D2, as these documents related to different systems, VRPs and VLPs.

The experiments of document D2 could not address interference due to the fact of the saturated immune insult (see page 5228, left hand column).

The fact that the investigators of document D2 performed a study to determine serum IgG in response to trivalent inoculum was clearly indicative of their concern that interference was a possible problem.

The position taken by the appellant with respect to interference was contradictory to its position taken before the opposition division (see decision under appeal, sections 24 and 42).

The skilled person was not motivated to arrive at the claimed subject-matter.

Auxiliary request B6d
Admission into the appeal proceedings (Article 12(4) RPBA 2007)

The amendment in auxiliary request B6d addressed a new objection raised under Article 100(c) EPC. The request was filed in response to the attacks based on document D3 in combination with document D2 and the respondent's change in position as regards interference and should be admitted.

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

The respondent requested that the appeal be dismissed and that the patent be maintained in amended form on the basis of the set of claims of the main request or alternatively, that the patent be maintained in amended form on the basis of the set of claims of one of the auxiliary requests B5a, B5b, B5c, B6 and B6d, that auxiliary requests B5c and B6d be admitted into the appeal proceedings and that "newly filed attacks" provided for the first time by the appellant in the statement of grounds of appeal be not admitted into the appeal proceedings.

Reasons for the Decision

Technical background and abbreviations used in the decision

1. The invention is in the field of vaccines for Noroviruses (see paragraph [0001] of the patent. Noroviruses are single-stranded, positive sense RNA viruses that have emerged as an important cause of epidemic outbreaks of nonbacterial human gastroenteritis (see e.g. paragraphs [0002] and [0003] of the patent). Noroviruses are divided into five genogroups (I to V) based on genome sequence similarity, however, only virus strains from genogroups I and II are known to widely infect humans (see e.g. document D2, page 5221, left hand column, first full paragraph). Noroviruses within a genogroup are further sub-divided into genotypes. Norwalk virus (NV) belongs to genotype I.1, Dijon171/96, Lordsdale isolate (LV) to genotype II.4, Houston virus (HV) to genotype II.1 and Snow Mountain virus (SM) to genotype II.2 (see e.g. paragraph [0020] of the patent

and document D3, page 5223, right hand column, last paragraph). When expressed recombinantly at high levels in eukaryotic expression system, the capsid proteins of noroviruses self-assemble into virus-like particles (VLPs) that structurally mimic native Norovirus virions (see e.g. paragraph [0019] of the patent). Norovirus VLPs are immunogenic but not infectious as they lack the viral RNA genome (see e.g. paragraph [0005] of the patent). Interference denotes the phenomenon that the immune response triggered by individual vaccines is compromised, i.e. not the same strength, when two or more vaccines are mixed together in the same formulation (see e.g. paragraph [0027] of the patent).

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

2. The claim, which is identical to claim 1 of the main request considered in the decision under appeal, is for
(1) a vaccine comprising
(2) a combination of two or more monovalent Norovirus VLPs,
(3) for use in a method of generating an immune response
(4) such that the combined VLP composition is able to elicit immunity against infection by each Norovirus genotype represented in the vaccine,
(5) wherein the immune response against a given VLP in the combination is at least 50% of the immune response of that same VLP when measured individually,
(6) wherein said monovalent Norovirus VLPs are derived from genogroup I and genogroup II viral sequences
[numbering added by the board for ease of reference, feature (5) is also referred to as "50% of the immune response"-feature in the following].

3. It is undisputed that a vaccine comprising a combination of two or more monovalent Norovirus VLPs characterised by features (5) and (6) is not disclosed *verbatim* in the application. The opposition division held that the claimed subject-matter resulted from the combination of features that were disclosed as preferred embodiments in the application as filed. On appeal, the appellant maintained that the subject-matter of the claim extended beyond the content of the application as filed.

4. According to established case law of the boards of appeal a combined selection of features cannot be derived directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the application as filed, in the absence of any pointer to the particular combination. The fact that features in question are mentioned in the application as being "preferred" may act as a pointer for a combined selection of features. Furthermore, examples are considered to provide preferred embodiments of an invention that can provide pointers towards a combination of features (see Case Law of the Boards of Appeal of the European Patent Office, 9th edition 2019, ("CLBA"), sections II.E.1.6.1 and II.E.1.6.2).

5. At issue is whether the application provides a pointer to the claimed combination of monovalent VLPs characterised by features (5) and (6).

6. The relevant passages of the application as filed, relied on in the decision under appeal and by the respondent as disclosing features (5) and (6), are reported below in full:

"*Purely by way of example the composition can contain monovalent VLPs from one or more strains of Norovirus genogroup I together with monovalent VLPs from one or more strains of Norovirus genogroup II. Preferably, the Norovirus VLP mixture is composed of the strains of Norwalk and Houston Noroviruses.*" (see page 10, lines 22 to 25, of the application).

"*The combination of monovalent or multivalent VLPs within the composition preferably would not block the immunogenicity of each VLP type. In particular it is preferred that there is no interference between Norovirus VLPs in the combination of the invention, such that the combined VLP composition of the invention is able to elicit immunity against infection by each Norovirus genotype represented in the vaccine. Suitably the immune response against a given VLP type in the combination is at least 50% of the immune response of that same VLP type when measured individually, preferably 100% or substantially 100%. The immune response may suitably be measured, for example, by antibody responses, as illustrated in the examples herein.*" (see page 11, lines 6 to 14, of the application).

7. It is evident from the previous point that page 10, lines 22 to 24, of the application discloses a composition containing monovalent VLPs from one or more strains of Norovirus genogroup I together with monovalent VLPs from one or more strains of Norovirus genogroup I "[p]*urely by way of example*" but not as a preferred embodiment. Indeed, the preferred Norovirus VLP mixture is explicitly disclosed as being composed of strains of Norwalk and Houston Noroviruses, i.e. genotype I.1 and II.4 viruses.

8. The passage on page 11 does not define the combination of monovalent Norovirus VLPs in terms of genogroups of Noroviruses nor does it disclose explicitly that the monovalent Norovirus VLPs in the composition are derived from genogroup I and genogroup II viral sequences (see point 6.). Furthermore, it discloses that, preferably, there is no interference between Norovirus VLPs in the combination of the invention.

9. A combination of VLPs wherein the immune response against a given VLP type in the combination is at least 50% of the immune response of that same VLP type when measured individually is also disclosed (see point 6.). However, such a combination is disclosed as being merely suitable, while the combination which is disclosed as being preferred is the one wherein the immune response against a given VLP type in the combination is 100% of the immune response of that same VLP type when measured alone (see point 6.).

10. A preference in the application for a vaccine having feature (5) or (6) is therefore not derivable from pages 10 and 11 of the application. Thus, neither page 10 nor page 11 of the application provide an indication or pointer for the skilled person to combine features (5) and feature (6) with the remaining features characterising the vaccine of claim 1.

11. The respondent's line of argument to the effect that the claimed subject-matter resulted from the combination of a preferred embodiment on page 10 with a more preferred embodiment on page 11 is not found persuasive. The respondent's argument hinges on the assertion that example 12 implied a preference for the embodiment which is disclosed on page 10, lines 22 to 24, "purely by way of example" and that Fig. 12

disclosed that there was no interference between Norovirus VLPs present in the vaccine.

12. In Example 12, the immune response against Norwalk (genotype I.1) VLPs and Houston (genotype II.4) VLPs was studied in mice which were immunised with either Norwalk VLPs, Houston VLPs or a combination of Norwalk and Houston VLPs (see Figure 12). Therefore, Example 12 implies a preference for Norwalk VLPs and Houston VLPs, i.e. specific genotypes but not a preference for a combination of VLPs from genogroups I and II generally. This preference for Norwalk and Houston VLPs is also explicitly disclosed on page 10, lines 24 to 25, of the application (see also point 6. above) or on page 8, lines 20 to 23, of the application. The skilled person has no reason to re-interpret page 10, lines 22 to 24, of the application in light of Example 12 to mean that VLPs from genogroups I and II are not merely an example but generally preferred.

13. Moreover, Example 12 is concerned with cross-reactivity and is silent about interference. Whether or not the skilled person would have derived directly and unambiguously any information about interference from Fig 12. need not be decided, since the respondent's line of argument already fails because a preference for genogroups I and II is not derivable from Example 12.

14. The respondent's further line of argument that the application disclosed lists of converging alternatives from which elements could be selected in line with the findings in decision T 1621/16, is not found persuasive either.

15. In decision T 1621/16, the board held that amendments based on multiple selections from a list of converging alternatives, i.e. a list of options ranked from the least to the most preferred, wherein each of the more preferred alternatives is fully encompassed by all of the less preferred and broader options in the list, might be considered to meet the requirements of Article 123(2) EPC if at least two further conditions were met, the second condition being that the application should include a pointer to the combination of features resulting from the multiple selections (see Reasons, point 1.7.3).

16. In the case at hand, it can be left open whether features (5) and (6) are selected from a list of converging alternatives. Neither page 10 or page 11 or example 12 of the application provide a pointer to the selection of feature (5) and (6) of claim 1 (see points 10. and 12. above).

17. The board concludes from the above that the subject-matter of claim 1 of the main request extends beyond the content of the application as filed (Article 123(2) EPC).

Auxiliary requests B5a, B5b and B5c

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

18. The appellant had objected to the admittance of auxiliary request B5c. The board decided to admit the request into the appeal proceedings and, in view of the board's negative decision regarding added subject-matter, it is not necessary to provide reasons for this decision.

19. The respondent did not dispute that claim 1 of auxiliary requests B5a, B5b and B5c contains the same combination of features (5) and (6) as claim 1 of the main request or that the objections raised against claim 1 of the main request apply to claim 1 of these claim requests.

20. The board concludes that claim 1 of auxiliary requests B5a, B5b and B5c does not meet the requirements of Article 123(2) EPC for the same reasons, *mutatis mutandis*, as set out above for claim 1 of the main request.

Auxiliary request B6

Admission into the appeal proceedings (Article 12 (2) and (4) RPBA 2007, in conjunction with Article 13(2) RPBA 2020) of the objections under Article 56 EPC with respect to claim 1 of auxiliary request B6, as set out in the statement of grounds of appeal and maintained in the oral proceedings

21. In the statement of grounds of appeal, the appellant provided several substantiated lines of arguments as to why the subject-matter of the claims of the main request lacked an inventive step. One of these lines of argument relied on the disclosure in document D3 as the starting point for the assessment of inventive step and on its combination with the disclosure in document D2 (see section VI. above). With respect to the set of claims of auxiliary request B6 (see section VI. above), the statement of grounds of appeal noted that claim 1 included the feature from claim 2 of the main request and that it was "obvious over the prior art assessed above" (see section VI. above).

22. The respondent objected to the admission of the line of argument based on document D3 into the appeal proceedings.

23. In the board's view, the appellant's line of argument based on document D3 does not raise a fresh case but aims at further supporting the case made during opposition proceedings without going beyond the legal and factual framework that was established before the opposition division (see notice of opposition, points 8.1 to 8.4.2). Furthermore, the line of argument submitted in the statement of grounds of appeal with respect to the set of claims of auxiliary request B6 (see section VI. above) is understood by the board to build upon all lines of arguments as to lack of inventive step raised for the main request, including the line starting from document D3.

24. The board therefore decided that a line of argument as to lack of inventive step of claim 1 of auxiliary request B6 starting from the disclosure in document D3 was substantiated in the statement of grounds of appeal (Article 12(2) RPBA 2007) and saw no reason to exclude it from the appeal proceedings in the exercise of its discretion (Article 12(4) RPBA 2007). Furthermore, since the appellant's line of reasoning presented at the oral proceedings was not an amendment of it's case it was considered in full (Article 13(2) RPBA).

Claim construction - claim 1

25. The board agrees with the respondent that the expression "*comprising a combination of two or more monovalent Norovirus virus-like particles (VLPs)*" can be understood to relate, as one embodiment, to a

mixture of two or more monovalent Norovirus VLPs.

26. The board also agrees with the respondent that the expression "*monovalent Norovirus VLP*", being unclear, can be construed in accordance with paragraph [0025] of the patent to mean that the VLPs contain antigenic proteins, e.g. VP1 and/or VP2, from only one Norovirus genogroup.

27. However, the board disagrees with the respondent's construction of the expression "*wherein the immune response against a given VLP in the combination is at least 50% of the immune response of that same VLP when measured individually*" to mean that the VLPs derived from genotypes I.1 and II.4 each contribute 50% of the immune response so that the immune response is 100%, i.e. there is no interference.

28. The respondent's construction of the expression, offered at the oral proceedings, contradicts the explicit wording of the claim and the skilled person's understanding of the expression "no interference". It furthermore contradicts the respondent's construction of the expression of "no interference" proposed in the written procedure where they submitted that no interference meant that "*Each immune response triggered by the specific VLP type in the combination is not compromised by the combination and is the same strength as that of the single vaccination.*" (see letter dated 24 April 2020, page 25, first paragraph).

29. In view of the above, the board considers that the expression at issue means that the strength of the immune response triggered by the specific VLP type in the combination need not be the same strength - but only at least 50% - of the immune response triggered

when the same VLP type is used individually. Therefore, the board agrees with the appellant that the expression allows for interference to occur, i.e. it is not synonymous with "no interference".

30. In summary, the board considers that claim 1 is to be understood as a purpose-related product claim (Article 54(5) EPC) where the product is a mixture of two or more monovalent Norovirus VLPs derived from genotypes I.1 and II.4, wherein the immune response triggered by the specific VLP type in the combination can be compromised by the combination such that it need not be the same strength but only at least 50% of the immune response when the same VLP is administered individually.

Inventive step (Article 56 EPC) - claim 1

Closest prior art

31. The prior art disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common is normally the closest prior art.

32. The parties disagreed on whether the disclosure in document D3 or in document D4 was to be taken as the starting point for the assessment of inventive step.

33. The claimed invention concerns a Norovirus vaccine comprising self-assembled VLPs from Norovirus antigens derived from different genotypes for generating a broad immune response.

34. Document D3 relates to a vaccine comprising monovalent VLPs from Norovirus Dijon171/96 and its use in mice to generate specific humoral and cellular Th1/Th2-like immune responses (see title, abstract and page 1085, left hand column, last paragraph and right hand column). Dijon171/96 is a genogroup II Grimsby-like strain (Lordsdale genotype), i.e. a II.4 strain (see document D3, page 1079, right hand column, lines 7 to 10 and document D2, page 5222, left hand column, first paragraph and page 5223, right hand column, last paragraph). Document D3 furthermore discloses that Noroviruses of genogroup I and genogroup II show genetic and antigenic differences and that recombinant expression of Norwalk virus (NV) ORF2, encoding the major capsid protein, yields self-assembled VLPs (rNV VLPs) which are antigenically similar to the native particles. Furthermore it discloses that "*rNV VLPs have been considered as a candidate vaccine for NV infections in humans on the basis of data obtained in mice [8, 10-12] as well as in humans* [13]" (see page 1079, paragraph bridging left and right hand column) and continues by stating that "*because of the important genetic variability of the capsid proteins of noroviruses, it may be important to include different VLPs in the vaccinal preparations to induce a more broadly immune response*" (ibid.). The document given as a reference for the human studies, reference [13], is document D4 in the appeal proceedings. Document D3 concludes that the Th1/Th2-like cellular response observed in its studies may also be important for protection after immunisation with calcivirus (=Norovirus) VLPs and that VLPs are being examined as candidate vaccines for a number of other viral pathogens and have been shown to induce both T cell and B cell effectors as well as protection when

administered in the presence of a mucosal adjuvant.

35. Document D4 discloses a vaccine comprising rNV VLPs that is safe and immunogenic in healthy volunteers when given orally (see title and abstract). Document D4 is silent about monovalent VLPs from different genogroups/ genotypes, about the genetic variability of the capsid proteins of noroviruses or the aim of inducing a broad immune response and how this might be achieved.

36. In the board's judgement, based on shared purpose and structure, the disclosure in document D3 is the more suitable starting point and more promising springboard for the assessment of inventive step. The respondent's argument that document D4 is the closest prior art because it concerns a human study using Norovirus VLPs specific for the Norwalk virus is not persuasive because, although document D4 reports human studies while document D3 reports mice studies, the human data reported in document D4 are also summarised in document D3 (see point 34. above)

37. It is moreover established case law of the boards of appeal that if the skilled person has a choice of several workable routes starting from different disclosures which might lead to the invention, the rationale of the problem-solution approach requires that the invention be assessed relative to all these possible routes, before an inventive step can be acknowledged. Conversely, if the invention is obvious to the skilled person in respect of at least one of these routes, as in the case at hand (see point 42. and following below) there is no need to consider other starting points, such as the disclosure in document D4, before concluding that an inventive step is lacking

(see CLBA, section I.D.3.1).

Objective technical problem

38. The claimed subject-matter differs from the disclosure in document D3 in that the vaccine comprises in addition to the monovalent Norovirus VLP derived from Dijon171/96 (genotype II.4), a monovalent Norovirus VLP derived from genotype I.1.

39. The application discloses that, in mice, immunisation with a VLP mixture comprising Houston (II.4) VLPs and Norwalk (I.1) VLPs raised an immune response against each strain of Norovirus in the mixture (see Example 11 and Figure 11). The board therefore agrees with the appellant that the technical effect linked to this difference is that an immune response against more than one Norovirus genotype is raised.

40. The respondent's assertion that "no interference" is a further technical effect associated with the difference is not found persuasive in view of the claim construction applied by the board (see point 30. above). The objective technical problem can thus not be formulated as suggested by the respondent, i.e. as to provide a broad-spectrum vaccine against Noroviruses, in which the components do not interfere with each other.

41. Instead, the board considers that the objective technical problem to be solved by the claimed subject-matter is the provision of broad-spectrum vaccine against Noroviruses.

Obviousness of the claimed solution

42. The question to be answered in assessing obviousness is whether the skilled person starting from the disclosure of a vaccine comprising monovalent VLPs derived from Dijon171/96 VLPs in document D3 and seeking to solve the objective technical problem formulated above would have modified the vaccine disclosed in document D3 to arrive at the claimed solution.

43. Document D3 mentions the genetic variability of the capsid protein of noroviruses and indeed suggests including different VLPs in vaccine preparations in order to produce a broader immune response (see point 34. above). Furthermore, document D3 discloses VLPs derived from Noroviruses belonging to different genotypes, namely Dijon171/96 VLPs (II.4) and rNV VLPs (I.1) (see point 34. above), that these VLPs are immunogenic in mice when administered individually (see page 1085, left hand column, last paragraph) and that rNV VLPs have already been considered as a candidate vaccine for NV infections in humans, based *inter alia* on data obtained in mice (see point 34. above).

44. The board considers that the teaching in document D3 would have prompted the skilled person to combine Dijon171/96 VLPs (II.4) and rNV VLPs (I.1) in order to provide a vaccine against a broad panel of Noroviruses. In the board's judgement, the skilled person had a reasonable expectation that this combination would generate an immune response against both VLPs in the vaccine and would have expected that the immune response against each VLP would be at least 50% of the immune response of that same VLP when measured individually.

45. The reasons for this are that, as set out above, document D3 discloses that Dijon171/96 VLPs (II.4) and rNV VLPs (I.1) are immunogenic when administered individually. The authors of document D3 reported no concerns about any possible interference between Norovirus VLPs.

46. Furthermore, there is no evidence on file that the skilled person at the relevant date of the patent *a priori* considered that a potential interference between VLPs from the specific Noroviruses as recited in claim 1 would mean that the expectation of success of attaining an significant immune response from each VLP in the claimed composition was less than reasonable.

47. On the contrary, document D2 reports that mice inoculated with alphavirus vectors expressing Norovirus strain-specific recombinant VLPs derived from the three Norovirus strains NV (I.1), SM (II.2), HV (II.1) "*produced a robust antibody response*" to all VLPs in the mixture (see document D2, page 5228, left hand column, second paragraph, lines 15 to 28; page 5223, right hand column, last paragraph). No significant differences in mean IgG titers between serum IgG responses following inoculation with individual versus multivalent inocula were seen for all three antigens in mice, i.e. the combination elicited immunity against each virus without any significant interference (see Fig. 6A.). Document D2 thus provides evidence that interference between Norovirus VLPs from different genotypes was not an issue at the relevant date of the patent.

48. The board agrees with the appellant that the person skilled in the art would have taken document D2 into account since it relates to Norovirus combination

vaccines (see title and abstract). While document D2 concerns Venezuelan equine encephalitis virus (VEE) replicon particles (VRPs) expressing antigens of Norovirus, the skilled person understood from document D2 that the VRP vaccines form a combination of monovalent VLPs *in vivo*, i.e. that the VLPs are the immunogenic entity in document D2 (see page 5228, left hand column, second paragraph). These VLPs are indistinguishable from wild-type virus in their morphology and antigenicity (see document D2, page 5221, right hand column, first full paragraph). Document D3 (see page 1079, left hand column, lines 7 to 12) and D15 (see page 733, right hand column, full paragraph, lines 12 to 13 and sentence bridging pages 738 and 739) confirm that the skilled person knew that VLPs produced by VRPs are self-assembled VLPs that are similar to native VLPs or baculovirus produced VLPs.

49. The respondent's criticism of the data reported in document D2 is not warranted for the following reasons. Firstly, the skilled person would have had no reason to doubt the teaching of document D2, since it is a peer-reviewed scientific article. Secondly, the production of intact VLPs was confirmed in document D2 by transmission electron microscopy (see page 5222, left hand column, end of second paragraph) and document D2 provides evidence that, despite a possibly saturated immune insult (see page 5228, left hand column), IgG titers induced by monovalent and trivalent inocula are not statistically different (see Fig. 6A), i.e. no interference occurs.

50. The main argument of the respondent in support of the presence of inventive step was that that the skilled person would have been worried about interference and therefore this would have prevented them from combining

different VLPs, in view of the testing that would be required and the unpredictable outcome of such tests.

51. This line of reasoning is not persuasive. Document D3 already provides an incentive to combine different VLPs to induce a broader immune and even suggests it explicitly (see points 34. and 44. above). Moreover, documents D6 and D7, relied on by the respondent in this context, do not support its case for the following reasons.

52. Document D6 discloses "*The compatibility of rotavirus and oral poliovirus vaccines will have to be demonstrated, because these vaccines would ultimately be administered simultaneously as part of any routine immunization program. Limited studies have not shown interference between RRV-based rotavirus and poliovirus vaccines (59,67, 70) but have shown a decreased response to bovine rotavirus strain RIT4237 when this vaccine was given simultaneously with poliovirus vaccine (49, 143).*" (see page 431, left hand column, concluding paragraph).

53. Document D7 discloses "*Preferably the combination of VLPs within the vaccine does not reduce the immunogenicity of each VLP type. In particular it is preferred that there is no interference between HPV VLPs in the combination of the invention, such that the combined VLP vaccine of the invention is able to offer effective protection against infection by each HPV genotype represented in the vaccine*" (see page 4, last paragraph) and "*An immunogenicity study was performed in Balb/C mice ... No interference is observed when the four VLPs (VLPs16, 18, 31 & 45) are delivered as a combination*" (see Example 3).

54. Documents D6 and D7 are therefore evidence that the skilled person was aware of the possibility that different vaccines, when given simultaneously, might affect the immune response to the individual components (see document D6, page 427, left hand column, last paragraph) and that it was preferable to avoid interference (see document D7, page 4, last paragraph). However, these documents also show that the skilled person, aware of the possibility of interference, would perform immunogenicity studies to investigate the compatibility of the individual components in the envisaged combination vaccine (see document, D6, page 431, right hand column, last paragraph; document D7, Example 3). In other words, these documents demonstrate that the possibility of interference occurring would not have stopped the skilled person from pursuing combination vaccines, but rather they would have simply tested the envisaged combinations for possible immune interference. The same conclusion can be drawn from the fact that the investigators of document D2 did perform a study to determine serum IgG in response to trivalent inoculum.

55. Indeed, the respondent itself submitted that "Thus, in general, when considering combination treatment of multiple vaccines, the skilled person "was a priori worried about the possibility of interference" and would perform the required assays to ensure that interference was not an issue." (see reply, page 58, third paragraph).

56. According to the established case law of the boards of appeal, if the skilled person in view of the teaching of the prior art has already envisaged a combination of compounds and they only need to determine by routine tests whether such a combination has a desired effect,

they are in a "try and see" situation. In such situations the concept of "reasonable expectation of success" does not apply because the skilled person would prefer to verify whether the potential solution they had conceived worked, rather than abandon the project because success was not certain (see CLBA, section I.D.8.7.2).

57. It has already been established that the skilled person would have envisaged the combination of Dijon171/96 VLPs and rNV VLPs (see point 44. above). Thus, they would merely have to perform the tests that were performed in document D3 with Dijon171/96 VLPs with the combination of Dijon171/96 VLPs and rNV VLPs to find out whether this combination induces a broader immune response. While the results of these tests are generally unpredictable, in the case at hand, the skilled person had very good reasons to expect success (see point 47. above).

58. The respondent's further line of argument to the effect that the skilled person had no reasonable expectation of success that the combination of Norovirus VLPs derived from Dijon171/96 and NV would result in "no interference as claimed" fails for the reasons set out in point 56. above and also in view of the claim construction adopted by the board (see point 30. above).

59. Finally, whether or not the appellant had acknowledged in the first instance proceedings that the skilled person was worried about interference is of no consequence. It has been established above (see points 54. to 55.) that the skilled person, should they be worried about interference, would have performed tests to ensure that interference would not be an

issue. The reasoning of the opposition division that "*as acknowledged by both parties, the skilled artisan was a priori worried about the possibility of interference. In that case, the skilled artisan had no incentive to embark in* [sic] *a combination approach. On the contrary common knowledge at the time would have discouraged the artisan from doing that. The contribution of the invention lies precisely in going against accepted wisdom, and finding that the problem of interference - in the case of NoV- was no problem at all*" (see decision under appeal, point 24), therefore, cannot hold.

60. In conclusion, none of the respondent's arguments persuades the board that the skilled person, faced with the objective technical problem of providing a broad-spectrum vaccine against Noroviruses, would have been deterred from following the prompting of document D3 to combine Dijon171/96 VLPs (II.4) and rNV VLPs (I.1) in a vaccine preparation, with a reasonable expectation of success of inducing a broader immune response against Noroviruses. The subject-matter of claim 1 lacks an inventive step.

Auxiliary request B6d

Admission into the appeal proceedings (Article 12(4) RPBA 2007)

61. The request was filed by the respondent in reply to the statement of grounds of appeal. The appellant objected to its admission, arguing that it could have been filed earlier.

62. Admittance of this request is governed by Article 12(4) RPBA 2007. Under Article 12(4) RPBA 2007, the board has discretion to hold requests filed with

the (statement of grounds of appeal) or the reply thereto inadmissible if they could have been presented in the proceedings before the opposition division. Admittance of requests newly filed with the reply to the statement of grounds of appeal hinges, *inter alia*, on the question whether a party was in a position to make its submissions earlier, and whether it could have been expected to do so under the circumstances (see CLBA, section V.A.4.11.1).

63. When filing auxiliary request B6d, the respondent submitted that it was filed in response to the appellant's new objection under Article 100(c) EPC to the feature "combination of two or more monovalent Norovirus virus-like particles (VLPs)" (see section VII. above).

64. However, an objection under Article 100(c) EPC to the feature "*combination of two or more monovalent Norovirus virus-like particles (VLPs)*" had already been raised in the opposition proceedings (see notice of opposition, point 3.1.1). If the respondent felt that the objection could be addressed by amending claim 1 to limit the claimed vaccine to a combination "of no more than two" monovalent Norovirus VLPs it could and should have done this in the proceedings before the opposition division.

65. During the oral proceedings before the board, the respondent submitted that auxiliary request B6d was filed in reaction to a new line of argument based on document D3 in combination with document D2. However, an objection based on document D3 in combination with document D2 had also been raised in the opposition proceedings against the subject-matter of claim 1 as granted and dependent claim 9 (see notice of

opposition, points 8.1 to 8.4.2 and point 23. above). Any amendments to address this objection could thus have been filed in the proceedings before the opposition division. Furthermore, when filing auxiliary request B6d, the respondent relied on the limitation to VLPs derived from genotypes I.1 and II.4 - i.e. on the same feature as present in auxiliary request B6 - as establishing inventive step and not on the feature "of no more than two" (see section VII. above).

66. The board concludes from the above that the respondent was not only in a position to make its submissions earlier, but that it could have been expected to do so under the circumstances.

67. Therefore, the board decided not to admit auxiliary request B6d into the appeal proceedings.

Conclusions

68. The main request and auxiliary requests B5a, B5b, B5c and B6 are not allowable and auxiliary request B6d is not admitted into the appeal proceedings. Therefore, the decision under appeal must be set aside and the patent must be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

A. Chavinier-Tomsic A. Chakravarty

Decision electronically authenticated