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Datasheet for the decision of 12 December 2024

Case Number: T 1789/22 - 3.3.04

Application Number: 13736518.5

Publication Number: 2869843

IPC: A61K39/245, C07K14/045, C12N7/02

Language of the proceedings: EN

Title of invention:
Complexes of cytomegalovirus proteins

Patent Proprietor:
GlaxoSmithKline Biologicals SA

Opponents:
Appleyard Lees IP LLP / Fleck Barbara
Sanofi Pasteur

Headword:
HCMV complexes/GLAXOSMITHKLINE

Relevant legal provisions:
EPC Art. 107, 111(1), 56
EPC R. 80
RPBA 2020 Art. 13(1)

Keyword:

Appeal decision - remittal to the department of first instance (no)
Amendment occasioned by ground for opposition - (yes) - amendments allowable (yes)
Amendment to appeal case - justification by party (no)
Examination of own motion - appeal proceedings
Inventive step - (yes)

Decisions cited:

G 0002/91, G 0007/91, G 0008/91, G 0009/91, G 0010/91, G 0009/92, T 0588/90, T 0737/92, T 0646/02, T 0750/11, T 2094/12, T 0807/16, T 0862/16, T 0146/17, T 1042/18, T 0256/19, T 0155/20

Catchword:

1. For considerations about the object of appeal proceedings and the rights of a non-appealing party, see Reasons, points 1 to 4. The provisions of Article 107, second sentence, EPC guarantee a non-appealing party the right to participate to pending appeal proceedings. However, they do not provide it an autonomous right to have requests which go beyond the scope of the appeal as defined by the appellant's statement of grounds of appeal, decided by the board (as a direct consequence of G 2/91, Headnote). By not filing an appeal, a non-appealing party has not contested the findings of the opposition division, beyond the framework of the appeal filed by the appellant.

2. A proprietor cannot be expected to file an amended description in appeal proceedings until an allowable set of claims is found. The lack of an adapted description constitutes no obstacle to the admittance of an amended set of claims into the appeal proceedings (see Reasons points 6.3 and 6.4).

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Case Number: T 1789/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 12 December 2024

Appellant: (Joint opponents - opponent 1)	Appleyard Lees IP LLP / Fleck Barbara 15 Clare Road Halifax, Yorkshire HX1 2HY (GB)
Representative:	Zwicker, Jörk Zwicker Schnappauf & Partner Patentanwälte PartG mbB Hansastraße 32 80686 München (DE)
Respondent: (Patent Proprietor)	GlaxoSmithKline Biologicals SA Rue de l'Institut 89 1330 Rixensart (BE)
Representative:	Thornley, Rachel Mary GSK Legal & Compliance - Global Patents 79 New Oxford Street London WC1A 1DG (GB)
Party as of right: (Opponent 2)	Sanofi Pasteur 14 Espace Henri Vallée 69007 Lyon (FR)
Representative:	Zwicker, Jörk ZSP Patentanwälte PartG mbB Hansastraße 32 80686 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 May 2022 rejecting the opposition filed against European patent No. 2869843 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	D. Luis Alves
	A. Bacchin

Summary of Facts and Submissions

I. European patent EP 2 869 843, entitled "*Complexes of cytomegalovirus proteins*", was granted on European patent application No. 13 736 518.5.

Claims 1, 5, 8, 10 and 11 read:

"1. An isolated human Cytomegalovirus (HCMV) pentameric complex comprising: HCMV gH, HCMV gL, HCMV pUL128, HCMV pUL130, and HCMV pUL131A, wherein said gH lacks a transmembrane domain.

5. An immunogenic composition comprising the isolated pentameric complex of any one of claims 1-4.

8. A process for producing the isolated HCMV pentameric complex of any one of claims 1-4, said process comprising (i) growing cells expressing gH lacking the transmembrane domain, gL, pUL128, pUL130, and pUL131A in a growth medium; and (ii) purifying said HCMV pentameric complex.

10. The immunogenic composition of any one of claims 5 to 7, for use in treating HCMV infection.

11. The immunogenic composition of claims 5 to 7, for use to raise antibodies in a mammal."

II. Two oppositions were filed, invoking the grounds for opposition under Article 100(a) EPC, for lack of novelty (Article 54 EPC) and lack of inventive step

(Article 56 EPC), as well as the grounds for opposition under Article 100(b) and (c) EPC.

III. The opposition division rejected the oppositions. The joint-opponents 1 (appellant) filed an appeal against that decision.

The patent proprietor is respondent in this appeal.

Opponent 2 is a party as of right in this appeal proceedings.

IV. With the statement setting out the grounds of appeal, the appellant submitted arguments contesting the decision under appeal in the following aspects: novelty of claims 1, 2 and 8 in view of documents D6 and D13, and inventive step when document D13 is taken to represent the closest prior art. The appellant did not contest the decision in respect of Article 100(c) EPC or Article 100(b) EPC. Further, the appellant requested remittal of the case to the opposition division and reimbursement of the appeal fee, for reasons of procedural violations.

V. With the reply to the statement setting out the grounds of appeal, the respondents filed auxiliary requests 1 to 6. These requests had been filed as auxiliary requests 4 to 9 in opposition proceedings on 2 November 2020.

VI. The party as of right-opponent 2 submitted arguments with the letter dated 3 February 2023, filed in reply to the invitation to file observations to the appellant-opponent 1's statement of grounds of appeal.

VII. The board appointed oral proceedings.

VIII. With letter dated 20 September 2024 the party as of right-opponent 2 informed the board that they would not be attending the oral proceedings.

IX. The appellant made further submissions with the letter dated 15 October 2024, essentially adopting and agreeing to the submissions made by the party as of right with its letter dated 3 February 2023.

X. In a communication pursuant to Article 15(1) RPBA, the board informed the parties of its preliminary opinion, *inter alia* that:
- the submissions of the party as of right were to be considered only as far as they did not extend beyond the scope of the appeal as defined by the statement of grounds of appeal;
- the appellant's subsequent submission, adopting the party as of right's submissions, was to be considered subject to the procedural limitations in Article 13(1) RPBA;
- the respondent's request that appellant's submissions in relation to claim interpretation not be admitted, must be separated from the need for the board to construe the claims vis-à-vis the issues to be decided; and
- the board intended to discuss and decide on the auxiliary requests if need be and as far as they did not contain subject-matter which had not been dealt with for the main request; of particular relevance might be whether the amendments pertained to the same matters dealt with in the decision under appeal and the arguments submitted in appeal proceedings.

XI. The appellant made further submissions with the letters dated 11 November 2024 and 6 December 2024.

XII. The respondent made further submissions with two letters dated 3 December 2024, withdrawing the request for oral proceedings and requesting as main request that the patent be maintained on the basis of the claims according to auxiliary request 1.

XIII. The set of claims of the main request (former auxiliary request 1) consists of 10 claims. Independent claims 1, 7, 9 and 10 read:

"1. An immunogenic composition comprising an isolated human Cytomegalovirus (HCMV) pentameric complex comprising: HCMV gH, HCMV gL, HCMV pUL128, HCMV pUL130, and HCMV pUL131A, wherein said gH lacks a transmembrane domain.

7. A process for producing the immunogenic composition of any one of claims 1-4, said process comprising (i) growing cells expressing gH lacking the transmembrane domain, gL, pUL128, pUL130, and pUL131A in a growth medium; (ii) purifying said HCMV pentameric complex, and (iii) combining the purified HCMV pentameric complex with a pharmaceutically acceptable carrier.

9. The immunogenic composition of any one of claims 1 to 6, for use in treating HCMV infection.

10. The immunogenic composition of claims 1 to 6, for use to raise antibodies in a mammal."

XIV. The board issued a communication requesting the respondent to clarify whether the former main request and the lower ranking requests were maintained.

XV. With a letter dated 6 December 2024 the respondent clarified that auxiliary request 4 was renumbered to auxiliary request 1, and all other claim requests were withdrawn.

XVI. The oral proceedings took place as scheduled, in the presence of the appellant and absence of the respondent and the party as of right, both having previously announced their absences. The appellant withdrew the request to remit the case to the opposition division due to procedural violations. At the end of the oral proceedings the chair announced the board's decision.

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

D6: Ryckman, B.J. *et al.*, Journal of Virology 82(1), 2008, pages 60-70

D13: WO-A-2012/051211

D27: Manley, K. *et al.*, Cell Host & Microbe 10, 2011, pages 197-209

D31: WO-A-2007/146024

D41: Block, H. *et al.*, Methods in Enzymology 463, 2009, pages 439-473

D42: Kashino, Y., Journal of Chromatography B 797, 2003, pages 191-216

XVIII. The appellant's arguments, where relevant to this decision, may be summarised as follows:

Object of the appeal proceedings
Novelty objections

The main request corresponded to auxiliary request 1 filed with the respondent's reply to the appeal.

Claim 1 corresponded to claim 5 in the claims as granted.

No auxiliary requests had been discussed during opposition proceedings. Therefore, they were not addressed in the decision under appeal, and there had been no opportunity to address them when filing the appeal.

In the appeal proceedings, the auxiliary requests were first present with the respondent's reply to the appeal. Moreover, the main request should be considered as having been filed only on 3 December 2025, despite having been filed as auxiliary request 1 with the reply to the appeal in February 2022. Indeed, a request can only be considered filed once it has been substantiated. In conclusion, the respondent amended their case and the opponents could not anticipate which claims the respondent would pursue. Thus, these requests were addressed at the first possible opportunity.

The statement of grounds of appeal did not include any statements applying to claim 5 as granted merely because it was never in dispute that the isolated complex of claim 1 was immunogenic, as required for the composition of claim 5. The complex itself was immunogenic, not any additional component of the composition. Also in document D13, the complex itself was immunogenic. This was consistent with the patent and the respondent's argument in their reply to the appeal that, relative to claim 1 as granted, claim 1 as amended provided further clarification of the subject-matter.

There was no difference between claims 1 and 5 as granted. Claim 5 was directed to a composition, which was different from a claim directed to a pharmaceutical composition or vaccine (see paragraphs [0092] to [0093] of the patent). It was not possible to read further features into the term "immunogenic", which merely defined a property of the pentameric complex.

The fact that the statement of grounds of appeal did not mention claim 5 when specifying which claims as granted were not novel, did not exclude that also claim 5 as granted was not novel.

Main request (filed as auxiliary request 1 with the statement of grounds of appeal)

Admittance into the appeal proceedings

This request should not be admitted since it did not include an adapted description and was thus incomplete. As the respondent was not present at the oral proceedings, they could not complete it either. Therefore, the board could not reach a final decision (see T 1194/08 and Case Law of the Boards of Appeal of the EPO, 10th edn., 2022, (CLBA), V.A.5.5.4a)).

Rule 80 EPC

The request should also not be admitted as it did not comply with the requirements of Rule 80 EPC: step (iii) had been introduced into claim 7, but this amendment was not occasioned by a ground for opposition. Furthermore, the reference to a "pharmaceutically acceptable carrier" in this step was unnecessary. The respondent provided no explanation for this amendment.

Therefore, the request should not be admitted into the appeal proceedings. Otherwise its allowability should be considered under Rule 80 EPC. The board had no discretionary power on this matter (see T 750/11, T 256/19 and CLBA IV.C.5.1.2a)).

Claim interpretation

The term "immunogenic composition" did not require suitability for administration to a subject. The term "immunogenic" simply was a feature inherent to the complex, and did not limit the claim in any way.

Novelty (Article 54 EPC)

The subject-matter of claim 1 was not novel in view of the disclosure in each of documents D6 and D13. Claim 1 corresponded to claim 5 of the request held allowable by the opposition division. Although this claim was not specifically addressed in the statement of grounds of appeal, it was not different to claim 1, directed to the isolated complex.

Request for the board to consider ex officio novelty or alternatively remit the case to the opposition division

The board could of own motion examine novelty of the claims of this request (see T 862/16 and V.A.3.3.1). Article 12(1) RPBA placed restrictions on the parties but not on the Board. It could also not take precedence over the EPC, as confirmed in decision R 16/13.

The request to remit the case was not accompanied by reasons.

Inventive step (Article 56 EPC)

The closest prior art was represented by the expressed constructs A555 and A556 disclosed in document D13. These complexes comprised the same protein components as the pentameric complex of claim 1 (see Figure 18). There was no reason why these constructs would not be expressed as pentameric complexes, in view of the expression of the construct A527 as a pentameric complex (see example 6). This document also disclosed the use in immunisation of self-replicating RNA, with examples that included the constructs of Figure 18 (see example 6).

The difference between claim 1 and the closest prior art described above was a different use of the protein in claim 1 and different way of providing the pentameric complex to the immune system. No fundamental difference regarding immunisation could be attributed to this difference.

Thus, the objective technical problem was "the provision of an alternative immunogenic composition allowing for immunisation against an HCMV pentamer".

Document D31 disclosed immunogenic compositions comprising protein complexes (see claim 1). The skilled person would have expressed the proteins and administered the complex in protein form instead of the RNA construct. This can be also seen in the patent, where the starting point was also RNA (see example 1 and paragraph [0150]).

The counter-argument that there were barriers to the use of protein constructs had not been substantiated. In fact, protein vaccines had been used for decades.

Moreover, the only alternative to solve the above-formulated problem was to provide a protein vaccine.

XIX. The arguments of the party as of right-opponent 2, where relevant to this decision, may be summarised as follows:

Remittal to the opposition division

For any of the auxiliary requests filed with the statement of grounds of appeal, the case should be remitted to the opposition division, as they had not been discussed during opposition proceedings.

Novelty (Article 54 EPC)

The objections below were directed to claims 1 to 4 of the main request in the decision under appeal. These claims are not present in the main request being considered in appeal.

Document D13 directly and unambiguously disclosed a pentameric complex comprising the components of the claimed complex. The complex was removed from its environment, and therefore isolated in the meaning of the patent. Thus, the subject-matter of claims 1 to 4 (referring to the main request in the decision under appeal) was not novel.

Document D6 disclosed all the proteins in the complex defined in claim 1. Co-expression of each of these proteins inevitably led to the pentameric form. Therefore, a purified complex, thus an isolated complex, was disclosed. The subject-matter of claims 1

to 4 (referring to the main request in the decision under appeal) was not novel.

Also document D27 disclosed the pentameric complex removed from its environment.

Inventive step

Claims 1 to 9 (referring to the main request in the decision under appeal) were not limited by any use of the isolated complex or composition comprising it. Therefore, also documents D6 and D13 could be taken to represent the closest prior art. If the isolated pentameric complex were considered novel over any of these disclosures, any difference would be trivial and the skilled person would consider it. Therefore, the claimed subject-matter did not involve an inventive step.

The claimed subject-matter was also obvious from the disclosure in document D31.

XX. The respondent's arguments, where relevant to this decision, may be summarised as follows:

Object of the appeal proceedings

The statement of grounds of appeal filed by opponent 1 should constitute the opponents' complete appeal case. This established the framework for the appeal. As opponent 2 did not file an appeal, their response to the notification of the statement of grounds of appeal should not be considered a response under Article 12(1) RPBA. Thus, it should not be allowed to broaden the scope of the appeal with opponent 2's submissions. Therefore, submissions of opponent 2 concerning the

lack of novelty in view of document D27, and the lack of inventive step in view of documents D6 and D31, should not be admitted into the appeal proceedings.

Furthermore, the arguments relating to claim interpretation filed by both opponents should not be admitted, as these could have been filed during the opposition proceedings and considered in the decision under appeal.

Main request (filed as auxiliary request 1 with the statement of grounds of appeal)

Admittance into the appeal proceedings

This request was filed as auxiliary request 1 with the statement of grounds of appeal and was identical to auxiliary request 4 before the opposition division. Therefore, it did not constitute an amendment to the respondent's case.

In view of the amendment to claim 1, claim 7 had been amended to refer to an "immunogenic composition" and to include an additional process step. These amendments further clarified that the invention related to the isolated HCMV pentameric complex as claimed to be used as an antigen within an immunogenic composition (i.e. a protein subunit vaccine composition).

Remittal to the opposition division

The case should not be remitted because opponent 2 did not outline any "special reasons" as required by Article 11 RPBA to justify remittal.

Furthermore the main request should not be remitted because it did not contain subject-matter that had not been dealt with for the request held allowable in the decision under appeal. All matters pertaining to this request had been discussed in the decision under appeal and in the parties' submissions.

Novelty

Arguments pertaining to novelty in view of document D27 should not be admitted as they extended beyond the scope of the appeal.

Claim 1 was directed to an immunogenic composition. The cell culture medium or cell supernatant disclosed in document D6 could not be an immunogenic composition since it contained traces of either a radioactive material or a cross-linking agent, which made them incompatible with administration to a subject.

Inventive step

The arguments pertaining to inventive step in view of any of D6, D13 or D31 as closest prior art should not be admitted. The appellant's case was limited to contesting the choice of document D31 as closest prior art.

In case the arguments were admitted, document D13 could not be considered the closest prior art because it concerned a self-amplifying mRNA (SAM) vaccine approach for expressing CMV complexes *in vivo*. The benefit of using the body's own cells to produce the vaccine was that only the construct needed to be manufactured, circumventing the need to provide an immunogenic

composition containing isolated CMV complexes. The SAM vaccines aimed at avoiding the need for isolation.

Requests of the parties relevant for the decision

XXI. The appellant requested:
- that the decision under appeal be set aside and that the patent be revoked in its entirety;
- that the new main request and new auxiliary request 1, filed respectively as auxiliary request 1 and auxiliary request 4 with the reply to the statement of grounds of appeal, not be admitted and that documents D41 and D42 be admitted into the appeal proceedings;
- that the Board raise *ex officio* a novelty attack against claim 1 of the new main request;
- alternatively, that the Board remit the case to the opposition division;
- that the new main request be considered non-allowable for lack of compliance with Rule 80 EPC, or because of lack of inventive step starting from document D13, in combination with the common general knowledge, as reflected in documents D41 and D42;
- that the Board either admit or raise *ex officio* objections as to lack of inventive step starting from documents D6 or D31.

The respondent requested in writing:
-that the patent be maintained in amended form on the basis of the claims of the main request, filed as auxiliary request 1 with the reply to the statement of grounds of appeal;
- alternatively, that the patent be maintained in amended form on the basis of the claims of auxiliary

request 1, filed as auxiliary request 4 with the reply to the statement of grounds of appeal;
- that the appellant's submissions in relation to claim interpretation and novelty be not admitted into the appeal proceedings;
- that the appellant's submissions in relation to inventive step in view of document D13 as closest prior art not be admitted into the appeal proceedings;
- that, should the board find that document D31 represents the closest prior art, the subject-matter of the claims as granted be considered to involve an inventive step since the appellant did not dispute this part of the decision;
- that the case not be remitted to the opposition division for consideration of Article 83 EPC;
- that the case not be remitted to the opposition division for consideration of the auxiliary requests;
- that the submissions of opponent 2 not be admitted into the appeal proceedings;
-that the sections 1 and 4 to 6 of the appellant's letter dated 11 November 2024 not be admitted into the appeal proceedings.

The party as of right-opponent 2 requested in writing:
- that the decision under appeal be set aside and the patent be revoked in its entirety;
- that, should the board find that the main request did not comply with the requirements of the EPC, the case be remitted to the opposition division for consideration of the auxiliary requests.

Reasons for the Decision

Object of the appeal proceedings

Legal framework

1. As established by the Enlarged Board of Appeal in decision G 9/91, the power of an Opposition Division or a Board of Appeal to decide on the maintenance of a patent depends on the extent to which the patent is opposed under Rule 76(2)(c) EPC. There is no power to decide and hence no authority to "examine the facts" beyond the extent to which the patent is attacked in the notice of opposition. Likewise the EPO has no competence to deal with non-opposed subject-matter (see G 9/91, Reasons 10 as confirmed by T 588/90, Reasons 4, T 737/92, Reasons 2.1, T 646/02, Reasons 2, T 2094/12, Reasons 1.1 to 2).

2. With regard to opposition appeal proceedings, in addition the statement of grounds of appeal determines the object of the appeal proceedings and the legal and factual framework for the review of the appealed decision by the board. In other words, the statement of grounds of appeal determines the extent to which amendment or cancellation of the appealed decision is requested (see e.g. G 9/92, Reasons 1).

3. The appellant can adduce new facts and evidence during appeal proceedings, but their consideration will then be subject to the discretion afforded to the board under Article 114(2) EPC and Articles 12 and 13 RPBA to reject late-filed submissions. These restrictions are independent of those indicated above (see point 1.) regarding new grounds for opposition or new opposed

subject-matter and have a cumulative effect (cf. e.g. T 1042/18, Headnote 1, and Reasons 4.5).

4. As regards a non-appealing party, the provisions of Article 107, second sentence, EPC guarantee its right to participate to pending appeal proceedings. However, they do not provide it an autonomous right to have requests which go beyond the scope of the appeal as defined by the appellant's statement of grounds of appeal, decided by the board (as a direct consequence of G 2/91, Headnote). By not filing an appeal, a non-appealing party has not contested the findings of the opposition division, beyond the framework of the appeal filed by the appellant.

Application to the present case

5. In the present case, with the statement of grounds of appeal, the appellant contested the decision under appeal in relation to novelty in view of documents D6 and D13, and in relation to inventive step when document D13 is taken to represent the closest prior art. Moreover, in the context of novelty, the objections to then main request specifically identified claims 1, 2 and 8 only. Novelty of claim 5 of the then main request was not objected to.

This determines the legal and factual framework for review by the board.

5.1 Despite other attacks having been raised in the notices of opposition, also with regard to different subject-matter, i.e. further claims, and despite the opposition division having decided on these, the appellant did not contest the decision regarding the other attacks on novelty, such as in view of document D27, or for

inventive step starting from document D31; nor did it contest the decision in respect of Article 100(c) EPC or Article 100(b) EPC (see point IV. above).

5.2 The submissions of the party as of right-opponent 2 included objections under lack of novelty in view of document D27 and lack of inventive step where documents D6 and D31 were taken to represent the closest prior art. Since the opposition division took a decision on these lines of attack in favour of the respondent, an appeal should have been filed to have these findings reviewed, rather than merely contesting them in the reply to the statement of grounds of appeal. However, as indicated above, the appeal of the appellant did not contest the decision in these respects, therefore these objections are outside the legal and factual framework for review by the board. Their consideration is in principle not excluded but is subject to the discretion accorded to the board under Article 114(2) EPC and Articles 12 and 13 RPBA.

5.3 The same applies to the appellant's submission dated 15 October 2024, particularly to the fact that party as of right-opponent 2’s submissions were agreed upon and adopted by the appellant. Under the circumstances of the case, their consideration in appeal is subject to the procedural limitations of Article 13(1) RPBA. It is undisputed that re-submitting objections of lack of novelty and of inventive step against non-appealed subject matter, after having indicated the intention not to contest the findings of the opposition division in this respect, is an amendment to the appeal case, which is subject to justification. The board notes that the appellant provided no justification for not having raised these objections with the statement of grounds of appeal, and the board cannot see any either.

Moreover admitting these several additional attacks would be detrimental to procedural economy and unfair for the respondent, who relied on these parts of the appealed decision not having being contested.

5.4 Accordingly, the objections filed by the appellant with this letter were not admitted into the appeal proceedings. The same applies to the corresponding objections filed by the part as of right.

Main request (auxiliary request 1 filed with the statement of grounds of appeal)

Admittance into the appeal proceedings

6. *Lack of an adapted description*

6.1 This claim set was filed as auxiliary request 1 with the statement of grounds of appeal and is identical to auxiliary request 4 before the opposition division. The appellant argued that the lack of an adapted description was a reason to not admit the request into the appeal proceedings.

6.2 The appellant referred to the Case Law of the Boards of Appeal of the EPO (CLBA), 10th edn., 2022, V.5.5.4a). That section deals with the consequences for an applicant or patent proprietor of its absence at oral proceedings. In case of amendments, this party must expect that a decision may be based on objections which arise in their absence. This includes also objections to admittance of amended claims. Further, this party cannot rely on the case being remitted to the opposition division for adaptation of the description.

6.3 However, there is also a whole body of decisions of the boards of appeal in which the cases where remitted to the opposition division for adaptation of the description to the claims found allowable. This practice is common where the patent proprietor attends the oral proceedings. The board sees no reason to deviate from it where the patent proprietor does not attend the oral proceedings. Decisions addressing requests to not admit a set of claims due to lack of an adapted description, where the board acknowledged the practice of allowing an adapted description to be filed once there is an allowable set of claims, possibly before the opposition division, include T 0807/16 (see Reasons 1.4), T 146/17 (see Reasons 1.2 and 1.3), and T 155/20 (see Reasons point 1.4).

6.4 In view of this long-standing practice, the proprietor cannot be expected to file an amended description until an allowable set of claims is found. Taking into account that the board had not indicated prior to the oral proceedings that it intended to deviate from this established practice, applying the principle of legitimate expectations, the board decided that the lack of an adapted description constituted no obstacle to the admittance of the request into the appeal proceedings.

7. *Rule 80 EPC*

7.1 Pursuant to Rule 80 EPC, the claims 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 an opponent.

7.2 In the present case, it was not contested that the amendment to claim 1 was occasioned by a ground for

opposition. Claim 1 of the main request is now directed to an immunogenic composition comprising an isolated complex, rather than to the isolated complex as in claim 1 as granted. Claim 7 was amended such that it refers to a process of producing the immunogenic composition and includes a step of combining the complex with a pharmaceutically acceptable carrier. The board considers that the amendments to claim 7, which according to the respondent were intended for consistency with claim 1 as amended, were carried out for the same reasons as the amendment to claim 1. The appellant questioned the need to introduce the additional step and the reference therein to a "pharmaceutically acceptable carrier". However, the board considers that the introduction of this process step is a legitimate reaction aiming at limiting the process claim in the same way as product claim 1. Indeed, step (ii) is for purification of the complex. Therefore, it can be argued that the result of the two process steps (i) and (ii) was not a composition, and that the introduction of additional step (iii) avoids a possible inconsistency within the claim. In light of the above, the requirements of Rule 80 EPC are met.

7.3 In this context, the appellant cited decisions T 750/11 and T 256/19, which are considered in the following in turn.

7.3.1 In decision T 750/11, the board held that an amendment that was a serious attempt to overcome a ground for opposition, was admissible under Rule 80 EPC. An amendment which limited the claimed subject-matter formally complied with Rule 80 EPC. Whether that amendment actually overcame the ground for opposition was a separate matter to be settled (Reasons 2.3.2). The main point was the distinction between these two

issues. Therefore, this decision is not relevant to the present case because the issue decided is not in dispute here. Rather, the decisive issue in the present case is whether the introduction of step (iii) in claim 7, and the further amendment by which it refers to a composition instead of an isolated complex, aim to introduce the same limitations as introduced in claim 1. As set out in point 7.2 above, the board considers they do.

7.3.2 In decision T 256/19, the board held that Rule 80 EPC represents a non-discretionary provision of the EPC that relates to the allowability of the patent as amended rather than to its admittance into the proceedings (Reasons 4.7). Rule 80 EPC was not a basis to disregard an amended version of a patent. The board held that the amended version before it could not be disregarded in the appeal proceedings, however it did not counter any of the invoked grounds for opposition and therefore was not allowable under Rule 80 EPC (Reasons 4.8).

7.3.3 In this context, the appellant also requested the board to consider the requirements in Rule 80 EPC as a matter of allowability of the amendments.

7.3.4 The present board concurs with the finding in T 256/19 that Rule 80 EPC is a non-discretionary provision, the compliance with which is to be assessed at any stage of the proceedings. However, Rule 80 EPC by merely requiring that amendments are *occasioned* by a ground for opposition under Article 100 EPC cannot be understood as a requirement for allowability. Whether the amendments actually overcome the ground for opposition which they intend to address, i.e. whether the amendments are also allowable, is a matter to be

assessed in substance and does not pertain to the admissibility of the amendments.

7.3.5 Whether the amendments address a ground for opposition, was considered by the board above (see point 7.2). There the board concluded that the amended method step (iii) was required due to the introduction of "immunogenic composition", the latter being the limitation that was introduced to claim 1. The board is thus satisfied that the amendments meet the requirements of Rule 80 EPC.

7.4 In view of the conclusions under points 6.4, 7.2 and 7.3.5, the board decided to admit the main request into the proceedings.

Request to remit the case to the opposition division

8. Party as of right-opponent 2 requested that any auxiliary request be remitted to the opposition division for consideration, on the ground that "*these had not been discussed during first instance proceedings*". However, they did not specify which aspects of the claims had not been discussed.

9. However, a decision to remit the case cannot be justified in general terms by a reference to the primary object of the appeal proceedings to review the decision. For that reason alone, the request is not allowable, since it was not based on any specific circumstances of the case. Nevertheless, in the present case the board considers that the amendments in the main request do not raise any matters not dealt with in the decision under appeal, for the reasons given below.

10. A further request for remittal to the opposition division was filed by the appellant for consideration of the novelty attack against claim 1 of the main request (see point XXI.). This request is addressed in points 16. and 17. below.

Novelty (Article 54 EPC)

Object of the appeal proceedings - claim 1

11. Claim 1 of the main request is directed to a composition comprising an isolated pentameric complex. This was also the subject-matter of independent claim 5 of the main request (claims as granted) held allowable in the decision under appeal. With the statement of grounds of appeal, the appellant did not contest the decision in respect of novelty of claim 5. Instead, the submissions were specific to claims 1, 2 and 8. As set out above, the statement of grounds of appeal defines the framework of the appeal and in the present case it did not include novelty of claim 5 of the request held allowable by the opposition division (see points 2., 5. and 5.1). Accordingly, novelty of claim 1 of the main request is not open for review by the board in this appeal proceedings.

11.1 An exception to this principle is provided by subject-matters covered by dependent claims that depend on an opposed independent claim, provided their validity is *prima facie* in doubt on the basis of already available information. Such dependent subject-matters have to be considered as being implicitly covered by the opposition (cf. G 9/91, Reasons 11).

12. The remaining issue was therefore whether, in absence of any mention of claim 5 as granted in the appellant's

submissions on novelty, the objections raised to another claim applied straightforwardly to this claim. The board is convinced that the arguments against claim 1 as granted cannot be directly transferred to claim 5. The latter is directed to an "immunogenic composition". The appellant provided several arguments with respect to this term. They argued that the term "immunogenic" was not an additional feature but merely a property of the isolated complex contained in the composition. Further, the "composition comprising the isolated pentameric complex" in the present claims was no different to the "isolated pentameric complex", unlike claims specifying a vaccine or a pharmaceutical composition. However, these two arguments precisely illustrate that the additional features in claim 5 raise additional issues for discussion. This is also illustrated by the respondent's arguments that the term "immunogenic composition" implied a suitability for administration to a subject. However, there had been no discussion on this feature in the context of novelty, which the board could directly transfer to claim 5 as granted.

13. In conclusion, the board considers that novelty of claim 5 as granted was not contested in the statement of grounds of appeal and for this reason the objection against claim 1 of the main request before the board extends beyond the legal and factual framework of the appeal, as defined by the statement of grounds of appeal.

14. Since claims 7, 9 and 10 include the features of claim 1, the same applies to these claims.

Request for the board to consider ex officio a novelty objection

15. At the oral proceedings in appeal, the appellant requested the board to raise *ex officio* a novelty objection against claim 1 of the new main request and referred in particular to decision T 862/16. Alternatively it requested to remit the case to the opposition division for consideration of novelty.

15.1 The board does not disregard, as explained in T 862/16, that Articles 111(1) and 114(1) EPC in principle confer to a board the power to raise *ex officio* new objections also in appeal proceedings. This power is however subject to limitations and must be applied respecting the parties' right to be heard.

15.2 In the case of opposition appeal proceedings, the Enlarged Board of Appeal gave reasons for applying the principle of *ex officio* examination pursuant to Article 114(1) EPC in a more restrictive manner than in opposition proceedings (G 10/91, Reasons 18). Due to the judicial nature of the appeal procedure (cf. G 7/91 and G 8/91, Reasons 7), and considering that the main aim of the *inter partes* appeal procedure is to give the losing party the opportunity to contest the opposition division's decision, such procedure is less investigative than an administrative one. Accordingly there's limited room for *ex officio* examination.

15.3 In the case at hand the board is requested to extend an objection for lack of novelty to an independent claim having been the object of a novelty objection, which had no longer been pursued by the appellant in its statement of grounds of appeal. By limiting its appeal to only certain subject-matters, the appellant

deliberately refrained from making use of their right to contest the decision under appeal in its entirety. Moreover, the possibility to extend an objection to dependent claims (see point 11.1 above) does not apply here. The requested extension relates to an independent claim and the subject-matter cannot be regarded as being implicitly covered by the statement of grounds of appeal (see point 12 above). Furthermore had the board considered the validity of independent claim 1 as *prima facie* in doubt, it could have raised such an objection on its own motion at an earlier stage than at oral proceedings. Moreover, as the respondent/patent proprietor was not present at the oral proceedings, admitting this late request from the appellant would have required postponement of the appeal proceedings to safeguard the respondent's right to be heard. However, this would have undermined fair proceedings and procedural economy, which were the same reasons for not admitting the appellant's submissions under Article 13(1) RPBA. For this reason the board refused the request to raise a novelty attack against claim 1 *ex officio*.

Request for remittal for consideration of novelty (and inventive step)

16. The appellant requested remittal of the case for discussion of this claim request, in case the board decided not to raise *ex officio* an objection as regards novelty of claim 1 (see points 15. to 15.3 above). The board did not see a reason to remit since claim 1 corresponds to claim 5 as granted, underlying the decision under appeal, and the opponents had therefore the opportunity to raise any objections to this claim. Most importantly, a remittal for considering novelty of claim 1 would be purposeless, since the opposition

division had already considered the novelty and inventive step attacks also regarding granted claim 5, and found that the claimed subject matter was novel and inventive.

17. Furthermore, a remittal for consideration of inventive step foreseeably could not lead to any new discussion, since the decision under appeal already discussed the provision of immunogenic compositions, as did the parties in appeal. The discussion on inventive step revolved around compositions for eliciting an immune response against HCMV (see point 17 of the decision under appeal). The opposition division considered the opponents' arguments based on document D13 (see point 17.4.1.) and gave specific reasons why the subject-matter involved an inventive step in view of D13 (see point 17.5.1). Although a large part of the opposition division's reasoning was dedicated to the choice of closest prior art, it discussed in detail the differences to the claimed subject-matter from the point of view of providing an immunogenic composition (see page 24, first full sentence) and provided considerations on obviousness (see page 22, second to fourth paragraphs). Therefore, the subject-matter of the main request had been conclusively dealt with in the decision under appeal.

18. Claim interpretation

18.1 Respondent's request that the opponents' arguments be not admitted into the appeal proceedings

18.1.1 The respondent requested that none of the arguments of the appellant and party as of right in this regard be admitted into the appeal proceedings, on the grounds that during opposition proceedings these parties had

not made use of the opportunity to present arguments contesting the opposition division's claim interpretation.

18.1.2 The respondent's request does not identify which arguments in this context are new in appeal proceedings. The board has not identified any either.

18.2 "Immunogenic composition"

18.2.1 The parties were in dispute as to the meaning of the term "immunogenic composition" in claim 1, however, for the present decision it is not necessary to go into the limitations that might be implied by this term.

18.3 No further arguments crucial for the decision were brought forward concerning claim interpretation.

Inventive step (Article 56 EPC)

19. *Object of the appeal proceedings - objections against claim 1*

19.1 As set out above (see points 11. to 13.), the board considered that novelty of claim 5 as granted had not been contested with the statement of grounds of appeal. As regards inventive step, the situation is however different, as with the statement of grounds of appeal the objections included considerations about the provision of immunogens for vaccines (see for example the formulation of the objective technical problem). The board considers that those objections apply directly to an immunogenic composition comprising the isolated complex and consequently to the subject-matter of present claim 1.

19.2 As set out above (see points 5.1 and 5.2) the board considers that objections based on documents D6 and D31 as closest prior art are outside the legal and factual framework of this appeal proceedings.

19.3 The respondent requested the board to not admit objections based on document D13 as closest prior art, for the reason that the opposition division's decision on this point had not been contested and the arguments of the appellant were a mere repetition of those submitted in opposition proceedings without addressing the reasons in the decision.

19.3.1 In the statement of grounds of appeal, the appellant contested the choice of closest prior art and developed an inventive step objection starting from document D13.

19.3.2 The board considers that these clearly set out reasons why the appellant contests the decision in respect of inventive step.

19.4 *Inventive step objections based on the disclosure in documents D13 and D31 in combination*

19.4.1 In the statement of grounds of appeal the appellant contested the choice of closest prior art in the decision under appeal and developed a problem solution approach starting from document D13. The analysis of obviousness referred to the common general knowledge as represented by documents D41 and D42, arguing that the skilled person was aware that "*proteins to be used as immunogens or indeed as antigens in diagnostics should be isolated, in order inter alia, to avoid the preparation of non-target antibodies*" (see point 4.3.2 refering to point 4.3.5.8.1 of opponent 1's letter of 28 February 2022). Thus, as discussed above (see point

19.1), the inventive step objections against claim 1 as granted, which was directed to an isolated pentameric complex, already took into account the provision of an immunogen. However, document D31 was not cited in the statement of grounds of appeal when setting out the problem-solution approach.

19.4.2 Also the submissions of party as of right-opponent 2 did not refer to document D13 in combination with document D31. Instead it was argued that in case the isolated complex were considered novel in view of document D13, then any difference would have been considered by the skilled person in view of its common general knowledge. The same applies to the appellant's letter dated 15 October 2024. The appellant's letters dated 11 November 2024 and 6 December 2024 reinforce that document D13 may be taken as a starting point for the assessment of inventive step, the former also addressing obviousness but without citing any specific document.

19.4.3 In conclusion, this objection was presented for the first time at oral proceedings before the board and therefore was not taken into account as no exceptional circumstances were present in accordance with Article 13(2) RPBA.

20. *Problem-solution approach*

20.1 *Closest prior art*

20.1.1 Claim 1 is directed to an immunogenic composition comprising an isolated complex of human cytomegalovirus (HCMV) proteins gH, gL, pUL128, pUL130 and pUL131A, with gH in a form without the transmembrane domain.

20.1.2 Document D13 concerns RNA vaccines for eliciting an immune response against human cytomegalovirus (HCMV). It discloses that complexes of HCMV proteins had already been studied for use as vaccines, such as the trimeric complex gH/gL/gO of viral envelope proteins. It was also known that the complex gL/gH could associate with UL128, UL130 and UL131A to form a pentameric complex, required for viral entry into several cell types (see D13, paragraphs [04] to [05]). Protein complexes could be obtained by introducing nucleic acid constructs encoding each of its component proteins into a cell, for co-expression (see paragraphs [06] and [07]).

As in the patent in suit, the aim in this document is to elicit an immune reaction against a protein complex. Unlike the patent in suit, the aim is to provide self-replicating RNA constructs for delivery. These constructs encode in one construct all the protein components to be co-expressed (see paragraph [09]).

Examples of such constructs are given in schematic form in Figure 18. Constructs A555 and A556 include the components to express all the proteins of the complex in claim 1 of the main request. Example 6 concerns constructs encoding two proteins or five proteins, in various formulations. Construct A527 was expressed and its presence as a pentameric complex was confirmed.

20.1.3 The parties were in disagreement as to whether the statements relating generally to all other complexes illustrated in Figure 18 could be seen as disclosures of their expression and assembly in the form of pentameric complexes and whether these were provided in isolated form. There was however agreement that no protein complexes were disclosed in the context of a

composition for eliciting an immune reaction.

20.2 *Objective technical problem*

20.2.1 The appellant argued that no technical effect regarding immunisation could be attributed to the provision of the pentameric complex in protein form instead of an RNA construct. The problem was formulated as "the provision of an alternative composition allowing for immunisation against an HCMV pentamer". The claimed solution was an immunogenic composition comprising isolated pentameric complex comprising the HCMV proteins gH, gL, pUL128, pUL130 and pUL131A, wherein gH lacks a transmembrane domain.

20.3 *Obviousness*

20.3.1 To determine whether the claimed solution was obvious, the question to be answered is whether the skilled person, in the expectation of solving the above-posed problem, would have modified the teaching in the closest prior art in the light of other teachings so as to arrive at the claimed invention (see CLBA, I.D.5).

20.3.2 The board considers that document D13, in isolation, does not provide any motivation for providing a protein form of an HCMV pentamer, since it precisely aims at avoiding the preparation of such complexes. Furthermore, it provides no motivation to choose any of the complexes of Figure 18 over the others. None of them, apart from the construct A527, has been tested for immunogenicity. In example 6, this is also the most relevant construct since it is stated that its expression was detected and the pentameric complex form confirmed. Moreover, according to this document, a direct comparison of immune responses elicited by a

complex containing soluble gH versus a complex containing full length gH revealed that the former leads to a weaker response (see paragraph [223]). The appellant pointed to the common general knowledge that a His-tag can be used to purify proteins carrying it. However, this common general knowledge is only relevant to the question of isolating proteins and protein complexes. It does not provide any motivation specific to the issue of immunogenic compositions for immunisation against HCMV complexes.

20.3.3 For these reasons, the subject-matter of claim 1 of the main request involves an inventive step (Article 56 EPC). The same applies to the subject-matter of claims 2 to 6, all defining further features of the composition of claim 1, that of claims 7 and 8, directed to a process of producing the composition defined in claim 1 and to the composition limited to the uses in claims 9 and 10.

21. *Consideration by the board ex officio of further objections*

21.1 The appellant requested the board to consider *ex officio* attacks which were not admitted into the appeal proceedings. Here the board refers to the reasons set out under novelty, point 15. to 15.3.

22. *Documents D41 and D42*

22.1 The appellant requested these documents to be admitted into the appeal proceedings, in case it were contested that it was common general knowledge to purify proteins via a His-tag. The board took into account this common general knowledge without the need to refer to these

documents. Therefore, no decision on their admittance into the appeal proceedings needed to be taken.

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 10 of the main request, filed as auxiliary request 1 with the reply to the statement of grounds of appeal, a description and drawings possibly to be adapted thereto.

The Registrar: The Chairwoman:

A. Wille M. Pregetter

Decision electronically authenticated