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Datasheet for the decision of 12 May 2015

Case Number: T 0621/11 - 3.3.02

Application Number: 98939886.2

Publication Number: 1003533

IPC: A61K35/76, C12N7/01, A61K48/00, A61P35/04

Language of the proceedings: EN

Title of invention:
USE OF HERPES VECTORS FOR TUMOR THERAPY

Patent Proprietor:
Georgetown University

Opponent:
BIOVEX LIMITED

Headword:
HSV for tumor therapy/GEORGETOWN

Relevant legal provisions:
EPC Art. 123(2), 123(3)
RPBA Art. 13

Keyword:
Main request - added subject-matter (yes)
Late-filed objection under Article 123(3) EPC - admissible (yes)
Auxiliary requests 1, 2, 3 - extension of protection conferred (yes)
Auxiliary requests 1-A, 4, 5 - admissible (no)

Decisions cited:
G 0009/91

Catchword:

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Case Number: T 0621/11 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 12 May 2015

Appellant: (Patent Proprietor)	Georgetown University 37th & O Streets, N.W. Washington, DC 20057 (US)
Representative:	Bösl, Raphael Konrad Isenbruck Bösl Hörschler LLP Patentanwälte Prinzregentenstraße 68 81675 München (DE)
Appellant: (Opponent)	BIOVEX LIMITED 70 Milton Park Abingdon Oxford OX14 4RX (GB)
Representative:	Dörries, Hans Ulrich df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 DE-80333 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 20 January 2011 concerning maintenance of the European Patent No. 1003533 in amended form.**

Composition of the Board:

Chairman	U. Oswald
Members:	K. Giebeler
	R. Cramer

Summary of Facts and Submissions

I. European patent No. EP1003533, based on European patent application No. 98939886.2, published as WO 99/07394 (hereafter referred to as "the application as filed") and entitled "Use of herpes vectors for tumor therapy", was granted with 17 claims.

II. Claim 1 of the application as filed reads:

"A method of eliciting a systemic antitumor immune response in a patient who presents with or who is at risk of developing multiple metastatic tumors of a given cell type, comprising the step of inoculating a tumor in the patient with a pharmaceutical composition consisting essentially of:

(A) a herpes simplex virus (HSV) that infects tumor cells but that does not spread in normal cells, wherein the genome of the herpes simplex virus comprises at least one expressible nucleotide sequence coding for at least one immune modulator, and

(B) a pharmaceutically acceptable vehicle for the virus, such that an immune response is induced that is specific for the tumor cell type and that kills cells of the inoculated tumor and of a non-inoculated tumor."

III. Claim 1 as granted reads:

"1. Use of a composition comprising
a herpes simplex virus (HSV) that replicates in dividing cells and exhibits attenuated replication in non-dividing cells, and that comprises one or more expressible nucleotide sequences encoding one or more cytokines or at least one other immune modulator, and
a pharmaceutically acceptable vehicle for the virus

for the preparation of a medicament for treating or preventing a metastasis of a tumor of a given cell type by eliciting a systemic antitumor immune response in a patient who presents with or who is at risk of developing multiple metastatic tumors of a given cell type,
wherein the medicament is suitable for inoculating the tumor in a patient."

Claims 2 to 17 as granted are directly or indirectly dependent on claim 1.

IV. Notice of opposition was filed against the granted patent on the grounds of lack of novelty and inventive step (Article 100(a) EPC), insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

V. The opposition division decided that the claims of the main request did not meet the requirements of Article 123(2) EPC and that the subject-matter of the claims of auxiliary request 1 did not involve an inventive step (Article 56 EPC), but that auxiliary request 2 met all the requirements of the EPC.

VI. Both the proprietor and the opponent filed appeals against the opposition division's decision.

VII. With its grounds of appeal, the appellant-proprietor filed a main request and auxiliary requests 1 to 5. With its response dated 18 October 2011 to the appeal of the appellant-opponent, the appellant-proprietor filed new auxiliary requests 1 to 13.

VIII. On 15 December 2014, the board issued a communication as an annex to the summons to oral proceedings,

expressing its preliminary opinion. In particular, several objections concerning the allowability of the claims of the main request under Article 123(2) EPC were raised.

IX. The appellant-proprietor filed further observations with letter of 10 April 2015, together with a new main request and new auxiliary requests 1 to 5.

X. The appellant-opponent filed further observations with letter of 6 May 2015.

XI. Claim 1 of the main request is identical to claim 1 of auxiliary request 2 held allowable by the opposition division and reads as follows:

"Use of a composition comprising
a herpes simplex virus (HSV) that replicates in dividing cells and exhibits attenuated replication in non-dividing cells, and that comprises one or more expressible nucleotide sequences encoding one or more cytokines or at least one other immune modulator, and
a pharmaceutically acceptable vehicle for the virus
for the preparation of a medicament for treating a metastasis of a tumor of a given cell type by eliciting a systemic antitumor immune response in a patient who presents with multiple metastatic tumors of a given cell type,
wherein the medicament is suitable for inoculating the tumor in a patient."

XII. Claim 1 of auxiliary request 1 reads as follows:

"Use of a composition comprising
a herpes simplex virus (HSV) that replicates in dividing cells and exhibits attenuated replication in

non-dividing cells, and that comprises one or more expressible nucleotide sequences encoding one or more cytokines or at least one other immune modulator, and a pharmaceutically acceptable vehicle for the virus for the preparation of a medicament for treating a metastasis of a tumor of a given cell type by eliciting a systemic antitumor immune response in a patient who presents with multiple metastatic tumors of a given cell type,
wherein a tumor of the patient is inoculated with the medicament, and
wherein said composition induces an immune response that is specific for the tumor cell type and that kills cells of the inoculated tumor and of a non-inoculated tumor."

XIII. Claim 1 of auxiliary request 2 reads as follows:

"Use of a composition comprising
a herpes simplex virus (HSV) that replicates in dividing cells and exhibits attenuated replication in non-dividing cells, and that comprises one or more expressible nucleotide sequences encoding one or more cytokines or at least one other immune modulator, and a pharmaceutically acceptable vehicle for the virus for the preparation of a medicament for treating a metastasis of a tumor of a given cell type by eliciting a systemic antitumor immune response in a patient who presents with multiple metastatic tumors of a given cell type,
wherein a tumor of the patient is inoculated with the medicament, and
wherein said composition induces an immune response that is specific for the tumor cell type and that kills cells of the inoculated tumor and of a non-inoculated tumor, and wherein said metastasis is not inoculated."

XIV. Claim 1 of auxiliary request 3 reads as follows:

"Use of a composition comprising
a herpes simplex virus (HSV) that replicates in dividing cells and exhibits attenuated replication in non-dividing cells, and that comprises one or more expressible nucleotide sequences encoding IL-12 or GM-CSF, and
a pharmaceutically acceptable vehicle for the virus
for the preparation of a medicament for treating a metastasis of a tumor of a given cell type by eliciting a systemic antitumor immune response in a patient who presents with multiple metastatic tumors of a given cell type,
wherein a tumor of the patient is inoculated with the medicament, and
wherein said composition induces an immune response that is specific for the tumor cell type and that kills cells of the inoculated tumor and of a non-inoculated tumor."

XV. Claim 1 of auxiliary request 4 reads as follows:

"Use of a composition comprising
a herpes simplex virus (HSV) that replicates in dividing cells and exhibits attenuated replication in non-dividing cells, and that comprises one or more expressible nucleotide sequences encoding GM-CSF, and
a pharmaceutically acceptable vehicle for the virus
for the preparation of a medicament for treating a metastasis of a tumor of a given cell type by eliciting a systemic antitumor immune response in a patient who presents with multiple metastatic tumors of a given cell type,

wherein a tumor of the patient is inoculated with the medicament, and
wherein said composition induces an immune response that is specific for the tumor cell type and that kills cells of the inoculated tumor and of a non-inoculated tumor, and
wherein the tumor cells are melanoma cells."

XVI. Claim 1 of auxiliary request 5 reads as follows:

"Use of a composition comprising
a herpes simplex virus (HSV) that replicates in dividing cells and exhibits attenuated replication in non-dividing cells, and that comprises one or more expressible nucleotide sequences encoding GM-CSF, and
a pharmaceutically acceptable vehicle for the virus
for the preparation of a medicament for treating a metastasis of a tumor of a given cell type by eliciting a systemic antitumor immune response in a patient who presents with multiple metastatic tumors of a given cell type,
wherein a tumor of the patient is inoculated with the medicament, and
wherein said composition induces an immune response that is specific for the tumor cell type and that kills cells of the inoculated tumor and of a non-inoculated tumor,
wherein said metastasis is not inoculated and
wherein the tumor cells are melanoma cells."

XVII. Oral proceedings were held on 12 May 2015. During the oral proceedings, the appellant-proprietor filed an additional request, referred to as auxiliary request 1-A. Claim 1 of this request reads as follows:

"Use of a composition comprising
a herpes simplex virus (HSV) that replicates in dividing cells and exhibits attenuated replication in non-dividing cells, and that comprises one or more expressible nucleotide sequences encoding one or more cytokines or at least one other immune modulator, and
a pharmaceutically acceptable vehicle for the virus
for the preparation of a medicament for treating a metastasis of a tumor of a given cell type by eliciting a systemic antitumor immune response in a patient who presents with multiple metastatic tumors of a given cell type,
wherein a tumor of said cell type of the patient is inoculated with the medicament, and
wherein said composition induces an immune response that is specific for the tumor cell type and that kills cells of the inoculated tumor and of a non-inoculated tumor."

XVIII. The appellant-opponent's arguments, insofar as they are relevant for the present decision, may be summarised as follows:

Admissibility of claim requests

None of the claim requests should be admitted into the proceedings. The main request was filed only one month before the oral proceedings and did not constitute a *bona fide* response to the objections under Article 123(2) EPC raised in the board's communication.
The same applied to auxiliary requests 1 and 2 to 5; these requests were *prima facie* not allowable under Article 123(2) EPC and additionally raised new issues under Articles 123(3), 83 and 84 EPC. Auxiliary request 1-A filed during the oral proceedings should not be

admitted into the proceedings because it did not resolve the problem under Article 123(3) EPC.

Main request - Article 123(2) EPC

Claim 1 did not comply with Article 123(2) EPC because the application as filed disclosed only methods which comprised a mandatory step of inoculating the tumour; this step was omitted in claim 1. Furthermore, the application as filed did not disclose that the primary tumour was to be inoculated.

Auxiliary requests 1, 2 and 3 - Article 123(3) EPC

Claim 1 of these requests extended the scope of the claims as granted because it did not require the medicament to be suitable for inoculating the (primary) tumour that gave rise to the metastasis to be treated.

XIX. The appellant-proprietor's arguments, insofar as they are relevant for the present decision, may be summarised as follows:

Admissibility of claim requests

All claim requests should be admitted into the proceedings. The main request corresponded to auxiliary request 2 held allowable by the opposition division and differed from auxiliary request 5 filed on 18 October 2011 only in the presence of claim 12. Auxiliary requests 1, 2 and 3 were based on requests already filed with the response to the appellant-opponent's appeal. Auxiliary requests 4 and 5 aimed to address possible problems under Article 123(2) EPC with respect to dependent claim 15 of the main request. Auxiliary request 1-A constituted a direct response to

the objection under Article 123(3) EPC raised by the appellant-opponent for the first time only a few days before the oral proceedings; said request could thus not have been filed earlier.

Main request - Article 123(2) EPC

Claim 1 was directly and unambiguously derivable from the application as filed because Examples 5 to 7 disclosed the bilateral tumour model which was a model for metastasis, and any reference to a non-inoculated tumour in the application as filed was thus to be equated to a reference to a metastatic tumour. It was furthermore directly and unambiguously derivable from the application as filed that the disclosed medicament was suitable for inoculating the tumour in a patient, because if it were not suitable the disclosed method would not work.

Auxiliary requests 1, 2 and 3 - Article 123(3) EPC

Claim 1 of these requests contained additional, limiting features when compared to granted claim 1 and there was thus no extension of the scope of protection. Moreover, the appellant-opponent had presented neither any real-world example nor any documentary evidence which proved that the amended claims covered subject-matter not covered by the granted claims.

XX. The final requests of the parties were:

The appellant-proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or on the basis of one of auxiliary requests 1 to 5, all submitted with letter of 10 April 2015, or on the basis

of auxiliary request 1-A filed during the oral proceedings.

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

Reasons for the Decision

1. The appeal is admissible.

2. Main request

2.1 Admissibility

2.1.1 According to Article 12(2) of the Rules of Procedure of the Boards of Appeal (RPBA), the statement of grounds of appeal and the reply thereto must contain the party's complete case. Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the board's discretion, which is to be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy (Article 13(1) RPBA). Amendments sought to be made after oral proceedings have been arranged are not to be admitted if they raise issues which the board or the other party cannot reasonably be expected to deal with without adjournment of the oral proceedings (Article 13(3) RPBA).

2.1.2 The main request, which was filed one month before the oral proceedings, is identical to auxiliary request 2 held allowable by the opposition division. It differs

from auxiliary request V filed with the appellant-proprietor's response of 18 October 2011 to the appellant-opponent's appeal only in the presence of dependent claim 12.

The board considers that this amendment does not change the subject-matter of the appeal and does not introduce new issues or render the appeal more complicated.

Therefore, the board, in exercising its discretion under Article 13(1) RPBA, decides to admit the main request into the proceedings.

2.2 Article 123(2) EPC

2.2.1 Claim 1 relates to the use of a composition comprising a mutated herpes simplex virus and a pharmaceutically acceptable vehicle for the preparation of a medicament for treating a metastasis of a tumour of a given cell type by eliciting a systemic antitumour immune response in a patient who presents with multiple metastatic tumours of a given cell type, wherein the medicament is suitable for inoculating the tumour in a patient; the claim is thus drafted in the format of a Swiss-type claim.

2.2.2 Article 123(2) EPC stipulates that a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. It is the established case law of the Boards of Appeal that the content of an application comprises the disclosure directly and unambiguously derivable from it.

2.2.3 The application as filed discloses a method of eliciting a systemic antitumour immune response in a

patient, which method comprises the step of inoculating a tumour in the patient with a mutated herpes simplex virus (see page 7, lines 16-21; claims 1, 17, 28, 30 and 31 of the application as filed). There is no disclosure in the application as filed of any such method which need not comprise the step of inoculating a tumour. However, claim 1 of the main request merely requires that "the medicament is **suitable** for inoculating the tumor in a patient"; the claimed use does not comprise the step of "inoculating a tumor in the patient" as an obligatory feature. Therefore, the claimed use extends beyond the content of the application as filed.

2.2.4 Furthermore, claim 1 refers to the preparation of a medicament for treating a metastasis of a tumour and states that the medicament is suitable for "inoculating **the** tumor in a patient". This means that the medicament is suitable for inoculating the primary tumour giving rise to the metastasis to be treated. However, the application as filed refers only to methods comprising the step of "inoculating **a** tumor in the patient" (see for instance page 7, lines 16-21; claim 1 of the application as filed), without stating that the (primary) tumour giving rise to the metastasis to be treated is to be inoculated. Whereas several passages of the application as filed make a distinction between the inoculated tumour and non-inoculated tumours (e.g. page 7, lines 16-24; page 10, line 34, to page 11, line 2; page 11, lines 4-6; page 16, lines 4-10), there is no teaching that the inoculated tumour is the primary tumour giving rise to the metastasis. Therefore, the information that the medicament is suitable for inoculating the primary tumour giving rise to the metastasis, rather than for inoculating any one tumour of the patient presenting with multiple metastatic

tumours of a given cell type, is not directly and unambiguously derivable from the application as filed.

The appellant-proprietor pointed out that the examples section of the application as filed (page 25, line 24 onwards) described the "subcutaneous tumor model", which was a model for metastasis. In said model, a tumour mass was injected subcutaneously in the right and left flanks of the mouse, whereas the medicament was only injected in one flank; if an effect occurred on the other flank, this proved that the medicament could treat metastases. According to the appellant-proprietor, the distant tumour mass was a metastasis of the tumour mass of the other flank; consequently, the references in the application as filed to non-inoculated tumours (e.g. page 11, lines 4-6; page 16, lines 4-7) were to be equated to metastases.

The board cannot follow this line of argument because, in the subcutaneous tumour model specified in the application as filed, CT26 tumour cells are injected in both flanks of mice and give rise to tumours, and the tumours of one flank are not the metastases of a tumour or tumours of the other flank. For this reason alone, the information that the primary tumour is to be inoculated cannot be directly and unambiguously derived from the disclosure of the subcutaneous tumour model in the application as filed.

2.2.5 Consequently, claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

3. Auxiliary request 1

3.1 Admissibility

Auxiliary request 1, which was filed one month before the oral proceedings, differs from auxiliary request VII filed with the appellant-proprietor's response of 18 October 2011 to the appellant-opponent's appeal only in the deletion of several dependent claims. This deletion is seen as a *bona fide* attempt to address objections under Article 123(2) EPC expressed in the board's communication accompanying the summons to oral proceedings. Therefore, the board, in exercising its discretion under Article 13(1) RPBA, decides to admit auxiliary request 1 into the proceedings.

3.2 Article 123(3) EPC

3.2.1 The appellant-proprietor requested that the Article 123(3) EPC objection raised by the appellant-opponent should not be admitted into the proceedings as being late-filed; he had become aware of this new objection only a few days before the oral proceedings and could thus not deal with it without the adjournment of the oral proceedings.

3.2.2 Amendments to the claims or other parts of a patent made in the course of opposition or appeal proceedings are to be fully examined for compatibility with the requirements of the EPC, e.g. with regard to the provisions of Article 123(2) and (3) EPC (see G 9/91, OJ EPO 1993, 408, 19).

3.2.3 In the present case, the board considers the objection under Article 123(3) EPC raised by the appellant-opponent in its letter of 6 May 2015 with respect to auxiliary request 1 filed by the appellant-proprietor one month before the oral proceedings to be fundamental and highly pertinent.

It is true that the appellant-opponent could in principle have raised this objection earlier, since the claim under consideration had already been filed as claim 1 of auxiliary request VII on 18 October 2011.

However, given the nature of the objection, the board considers that the time available for the appellant-proprietor to consider the objection and prepare counter-argumentation, i.e. at least five days, was sufficient. The appellant-proprietor could thus be expected to deal with the objection without adjournment of the oral proceedings.

Therefore, the board admits this objection into the proceedings.

3.2.4 Article 123(3) EPC stipulates that the claims of a patent as granted may not be amended in such a way as to extend the protection conferred. In order to decide whether or not an amendment of the patent in suit satisfies that requirement, it is necessary to compare the protection conferred by the claims before amendment, i.e. as granted, with that of the claims after amendment. It is the established case law of the Boards of Appeal that a very rigorous standard, namely that of "beyond reasonable doubt", is to be applied when checking the allowability of amendments under Article 123(3) EPC, such that the slightest doubt that the scope of the patent as amended could cover embodiments not covered by the unamended patent would preclude the allowability of the amendment.

3.2.5 Claim 1 of auxiliary request 1 is directed to the use of a defined composition for the preparation of a medicament for treating a metastasis of a tumour of a

given cell type, wherein a tumour (i.e. any tumour) of the patient is inoculated with the medicament.

Claim 1 as granted is directed to the use of a defined composition for the preparation of a medicament for treating a metastasis of a tumour of a given cell type, wherein the medicament is suitable for inoculating the tumour (i.e. the primary tumour which gave rise to the metastasis to be treated) in a patient.

This means that according to the use of claim 1 of auxiliary request 1, the medicament only has to be suitable for inoculating a tumour (i.e. any tumour) in the patient, but does not necessarily have to be suitable for inoculating the primary tumour which gave rise to the metastasis to be treated, contrary to the use of claim 1 as granted. Hence claim 1 covers uses of medicaments not covered by claim 1 as granted.

Therefore, the scope of the claims as granted has been extended.

3.2.6 The appellant-proprietor argued that the scope of the claims as granted had not been extended, because the appellant-opponent's objection was merely hypothetical and not based on any documentary proof.

The board cannot follow this argument and considers that documentary evidence disclosing embodiments covered by the amended claim and not covered by the claims as granted is not required in order to arrive at a finding of contravention of Article 123(3) EPC, because the extension of protection is apparent from a comparison of the amended claim with the claims as granted, as set out above.

3.2.7 The appellant-proprietor further submitted that the scope of the claims as granted had not been extended, because additional limitations had been introduced into claim 1 of the first auxiliary request, i.e. the features that a tumour of the patient is inoculated with the medicament and that the composition induces an immune response that is specific for the tumour cell type and that kills cells of the inoculated tumour and of a non-inoculated tumour.

The board is not convinced by this argument, because the additional features introduced into claim 1 of auxiliary request 1 do not limit the medicament to one that is suitable for inoculating the primary tumour giving rise to the metastasis to be treated, and thus cannot remedy the extension of protection set out above.

3.2.8 The board concludes that claim 1 of auxiliary request 1 has been amended in such a way that the extent of protection conferred has been extended, contrary to Article 123(3) EPC.

4. Auxiliary request 1-A - admissibility

4.1 Auxiliary request 1-A was filed at the oral proceedings; its claim 1 differs from claim 1 of auxiliary request 1 in that the words "said cell type of" have been added.

4.2 The board has to decide on the admissibility of this request. According to the established case law of the Boards of Appeal, claims filed during oral proceedings must *prima facie* overcome the issue raised, without giving rise to new ones, in order to be admissible.

4.3 The board acknowledges that auxiliary request 1-A constitutes an attempt to overcome the Article 123(3) EPC problem in claim 1 of auxiliary request 1. However, the board considers that the addition of the reference to "said cell type" in claim 1 does not *prima facie* overcome the problem of contravention of Article 123(3) EPC. This is because claim 1 of auxiliary request 1-A covers uses wherein a patient carries primary and metastatic tumours of the same given cell type, and the medicament is suitable for inoculating a metastasis, but not for inoculating the primary tumour that gave rise to the metastasis to be treated, contrary to the medicament in claim 1 as granted.

4.4 Since claim 1 does not *prima facie* overcome the outstanding Article 123(3) EPC issue, the board decides not to admit auxiliary request 1-A into the proceedings.

5. Auxiliary request 2

5.1 Admissibility

Auxiliary request 2 was filed one month before the oral proceedings and differs from auxiliary request VIII filed with the appellant-proprietor's response of 18 October 2011 to the appellant-opponent's appeal only in the deletion of several dependent claims. The board decides to admit auxiliary request 2 into the proceedings for the same reasons as set out in point 3.1 above for auxiliary request 1.

5.2 Article 123(3) EPC

Claim 1 of auxiliary request 2 differs from claim 1 of auxiliary request 1 in the addition of the feature "and

wherein said metastasis is not inoculated", "said metastasis" being the metastasis of a tumour of a given cell type which is to be treated by the medicament.

The board considers that this amendment does not overcome the Article 123(3) EPC problem set out above for claim 1 of auxiliary request 1, because the tumour that is inoculated does not have to be the primary tumour giving rise to the metastasis to be treated; it can be a further primary tumour which is not the one that gave rise to the metastasis to be treated, or a metastasis other than the one that is to be treated. Hence the claim does not require the medicament to be suitable for inoculating the primary tumour that gave rise to the metastasis to be treated, contrary to claim 1 as granted.

Consequently, auxiliary request 2 does not comply with Article 123(3) EPC.

6. Auxiliary request 3

6.1 Admissibility

Auxiliary request 3 was filed one month before the oral proceedings and differs from auxiliary request XII filed with the appellant-proprietor's response of 18 October 2011 to the appellant-opponent's appeal only in the deletion of dependent claims. The board decides to admit auxiliary request 3 into the proceedings for the same reasons as set out in point 3.1 above for auxiliary request 1.

6.2 Article 123(3) EPC

Claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 1 in that the one or more expressible nucleotide sequences comprised in the herpes simplex virus encode IL-12 or GM-CSF. This amendment does not overcome the Article 123(3) EPC problem set out above for claim 1 of auxiliary request 1, since the claim does also not require the medicament to be suitable for inoculating the primary tumour that gave rise to the metastasis to be treated, contrary to claim 1 as granted.

Therefore, auxiliary request 3 does not comply with Article 123(3) EPC.

7. Auxiliary requests 4 and 5 - admissibility

7.1 Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 1 in that it defines the cytokine as GM-CSF and the tumour cells as melanoma cells. Claim 1 of auxiliary request 5 contains the same amendments, in addition to the feature also present in claim 1 of auxiliary request 2 that "said metastasis is not inoculated".

7.2 Claims 1 of both auxiliary requests 4 and 5 were filed for the very first time one month before the oral proceedings, i.e. they were filed neither in the first-instance proceedings nor with the grounds of appeal or the reply to the appellant-opponent's grounds of appeal.

7.3 The board considers that these amendments introduce new issues with respect to Article 123(2) EPC, and their introduction into the proceedings would run counter to procedural economy.

7.4 The appellant-proprietor has submitted that the filing of auxiliary requests 4 and 5 aimed to address the comment by the board in its communication accompanying the summons that the allowability of dependent claim 15 of the main request under Article 123(2) EPC would be discussed at the oral proceedings.

The board fails to see how the filing of a new independent claim would address said comment concerning a dependent claim.

Moreover, the amendments in auxiliary requests 4 and 5 do not overcome the problem under Article 123(3) EPC as set out above with respect to auxiliary requests 1, 2 and 3.

7.5 Therefore, the board, in exercising its discretion under Article 13(1) RPBA, decides not to admit auxiliary requests 4 and 5 into the proceedings.

8. It follows from the above that none of the admissible claim requests fulfils the requirements of Article 123(2) and (3) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

K. Götz-Wein U. Oswald

Decision electronically authenticated