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Datasheet for the decision of 28 May 2024

Case Number: T 2342/22 - 3.3.04

Application Number: 11849221.4

Publication Number: 2651442

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Language of the proceedings: EN

Title of invention:
Universal anti-tag chimeric antigen receptor-expressing T cells and methods of treating cancer

Patent Proprietor:
University of Maryland, Baltimore

Opponents:
AvenCell Europe GmbH
Strawman Limited

Headword:
Universal CAR-T cells/UNIVERSITY of MARYLAND

Relevant legal provisions:
EPC Art. 84, 123(2), 87, 54, 56
RPBA 2020 Art. 13(2)

Keyword:
Main request and auxiliary requests 2,5,7,9,12,13 - lack of clarity
Priority - only partially valid
Auxiliary requests 1, 3, 4, 6, 8, 10, 11, 14 to 18, 20 to 22 - added matter
Auxiliary request 19 - admission (yes)
Auxiliary request 19 - lack of inventive step
Auxiliary request 23 - admission (no)

Decisions cited:
T 1523/07, T 2522/10

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Case Number: T 2342/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 28 May 2024

Appellant: (Patent Proprietor)	University of Maryland, Baltimore 620 West Lexington Street, 4th Floor Baltimore, MD 21201 (US)
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Appellant: (Opponent 1)	AvenCell Europe GmbH Tatzberg 47 01307 Dresden (DE)
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Appellant: (Opponent 2)	Strawman Limited Orchard Lea Horns Lane Combe, Witney Oxfordshire OX29 8NH (GB)
Representative:	Potter Clarkson Chapel Quarter Mount Street Nottingham NG1 6HQ (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 25 August 2022 concerning maintenance of the European Patent No. 2651442 in amended form.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	O. Lechner
	A. Bacchin

Summary of Facts and Submissions

I. The appeals by the patent proprietor and the two opponents lie from the opposition division's interlocutory decision that the patent as amended in the form of auxiliary request 8 submitted during the oral proceedings on 15 June 2022 and the adapted description met the requirements of the EPC.

As all parties have filed an appeal, they are referred to below according to their roles in the opposition proceedings.

II. The patent was granted on European patent application No. 11 849 221.4, which had been filed as an international application published as WO 2012/082841 (the "application as filed") and claiming priority from US 61/422,681 (document D3, filed on 14 December 2010).

III. In its interlocutory decision, the opposition division held that the claims of the main request and auxiliary requests 2 to 6 were not clear (Article 84 EPC), that the set of claims according to main request "a" and according to auxiliary request 7 only enjoyed partial priority rights and lacked novelty under Article 54 EPC, that the set of claims according to auxiliary request 1 lacked an inventive step under Article 56 EPC, and that auxiliary request 8 (as filed during oral proceedings before the opposition division) complied with the requirements of the EPC.

IV. With its statement of grounds of appeal, the patent proprietor submitted sets of claims according to a main request (identical to the main request first filed on 15 June 2021) and auxiliary requests 1 to 15. Auxiliary

request 1 was newly filed with the statement of grounds of appeal. Auxiliary request 2 is identical to main request "a" filed on 10 June 2022, which itself is identical to auxiliary request 7 filed on 1 June 2022. Auxiliary request 3 was newly filed with the statement of grounds of appeal. Auxiliary request 4 is identical to auxiliary request 1 filed on 15 June 2021. Auxiliary request 5 is identical to auxiliary request 2 filed on 15 June 2021. Auxiliary request 6 was newly filed with the statement of grounds of appeal. Auxiliary request 7 is identical to auxiliary request 3 filed on 15 June 2021. Auxiliary request 8 was newly filed with the statement of grounds of appeal. Auxiliary request 9 is identical to auxiliary request 4 filed on 15 June 2021. Auxiliary requests 10 and 11 were newly filed with the statement of grounds of appeal. Auxiliary request 12 is identical to auxiliary request 5 filed on 15 June 2021. Auxiliary request 13 is identical to auxiliary request 6 filed on 1 June 2022. Auxiliary request 14 was newly filed with the statement of grounds of appeal. Auxiliary request 15 is identical to auxiliary request 8, filed on 15 June 2022 during the oral proceedings before the opposition division, and was the request on the basis of which the opposition division decided, in its interlocutory decision, to maintain the patent in amended form.

The patent proprietor also provided adapted descriptions for the sets of claims according to the main request (filed with the statement of grounds of appeal) and auxiliary request 15.

V. All parties replied to the statements of grounds of appeal.

VI. In reaction to the board's communication under Article 15(1) RPBA, the patent proprietor submitted sets of claims according to auxiliary requests 16 to 22.

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

During the oral proceedings, the patent proprietor submitted a new set of claims according to auxiliary request 23.

At the end of the proceedings the Chairwoman announced the board's decision.

VIII. Claims 1 to 10 of the main request read:

"1. A formulation of tagged proteins and a therapeutically-effective population of anti-tag chimeric antigen receptor (AT-CAR) expressing T cells, wherein the protein is an antibody or an antigen-binding fragment thereof which binds a tumor-associated antigen (TAA) and the AT-CAR comprises a tag-binding domain, a transmembrane domain, and a T cell activation domain, wherein the tag-binding domain is an antibody or an antigen-binding fragment that is a single chain variable fragment (scFv) and wherein the AT-CAR-expressing T cells bind the tag of the tagged proteins and induce cancer cell death, for use in a combination therapy for treating cancer in a subject wherein said formulation of tagged proteins and said population of (AT-CAR)-expressing T cells are both administered to the subject, thereby treating cancer in the subject.

2. The formulation of tagged proteins and therapeutically-effective population of AT-CAR-

expressing T cells for use as claimed in claim 1, wherein the tag is selected from the group consisting of fluorescein isothiocyanate (FITC), streptavidin, biotin, peridinin chlorophyll protein complex, green fluorescent protein, phycoerythrin (PE), horse radish peroxidase, palmitoylation, nitrosylation, alkalanine [*sic*] phosphatase, glucose oxidase, and maltose binding protein.

3. The formulation of tagged proteins and therapeutically-effective population of AT-CAR-expressing T cells for use as claimed in claim 1 or 2, wherein the tag-binding domain specifically binds FITC, biotin, PE or streptavidin.

4. The formulation of tagged proteins and therapeutically-effective population of AT-CAR-expressing T cells for use as claimed in any one of claims 1 to 3, wherein the T cell activation domain comprises the cytoplasmic region of CD28, the cytoplasmic region of CD137 (41BB) and the cytoplasmic region of CD3ζ.

5. The formulation of tagged proteins and therapeutically-effective population of AT-CAR-expressing T cells for use as claimed in any one of claims 1-4, wherein the formulation(s) of tagged proteins are to be administered to the subject prior to administration of the therapeutically-effective population(s) of AT-CAR-expressing T cells.

6. The formulation of tagged proteins and therapeutically-effective population of AT-CAR-expressing T cells for use as claimed in any one of claims 1-5, wherein the formulation of tagged proteins and the therapeutically-effective population of AT-CAR-

expressing T cells are to be administered to the subject in any order.

7. The formulation of tagged proteins and therapeutically-effective population of AT-CAR-expressing T cells for use as claimed in any one of claims 1-6, wherein AT-CAR-expressing T cell binding to the tagged proteins induces cytolytic activation of the T cells.

8. The formulation of tagged proteins and therapeutically-effective population of AT-CAR-expressing T cells for use as claimed in any one of claims 1-7, wherein the subject is a human.

9. The formulation of tagged proteins and therapeutically-effective population of AT-CAR-expressing T cells for use as claimed in any one of claims 4-8, wherein the antigen-binding fragment that is the tag binding domain is a single chain variable fragment (scFv) that specifically binds FITC, biotin, PE or streptavidin.

10. Use of a formulation of tagged proteins as defined in claim 1 or 2 and a therapeutically-effective population of AT-CAR-expressing T cells as defined in any one of claims 1, 3, 4 or 9 for the preparation of a medicament for treating cancer in a subject, wherein said treatment is by a method as defined in any one of claims 1, 5, 6, 7 or 8."

Auxiliary request 1 differs from the main request only in that "formulation(s)" and "population(s)" in claim 5 have been amended to "formulation" and "population". In addition, in auxiliary request 1, claim 6 is dependent

on claims 1 to 4 (as opposed to claims 1 to 5 in the main request).

Auxiliary request 3 differs from auxiliary request 1 by the deletion of claim 6 and the corresponding adjustment of claim dependencies.

Claim 1 of auxiliary request 19 reads (with amendments compared to claim 1 of the main request underlined by the board):

"1. A formulation of tagged proteins and a therapeutically-effective population of anti-tag chimeric antigen receptor (AT-CAR) expressing T cells, wherein the protein is an antibody or an antigen-binding fragment thereof which binds a tumor-associated antigen (TAA) and the AT-CAR comprises a tag-binding domain, a transmembrane domain, and a T cell activation domain, wherein the tag-binding domain is an antibody or an antigen-binding fragment that is a single chain variable fragment (scFv) and wherein the AT-CAR-expressing T cells bind the tag of the tagged proteins and induce cancer cell death, for use in a combination therapy for treating cancer in a subject, wherein cells of said cancer express said TAA and wherein said formulation of tagged proteins and said population of (AT-CAR)-expressing T cells are both administered to the subject, thereby treating cancer in the subject."

For reasons of conciseness, the claims corresponding to claims 1, 5 and 6 of the main request in auxiliary requests 2, 4 to 18 and 20 to 22 are not reported in the text of the decision; instead, reference is made to the electronic file.

Claim 1 of auxiliary request 23 reads:

"1. A formulation of tagged proteins and a therapeutically-effective population of anti-tag chimeric antigen receptor (AT-CAR) expressing T cells, wherein the protein is an antibody or an antigen-binding fragment thereof which binds a tumor-associated antigen (TAA) and the AT-CAR comprises a tag-binding domain, a transmembrane domain, and a T cell activation domain, wherein the tag-binding domain is an antibody or an antigen-binding fragment that is a single chain variable fragment (scFv) and wherein the AT-CAR-expressing T cells bind the tag of the tagged proteins and induce cancer cell death, for use in treating cancer in a subject, wherein cells of said cancer express said TAA and wherein said formulation of tagged proteins are [*sic*] to be administered to the subject prior to administration of the therapeutically-effective population of (AT-CAR)-expressing T cells, thereby treating cancer in the subject."

IX. Reference is made to the following documents:

D3: US 61/422,681, filed on 14 December 2010, 4 pages

D8: B. Clémenceau et al., Blood 107(12), 2006, 4669-4677

D9: S. Ang et al., Molecular Therapy 19, Supplement 1, 2011, S137-S138

D53: US 2008/0003225 Al

X. The patent proprietor's arguments relevant to the decision, can be summarised as follows.

(a) Main request and auxiliary requests 2, 5, 7, 9, 12 and 13

Clarity - Article 84 EPC

Claim 5 - main request and auxiliary requests 2, 7, 12 and 13

Claim 5 had been objected to for lack of clarity due to its reference to "formulation(s)" and "population(s)", whereas claim 1 uses the singular. This was an obvious error, and dependent claim 5 would be read as referring to a formulation and a population, consistent with independent claim 1. On a normal reading, no clarity issue arose.

Claim 6 - main request and auxiliary requests 5, 7 and 9

The inconsistency between claim 5 and claim 6 regarding the order of administration of tagged protein and AT-CAR T cells was not commented on by the patent proprietor.

(b) Auxiliary request 3

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

Auxiliary request 3 was identical to auxiliary request 2 which had been filed during the opposition proceedings as main request "a" on 10 June 2022 and auxiliary request 7 on 1 June 2022, except that the back reference in claim 5 had been corrected.

Amendments - Article 123(2) EPC

Auxiliary request 3 differed from the main request only in the correction of plural to singular terms in claim 5. In auxiliary request 3, claim 6 was deleted. These amendments did not give rise to added subject-matter concerns.

(i) Claim 1 - tumour associated antigen (TAA) being expressed on a cancer cell

In agreement with the opposition division's findings in point 30.6 of the decision under appeal, there was no need to explicitly state in claim 1 that the tagged protein binds to a TAA expressed on/by cells of the cancer to be treated since this was necessarily implied. It was speculation that therapy might be achieved if the TAA is anywhere other than on the target cancer cells. This was an impermissible clarity objection. Moreover, paragraph [0031] of the application as filed referred to tagged proteins that bind to a TAA with no reference to target cells.

(ii) Claims 5 to 9 - combination of features

Claim 5 depended on, *inter alia*, claim 2 (defining specific tags) and claims 3 and 4 (structural features of the AT-CAR). These combinations were disclosed in the application as filed as preferred embodiments. Paragraph [0048] identified the claimed tags as exemplary, while paragraph [0013] referred to the tag-binding and T cell activation domains as preferred features, consistent with the examples in paragraph [0071].

Furthermore, prior administration of tagged proteins was also disclosed as a preferred embodiment (paragraph [0074]) and illustrated in the examples. All combined features were individually disclosed as preferred and explicitly envisaged in combination, with no unallowable selection or added subject-matter.

The induction of cytolysis as provided in claim 6 of auxiliary request 3 was the aim of the invention and the mechanism by which CAR T cells acted.

Claim 7 of auxiliary request 3 referred to the treatment of humans - which was clearly the preferred target for the treatment. As noted by appellant 2, CAR T cells were intended for human treatment.

A basis for claim 8 could be found in paragraphs [0013] and [0038] of the application as filed.

Claim 9 of auxiliary request 3 had the same scope as the claims it referred to but was drafted in the Swiss-style claim format.

(c) *Auxiliary requests* 1, 4, 6, 8, 10, 11, 14 to 18 and 20 to 22

Amendments - Article 123(2) EPC

No arguments under Article 123(2) EPC were put forward on auxiliary requests 1, 4, 6, 8, 10, 11, 14 to 18 and 20 to 22 that go beyond those discussed for auxiliary request 3.

(d) Auxiliary request 19

Admission - Article 13(2) RPBA

Auxiliary request 19 had been filed in reaction to objections under Article 123(2) EPC raised for the first time in point 17 in the communication of the Board of Appeal pursuant to Article 15(1) of the RPBA. It differed from auxiliary request 7 (first filed on 15 June 2021 as auxiliary request 3) admitted by the opposition division only by the deletion of contested claims 5 to 9 and thus did not represent an amendment to the case.

Priority - Article 87 EPC

Order of administration

The figure in document D3 showed a specific sequence, i.e. administration of the tagged antibody (step 3) followed by AT-CAR T cells (step 4). However, document D3 was not limited to this timing and supported the broader concept of combination therapy, consistent with its overall teaching.

Page 1 of document D3 disclosed combination therapy without specifying timing, and it would be implicit that both components were administered separately. As claim 1 did not define the order of administration, this feature was entitled to priority from document D3.

Novelty - Article 54 EPC

Document D9

Document D9 did not disclose the use of antigen-binding fragments as tagged proteins, nor the order of CAR T-cell administration. The subject-matter of claim 1 was therefore novel over the disclosure in document D9.

Document D8 and D53

Documents D8 (scientific article) and D53 (corresponding US patent application) were relevant irrespective of priority entitlement. They disclosed T cells expressing CD16-like receptors capable of mediating immune effector functions, particularly antibody-dependent cellular cytotoxicity (ADCC). However, these receptors were structurally and functionally distinct from the anti-tag antibodies or single-chain variable fragments (scFvs) of claim 1. As neither document disclosed an antibody or scFv as the tag-binding domain, they did not anticipate the claimed subject-matter.

Inventive step - Article 56 EPC

The patent proprietor made no comments on inventive step starting from document D9 as the closest prior art.

(e) Auxiliary request 23

Admission - Article 13(2) RPBA

To avoid an unnecessary proliferation of auxiliary requests in light of the different features discussed

under priority, the amendments in new auxiliary request 23 had not been made earlier. The opposition division, as well as the board in its preliminary opinion, considered the expression of the TAA by cancer cells to be implicit. However, the board's change of opinion on this issue necessitated the amendment, which was a simple clarification aimed at addressing an objection under Article 123(2) EPC. This amendment was independent of the remaining features in claim 1. Additionally, point 1.6.20 of the patent proprietor's statement of grounds of appeal reserved the right to file further claim requests combining the different features amended in the various claim requests submitted with the statement of grounds of appeal.

XI. The opponents' arguments relevant to the decision, can be summarised as follows.

(a) Main request and auxiliary requests 2, 5, 7, 9, 12 and 13

Clarity - Article 84 EPC

Claim 5 - main request and auxiliary requests 2, 7, 12 and 13

The granted claims referred to "one or more" populations of AT-CAR-T cells and formulations of tagged proteins, described as "multiplexing" in the decision under appeal. The main request was amended to "a population" and "a formulation", thus excluding multiplexing. However, claim 5 retained the plural forms, reinserting multiplexing and creating an inconsistency with claim 1.

Claim 6 - main request and auxiliary requests 5, 7 and 9

Claim 6 referred back to claim 5, which specified administration of the formulation prior to the AT-CAR T cells, thus defining a fixed sequence. However, claim 6 allowed administration in any order, contradicting the limitation in claim 5. This internal inconsistency resulted in a lack of clarity.

(b) Auxiliary request 3

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

Auxiliary request 3 could and should have been filed during the opposition proceedings. Auxiliary request 3 did not overcome the objections under Article 123(2) EPC raised during the opposition proceedings.

Amendments - Article 123(2) EPC

(i) Claim 1 - TAA being expressed on a cancer cell

There was no direct and unambiguous disclosure in the application as filed and especially in paragraph [0047] for a TAA not being expressed on a cancer cell.

(ii) Claims 5 to 9 - combination of features

In auxiliary request 3, claims 5 and 6 created claim dependencies that resulted in combinations not disclosed in the application as filed. For instance, claim 6 of auxiliary request 3 depended on claims 1 to 5, combining features such as a defined AT-CAR structure (claim 4), a specific tag (claim 2), and a

fixed administration order (claim 5). However, claim 7 of the application as filed depended only on claims 1 to 3, and no such combination was directly and unambiguously derivable from the application as filed.

Moreover, the administration order in claim 5 reflected a selection from three alternatives in original claims 16 to 18, with no preference indicated (paragraph [0060]). The resulting subject-matter thus extended beyond the content of the application as filed.

(c) *Auxiliary requests 1, 4, 6, 8, 10, 11, 14 to 18 and 20 to 22*

Amendments - Article 123(2) EPC - auxiliary requests 1, 4, 6, 8, 10, 11, 14 to 18 and 20 to 22

The subject-matter of auxiliary requests 1, 4, 6, 8, 10, 11, 14 to 18 and 20 to 22 extended beyond the content of the application as filed. Claim 1 of these requests defined a tagged protein comprising an antibody that binds to a TAA, without specifying that the TAA was expressed on the surface of the target cell. However, paragraph [0047] of the application as filed required expression on the cell surface, and no basis had been provided for omitting this feature.

Additionally, the dependencies of certain claims in, e.g. auxiliary requests 1, 4 and 15 (and others), resulted in feature combinations not directly and unambiguously derivable from the application as filed.

(d) Auxiliary request 19

Admission - Article 13(2) RPBA

Auxiliary request 19 had been filed very late, namely five weeks after the issue of the communication of the Board of Appeal pursuant to Article 15(1) of the RPBA and only two working days before the oral proceedings in appeal. This new claim request was not convergent. The objections to the deleted claims had been raised during the opposition proceedings and had been summarised in point 30.3.2 of the decision under appeal.

It was foreseeable that the board might reconsider both the opposition division's decision and its own preliminary opinion. Although the patent proprietor argued against the objections under Article 123(2) EPC, it had not responded by filing claim requests. Even if the amendments were minor, consisting merely of the deletion of dependent claims, the patent proprietor had failed to demonstrate exceptional circumstances, and no cogent reasons were provided to justify filing these requests.

Priority - Article 87 EPC

Priority document D3 did not disclose an example but described the invention in general terms.

Order of administration

Document D3 disclosed an administration sequence, i.e. tagged proteins followed by AT-CAR T cells ("Step 3" and "Step 4"; page 7, paragraph 3). In contrast, claim 1 allowed administration in any order. While the

sequence might have clinical relevance, document D3 did not directly and unambiguously disclose alternative administration regimes beyond the one explicitly described.

Novelty - Article 54 EPC

Document D9

Document D9 was citable prior art for subject-matter related to any order of administration, except for when the tagged proteins are administered prior to the AT-CAR T cells.

Document D9 disclosed a combination cancer therapy using fluorescein isothiocyanate (FITC)-conjugated therapeutic molecules (such as antibodies) specific for tumour antigens and CAR T cells specific for FITC. Thus, the subject-matter of claim 1 lacked novelty.

Documents D53

Document D53 disclosed a combination cancer therapy involving an antibody specific to a TAA and T cells expressing the extracellular domain of CD16 (low-affinity immunoglobulin gamma Fc receptor IIIa, FcγRIIIa), enabling antibody binding and ADCC activation (paragraphs [0039] to [0042], [0143], [0146]; claim 1). The chimeric receptors comprised the CD16 extracellular domain, a transmembrane domain, and an intracellular signalling domain from either Fc epsilon receptor I gamma (FcεRIγ, CD16/γ, paragraph [0043]) or CD3ζ (CD16/ζ, paragraph [0044]).

The extracellular domains of CD16/γ and CD16/ζ in document D53 fulfilled the definition of a tag-binding

domain as per claim 1 of auxiliary request 19. The patent in suit confirmed that FcεRIγ and CD3ζ triggered T-cell activation (paragraph [0037]). Thus, T cells expressing CD16/γ or CD16/ζ as in document D53 exhibited all features of the claimed AT-CAR T cells capable of binding to IgG1.

Claim 1 defined the tag-binding domain as an antibody or scFv with specificity for a tag, including tag-less antibodies such as IgG1 (paragraphs [0028] and [0029]). Functionally and structurally, the CD16-like receptors of document D53 and the antibody or scFv of claim 1 were equivalent. Therefore, the tag-binding domain in claim 1 did not confer novelty over document D53.

Document D8

Document D8 disclosed a similar therapeutic approach to document D53, involving rituximab in combination with T cells expressing the CD16/γ receptor for cancer treatment (abstract; page 4669, right-hand column, lines 8 to 11; page 4670, left-hand column, lines 54 to 60; page 4671, right-hand column, lines 5 to 7; page 4674, right-hand column, lines 36 to 39). Consequently, at least claim 1 lacked novelty over document D8 for the same reasons as outlined for document D53.

Inventive step - Article 56 EPC

Document D9 represented the closest prior art for features not entitled to partial priority based on document D3's disclosure, specifically, (i) for any administration order other than the tagged protein being administered prior to the CAR T cells and (ii)

for the tagged protein being an antibody's antigen-binding fragment.

The subject-matter of claim 1 differed from the disclosure in document D9 in that the order of administration allowed for either simultaneous administration of the tagged protein and CAR T cells or administering the CAR T cells before the tagged protein.

The patent disclosed only an effect for a treatment comprising the administration of the tagged proteins to the subject prior to administration of the therapeutically effective population of AT-CAR-expressing T cells. No technical effect had been provided for any other order of administration.

The objective technical problem was the provision of an alternative administration regimen.

Starting from the disclosure of document D9, it would have been obvious for a person skilled in the art to arrive at the two possible orders of administrations.

(e) Auxiliary request 23

Admission - Article 13(2) RPBA

The amendments in this new auxiliary request addressed the added-matter objections under Article 123(2) EPC discussed for previous claim requests. They also addressed the objection of lack of a valid priority claim and the finding of partial priority for auxiliary request 19. Both objections were raised in and have been discussed since the opposition proceedings, so the patent proprietor should have filed any such amendment

earlier in the proceedings. The board's change of opinion on the objection under Article 123(2) EPC did not constitute exceptional circumstances within the meaning of Article 13(2) RPBA. Auxiliary request 23 was not to be admitted into the proceedings.

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

(a) The appellant I (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of a set of claims according to the main request or any one of auxiliary requests 1 to 15, all filed with the statement of grounds of appeal or any one of auxiliary requests 16 to 22 as filed by letter dated 23 May 2024, or auxiliary request 23 as filed during the oral proceedings in appeal.

(b) The appellants II and III (opponents 1 and 2) requested that the decision under appeal be set aside and that the patent be revoked. The opponents also requested that auxiliary requests 1, 3, 6, 8, 10, 11, 14 and 23 not be admitted. Opponent 1 in addition requested that auxiliary requests 2 and 13 not be admitted. Opponent 2 further objected to the admission of auxiliary requests 16 to 22.

Reasons for the Decision

1. The opponents objected to the admission of some auxiliary requests (see point XII.(b) above). In view of the conclusion reached in substance, no detailed reasons are provided for the admission of these requests in the current decision. For

auxiliary request 19 and its admission, see the reasons provided in points 27. to 34. For the non admission of auxiliary request 23, see the reasons provided in points 51. to 59.

Main request and auxiliary requests 2, 5, 7, 9, 12 and 13

Clarity - Article 84 EPC

One or a plurality of formulation(s) or population(s) - claim 5 - main request and auxiliary requests 2, 7, 12 and 13

2. Claim 1 of the main request relates to "[a] formulation of tagged proteins and a therapeutically-effective population of anti-tag chimeric antigen receptor (AT-CAR) expressing T cells [...] wherein said formulation of tagged proteins and said population of (AT-CAR)-expressing T cells are both administered". The claim exclusively uses the singular form of the terms "formulation" and "population".

Claim 5, on the other hand, relates to "[t]he formulation of tagged proteins and therapeutically-effective population of AT-CAR-expressing T cells for use as claimed in any one of claims 1 to 4, wherein the formulation(s) of tagged proteins are to be administered to the subject prior to administration of the therapeutically-effective population(s) of AT-CAR-expressing T cells."

3. The terms "formulation(s)" and "population(s)" were used in the granted set of claims. However, claim 1 as granted related to "[o]ne or more formulations of tagged proteins and one or more therapeutically-effective populations of anti-tag chimeric antigen receptor (AT-CAR) expressing T cells". The clarity

issue results from the amendments carried out in claim 1 and is thus open to examination for compliance with the requirements of Article 84 EPC (G 3/14, Catchword).

4. The optional plural language used in claim 5, i.e. "formulation(s)" and "population(s)", is inconsistent with the singular language, i.e. "said formulation" and "a population", used in claim 1 of the main request and creates ambiguity when interpreting the claims.

5. Thus, claim 5 of the main request lacks clarity within the meaning of Article 84 EPC. The same clarity objection applies to claim 5 of auxiliary requests 2, 7, 12 and 13.

Order of administration - claim 6 - main request and auxiliary requests 5, 7 and 9

6. Claim 5 of the main request specifies that the formulation(s) of tagged proteins must be administered to the subject prior to the administration of the population(s) of AT-CAR-expressing T cells. Claim 6, which also depends on claim 5, on the other hand, states that the tagged protein formulation and the population of AT-CAR-expressing T cells can be administered to the subject in any order. This inconsistency results in a lack of clarity under Article 84 EPC.

7. The same inconsistency is present between claims 5 and 6 of auxiliary requests 5, 7 and 9, which thus also lack clarity within the meaning of Article 84 EPC.

Auxiliary request 3

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

8. Auxiliary Request 3 differs from the main request in the following ways. In claim 5, the plural terms "formulation(s)" and "population(s)" have been amended to the singular "formulation" and "population", respectively. Claim 6 of the main request has been deleted, and the claim numbering and dependencies have been adjusted accordingly. Thus, auxiliary request 3 overcomes the clarity objections raised against claims 5 and 6 of the main request (see points 2. to 4. and 6. above).

9. The opponents argued that auxiliary requests 3 should not be admitted since it was late filed and also gave rise to added-matter problems under Article 123(2) EPC, as in the higher-ranking claim requests.

10. The board is of the opinion that since auxiliary request 3 was filed in reaction to a clarity objection raised at the oral proceedings before the opposition division, it was, as a rule, legitimate to file it with the statement of grounds of appeal. The mere existence of an objection under Article 123(2) EPC against a feature in a claim request is, in the current circumstances, not to be considered as such prejudicial to its admission. In fact, none of the parties could know how the board would decide on the issue, which pertained to the merits of the current appeal. Consequently, the board decided to admit auxiliary request 3 into the proceedings (Article 12(4) and (6) RPBA).

Amendments - Article 123(2) EPC

(i) Claim 1 - tumour associated antigen (TAA) being expressed on a cancer cell

11. The application as filed discloses the TAA being expressed by and on the target cell, i.e. a cancer cell. However, the subject-matter of claim 1 of auxiliary request 3 is not restricted to the TAA expressed by the target cell.

12. The patent proprietor indicated paragraphs [0031] and [0056] of the application as filed as providing a suitable basis. It stated that it was implicit to a person skilled in the art, as also argued by the opposition division, that the system must kill the cancer cell. Therefore, the skilled person would realise that the TAA must inevitably be expressed on the target cancer cell. Omitting a qualifier that was necessarily implied did not introduce a new technical teaching in breach of Article 123(2) EPC.

13. The board considers that paragraph [0031] of the application as filed relates exclusively to the requirements for the AT-CARs used, from which no general teaching on the properties of the TAA can be derived.

Paragraph [0056] of the application as filed describes methods for treating cancer, requiring that the tagged proteins bind to a cancer cell and that the AT-CAR-expressing T cells bind to the tagged proteins and induce cancer cell death. Binding of the tagged proteins to a cancer cell, however, requires that the target, i.e. the TAA, be expressed by the cancer cell.

Paragraphs [0047], [0049] and [0050] of the application as filed, which were relied upon by the patent proprietor, relate to the properties of tagged proteins. These paragraphs disclose a naked (tag-less) protein (such as an antibody) or an antibody that binds to a TAA or a tumour-specific antigen expressed by the target cell. Paragraph [0050] of the application as filed, which was also cited in this context, discloses that the tagged protein binds to the cancer cell, a process that requires the cancer cell to express the TAA.

14. Thus, all text passages relating to the tagged protein(s) and the mechanism leading to cancer cell death require that the TAA be expressed by the cancer cell.

15. In accordance with the case law of the boards, an implicit disclosure requires that the feature in question is the inevitable consequence of the features which are explicitly disclosed (see e.g. T 1523/07, Reasons 2.4 or T 2522/10, Reasons 4).

16. The board considers that the functional feature "wherein the AT-CAR-expressing T cells bind the tag of the tagged proteins and induce cancer cell death" does not allow a concrete technical feature to be read into the claimed subject-matter as implicitly present.

Therefore, the board concluded that omitting the requirement for cancer cells to express the TAA extends beyond the content of the application as filed.

17. Consequently, the subject-matter of claim 1 extends beyond the content of the application as filed within the meaning of Article 123(2) EPC.

(ii) Claims 5 to 9 - combination of features

18. Claim 4 (on which claim 5, *inter alia*, depends) relates to a CAR defined to comprise a T cell activation domain comprising the cytoplasmic regions of CD28, CD137 (41BB) and CD3ζ. When looking for a basis in the application as filed, this combination is the result of selecting from the options provided in claim 13 or paragraph [0013], i.e. "the activation domain comprises one or more of the cytoplasmic region of CD28, the cytoplasmic region of CD137 (41BB), OX40, HVEM, CD31; and FcRε".

The subject-matter of claim 5, which relates to the administration of the tagged proteins to the subject prior to administration of the therapeutically-effective population of AT-CAR-expressing T cells, requires an additional selection from three possibilities disclosed in the application as filed: claim 16 (tagged proteins are administered to the subject prior to administration of the therapeutically-effective population(s) of AT-CAR-expressing T cells), claim 17 (tagged proteins are administered to the subject concurrently) or claim 18 (tagged proteins are administered to the subject after administration of the therapeutically effective population(s) of AT-CAR-expressing T cells), or the corresponding paragraphs [0016] to [0018] of the description of the application as filed, namely that the tagged proteins are administered prior to the AT-CAR T cells.

Thus, when dependent on claim 4, the subject-matter of claim 5 requires a two-fold selection since none of claims 16 to 18 (and corresponding paragraphs [0016] to [0018] of the application as filed), dependent on

claims 1 to 3, specify a particular cytoplasmic domain composition. The resulting combination is not directly and unambiguously derivable from the application as filed.

19. Similarly, claims 6 to 9 of auxiliary request 3 depend on several of or all the preceding claims and thus involve combinations of features for which the application as filed does not provide direct and unambiguous disclosure. For example, claims 6 and 7 are based on the features of claims 20 (cytolytic activation of the T cells) and 21 (subject is human) of the application as filed, which are dependent on claims 1 to 3 but not, e.g. on claims 8 (tag-binding domain is an antibody or antigen-binding fragment) or 9 (tag-binding domain specifically binds FITC, biotin, PE, histidine or streptavidin). In auxiliary request 3, claims 6 and 7 depend on all preceding claims, thus creating new combinations of features not disclosed in this combination in the application as filed.

This results in a combination of features not directly and unambiguously derivable from the application as filed.

The same reasoning applies to claims 8 and 9, which also rely on dependencies that combine features from originally unrelated claims.

20. In the application as filed, paragraph [0048] mentions exemplary tags but does not link them to the cytoplasmic domains of claim 4 or the administration sequence of claim 5. Paragraph [0013] describes preferred domains and combinations but does not connect them to the administration order of claim 16 or the tagged proteins in paragraph [0074]. Paragraph [0074]

addresses prior administration but does not link it to the structural features of claims 3 and 4.

21. The examples of the application as filed do not explicitly combine specific tags, cytoplasmic domains, and an administration order as required by claims 6 to 9 and thus also do not provide a pointer towards the claimed subject-matter.

22. Thus, claims 5 to 9 contain subject-matter which extends beyond the content of the application as filed.

(iii) Admission of the new line of argument under Article 123(2) EPC

23. In view of the findings under points 11. to 22. above, the board does not need to decide on the patent proprietor's request not to admit the new line of argument submitted by opponent 1 under Article 123(2) EPC against claims 2 to 4 in view of their dependencies on claim 1 and against claim 1 in view of the combination of features which were only in original claims 5 and 7.

Auxiliary requests 1, 4, 6, 8, 10, 11, 14 to 18 and 20 to 22

Amendments - Article 123(2) EPC - auxiliary requests 1, 4, 6, 8, 10, 11, 14 to 18 and 20 to 22

(i) Claim 1 - TAA being expressed on a cancer cell

24. Claim 1 of auxiliary requests 1, 4, 6, 8, 10, 11, 14 to 18 and 20 to 22 also does not specify that the cancer cells express the TAA. Thus, the objection raised in points 11. to 16. against claim 1 of auxiliary

request 3 applies *mutatis mutandis* to claim 1 of these auxiliary requests.

(ii) Claims 4 to 10 - combination of features

25. The combination of features of claims 5 to 10 of auxiliary request 1; claims 5 to 9 of auxiliary requests 6, 8, 10, 11 and 14 is not directly and unambiguously derivable from the application as filed for the same reasons as provided for claims 5 to 9 of auxiliary request 3 in points 18. to 22. above.

26. Claim 4 of auxiliary requests 4 and 15, which depends on claim 1 comprising the feature "wherein said formulation of tagged proteins are [*sic*] to be administered to the subject prior to administration of the therapeutically-effective population of (AT-CAR)-expressing T cells" - i.e. the feature of claim 5 of auxiliary request 3 - introduces subject-matter that is not directly and unambiguously derivable from the application as filed, *mutatis mutandis* for the same reasons as set out in point 18. above for claim 5 of auxiliary request 3.

Analogously, the subject-matter of claims 5 to 8 of auxiliary requests 4 and 15 is not directly and unambiguously derivable from the application as filed, *mutatis mutandis* for the same reasons as set out in points 19. to 21. above for claims 6 to 9 of auxiliary request 3.

Auxiliary request 19

Admission - Article 13(2) RPBA

27. Auxiliary request 19 was filed after notification of the board's communication under Article 15(1) RPBA. Its admission into the appeal proceedings, which was objected to by the opponents, is subject to the provisions of Article 13(2) RPBA, in line with which amendments to a party's appeal case made after notification of a communication under Article 15(1) RPBA are, as a rule, not to be taken into account by the board unless there are exceptional circumstances justified with cogent reasons by the party concerned.

28. Claim 1 of auxiliary request 19 is identical to claim 1 of auxiliary request 7 filed with the statement of grounds of appeal, which was first filed as auxiliary request 3 on 15 June 2021 with the patent proprietor's observations in reaction to the notice of opposition. Auxiliary request 19 differs from auxiliary request 7 in that dependent claims 5 to 9 have been deleted.

29. It is therefore apparent that the newly filed auxiliary request 19 is based on an auxiliary request that was filed and decided upon in the first-instance opposition proceedings, except for the further deletion of the dependent claims. The board considers that the current amendment does not involve new issues to be considered (see also Case Law of the Boards of Appeal of the EPO, 10th edn., 2022, V.A.4.5.5.g)).

30. Opponent 2 nevertheless objected to the admission of auxiliary request 19, essentially for being late filed.

31. The relevant objections under Article 123(2) EPC concerning an undisclosed combination of features in the dependent claims, which necessitated the deletion of dependent claims, were raised in opponent 2's statement of grounds of appeal against claims 5 and 6 of auxiliary requests 1 and 8 underlying the decision under appeal. However, even though the technical features in claim 1 of the respective auxiliary requests 1 and 8 were different, the objections of added matter against claims 5 and 6, in view of their dependency on the respective claim 1, did not take these differences into account (see points 9.25 for auxiliary request 1 referring to the reasons for auxiliary request 8, provided in points 10.13 to 10.17). Thus, these objections were not sufficiently substantiated. Furthermore, with opponent 2's reply to the patent proprietor's statement of grounds of appeal, these objections were raised solely for auxiliary requests 4 and 15, which are identical to auxiliary requests 1 and 8 in the decision under appeal, by mere reference to the reasons provided in the statement of grounds of appeal (see opponent 2's reply pages 2 and 4).

32. Opponent 2's reply to the patent proprietor's statement of grounds of appeal mentioned that auxiliary requests 7 and 8 "*include added subject matter*" (page 3, first two full paragraphs). However, this objection was not substantiated (Article 12(3) RPBA).

33. Opponent 1 did not raise any corresponding added-matter objections in its statement of grounds of appeal or in its reply to the patent proprietor's statement of grounds of appeal.

34. The board considers that given the procedural history of objections pursuant to Article 123(2) EPC raised against the combination of features in the dependent claims, as explained above, auxiliary request 19 could, but not necessarily should, have been filed earlier. These objections were properly identified in such a way that the patent proprietor had reason to react only to the board's communication under Article 15(1) RPBA. These facts amount to exceptional circumstances justifying the deletion of dependent claims 5 to 9 only in reaction to the notification of the communication of the Board of Appeal pursuant to Article 15(1) of the RPBA. Consequently, auxiliary request 19 was admitted into the proceedings (Article 13(2) RPBA).

Priority - Article 87 EPC

35. The priority document of the patent in suit, document D3, discloses on the page entitled "*The Invention*" (text page 1) that the universal AT-CARs are composed of an antibody or single-chain variable fragment (scFv) specific to a tag conjugated to another protein or peptide, and include intracellular signalling domains with activation motifs comprising CD3ζ, 41BB (CD137) and CD28 intracellular sequences. The tag is described to be conjugated to a peptide or protein such as an antibody which exhibits high affinity to one or more molecules expressed on the target tissue cell, such as a cancer. Suitable tags are provided in Table 1 on text page 3. The last paragraph of the second text page, which is entitled "*Universal anti-tag chimeric antigen receptor (ATCAR)*" describes a four-step approach in which in step 1 immune cells (e.g. T cells) are modified to express the tag specific antibodies or scFvs; in step 2 a tag is conjugated to a protein or peptide such as an antibody; in step 3 the

tagged antibody is injected into patients (e.g. cancer patients) to bind to the tumour antigen on target cells; and in step 4 the AT-CAR T cells are injected into cancer patients and the AT-CAR binds to the tagged antibody that will activate the immune cell to eliminate the target cell.

36. Contrary to the appellant's line of argument, document D3 does not disclose a general concept of combination therapy irrespective of administration order. The only embodiment described — both in Figure 1 and the accompanying text — requires sequential administration, with the tagged antibody administered first (step 3) and AT-CAR T cells second (step 4). No other passage in document D3 describes or implies a different order of administration.

37. Thus, the subject-matter of claim 1 of auxiliary request 19 enjoys partial priority (of 14 December 2010) only for a combined treatment in which the tagged protein is administered prior to the AT-CAR T cells.

38. Since document D3 specifies the administration of the tagged antibody or antigen-binding fragment thereof prior to the AT-CAR T cells, the claimed priority of the patent in suit is not valid for at least the subject-matter relating to administration of the tagged antibody or antigen-binding fragment thereof concomitantly with or after administration of the AT-CAR T cells.

Novelty - Article 54 EPC

Document D9 - Article 54(2) EPC

39. The congress abstract document D9 was published in May 2011, i.e. between the priority date (14 December 2010) and the filing date (14 December 2011) of the patent in suit.

40. Document D9 discloses a CAR comprising an anti-FITC scFv fused to human CD28 and CD3ζ signalling endodomains. A transmembrane domain is not explicitly mentioned but is considered implicit to the generally known structure of a CAR. Tumours are targeted using FITC-conjugated therapeutic molecules such as monoclonal antibodies specific for one or more tumour antigen(s) of interest. This approach should allow a single infusion of CAR T cells to be adapted to the changing needs of the tumour microenvironment, as the CAR platform has tunable specificity, rather than generating a panel of CARs specific for a single antigen. In addition, it allows the mixing and matching of multiple FITC-conjugated adaptor molecules to simultaneously target different antigens in different cell types or to target cells expressing single antigens or combinations of antigens (see abstract). Document D9 does not provide direct and unambiguous disclosure of an order of administration for the tagged protein and the AT-CAR T cell.

41. The board does not agree with the opponents that any order of administration could be inferred from the following passage in document D9: "*We show that using adapter molecules allows for investigators to change the specificity of CAR' T cells, useful in cases of antigen escape variants in tumors under attack. This*

approach enables one infusion of CAR-T cells to be adapted to meet the changing needs of the tumor microenvironment as the CAR platform has tuneable specificity as opposed to generating a panel of CARs with specificity for a single antigen."

42. Since document D9 fails to disclose an order of administration not covered by the partial priority right conferred by the disclosure in document D3, the board considers that the disclosure of document D9 cannot anticipate the subject-matter of claim 1 within the meaning of Article 54 EPC.

Document D53 - Article 54(2) EPC

43. Document D53 discloses a method for enhancing antibody-dependent cellular toxicity (ADCC) comprising the administration of an effective amount of T cells expressing a CAR consisting of a chimeric CD16-like receptor (selected from CD16 receptors (a cell surface receptor able to bind to IgG1 and/or IgG3 and capable of mediating signals that suffice to induce immune effector functions and in particular ADCC, paragraph [0042]), CD16/γ chimeric receptors (extracellular domain of CD16 and the intracellular domain of FcεRIγ, paragraph [0043]) and CD16/ζ chimeric receptors (extracellular domain of CD16 and the intracellular domain of the T cell receptor zeta (TCRζ) chain, paragraph [0044], claim 1)). T cells expressing the CD16 CAR can bind to the constant region of antibodies via their CD16 receptors, activating in this way their mechanism of ADCC (paragraph [0039]). Administration of T cells expressing a CD16-like receptor should enhance the effect of immuno-therapeutic agents (such as tumour antigens (paragraph [0055], claims 6 and 7) or therapeutic monoclonal antibodies (paragraph [0056],

claims 6 and 8) via the enhancement of ADCC. The T cells expressing a CD16-like receptor are used for treating, e.g. cancer (see claims 11 and 12), optionally in combination with monoclonal antibody anti-cancer therapy (paragraphs [0064] and [0067]).

44. The CAR described in document D53 utilises the extracellular domain of CD16 as the tag-binding domain but not an antibody or an antigen-binding fragment of the antibody, such as an scFv. Therefore, the teaching of document D53 does not anticipate the subject-matter of claims 1 and 5.

Document D8 - Article 54(2) EPC

45. Document D8 relates to a similar disclosure as document D53 and discloses the humanised (anti-CD20) antibody rituximab and a T cell expressing a CAR consisting of the extracellular domain of FcγRIII (CD16) and the transmembrane and cytoplasmic domain of FcεRIγ (CD16/γ) for the treatment of cancer. The newly expressed Fc receptor enables the T cells to kill an autologous B-lymphoblastoid cell line (BLCL) coated with anti-CD20 mAb through ADCC (abstract, page 4669, right-hand column, lines 8 to 11; page 4670, left-hand column, lines 54 to 60; page 4671, right-hand column, lines 5 to 7; page 4674, right-hand column, lines 36 to 39).

46. As with document D53, there is no teaching that the tag-binding domain is an antibody or an antigen-binding fragment thereof such as an scFv. Therefore, the teaching of document D8 does not anticipate the subject-matter of claims 1 and 5.

Inventive step

Closest prior art

47. Document D9 is citable as a closest prior-art document for subject-matter relating to a combination therapy in which the tagged protein is administered concomitantly or after the AT-CAR T cells, i.e. for the claimed subject-matter of claim 1 for which the patent in suit does not enjoy priority from document D3 (see point 38. above).

48. A summary of the disclosure of document D9 is provided in point 40. above.

Difference, its technical effect and the objective technical problem

49. The subject-matter of claim 1 which does not enjoy priority from document D3 differs from the relevant disclosure of document D9 in that the tagged antibody or antigen-binding fragment thereof is administered concomitantly or after the AT-CAR expressing T cells.

The application as filed does not provide any technical effect for this difference.

The objective technical problem is the provision of an alternative administration regimen.

The claimed solution is as defined in claim 1.

Obviousness

50. Starting from document D9 as the closest prior art, which discloses the use of a FITC-tagged adapter

molecule in combination with AT-CAR T cells but does not specify an administration regimen, the skilled person would recognise that document D9 leaves open three alternative possibilities: administering the tagged adapter molecule prior to, simultaneously with or after the AT-CAR T cells.

As discussed in points 36. to 38., priority document D3 discloses only administration of the tagged antibody or antigen-binding fragment thereof prior to the AT-CAR T cells, which is one of the options encompassed by the disclosure of document D9. Since no unexpected technical effect is associated with any of these administration orders, the two remaining options, i.e. administering the tagged antibody or antigen-binding fragment thereof simultaneously with, or after the AT-CAR T cells, are equally viable alternatives. The arbitrary selection of one of them does not involve an inventive step.

Consequently, the subject-matter of claim 1 does not involve an inventive step.

Auxiliary request 23

Admission - Article 13(2) RPBA

51. In reaction to the board's decision on inventive step for auxiliary request 19 in view of document D9, the patent proprietor submitted a new set of claims according to auxiliary request 23 during the oral proceedings.

52. The admission of auxiliary request 23 into the appeal proceedings is subject to the discretion of the board,

which must be exercised pursuant to Article 13(2) RPBA (see point 27. above).

53. Claim 1 of auxiliary request 23 differs from claim 1 of auxiliary request 19 by specifying that the tagged protein must be administered prior to the AT-CAR T cells and thus addresses the findings that auxiliary request 19 enjoyed only partial priority, as discussed above in points 35. and 38.

Furthermore, claim 1 of auxiliary request 23 is identical to claim 1 of auxiliary requests 4 and 16, but with the additional feature that cells of the cancer to be treated must express the TAA. Compared to auxiliary request 4, dependent claims 4 to 7 were deleted. These amendments address the added-matter objections discussed in points 11. to 17. and 19. to 22. above.

Thus, auxiliary request 23 contains amendments that address, in combination, the objection on added matter concerning the TAA being expressed by the cancer cell and the objection to the validity of priority which led to the conclusion that only partial priority is enjoyed for the order of administration according to which the tagged protein is administered prior to the AT-CAR T cell. Both these objections were discussed in opposition proceedings and dealt with in the decision under appeal.

54. The objection regarding the omission of the feature specifying that the TAA must be expressed by the cells of the cancer to be treated was discussed during the opposition proceedings, and the opposition division decided on it in favour of the patent proprietor on the ground that the feature was implicitly disclosed (see

point 30.6 of the decision under appeal). The objection was reiterated in opponent 2's statement of grounds of appeal (see point 10.4) and, in response to it, the patent proprietor filed several auxiliary requests (see auxiliary requests 7, 8 and 19), in which claim 1 specifies that the cells of the cancer to be treated must express the TAA targeted by the tagged protein.

55. As regards the validity of the priority claim, the decision under appeal also indicates that the priority claim for the feature relating to the order of administration was a critical issue (see point 21.3.1 of the opposition division's decision). The patent proprietor addressed this in appeal by filing additional auxiliary requests (see auxiliary requests 4, 15, 16 and 22).

56. However, the patent proprietor did not file an auxiliary request like current auxiliary request 23, which addresses both objections in a combined manner, despite having reasons, and the opportunity, to do so earlier. A board may deviate from the opposition division's decision if it finds the arguments of another party more convincing. Waiting until the oral proceedings before the board to file amendments that address in a combined manner objections considered decisive since the opposition proceedings runs the risk that the board will not admit them.

57. The patent proprietor argued that, in the interest of conciseness, it had not submitted all possible permutations of the different claim requests. However, it had reserved the right in point 1.6.20 of its statement of grounds of appeal to combine the various amendments.

58. Although the board agrees that, depending on the circumstances, the filing of multiple auxiliary requests might be against procedural economy, no right of filing late requests can be reserved or derived from a general statement such as the one made in point 1.6.20 of the patent proprietor's statement of grounds of appeal. Such an unsubstantiated statement does not qualify as a cogent reason which could be considered an exceptional circumstance.

59. The board considers that a set of claims addressing the issues that the cancer cells must express the TAA and that the tagged protein must be administered prior to the AT-CAR T cells should have been filed earlier in the proceedings. Thus, auxiliary request 23 was not admitted into the proceedings (Article 13(2) RPBA).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

A. Wille M. Pregetter

Decision electronically authenticated