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**Datasheet for the decision  
of 4 February 2025**

**Case Number:** T 0143/23 - 3.3.04

**Application Number:** 14853953.9

**Publication Number:** 3057585

**IPC:** A61K31/351

**Language of the proceedings:** EN

**Title of invention:**

Pegylated drug-linkers for improved ligand-drug conjugate  
pharmacokinetics

**Patent Proprietor:**

Seagen Inc.

**Opponent:**

European Oppositions Limited

**Relevant legal provisions:**

EPC Art. 123(3), 123(2)

**Keyword:**

Amendments - extension of the protection conferred (no)



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**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 0143/23 - 3.3.04

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.04**  
**of 4 February 2025**

**Appellant:** Seagen Inc.  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 25 November  
2022 revoking European patent No. 3057585  
pursuant to Article 101(3)(b) EPC.**

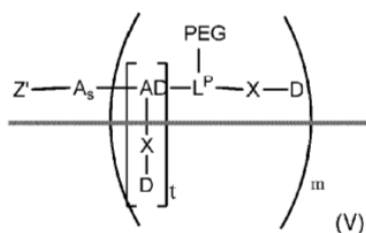
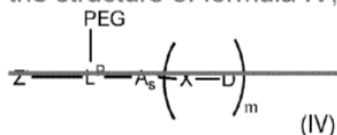
**Composition of the Board:**

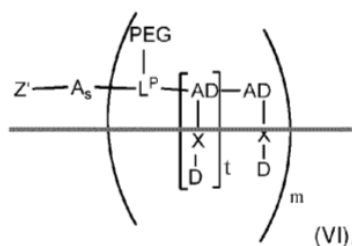
**Chairwoman** M. Pregetter  
**Members:** R. Hauss  
R. Romandini

## Summary of Facts and Submissions

- I. European patent No. 3 057 585 (patent in suit) was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.
- II. The patent proprietor requested that the patent be maintained as granted (main request). Over the course of the written opposition proceedings, it submitted amended sets of claims as auxiliary requests 1 to 32. A further amended set of claims was filed as auxiliary request 33 at the oral proceedings before the opposition division.
- III. Auxiliary request 33 consists of one claim (claim 1). It corresponds to claim 12 as granted, from which certain passages have been deleted. In the following marked-up representation of claim 1, the deleted parts are struck through, which allows its wording to be compared with that of claim 12 as granted.

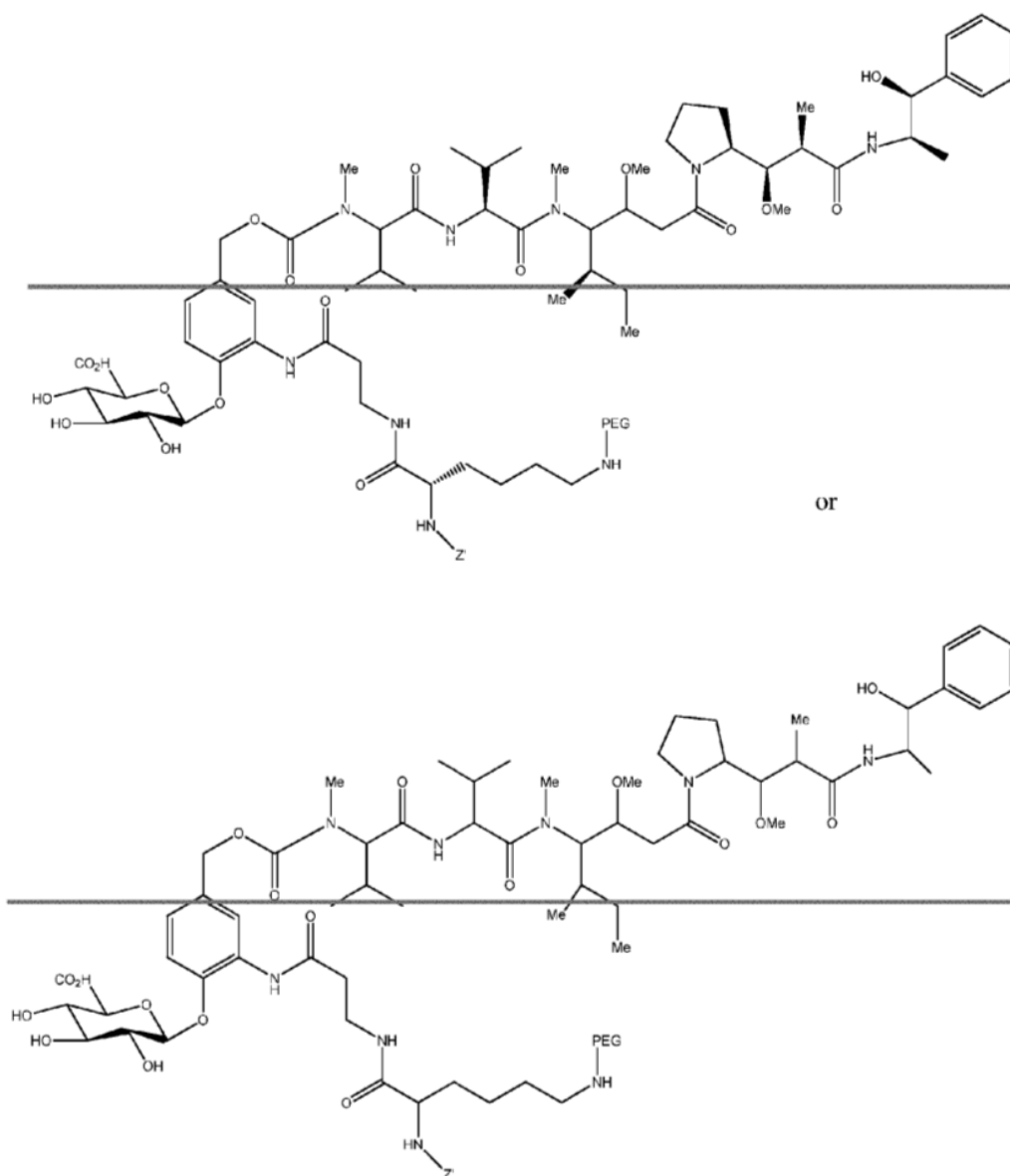
**12. A Drug-Linker Compound** ~~wherein the Drug-Linker compound is represented by the structure of formula IV, V, or VI:~~





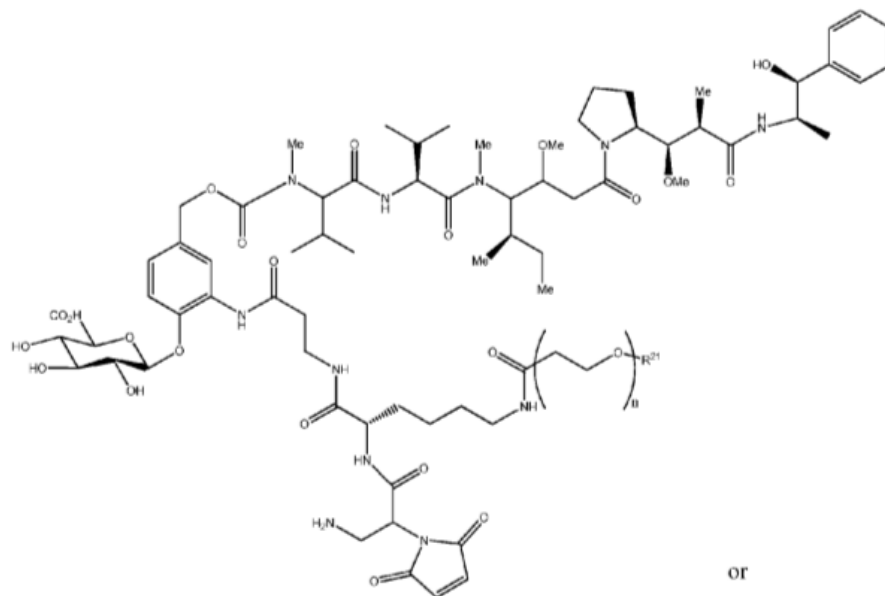
or a pharmaceutically acceptable salt thereof, wherein D, PEG, X, L<sup>p</sup>, A, AD, subscript t, subscript m, and subscript s are defined as in claim 1, Z' is a Stretcher Unit capable of forming a covalent attachment to a Ligand Unit;

particularly wherein the Drug Linker Compound has the structure of:

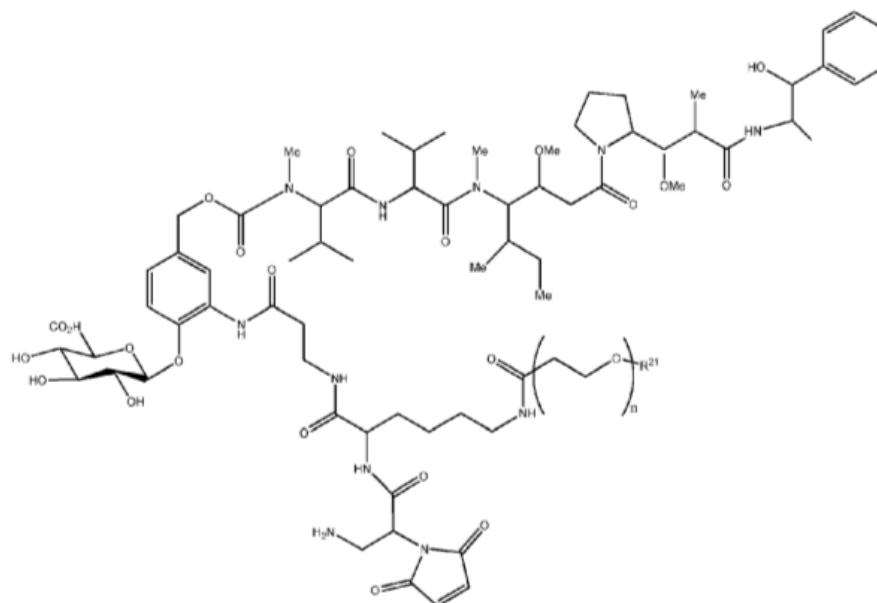


or a pharmaceutically acceptable salt thereof,  
or particularly wherein the Drug Linker Compound has the structure of:

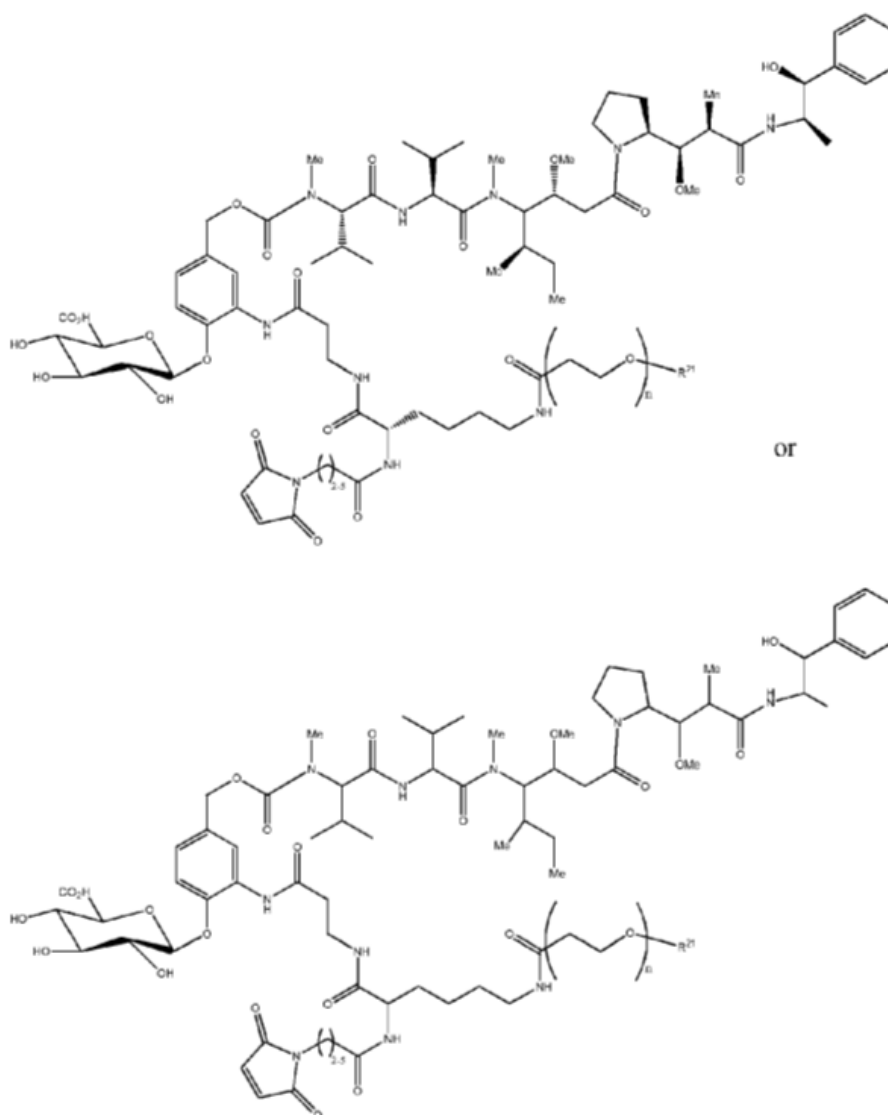




OR



or a pharmaceutically acceptable salt thereof, wherein R<sup>21</sup> is a PEG Capping Unit and subscript n is an integer ranging from 6 to 72, 8 to 72, or 8 to 24, particularly subscript n is 8, 12, or 24 and R<sup>21</sup> is a PEG Capping Unit, wherein the PEG Capping Unit is methyl, ethyl or propyl, or particularly wherein the Drug-Linker Compound has the structure of



or a pharmaceutically acceptable salt thereof, wherein R<sup>21</sup> is a PEG Capping Unit and subscript n ranges from 6 to 72, from 8 to 72, or from 8 to 24, particularly subscript n is 8, 12, or 24 and R<sup>21</sup> is a PEG Capping Unit, wherein the PEG Capping Unit is methyl, ethyl or propyl.

IV. The decision under appeal is the opposition division's decision revoking the patent in suit, announced on 13 October 2022 and posted on 25 November 2022. According to the decision under appeal, the opposition division admitted documents D22 and D23, *inter alia*. The subject-matter claimed in the main request and

auxiliary requests 1 to 32 was not allowable under Articles 100(b) and 83 EPC. After admitting auxiliary request 33, the opposition division ruled that this request was not allowable under Article 123(3) EPC.

- V. The patent proprietor (appellant) filed an appeal against this decision. With its statement setting out the grounds of appeal, the appellant maintained the main request and auxiliary requests 1 to 33 that were considered in the decision under appeal.
- VI. Over the course of the written appeal proceedings, the appellant filed documents D24 and D27, and the opponent (respondent) filed documents D25 and D26 as further evidence.
- VII. The board issued a summons to oral proceedings.
- VIII. A submission dated 27 June 2024 was filed by a third party.
- IX. In a communication under Article 15(1) RPBA issued in preparation for oral proceedings and advising the parties of its preliminary opinion, the board made the following points, *inter alia*:
- In light of the objections relating to insufficiency of disclosure and added subject-matter, the main request and auxiliary requests 1 to 32 were considered unallowable.
  - Claim 1 of auxiliary request 33, if adopted, would not be extending the protection conferred (Article 123(3) EPC).
  - The board was minded to remit the case to the opposition division on the basis of the sole claim in auxiliary request 33 (Article 111(1) EPC).

X. In response to the board's preliminary opinion, the appellant withdrew its main request and auxiliary requests 1 to 32.

XI. Oral proceedings before the board took place on 4 February 2025. The debate addressed the issue of whether auxiliary request 33 complied with the prohibition set out in Article 123(3) EPC.

XII. The board's decision relates to whether auxiliary request 33 complies with the requirements of Article 123 EPC.

XIII. The respondent's relevant arguments may be summarised as follows:

Claim 12 as granted would be understood by the person skilled in the art as providing a general definition of the claimed Drug-Linker Compounds by formulas (IV), (V) and (VI), followed by eight further Markush formulas representing more limited embodiments of this general definition.

This was because the formulation *"or particularly wherein the Drug-Linker Compound has the structure of ..."* chosen in claim 12 as granted indicated that the eight further Markush formulas were included as preferred embodiments of formulas (IV), (V) or (VI) rather than as separate alternative options.

The definition of formulas (IV), (V) and (VI) in claim 12 as granted included the following requirement:

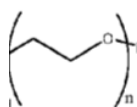
*"wherein D, PEG, X, L<sup>P</sup>, A, AD, subscript t, subscript m and subscript s are defined as in claim 1".*

In particular, the definition of the "PEG" moiety in claim 1 as granted included the requirement that the Polyethylene Glycol Unit and the Drug Unit be in a

parallel orientation and that the Polyethylene Glycol Unit mask the hydrophobicity of the hydrophobic Drug Unit.

It would be understood that this limitation equally applied to the embodiments represented by the eight further Markush formulas in claim 12 as granted.

The person skilled in the art would also understand that each Markush formula was directed to a broad range of compounds, that the unit rendered as



in the last four Markush formulas of claim 12 as granted was a PEG Unit, and that the definition of PEG according to claim 12 and, by back-reference, claim 1 as granted therefore had to apply to this unit, too.

Even if the functional definition relating to a masking function might have resulted in a confusing and complicated parameter, this masking function was presented in the patent as being at the core of the claimed invention. It was thus readily apparent that it must be present as a limiting feature in all the embodiments of the invention according to claim 12 as granted, including the embodiments represented by the eight further Markush formulas in this claim.

For these reasons, the functional limitation requiring a masking effect brought about by parallel orientation also applied to those embodiments of formulas (IV), (V) and (VI) described by the eight more restricted Markush formulas present in claim 12 as granted, including the four Markush formulas now retained in amended claim 1 of auxiliary request 33.

The amendment deleting formulas (IV), (V) and (VI) removed this limitation and, as a consequence, had the effect of broadening the definition of the Markush formulas in auxiliary request 33 in comparison with their more limited scope in claim 12 as granted.

XIV. The appellant's relevant arguments may be summarised as follows:

The individualised Markush formulas now retained in claim 1 of auxiliary request 33 were fully defined in claim 12 as granted by their chemical structures without any reference to formulas (IV) to (VI) or to the associated generic groups D, PEG, X, L<sup>P</sup>, A and AD. Therefore, any limitations in the definitions of D, PEG, X, L<sup>P</sup>, A or AD applied only to formulas (IV) to (VI) but not to these four individualised Markush formulas. The expression "particularly" used in claim 12 as granted also confirmed, in any case, that the individualised structural formulas were specific embodiments of the preceding general definition. Since the definition of the compounds in claim 1 of auxiliary request 33 had not changed in comparison with claim 12 as granted, there could be no extension in scope.

XV. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further examination of the grounds for opposition on the basis of auxiliary request 33, filed on 13 October 2022 during the oral proceedings before the opposition division.

The appellant furthermore requested that document D27 be admitted. The appellant also requested that the content of documents D22 and D23 not be taken into consideration, and that the following not be admitted:

- documents D25 and D26

- any written submissions by the respondent concerning the patentability of auxiliary request 33 under Article 100(a) EPC and filed after its reply to the appeal
- the third-party observations dated 27 June 2024

XVI. The respondent requested that the appeal be dismissed or, in the alternative, that the case be remitted to the opposition division for consideration of the objections raised under Article 100(a) EPC.

If the board were to consider the objections raised under Article 100(a) EPC, the respondent wished to rely on the arguments it made during the opposition proceedings.

The respondent furthermore requested that documents D22 and D23 be taken into consideration, that documents D25 and D26 be admitted, and that documents D24, D27 and the appellant's associated arguments not be admitted.

## **Reasons for the Decision**

1. Extension of protection (Article 123(3) EPC)
  - 1.1 Claim 1 of auxiliary request 33, the only claim of this request, relates to a "Drug-Linker Compound". It corresponds to claim 12 as granted but differs from it in that the definition of the Drug-Linker Compound by general formulas (IV), (V) and (VI) and the four following Markush formulas have been deleted. Only the last four Markush formulas in claim 12 as granted have been retained, without any modification, in the amended claim 1 of auxiliary request 33 (see point III. above).

- 1.2 According to Article 123(3) EPC, a European patent may not be amended in such a way as to extend the protection it confers.
- 1.3 If, in claim 12 as granted, the last four Markush formulas were claimed as separate alternatives, the amendment claiming the identical formulas in claim 1 of auxiliary request 33 would not extend the protection conferred.
- 1.4 Both parties maintained, however, that the last four Markush formulas in claim 12 as granted must be understood not as separate alternatives but as (preferred) embodiments of the general definition of the Ligand-Drug Conjugate according to formulas (IV), (V) or (VI) in the introductory part of that claim. While the board is not bound by this understanding, it is taken into account in the following considerations.
- 1.5 The issue in dispute was whether, in claim 12 as granted, the preceding definition by formulas (IV), (V) and (VI) imposed any limitation on the four Markush formulas in question.
- 1.6 The respondent argued that such limitations indeed existed with regard to the PEG Unit and its function. Still according to the respondent, as claim 1 of auxiliary request 33 no longer contained such limitations, this claim, if adopted, would have the effect of extending the protection conferred in comparison with the scope of the corresponding Markush formulas in claim 12 as granted.

- 1.7 The board arrived at a different conclusion, for the following reasons.
- 1.7.1 The last four Markush formulas in claim 12 are defined structurally, without any reference to formulas (IV), (V) or (VI) or their generic moieties D, PEG, X, L<sup>P</sup>, A and AD.
- 1.7.2 The respondent nevertheless argued that the definition of the PEG Unit provided in the context of formulas (IV), (V) and (VI) of claim 12 as granted must also apply to the last four Markush formulas in this claim with a limiting effect.
- 1.7.3 According to claim 12 as granted, PEG is as defined in claim 1. According to claim 1 as granted, this definition is structural (see the patent in suit, claim 1, page 165, line 43):
- "PEG is the Polyethylene Glycol Unit, wherein the PEG Unit comprises from 4 to 72 (OCH<sub>2</sub>CH<sub>2</sub>) subunits".*
- 1.7.4 The skeletal representation of the relevant polyethylene glycol moieties in the last four Markush formulas in claim 12 as granted translates to R<sup>21</sup>-(OCH<sub>2</sub>CH<sub>2</sub>)<sub>n</sub>-CO-, where R<sup>21</sup> is a capping unit. The subscript "n" is defined as an integer ranging from 6 to 72, which means that there are 6 to 72 (OCH<sub>2</sub>CH<sub>2</sub>) subunits (see point III. above).
- 1.7.5 This entire range, by its own definition, is within the scope of the definition of the PEG Unit in claim 1 as granted in any case.
- 1.7.6 In fact, the functional limitations on which the respondent's objection is based (see point XIII. above) are not found in the definition of the PEG Unit, but

instead in the definition of the so-called "Parallel Connector Unit", L<sup>P</sup>.

1.7.7 According to claim 12 as granted, L<sup>P</sup> is as defined in claim 1. According to claim 1 as granted (see the patent in suit, claim 1, page 165, lines 46 to 49),

*"L<sup>P</sup> is the Parallel Connector Unit, which serves to connect the Ligand Unit to the Polyethylene Glycol Unit and the hydrophobic Drug Unit so that the Polyethylene Glycol Unit and the Drug Unit are in a parallel orientation, wherein the Polyethylene Glycol Unit in said parallel orientation masks the hydrophobicity of the hydrophobic Drug Unit".*

1.7.8 However, the last four Markush formulas in claim 12 as granted do not make reference to the L<sup>P</sup> Unit and its generic definition. Instead, the part of the structure that links the PEG moiety to the drug, which according to the terminology used in the patent in suit involves the Parallel Connector Unit L<sup>P</sup> and the Releasable Assembly Unit X, is fully defined by a chemical structure in each of the four Markush formulas in question. Hence, the generic definition of the L<sup>P</sup> Unit cannot confer any limitation on the definition of the last four Markush formulas in claim 12 as granted.

1.7.9 The respondent stressed that these Markush formulas still related to a range of multiple compounds, but did not give any reason why any of these would not meet the functional requirements in question, especially in a situation in which the last four Markush formulas in claim 12 as granted all have the same drug moiety, namely MMAE (monomethyl auristatin E) conjugated via its N-terminus (see paragraph [0210] of the patent in suit), the part linking the drug to the polyethylene

glycol moiety is fixed, and the polyethylene glycol moiety has a fixed minimum of (OCH<sub>2</sub>CH<sub>2</sub>) subunits.

- 1.8 For these reasons, the amendments introduced in auxiliary request 33 do not extend the protection conferred by the patent within the meaning of Article 123(3) EPC.
- 1.9 The amendment deleting a partly functional definition in favour of a purely structural definition of the Drug-Linker Compound is also in line with the established case law of the Boards of Appeal, according to which the use of functional features is only permissible if the technical features in question cannot otherwise be defined more precisely without unduly restricting the scope of the invention.
2. Added subject-matter (Article 123(2) EPC)
  - 2.1 The respondent did not raise any objections under Article 123(2) EPC against auxiliary request 33.
  - 2.2 The board does not have any objections in this regard either.
3. Requests relating to the admittance of evidence and other submissions
  - 3.1 The parties did not rely on any of documents D22, D23, D24, D25, D26 or D27 for their reasoning concerning the compliance of auxiliary request 33 with the prohibition under Article 123(3) EPC. As a consequence, no decision was required on whether the opposition division correctly exercised its discretion in taking documents D22 and D23 into account, or on whether any of documents D24 to D27 should be admitted.

- 3.2 Since the board did not decide on the allowability of auxiliary request 33 under Article 100(a) EPC, a decision on the admittance of the respondent's submissions on this issue was not required.
- 3.3 Since the observations filed by a third party during the appeal proceedings (see point VIII. above) did not address the compliance of auxiliary request 33 with Article 123 EPC, a decision on their admittance was not required.
4. Remittal of the case (Article 111(1) EPC)
- 4.1 The decision under appeal concerns only the objections raised under Articles 100(c), 123(2), 100(b) and 83 EPC against the main request and auxiliary requests 1 to 32 and the objections raised under Article 123(3) EPC against auxiliary request 33.
- 4.2 Since the appellant withdrew the higher-ranking requests (see point X. above), the only issue remaining as the subject of the appeal proceedings was the compliance of auxiliary request 33 with Article 123(3) EPC.
- 4.3 In view of the finding that auxiliary request 33 complies with Article 123 EPC, the board considers it appropriate to remit the case to the opposition division. Remittal is justified because (i) the opposition division has not yet ruled on the objections relating to lack of novelty and inventive step (see point IV. above), and (ii) both parties requested it (see points XV. and XVI. above).

## 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 for further prosecution.

The Registrar:

The Chairwoman:



I. Aperribay

M. Pregetter

Decision electronically authenticated