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Case Number: T 1603/10 - 3.3.04

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Language of the proceedings: EN

Title of invention:
Tumor specific oligosaccharide epitopes and use thereof

Applicant:
Glykos Finland Oy

Headword:
Enzyme-based tumor targeting/GLYKOS

Relevant legal provisions:
EPC Art. 111(1), 123(2)

Keyword:
Amendments - allowable (yes)
Appeal decision - remittal to the examining division (yes)

Decisions cited:

Catchword:

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Case Number: T 1603/10 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 18 July 2016

Appellant: (Applicant)	Glykos Finland Oy Viikinkaari 6 00790 Helsinki (FI)
Representative:	Karvinen, Leena Maria Seppo Laine Oy Itämerenkatu 3 B 00180 Helsinki (FI)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 16 March 2010 refusing European patent application No. 03792440.4 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairwoman	G. Alt
Members:	M. Montrone
	M. Blasi

Summary of Facts and Submissions

I. This appeal was lodged by the applicant (hereinafter "the appellant") against the decision of the examining division to refuse European patent application No. 03 792 440 which was filed as an international application and published as WO 2004/017810 (hereinafter "the application as filed"). The title of the application is "*Tumor specific oligosaccharide epitopes and use thereof*".

II. In the decision under appeal the examining division held that the main and auxiliary request included subject-matter which extended beyond the content of the application as filed, contrary to Article 123(2) EPC. Regarding the main request, the examining divsion considered that the feature "*wherein said substance comprises UDP-GlcA*" in claims 1 and 38 was not disclosed in the application as filed. The same applied to the feature "*wherein the substrate is a monosaccharide modified by a chemoselective group*" of claim 32, the feature "*wherein the monosaccharide is transferred to terminal GlcNAc, or to an O-linked GlcNAc structure*" of claim 33, the transfer of a monosaccharide "*to a protein*" of claim 38, the subject-matter of claims 41 and 43, the feature "*when GlcNAc is part of the core structure the core is the glycan core excluding a terminal GlcNAc residue*" of claim 42 and the feature "*the use of a composition comprising UDP-Gal or UDP-Gal conjugated to polyethylene glycol*" of claim 45.

The subject-matter objected to in claims 32, 33, 38 and 41 to 43 of the main request was also present in the corresponding claims of the auxiliary request, which therefore also did not meet the requirements of Article 123(2) EPC.

III. With its statement of grounds of appeal, the appellant submitted a main and two auxiliary requests.

IV. In reply to a first communication of the board setting out its preliminary opinion that the subject-matter of several claims of the three claim requests contained added matter, the appellant filed a new main and two auxiliary requests and requested oral proceedings.

V. The board issued a summons to oral proceedings and informed the appellant in a subsequent second communication that none of the newly submitted claim requests met the requirements of Article 123(2) EPC. The appellant was also notified that if a claim request was filed that met the requirements of Article 123(2) EPC, the oral proceedings would be cancelled, the proceedings continued in writing, and the case remitted to the examining division for further prosecution.

VI. The appellant in reply submitted a new main request and two auxiliary requests which replaced all the requests on file.

Claims 1 to 7 of the main request read:

"1. A composition comprising
i) a nucleotide sugar capable of being transferred specifically to the surface of a pathogenic entity or malignant cell or tissue by a transferring enzyme making a covalent linkage between said nucleotide sugar and an acceptor structure of said surface, wherein said nucleotide sugar is conjugated to an immunologically active substance and/or a toxic substance, wherein said nucleoside sugar is UDP-Gal, UDP-GalNAc, UDP-Glc or UDP-GlcNAc and an immunologically active substance or a toxic substance is linked to carbon number 2 of the Gal,

GalNAc, Glc or GlcNAc residues of UDP-Gal, UDP-GalNAc, UDP-Glc or UDP-GlcNAc, respectively; and
ii) glycosyltransferase or transglycosylating enzyme;
for use as a medicine.

2. A conjugate for use in the treatment or diagnostics of cancer or tumor comprising a 2-modified monosaccharide derivative comprising a glycosidically linked nucleotide residue transferred in vitro to a terminal GlcNAc-antigen on cancer cells, tumor or a therapeutic protein by a glycosyltransferase enzyme.

3. The conjugate according to claim 2 for use in the treatment or diagnostics of cancer or tumor, wherein said 2-modified monosaccharide derivative is according to the formula UDP-GalN[-S]-D, wherein
S is an optional spacer group, and
D is a derivatizing group including molecular labels or a toxic agent, a prodrug or a prodrug releasing substance.

4. The conjugate according to claim 2 for use in the treatment or diagnostics of cancer or tumor, wherein said glycosyltransferase enzyme is a galactosyltransferase which is engineered to transfer effectively 2-modified monosaccharides.

5. The conjugate according to claim 2 for use in the treatment or diagnostics of cancer or tumor, wherein said 2-modified monosaccharide derivative is according to the formula C2 Nu-Hex(L-S-T) wherein Hex is Gal or Glc, Nu is a nucleotide activating the 2-modified monosaccharide, L is linking atom on carbon 2 of the hexose, S is a spacer group or nothing, and T is the group to be transferred.

6. The conjugate according to claim 5 for use in the treatment or diagnostics of cancer or tumor, wherein Nu is UDP, GDP, TDP or ADP.

7. The conjugate according to claim 6 for use in the treatment or diagnostics of cancer or tumor, wherein T is a chemoselective and protein/tissue compatible linking group."

VII. The board cancelled the scheduled oral proceedings.

VIII. The appellant's arguments submitted in writing may be summarised as follows. References below are to passages and claims in the application as filed.

Main request

Amendments (Article 123(2) EPC)

The subject-matter of claim 1 was based on claim 57.

The subject-matter of claim 2 was based on claims 46 and 53 in combination with the disclosure in lines 14 to 29 on page 26 and lines 20 to 38 on page 27.

The subject-matter of claim 3 was based on claim 48 in combination with the disclosure in lines 29 to 37 on page 27.

The subject-matter of claim 4 was based on claim 50 in combination with the disclosure in lines 1 to 17 on page 28.

The subject-matter of claims 5 and 6 was disclosed in lines 11 to 19 on page 29.

The subject-matter of claim 7 was derivable from lines 9 to 10 on page 30.

IX. The appellant requested that the decision under appeal be set aside and that the examination of the application be continued pursuant to Article 111(1) EPC.

Reasons for the Decision

Allowability of the appeal

1. As the claims and subject-matter objected to have been deleted, the amended main request overcomes all the reasons for refusal given in the decision under appeal. Therefore, the appeal is allowable.

Remittal (Article 111(1) EPC)

2. According to Article 111(1) EPC, "*Following the examination as to the allowability of the appeal, the Board of Appeal shall decide on the appeal. The Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution*."

3. For reasons of procedural economy, the board has decided in the present case to exercise its discretion in accordance with the first half of the second sentence of the provision cited above, and itself assessed the compliance with Article 123(2) EPC of the further amendments in the main request.

4. Given however that Article 123(2) EPC was the only issue dealt with in the decision under appeal, the board considered it appropriate to remit the case to the examining division for examination of the remaining patentability requirements.

Main request

Amendments (Article 123(2) EPC)

5. In the following, the references are to passages and claims in the application as filed.

6. The subject-matter of claim 1 can be derived from claim 57 reading "*A composition comprising an enzyme substrate, capable of being transferred specifically to a surface of a pathogenic entity or malignant cell or tissue by a transferring enzyme making a covalent linkage between said enzyme substrate and an acceptor structure of said surface, optionally conjugated to an immunologically active substance and/or a toxic substance for use as a medicine*". That "*glycosyl transferase*" or "*transglycosylating enzyme*" are transferring enzymes, that "*a nucleotide sugar*" is a substrate for these enzymes, and that "*immunologically active substance or the toxic substance* [...] *is linked to carbon number 2 or 6 of the Gal, GalNAc, Glc or GlcNAc residues of UDP-Gal, UDP-GalNAc, UDP-Glc or UDP-GlcNAc, respectively*" (underlining by the board) are conjugated to the nucleotide sugars, is disclosed in claims 59, 60 and 63 respectively, which are all dependent on claim 57.

7. The subject-matter of claim 2 can be derived from claims 46 and 53 which disclose in combination a "*Method of treatment or diagnosis of cancer or tumor comprising transferring a modified monosaccharide derivative to cancer cells or tumor or on a therapeutic protein by a glycosyl transferase* [...]".

8. Conjugates comprising 2-modified monosaccharide derivatives which are glycosidically linked to nucleotide residues are derivable from lines 28 to 30 on page 26 of the application reading: "*a glycosidically linked nucleotide residue. The preferred monosaccharide derivatives are 2-modified*". The transfer to terminal GlcNAc-structures is disclosed on page 26, lines 4 to 6 and 14: "*binding to the cancer or tumor specific oligosaccharide sequences* [...] *recognizing the terminal GlcNAc-structures*", *i.e.* by "*targetting* [sic] *terminal GlcNAc*". That this transfer occurs under *in vitro* conditions is derivable from page 27, lines 22 to 24 which teaches "*enzyme based therapeutic and diagnostic targeting and/or labeling terminal GlcNAc-residues in vivo or ex vivo*", since "*ex vivo*" is a synonym of "*in vitro*".

9. The subject-matter of claim 3 is derivable from page 26, lines 31 to 37 disclosing "*A preferred theraphautic* [sic] *or diagnostic monosaccharide derivative is UDP-GalN[-S]-D, wherein S is an optional spacer group, D is derivatizing group including molecular labels [...], or a toxic agent, prodrug or prodrug releasing substance as described for other cancer or tumor targetting* [sic] *methods*".

10. The subject-matter of claim 4 is disclosed on page 27, lines 4 and 5 reading "*A preferred enzyme to be used is*

a galactosyltransferase which is engineered to transfer effectively 2-modified monosaccharides".

11. Concerning the subject-matter of claim 5, page 29 reports in lines 11 to 16 that "*The invention is further directed to the nucleotide sugar conjugates for transferring specific substances T according to the invention according to the Formula C2: Nu-Hex(L-S-T) Wherein* [sic] *Hex, L, S and T are as above in Formula C1 and Nu is a nucleotide activating the carbohydrate conjugate according to the invention*" (underlining by the board).

With regard to the definition of Hex, L, S and T in the context of Formula C1, page 28 teaches in lines 26 to 29 that "*Wherein Hex is hexose preferably Gal or Glc, L is linking atom on carbon 2 of the hexose* [...] *S is spacer group or atom or nothing*".

12. The subject-matter of claim 6 is disclosed on page 29, line 17 which reads "*Preferred nucleotides includes* [sic] *UDP, GDP, TDP, and ADP depending on the preference of the glycosyltransferase used*".

13. Lastly, the subject-matter of claim 7 is derivable from lines 9 and 10 on page 30 reading "*The present invention is directed to substances according to the formulas C1-C3 when the T group to be targeted is a chemoselective and protein/tissue compatible linking group*".

14. Therefore, the board is satisfied that the subject-matter of claims 1 to 7 has a basis in the application as filed and hence meets the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution.

The Registrar: The Chairwoman:

P. Cremona G. Alt

Decision electronically authenticated