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**Datasheet for the decision  
of 11 October 2013**

**Case Number:** T 1140/10 - 3.3.02

**Application Number:** 02752182.2

**Publication Number:** 1458242

**IPC:** A01N 65/00

**Language of the proceedings:** EN

**Title of invention:**

Polyvalent conjugate vaccine for cancer

**Applicant:**

Sloan-Kettering Institute for  
Cancer Research

**Headword:**

Conjugate vaccine/SLOAN-KETTERING INSTITUTE

**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

"Inventive step - (no): arbitrary choice"

**Decisions cited:**

-

**Catchword:**

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Case Number: T 1140/10 - 3.3.02

**DECISION**  
of the Technical Board of Appeal 3.3.02  
of 11 October 2013

**Appellant:**  
(Applicant)

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**Decision under appeal:**

**Decision of the Examining Division of the  
European Patent Office posted 29 December 2009  
refusing European patent application  
No. 02752182.2 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** H. Kellner  
L. Bühler

## Summary of Facts and Submissions

- I. European patent application No. 02 752 182.2, based on PCT/US2002/021348 and published as WO 2003/003985, was refused by a decision of the examining division on the basis of Article 97(2) EPC for lack of inventive step under Article 56 EPC.

Claim 1 of the single request before the examining division, contained in the applicant's letter of 31 March 2008 and received by the EPO on the same day, reads as follows:

"A heptavalent vaccine, comprising conjugated antigens, wherein the antigens are glycosylated MUC-1-G5, Globo H, GM2, LeY, Tn(c), sTN(c), and TF (c)."

The examining division had issued its decision on 29 December 2009 after having summoned to oral proceedings with communication of 24 June 2009 and having indicated, in the annex to this summons, the reasons why it intended to refuse claims 1 to 5 under Article 97(2) in combination with Article 56 EPC.

In reply to this annex, the applicant had only indicated, by letter of 24 November 2009, that he would not be attending the oral proceedings.

Therefore, the oral proceedings had been conducted in its absence and, according to the minutes posted on 28 December 2009, at the end of these oral proceedings the decision of refusal had been announced.

II. The documents cited during the proceedings before the examining division and the board of appeal include the following:

- (3) Ragupathi, G. et al., "Carbohydrate antigens as targets for active specific immunotherapy", *Cancer Immunology & Immunotherapy* 43(3), 1996, 152-157
- (7) Kim, S. et al., "Effect of immunological adjuvant combinations on the antibody and T-cell response to vaccination with MUC1-KLH and GD3-KLH conjugates", *Vaccine* 19, 2000, 530-537
- (10) Ragupathi, G. et al., "Comparison of the antibody response to monovalent and polyvalent conjugate cancer vaccines", *Proceedings of the American Association for Cancer Research* 41, 2000, abstract 5557, 874-875
- (12) Livingston, P. et al., "Autoimmune and antitumor consequences of antibodies against antigens shared by normal and malignant tissues", *Journal of Clinical Immunology* 20(2), 2000, 85-93,

III. The examining division held the subject-matter of the single request to be obvious with respect to a combination of one of documents (10) or (7) and document (12) or document (3).

Since no specific technical effect with respect to the state of the art could be associated with the heptavalent combination as claimed, the problem could at best be formulated as the provision of a polyvalent

combination of cancer antigens e.g. as an alternative to the tetravalent combination of document (10).

Further antigens were known from documents (12) or (3).

Thus, the subject-matter as claimed had to be regarded as the product of an arbitrary choice which did not involve inventive activity.

- IV. The applicant lodged an appeal against the decision of the examining division and, maintaining the set of claims the division had decided on, filed a statement of grounds of appeal.

No further set of claims as a basis for a request for granting a patent was submitted and no oral proceedings were requested.

- V. The arguments of the appellant in the written proceedings may be summarised as follows:

The only way the skilled person, starting from document (10), could arrive at the claimed invention was to remove two of the valences from the tetravalent vaccine of this document and add five different valences selected from document (12) or document (3). Such a teaching was present nowhere in the prior art.

Thus, having regard to the documents on file, the subject-matter of the application in suit was not obvious to the skilled person.

- VI. The appellant requested that the decision under appeal be set aside and, implicitly, that a patent be granted

on the basis of the set of claims filed with letter of 31 March 2008.

### **Reasons for the Decision**

1. The appeal is admissible.

In its notice of appeal, the appellant requested that the decision of the examining division be set aside, which according to the jurisprudence of the boards is to be seen as a request for granting a patent on the basis of the claims on which the contested decision is based.

Therefore, Rule 99(1)(c) requiring the notice of appeal to contain a request defining the subject of the appeal is fulfilled.

2. The claims on file are based on the claims and the description as originally filed (Article 123(2) EPC).

The board is also satisfied that the requirements of Articles 84 and 83 EPC are fulfilled.

3. The subject-matter of the single request is new.

Neither documents (10) or (7) nor the others introduced into the proceedings refer to a heptavalent vaccine comprising conjugated antigens, wherein the antigens are glycosylated MUC-1-G5, Globo H, GM2, LeY, Tn(c), sTN(c), and TF (c).

The requirement of Article 54(1) EPC is fulfilled.

4. *Inventive step*

4.1 The subject-matter of claim 1 of the single request concerns a "heptavalent vaccine, comprising conjugated antigens, wherein the antigens are glycosylated MUC-1-G5, Globo H, GM2, LeY, Tn(c), sTN(c), and TF (c)".

4.2 Document (10) represents the closest state of the art.

This document relates to a conjugate containing the antigens GD3, LeY, MUC1, and MUC2, each conjugated to KLH. The antigens are mixed and administered to mice at one site. Thus a model is presented for a polyvalent vaccine in which the immunogenicity of the four individual antigen conjugates is not affected by mixing them together and administering them at a single site (see in particular the part of the article of document (10) on page 875).

4.3 In the absence of any comparative study with respect the closest state of the art that could indicate a specific technical effect associated with the heptavalent combination as claimed, the technical problem underlying the application in suit can only be seen in the provision of a further polyvalent vaccine.

4.4 The proposed solution to this problem is the provision of a vaccine containing the seven antigens according to claim 1 of the request.

4.5 Having regard to examples set out in the application in suit (see pages 38 to 76, 84 to 98 and 100 to 105 of

WO 2003/003985), the board is satisfied that the problem has been solved.

- 4.6 Faced with the problem defined above, the skilled person is also aware of document (12).

This document refers to polyvalent vaccines and indicates the possible targets for vaccine construction (see document (12), in particular page 90, right-hand column and table II, figure 1 and related text on page 87, left-hand column, last paragraph to page 88, right-hand column, first paragraph).

In trying to find a further polyvalent vaccine, the person skilled in the art takes into account the teaching of document (12), in particular the targets in table II, and accordingly is led *inter alia* to the use of Globo H, GM2, Tn(c), STN(c), and TF (c) in addition to MUC1 and LeY.

- 4.7 Consequently, the board can only conclude that the subject-matter of claim 1 of the request with regard to number and kind of the antigens contained represents an arbitrary choice in view of the teaching of document (10) and, therefore, does not involve an inventive step (Article 56 EPC).

5. The appellant argued that the claimed invention comprised an inventive step because there was no teaching in the prior art to remove two valences from the tetravalent vaccine of document (10) and add the five vaccines further defined in claim 1 as filed.

The board cannot share this opinion:



In the absence of comparative experiments with regard to the specific polyvalent vaccine disclosed in document (10), the problem to be solved is not the further development of the specific, exemplified vaccine towards a special effect obtained by the teaching of the application in suit, but just the provision of an alternative to some polyvalent vaccine as taught in this piece of prior art. In order to find such an alternative, the skilled person is free in defining the number of vaccines and in choosing any of the relevant vaccines (for instance those to be found in document (12), table II).

Consequently, in these circumstances, the appellant's arguments cannot succeed.

6. The board concludes that the subject-matter of the application in suit is obvious with regard to the state of the art (Article 56 EPC).

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

N. Maslin

U. Oswald