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## Datasheet for the decision of 26 November 2013

**Case Number:** T 0865/11 - 3.3.04

**Application Number:** 97943976.7

**Publication Number:** 939645

**IPC:** A61K 39/00, A61K 39/385

**Language of the proceedings:** EN

**Title of invention:**
Cancer therapy using an oncogene product and a foreign MHC molecule

**Applicant:**
Maudsley, David John

**Headword:**
Cancer therapy/MAUDSLEY

**Relevant legal provisions:**
EPC Art. 84, 111(1), 123(2)

**Keyword:**
"Main request - added matter (no), clarity (yes), support (yes)"

**Decisions cited:**
-

**Catchword:**
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 0865/11 - 3.3.04

# D E C I S I O N
**of the Technical Board of Appeal 3.3.04**
**of 26 November 2013**

**Appellant:** (Applicant)
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**Representative:**
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**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted on 19 October 2010 refusing European patent application No. 97943976.7 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman:** M.-B. Tardo-Dino
**Members:** B. Claes
R. Morawetz

## Summary of Facts and Submissions

I. The appeal was lodged by the applicant (hereinafter "appellant") against the decision of the examining division to refuse European patent application 97943976.7 with the title "*Cancer therapy using an oncogene product and a foreign MHC molecule*" which was published as international application WO 98/14205.

II. The examining division decided that the subject-matter of claim 1 of the main request and of auxiliary requests 1 to 3 before it did not comply with the requirements of Article 84 EPC.

Claim 1 of the main request before the examining division read:

"1. Use of an immunogen for the manufacture of a medicament for use in prevention or treatment of an oncogene-associated tumour in a mammal, wherein the immunogen comprises MHC molecules foreign with respect to the mammal and a peptide, or gene encoding a peptide, that corresponds to the immunogenic region of the oncogene in the mammal, but which is not derived from the tumour in the mammal."

The examining division's reasons can be summarised as follows:

The components of the active ingredient were not clearly defined (Article 84 EPC). In particular the "MHC molecules", the "peptide" and the "oncogene" were merely defined by reference to the subject to be treated which was an undefined patient. Furthermore,

the functional definition "immunogenic region of the oncogene in the mammal" left it up to the skilled person to identify which peptides would display the desired activity (Article 84 EPC).

Since the oncogene was not further defined, the feature of a peptide "corresponding to an immunogenic region of the oncogene" was not supported by the application as filed over the whole scope of the claim (Article 84 EPC). Furthermore, claim 1 encompassed also cell-free embodiments and was not restricted to allogeneic cells. The application was based on the realisation that, contrary to a prejudice in the art, it was possible to use the composition without having to use the cells of the subject to be treated, and it was up to the applicant to show that the various embodiments covered by the claim did indeed provide the unexpected result, which he had failed to do. The embodiments of the claim relating to cell-free systems and xenogeneic cells did therefore not find support in the application as filed (Article 84 EPC).

The objections also applied *mutatis mutandis*, albeit in part, to claim 1 of the auxiliary requests.

III. With the statement of the grounds of appeal, the appellant filed a new main request and new auxiliary requests 1 to 3. The new requests corresponded to the requests before the examining division but were drafted in the further medical use format as foreseen in Article 54(5) of EPC 2000. The appellant argued that the claims of the requests complied with the requirements of Article 84 EPC.

IV. Oral proceedings took place on 26 November 2013. During these oral proceedings the appellant submitted a new main request and auxiliary request 1 and argued that claim 1 of the main request complied with the requirements of Article 84 EPC.

Independent claim 1 of the main request read:

"1. A cellular immunogen for use in the treatment of an oncogene-associated tumour in a mammal, wherein the cellular immunogen is a cell which comprises MHC molecules foreign with respect to the mammal and the expression product of the oncogene corresponding to the tumour-associated oncogene."

Claims 2 to 7 were dependent on claim 1.

V. The appellant requested that the decision under appeal be set aside and the case be remitted to the department of first instance for further prosecution on the basis of the requests submitted during oral proceedings.

VI. The appellant's arguments can be summarised as follows:

*New main request - claim 1*

- Claim 1 found a basis in the application as filed and complied therefore with the requirements of Article 123(2) EPC.

- Furthermore, the amendments to the claim rendered the objections of the examining division relating to clarity and support (Article 84 EPC) moot.

## Reasons for the Decision

1. The appeal is admissible.

*New main request*

*Added matter (Article 123(2) EPC)*

2. The board is satisfied that a basis can be found for claim 1 and dependent claims 2 to 7 in the application as filed.

3. In particular, in claim 1, with reference to the application as filed, the feature "cellular immunogen" finds a basis on page 5, line 5 and page 7, line 5; the feature "for use in the treatment of an oncogene-associated tumour in a mammal" finds a basis in claim 1 and on page 7, lines 5 to 7; the feature "is a cell" finds a basis in claim 2; the feature "which comprises MHC molecules foreign with respect to the mammal" finds a basis in claim 1 and the feature "and the expression product of the oncogene corresponding to the oncogene in the tumour" finds a basis on page 5, lines 5 to 10 and page 6, lines 17 to 21.

4. The dependent claims are identical to dependent claims 3 to 8 as filed, whereby claim 6 is restricted in its dependency to claims 1 to 3, while corresponding claim 7 as filed refers to "any preceding claim".

5. Accordingly, the claims comply with the requirements of Article 123(2) EPC.

*New main request - claim 1 - clarity and support (Article 84 EPC)*

6. The pivotal issue in the present appeal is the compliance of claim 1 with the requirements of Article 84 EPC, this being the sole reason given in the appealed decision for the refusal of the patent application.

7. Claim 1 of the new main request is extensively amended as compared to claim 1 of the main request before the examining division. Thus, the feature "a peptide, or gene encoding a peptide, that corresponds to the immunogenic region of the oncogene in the mammal, but which is not derived from the tumour in the mammal" is no longer contained in claim 1 and is replaced by the wording "the expression product of the oncogene corresponding to the tumour-associated oncogene". Furthermore, claim 1 now excludes cell-free embodiments.

8. The amendments address and overcome some of the objections raised by the examining division in the impugned decision (see section II) under Article 84 EPC. However, a number of objections raised by the examining division would still appear to apply to claim 1, if the board were to sustain them.

8.1 The examining division found that the components of the active ingredient of the claim, in particular the "MHC molecules" and the "oncogene" were merely defined by reference to an unidentified subject to be treated thereby lacking clarity (Article 84 EPC).

The board considers however that the features "MHC molecules foreign with respect to the mammal" and "the expression product of the oncogene corresponding to the tumour-associated oncogene" directly relate to the patient or patient group to be treated by the claimed cellular immunogen, i.e. mammals suffering from an oncogene-associated tumour. Both features have a clear, albeit broad, meaning for the skilled person and allow the skilled person to determine whether or not he is acting within the ambit of the claim. The board is therefore satisfied that the claim complies with the clarity requirement of Article 84 EPC.

8.2 The examining division found furthermore that the application was based on the realisation that, contrary to a prejudice in the art, it was possible to use a composition which was not based on cells of the subject to be treated. Although the effect was shown in the application for allogeneic cells, it had not been shown that xenogeneic cells could provide the claimed effect. Therefore, embodiments of the claim relating to xenogeneic cells did not find support in the application as filed (Article 84 EPC).

However, the board considers that the patent application, in its general description and in its example, describes the invention as being a cell that is capable of expressing MHC molecules foreign with respect to the mammal and an expression product of at least an immunogenic region of the oncogene, which when administered to a mammal can elicit a vigorous T-cell response contributing to the elimination of the tumour cells of the mammal (see e.g. page 4, lines 15 to 25). It is the presentation of the expression product of the

oncogene in the context of the cellular system comprising MHC molecules which are foreign to the patient which according to the invention provides the technical effect (see e.g. page 5, lines 18 to 19). Accordingly, the board considers that the application as filed also supports those embodiments where the cellular immunogen is xenogeneic.

9. In view of the above considerations the board is satisfied that claim 1 complies with the requirements of Article 84 EPC.

*Remittal to the department of first instance*

10. The sole reason for the refusal of the patent application referred to in the appealed decision is the non-compliance of the claims of the requests then pending before the examining division with the requirements of Article 84 EPC. Independent claim 1 of the new main request contains extensive amendments to the appellant's case as follows from a comparison of its wording with that of claim 1 of the requests before the examining division (see sections II and IV above). This means *inter alia* that further prior art might be relevant which has not yet been considered by the examining division.

11. Pursuant to Article 111(1) EPC, following the examination as to the allowability of the appeal, the board shall decide on the appeal and, in this respect, it may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case for further prosecution.

12. In a case such as the present one where the appealed decision is based solely on the requirements of Article 84 EPC and substantial amendments have been made to the claims to overcome the objections in the appealed decision with possible consequences for the relevant prior art, the board considers that it is not in a position to judge on all the possible relevant facts and it is more appropriate that the prosecution in relation to further requirements of the EPC should be carried out by the department of first instance thereby also securing the applicant's right to two instances.

13. For the above reasons, the board has decided to exercise its discretion under Article 111(1) EPC to remit the case to the first instance department for further prosecution on the basis of the patent application documents on file including the claims of the main request.

**Order**

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

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of the main request filed during oral proceedings on 26 November 2013.

The Registrar The Chairman

P. Cremona M.-B. Tardo-Dino