

Internal distribution code:

- (A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

**Datasheet for the decision
of 7 May 2015**

Case Number: T 0541/11 - 3.3.02

Application Number: 97954555.5

Publication Number: 0959893

IPC: A61K35/12, A61K35/56, C12N5/06,
C12N5/10, C12N5/18, C12N5/22,
C12N15/12, C12N15/06,
C12N15/63, C12N15/85

Language of the proceedings: EN

Title of invention:
STIMULATION OF AN IMMUNE RESPONSE TO A DIFFERENTIATION ANTIGEN
STIMULATED BY AN ALTERED ANTIGEN

Applicant:
Sloan-Kettering Institute for
Cancer Research

Headword:
Stimulation of immune response to differentiation antigen/
SLOAN-KETTERING

Relevant legal provisions:
EPC Art. 123(2)
RPBA Art. 15(3)

Keyword:
Amendments - added subject-matter (yes)
Oral proceedings - held in absence of appellant

Decisions cited:
G 0004/92, T 0296/96

Catchword:



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0541/11 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 7 May 2015

Appellant: Sloan-Kettering Institute for
(Applicant) Cancer Research
1275 York Avenue
New York,
New York 10021 (US)

Representative: Murphy, Colm Damien
Venner Shipley LLP
200 Aldersgate
London EC1A 4HD (GB)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 21 October 2010
refusing European patent application No.
97954555.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman U. Oswald
Members: T. Sommerfeld
S. Fernández de Córdoba

Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division pronounced on 11 October 2010 and posted on 21 October 2010, in which European patent application 97954555.5, based on the international application published as WO98/25574, was refused under Article 97(2) EPC.
- II. The decision of the examining division is based on the sets of claims of the main request and auxiliary requests 1 and 2, all filed with letter of 10 September 2010.

The **main request** comprised 6 claims, of which independent claim 1 read as follows:

"1. For use in the manufacture of a medicament for stimulating an immune response to a tissue expressing a target differentiation antigen in a tissue of an individual of a first mammalian species, an expressible nucleic acid sequence encoding a therapeutic differentiation antigen of the same type as the target differentiation antigen derived from a second mammalian species, different from the first mammalian species, wherein the expressible nucleic acid sequence is expressible in the individual of the first species and comprises a plasmid vector."

Claim 1 of **auxiliary request 1** differed from claim 1 of the main request in that the target differentiation antigen was to be selected from the group consisting of Melan-A/MART-1, Pmel17, tyrosinase, gp75, CD19, CD20, mucin polypeptide muc-1, her2/neu, prostate specific antigen, prostatic acid phosphatase, and prostate specific membrane antigen.

In claim 1 of **auxiliary request 2** the target differentiation antigen was to be selected from the group consisting of tyrosinase, gp75, and prostate specific membrane antigen.

III. The examining division decided that none of the requests on file complied with Articles 123(2), 83 and 56 EPC.

As regards Article 123(2) EPC, the examining division considered that no basis could be found in the application as filed for the reference to mammalian species, in particular for the combination of a first and a second mammalian species.

IV. The applicant (hereinafter, the appellant) lodged an appeal against the decision of the examining division, requesting that the decision be set aside and that a patent be granted according to the main claim request or the first and second auxiliary requests which had been refused by the examining division. All claim requests were re-filed with the grounds of appeal.

V. As an annex to the summons to oral proceedings, the board issued a communication pursuant to Article 15(1) RPBA.

In said communication, the board summarised the situation and expressed a detailed opinion on all claim sets on file, as regards Article 123(2) EPC and Article 84 EPC, and included observations in relation to inventive step.

- VI. The appellant did not file any substantive reply to the board's communication but instead informed the board that it would not attend oral proceedings.
- VII. Oral proceedings took place as scheduled in the absence of the appellant.
- VIII. The appellant's arguments, in so far as relevant to the present decision, may be summarised as follows:

Basis for claim 1 could be found on page 3, first paragraph, stating that the invention was applicable to mammalian species, and page 7, first paragraph, teaching administration of a xenogenic differentiation antigen of the same type as the target differentiation antigen. Page 7, first paragraph provided an example for the treatment of human wherein the preferred xenogenic antigens included those from rodents but could come from any other mammalian species as well. The skilled person would clearly interpret these passages as teaching that the invention could be applicable to any mammalian species as long as the individual being treated and the source of the differentiation antigen belonged to different mammalian species.

- IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, alternatively, on the basis of the first or second auxiliary requests, all filed with the grounds of appeal.

Reasons for the Decision

- 1. The appeal is admissible.

2. The oral proceedings before the board took place in the absence of the appellant who had been duly summoned but decided not to attend.

The present decision is based on facts and evidence put forward during the written proceedings and on which the appellant has had an opportunity to comment.

Therefore the conditions set forth in Enlarged Board of Appeal opinion G 4/92, OJ EPO 1994, 149, are met.

Moreover, as stipulated by Article 15(3) RPBA the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case.

3. Main request - Article 123(2) EPC

- 3.1 According to Article 123(2) EPC, the European patent application or the European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

In accordance with established board case law, the relevant question to be decided in assessing Article 123(2) EPC is whether the proposed amendments are directly and unambiguously derivable from the application as filed, meaning that they must not result in the introduction of technical information which a skilled person would not have objectively derived from the application as filed.

Moreover, the content of a document as originally filed may not be seen as a reservoir of features from which features pertaining to separate embodiments can be combined in order to artificially create a particular embodiment (T 296/96 of 12 January 2000, point 3.1 of the Reasons for the Decision).

3.2 Claim 1 of the main request is directed to a second medical use, wherein the medical use consists of stimulating an immune response in a tissue expressing a target differentiation antigen of an individual of a first mammalian species and the therapeutic agent is an expressible nucleic acid sequence encoding a therapeutic differentiation antigen derived from a second mammalian species, different from the first mammalian species.

3.3 As indicated in the communication accompanying the summons for oral proceedings, such a subject-matter involving a first mammalian species and a second mammalian species, different from the first species, is not directly and unambiguously disclosed in the application as filed. The passages indicated by the appellant are not considered to form a suitable basis, for the following reasons:

3.3.1 On page 3, lines 1 to 5, methods for stimulating an immune response against a target differentiation antigen are disclosed in general terms; "[t]he subject individual is preferably human, although the invention can be applied in veterinary applications to animal species, preferably mammalian or avian species" (page 3, lines 3 to 5). There is no mention at all in this passage that two different species, let alone two different mammalian species, are involved. Instead, reference is only made to the subject to be treated,

which is preferably human or another animal species, preferably mammalian or avian. Mention of two different species - but no reference to mammalian - is made in lines 20 to 26 of the same page, in relation to the first and third of the three different embodiments of the invention: the first embodiment involves the use of a therapeutic differentiation antigen and a target differentiation antigen which are from the same species, but wherein the therapeutic differentiation antigen is produced by expression in cells of a second species different from the first species, while in the third embodiment the therapeutic differentiation antigen is a xenogeneic differentiation antigen (i.e. from a different species). As stated above, there is no reference in this passage to two different mammalian species.

3.3.2 The third embodiment, namely the one involving the use of xenogeneic differentiation antigens, is disclosed in more detail on page 7, first paragraph, wherein it is further stated that "[f]or treatment of humans, preferred xenogeneic antigens will be rodent antigens, but could come from other mammals such as dog, cat, cow, or sheep, or from birds, fish, amphibian, reptile, insect or other more distantly related species." This passage can thus only provide a basis for the combination of human as first species with other mammalian (as one among at least 6 alternatives) as second species: it does not provide a basis for the combination of any first mammalian species with any second mammalian species, nor for an embodiment wherein the second species is human (as in present claim 3).

3.4 Accordingly, the board comes to the conclusion that the main request contravenes the requirements of Article 123(2) EPC.

4. First and second auxiliary requests - Article 123(2)
EPC

4.1 The same combination of features which was discussed above is also present in claim 1 of the first and second auxiliary requests. Therefore, none of these requests complies with Article 123(2) EPC either.

5. Accordingly none of the claim requests on file is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



N. Maslin

U. Oswald

Decision electronically authenticated