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D E C I S I O N
of 15 November 2002

Case Number: T 0756/00 - 3.3.4

Application Number: 96202773.6

Publication Number: 0755683

IPC: A61K 39/395

Language of the proceedings: EN

Title of invention:
Immunotherapy of tumor with monoclonal antibody against the 17-1A antigen

Applicant:
CENTOCOR, INC.

Opponent:
-

Headword:
Immunotherapy/CENTOCOR INC.

Relevant legal provisions:
EPC Art. 76(1), 97(1)

Keyword:
"Divisional application going beyond patent application as filed, after amendment (no) - remittal (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0756/00 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 15 November 2002

Appellant: CENTOCOR INC.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 11 February 2000 refusing European patent application No. 96 202 773.6 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairwoman: U. M. Kinkeldey
Members: R. E. Gramaglia
S. U. Hoffman

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division issued on 11 February 2000 whereby European patent application No. 96 202 773.6 (published as EP-A1-0 755 683), a divisional application of European patent application No. 87 306 083.4, published as EP-A2-0 252 741 ("the parent application"), was refused pursuant to Article 97(1) EPC. Basis of the rejection were claims 1 to 4 filed at the oral proceedings on 17 December 1999.

II. The examining division found that, contrary to the requirements of Article 76(1) EPC, the claimed subject-matter extended beyond that of the parent application as filed.

III. During the oral proceedings held on 15 November 2002, the appellant submitted a sole request (claims 1 to 6) in replacement of any preceding request, of which claim 1 read as follows:

"Use of a murine monoclonal antibody which specifically binds to an epitope of the 17-1A antigen for the manufacture of a medicament for therapeutic use, wherein the therapeutic use is the treatment of metastases of a carcinoma originating from a 17-1A-positive tissue by a combination of: (a) the parenteral administration of sequential multiple doses of at least 100 milligrams per dose for a total dose of 0.2 to 5.0 grams of antibody to yield high plasma levels to enhance transit of the antibody from the intravascular space into the tumour bed and thus provide high concentrations of antibody to the locus of action, and (b) other forms of tumour therapy, whereby

the antibody administration in part (a) is adjuvant to the tumour therapy in part (b)."

Claim 2 precised that the metastases referred to in claim 1 were "micro or mini-metastases", whereas claims 3 to 6 were addressed to further embodiments of the use of claims 1 or 2.

IV. In support of this request the appellant submitted that, compared with claim 1 of the application as filed, the definition of the tumour had been further limited to metastases of a carcinoma originating from a 17-1A-positive tissue. There was a basis on page 11, lines 18 to 19 and on page 3 of the "A2" parent application as filed for this amendment.

V. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 6 of the sole request submitted during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.

Article 76(1) EPC

2. This Article states that the "European divisional application ... may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed". In the present case, claims 1 to 6 of the appellant's sole request have to be compared with the description of the parent application, there being no added subject-matter in the

claims of the divisional application as filed.

3. Claim 1 at issue differs from claim 1 of the parent application as filed:

"1. Use of a murine monoclonal antibody which specifically binds to an epitope of 17-1A antigen (or of a mixture of at least two of such antibodies) for the manufacture of a medicament for treating gastrointestinal tumor (e.g. gastrointestinal adenocarcinoma, colorectal or pancreatic carcinoma) by the parenteral administration (e.g. by intravenous infusion) of multiple doses of at least 100 milligrams or more per dose for a total dose of 0.2-5 grams (e.g. 1 to 5 grams) of antibody."

in that:

(i) The therapeutic use is now the treatment of "metastases of a carcinoma originating from a 17-1A-positive tissue".

(ii) It has been emphasized that the technical effect looked for by using the particular dose regimen and mode of administration of the antibody is "to yield high plasma levels to enhance transit of the antibody from the intravascular space into the tumour bed and thus provide high concentrations of antibody to the locus of action"

(iii) Immunotherapy with the antibody is now adjuvant to other forms of cancer therapy.

4. As for feature (i) above, it is stated on page 1,

lines 61 to 62 of the "A2" parent application as filed that "murine antibody therapy can be useful as adjuvant therapy directed against micro- or mini-metastases". Moreover, it can be derived from page 3 thereof, under the heading "Patient Population", that the twenty patients under study had "metastatic disease". Finally, there is a sentence on page 11, lines 18 to 19 of the "A2" parent application, according to which "The 17-1A Ag is...also present in most carcinomas originating from 17-1A-positive tissues". Therefore, in the board's judgement, the therapeutic use now claimed, ie the treatment of "metastases of a carcinoma originating from a 17-1A-positive tissue" can be directly and unambiguously derived from the parent application.

5. As regards feature (ii) above, this can be derived from page 2, lines 26 to 28 and 37 to 42 of the "A2" parent application, whereas feature (iii) is disclosed on page 2, lines 23 and 62 thereof.

6. Claim 2 finds a basis on page 2, line 62 of the "A2" parent application. Claim 3 has a counterpart on page 2, line 61. Claim 4 has a basis on page 2, lines 60 to 63. Claim 5 has a basis on page 2, line 46, whereas claim 6 can be derived from page 2, line 45 thereof.

7. In view of the foregoing, the board is satisfied that the subject-matter of claims 1 to 6 of the appellant's sole request satisfies the requirements of Article 76(1) EPC.

Remittal

8. The present application was rejected for reasons of

non-compliance with Article 76 (1) EPC only and was based on claims with a different content to that of the claims presently on file. Consequently, in order not to deprive the appellant of his right to have his invention examined by two instances, and in accordance with the established jurisprudence of the boards of appeal, the board uses its discretion under Article 111(1), second sentence, EPC, and remits the case to the first instance for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution on the basis of the sole request submitted during the oral proceedings.

The Registrar: The Chairwoman:

P. Cremona U.M. Kinkeldey