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**Datasheet for the decision
of 27 July 2010**

Case Number: T 1907/06 - 3.3.02

Application Number: 99935854.2

Publication Number: 1100512

IPC: A61K 31/70

Language of the proceedings: EN

Title of invention:

Preparation of thioarabinofuranosyl compounds and use thereof

Applicant:

Southern Research Institute

Opponent:

-

Headword:

Thioarabinofuranosyl/SOUTHERN RESEARCH INSTITUTE

Relevant legal provisions:

EPC Art. 111

Relevant legal provisions (EPC 1973):

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Keyword:

"Remittal - yes: unexamined issues"

Decisions cited:

-

Catchword:

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Case Number: T 1907/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 27 July 2010

Appellant: Southern Research Institute
2000 Ninth Avenue South
Birmingham
Alabama 35205 (US)

Representative: Pellegri, Alberto
Società Italiana Brevetti S.p.A.
Via Avegno, 6
I-21100 Varese (IT)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 14 June 2006
refusing European patent application
No. 99935854.2 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: A. Lindner
Members: J. Riolo
J. Van Moer

Summary of Facts and Submissions

- I. European patent application No. 99935854.2 was refused by a decision of the Examining Division dated 14 June 2006 under Article 97(1) EPC 1973 in conjunction with Articles 56 and 82 EPC 1973.
- II. The decision was based on the sole request filed with letter dated 3 November 2005.

Independent claims 1, 3, 4 and 9 of this request read as follows:

1. Use of at least one compound selected from the group consisting of 1-(4-thio- β -D-arabinofuranosyl) 5-fluorocytosine and 1-(4-thio- β -D-arabinofuranosyl) cytosine for preparing a medicament for the treatment of a cancer in a mammalian.

3. The use of 1-(4-thio- β -D-arabinofuranosyl) 5-fluorocytosine for preparing a medicament for inhibiting DNA replication in a mammalian cell.

4. The use of 1-(4-thio- β -D-arabinofuranosyl) cytosine for preparing a medicament for inhibiting DNA replication in a mammalian cell.

9. A method for producing a compound of claim 1, which comprises:

A) reacting a 2,3,5-tri-O-aryl or alkyl-4-xylose diaryl or dialkyl dithioacetal in the presence of a leaving group at the 4 hydroxyl position to produce the corresponding 1,4-dithio-D-arabinofuranoside;

- B) reacting said arabinofuranoside from step A) to acidolysis to form the corresponding O-acetyl-4-thio-D arabinofuranose;
- C) reacting said O-acetyl-4-thio-D-arabinofuranose from step B) with a cytosine, to form the corresponding 4-thio- α , β -D-arabinofuranosyl compound;
- D) converting said arabinofuranosyl compound from step C) by hydrolysis to the corresponding thio sugar derivative; and
- E) separating out the α form of the anomeric mixture of step D) to thereby obtain the compound.

III. The reasons for the decision can be summarised as follows:

The Examining Division refused the European patent application on the ground that the subject-matter of the application was rendered obvious by the disclosure in closest prior art document (1) (J. Med. Chem., vol. 17, n° 5, 1974, pages 535-537), which presented in vivo data for thio-nucleoside in relation to its nucleoside analogue, which has been used clinically against acute leukemia and lymphoma, and expressed the hope for lower toxicity and lower deamination.

The Examining Division was also of the opinion that no unifying technical relationship could be recognized between the subject-matter of use claims 1 to 8 and the subject-matter of method claims 9 to 13, so that the application did not meet the requirement of unity of invention (Article 82 EPC).

IV. The appellant (applicant) lodged an appeal against the said decision.

V. Oral proceedings were held on 27 July 2010.

At the oral proceedings, the appellant filed a new set of claims as sole request replacing all previous requests.

This set of claims reads:

1. Use of at least one compound selected from the group consisting of 1-(4-thio- β -D-arabinofuranosyl) 5-fluorocytosine and 1-(4-thio- β -D-arabinofuranosyl) cytosine for preparing a medicament for the treatment of a cancer in a mammalian, wherein said cancer belongs to the group consisting of melanoma, prostate cancer, mammary cancer, renal cancer, colon cancer, lung cancer.

2. The use of 1-(4-thio- β -D-arabinofuranosyl) 5-fluorocytosine for preparing a medicament for inhibiting DNA replication in a mammalian cell.

3. The use of 1-(4-thio- β -D-arabinofuranosyl) cytosine for preparing a medicament for inhibiting DNA replication in a mammalian cell.

VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the sole request filed during the oral proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. The Board notes that independent claim 1 of the set of claims of the sole request is identical to dependent claim 2 of the set of claims of the request before the Examining Division but restricted to solid tumours only, i.e. the indication relating to leukemia and lymphoma has been deleted.

Moreover, all the method claims have been deleted, so that the non-unity objection is overcome.

The Board observes that, as a consequence of the restriction of claim 1 to solid tumours, the subject-matter of the claim relating to the treatment of leukemia and lymphoma is no longer at issue.

Under these circumstances, the decision of the Examining Division, which was strictly confined to the subject-matter of independent use claim 1 in the light of document (1), relating to the treatment of the non-solid tumours leukemia and lymphoma, no longer holds good and the decision under appeal has to be set aside.

The Board notes also that the subject-matter of independent claim 3 and independent claim 4 of the set of claims before the Examining Division has not been dealt with per se in the Examining Division's decision.

These claims deserve however a complete examination, in particular as to novelty, since they concern distinct

subject-matter which is even not restricted to any therapeutical use.

3. Remittal to the department of first instance

3.1 Although the EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party may be given the opportunity of two readings of the important elements of the case. The essential function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In particular, remittal is considered by the boards in cases where a first-instance department issues a decision against a party based solely upon one particular issue which is decisive for the case, and leaves other essential issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first-instance department for consideration of the undecided issues (Article 111 EPC).

3.2 The observations made above apply fully to the present case. The Examining Division decided that the subject-matter of independent use claim 1 was not patentable on the grounds of lack of inventive step (Article 56 EPC) vis-à-vis document (1), which concerned non-solid tumours. This document (1) is however of less relevance

with respect to the restricted subject-matter according to claim 1 of the set of claims filed during the oral proceedings, as it is silent as far as solid tumours are concerned.

The Examining Division's decision also disregarded the patentability of the subject-matter of independent use claims 3 and 4 per se, which relates to the inhibition of DNA replication in a mammalian cell.

All these issues, however, form the basis for the request that a patent be granted and must therefore be considered as essential substantive issues in the present case.

3.3 Thus, in view of the above considerations, the Board has reached the conclusion that, in the circumstances of the present case, it is necessary to remit 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 request filed during the oral proceedings.

The Registrar

The Chairman

N. Maslin

A. Lindner