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**Datasheet for the decision
of 11 May 2010**

Case Number: T 0972/04 - 3.3.02

Application Number: 98957803.4

Publication Number: 1037625

IPC: A61K 31/285

Language of the proceedings: EN

Title of invention:

Process for producing arsenic trioxide formulations and methods for treating cancer using arsenic trioxide or melarsoprol

Applicant:

MEMORIAL SLOAN-KETTERING CANCER CENTER

Headword:

Arsenic trioxide formulations/SLOAN-KETTERING

Relevant legal provisions:

EPC Art. 123(2)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Amendments - added subject-matter (yes): Particular features in claims not individualised in original application"

Decisions cited:

-

Catchword:

-



Case Number: T 0972/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 11 May 2010

Appellant: MEMORIAL SLOAN-KETTERING CANCER CENTER
1275 York Avenue
New York, NY 10021 (US)

Representative: Warner, James Alexander
Carpmaels & Ransford
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 20 January 2004
refusing European patent application
No. 98957803.4 pursuant to Article 97(1) EPC
1973.

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
J. Van Moer

Summary of Facts and Submissions

I. European patent application No. 98 957 803.4, published as WO 99/24029 and based on the international application PCT/US98/24024 was refused by a decision of the examining division on the basis of Article 97(1) EPC 1973.

II. Claim 1 of the main request before the examining division read as follows:

"The use of arsenic trioxide for manufacturing a medicament for the treatment of acute myelogenous leukaemia by administering to a human a therapeutically effective amount of about 0.15mg of arsenic trioxide per kg body weight of the human per day."

III. The examining division held the subject-matter of the main request and of the auxiliary request 2 not to be new with respect to document (4).

The first auxiliary request was not allowable under Article 123(2) EPC.

IV. The appellant lodged an appeal against the decision of the examining division.

V. A communication was sent out on 14 February 2008, *inter alia* drawing the appellant's attention to possible problems concerning Article 123(2) EPC.

VI. By letter of 8 April 2010 the applicant filed three new sets of claims as the main request and as the first and

second auxiliary requests replacing all previously filed requests.

The wording of claim 1 of the main request is:

"Arsenic trioxide for use in a method of treating acute myelogenous leukaemia in a human, wherein said treatment comprises administering about 0.15 mg of arsenic per kg per day to said human."

Claim 1 of auxiliary request 1 differs from claim 1 of the main request only in the additional wording "determining the weight of said human and" after "... treatment comprises".

Claim 1 of auxiliary request 2 reads (differences with respect to auxiliary request 1 are in bold):

"Arsenic trioxide for use in a method of treating acute **promyelocytic** leukaemia in a human, wherein said treatment comprises determining the weight of said human and administering about 0.15 mg of arsenic per kg per day to said human."

VII. Oral proceedings took place on 11 May 2010.

After discussion at the oral proceedings, the appellant filed a further set of claims as the third auxiliary request.

The wording of claim 1 of the third auxiliary request is:

"Arsenic trioxide for treating acute myelogenous leukaemia in a human, wherein said treatment comprises administering about 0.15 mg of arsenic per kg per day to said human, wherein the arsenic trioxide is administered by intravenous infusion."

This auxiliary request was admitted into the proceedings.

VIII. The arguments of the appellant both in the written procedure and in the oral proceedings may be summarised as follows:

The subject-matter, as far as common to all claims 1 of all requests was disclosed - if not as a combination of claims 1 and 8 as originally filed - but as a combination of page 20, lines 14 to 20 of the application as originally filed and original claim 1.

The feature "wherein the arsenic trioxide is administered by intravenous infusion" was not compulsory with respect to the teaching in page 20, lines 14 to 20, because on page 19, lines 4 to 9, a multitude of routes of administration was set out, which was applicable to this teaching.

Claim 1 of the second auxiliary request was disclosed in example 6 as originally filed, on page 17, lines 29 to 34 of the application as originally filed and as far as the step of determining the weight of the human was

concerned as implicit disclosure of numerous mentioning of "weight based dosing".

- IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of one of the sets of claims filed as main request or first or second auxiliary request with letter of 8 April 2010 or third auxiliary request submitted during oral proceedings.

Reasons for the Decision

1. The appeal is admissible.
2. The amended claims filed by the appellant as auxiliary request 3 represent an attempt to overcome the objections raised during the proceedings. Consequently, they are admitted into the proceedings.
3. *Claim 1 of the main request; original disclosure (Article 123(2) EPC)*
 - 3.1 *Claims as originally filed as a source of original disclosure*
 - 3.1.1 Claims 1 to 5 as originally filed relate to four different diseases to be treated by means of arsenic trioxide since claims 2 to 5 after claim 1 do not concern particular embodiments of the subject-matter of claim 1 but independent alternatives having equal weights without any preference, namely
 - acute myelogenous leukaemia (claim 1)

- chronic myelogenous leukaemia (claim 2)
- solid cancer (claim 3)
- leukaemia resistant to treatment with retinoids (claim 5).

In addition, also claims 7 and 8 - both claims referring to claims 1,2,3,4, or 5 in unison - concern two independent alternatives, namely

- administration of about 2.5 to 4.5 mg of arsenic trioxide per day (claim 7) and
- administration of about 0.15 mg of arsenic trioxide per kg body weight of the human per day (claim 8).

3.1.2 Claim 1 of the main request essentially relates to

- arsenic trioxide
- for treating acute myelogenous leukaemia by way of
- administering about 0.15 mg ... per kg per day to said human.

3.1.3 Nothing in the wording of the claims as originally filed links the regimen "administering about 0.15 mg ... per kg per day" (original claim 8) specifically to the disease "acute myelogenous leukaemia" (original claim 1). Accordingly, the teaching of claim 1 of the main request cannot be regarded as individualised in the set of claims as originally filed.

3.2 *The description as originally filed per se or in context with the claims as the source of the original disclosure*

3.2.1 There is no teaching in the description as originally filed that "acute myelogenous leukaemia" was the preferred disease or the preferred leukaemia to be treated.

3.2.2 On page 20, lines 14 to 20 of the application as originally filed, the following statement can be found:

"An exemplary course of treatment of a patient with leukemia, lymphoma, or solid cancer can involve daily administration by intravenous infusion of arsenic trioxide in an aqueous solution ... Preferably, about 0.15 mg arsenic trioxide per kg body weight per day is used."

This means at the utmost a clear and unambiguous disclosure that

- either leukaemia
- or lymphoma
- or solid cancer

is to be treated by way of a dose regimen of

- 0.15 mg arsenic trioxide per kg body weight per day.

But the teaching that this dose regimen is linked to "acute myelogenous leukaemia" is missing and cannot be derived from claim 1 as originally filed either because

that claim itself only represents one of four alternatives without any preference.

- 3.2.3 Thus, there is no suggestion anywhere in the application as originally filed that the regimen "administering about 0.15 mg ... per kg per day" relates specifically to the disease "acute myelogenous leukaemia".

As a consequence, the teaching of claim 1 of the main request is not individualised in the application as originally filed and represents an unallowable extension of its content (Article 123(2) EPC).

4. *First and third auxiliary requests*

As claims 1 of these requests contain the same combination of features as claim 1 of the main request (see point 3.1.2 of this decision), the reasoning and conclusion are the same; the teaching of these claims is not originally disclosed either.

5. *Second auxiliary request*

5.1 Claim 1 of this request essentially relates to

- arsenic trioxide
- for treating acute **promyelocytic** leukaemia by way of
- administering about 0.15 mg ... per kg per day to said human.

Acute promye006Cocytic leukaemia does not appear in the claims as originally filed.

5.2 *The description as originally filed as the source of the original disclosure*

5.2.1 There is no literal disclosure in the description as filed that "acute promyelocytic leukaemia" was the preferred disease or the preferred leukaemia to be treated.

From the statement on page 20, lines 14 to 20 of the application as originally filed, cited under point 3.2.2 of this decision, a selected embodiment that

- leukaemia

is to be treated by way of a dose regimen of

- 0.15 mg arsenic trioxide per kg body weight per day.

may be derived. But the teaching that this dose regimen was linked to "acute promyelocytic leukaemia" is missing.

5.2.2 Example 6, starting on page 28 of the application as originally filed, relates to treatment of acute promyelocytic leukaemia (APL), but, on the one hand, only to APL confirmed by cytogenetics or fluorescence in situ hybridization (FISH) analysis for a t(15;17) translocation, or by reverse transcriptase polymerase reaction (RT-PCR) assay for PML/RAR- α and, on the other hand, to the extent that a dose regimen of 0.15 mg arsenic trioxide per kg body weight per day is applied, to children only (see page 29, lines 14 to 17 and lines 27 to 30).

There is no teaching, that a generalisation to all groups of APL or to the whole range of weights of patients is envisaged, not even on page 17, lines 29 to 34 of the application as originally filed, as the appellant argued, because "0.15 mg arsenic trioxide per kg body weight per day" is not mentioned there and even an upper limit of a daily dosage of 10 mg is set out which is not contained in the claim.

- 5.2.3 Thus, there is no suggestion anywhere in the application as originally filed that the regimen "administering about 0.15 mg ... per kg per day" relates specifically to the disease "acute promyelocytic leukaemia" in general.

As a consequence, the teaching of claim 1 of the second auxiliary request is not individualised in the application as originally filed and represents an unallowable extension of its content (Article 123(2) EPC).

6. The board concludes that the subject-matter of claims 1 of the main request and the first, second and third auxiliary requests of the application in suit was not disclosed in the application as originally filed (Article 123(2) EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

N. Maslin

U. Oswald