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Datasheet for the decision of 15 September 2014

Case Number: T 0369/11 - 3.3.02

Application Number: 99944531.5

Publication Number: 1109547

IPC: A61K31/335

Language of the proceedings: EN

Title of invention:
NEW USE OF TAXOID DERIVATIVES

Applicant:
Aventis Pharma S.A.

Headword:
Use of cabazitaxel for treating glioblastoma/AVENTIS

Relevant legal provisions:
EPC Art. 123(2), 54, 56

Keyword:
New main request at appeal proceedings: allowable (yes)

Decisions cited:

Catchword:

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Case Number: T 0369/11 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 15 September 2014

Appellant: (Applicant)	Aventis Pharma S.A. 20, avenue Raymond Aron 92160 Antony (FR)
Representative:	Dernoncour, Roxane Aventis Pharma S.A. 20 Avenue Raymond Aron 92165 Antony Cedex (FR)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 20 September 2010 refusing European patent application No. 99944531.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	U. Oswald
Members:	M. C. Ortega Plaza
	R. Cramer

Summary of Facts and Submissions

I. European patent application No. 99944531.5, based on the international application published as WO 00/09120, was filed with 11 claims.

II. The following document was cited in the examination and appeal proceedings:

D1 WO 96/30355

III. The present appeal lies from a decision of the examining division refusing the application under Article 97(2) EPC.

IV. The examining division considered that, in view of the closest prior-art document D1, the subject-matter claimed in claim 1 (single claim) of the amended set of claims filed with the letter of 18 April 2008 did not involve an inventive step (Article 56 EPC).

Claim 1 of the request serving as the basis for the examining division's decision read as follows:

"1. Use of 4α-acetoxy-2α-benzoyloxy-5ß,20-epoxy-1ß-hydroxy-7ß,10ß-dimethoxy-9-oxo-11-taxen-13α-yl(2R, 3R)-3-tert-butoxycarbonyl amino-2-hydroxy-3-phenylpropionate for preparing a medicine for treating abnormal cell proliferation in the brain wherein the drug is administered by intravenous route."

V. The applicant (appellant) lodged an appeal against said decision and filed a statement of grounds of appeal. With its grounds of appeal the appellant maintained the request before the examining division as its main and sole request.

VI. A board's communication pursuant to Rule 100(2) EPC and Article 12(1)(c) RPBA was sent on 25 April 2014. In said communication the board confirmed that document D1 represented the closest prior art and expressed the opinion that the appellant's request failed because of lack of inventive step (Article 56 EPC).

VII. With its letter dated 19 June 2014 the appellant filed a response to said board's communication. It also filed anew a copy of its main request (identical to the request serving as the basis for the examining division's decision) and an auxiliary request (one single claim). The appellant requested as a precautionary measure oral proceedings pursuant to Article 116 EPC.

Claim 1 of the auxiliary request filed with the letter of 19 June 2014 read as follows:

"1. Use of 4α-acetoxy-2α-benzoyloxy-5ß,20-epoxy-1ß-hydroxy-7ß,10ß-dimethoxy-9-oxo-11-taxen-13α-yl(2R, 3R)-3-tert-butoxycarbonyl amino-2-hydroxy-3-phenylpropionate for preparing a medicine for treating abnormal cell proliferation in the brain, wherein the drug is administered by intravenous route, and wherein the abnormal cell proliferation in the brain is glioblastoma."

VIII. A communication of the board pursuant to Article 15(1) RPBA was sent on 8 July 2014 as an annex to the summons to oral proceedings to be held on 21 November 2014.

In said communication the board informed the appellant that the auxiliary request filed with its letter of 19 June 2014 was admitted into the proceedings since it

represented a clear and direct response to the board's communication sent on 25 April 2014. Moreover, the board maintained its observations in relation to the main request but expressed a positive preliminary opinion in relation to the auxiliary request.

IX. With a letter dated 30 July 2014 the appellant **withdrew its previous main request** (set of claims serving as the basis for the examining division's decision) and promoted its auxiliary request filed on 19 June 2014 to main request.

The appellant also stated that "*if oral proceedings were maintained*" then it requested that they should held as a video conference and that it "*renounced in advance and irrevocably its right to oral proceedings held in the traditional form at the EPO premises on the same subject after the requested video conference*".

X. On 31 July 2014 oral proceedings scheduled for 21 November 2014 were cancelled and the appellant was informed accordingly.

XI. The appellant's submissions may be summarised as follows:

Document D1 was the closest prior art. D1 disclosed the use of taxoid compounds of formula I (which included 4α-acetoxy-2α-benzoyloxy-5ß,20-epoxy-1ß-hydroxy-7ß,10ß-dimethoxy-9-oxo-11-taxen-13α-yl(2R,3R)-3-tert-butoxycarbonyl amino-2-hydroxy-3-phenylpropionate, i.e. cabazitaxel) to treat abnormal cell proliferation in numerous tissues and/or organs, wherein said compounds could be administered by several possible routes. The brain was mentioned among a very long list of tissues and organs. The technical problem to be solved was to

provide a taxoid compound for treating brain cancer. There was no hint in document D1 to select cabazitaxel for treating the brain by intravenous administration. Document D1 did not contain any pharmacological or physiological data and mentioned in general terms the anti-tumour activity of taxoid compounds of formula I and suggested their use in colon and ovarian cancer. Document D1 mentioned as specific cancers neuroblastoma and Wilm's tumour. Nothing in document D1 indicated to the skilled person that cabazitaxel could be efficient for treating glioblastoma.

XII. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of its main request which had been filed with the letter of 19 June 2014 as auxiliary request.

Reasons for the Decision

1. The appeal is admissible.

2. In view of the fact that the appellant's new main request (sole request) is found to be allowable, there is no longer any reason to maintain the oral proceedings initially scheduled for 21 November 2014.

3. Main request (sole request)

3.1 The new main request consists of one single claim in Swiss-type form which relates to the use of cabazitaxel for treating abnormal cell proliferation in the brain, wherein the **abnormal cell proliferation in the brain is glioblastoma**. The claim also specifies that the administration route is intravenous.

3.2 The main request meets the requirements of Articles 123(2) and 84 EPC.

Cabazitaxel is the compound of formula Ia on page 6 of the application as filed. Examples 1 and 2 in the application as filed disclose cabazitaxel, administered by the intravenous route, and its pharmacological activities. Moreover, example 2 of the application as filed specifically discloses the use of cabazitaxel in a valid animal model for human glioblastoma, which is the specific abnormal cell proliferation in the brain to be treated according to claim 1.

3.3 The subject-matter claimed in the main request is novel vis-à-vis the cited prior art. Document D1 discloses the compound cabazitaxel (claim 13 of document D1) but does not disclose it for the specific use claimed (Article 54 EPC).

3.4 As regards inventive step, document D1 represents the closest prior art.

Document D1 discloses taxoid compounds of formula I (generic Markush formula with broad definitions for radicals and residues). Cabazitaxel is specifically disclosed as one of the compounds of formula I (claims 1 and 13 of document D1). Document D1 discloses generally that the compounds of formula I possess anti-tumour and anti-leukaemia activities (page 5). Further, document D1 generally discloses, for the compounds defined by the generic formula I, anti-tumour activity in relation to melanoma B16, colon cancer and leukaemia P388 resistant to doxorubicin. Document D1 also discloses in general terms that the compounds of formula I are active against abnormal cell proliferation in different tissues and/or organs, *inter*

alia muscular tissue, osseous or conjunctive tissues, skin, brain, lungs, sexual organs, lymphatic or renal systems, mammary or blood cells, liver, digestive apparatus, pancreas and thyroid or adrenal glands (pages 39 and 40). Among the long list of conditions given on page 40 neuroblastoma and Wilm's tumour are mentioned. According to the teaching in document D1, the products can be administered by the parenteral route, *inter alia* intravenously (page 40, lines 15 to 17).

In the light of the closest prior art the problem to be solved lies in the provision of an **effective treatment for brain cancer**.

The solution proposed in claim 1 is to use cabazitaxel against glioblastoma.

The problem has been actually solved in the light of example 2 of the application as filed.

The proposed solution is not rendered obvious by the content of document D1, since there is no hint in said document to choose cabazitaxel from the long list of possible compounds of formula I and expect it to be effective for treating glioblastoma. In fact glioblastoma is not even mentioned among the very long lists of possible abnormal cell proliferation in the very long lists of possible tissues and organs.

Consequently, the subject-matter claimed in claim 1 of the main request meets the requirements of Article 56 EPC.

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 with the order to grant a patent on the basis of the main request (single claim) filed as auxiliary request with the letter of 19 June 2014, and a description to be adapted.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated