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D E C I S I O N
of 20 September 2005

Case Number: W 0043/04 - 3.3.2

Application Number: PCT EP2003/009166

Publication Number: WO 2004/018000

IPC: A61K 47/48

Language of the proceedings: EN

Title of invention:
Compositions and methods for treating cancer using cytotoxic CD44 antibody immunoconjugates and chemotherapeutic agents

Applicant:
BOEHRINGER INGELHEIM INTERNATIONAL GMBH

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 34(3)(a)
EPC R. 68.2, 64.1, 64.2, 65.2, 68.3(c)

Keyword:
An oral disclosure under Rule 64.2 PCT is not prior art relevant for the consideration of inventive step and cannot be used in the reasoning accompanying the invitation to pay additional fees.

Decisions cited:
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Catchword:
-

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Case Number: W 0043/04 - 3.3.2

International Application No. PCT/EP2003/009166

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 20 September 2005

Applicant: BOEHRINGER INGELHEIM INTERNATIONAL GMBH
Binger Strasse 173
D-55216 Ingelheim/Rhein (DE)

Representative: -

Decision under appeal: **Protest according to Rule 68.3(c) of the Patent Cooperation Treaty made by the applicants against the invitation of the European Patent Office (International Preliminary Examining Authority) to restrict the claims or pay additional fees dated 26 July 2004.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
B. Günzel

Summary of Facts and Submissions

I. On 19 August 2003 the applicant filed an international patent application, PCT/EP 2003/009166, claiming priority from European application No. 02 018 686.2 of 21 August 2002 and comprising a set of 49 claims, of which independent claim 1 read as follows:

"1. Use of a compound of formula

$$\mathbf{A(LB)_n}$$

wherein

A is an antibody molecule which is specific for CD44;
L is a linker moiety;
B is a compound which is toxic to cells; and
n is a decimal number with n = 1 to 10

for the preparation of a pharmaceutical composition for the treatment of cancer, wherein said compound is used or is for use in combination with a chemotherapeutic agent."

II. With its communication under Rule 66 PCT dated 26 July 2004, the European Patent Office, acting as an International Preliminary Examining Authority (IPEA), invited the applicant pursuant to Article 34(3)(a) and Rule 68.2 PCT to pay 12 additional fees.

It defined the problem underlying the present application as the provision of uses and compositions for the treatment of cancer and the solution of this problem, as combinations of a conjugate of an antibody against CD44 to a maytansinoid and an anticancer drug.

It determined the technical feature which a priori linked these subject-matters together by the fact that an anti-CD44 antibody - maytansinoid conjugate is combined with another anticancer drug.

It pointed out that prior art document WO 01/24763 (document (1)) described several combinations of an antibody - maytansinoid conjugate with another anticancer drug and that the present application could be distinguished from this prior art only by the fact that a different antibody was used for targeting the maytansinoid toxin.

It noted that this specific conjugate had been disclosed at the congress "Targeted Therapies - First International Congress: 16-18 August 2002, Washington, DC, USA", as reported in IDRUGS, vol. 5, No. 10, October 2002 (2002-10), pages 949-954, XP008031 295 ISSN: 1369-7056 (document (2)).

It concluded then that the contribution that the present application makes, as a whole, over the prior art therefore resided in the fact that this specific antibody-maytansinoid conjugate was combined with another anticancer drug.

It considered that this concept was not inventive since it was usual in anticancer therapy to administer combination therapies and since several specific combinations of an antibody-maytansinoid conjugate with another anticancer drug were disclosed in document (1).

It inferred from this finding that there was lack of unity, the claims covering 13 different groups of inventions.

III. In its reply faxed 27 July 2004, the applicant paid one additional examination fee under protest pursuant to Rule 68.3(c) PCT.

In support of the protest, the applicant argued in its statement under Rule 68.3(c) PCT that the reasoning of the IEPA did not indicate why the selection of a specific anti-CD44 antibody in combination with an anticancer agent was not unitary.

It also argued that the amount of fees requested was excessive and based on arbitrary sub-groups.

In this respect, it pointed out that the division into sub-groups was made on the basis of claim 48 and that the previous dependent claims were not analysed by the IPEA.

It stressed that for example claim 13 related to an microtubule stabilising agent, as the chemotherapeutic agent, which linked groups 1, 2, 6, 7 and 8 together.

IV. In a prior review pursuant to Rule 68.3(e) PCT dated 20 October 2004, the IPEA found the invitation to pay additional fees to be justified and invited the applicant to pay the protest fee.

The review panel considered that as the applicant had paid only one single further examination fee there was no need for it to deal with the argument of the applicant with respect to the amount of fees requested

and to decide whether the amount of € 18 360 was excessive or not.

In substance, the review panel considered that the reasoning given in the invitation to pay additional fees was wholly correct, that the applicant had not provided convincing arguments and that, based on the disclosure of documents (1) and (2), the international application lacked unity a posteriori.

V. With a letter of 15 November 2004, the applicant paid the protest fee according to Rule 68.3(e) PCT.

Reasons for the Decision

1. The protest complies with the requirements of Rule 68.3(c) and (e) PCT and is therefore admissible.

2. If, pursuant to Article 34(3)(a) PCT, the IPEA invites the applicant to restrict the claims to comply with the requirement of unity of invention or to pay additional fees, it must, according to Rule 68.2 PCT, specify the reasons for which the international application is not considered as complying with the requirement of unity of invention.

2.1 According to the established jurisprudence of the boards of appeal, when deciding whether the protest is justified, it has to be judged whether the reasons given in the invitation to restrict or to pay additional fees issued by the IPEA justify its finding of non-unity.

2.2 In the present case, the IPEA's invitation to pay additional fees is based on documents (1) and (2).

2.2.1 Document (2) is an **oral** disclosure made during the First International Congress on Targeted Therapies held on 16-18 August 2002 in Washington, DC, USA.

This lecture was reproduced in a **written** article in the review IDRUGS, vol. 5, No. 10 on pages 949-954 and published in October 2002.

2.2.2 As mentioned in point I of the summary of facts and submissions, the present international application benefits from the priority of earlier application No. EP 02018686.2 of 21 August 2002.

The IPEA had not contested the validity of the claimed priority date, so that, in the absence of any evidence to the contrary, the board considers that the **relevant date** for the present international application is its priority date of 21 August 2002 (Rule 64.1(b)(ii) PCT).

2.2.3 Rule 64.1(a) PCT reads:
"For the purposes of Article 33(2) and (3), everything made available to the public anywhere in the world by means of **written** disclosure (including drawings and other illustrations) shall be considered prior art provided that such making available occurred prior **to the relevant date**".

Accordingly, document (2) is not a prior art document pursuant to Rule 64.1(a) PCT.

Moreover, Rule 64.2 PCT specifically deals with the case where non-written disclosures made available to the public occurred by means of an oral disclosure before the relevant date as defined in Rule 64.1(b) PCT and the date of such non-written disclosure is indicated in a written disclosure which has been made available to the public on a date which is later than the relevant date.

In that case, it is stipulated in this rule that the non-written disclosure will not be considered part of the prior art for the purposes of Article 33(2) and (3) PCT.

2.2.4 From the above, neither the article published in IDRUGS, vol. 5, No. 10, pages 949-954 nor the oral disclosure made during the First International Congress on Targeted Therapies held on 16-18 August 2002 in Washington, DC, USA is prior art relevant for the consideration of inventive step (Rule 65.2 PCT).

3. The reasoning of the IPEA regarding the non-unity is therefore based on a wrong application of the PCT as regards its finding that a conjugate of an anti CD44 antibody with maytansinoid was anticipated by document (2) and that as a consequence, there was lack of inventive step and non-unity a posteriori.

As stressed by the applicant in its letter dated 27 July 2004 and as apparent throughout the application, a conjugate comprising an antibody molecule which is specific for CD44 is however a key feature of the claimed invention and, consequently, of the common inventive concept.

4. The Board therefore finds the applicant's protest entirely justified so that the additional fee and the protest fee must be refunded in accordance with Rule 68.3(c) PCT.

Order

For these reasons it is decided that:

The additional examining fee and the protest fee are to be reimbursed.

The Registrar The Chairman:

A. Townend U. Oswald