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Datasheet for the decision of 10 May 2007

Case Number: W 0029/06 - 3.3.04

Application Number: PCT/EP 2005/013143

Publication Number: WO 2006/061217

IPC: C07K 14/81

Language of the proceedings: EN

Title of invention:
Saquinavir derivatives useful in immunoassay

Applicant:
Roche Diagnostics GmbH

Opponent:
-

Headword:
Saquinavir derivatives/ROCHE

Relevant legal provisions:
PCT Art. 17(3)(a)
PCT R. 13, 40
EPC Art. 154(3)

Keyword:
"Competence of the Boards of Appeal for examining the protest (yes)"
"Invitation to pay additional fees sufficiently reasoned (no)"
"Refund of additional search fee (yes)"
"Refund of protest fee (yes)"

Decisions cited:
W 0004/85, W 0020/06

Catchword:
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Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: W 0029/06 - 3.3.04

International Application No. PCT/EP 2005/013143

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 10 May 2007

Applicant: Roche Diagnostics GmbH et al.
Sandhofer Strasse 116
D-68305 Mannheim (DE)

Decision under appeal: **Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 9 June 2006.**

Composition of the Board:

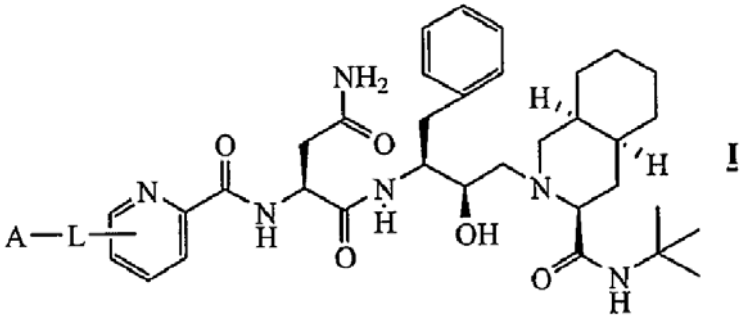
Chair: U. Kinkeldey
Members: R. Gramaglia
T. Bokor

Summary of Facts and Submissions

I. International patent application no. PCT/EP2005/013143 published as WO 2006/061217 and having the title "Saquinavir derivatives useful in immunoassays" was filed on 8 December 2005 with 15 claims.

Claims 1, 4, 6 to 9, 11, and 13 to 15 read as follows:

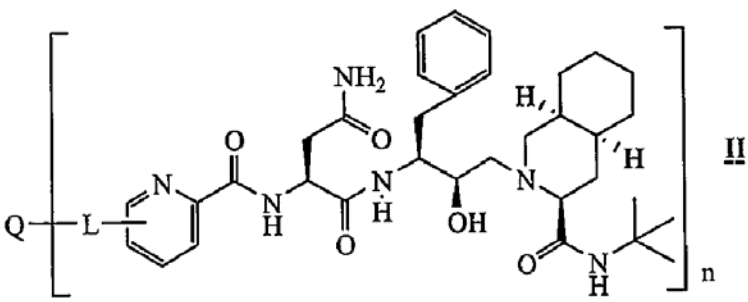
"1. A compound having the structure



I

wherein L is a linking group comprising 0 to 40 carbon atoms arranged in a straight or a branched chain, saturated or unsaturated, and containing up to two ring structures and 0-20 heteroatoms, with the proviso that not more than two heteroatoms may be linked in sequence, and A is an activated functionality selected from the group consisting of active esters, isocyanates, isothiocyanates, thiols, imidoesters, anhydrides, maleimides, thiolactones, diazonium groups, and aldehydes."

"4. A compound having the structure



II

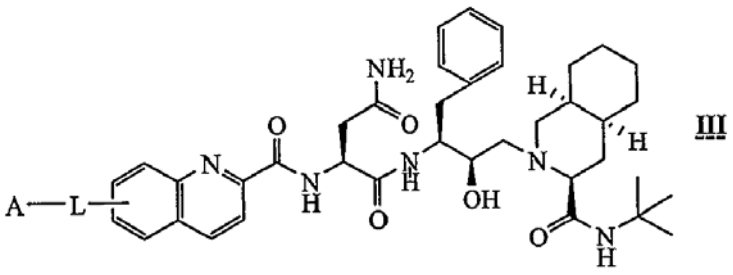
wherein L is a linking group comprising 0 to 40 carbon atoms arranged in a straight or a branched chain, saturated or unsaturated, and containing up to two ring structures and 0-20 heteroatoms, with the proviso that not more than two heteroatoms may be linked in sequence, and Q is selected from the group consisting of polypeptides, polysaccharides, synthetic polymers, and non-isotopic labels, and n is a number from 1 to 50 per kilodaltons molecular weight of Q."

"6. The compound succinimido-oxycarbonyl-ethylamino-glycyl-glycyl-glutaryl-aminomethyl-(pyr)saquinavir conjugate with KLH (**25**)."

"7. The compound succinimido-oxycarbonyl-ethylamino-glycyl-glycyl-glutaryl-aminomethyl-(pyr)saquinavir conjugate with BSA (**26**)."

"8. The compound succinimido-benzoyl-aminocaproyl-aminomethyl-(pyr)saquinavir conjugate with BSA (**27**)."

"9. A compound having the structure

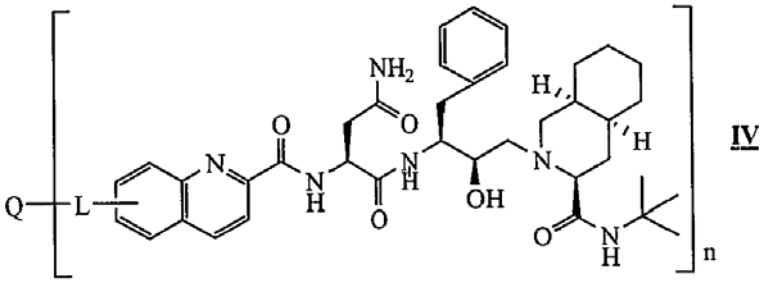


III

wherein L is a linking group comprising 0 to 40 carbon atoms arranged in a straight or a branched chain, saturated or unsaturated, and containing up to two ring structures and 0-20 heteroatoms, with the proviso that not more than two heteroatoms may

be linked in sequence, and A is an activated functionality selected from the group consisting of active esters, isocyanates, isothiocyanates, thiols, imidoesters, anhydrides, maleimides, thiolactones, diazonium groups, and aldehydes."

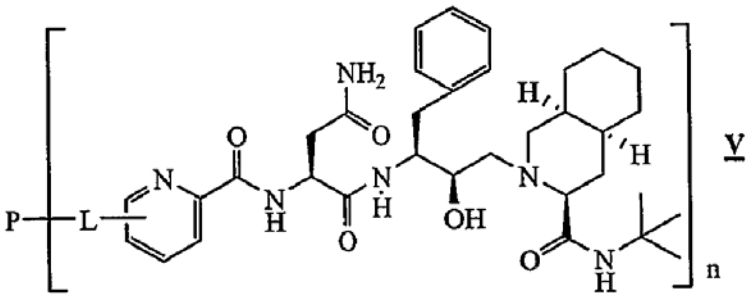
"11. A compound having the structure



IV

wherein L is a linking group comprising 0 to 40 carbon atoms arranged in a straight or a branched chain, saturated or unsaturated, and containing up to two ring structures and 0-20 heteroatoms, with the proviso that not more than two heteroatoms may be linked in sequence, and Q is selected from the group consisting of polypeptides, polysaccharides, synthetic polymers, and non-isotopic labels, and n is a number from 1 to 50 per kilodaltons molecular weight of Q."

"13. An antibody generated in response to a compound having the structure:



V

wherein L is a linking group comprising 0 to 40 carbon atoms arranged in a straight or a branched chain, saturated or unsaturated, and containing up

to two ring structures and 0-20 heteroatoms, with the proviso that not more than two heteroatoms may be linked in sequence, P is a polypeptide, and n is a number from 1 to 50 per kilodaltons molecular weight of P."

"14. A monoclonal antibody specific for saquinavir having less than 1% cross-reactivity with nelfinavir and with saquinavir metabolites M4 and M6."

"15. Murine hybridoma SAQ 137.3 having ATCC No. PTA-6329."

II. On 9 June 2006, the European Patent Office (EPO), acting in its capacity as International Searching Authority (ISA) under Article 16 PCT and Article 154 EPC, informed the applicant that the application did not comply with the requirement of unity of invention (Rule 13.1 PCT) and invited the applicant to pay within a time limit of one month three additional search fees in accordance with Article 17(3)(a) PCT and Rule 40.1. PCT.

III. In the invitation to pay additional fees, the ISA defined the four inventions to which the application related as follows:

"1. claims: 1-3, 9, 10

Derivatives according to formulae I and III with a group A as "activated functionality"

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2. claims: 4, 5, 11, 12

Derivatives of formulae II and IV with a group Q (polypeptides, polysaccharides etc.)

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3. claims: 6-8

Conjugates of specific Saquinavir derivatives with KLH and BSA

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4. claims: 13-15

Antibody generated in response to or specific for Saquinavir derivatives"

The ISA stated that there was non-unity *a priori*, since the derivatives according to formulae I to IV, the conjugates and the antibodies represented different solutions to the possible problem of determining Saquinavir in biological samples. In addition, the structural variations related to subjects 1 and 2 diverged in different directions which were not so linked to support unity of invention. On the one hand, activated functionalities A were claimed and on the other hand, polymeric groups Q were attached to the basic molecule. In view of the completely different reactivity of groups A and Q, a common inventive concept could not be recognized.

IV. The communication of 9 June 2006 also contained the results of the partial international search.

V. With letter dated 10 July 2006, the applicant paid three additional fees under protest. The three additional fees and the protest fee should be charged

from its deposit account. Further examination of the protest was requested.

The applicant argued that the application complied with the requirement of unity of invention. Group 1 claims encompassed Saquinavir derivatives with a group A as activated functionality. This activated functionality of the hapten in group 1 was used to attach polypeptides or polysaccharides (Q) or the like to the hapten of group 1 claims, thus creating a conjugate that could be used as an immunogen, as claimed in group 2 claims. All group 3 claims fell under the claims in group 2 (polypeptide conjugates). The hapten derivatives could be regarded as intermediate products in the process of creating protein conjugates of these hapten derivatives. Concerning the group 4 claims directed to antibodies generated in response to a compound as claimed in groups 2 or 3 claims, the central idea, i.e. creating compounds suitable as immunogens to provide Saquinavir specific conjugates and antibodies thereto, stayed the same. Group 4 claims could therefore be regarded as the final compound produced via intermediate compounds in group 1 (haptens) and groups 2 and 3 (polypeptide conjugates of the haptens that function as immunogens).

VI. On 6 September 2006, the ISA invited the applicant to pay a protest fee (unless such fee had already been paid) and informed the applicant that a prior review had reached the conclusion that the invitation to pay additional search fees was justified in part. As the applicant's arguments concerning the unity of invention of groups 1 to 3 could be followed, two of the additional search fees paid by the applicant would be

refunded. However, the non-unity objection with regard to group 4 was maintained.

VII. With letter of 12 September 2006, the applicant confirmed its previous request (see section V.) to charge its deposit account for the payment of the protest fee.

Reasons for the Decision

1. Given that the international application under consideration has an international filing date of 8 December 2005, the protest is subject to the provisions of the PCT as in force from 1 April 2005.

2. The board is competent to decide on the protest, following decision W 20/06 (3 April 2007), points 1 to 9 of the Reasons. Also, the protest fee was paid in time, and the protest is considered to have been made (Rule 40.2(e) PCT, second sentence).

3. The protest is reasoned and thus admissible.

Invitation to pay additional fees insufficiently reasoned

4. As a result of its "prior review", the ISA informed the applicant that the two additional search fees paid by the applicant for groups 2 and 3 would be refunded. Only the non-unity objection for group 4 was maintained by the ISA.

Under these circumstances, the board is only concerned with the question whether or not the invitation to pay

additional search fees in respect of group 4 was justified.

5. Rule 40.1 PCT stipulates that the invitation under Article 17(3)(a) PCT to pay additional fees must specify the reasons why the international application is not considered to comply with the requirement of unity of invention. The purpose of setting out reasons is to enable the applicant (and the board in case of a protest) to examine whether the invitation is justified.

6. In decision W 4/85 (OJ EPO 1987, 63) and many subsequent decisions, the Boards of Appeal expressed the view that the requirement to give reasons in an invitation pursuant to Article 17(3)(a) PCT was so fundamental that an unsubstantiated invitation could not be regarded as legally effective.

7. In the invitation to pay additional fees issued by the ISA, it is stated that "In the present case there is non-unity a priori, since the derivatives according to formulae I-IV, the conjiugates [*sic*] and the antibodies represent different solutions to the possible problem of determining Saquinavir in biological samples".
No further comments are made with respect to the antibodies of group 4. While the ISA acknowledges that the listed groups of inventions solve a common problem, it gives no reason why the solution to the stated problem as provided by the subject-matter of group 4 is not so linked as to form a single general inventive concept with any of the solutions to the problem as provided by the subject-matter of the other groups of inventions.

8. In decision W 4/85 (*supra*), it is, however further stated that in straightforward cases, all that may be necessary to substantiate a lack of unity is a list of the different groups of subject-matter in the application. It has to be examined whether such a case is before the board here.

9. The international application relates to certain derivatives of the HIV protease inhibitor saquinavir and to antibodies generated in response to such derivatives of saquinavir. There is no reason *a priori* why an antigen or hapten should not be included in the same application as an antibody binding the antigen or hapten, as both kinds of products could be understood to involve corresponding special technical features. It is well known and common practice to claim antigens and antibodies binding thereto in one and the same patent application and/or patent. There is no straightforward reason why this should be different in the case before the board.

10. Thus, if the ISA is not willing to follow the above mentioned approach that antigens and antibodies directed there against can be claimed in one application, then more detailed reasons would have been necessary to substantiate the non-unity objection in the invitation to pay additional fees. In their absence, the invitation to pay does not meet the requirements of Rule 40.1 PCT, and therefore does not provide a basis for retaining the additional search fee paid under protest.

Order

For these reasons it is decided that:

1. Refund of the additional search fee paid by the applicant is ordered.

2. The protest fee shall be refunded.

The Registrar: The Chair:

P. Cremona U. Kinkeldey