BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

A		B		C	X

File Number: W 39/91 - 3.3.2

Application No.: PCT/US90/07210

Publication No.: WO 9109872

Title of invention: Polypeptides selectively reactive with antibodies against human immunodeficiency virus and vaccines comprising the polypeptides

Classification: C07K 15/00

D E C I S I O N
of 21 September 1992

Applicant: Univax Biologics, Inc.

Headword: Polypeptides/UNIVAX

PCT Article 17(3)(a) and Rules 13 and 40

Keyword: "Non-unity a posteriori (no) - inadequate reasons"
Non-existence of a common link not a clear case"

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : W 39/91 - 3.3.2
International Application No. PCT/US90 07210

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 21 September 1992

Applicant : Univax Biologics, Inc.
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Representative : Mr S.A. Bent
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Subject of the Decision : Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fee) of the European Patent Office (branch at The Hague) dated 16 July 1991.

Composition of the Board :

Chairman : P.A.M. Lançon
Members : U. Kinkeldey
R. Schulte

Summary of Facts and Submissions

I. The Applicants filed an international patent application PCT/US90/07210 with 17 claims. Claim 1 reads as follows:

"1. A fusion protein comprised of:

an amino acid sequence selected from the group consisting of NVTENFNMWKN, KAKRRVVQREKRAVG, ERYLKDQQLLGIWGCSGKLIC and EESQNQQEKNEQELLELDKWA; and

a non-HIV polypeptide sequence, such that said amino-acid sequence and said polypeptide sequence comprise the backbone of said fusion protein, wherein said fusion protein reacts with an HIV-positive serum."

II. The EPO acting as an International Search Authority (ISA) sent to the Applicants an invitation to pay three additional search fees pursuant to Article 17(3)(a) and Rule 40.1 PCT.

Further, the ISA considered Claims 9 to 13 as to relate to methods for treatment of the human or animal body by surgery or therapy as well as diagnostic methods and therefore these claims were not searched.

With regard to non-unity of the remaining Claims 1 to 8 and 14 to 17 the ISA found that:

"The general problem underlying the invention stated in the claim 1 is not novel and the solution to the general problem does not involve an inventive step having regard to the state of the art as illustrated by eg.

1. Chemical Abstracts, volume 111, no. 9, 28 August 1989, (Shafferman, Avigodor et al); "Patterns of antibody recognition of selected conserved amino acid sequences from the HIV envelope in sera from

different stages of HIV infection", see abstract 76027v, & AIDS Res. Hum. Retro-viruses 1989, 5(1), 33-39

2. Dialog Information Service, File 157, AIDSLINE accession no. 06475126, Lenz, A et al: "Serologic AIDS diagnosis with polypeptides obtained by genetic technics of the human immunodeficiency virus (HIV - 1)A", & Klin Wochensohr Nov 2 1987, 65 (21) p1042-7

3. EP, A2, 0 305 777 (BEHRINGWERKE) 8 March 1989".

The ISA then considered all cited documents to pertain to fusion proteins which were reactive with HIV positive sera. The original single general inventive concept was thus not acceptable any more and led to the regrouping of the four different HIV oligo-peptide fusion proteins in the following manner:

"A. A fusion protein comprising the amino acid sequence NVTENFNMWKN and further applications thereof according to claims 1-4, 8 and 14-17.

B. A fusion protein comprising the amino acid sequence KAKRRVVQEKRAVG and further applications thereof according to claims 1-4, 8 and 14-17.

C. A fusion protein comprising the amino acid sequence ERYLKDQQLLGIWGCSGKLIC and further applications thereof according to claims 1-8 and 14-17.

D. A fusion protein comprising the amino acid sequence EESQNQQEKNEQELLELDKWA and further applications thereof according to claims 1-4, 8 and 14-17."

III. The Applicants paid the fees under protest. In support of it they submitted that Claim 1 was a generic claim which linked the four specific embodiments of the recited fusion protein under a single general inventive concept. Although the inventions were classified in four groups which might require a more extensive search, breadth of a required search was not a factor to be considered in determining unity of invention. The mere fact that the claimed inventions were separately classified was an improper basis on which to issue an objection for lack of unity. It was the requirement of Rule 13.1 PCT providing that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. The preferred embodiments of Claim 1 were to be subsumed as a group of inventions under a general inventive concept.

Reasons for the Decision

1. The protest is admissible.

2. Rule 40.1 PCT requires that the invitation to pay additional search fees has to be reasoned so that a Board of Appeal can review the justification of the requested additional search fees.

3. The ISA based its finding of lack of unity on the disclosure of documents found by a search, i.e. a posteriori (see list of documents above in paragraph II). According to the ISA the general problem underlying the invention stated in Claim 1 was not novel and the solution to the general problem did not involve an inventive step having regard to the state of the art as illustrated by the three mentioned documents. From this statement it follows that the ISA did not object to novelty of Claim 1

but rather to lack of an inventive step. To arrive at this conclusion it is a mandatory precondition to firstly identify the closest prior art document by a comprehensive study and analysis of at least the three mentioned documents in the invitation; then, secondly, the problem in the light of the closest prior art document has to be stated. A conclusion to non-unity then, however, should only be drawn in clear cases and giving the Applicants fair treatment (see decision G 1/89, OJ EPO 1991, 155).

4. Although the reasons in the invitation given by the ISA are actually stringent, they contain the statement that the cited documents all pertain to fusion proteins comprising one or more HIV gag or env peptides/polypeptides fused to a non HIV polypeptide and that the fusion proteins were reactive with HIV positive sera. The Board concludes that the ISA considered Claim 1 to be novel but not to involve an inventive step in the light of each of the prior art documents cited (see paragraph II above). Thus the four fusion proteins of Claim 1 were no longer linked together to fulfil the requirement of unity under Rule 13.1 PCT.

5. The Board carried out an analysis of the disclosure of each of the three prior art documents mentioned by the ISA and concludes that in document (1) six amino acid sequences are disclosed which encode conserved regions of the HIV-env gene (three from gp 120 and three from gp 41) which were considered to contain potential antigenic domains. Three of these sequences counting from 11 to 20 amino acids were fused to the N-terminus of ß-galactosidase by recombinant DNA techniques, and the purified chimeric proteins were used to titer sera from HIV-infected individuals of various stages. Document (2) (see paragraph II above) discloses fusion proteins which are produced by expressing viral antigens in procaryotic

systems. The peptides representing epitopes of structural core (gag)- and envelope (env)- proteins of HIV are produced in E.coli as stable immunogenic ß-galactosidase fusion proteins. The fusion proteins are used for serologic testing for HIV. Document (3) (see paragraph II above), finally, discloses the production of unprocessed HIV-1 envelope- and core- proteins by expression in E.coli fused to the amino-terminal end of E.coli ß-galactosidase, whereby the fusion proteins are protected of proteolytic destruction. The fusion proteins produced were all recognised by HIV-1-antibody positive sera of patients.

6. A priori and taking into account solely the disclosure of the international patent application, the problem to be solved seems to be the improvement of diagnosis, treatment and prevention of HIV infection. One has to conclude that each of the above analysed prior art documents already provides solutions to this problem by preparing fusion proteins which contain part of the HIV-protein and part of a non-HIV-protein, wherein the fusion protein reacts with an HIV-positive serum. The ISA's position that by each of the prior art documents discussed above an a priori common link, holding together the four amino acid sequences mentioned in Claim 1 is no longer existent, can thus be followed.

7. The Board considers document (1) as the closest prior art because it already mentions the length of the amino acid sequence stemming from the HIV-protein, namely the number of 11-20 amino acids. The amino acid sequences mentioned in Claim 1 of the international patent application (see paragraph I above) have a number of amino acids of 11, 15 and two of them 21.

In the light of the mentioned closest prior art the technical problem to be solved can be seen in the

provision of further alternatives to the fusion proteins described there.

8. Whether or not the four alternatives claimed in Claim 1 of the international patent application are linked together in a way to fulfil the requirement of unity within the meaning of Rule 13.1 PCT, be it by common structure which is not at the same time identical with the alternatives already provided in the state of the art, or be it by common effects or functions which distinguish them from those fusion proteins described in the prior art is a question which only can be answered after having extensively studied those features which distinguishes the four alternatives of Claim 1 from this prior art and whether these features may contain a common link. The ISA did not provide this information in its invitation. As far as the Board, after a preliminary examination, can see, the four claimed amino acid sequences which are the features of Claim 1 considered to be different from the proteins of the prior art, have apparently no common link in their structure. They relate to four different highly conserved polypeptide sequences of the HIV proteins gp 41 and gp 120 containing essentially different amino acids. They may, however, have common functions or effects different from those proteins disclosed in document (1) which could form the necessary link.

9. At present, the Board is not in a position to decide on unity of invention because neither the ISA carried out the respective analysis, nor did the applicants argue in substance about any of the decisive, above-mentioned criteria for a unifying concept of the invention. The applicants relied on the argument that breadth of a required search was not a factor to be considered in determining unity of invention and further that Rule 13.1 PCT provided that the international application shall

relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. The preferred embodiments of Claim 1 were to be subsumed as a group of inventions under a general inventive concept.

10. Thus, the submissions and facts on file do not allow the present case to be considered as a clear one within the meaning of decision G 1/89 (see above point 3). In such a borderline case the ISA should refrain from considering an application as not complying with the requirement of unity of invention. In the absence of an adequate reasoning of the ISA's invitation the Board gives the benefit of doubt to the Appellants. Therefore, the three additional search fees have to be reimbursed.

Order

For these reasons, it is decided that:

Reimbursement of the three additional fees is ordered.

The Registrar: The Chairman:

P. Martorana P. Lançon

Schmitt 12.10.92

Ulbrich 8.10.92

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