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File Number: W 3/92 - **332**
Application No.: PCT/EP91/01479
Publication No.: WO 9202621
Title of invention: Allergens of alder pollen and applications thereof

Classification: C12N 15/29

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

Applicant: Biomay Biotechnik Prod. und
Hanel GmbH et al

Headword: Allergens/BIOMAY

PCT Article 17(3)(a), Rules 13.1 and 40.1

Keyword: "Invitation not accompanied by a reasoned statement - failure to
determine the technical problem"
"Reimbursement of additional search fee"



Case Number : W 3/92 -
International Application No. PCT/EP91/01479

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

Applicant : Biomay Biotechnik Produktions und
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Representative : P. Itze
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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 30 December 1991.

Composition of the Board :

Chairman : A. Nuss
Members : U. Kinkeldey
R. Schulte

Summary of Facts and Submissions

- I. International patent application PCT/EP91/01479 was filed at the European Patent Office. Claim 1 reads as follows:
- "1. A recombinant DNA molecule comprising a DNA coding for a polypeptide having at least one epitope of an allergen of trees of the order Fagales, the allergen is selected from the group Aln g I, Cor a I or Bet v I."
- II. The European Patent Office, as competent International Search Authority (ISA), issued an invitation pursuant to Article 17(3)(a) and Rule 40.1 PCT to pay two additional fees. The ISA considered the application not to comply with the requirements of unity of invention as set out in Rule 13.1 of the PCT.
- III. Said invitation was accompanied by a reasoning which identified the three groups of invention as follows:
- (1) Claims 4 to 7, 22 completely; 1 to 3, 15 to 21, 25 to 32 partially:
Alder major allergen Aln g I: recombinant DNA clones, polypeptides, and epitopes, uses thereof.
 - (2) Claims 8 to 11, 23 completely; 1 to 3, 15 to 21, 25 to 32 partially:
Hazel major allergen Cor a I: recombinant DNA clones, polypeptides and epitopes, uses thereof.
 - (3) Claims 12 to 14, 24 completely; 1 to 3, 15 to 21, 25 to 32 partially:
Birch major allergen Bet v I: recombinant DNA clones, polypeptides and epitopes, uses thereof.

Under the heading "Lack of Unity of the Invention" the ISA continued in its invitation that the unifying principle was seen a priori to be the one of cloning genes for polypeptides encoding epitopes of allergens of trees of the order Fagales and the production of these polypeptides. It was; however, clear from the prior art that the gene for the Birch major allergen (Bet v I) had in fact been cloned and sequenced (Embo J 8: 1,935 to 1,938) and furthermore that the polypeptide had been purified and sequenced (J Allergy Clin Immunol 81: 265). In addition synthetic allergenic epitopes for the Birch allergen had been described (Int Arch Allergy Appl Immunol 89: 410 to 415).

The unifying concept was thus known in the prior art and the cloning of each allergen of Claim 1 (Aln g I, Cor a I, and Bet v I) each derived from separate genera and being essentially different are regarded as non-unitary according to Rule 13.1 PCT.

- IV. Within the prescribed time limit the Applicant's paid the additional fees under protest and requested one additional research-fee to be reimbursed.

Non-unity of the third group of inventions specified by the ISA, relating to the cloning of Bet v I was explicitly acknowledged.

Unity of groups (1) and (2) specified by the ISA, however, was given due to the fact that the sequences of Aln g I and Cor a I were published for the first time in the application and both sequences showed high homology proved by cross-hybridisation. Also the reactive parts of the sequences were homologous.

Reasons for the Decision

1. The protest is admissible.

2. The Applicants do not contest that the international patent application relates to two inventions, namely to the groups of invention (1) and (2) on the one hand and group (3) on the other hand. For the latter no refund of the additional search fee is requested (see paragraph IV above). Under these circumstances, the Board is only concerned with the question of unity of invention of groups (1) and (2) as defined in the invitation (Rule 40.2(c) PCT, first sentence).

3. If an invitation to pay additional search fees under Article 17(3)(a) PCT by the EPO, acting as the ISA, is made, Rule 40.1 PCT requires this to be reasoned. Based on the grounds for non-unity given by the ISA in its invitation an appellate competent body, namely a Board of Appeal in cases where the EPO acts as the ISA, should be in a position of reviewing the justification of the requested additional fee. This requirement was subject-matter of decision W 04/85, OJ EPO 1987, 63 and many subsequent decisions where 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. The principle of these decisions was further specified in decisions W 11/89 of 9 October 1989, W 14/89 of 26 September 1990 and W 6/91 of 3 April 1992, where it was decided that the determination of the technical problem underlying the invention is a mandatory pre-condition for the assessment of unity of invention, i.e. whether or not the subject-matter claimed as solution of such a problem represents a single general inventive concept. The disregard of this principle was

considered to be in itself sufficient justification for the reimbursement of the additional search fees.

4. As becomes apparent from the "reasons" given by the ISA (see above paragraph III) the invitation contains only statements or allegations that in view of the disclosure of certain documents "the unifying concept is thus known in the prior art ...". There is no analysis as to what the ISA considered to be the closest prior art or of the particular technical problem in view of one of the three prior art documents cited, let alone of the disclosure of the international application. The facts of the present case are, therefore, in line with the facts of, for example, above-mentioned decision W 6/91, where the justification for the reimbursement of the additional fees was based on the lack of the definition of the problem to be solved.

5. In decision W 4/85 (see above point 3), it is, however, further stated that in straight forward 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 is to be examined, whether such a case is before the Board here.

6. The international patent application relates to complex recombinant DNA molecules encoding epitopes of specific allergens, prepared by genetic engineering.

However, even in this situation, the circumstances of a case might be such that the non-unity is apparent at first glance. On the face of it, the two recombinant DNA molecules remaining now in Claim 1 could well concern entirely unrelated solutions of either a common technical problem or of distinct technical problems, because they relate to two different DNA-molecules, which are presented

as alternatives in this claim. On the other hand, it cannot be excluded that a comprehensive study of the description of the international patent application and the prior art could lead to the conclusion that the two products are technically so closely interconnected that a unifying concept would be acknowledged. It is thus clear that it cannot be readily established whether or not the claimed subject-matter lacks unity of invention.

Consequently, the present case cannot be considered straightforward.

7. Since this is so, the Board is also of the opinion, that the ISA did not take into account the principles laid down by the Enlarged Board of Appeal in the decisions G 1/89 and G 2/89 (OJ EPO 1991, 155 and 166) stating, that the Applicant should be given fair treatment and additional fees should be charged under Article 17(3)(a) PCT only in clear cases.
8. It follows from all the above that the invitation was issued in violation of the requirements laid down in Rule 40.1 PCT. It is not, therefore, legally effective.

Order

For these reasons, it is decided that:

Reimbursement of one additional fee paid by the Applicant is ordered.

The Registrar:

The Chairman:

P. Martorana

A. Nuss