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File Number: W 22/92 - 3.3.2

Application No.: PCT/US 91/05446

Publication No.:

Title of invention: Reduction or prevention of sensitization to drugs

Classification: A61K 33/02

DECISION  
of 16 November 1992

Applicant: Alza Corporation

Headword: Sensitization/ALZA

PCT Article 17(3)(a); Rule 13.1; Rule 40

Keyword: "Non-unity 'a priori' - partially contested - unity of invention  
acknowledged to the extent requested in the protest"



Case Number : W 22/92 - 3.3.2  
International Application No. PCT/US 91/05446

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 16 November 1992

**Applicant :** Alza Corporation  
950 Page Mile Road  
P.O. Box 10950  
Palo Alto  
California 94303-0802 (US)

**Representative :**

**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 18 February 1992.

**Composition of the Board :**

**Chairman :** P.A.M. Lançon  
**Members :** I.A. Holliday  
E.M.C. Holtz

**Summary of Facts and Submissions**

- I. The Applicant filed international patent application PCT US/91/05446.
  
- II. The EPO, acting as International Search Authority (ISA) sent to the Applicant an invitation to pay two additional search fees in accordance with Article 17(3)(a) and Rule 40.1 PCT.

The ISA indicated that the subject-matter claimed related to three inventions set out as follows:

- 1. Claims 1-3, 6-10, 13-19: Sensitizing drug and weak base composition
  
- 2. Claims 4,5,11,12,20,21: Sensitizing drug and ionophore composition
  
- 3. Claims 25-29: Transdermal drug delivery device.

- III. The Applicant accepted that Claims 25-29 related to a separate invention but argued that Claims 1-24 related to a single invention. Thus, one of the additional search fees was paid under protest.

The Applicant argued that Claims 1-24 covered only one invention namely a sensitizing drug and an antigen-processing inhibiting agent. An ionophore (Claim 4) and a weak base (Claim 6) were merely examples of such inhibiting agents. Even if it could be argued that Claims 4 and 6 related to separate inventions, these must at least be regarded as "a group of inventions so linked as to form a single general inventive concept" in terms of Rule 13.1 PCT.

## Reasons for the Decision

1. The protest is admissible.
2. Adequate reasoning under Rule 40.1 PCT
  - 2.1 Rule 40.1 PCT stipulates that the invitation provided for in Article 17(3)(a) PCT must specify the reasons why the International application is not deemed to comply with the requirements of unity of invention. The purpose of setting out reasons is to enable the Applicant and, in the case of a protest, also the appeal body to examine whether the request to pay additional fees owing to lack of unity of the invention is justified. At the least, the considerations that motivated the decision must be readily comprehended from the reasons indicated in the invitation of the ISA.
  - 2.2 In two earlier published decisions (W 4/85, OJ EPO 1987, 63 and W 7/86, OJ EPO 1987, 67) the Boards of Appeal have already expressed the view that the requirement to give reasons in an invitation pursuant to Article 17(3)(a) and Rule 40.1 PCT is so fundamental that an unsubstantiated invitation cannot be regarded as legally effective. The first mentioned decision states 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. However, in the latter decision, it was deemed appropriate to add that such is rarely the case.
  - 2.3 In the present case the list of inventions set out above was accompanied only by an explanation concerning the mechanics of the search but no reasons were given why the ISA considered the respective subject-matter to relate to

three inventions. It is, however, clear that the Applicant understood the nature of the plurality objection in preparing arguments to refute it.

Since the sheet accompanying Form PCT/ISA 6 contained no reference to the prior art, it is apparent that an objection "a priori" is intended.

3. Unity of invention

3.1 In the case of a protest under Rule 40(2) PCT, where an objection a priori is raised, no examination of the merits of the claims in comparison with the state of the art has been carried out. The only way to determine the technical problem (in contradistinction to the normal approach) is to rely on the description of the application and the provisional acknowledgement of the prior art therein, if given. According to the description, the problem underlying the application is to prevent the sensitization of the skin which occurs during the elicitation phase when certain drugs are applied transdermally (page 2, lines 28-32; page 4, lines 21-23). The problem is solved by applying to the patent over a predetermined period: (a) a therapeutically effective amount of a sensitizing drug and (b) an antigen processing-inhibiting agent in an amount effective to inhibit the processing of the drug as an antigen (page 4, line 30 to page 5, line 2 and Claim 1). Skin sensitization has been shown to occur when the drug acts as an antigen which causes a proliferation of T cells which recognise the antigen. Prior art referred to on page 3 of the application indicates that low pH is a factor in such activity. Both an ionophore and a weak base are shown to raise the pH in the lysosomal membranes of the skin and thus inhibit antigen processing. It is accordingly the opinion of the Board, in the absence of any prior art which destroys the generality of Claim 1,

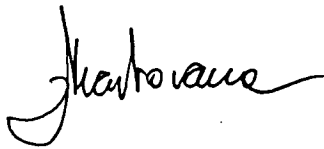
that the use of an ionophore and a weak base are alternatives which fall within the same general inventive concept. The requirements of Article 13.1 are therefore satisfied and the additional search fee paid under protest must be refunded.

Order

For these reasons, it is decided that:

Reimbursement of the additional fee to the Applicant is ordered.

The Registrar:




P. Martorana

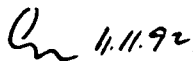
The Chairman:



P. Lançon



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