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**D E C I S I O N**  
**of 19 September 2005**

**Case Number:** W 0014/04 - 3.3.2

**Application Number:** PCT/US03/02797

**Publication Number:** WO 03/105811

**IPC:** A61K 9/50

**Language of the proceedings:** EN

**Title of invention:**

Controlled Release Compositions and Methods for using same

**Applicant:**

SOUTHWEST RESEARCH INSTITUTE

**Opponent:**

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**Headword:**

Release compositions/SOUTHWEST RESEARCH INSTITUTE

**Relevant legal provisions:**

PCT Art. 17(3) (a)

PCT R. 40, 13

**Keyword:**

"Lack of reasoning"

**Decisions cited:**

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**Catchword:**

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Case Number: W 0014/04 - 3.3.2

International Application No. PCT/US03/02797

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.2  
of 19 September 2005

**Applicant:** SOUTHWEST RESEARCH INSTITUTE  
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**Representative:** Morris, Paula D.  
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**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 10 October 2003.

**Composition of the Board:**

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

## Summary of Facts and Submissions

I. On 10 October 2003, the International Searching Authority (ISA) dispatched an invitation to the Applicant to pay three additional search fees on the grounds that the international application contained, *inter alia*, the following four inventions:

Invention 1:

Claims 1, 3, 4, 6-8, 9-18 partially, 20 partially, 22-60 partially:

Microcapsules adapted to provide controlled release of an active agent, for mucosal delivery of antihistamines or anticholinergics comprising:

- 1.1 a shell comprising a release retardant (claim 1, 4, 8-18 partially, 20 partially, 22-60 partially) or
- 1.2 an absorption enhancer (claims 3,6,7,8-18 partially, 20 partially, 22-60 partially).

Invention 2:

Claims 2,5,9-18 partially, 19,20 partially, 21,22-60 partially:

Microcapsules adapted to provide controlled release of an active agent, for mucosal delivery of antihistamines or anticholinergics comprising a single enantiomer of the active agent.

Invention 3:

Claims 61-88

Method for alleviating motion sickness or allergy comprising administering a highest pharmacological activity enantiomer of a phenothiazine

Invention 4:

Claims 89-97

method for resolving the (+) and (-) enantiomer of ethopropazine

It mentioned that all subject-matters mentioned under invention 1, although not necessarily linked by a common concept, could be searched without particular effort, so that it would not justify to ask for more than one search fee.

As to a link between invention 1, 2 and 3, the ISA considered in substance that, since document (1) (Pharmacological Research, vol. 38, July 1998, pages 35-39) already disclosed an anti-histamine (promethazine), microencapsulated in microspheres (page 36, left-hand column, paragraph 2; page 38, right-hand column, lines 13-18), no structural feature could be seen which could be considered as a special feature within the meaning of Rule 13.2 PCT.

Concerning invention 4, it expressed the view that it was clearly concerned with a different problem than the one in the groups 1 to 3.

II. The Applicant replied to the invitation in due time by paying under protest the three additional search fees on 24 November 2003.

In summary, it submitted that the ISA failed to demonstrate that the prior art disclosed microcapsules adapted to provide controlled release of an active agent, for mucosal delivery of antihistamines with

minimal side effect similar to the ones claimed in its application.

III. In response to the applicant's payment of three additional fees under protest, on 29 March 2004 the Review Panel of the EPO communicated to the applicant the result of a prior review under Rule 40.2(e) PCT of the justification for the invitation to pay additional search fees.

It first observed that the applicant had only provided observations relevant to inventions 1 and 2.

It considered that the argumentation given by the applicant did not invalidate the ISA's reasoning leading to the non unity invention.

However, it ordered the refund of one additional search fee as, in its opinion, "the extra necessary search effort for invention 2 did not justify the levying of an additional search fee".

It further invited the Applicant to pay a protest fee for the examination of the protest (Rule 40.2(e) PCT).

IV. On 29 April 2004 the applicant paid the protest fee.

### **Reasons for the Decision**

1. PCT Rule 40.2.(c) provides that: "Any applicant may pay the additional fee under protest, that is, accompanied by a reasoned statement to the effect that the international application complies with the requirement

- of unity of invention or that the amount of the required additional fee is excessive."
2. The purpose of the protest procedure under Rule 40.2(c) PCT is to enable the justification for the invitation to pay to be submitted to substantive review; however the Board's competence to examine is limited to the issue of whether or not, considering the reasons stated by the ISA and the submissions made in support of the protest, retaining additional search fees was justified. The Board cannot investigate ex officio whether an objection of lack of unity would have justified for other reasons.
  3. In the present case, the search fee paid for invention 2 was reimbursed, so that only the fees relating to inventions 3 and 4 are still in dispute. However, the appellant did not make any submissions at all as to inventions 3 and 4. As a consequence, and because the reasons given by the ISA are not manifestly untenable, there is nothing the Board could examine as regards the fees paid for the search of inventions 3 and 4. As a consequence, in the Board's view, although the protest has to be dismissed the protest fee should be reimbursed.

**Order**

**For these reasons it is decided that:**

1. The protest is dismissed.
2. The protest fee is to be reimbursed.

The Registrar:

The Chairman:

A. Townend

U. Oswald