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**D E C I S I O N**  
of 10 April 2003

**Case Number:** W 0019/02 - 3.3.4

**Application Number:** PCT/GB 02/00557

**Publication Number:** WO 02064108

**IPC:** A61K 9/00

**Language of the proceedings:** EN

**Title of invention:**  
Delivery of biologically active agents

**Applicant:**  
Medical Research Council

**Opponent:**  
-

**Headword:**  
Drug delivery/MEDICAL RESEARCH COUNCIL

**Relevant legal provisions:**  
PCT Art. 17(3)(a), 17(2)(a)(i)  
PCT R. 40.1, 40.2(e), 13.1, 13.3, 13.2, 39.1(iv)  
EPC R. 105(3)

**Keyword:**  
"Lack of unity *a posteriori* (no)"

**Decisions cited:**  
G 0001/89, W 0006/90

**Catchword:**  
-



**Case Number:** W 0019/02 - 3.3.4  
**International Application No.** PCT/GB 02/00557

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.4**  
**of 10 April 2003**

**Applicant:** MEDICAL RESEARCH COUNCIL  
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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 fees) of the European Patent Office (International Searching Authority) dated 5 June 2002.

**Composition of the Board:**

**Chairman:** U. M. Kinkeldey  
**Members:** R. E. Gramaglia  
B. Günzel

## Summary of Facts and Submissions

I. International patent application PCT/GB 02/00557 was filed on 11 February 2002 with 26 claims, of which claims 1, 7, 8, 12, 16, 18, 20 and 23 to 26 read as follows:

"1. A method of delivering a biologically active agent to the cervix, the method comprising using a needleless injector.

7. A method of ripening the female cervix, the method comprising administering a cervical ripening agent to the cervix using a needleless injector.

8. A system for delivering a biologically active agent to the cervix comprising an agent which is biologically active on the cervix and a needleless injector.

12. A needleless injector loaded for injection with an agent which is biologically active on the cervix.

16. A vial for insertion into, and containing an agent for delivery by, a needleless injector wherein the agent is an agent which is biologically active on the cervix.

18. A method of preparing a needleless injector for use in delivering a biologically active agent to the cervix, the method comprising loading the injector with the biologically active agent.

20. A pharmaceutical formulation comprising an agent for delivery to the cervix and a carrier suitable for use in a needleless injector.

23. Use of a cervical ripening agent in the manufacture of a medicament for treating a female in need of a cervical ripening agent wherein the cervical ripening agent is for delivery using a needleless injector.

24. Any novel method for delivering a biologically active agent to the cervix, as described herein.

25. Any novel needleless injector loaded with an agent for delivery to the cervix, as described therein.

26. Any novel vial for use in a needleless injector and containing an agent for delivery to the cervix as described herein."

Claims 2 to 6, 9 to 11, 13 to 15, 17, 19 and 21 to 22 concerned specific embodiments of the method of claim 1, the system of claim 8, the needleless injector of claim 12, the vial of claim 16, the method of claim 18 and the pharmaceutical formulation according to claim 20, respectively.

II. On 5 June 2002 the European Patent Office (EPO), acting as an International Searching Authority (ISA), invited the Applicant to pay within a time limit of 30 days three additional search fees pursuant to Article 17(3)(a) and Rule 40.1 PCT and issued a partial search report on claims 1 to 11 (partially), 16, 17 and 20 to 26 (partially) relating to the invention first mentioned. As regarded this partial search, the ISA pointed out that although claims 1 to 7 related to a method of treatment of the human/animal body, the search had nevertheless been carried out, based on the alleged effects of the composition.

III. The invitation further stated that the application related to four groups of inventions:

1. Claims: 1 to 11 (in part), 16, 17 and 20 to 26 (in part)

Pharmaceutical composition for the ripening of the cervix containing a prostaglandin;

2. Claims: 1 to 11 (in part), 16, 17 and 20 to 26 (in part)

Pharmaceutical composition for the ripening of the cervix containing MCP-1;

3. Claims: 1 to 11 (in part), 16, 17 and 20 to 26 (in part)

Pharmaceutical composition for the ripening of the cervix containing interleukin 8; and

4. Claims: 12 to 15, 18 and 19  
A needleless injector and its method of manufacture.

IV. The ISA further observed that the problem underlying the application was the provision of an injectable pharmaceutical composition containing a ripening agent for the cervix. The proposed solution was an injectable pharmaceutical composition containing as ripening agents prostaglandins, MCP-1 or IL-8. However, this common feature (injectable pharmaceutical composition comprising a cervical ripening agent) was already known in the prior art, for example, from the following documents:

- (1) US-A-5,908,829, which disclosed an injectable pharmaceutical composition for cervical ripening containing MCP-1 and prostaglandin; and
- (2) EP-A-0 543 476, which disclosed an injectable pharmaceutical composition for cervical ripening containing IL-8 and prostaglandin.

In view of this state of the art, the above common concept was no longer new and the problem underlying the present application had to be redefined as the provision of further pharmaceutical compositions for cervical ripening, inventions 1 to 3 above (see Section III supra) being each a separate solution to this problem.

The ISA further argued that the above groups 1 to 3 of inventions were not linked to each other by any other special technical feature in the sense of Rules 13(1) and (2) PCT so as to form a single inventive concept. Moreover, since no common technical feature existed between a pharmaceutical composition and a needleless injector/its method of manufacture, a single inventive concept was also missing between group 4 of inventions (claims 12 to 15, 18 and 19) and the remaining groups of inventions 1 to 3 (see Section III supra).

- V. On 4 July 2002, the Applicant paid three additional fees under protest pursuant to Rule 40.2(c) PCT. In support of the protest, the Applicant submitted that groups 1 to 4 were linked by the common utility of providing a new and inventive method of delivery of a biologically active agent to the cervix using a

needleless injector. The Applicant further noted that the amount of the additional fee was excessive, since the claimed invention could have readily been searched by reference to a reasonable number of classifications.

- VI. With a notification dated 19 September 2002, a review panel within the meaning of Rules 105(3) EPC and 68.3(c) PCT confirmed the ISA's opinion regarding lack of unity. However, it considered that the partial search performed by the ISA (see Section II supra) also covered inventions 1 to 3 and ordered a refund of two of the three additional search fees.
- VII. By the same date, the ISA issued the search report established for groups 1 to 4 of inventions.
- VIII. The Appellant requests that the additional fees and the protest fee be refunded.

### **Reasons for the Decision**

- 1. The protest is admissible.
- 2. According to Rule 13.1 PCT, the international patent application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. If the ISA considers that the claims lack this unity, it is empowered, under Article 17(3)(a) PCT, to invite the Applicant to pay additional fees.
- 3. Lack of unity may be directly evident a priori, i.e. before the examination of the merits of the claims in comparison with the state of the art revealed by the

search (cf., for example, decision W 6/90, OJ EPO 1991, 438). Alternatively, having regard to decision G 1/89 of the Enlarged Board of Appeal (OJ EPO 1991, 155), the ISA is also empowered to raise an objection *a posteriori*, i.e. after having taken the prior art revealed by the search into closer consideration. This practice is laid down in the PCT Search Guidelines, Chapter VII, 9 which are the basis for a uniform practice of all International Searching Authorities. The Enlarged Board of Appeal indicated that such consideration represents only a provisional opinion on novelty and inventive step which is in no way binding upon the authorities subsequently responsible for the substantive examination of the application (point 8.1 of the Reasons for the decision). In point 8.2 of the Reasons, the Enlarged Board mentioned that such invitation to pay additional fees should always be made "with a view to giving the Applicant fair treatment" and should only be made in clear cases.

4. According to Rule 13.3 PCT, the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.
5. Since the review panel already ordered a refund of two of the three additional search fees (see Section VI *supra*), it remains only to be decided whether or not one additional search fee and the protest fee have to be refunded.
6. The ISA has based its finding of lack of unity upon *a posteriori* considerations. It found that the common inventive concept underlying the present claims was the



provision of an injectable pharmaceutical composition containing a ripening agent for the cervix. The proposed solution was an injectable pharmaceutical composition containing as ripening agents prostaglandins, MCP-1 or IL-8. However, this common feature (injectable pharmaceutical composition comprising a cervical ripening agent) was already known in the prior art, for example, from documents (1) and (2). Furthermore, the ISA considered that a single inventive concept was also missing between group 4 of inventions (claims 12 to 15, 18 and 19) and the remaining groups of inventions 1 to 3 (see Section III supra). Thus, in the absence of other technical features which would be suitable to link the claimed subject-matter together as required by Rule 13.2 PCT, the subject-matter of the present claims did not relate to one invention but to four separate ones.

7. However, none of the claims at issue (see Section I supra) is addressed to an injectable pharmaceutical composition comprising a cervical ripening agent. Therefore, the board disagrees to the finding by the ISA that the technical problem solved by the claimed subject-matter lies with the provision of an injectable pharmaceutical composition containing as cervix ripening agents prostaglandins, MCP-1 or IL-8.
8. In order to define the underlying technical problem, the closest state of the art has to be defined taking rather into account that the objected claims **all** directly or indirectly rely on a **needleless** injector and its use for administering a biologically active agent to the cervix.
9. This combination of features is disclosed in none of

the documents cited in the search report. In fact, documents (1) and (2) are concerned with the administration of medicaments to the cervix by means other than a needleless injector (see paragraph 11 *infra*). As for document

(3) O'Brien J.M. et al., *Ultrasound Obstet. Gynecol.*, Vol. 13, pages 137-139 (1999),

it is concerned with the assessment of cervical dimension during endovaginal sonographic examinations, wherein 10 ml of a normal saline solution was placed intravaginally via a needleless syringe. However, this technique cannot be considered as a method for administering a biologically active product to the cervix by means of a needleless syringe since normal saline is no biologically active product to the cervix. Moreover, no contact occurs between the syringe and the cervix in the procedure disclosed in document (3). The needleless injectors according to the present application, however, require a direct contact to the cervix/vaginal fornix (see page 6, lines 10 to 19), since injection of the drug occurs at high pressure (see page 3, lines 28 to 30).

10. The closest state of the art is thus represented by document (1) or (2). The former (see column 7, line 27) discloses a pharmaceutical composition containing the cervix ripening agent MCP-1. In column 4, lines 28 to 31 thereof, it is suggested that this medicament be administered "as a gel or cream or by injection into the cervix". Document (2) (see column 4, lines 2 to 19) discloses a pharmaceutical composition containing the cervix ripening agent IL-8. In column 6, lines 34 to 36, it is suggested that this medicament be

administered "in form of a gel, ointment or local injection". Compared with this prior art, the present application purports to solve the problem of providing an alternative method for administering a biologically active product to the cervix (see page 1, line 29 to page 2, line 24 of the application). This problem is solved by the use of a needleless injector (see page 3, line 4 to 6). The advantageous technical effects achieved using a needleless injector compared with other methods of administration are pointed on page 9, lines 15 to 19 and in Example 3 of the description.

11. In view of the foregoing, the board also disagrees to the ISA's finding that there is no common technical feature susceptible of linking the subject matter of groups 1-4 of inventions together. In fact, once claims 1 to 7 and 24 are left out of consideration because they relate to methods of treatment of the human/animal body (see Article 17(2)(a)(i) and Rule 39.1(iv) PCT), the remaining independent claims relate to kits of parts comprising two components (claims 8 to 17, 25 and 26), namely a needleless injector or a part thereof in combination with an agent biologically active to the cervix, or to a pharmaceutical composition comprising two ingredients (claims 20 to 22), all of which are specifically designed for performing the administration via a needleless injector of a biologically active substance to the cervix. Moreover, claims 18 and 19 are also unitary with claim 8, since they relate to a method for making the kit of parts of claim 8. Finally, claim 23, drafted according to a second/further medical use claim, is also unitary with the remaining claims since it relies on the new mode of administration according to the application at issue.

12. Therefore, the board cannot follow the ISA's reasoning, according to which the searched subject-matter (inventions 1 to 4) is not considered as complying with the requirement of unity of invention. Hence, the invitation provided for in Article 17(3)(a) and Rule 40.1 PCT to pay 3 (three) additional search fees for inventions 1 to 4 cannot be regarded as legally effective, as it does not satisfy the requirement of Rule 40.1 PCT.

## **Order**

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

1. Refund of one additional search fee paid by the Applicant is ordered.
2. The protest fee shall be refunded.

The Registrar:

The Chairwoman:

P. Cremona

U. M. Kinkeldey