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**D E C I S I O N**  
**of 10 November 2005**

**Case Number:** T 1377/04 - 3.2.02

**Application Number:** 00975329.4

**Publication Number:** 1225938

**IPC:** A61M 5/28

**Language of the proceedings:** EN

**Title of invention:**

Medicament cartridge and injection device

**Applicant:**

Antares Pharma, Inc.

**Opponent:**

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**Headword:**

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**Relevant legal provisions:**

EPC Art. 54, 56, 122

**Keyword:**

"Novelty and Inventive step (yes, after amendments)"

"Reimbursement of fee for reestablishment of rights (yes)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 1377/04 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 10 November 2005

**Appellant:** Antares Pharma, Inc.  
13755 1st Avenue North  
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**Representative:** Holme, Edvard  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 28 May 2004  
refusing European application No. 00975329.4  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** D. Valle  
E. Dufrasne

## Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal on 23 July 2004 against the decision of the examining division posted on 28 May 2004 refusing the European patent application 00975329.4. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 30 September 2004.

II. The examining division held that the application did not meet the requirement of Articles 52 and 54 EPC (lack of novelty) having the regard to the teaching of

D1 = US - A - 4 171 698.

Additionally the following documents are cited in the contested decision:

D2 = US - A - 3 811 441

D3 = GB - A - 1 181 037.

III. Oral proceedings took place on 10 November 2005.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of:

claims: 1 to 8 and

description: pages 1 to 7

as submitted during oral proceedings;

Figures: 1 to 10 as published (WO - A - 01/30424).

IV. Claim 1 reads as follows:

"An injection device, comprising a medicament cartridge (12, 112, 212) for an injection system comprising:

- a liquid based medicament;
- a tube (14) having first and second ends (16, 18) and a lumen (15) with a longitudinal axis for retaining the medicament therein;
- a needle (20) operatively associated with the second end (18) of the tube (14) and having a piercing end (19) extending into the lumen (15), said needle (20) has an injection tip (21) opposite the piercing end (19), which injection tip is extending beyond the second end of the tube
- a first stopper (22) located near the second end (18) moveable within the lumen along the longitudinal axis; and
- a second stopper (24) located near the first end (16) moveable within the lumen along the longitudinal axis,
- movement of the first stopper (22) towards the needle (20) is able to cause the piercing end (19) of the needle (20) to pierce the first stopper (22) to create a fluid pathway for the medicament through the needle, and
- movement of the second stopper towards the second end (18) of the tube is able to compress the medicament held between the second stopper (24) and the first stopper (22) so that the medicament is expelled through the fluid pathway, characterized in, that

- the tube (14) defines the lumen (15) and the first and the second stoppers are disposed within and against the wall forming lumen (15) thereby preventing the medicament contained in the cartridge (12, 112, 212) from contacting the needle (20) prior to firing of the cartridge."

V. In support of his request the appellant relied essentially on the following submissions.

The subject-matter of the independent claim 1 was new and involved an inventive step, since no document of the available state of the art contained sufficient hints to lead the skilled person to the combination of features presented in the claimed invention.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Amendments*

Claim 1 is supported by claim 1, page 2, line 2, page 4 lines 7 to 13, and Figures 1 to 6, all as published in WO - A - 01/30424. Claim 2 is supported by claim 2, claim 3 is supported by page 2, lines 25, 26; claims 4 and 5 are supported by claims 7 and 8 respectively; claim 6 is supported by claims 9 and 10; claim 7 is supported by claim 15; and claim 8 is supported by page 4, lines 14 to 16, all as published in WO - A - 01/30424.

The description has been adapted to the newly filed claims.

Accordingly, the amendments comply with Article 123(2) EPC.

### 3. *Novelty*

3.1 Each of D2 and D3 disclose an injection device, comprising a medicament cartridge (D2: 26/D3: 2) for an injection system comprising:

- a liquid based medicament (within 26/2);
- a tube (14/1) having first and second ends and a lumen with a longitudinal axis for retaining the medicament therein;
- a needle (54/7) operatively associated with the second end of the tube and having a piercing end (57/8) extending into the lumen, said needle having an injection tip (55/17) opposite the piercing end, which injection tip is extending beyond the second end of the tube;
- a first stopper (front portion of 30, 32/10, 11) located near the second end moveable within the lumen along the longitudinal axis; and
- a second stopper (34/12) located near the first end moveable within the lumen along the longitudinal axis,
- movement of the first stopper towards the needle being able to cause the piercing end of the needle to pierce the first stopper to create a fluid pathway for the medicament through the needle (see Figures 2 and 3/1 and 2), and

- movement of the second stopper towards the second end of the tube being able to compress the medicament held between the second stopper and the first stopper so that the medicament is expelled through the fluid pathway (see Figure 2/2).

However, D2 and D3 do not disclose that

- the tube defines the lumen and the first and the second stoppers are disposed within and against the wall forming the lumen thereby preventing the medicament contained in the cartridge from contacting the needle prior to firing of the cartridge.

3.2 D1 is less relevant than D2 and D3, since the needle (19) which is operatively associated with the second end of the tube (11), and which has an injection tip extending beyond the second end of the tube, does not comprise a piercing end extending into the lumen for piercing of the first stopper. The injection device according to D1 comprises a separate piercing cannula (29) which is provided for piercing the first stopper (20) and a sealing element (32) before the needle (19) of this device is fixed to the tube (11). Furthermore, the injection device according to D1 does not contain a liquid based medicament, let alone a liquid based medicament held between the first and second stoppers (20, 50). D1 refers to a syringe for injecting a medical agent (23) in form of a powder which is held between the first stopper (20) and the front end of the tube (11), wherein the medical agent is diluted by a diluent kept between the second stopper (50) and a

sealing element (32) before the injection of the diluted medical agent.

3.3 Therefore, the subject-matter of claim 1 is novel with respect to the available prior art.

4. *Inventive step*

4.1 Starting from D2 or D3, the object underlying the present invention has to be seen in providing a simplified and cheaper device.

This object is achieved by the injection device according to claim 1, in particular by the omission of a separate container for the liquid based medicament arranged within the tube of the injection device as suggested by D2 and D3, so that the tube itself defines the lumen for retaining the medicament, and the first and second stoppers are disposed within and against the walls forming this lumen.

4.2 There are no hints in the available prior art which can lead the skilled person in an obvious way to the claimed invention. In particular there is no suggestion to omit the separate container for the medical agent in an injection device, wherein the medical agent is prevented from contacting the injection needle prior to firing the injection device. On the contrary, all present documents referring to such an injection device suggest the provision of a separate container for the medical agent, which has to be arranged within an outer tube.



4.3 With respect to the above findings, the subject-matter of the independent claim 1 also involves an inventive step.

5. *Reimbursement of the fee for reestablishment of rights*

The appellant filed its statement of grounds for appeal on 30 September 2004, before the expiring date of 8 October 2004.

On 19 October 2004 the EPO informed the appellant during a telephonic conversation that the statement of grounds filed on 30 September 2004 did not contain (as stated therein) the amended claims as attachment and that the appellant had the possibility of filing a request of reestablishment of rights according to Article 122 EPC.

Subsequently the appellant filed with letter of 20 October 2004 (received on the same day) a corresponding request and paid the prescribed fee.

The board is of the opinion that the appellant did not need to file a request of reestablishment of rights according to Article 122 EPC and that the paid fee should be reimbursed.

It is generally acknowledged that the appellant can integrate the statement of grounds for lost or missing parts also after the time for appeal has expired, subject to the permission of the board. He has done that with letter of 20 October 2004 (received on the same day). Therefore the board sees no reasons to deny

the appellant to complete the statement of grounds with the new claims.

## **Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent on the basis of:

claims: 1 to 8 and

description: pages 1 to 7

as submitted during oral proceedings;

Figures: 1 to 10 as published (WO - A - 01/30424).

The Registrar:

The Chairman:

V. Commare

T. Kriner