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Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 0294/98 - 3.2.2

# D E C I S I O N
## of 26 January 2001
## correcting an error in the decision of the Technical Board of Appeal 3.2.2 of 26 October 2000

**Appellant:** Arrow Interventional, Inc.
9 Plymouth Street
Everett
MA 02149 (US)

**Representative:** Dixon, Donald Cossar
Gee & Co.
Chancery House
Chancery Lane
London WC2A 1QU (GB)

**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted 16 July 1997 refusing European patent application No. 92 914 299.0 pursuant to Article 97(1) EPC.**

**Composition of the Board:**

**Chairman:** W. D. Weiß
**Members:** R. Ries
R. T. Menapace

In application of Rule 89 EPC, the decision of the Technical Board of Appeal dated 26 October 2000 is hereby corrected as follows:

On page 6, line 22

the wording "characterized in that said member is a foam." is replaced by:

"characterized in that said member is a sealed form."

The Registrar:

V. Commare

The Chairman:

W. D. Weiß

0251.B

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# D E C I S I O N
## of 26 October 2000

**Case Number:** T 0294/98 - 3.2.2

**Application Number:** 92914299.0

**Publication Number:** 0593574

**IPC:** A61M 5/142

**Language of the proceedings:** EN

**Title of invention:**
Implantable Drug Infusion Reservior

**Applicant:**
Arrow Interventional, Inc.

**Opponent:**
-

**Headword:**
-

**Relevant legal provisions:**
EPC Art. 56

**Keyword:**
"Inventive step (no)"

**Decisions cited:**
-

**Catchword:**
-

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## Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal against the decision of the Examining Division to refuse the application No. 92 914 299.0.

The Examining Division held hat the application did not meet the requirements of Article 56 EPC (lack of inventive step), having regard to the documents:

D1: US-A-4 337 769

D3: US-A-3 840 009.

II. In an official communication by the Board, reference was also made to documents:

D2: US-A-4 838 887

D4: DE-C-3 507 818 and

D5: Affidavit of P. Olive submitted by the appellant on 16 May 1997.

In addition, the appellant was informed of the Board's provisional opinion that the subject matter contained in claim 1 of the main request would fail to involve an inventive step and that the amendments to claim 1 according to the auxiliary request did not appear to have a basis in the documents as originally filed.

III. Oral proceedings took place on 26 October 2000. The appellant requested that

- the decision under appeal be set aside and

- a patent be granted on the basis of the main request or, alteratively, of the auxiliary request both filed with the letter setting out the grounds of appeal on 20 November 1997.

IV. Claim 1 of the main request reads as follows:

"1. An implantable infusion system (10') comprising:
a housing (10);
a chamber (12) in said housing;
a penetrable septum (20) mounted in said housing for providing access to said chamber from an external point for charging said chamber with a fluid (53) to be dispensed;
an outlet (64) providing fluid communication between said chamber and a remote location for dispensing said fluid; and
a resilient compressible member (14) filling substantially that portion of said chamber unoccupied by said fluid for providing a force urging said fluid from said chamber into said outlet by expansion and contracting upon filling said chamber with fluid,
characterized in that said member is a foam."

Claim 1 of the auxiliary request differs from the main request by the following wording given in bold letters:

"a resilient member (14) **in intimate contact with said fluid** for providing a force urging said fluid from said chamber into said outlet by expansion and contracting upon filling said chamber with fluid, characterized in that said member is a **sealed foam providing a substantially non-temperature-dependent force.**"

IV. The appellant essentially argued as follows:

The design of the implantable positive pressure infusion reservoir claimed in the present application is exclusively intended for intracorporeal use. Having regard to the very specific design requirements for an implantable pump such as small size, light weight, long life without maintenance and biocompatibility, an implantable pump designer looking for an inexpensive implantable drug infusion reservoir of simple construction and which is easy to manufacture would not take into account prior art references pertaining to external, non-implantable drug delivery devices. Contrary to the implantable technology disclosed in document D3, document D1 is concerned with an external pump for liquid administration utilizing a positive pressure reservoir. Moreover, the collapsible bag reservoir sandwiched between the two foam elements disclosed in D1 could not be turned into a refillable implantable pump reservoir since the refill port (21) is located at the edge of the device and would, therefore, not be accessible to a hypodermic refill needle. Hence, the device given in document D1 is totally unsuitable for implantation as stated in the Affidavit of Peter R. Olive (document D5). Given that the skilled practitioner would not have considered a combination of the technical teaching given in documents D3 and D1, the impugned decision is incorrect in its conclusion that the subject matter of claim 1 lacks an inventive step.

## Reasons for the Decision

1. *The closest prior art*

Among the documents D1 to D4, citation D2 represents the closest prior art since this document specifically refers to an implantable infusion pump for dispensing infusate (cf. D2, in particular Figure 3). The pump comprises a rigid housing (14), a chamber in said housing (18), a penetrable septum (12) mounted on the housing and transcutaneously accessible, an outlet port (64) and a resilient compressible chamber (20) (the bellows and the Freon charging fluid) providing a force by expansion to urge the drug fluid from the drug reservoir (18) to the outlet port (64) and contracting upon filling the reservoir (cf. D2, column 3, lines 1 to 55, column 5, lines 55 to column 6, lines 31).

The infusion device described in document D2 contrasts with the claimed pump by the use of the "bellows - two phase pressurized chamber pump technology" which, due to its sophisticated construction, is a major contributing factor to the cost and imposes shape limitations on the implantable drug infusion system.

2. *The problem to be solved*

Starting from this prior art, the problem underlying the present application, therefore, resides in providing an inexpensive implantable drug infusion pump which uses a minimum number of parts, is economic and easy to manufacture without any loss of volumetric efficiency compared to the traditional bellows devices and which produces a relatively constant fluid pressure (cf. the patent application page 2, lines 11 to 23).

The solution to this problem consists in selecting a flexible resilient foam member which, instead of the Freon two-phase pressurizing chamber (20) depicted in document D2, acts both as a drug storage reservoir and as the pressure motive force to expel the drug from the reservoir (cf. the patent application page 2, lines 23 to page 3, lines 6).

3. *Inventive step*

The claimed solution to the above mentioned technical problem is, however, derivable from document D1 in an obvious manner by a skilled person. Contrary to the appellant's view, the medical engineer when looking for a solution to the technical problem defined above would not restrict his search to documents relating exclusively to the **implantable** infusion pump technology, but would also consider the various pressure administration modules proposed in the prior art for either or both implantable or non-implantable devices, and therefore, would also come across document D1. This document discloses a convenient, simple and inexpensive pressure infusion module for administering small amounts of critical medications (cf. column 1, lines 36 to 45). The administration device comprises a flexible compressed cellular foam material positioned within a rigid housing and exerting pressure on the reservoir to expel the liquid drug through the outlet tube. It is the basic principle that a resilient cellular foam member is compressed by inserting parenteral liquid into the bag and, due to the pressure exerted by the compressed foam, the liquid in the bag is expelled independently of the force of gravity and without the need for an auxiliary pump (cf. D1, column 2, lines 3 to 17, 52 to 56; column 3, lines 28 to 60; column 4, lines 18 to 21). This known basic principle of using the pressure motive force of a

flexible compressed foam member to expel a liquid drug from a reservoir has also been resorted to in the present application. Besides, no information is found anywhere in document D1 to dissuade a skilled person from using a compressed foam member in implantable infusion systems. Contrary to the appellant's position, a skilled person would seriously contemplate the use of the compressed cellular material disclosed in D1, irrespective of whether the pressure infusion module according to D1 would be suited for subcutaneous insertion or not because this technical solution meets his search for a simple, inexpensive pump system in replacement for the expensive conventional prior art bellows. Before this background it is of minor importance that the device disclosed in D1 - compared with the claimed infusion system - additionally includes a collapsible bag containing the infusate and sandwiched between the foam member, and that the bag cannot be refilled without difficulty through the needle-pierceable latex plug closing port (21). The collapsible bag represents a further safety measure to guard against the leakage of the rigid housing.

The subject matter of claim 1 of the main request, therefore, does not involve an inventive step.

4. Claim 1 of the auxiliary request is characterized by a sealed foam which provides **"substantially a non-temperature-dependent force"**. This wording, however, has no basis in the documents as originally filed. Objection, therefore, arises under Article 123(2) EPC. This statement was not challenged by the appellant.

Also the dependent claims 2 to 12 do not contain any technical feature which in combination with the features of claim 1 would give rise to patentable subject matter but merely concern components which are well established in the art.

## Order

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

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare W. D. Weiß