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**Datasheet for the decision  
of 27 October 2009**

**Case Number:** T 1473/07 - 3.2.02

**Application Number:** 01274336.5

**Publication Number:** 1357958

**IPC:** A61M 1/28

**Language of the proceedings:** EN

**Title of invention:**

Apparatus and method for regulating fluid pump pressures

**Applicant:**

DEKA PRODUCTS LIMITED PARTNERSHIP

**Opponent:**

-

**Headword:**

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**Relevant legal provisions:**

EPC Art. 52(1), 54, 56

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Novelty and inventive step (yes) - after amendments"

**Decisions cited:**

-

**Catchword:**

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Case Number: T 1473/07 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 27 October 2009

**Appellant:** DEKA PRODUCTS LIMITED PARTNERSHIP  
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**Representative:** Froud, Clive  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 28 February 2007  
refusing European application No. 01274336.5  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** M. Noel  
**Members:** S. Chowdhury  
M. J. Vogel

## Summary of Facts and Submissions

- I. This appeal is against the decision of the examining division dated 28 February 2007 to refuse European patent application No. 01 274 336.5.

The ground of refusal was that the subject-matter of claims 1 and 12 then on file lacked novelty having regard to D4 (US 4 976 162).

- II. On 26 April 2007 the appellant lodged an appeal against the decision and paid the prescribed fee on the same day. On 28 June 2007 a statement of grounds of appeal was filed.

Following a communication from the Board dated 13 March 2009 and further exchanges by telephone, the appellant requested that the decision be set aside and a patent be granted on the basis of the claims 1 to 16 filed on 16 September 2009.

- III. Independent claim 1 and 12 read as follows:

"1. A method for regulating fluid pump pressures, so as to produce a desired liquid pressure at a distal end of a fluid delivery line, comprising: providing a fluid flow control system, the fluid flow control system having at least a first liquid volume (302) in valved communication with a distal end (208) of a fluid line (204), a control volume (301) in pressure communication with the liquid volume (302), means for measuring pressure in the control volume (301) and means for adjusting the pressure in the control volume (301); characterized in that: the means for measuring the

pressure is calibrated while the liquid volume is not in fluid communication with the distal end of the fluid line; communication between the liquid volume (302) and the distal end (208) is established; a pressure of the control volume (301) is measured; and the pressure in the control volume (301) is adjusted in accordance with the measured pressure of the control volume and the measured calibration pressures so as to provide the desired pressure at the distal end of the fluid delivery line, such that a maximum allowable pressure may be delivered to the distal end of the line regardless of any difference in elevation between the pump and the distal end of the line, this having the effect of permitting maximising flow rates, while maintaining pressures within allowable limits.

12. A system for regulating fluid pump pressures so as to produce a desired liquid pressure at a distal end of a fluid delivery line, comprising: a fluid flow control device having at least a first liquid volume (302) in valved communication with a distal end (208) of a fluid line (204), a control volume (301) in pressure communication with the liquid volume (302) and pressure means (304) for pressurizing the liquid volume (302); a valve arrangement (306) for controlling fluid communication between the first liquid volume (302) and the distal end (208); and a transducer (305) for measuring a pressure of the control volume; characterized in that it comprises a controller allowing calibration of the means for measuring the pressure while the liquid volume is not in fluid communication with the distal end of the fluid line and for controlling the valve arrangement (306), the means for pressurizing the liquid volume (302) and adjusting

the pressure in accordance with the pressure measured by the transducer (305), so as to provide the desired pressure at the distal end of the fluid delivery line".

## **Reasons for the Decision**

1. The appeal is admissible.
2. Amendments

Claim 1 is based on claim 1 as originally filed, amplified for the sake of clarity with the following features:

*i) so as to produce a desired liquid pressure at a distal end of a fluid delivery line*

*ii) the means for measuring the pressure is calibrated while the liquid volume is not in fluid communication with the distal end of the line*

*iii) such that a maximum allowable pressure may be delivered to the distal end of the line regardless of any difference in elevation between the pump and the distal end of the line, this having the effect of permitting maximising flow rates, while maintaining pressures within allowable limits.*

Features i) and iii) explain the purpose of the claimed method and may be gleaned from pages 1 and 10 and from page 6, lines 16 to 21 of the application as originally filed (WO 03/011376). Feature ii) is disclosed, for example, in the paragraph linking pages 7 and 8, where

it is explained that the fluid in the liquid volumes 302 and 312 is isolated from the distal end of the line while the calibration of the transducer is performed. By calibration is meant that the measured pressures are correlated to a zero static head.

Claim 1 is satisfactory as regards Article 123 (2) EPC, accordingly. Claim 12 is similarly allowable.

### 3. Clarity

The Board had raised clarity objections against the claims and the description, but the appellant's counter arguments satisfied the Board in this respect. These objections were not pressed, accordingly.

### 4. Article 52 (1) EPC - Patentability

#### 4.1 The technical problem of the application

In the paragraph linking pages 1 and 2 of the application, it is explained that one problem with respect to fluid flow control devices in dialysis treatment is that patients want to minimize the time spent hooked up to a peritoneal dialysis machine, which may be achieved by increasing the pumping pressure. However, international specifications regulate the maximum and minimum pressures allowed in the patient's catheter (respectively 150 mm Hg and -75 mm Hg), and prior art dialysis machines used pumping pressures of about 75 mm Hg when pumping fluid into the patient.

If the dialysis machine and the patient are at the same elevation, the pressure applied at the pump will be

very close to the pressure at the patient's catheter. If, on the other hand, the dialysis machine is elevated above the patient, the pressure at the patient's catheter will be higher than the pressure applied at the pump. Consequently, to ensure a margin of safety, the pumping pressure is set well below the maximum allowable pressure to compensate for any uncertainty in the position of the patient relative to the dialysis machine. Thus, the flow rate is correspondingly decreased and the treatment time is increased.

The problem, then, is to retain the advantages of pressure-based pumps while improving the flow rate and maintaining the pressure within safe limits.

#### 4.2 The solution

The application addresses this problem by determining the difference in pressure between the pump and the distal end of the fluid line, and thus indirectly the height differential between the pump and the distal end of the fluid line, and adjusting the pressure applied by the pressure-based pump to achieve the desired pressure at the distal end regardless of any height differential between the pump and the distal end. In other words pressure-based pump systems may adapt to changes in a patient's position relative to the pump during treatment. By optimising the pressure in this manner, the flow rate, and hence the treatment time, may be optimised by applying the maximum allowable pressure.

The solution is fairly claimed in the independent claims. In particular, the method comprises

establishing communication between the liquid volume (302) and the distal end (208) of the line and measuring the pressure of the control volume (301). This gives the pressure at the distal end of the line, and hence any height variations may be detected and allowed for.

#### 4.3 Document D4

D4 describes a method for regulating fluid pump pressures so as to produce a desired liquid pressure at a distal end of a fluid delivery line, comprising: providing a fluid flow control system, the fluid flow control system having at least a first liquid volume in valved communication with a distal end of a fluid line 1, a control volume in pressure communication with the liquid volume, means 4 for measuring pressure in the control volume, and means (controller) for adjusting the pressure in the control volume.

D4 does not describe a calibration procedure, and at least for this reason it does not anticipate the presently claimed method or system. Novelty is not an issue, accordingly.

D4 discloses various embodiments, and in each case teaches isolating the dispensing chamber from the downstream line in order to measure volume dispensed by pumping, and all pressure measurements for flow caused by pumping are made only when the dispensing chamber is isolated from the downstream line, this being a key feature which enables the pump of D4 to determine the volume of fluid being pumped. For example, as may be seen from Figure 1 of D4, neither of the pressure



transducers 4, 5 has access to the patient line 1 when the valve B is closed, and pressure measurements are taken only when this valve is closed.

Since the D4 system does not measure the pressure when the valve B is open, it also does not measure the pressure at the distal end of the fluid line.

Therefore, D4 neither discloses nor suggests the method of claim 1 of the application. Claim 12 defines a system which includes a controller programmed to carry out the method of claim 1. Such a system is neither disclosed nor suggested in D4.

4.4 The other documents cited during the examination procedure also do not disclose or suggest the presently claimed invention.

4.5 For these reasons the claims meet the patentability requirements of Article 52 (1) EPC.

5. Remittal

Having established that the claims meet the patentability requirements of Article 52 (1) EPC, the Board deems it appropriate to remit the case to the examining division to supervise the adaptation of the description to 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 department of the first instance for further prosecution.

The Registrar

The Chairman

D. Sauter

M. Noel