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**Datasheet for the decision
of 6 December 2018**

Case Number: T 1832/13 - 3.2.02

Application Number: 03717852.2

Publication Number: 1494748

IPC: A61M39/20, A61J1/20, A61M5/32

Language of the proceedings: EN

Title of invention:
METHOD AND DEVICE FOR FLUID TRANSFER IN AN INFUSION SYSTEM

Applicant:
Carmel Pharma AB

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (yes)

Decisions cited:

Catchword:



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Case Number: T 1832/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 December 2018

Appellant: Carmel Pharma AB
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Representative: Hammond, Andrew David
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 21 March 2013
refusing European patent application No.
03717852.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman E. Dufrasne
Members: S. Böttcher
M. Stern

Summary of Facts and Submissions

I. The applicant filed an appeal against the decision of the Examining Division to refuse European patent application No. 03 717 852.2. The decision was dispatched on 21 March 2013.

Claim 1 of the main request was found to lack an inventive step over document:

D1: US-A-6,113,583

in combination with document:

D2: US-A-4,564,054.

II. Notice of appeal was received on 16 May 2013. The appeal fee was paid on 17 May 2013. The statement setting out the grounds of appeal was received on 19 June 2013.

III. With a communication dated 20 April 2018 the appellant was summoned to attend oral proceedings. In the communication the Board raised objections under Article 84 EPC against claim 1.

IV. By letter of 27 June 2018 the appellant filed a new main request, and provided comments to address the matters raised in the Board's communication.

V. On 19 July 2018 the appellant filed a further set of claims to be considered by the Board.

VI. Oral proceedings took place on 6 December 2018.

The appellant requested that the decision under appeal

be set aside and that a patent be granted on the basis of claims 1 to 15 filed during the oral proceedings, in replacement of all former requests.

VII. Claim 1 filed during oral proceedings reads as follows:

"A fluid transfer device for use in an infusion system, said fluid transfer device (100; 200) exhibiting a first end (101; 201), a second end (102; 202) opposite to said first end, said second end (102; 202) comprising a bayonet coupling member for coupling to a corresponding bayonet coupling member on an injection port (103; 203) of said infusion system (104; 204) to create a bayonet coupling, said fluid transfer device (100; 200) including at least a first member (105; 205), a hollow needle (106; 206) attached to said first member, a second member (107; 207) which is telescopically displaceable in relation to said first member (105; 205) in a way allowing said hollow needle (106; 206) to penetrate a flexible barrier member (108; 208) sealing said injection port (103; 203) in order to create a fluid passage from said first end (101; 201) via said injection port (103; 203) into said infusion system (104; 204), said second end (102; 202) exhibits a flexible membrane (111; 211) for being pressed against said flexible barrier member (108; 208) of said injection port (103; 204) in order to create a double-membrane sealing (108, 111; 108,211; 208, 211) around said hollow needle (106; 206) when creating said fluid passage into said infusion system (104; 204) whereby the first end (101; 201) exhibits a connecting portion (109; 209; 309; 409) for attachment to a drug bottle (110; 210) containing a fixed dose (D) of a medical substance, and that the connecting portion (109; 309) exhibits at least one locking member (113; 313) for grasping a bottle neck (114) of said drug bottle (110)

in order to create a permanent attachment, and that said connecting portion (109; 309) further exhibits a hollow piercing member (115) for penetrating a bottle cap (116) of said drug bottle (110) in order to extend said fluid passage into said drug bottle."

VIII. The appellant's arguments are essentially those on which the following reasons for this decision are based.

Reasons for the Decision

1. The appeal is admissible.
2. The invention

The invention relates to a fluid transfer device for use in an infusion system. The first end of the device exhibits a connecting portion for attachment to a drug bottle, the second end comprises a bayonet coupling member for coupling to a corresponding bayonet coupling member on an injection port (103) of an infusion system. The second end further exhibits a flexible membrane (111) for being pressed against a flexible barrier member of the injection port. A telescopically displaceable needle is arranged in the fluid transfer device in order to penetrate both the membrane and the barrier member in order to create a double membrane sealing when creating the fluid passage into the infusion system.

According to the application, this device can be safely disconnected from the infusion system, while eliminating the risk of potentially health-hazardous

substances escaping into the working environment.

3. Inventive step - Article 56 EPC

3.1 D1 discloses (column 8, lines 45 to 65; column 12, lines 9 to 21; Figures 1 and 6) a fluid transfer device for use in an infusion system, said fluid transfer device (10) exhibiting a first end and a second end opposite to said first end. The fluid transfer device (10) further includes at least a first member (34), a hollow needle (51) attached to said first member, and a second member (33) which is telescopically displaceable in relation to said first member (34) in order to create a fluid passage from said first end via an injection port (16) into said infusion system (12). The second end exhibits a flexible membrane (74). The first end exhibits a connecting portion (30) for attachment to a drug bottle (14) containing a fixed dose of a medical substance. The connecting portion (30) exhibits at least one locking member (60) for grasping a bottle neck of said drug bottle (14) in order to create a permanent attachment, and the connecting portion (30) further exhibits a hollow piercing member (53) for penetrating a bottle cap (22) of said drug bottle (14) in order to extend said fluid passage into said drug bottle.

3.2 Hence, the Board considers the following features of claim 1 not to be disclosed in D1:

- said second end comprises a bayonet coupling member for coupling to a corresponding bayonet coupling member on the injection port of said infusion system to create a bayonet coupling;

- the second member is telescopically displaceable in a way allowing said hollow needle to penetrate a flexible barrier member sealing said injection port;
- the flexible membrane is arranged for being pressed against said flexible barrier member of said injection port in order to create a double-membrane sealing around said hollow needle when creating said fluid passage into said infusion system.

3.3 In D1, the injection port does not have a flexible barrier member. The membrane (74) (corresponding to the flexible membrane according to the claim) forms part of the connector. The membrane (74) is located in a port connector (32), which has first portion (72) that extends into the port tube (16). It can be derived from Figure 6 that the needle (51) is not moveable far enough to extend beyond the front end of the first portion. Hence, even if there was a flexible barrier member in the port tube (16), it would not be possible for the needle to potentially penetrate this flexible barrier member. Furthermore, after insertion of the port connector into the port tube (16), the connector of D1 is fixedly attached to the injection port, e.g. by solvent bonding. This can be done either prior to shipping or later (column 12, lines 25 to 32). In any case, once connected to the port tube (16) the fluid transfer device (10) stays connected. Disconnection of the device after having performed the injection is not foreseen in D1.

3.4 Due to the bayonet coupling member on the second end it is possible to connect the fluid transfer device according to claim 1 to a corresponding bayonet coupling member of another component, e.g. an injection

port, and to disconnect the fluid transfer device after the injection has been performed. Since the flexible membrane is arranged to create a double membrane sealing around the needle in conjunction with a corresponding flexible barrier member on the injection port, the risk that hazardous substances escape into the environment during injection or after the disconnection is eliminated.

3.5 The objective technical problem solved by the distinguishing features is therefore to provide a fluid transfer device that can be safely disconnected from the infusion system after having performed the infusion.

3.6 The Board notes that D2 discloses a device for transferring fluid from a drug ampoule (24) to a syringe (15). The device has a first member (10) and a second member (20), which are connected to each other by a bayonet coupling (21). The first member can be connected to a syringe (15) and comprises a membrane (18) arranged to be placed in tight apposition against a membrane (19) of the second member. The second member can be snap fastened on a drug ampoule (24) comprising a rubber membrane (25). After connection of the second member to the ampoule a needle arranged in the first member penetrates the two membranes (18) and (19) and the rubber membrane (25) of the ampoule in order to suck up the medicine contained in the ampoule into the syringe (Figures 1 to 3 and column 2, lines 28 to 65).

Hence, in D2 the double membrane bayonet coupling is provided between the two parts of the fluid transfer device and not between the fluid transfer device and the ampoule. Thus, in the Board's opinion, the skilled person does not get any hint from D2 to replace the

fixed attachment of the connector to the injection port in D1 by a releasable bayonet coupling. In particular, D2 does not teach to provide a bayonet coupling member on one end of the fluid transfer device for coupling to a corresponding bayonet coupling member of another component which is not part of the device.

Moreover, D2 does not teach how to modify the arrangement of the membrane in D1 such that it can be pressed against a flexible barrier member sealing the injection port.

Thus, even though a double membrane bayonet coupling is generally known from D2, the skilled person would not implement it in the fluid transfer device of D1 in the way as claimed in claim 1.

- 3.7 It follows that the subject-matter of claim 1 involves an inventive step over the combination of D1 with D2.
- 3.8 The Board has no other objections against the main request or the adapted description, both filed during the oral proceedings.

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 first instance, with the order to grant a patent on the basis of:
 - claims 1 to 15 filed during the oral proceedings;
 - adapted description, pages 1 to 13, filed during the oral proceedings; and
 - figure pages 1/8 to 8/8 as published.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated