BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

D E C I S I O N
of 4 November 2002

Case Number: T 0359/00 - 3.2.2

Application Number: 92912949.2

Publication Number: 0592483

IPC: A61M 5/142

Language of the proceedings: EN

Title of invention:
Apparatus for patient-controlled infusion

Patentee:
O'Neil, Alexander George Brian, et al

Opponent:
VYGON

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 56

Keyword:
"Inventive step (yes, after amendment)"

Decisions cited:
-

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0359/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 4 November 2002

Appellant: (Proprietor of the patent)
O'Neil, Alexander George Brian
O'Neil, Christine
102 Lawler Street
Subiaco 6008, Perth W.A (AU)

Representative:
Pattullo, Norman
Murgitroyd and Company
165-169 Scotland Street
Glasgow G5 8PL (GB)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 15 December 1999 revoking European patent No. 0 592 483 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
R. T. Menapace

Summary of Facts and Submissions

I. The appellant (patent proprietor, O'Neil et al) lodged an appeal against the decision of the opposition division to revoke the patent No. 0 592 483. The decision was dispatched on 15 December 1999.

The appeal and the fee for the appeal were received on 11 February 2000. The statement setting out the grounds of appeal was received on 14 April 2000.

The opposition was filed against the whole patent and based on Article 100 (a) and 100 (c) EPC (lack of novelty and inventive step and the patent contained subject-matter not originally disclosed).

The opposition division decided that claim 1 of the main request did not involve an inventive step, the first auxiliary request did not comply with Article 123(3) EPC, and the second auxiliary request was late filed at the oral proceedings (Article 114(2) EPC) and raised too many problems to be considered at that late stage, and revoked the patent, accordingly.

II. Of the documents cited in the appeal procedure the Board considers the following as having the greatest relevance to the present case:

D1: WO-A-9 108 002
D2: WO-A-8 700 758
D9: US-A-4 828 551

The Board has also considered the document US-A-4 298 000 (D8) that was cited in the opposition proceedings.

III. During the course of the appeal proceedings the respondent withdrew therefrom. Following a telephone conversation with the rapporteur on 25 September 2002 the appellant, the sole party to the proceedings, on 15 October 2002 put forward the following request:

The appellant requests that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the following documents:

- Claim 1 filed by telefax dated 15 October 2002,

- Claims 2 to 13 as granted,

- Description page 2 filed by telefax dated 15 October 2002,

- Description pages 3 to 5 as granted,

- Figures as granted.

On 17 October 2002 the appellant confirmed that this was its main request.

IV. The independent claim 1 of this request reads as follows:

"Apparatus for patient-controlled infusion of a liquid medicament, the apparatus comprising a reservoir (3) for the medicament, a positive displacement pump (1) having a predetermined working volume, a first conduit (4) connecting the reservoir (3) to the pump (1) and comprising a fine bore tubing, a second conduit (6) extending from the pump and having a distal end to be inserted in the patient, and a one-way

valve (5) in the second conduit (6) permitting liquid flow from the pump (1) to the patient and preventing reverse flow, the pump (1) being manually operable to displace liquid through the valve (5) and comprising resilient restoring means (2) for returning the pump (1) to its initial state while drawing liquid from the reservoir (3) through the first conduit (4); the fine bore tubing being selected so that the flow rate of liquid medicament through the first conduit (4) is restricted to a rate chosen in conjunction with the working volume of the pump (1) to define a predetermined maximum dosage rate wherein the second conduit (6) is connected to the pump (1) by a dismountable connection (10) adapted to be terminated and reestablished repeatedly for introducing a priming liquid into the second conduit (6) without the priming liquid passing through the first conduit (4), and the fine bore tubing is connected directly into said second conduit."

V. In its written submissions the appellant argued as follows:

An important feature of the invention resided in the provision of means for introducing a priming liquid into the second conduit without the priming liquid passing through the first conduit. Thus the fine bore tubing was not primed at this stage because it was too difficult to force liquid through it, and its volume was so small that priming was not required.

In document D9 the metering orifice was not connected directly to either the pump or the successive bore and dispense fitting. This feature of the patent together with the disconnectable connection between the pump and

the second conduit provided the advantage that priming was easy and the apparatus was simple and efficient to use, which features were not taught by document D9 or any other document cited by the opponent.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

Claim 1 contains the following features not in original claim 1:

- the first conduit comprises a fine bore tubing
- the second conduit is connected to the pump by a dismountable connection
- this connection is adapted to be terminated and reestablished repeatedly for introducing a priming liquid into the second conduit without the priming liquid passing through the first conduit
- the fine bore tubing is connected directly into said second conduit.

2.1 The first of these features is supported by page 5, lines 10 to 20 of the application as originally filed.

The second and third of these features are supported by original claims 2 and 3. Also, on page 7, lines 1 to 23 it is made clear that the connector 10 is removable from the pump and applicable to a large syringe. If the

connector is so removable and applicable, then it is so in a repeatable manner.

The fourth of these features is supported by original claim 1, lines 7 and 8, which define the second conduit as extending from the pump, and the figures, which show that the first, fine bore conduit 4, is connected directly to the patient line 6, which is the second conduit.

Therefore, claim 1 is satisfactory as regards Article 123(2) EPC.

2.2 The first and second features, which are not contained in claim 1 as granted, are clearly restrictive to the scope of claim 1.

Therefore, the requirement of Article 123(3) EPC is also met.

3. *Novelty*

The opposition division found that the apparatus of claim 1 of the patent as granted was novel over the apparatus of document D9 by virtue of the dismountable connection 10 between the second conduit 6 and the syringe 1 (but that this difference did not involve an inventive step).

The Board, however, takes the contrary view, that the connection in document D9 between the dispense fitting 32 (D9, Figure 1) and the patient line is indeed dismountable. In column 4, lines 5 to 11 of document D9 the use of the apparatus is described, and the first step of this use is to fill the unit

(apparatus) by removing the cap and introducing medicine to fill all the cavities in the unit. The fill cap is then replaced and the unit connected into the patient's IV system. This means that the unit is disconnected from the patient's IV system during the filling step and, therefore, that the connection between the outlet conduit and the apparatus is dismountable. It is for this reason that the dispense fitting 32 is shown in Figure 1, and similarly in the other embodiments, as a spigot to which the outlet conduit is not shown as attached. In order to connect and disconnect the unit from the patient's IV system the patient line is pulled over the spigot or pulled off it, respectively.

However, the apparatus of new claim 1 is novel over the apparatus of document D9 because of the newly added feature at the end of the claim, ie the fine bore tubing is connected directly into said second conduit.

4. *Inventive step*

The patent in suit relates to patient-controlled analgesia (PCA) and to apparatus for patient-controlled infusion of a liquid medicament in which the flow rate of liquid medicament from a reservoir to the pump is restricted to define a predetermined maximum dosage rate. Such aspirating PCA devices are prone to small leaks allowing air bubbles to enter the system, which could be fatal, so the system has to be primed periodically.

An object of the invention is to permit easy priming of the apparatus, as set out at the end of page 2 of the application as originally filed. In the case of

apparatus in which a flow restriction system is provided between the reservoir and the pump, it takes a long time to prime the system, and it is desired to simplify this procedure.

The closest prior art is document D9 which also describes apparatus for patient-controlled infusion of a liquid medicament in which the flow rate of liquid medicament from a reservoir to the pump is restricted to define a predetermined maximum dosage rate.

This document also solves the problem that it takes a long time to prime the system through the restriction. Instead a second, fill fitting 28 is provided through which medicine is introduced to fill all the cavities in the unit (column 4, lines 5 to 11), by-passing the restriction. This means that the series of cavities 25, 48 (pump cavity), and 29, in addition to the check valves 26, 27, 30, and 31 are primed first, before the patient line is connected to the dispense fitting 32.

A first disadvantage of this is that it takes a relatively long time because before the patient line is primed the cavities 25, 48, and 29 must first be primed, and also the check valves 26, 27, 30, and 31 and bores 25 and 26 would offer some resistance to liquid flow.

A second disadvantage is the relative complexity of the apparatus in that a second (fill) fitting 28 is required in addition to the first (dispense) fitting 32.

The objectively determined achievement of the apparatus of claim 1 of the patent in suit over the apparatus of

document D9 is the overcoming of these disadvantages.

The inventor of the patent in suit realised that any air trapped in the fine bore of the first conduit is negligible, and simplified the apparatus of document D9 by doing away with the second (fill) fitting for priming the system, and by connecting the fine bore tubing directly into the second conduit, in addition to making the connection between the pump and the second conduit dismountable.

The priming is done, in the claimed apparatus, through the dismountable connection. Moreover, only the second conduit is primed and the inner parts of the pump and the fine bore tubing are not primed at this stage. Instead, after priming the second conduit the aspirating syringe is then re-applied to the connector with its plunger held down. On release of the plunger, fluid is drawn through the fine bore tube. This fluid is initially air which becomes trapped in the syringe, but the volume of air involved (equal to the internal volume of the fine bore tube) is so small that it does not affect the operation of the system (original page 7, lines 16 to 23).

As seen above, the method of priming the apparatus of document D9 and the apparatus of the patent in suit are quite different. Moreover, different the constructions of the two apparatus reflect the respective ways of priming them. No prior art document suggests such a method of priming apparatus of the type claimed, and consequently the apparatus for carrying out the method, and more specifically the combination of the features of claim 1, that the second conduit is connected to the pump by a dismountable connection and the fine bore

tubing is connected directly into said second conduit.

Of the other documents cited by the opponent the documents D1 and D8 describe a priming operation. D1 describes a priming operation briefly and without details on page 9. D8 describes a dispensing syringe without a separate reservoir and without a detachable conduit for priming the apparatus. Instead the syringe itself has parts movable between a metering position and a purging position, and the syringe itself is used to prime an outlet tube.

The other documents (D1 and D2) cited by the opponent that relate to apparatus of the type claimed, which is apparatus for patient-controlled infusion of a liquid medicament in which the flow rate of liquid medicament is restricted to define a predetermined maximum dosage rate, also demonstrate that the prior art apparatus consistently employed a pump having separate inlet and outlet conduits for a medicament rather than the arrangement as defined in the latter part of claim 1 of the patent in suit.

For these reasons the apparatus of claim 1 involves an inventive step.

Order

For these reasons it is decided:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent in amended form on the

basis of the following documents:

- claim 1 filed by telefax dated 15 October 2002,
- claims 2 to 13 as granted,
- description page 2 filed by telefax dated 15 October 2002,
- description pages 3 to 5 as granted,
- Figures as granted.

The Registrar: The Chairman:

V. Commare W. D. Weiß