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D E C I S I O N
of 21 November 2003

Case Number: T 0497/00 - 3.2.2

Application Number: 93114709.4

Publication Number: 0589328

IPC: A61M 5/145

Language of the proceedings: EN

Title of invention:
Syringe pump with graphical display of error conditions

Patentee:
Fresenius AG

Opponent:
B. Braun Melsungen AG

Headword:
-

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

Keyword:
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0497/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 21 November 2003

Appellant: (Proprietor of the patent)	Fresenius AG Gluckensteinweg 5 D-61350 Bad Homburg (DE)
Representative:	Rambelli, Paolo c/o JACOBACCI & PERANI S.p.A. Corso Regio Parco, 27 I-10152 Torino (IT)
Respondent: (Opponent)	B. Braum Melsungen AG Carl-Braun-Str. 1 D-34212 Melsungen (DE)
Representative:	Klingseinsen, Franz, Dipl.-Ing. Patentanwälte Dr. F. Zumstein Dipl.-Ing. F. Klingseisen Postfach 10 15 61 D-80089 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 22 March 2000 revoking European patent No. 0589328 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: S. S. Chowdhury
E. J. Dufrasne

Summary of Facts and Submissions

I. The appellant (patent proprietor, Fresenius AG) lodged an appeal against the decision of the opposition division to revoke the European patent No. 0 589 328. The decision was dispatched on 22 March 2000.

The appeal and the fee for the appeal were received on 17 May 2000. The statement setting out the grounds of appeal was received on 17 July 2000.

The opposition was filed against the whole patent and based on Article 100(a) EPC (lack of inventive step).

In response to the opposition the patent proprietor maintained the claims of the patent as granted. The opposition division decided that the subject-matter of claim 1 did not involve an inventive step, and revoked the patent, accordingly.

II. The following documents were relied upon in the appeal procedure:

D1: EP-A-0314 880

D2: DE-A-3 324 592

D3: Service Manual of PERFUSOR secura FT dated 09/91.

III. Oral proceedings before the Board took place on 21 November 2003, at the end of which the following requests forming the basis of the decision were put forward:

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or according to the auxiliary request filed with letter dated 16 October 2003.

The respondent (opponent B. Braun Melsungen A. G.) requested that the appeal be dismissed.

IV. Independent claim 1 of the main request reads as follows: -

"A syringe pump (8) for pumping fluid from a syringe having a barrel (12) and a plunger (18), the plunger having a flange (18a), the syringe pump comprising: a housing (10); a pusher (14) for pushing the plunger (18); clamp means (16) for engaging the syringe barrel (12) and holding the syringe barrel (12) in a stationary position relative to the housing (10); clamp detector means (42) for detecting whether or not the syringe is properly held in position relative to the housing (10) by the clamp means (16) and for producing an output indicative of whether the syringe is properly held in position relative to the housing (10); anti-siphon means (20) for engaging the plunger (18) and holding the plunger (18) stationary relative to the pusher (14), thereby preventing the plunger (18) from moving independently of the pusher (14); anti-siphon detector means (38) for detecting whether the plunger (18) is properly engaged by the anti-siphon means (20) and for producing an output indicative of whether the plunger (18) is properly engaged by the anti-siphon means (20), characterised in that it comprises: a display (24) made up of an outline (25) showing the syringe barrel (12) and the plunger (18), a first

indicium means (30), consisting of a light emitting diode, located at a point on the display (24) generally corresponding to the position on the syringe pump barrel, where the clamp engages the syringe barrel (12) and a second indicium means (32), consisting of a light emitting diode, located at a point on the display (24) generally corresponding to the position on the plunger (18) where the anti-siphon means (20) engages the plunger (18); electronic circuitry (45) for transmitting the outputs (66, 62) of the clamp detector means (42) and the anti-siphon detector means (38) respectively to the first and second indicia means (30, 32), whereby said first Indicium means (30) indicate whether or not the syringe is properly held relative to the housing (10) and said second indicium means (32) indicate whether or not the plunger (18) is properly engaged by the anti-siphon means (20).".

Claims 2 to 10 are dependent on claim 1.

V. The parties argued as follows:

Appellant

The contested decision was wrongly based on a combination of D1 and D2 in that it started from a wrongly defined technical problem which included elements of the solution and was made with hindsight. D1 gave no hint of the problem of providing the nature and location of errors in a syringe, it merely provided an alarm when any kind of error occured.

D1 and D3 were to be treated as separate documents. D1 disclosed no syringe clamp or a syringe clamp detector, it was only concerned with detecting the presence of a syringe.

Respondent

D3 was the practical embodiment of D1. The groove for locating the syringe in D1 acted as an axial clamp, but even if it were regarded merely as a holder this was equivalent to a clamp for the purposes of the technical problem set out in the patent. D1 disclosed two sensors, at different parts of the syringe and D3 had a blinking syringe symbol to indicate that there was an error in the syringe, which was already one step towards the solution of the patent in that the error indication was localised to the syringe. D2 described apparatus known to everyone and showed how flashing signs may be used to indicate positions of errors in a complex apparatus. The application of this general knowledge to D1 gave the claimed solution in an obvious manner.

As regards the fact that D3 signalled other error conditions also, claim 1 too did not exclude the display of further error conditions. Moreover, these further error conditions were also a step in the direction of locating the error, ie whether it was in the cable, the syringe, etc.

D1 and D3 did disclose anti-siphon means. There would inevitably be some play between the syringe pusher flange and the rear syringe holder both in the prior art apparatus and also in the patent in suit.

Reasons for the Decision

1. The appeal is admissible.

2. *Novelty*

The novelty of the claimed syringe pump has not been doubted during the opposition procedure, and does not constitute an issue at this stage.

3. *Inventive step*

3.1 In the absence of supporting evidence the Board does not accept the respondent's argument that D3 describes the practical embodiment of D1, and these must be treated as separated documents, accordingly. However, for the sake of argument, even if these documents were considered as describing the same apparatus and the features thereof were to be pooled together, the resulting device (referred to hereinafter as D1/D3) would not possess clamp detector means, anti-siphon means, and anti-siphon detector means as defined in claim 1.

Although D1/D3 discloses a clamp for a syringe, it is only the presence of a syringe and that the syringe is correctly positioned in the syringe housing, which are of importance, as stated in D1 in, for example, the abstract and column 2, lines 45 to 49, and in D3 on pages 6 and 13.

According to claim 1 of the patent in suit, on the other hand, it is required to detect whether or not the syringe is properly held in position relative to the housing by the clamp means, which means that it is the operation of the clamp that is supervised. This is a quite different function to detecting the correct placement of a syringe and constitutes a different safety feature.

The function of the anti-siphon means is defined in claim 1 as "anti-siphon means for engaging the plunger and holding the plunger stationary relative to the pusher, thereby preventing the plunger from moving independently of the pusher", and the patent in suit, indeed, shows the flange 12c of the plunger trapped by a catch 20 against a plate 22 in the pusher 14 such that no relative movement between the flange and the pusher is allowed.

By contrast, the apparatus of D1/D3 relies on relative movement between the plunger and the pusher in order to operate an optical switch. That this relative movement is a necessary feature may be seen upon comparison of Figures 6 and 7 of D1 and by inspecting the schematic drawing of the apparatus submitted by letter dated 24 January 2000 during the opposition procedure. This apparatus, therefore, does not teach anti-siphon means in the sense of the patent.

The anti-siphon detector means of claim 1 detect whether the plunger is properly engaged by the anti-siphon means and produces an output indicative of whether the plunger is properly engaged by the anti-siphon means. This is a different function to

detecting the correct placement of the syringe in the rear holder.

Therefore, the two safety features of claim 1, the clamp detector and the anti-siphon device and detector are not disclosed in the prior art.

3.2 Both D1 and D3 are concerned, inter alia, with correctly locating the syringe, an error signal is emitted if there is incorrect location of the syringe or if the syringe is not placed in the apparatus at all. In D1 there is a hint, at the very end of the description, that two syringe detectors may be provided at two different places in order to detect correct placement of the syringe. However, both detectors convey the same information, ie whether or not the syringe is correctly placed. Claim 1 of the patent in suit, on the other hand, requires two detectors that detect two different error conditions, neither of which is disclosed in D1/D3.

3.3 In the D1 apparatus the detector gives a signal enabling a motor to drive the plunger only if the following three conditions are met: (i) the syringe is properly placed in the holder, (ii) a knob is not pulled out to enable manual operation, and (iii) the syringe is not missing. Upon occurrence of any one of these three error conditions an alarm may be given. It is not said that the alarm is graphic, or even optical, it could be acoustic, for example. Moreover, the alarm does not give the location or nature of the error, it could go off for any of the above reasons.

In D3 a display has a syringe symbol which is not a graphic in the sense of the patent in suit (in that it has no appreciable extent such that LEDs may be placed at different portions thereof), it is merely a logo. An LED illuminates and the syringe logo flashes at the end of an infusion (page 14), or if the pressure is too high, or the syringe is empty, or wrongly fitted or not fitted at all, or a reset knob is released (page 20). On page 6 it is stated that a spring-mounted pressure plate provides a check on whether a syringe is fitted in the rear holder, and the user shall check that the syringe is properly positioned. This could be a visual check, there is no indication that this is connected to an alarm system, see also the bottom of page 12 and page 13. Page 20 summarises the warning conditions, and the table shows that the syringe flashes and an LED is energised and an audible alarm sounds if a fault occurs, but the syringe symbol may flash even if there is no fault.

In D3 the syringe symbol flashes if any one of the different faults occurs (see end of page 14 and first row of the table on page 20). Thus, an indication is given that "something is wrong" in the system, not necessarily in the syringe. There is no teaching to identify the nature or location of a specific fault in the syringe.

As stated above, D1/D3 teach only the detection of faulty placement of the syringe, and no other error at the syringe. However, even if an error other than faulty placement of the syringe were to be detected, then following the teaching of D1/D3, the same alarm would be activated. Thus even supposing that the user

of the syringe of D1/D3 were to install a clamp detector and an anti-siphon device, then at most yet another indication would be given that "something was wrong", not that there was a fault at the clamp or the anti-siphon device, just that a fault was present somewhere in the syringe.

3.4 The technical problem and solution of the patent in suit

As compared with this prior art, the syringe pump of claim 1 of the opposed patent enables the nature and the location of the fault to be diagnosed. The problem is solved thanks to the combination of the features of claim 1, particularly the clamp and an anti-siphon device, together with respective detectors, and first and indicium means located at respective points on a display made up of an outline showing the syringe barrel and the plunger and generally corresponding to the position on the syringe pump barrel. It is to be noted that this outline must necessarily have an appreciable extent in contrast to a logo in the form of a miniature syringe symbol.

3.5 The cited prior art does not disclose or suggest the use of dedicated alarms for different detectors in one syringe for the purpose of solving the above problem. Once separate alarms are dedicated to the clamp and the anti-siphon device, respectively, then these may be distributed over a graphic of the syringe, which enables the problem to be solved.

The impugned decision invokes document D2 with a view to denying inventive step of the claimed subject-matter. The Board accepts that this document adequetely illustrates that it was general knowledge that error conditions at different points of a complex system may be easily localised by means of a display having a set of LEDs, flashing symbols, etc distributed over the display. Nevertheless, a syringe is not a complex system, and there was no hint in the prior art that it might be useful to monitor two or more sources of error in a syringe or in a neighbouring technical field, or that it should be readily identifiable at which of these sources an error was occuring. Without these indicators to invoke D2 or other general knowledge amounts to employing hindsight in order to demonstrate that the claimed solution is obvious.

3.6 To summarise, there is no evidence in the prior art that it was necessary to monitor a syringe clamp or an anti-siphon device, and there is no hint to provide a separate error signal for malfunctioning of either device, and further to provide a display comprising of an outline of a syringe with an LED for the respective signal so that the nature and location of the error could be quickly ascertained.

For these reasons the subject-matter of claim 1 involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chairman:

V. Commare W. D. Weiß