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# D E C I S I O N
## of 27 January 2004

**Case Number:** T 0812/01 - 3.2.2

**Application Number:** 93114911.6

**Publication Number:** 0589356

**IPC:** A61M 5/145

**Language of the proceedings**: EN

**Title of invention:**
Syringe pump having continuous pressure monitoring and display

**Patentee:**
Fresenius AG

**Opponents:**
1. Terumo Corporation
2. B. Braun Melsungen AG

**Headword:**
-

**Relevant legal provisions:**
EPC Art. 54, 56, 84, 123(2)

**Keyword:**
"Lack of clarity, after amendments (main request)"
"Lack of inventive step (auxiliary requests)"

**Decisions cited:**
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**Catchword:**
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**Case Number:** T 0812/01 - 3.2.2

# D E C I S I O N
**of the Technical Board of Appeal 3.2.2**
**of 27 January 2004**

**Appellant:** (Patentee)
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 1)
Terumo Corporation
No. 44-1, Hatagaya 2-chome
Shibuya-ku,
Tokyo 151-0072 (JP)

**Representative:**
Grill, Matthias, Dipl.-Ing.
Patentanwälte
Tiedtke-Bühling-Kinne & Partner
Bavariaring 4
D-80336 München (DE)

**Respondent:** (Opponent 2)
B. Braun Melsungen AG
Postfach 1120
D-34209 Melsungen (DE)

**Representative:**
Klingseisen, Franz, Dipl.-Ing.
Patentanwälte,
Dr. F. Zumstein,
Dipl.-Ing. F. Klingseisen,
Bräuhausstrasse 4
D-80331 München (DE)

**Decision under appeal:**
**Interlocutory decision of the Opposition Division of the European Patent Office posted 17 May 2001 concerning maintenance of European patent No. 0589356 in amended form.**

**Composition of the Board:**

**Chairman:** W. D. Weiß
**Members:** M. G. Noel
E. Dufrasne

## Summary of Facts and Submissions

I. By interlocutory decision dated 17 May 2001, the opposition division decided to maintain the European patent in amended form with claims 1 to 5 in the version filed as first auxiliary request on 16 February 2001 and renumbered as second auxiliary request.

II. The state of the art considered by the first instance was represented, in particular, by the following documents:

D1: "evaluation", No. 120, March 1992, pages 1 to 16.

D2: "Welmed P3000 Infusion Syringe Pump - Operating Manual", March 1990, pages 1 to 41 (Translation into English of the original Dutch document), and

D5: EP-A-0 371 507 (parent of D12: US-A-5 078 682).

III. The appellant (patentee) lodged an appeal against this decision on 17 July 2001. Its statement of grounds was filed on 20 September 2001.

IV. Oral proceedings were held on 27 January 2004, at the end of which the requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of claims 1 to 6 submitted with the grounds of appeal on 14 September 2001 (main request) or on the basis of one of the four auxiliary requests submitted with letter dated 18 December 2003.

As a fall-back position, it requested that the patent be maintained in the form stipulated by the decision under appeal.

The respondents requested that the appeal be dismissed.

V. Claims 1 according to the different requests read as follows (identifying letters (a) to (d) introduced by the Board for ease of reference):

Main request:

"A syringe pump (8)for pumping fluid from a syringe (12), the pump comprising:

(a) means (36) for detecting the pressure in the syringe substantially continuously; and

(b) means (27, 28) for displaying the pressure in the syringe substantially continuously such that the pressure in the syringe can be monitored during pumping, **characterised** in that it further comprises:

(c) means (35) for selecting an acceptable pressure range in the syringe; and

(d) means (27a, 27b, 27c) for substantially continuously displaying the selected acceptable pressure range."

First auxiliary request: the features (a) to (c) of the main request and the following feature:

"(d) means (27a, 27b, 27c) for displaying the selected acceptable pressure range, adapted to digitally display information as to whether the substantially continuously displayed pressure in the syringe remains in the pre-selected range, thereby to allow the user to monitor the development of occlusions and take remedial action well before an occlusion becomes a problem."

Second auxiliary request: as above, but with the following replacement feature (d):

"(d) means (27a, 27b, 27c) for displaying the selected acceptable pressure range, adapted to digitally display information as to whether the substantially continuously displayed pressure in the syringe is approaching a pre-set occlusion pressure and remains within the pre-selected range, thereby to allow the user to monitor the development of occlusions and take remedial action well before an occlusion becomes a problem."

Third auxiliary request: as above, but with the following replacement feature (d):

"(d) means (27a, 27b, 27c) for displaying the selected acceptable pressure range,
wherein said means (27, 28) for displaying the pressure in the syringe substantially continuously and said means (27a, 27b, 27c) for displaying the selected acceptable pressure range constitute a digital display providing information as to whether the substantially continuously displayed pressure in the syringe is approaching a pre-set occlusion pressure and remains within the pre-selected range and what the actual

pressure in the syringe is, thereby to allow the user to take remedial action well before an occlusion becomes a problem."

Fourth auxiliary request: as above, but with the following replacement feature (d):

"(d) means (27a, 27b, 27c) for displaying the selected acceptable pressure range,
wherein said means (27, 28) for displaying the pressure in the syringe substantially continuously and said means (27a, 27b, 27c) for displaying the selected acceptable pressure range constitute a continuous pressure monitoring and display device providing information as to whether the substantially continuously displayed pressure in the syringe is approaching a pre-set occlusion pressure and remains within the pre-selected range and what the actual pressure in the syringe is, thereby to allow the user to monitor the development of occlusions and take remedial action well before an occlusion becomes a problem."

VI. The parties submitted the following arguments.

(i) The appellant

In claim 1 according to the main request the expression "substantially continuously displaying" associated with the selected acceptable pressure range was fairly supported by the application as filed since the invention, generally, referred to a continuous pressure monitoring and display device. Therefore, it included means for

displaying the detected pressure as well as the selected pressure range. Moreover, the expression was introduced for the sake of coherency with the precharacterising portion of claim 1.

There was no proof that document D2 as instruction manual had been available to the public and that it not merely constituted an internal document of the pump manufacturer. Further, D2 suggested the existence of different instruction manuals and possibly different corresponding versions of the syringe pump Welmed P3000.

In document D1 the seven-bar pressure display was designed to display only the upper level of the alarm pressure and not to display an acceptable pressure range including a lower pressure level. Even if in the described embodiment of the patent in suit the lower level of the pressure range was not actually used for the detection of occlusions, it could be used for other applications of the pump. Therefore, the subject-matter of claim 1 according to any request was novel and also involved an inventive step with respect to D1.

The various auxiliary requests were filed to specify more precisely the operation of the device and to distinguish it better from the state of the art. Although the features added to claim 1 were taken from different parts of the description, they all referred to the same embodiment and, therefore, were allowable.

(ii) The respondents

Having regard to the selected pressure range, the expression "substantially continuously displaying" added to claim 1 according to the main request was neither clear nor supported by the application as filed. Therefore, claim 1 had to be refused already on formal grounds.

Document D2 should be considered as prior art and admitted to the proceedings, since this operating manual contained information identical to that disclosed in D1 and referred to the same "Welmed P3000" syringe pump. In view of the proximity of the dates of D1 and D2 the possibility of several versions of the syringe pump functioning differently had to be excluded.

The subject-matter of claim 1 according to the first auxiliary request was not new nor did it imply any inventive step with respect to document D1, which disclosed means for simultaneously and continuously displaying the actual pressure in a syringe and a selected pressure range comprised between one and seven bars, i.e. between 0 and an occlusion pressure. The remaining functional features at the end of claim 1 constituted an arbitrary aggregation of information drawn-up from different parts of the description. Their combination, therefore, was not supported by the application as filed. Further, all these features were known from D1 and thus failed to add anything new to the subject-matter of claim 1.

The other auxiliary requests, which differed from the first auxiliary request by further details concerning the use of the device, all known from document D1, were also not acceptable, either.

## Reasons for the Decision

1. The appeal is admissible.

2. *Formal aspects*

2.1 Main request.

With respect to the version as granted, feature (d) was amended by replacing the word "indicating" by the expression "substantially continuously displaying". This feature relates to three liquid crystal display (LCD) segments 27a to 27c (cf. figures 1 and 7) for displaying on the display 27 an acceptable pressure range according to the values pre-selected manually by the user by means of switch 35. The display also includes a digital pointer 28 in the form of other LCD segments 28a to 28j, which informs the user with the actual (detected) pressure in the syringe (cf. application as filed, page 7, lines 19 to 26).

Even if neglecting the fact that the above expression was in the application as filed originally mentioned only in claim 1 and there associated with the pressure in the syringe, i.e. the pressure detected and displayed by the digital pointers 28a to 28j, such an indefinite term as "substantially" confers to the

characterising portion as a whole an unacceptable lack of clarity. As a consequence, claim 1 according to the main request is not allowable under Article 84 EPC.

2.2 Auxiliary requests

Although claim 1 according to the various auxiliary requests differs from the granted version by adding to the last feature (d) a combination of functional features which are taken up from different passages of the application as filed, all these features are associated with the use of the same embodiment. For this reason, the features added to claim 1 are fairly supported and do not extend the claimed subject-matter beyond the content of the application as filed, in accordance with Article 123(2) EPC.

However, the very last feature of claim 1 relating to "a remedial action to be taken before an occlusion becomes a problem" has manifestly no relationship with the device itself but with the intention of the user. Therefore, this feature is not to be considered when comparing the subject-matter of claim 1 with the state of the art.

3. *Closest prior art*

Document D1 which discloses all features of the precharacterising portion of claim 1 in suit, is an official report by a department of the British National Health Service NHS. These reports are "on medical equipment available to the NHS", see D1, page 15, "About Evaluation". This means that the equipment reported upon has been available to the public for some

time before the publication date of the respective report. There has also existed a users manual of which spare copies have been available free of charge, see D1, page 3 ("Product Support").

Document D2, according to its title page, is the Dutch version of a users manual of a "Welmed P3000 Infusion Syringe Pump", which is the type reported upon by D1. D2 (English translation), see page 2, last line, reads "WELMED Limited, 11/1989 Version March 1990". This means that the Dutch version of March 1990 corresponds to an original handbook issued by the British company WELMED Ltd. in November 1989. D2, on page 3, states: "Please read this Operating Manual carefully before using the Welmed P300 infusion syringe pump for the first time and keep it for reference". Moreover, D1 on page 14, point 1., states that the supply schedule of the P3000 infusion syringe pump includes an Operating Manual.

Whenever the documents D1 and D2 refer to the same detail of the pump Welmed 3000 no contradictions can be found in the respective informations: same general overview of the pump (compare the photograph in D1, page 2 and Figure 1 in D2); seven-bar pressure display (D1, page 6, right column and illustrated on Figure 1 of D2 by reference 23); detection and display of excessive pumping (occlusion) pressure (OCC); pump designed for use with syringes of the same capacity range, between 10 ml and 60 ml (compare D1, page 2, left column and D2, page 4, bottom). Therefore, the Board is satisfied that both documents refer to the same version of the syringe pump which was marketed

before the priority date together with D2 as the users manual.

Further, according to D1 (cf. page 3 "user evaluation"; page 10 "Acknowledgements"; page 12 "user evaluations"), the pump was tested and evaluated during several weeks in particular at the Royal United Hospital. It was, therefore, available to the public and there is no reason to consider that its Operating Manual D2 would not have been available therewith. For all these reasons the Board admitted document D2 into the proceedings, which form together with document D1 the same prior art related to Welmed P3000 syringe, which was also publicly available.

4. *Novelty*

In document D1 (cf. page 6 "occlusion alarm response"), the user can set an alarm pressure to any level within the seven-bar display, illustrated on Figure 1 of D2 by reference 23. Thus, according to the required syringe capacity (cf. D1, tables on pages 5 to 7), the user can set the alarm level low (one or two bars) or high (six bars). But whatever the pre-selected level is, which corresponds to the maximum acceptable pressure giving rise to the development of occlusions in the infusion line, the system constantly monitors the pumping pressure and simultaneously displays both the measured pressure and the alarm pressure level (flashing bar) (cf. D2, page 4, fifth paragraph and page 22, point 1). In use like during operational and alarm test, the user can observe the pump pressure rising until it reaches the selected alarm level (cf. D2, page 16, point 7).

Given that the pressure bars are numbered 0 to 6, 0 being the lowest level and normally not selected (cf. D1, page 6), the Welmed P3000 device allows for selecting and displaying the upper acceptable pressure, however not a lower pressure limit or a pressure range within the meaning of the present patent.

It results therefrom that the subject-matter of claim 1 according to any auxiliary request differs from the pump Welmed 3000 as described by documents D1 and D2 by means for selecting and displaying an acceptable pressure range (features (c) and (d)). Therefore, the subject-matter of claim 1 is novel under Article 54 EPC.

5. *Inventive step (first auxiliary request)*

5.1 Although D1 does not disclose the selection of a pressure range, the device allows for monitoring the pressure rising in the syringe up to a selected adjustable occlusion pressure alarm level (cf. D1, first paragraph).

Therefore, the same problem as in the present patent is addressed, requiring the user to be able to monitor the development of occlusions in the infusion line or inside the syringe and ensure that the pressure inside the syringe remains within the pre-selected range (cf. patent, column 1, lines 56 to 57 and column 2, lines 10 to 11). Since, however, the prevention of occlusions only requires monitoring of the increasing pressure and since further no other application was contemplated in the present patent, the knowledge of the lower limit of the pressure range plays no role in the said

prevention. Consequently, the simultaneous observation on the display of the syringe pump Welmed 3000 of the actual pressure and of the occlusion pressure reflected by the selected bar is sufficient to inform the user of a possible hazardous situation i.e. to solve the problem addressed in the present patent. Furthermore, since the device is also microprocessor-controlled (cf. D1, page 3, right column) it appears close at hand for a skilled person to select also a lower alarm pressure level, if necessary. Failing that, the lowest bar, numbered 0, still represents a lower reference level.

5.2 Document D5 (parent of D12) discloses a pumping device for continuously monitoring the pressure of a transfusion liquid during the transfusion treatment, so as to recognize at a glance on a display unit the deviation of the detected, digitized pressure (Px) from both the normal pressure (Pn) set as lower pressure level, and the alarm pressure (Pa), set as upper pressure level. This range is pre-selected before use by means of a setting device 114 (cf. Figure 2 and column 5, lines 27 to 31). During the transfusion, the display shows the position of the actual pressure within the range, for example in the form of a bar graph (cf. Figure 3b; column 4, line 55 to column 5, line 2). Therefore, a suggestion of monitoring the pressure rising within a pressure range was given by document D5. As a consequence, means for selecting and for displaying an acceptable pressure range according to feature (c) and the first part of feature (d) of claim 1, were also clearly suggested by document D5.

5.3 The remaining features of claim 1 do not contain any additional technical function of the device itself. Rather they are directed to the use of the device and so generally drafted, that they are also disclosed by the previously cited prior art documents. Thus, "means for digitally displaying information" is known from D1 which refers to microprocessor-controlled syringe pump using LCD display means. Moreover, as long as a pressure alarm has not been triggered, the actual pressure is displayed and monitored continuously to provide the user with information as to whether the pressure remains below the occlusion pressure (D1) or "within the preselected range" (D5). Further, as already mentioned before, the syringe pump of D1 allows the user "to monitor the development of occlusions".

It results therefrom that the remaining features (d) fail to add anything new or even inventive, to the subject-matter of claim 1 according to the first auxiliary request. Therefore, the provisions of Article 56 EPC are not met.

6. *Inventive step (other auxiliary requests)*

The second auxiliary request differs from the first auxiliary request by the provision in feature (d) of claim 1 that the (detected) displayed pressure "is approaching a pre-set occlusion pressure". As already considered in point 5.1 above, this feature is clearly disclosed in document D1.

The third auxiliary request differs from the second auxiliary request in that the display "constitutes a digital display" and provides information as to "what

the actual pressure in the syringe is". These two additional features are also known from document D1 as demonstrated above in points 5.3 and 4, respectively. Moreover, the second feature is already contained, with other words, in the precharacterising portion of claim 1.

The fourth auxiliary request differs from the third auxiliary request in that the pressure displaying means "constitute a continuous pressure monitoring". Again, this feature is well known from document D1 (point 4 above).

As a result, none of the auxiliary requests can be accepted for lack of any inventive contribution to the state of the art within the meaning of Article 56 EPC.

## Order

## For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare W. D. Weiß