BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Publication in the Official Journal ~~Yes~~ / No

File Number: T 691/90 - 3.2.2

Application No.: 84 302 107.2

Publication No.: 0 121 406

Title of invention: Dual source parenteral infusion apparatus

Classification: A61M 5/14

D E C I S I O N
of 29 July 1992

Applicant: CRITIKON, Inc.

Headword:

EPC Article 123(2)

Keyword: "Amendment beyond the content of the application as filed - no"

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 691/90 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 29 July 1992

Appellant : Critikon, Inc.
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Decision under appeal : Decision of Examining Division of the European Patent Office dated 19 January 1991 refusing European patent application No. 84 302 107.2 pursuant to Article 97(1) EPC.

Composition of the Board :

Chairman : G. Szabo
Members : J. Kollar
J. van Moer

Summary of Facts and Submissions

I. European patent application No. 84 302 107.2, filed on 28 March 1984 and published under publication No. 0 121 406 was refused by a decision of the Examining Division, dated 19 January 1990.

II. The decision was based on Claim 1 which had been further amended and filed as a Main Request during the Oral Proceedings held on 7 December 1989 after the Examining Division had informed the Applicant in a Communication under Rule 51(4) dated 1 February 1988 on the basis of which documents it intended to grant a patent. The only ground for the decision was that, because of absence of the drop rate comparison feature in the new Claim 1 according to said Main Request, the application had been amended in such a way that it contained subject-matter which extended beyond the content of the application as originally filed (Article 123(2) EPC). The feature in question required that "... to terminate the flow of supplemental solution ... when the measured flow detected in the supplementary drip chamber (26) is less than that detected in the primary drip chamber".

As to the version of Claim 1 according to the auxiliary request filed on 14 November 1989 the Examining Division stated, already at the end of the Oral Proceedings, that it did not consent to said auxiliary request in accordance with Rule 86(3).

III. On 15 March 1990, Notice of Appeal was filed against the decision and the fee for appeal simultaneously paid. The Statement of Grounds dated 21 May 1990 was received on 22 May 1990 and relied on three sets of claims being labelled Main Request, First Auxiliary Request and Second Auxiliary Request, respectively.

The Main Request comprises substantially the claims which were under consideration during the oral proceedings before the Examining Division on 7 December 1989. Claim 1 according to the Main Request reads as follows:

"1. A parenteral infusion apparatus, for delivering parental infusions from two sources, comprising:

a primary solution source (2) in fluid communication with a primary drip chamber (14) via first conduit means (4, 8);
a secondary solution source (24) in fluid communication with a secondary drip chamber (26) via second conduit means;
flow sensor means (18, 28) for detecting liquid flow rate through said primary and secondary drip chambers (14, 26);
connection means (10) in fluid communication with said first conduit means (4, 8) and with said secondary drip chamber (26) via third conduit means (30) for connecting said primary and secondary solution sources (2, 24) to a common conduit means (12, 22);
valve means (20) for controlling the flow of primary and secondary solutions through the common conduit means (12, 22); and
control means (16) for controlling the valve means, characterised in that;
the connection means (10) is located between the primary solution source (2) and the primary drip chamber (14);
a check valve (6) is located between the primary solution source (2) and the connection means (10);
a pinch valve (32) is operatively associated with the third conduit means (30); and
the control means (16) controls the pinch valve (32) selectively to prevent liquid flow through the third

conduit means (30) **in response to signals received by the control means (16) from the flow sensor means (28) associated with the secondary drip chamber (26)**" (emphasis added).

Essentially, the features typed in bold replaced those in the original claim.

IV. The Appellant submitted substantially the following arguments:

The object of the invention was to provide apparatus which could provide precise volumes of primary and supplementary solutions to a patient at precise flow rates and to prevent air from becoming trapped in the outlet conduit from the supplementary solution container. A skilled person reading the application would, so the Appellant, immediately recognise that the drop rate comparison feature was not an essential part of the invention but was merely one illustrative way in which said object of the invention could be met. In this respect, the Appellant referred to the declaration by Mr P.N. Eggers which had been submitted to the Examining Division. Furthermore, Claim 1 of the Main Request met, in the Appellant's view, all the criteria for inessentiality as set out in the Decision T 331/87 (OJ EPO 1991, 22, point 6) in that the skilled man would directly and unambiguously recognise that:

(1) the drop rate comparison feature was not explained as essential in the disclosure;
(2) the drop rate comparison feature is not, as such, indispensable for the technical problem it serves to solve; and
(3) the removal of the drop rate comparison feature from Claim 1 requires no real modification of other features to compensate for the change.

The Appellant finally alleged that Claim 1 of the Main Request did not go beyond the teaching of the application as filed but merely set out all the features which were essential for meeting the object of the invention.

V. Consequently, the Appellant requests that the decision under appeal be set aside and the case be remitted to the Examining Division with the instruction that the application be allowed to go to grant on the basis of the claims in the Main Request.

Reasons for the Decision

1. The appeal is admissible.

2. Claim 1 of the Main Request differs substantially from Claim 1 as originally filed by omitting the feature concerning the comparison of flow rates in two drip chambers and replacing it by the more general control features in the characterising portion of the discussed Claim 1.

It is the excision of the drop rate comparison feature, which was considered by the impugned decision to contravene Article 123(2) EPC, because it allegedly extended the subject-matter of the application beyond the content of this application as filed.

3. For the determination whether an amendment of a claim does or does not extend beyond the subject-matter of the application as filed, it is necessary to examine if the overall change in the content of the application originating from this amendment (whether by way of

addition, alteration or excision) results in the skilled person being presented with information which is not directly and unambiguously derivable from that previously presented by the application, even when account is taken of matter which is implicit to a person skilled in the art in what has been expressly mentioned (Guidelines, Part C, Chapter VI, 5.4). In other words, it is to examine whether the claim as amended is supported by the description as filed.

4. It is the view of the Board that the replacement or removal of a feature from a claim may not violate Article 123(2) EPC provided the skilled person would directly and unambiguously recognise that

(1) the feature was not explained, i.e. presented as essential in the disclosure,
(2) it is not, as such, indispensable for the function of the invention in the light of the technical problem it serves to solve, and
(3) the replacement or removal requires no real modification of other features to compensate for the change (following the Decisions T 260/85 (OJ EPO 1989, 105) and T 331/87).

The feature in question may be unessential even if it was incidentally but consistently presented in combination with other features of the invention.

5. It is therefore necessary to examine whether or not the person skilled in the art reading the application as filed would consider the drop rate comparison features as essential, in a limiting sense, to the function of the apparatus as described in the application.

5.1 From US-A-4 094 318 (D1), being the prior art coming closest to the subject-matter of Claim 1, an infusion apparatus is known for delivering infusion solutions to a patient. There is shown in D1 that a drip chamber and drop sensor are located immediately beneath each fluid source to measure the flow of each solution independently and the solutions only travel to the patient along the same conduit after they have each individually passed by the flow control mechanisms.

5.2 It can be seen from the application as originally filed (cf. page 1, lines 1 to 5 and page 2, lines 6 to 9) that the general problem to which the present invention relates was to provide a system which can provide precise volumes of primary and secondary solutions to a patient at precise flow rates. The application on page 3, line 10 to page 5, line 18 goes on to show that attempts have been made to solve this general problem. Page 4, lines 19 to 24 indicates that the proposed solutions to the general problem do not provide practically useful systems.

5.3 A study of the prior art to which reference is made in the application shows that the prior art had already solved part of the general problem. The prior art systems were already able to provide precise flow rates. However, the reason that the prior art systems are not practical is set forth on page 4, line 25 to page 5, line 4. It is indicated there that with the prior art systems there is a danger that air will get into the system and will be entrapped there, and that such air can then only be removed by disconnecting the secondary supply and re-priming it. On page 5, lines 4 and 5 it is indicated that the specific object of the invention is to prevent entrapment of air in the feed line from the secondary supply.

5.4 A skilled person looking at the apparatus disclosed in Figure 1 of the application as filed would readily discern that there are two features which act together to prevent air from entering the outlet conduit 30 from the supplementary solution container 24. The first of these is the pinch valve 32. This plainly prevents any further supplementary solution from leaving the supplementary drip chamber 26. Thus, as long as it is operated, i.e. it is open, while there is still some supplementary solution in the supplementary drip chamber no air will enter the outlet conduit 30.

5.5 The skilled person would then ask how it can be decided when the pinch valve 32 should be closed. Plainly, the pinch valve 32 must stop the flow when no solution is entering the supplementary drip chamber 26. It can be determined when this occurs using the supplementary drop sensor 28. Thus, the skilled person can clearly see from the application as filed that the second object of the invention is met by the use of the pinch valve 32 in this manner in combination with the supplementary drop sensor 28.

5.6 A skilled person reading the application as filed would immediately appreciate that in order to provide an apparatus which works and which meets all objects of the invention, the essential features are

- the control valve 20,
- the Y junction 10 located upstream of the control valve 20;
- the supplementary drop sensor 28;
- the pinch valve 32 controlled by the supplementary drop sensor 28 in the above sense; and
- the check valve 6 in primary solution feed line.

5.7 From this it follows that, without being mentioned expressis verbis in the application as filed, the embodiment of the invention as described in the original application, namely the feature relating to a comparison of the solution flow rates in the primary and supplementary drip chamber, only represents one illustrative way in which the second object of the invention can be met. The disclosure never emphasised the strict necessity of this particular solution in other situations. The removal of this from Claim 1 does not require any modification of the other features of the invention.

5.8 The original claim related to an apparatus comprising specified component parts. One of these, the shut-off control system within the conduit means was characterised by a purpose, i.e. "for terminating ... flow" under particular circumstances. This functional statement need not be understood in a limiting sense so as to exclude other kinds of control. It only states that the system must have the capability to terminate the flow in the above described situations if so desired. It is clear from the description of the device and from its normal function, that the means for the purpose, in particular control means (16), are capable to exercise selective control, and "prevent liquid flow through the third conduit means" also in other circumstances, but not necessarily immediately and always when the flow rate from the supplemented chamber drops below the rate from the primary chamber.

Such situations are recognisable from the disclosure as originally filed, and any broadening of the control aspect and capability of the apparatus is not "novel" vis-à-vis the same since this is directly and unequivocally implied. This also means, of course, that any strict limitation of

the means to the indicated capability, if the functional reference could at all be interpreted in this manner, would be unnecessary, i.e. inessential, and could be replaced by a broader functional reference, embracing of course termination as well. It is also apparent that the other newly introduced features of the characterising part represent features of the apparatus, which were also expressly disclosed in the application as filed. The claim is in many respects clearer and covers all essential means for the purposes envisaged.

5.9 Therefore, the excision of the feature relating to said drop rate comparison by replacing it by features being essential to the solution of the aforementioned problems, does not contravene Article 123(2) EPC.

5.10 Since novelty and inventive step have never been disputed by the Examining Division, there is no need to give in this decision any reasons in this respect. The claims in the Main Request therefore represent patentable inventions.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to grant a patent on the basis of the following documents:

Claims Claims 1 to 7 of the Main Request received on 22 May 1990 with letter dated 21 May 1990

Description Pages 1 to 8 received 26 May 1989 with letter dated 23 May 1992, with the insertion after "means" in line 29 of page 2 of "associated with the secondary drip chamber" (Rule 27(1)(c) EPC)

Drawings Sheets 1/2, 2/2 as originally filed.

The Registrar: The Chairman:

S. Fabiani G. Szabo