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D E C I S I O N
of 1 April 2003

Case Number: T 0999/00 - 3.2.2

Application Number: 93303126.2

Publication Number: 0568265

IPC: A61M 1/36

Language of the proceedings: EN

Title of invention:

Blow molded venous drip chamber for hemodialysis

Applicant:

DSU Medical Corporation

Opponent:

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Headword:

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Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (no)"

Decisions cited:

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Catchword:

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Case Number: T 0999/00 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 1 April 2003

Appellant: DSU Medical Corporation
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Representative: MacGregor, Gordon
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 31 May 2000
refusing European patent application
No. 93 303 126.2 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noel
U. J. Tronser

Summary of Facts and Submissions

- I. European patent application No. 93 303 126.2 (publication No. 0 568 265) was refused by the Examining Division on the grounds of lack of inventive step of its subject-matter vis-à-vis the state of the art represented, in particular, by documents:
- D2: GB-A-2 047 542, and
- D3: EP-A-0 143 064.
- II. The applicant had requested a decision according to the state of the file. The first instance, therefore, referred to the reasons already set forth in its preceding communications.
- III. The appellant (applicant) lodged an appeal against this decision. Its statement of grounds, received on 26 September 2000, was based on the set of claims 1 to 3 as refused. Oral proceedings was requested.
- IV. In the statement of grounds of appeal the appellant submitted that document D2 disclosed a dialysis apparatus comprising an injection site and a clamp, both positioned downstream of a venous bubble chamber. However, the apparatus did not include a bubble detector located in a specified position. In contrast thereto in the present invention, a bubble detector was located downstream of the injection site, which would detect any bubble that might have been introduced in the injection site.
- Document D3 disclosed a dialysis apparatus that included a venous chamber in the form of a debubbling

device and a bubble detector, but no injection site. Therefore, this document could not suggest positioning the bubble detector downstream of an injection site. Consequently, the contested decision was based on hindsight and an *ex post facto* analysis of the prior art vis-à-vis the subject-matter of claim 1.

- V. In a communication of the Board dated 30 October 2002 sent following a summons to attend oral proceedings, the appellant was informed of the preliminary view of the Board that the subject-matter of claim 1 did not seem to involve an inventive step vis-à-vis the teaching of documents D3 and D2. However, a new claim reworded so as to be based on a combination of features from claim 1 and 2 appeared to be acceptable.
- VI. By letter dated 25 February 2003 the appellant withdrew its request for oral proceedings and requested a written decision based on the written submissions already on file. However, no comments to the Board's communication were presented.
- VII. According to its statement of grounds the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims currently on file.
- VIII. Oral proceedings were maintained by the Board and held on 1 April 2003 in the absence of the appellant. At the end of the proceedings the Board decided that the appeal was to be dismissed.
- IX. Claim 1 reads as follows:

"Dialysis apparatus comprising a dialysis set mounted

in a dialysis machine, the dialysis set including a dialyzer connected by tubing with a venous chamber (12), a bubble detector (254) and a downstream clamp (256),

characterised by an injection site (250a) positioned downstream of the venous chamber (12) and upstream of both the bubble detector (254) and the downstream clamp (256), whereby drugs may be administered to a patient through the injection site, downstream of the venous chamber."

Reasons for the Decision

1. The appeal is admissible.

2. *Formal aspects*

The formal objections raised by the Board in its communication need not be answered since the claims are anyway unallowable on other grounds, as set out hereinafter.

3. *Inventive step*

3.1 Document D3 represents the closest prior art as it discloses all the features forming the precharacterising portion of claim 1, including a bubble detector, contrary to document D2. More specifically, D3 discloses with reference to Figure 1 a dialysis set comprising a dialyser 13 connected by tubing with a venous chamber 18 (debubbling device), a bubble detector 20 and a downstream clamp 26. However, an injection site is not provided.

The subject-matter of claim 1 differs therefrom by the feature of its characterising portion, in particular by the provision of an injection site 250a (Figure 13) positioned downstream of the venous chamber 252 and upstream of both the bubble detector 254 and the clamp 256. By this arrangement, drugs may be administered to a patient in a safe manner, i.e. in a manner avoiding the risk of air emboli and of expensive drugs being trapped on the filter or any other parts of the venous chamber. The achievement of these aims represents the technical problem upon which the present application is based (cf. patent application, page 11, lines 1 to 20).

- 3.2 Document D2 discloses (Figure 1) a dialysis set comprising, successively, a venous chamber 14, an injection site 112 and a clamp 114. The injection site is positioned downstream of the venous chamber and upstream of the clamp, whereby drugs may be administered to a patient through the injection site, downstream of the venous chamber. The only difference with respect to the characterising portion of claim 1 in suit is that the apparatus disclosed in document D2 does not include a bubble detector.

However, while injection sites are conventional in the medical field of injection devices (cf. D2, page 2, lines 55 to 61 and page 3, lines 43 to 46), the clamp is the element generally situated downstream of any other element present in the return circuit of the blood to the patient, in order to shut off the flow of fluid, whenever desired (cf. D2, page 3, lines 46 to 48 and D3, page 4, lines 28 to 30). Therefore, the positioning of the injection site upstream of the clamp involves no surprising effect. Moreover, it is generally known and presented as a rule in the patent

application itself (cf. page 10, line 25 to page 11, line 3) that no injections must be given below (downstream) the air detector/line clamp assembly in order to avoid the risk of air emboli to the patient. Consequently, to locate the injection site upstream of the couple air detector/clamp is the only possible option.

Starting from document D3, which already discloses the use of a bubble detector and a clamp, it was, therefore, obvious for a skilled person, who wanted to make use of an injection site such as that disclosed in D2, to locate it in the manner as claimed, i.e. upstream of both the clamp and the bubble detector.

It results therefrom that the subject-matter of claim 1 does not involve an inventive step within the meaning of Article 56 EPC, vis-à-vis the teachings of document D3 and D2 and the general knowledge of a person skilled in the art, as recited in the background of the present application.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß