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Datasheet for the decision of 5 December 2006

Case Number: T 1402/04 - 3.2.02

Application Number: 01958757.5

Publication Number: 1309368

IPC: A61M 5/31

Language of the proceedings: EN

Title of invention:
Method and arrangements in aseptic preparation

Applicant:
Carmel Pharma AB

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54

Keyword:
"Novelty (yes, after amendment)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1402/04 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 5 December 2006

Appellant: Carmel Pharma AB
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 17 August 2004 refusing European application No. 01958757.5 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

I. This appeal is against the decision of the examining division dated 17 August 2004 to refuse European patent application No. 01 958 757.5.

The main ground of refusal was that the application did not meet the novelty requirement of Article 52(1) EPC, having regard to document D3 (GB-A-938 777).

II. On 15 October 2004 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same day. On 15 November 2004 a statement of grounds of appeal was filed.

The appellant requests that the decision under appeal be set aside and that the application be remitted to the examining division for further prosecution on the basis of claims 1 to 22 filed by telefax dated 23 November 2006.

III. Independent claims 1, 12, and 14 read as follows:

"1. A method for antiseptic preparation by means of an injection syringe, said injection syringe comprising a container for an injection agent and an immovable connection nozzle attached to the container, the method involving the charging of the container with air, characterized in that charging the container with air causes air to pass through the connection nozzle and an air filter connected to the connection nozzle.

12. An injection syringe (101) for performing the method according to any of claims 1 or 3-10 and

including a container (113) for an injection agent, characterized in that the injection syringe's (101) connection nozzle (114) is equipped with an air filter (102) pre-mounted directly on the connection nozzle (114) and with an inlet directly connected to atmosphere and an outlet connected to the interior of the container (113).

14. A filter unit (2) for performing the method according to any of claims 1-2 or 4-10, said filter unit (2) comprising an air filter (23) and a housing (21) in which the air filter (23) is arranged, characterized in that the housing (21) is equipped with a connection device (22) arranged for direct connection to an injection syringe's (1) connection nozzle (114)."

Claim 2 to 11, 13, and 15 to 22 are dependent claims.

Reasons for the Decision

The appeal is admissible.

1. The decision under appeal argues in some detail with respect to claim 1 that the method thereof lacks novelty, but it merely asserts that the features of dependent claims 2-8, 11, and 18-19 are well known from D3, and that dependent claims 9, 10, 13, 15, 16 and 20-22 concern simple constructional measures and do not meet the inventive step requirement of Article 52(1) EPC.

In view of the rather perfunctory nature of the arguments under Article 52(1) EPC, if the appeal is

allowed, it would be appropriate pursuant to Article 111(1) EPC to remit the case to the examining division for further prosecution.

2. Amendments

Claim 1 is identical with claim 1 as originally filed.

Claim 12 is based on claim 12 as published (WO-A-02/11794) and additionally includes the words "pre-mounted directly on the connection nozzle (114)", which amendment is supported by, for example, the embodiments of Figures 1 to 3 which show that the air filter 23, 102 is directly mounted to the syringe's connection nozzle, and page 9 of WO-A-02/11794, lines 9 to 12.

Claim 14 is based on claim 14 as published and additionally includes the word "direct" to limit the filter thereof to one for direct connection to a syringe's connection nozzle. This limitation is also supported by the embodiments of Figures 1 to 3.

The amendments to the independent claims meet the requirement of Article 123(2) EPC, accordingly.

3. Claim 1

The claim defines a method for antiseptic preparation by means of an injection syringe, using a filter which is defined in the claim as an air filter. In the context this is understood to mean a barrier for bacterial and other such contaminants, as stated on page 3, lines 10 and 11. The method of claim 1 requires

air to pass through the filter while the syringe is being charged with air.

The document D3 describes a package (10) for a syringe (11) together with a needle (27) attached to the syringe nozzle (28) via a needle hub (26), which protects the syringe assembly from physical damage and from bacterial contamination during storage. The package assembly could equally be used for protecting other medical articles such as sutures, thermometers, etc (page 6, lines 102 to 107).

The syringe package assembly comprises a sleeve (12) and cap assembly (13) substantially enclosing the syringe barrel and a closure member (14) substantially enclosing the syringe needle, the closure member being closed off by a bacterial filter (21) at its free end.

This document describes constructional details of the filter, but it does not state or suggest either that the syringe barrel is to be charged with atmospheric air, or that the filter is to be used during such charging. This document only states that the closure member is retained on the needle until a charge of medicament is drawn into the syringe, after which the closure member may be replaced over the needle until the medicament is administered (page 3, lines 119 to 126).

The filter is part of the package assembly and not part of the syringe assembly. A package assembly is normally damaged in order to access its contents, and the package assembly is thereafter usually discarded. The filter of the package assembly of D3 is a purely

passive device which enables air to enter the package assembly while precluding entry of bacteria during storage of the syringe (see D3, page 2, lines 97 to 102). When the syringe is to be used it is removed from the package assembly, but the closure member may remain on the needle to protect until the medication is to be administered. The filter is discarded with the remainder of the package assembly when the syringe is to be used.

The impugned decision, on page 3, appears to acknowledge this fact, but says that the step of charging the syringe with air is an essential step in use of the syringe of D3, and that this would inevitably cause the passage of air through the filter at the end of the closure member.

This argument is flawed for three reasons, as follows: Firstly, it is not essential for every syringe to be charged with air and, in the absence of some statement to this effect in D3, it cannot be assumed that it would necessarily be performed with the syringe of D3. Secondly, even if it were to be assumed that the syringe of D3 would be charged with air, it is not clear that the filter at the end of the closure member would play a role in this since, as discussed above the filter is part of the package assembly which is discarded. Finally, charging the syringe with air, were this to be considered necessary, could be done in one of the other ways described in the prior art, as discussed in the opening passages of the application, and not necessarily by using an air filter.

For these reasons the document D3 does not disclose the method of claim 1, whose subject-matter is novel, accordingly.

4. Claim 12

4.1 Claim 12 requires the injection syringe thereof to comprise a connection nozzle equipped with an air filter pre-mounted directly on the connection nozzle. This feature is not disclosed in D3, the air filter of which is mounted at the outer end of the closure member which is part of a package assembly, as discussed above. The closure member is mounted on a needle hub and, therefore, indirectly on the nozzle of the syringe, and not directly as required by claim 14.

The injection syringe of claim 12 is novel, accordingly.

5. Claim 14

5.1 Claim 14 requires the filter unit to comprise a housing in which the air filter is arranged, which housing is equipped with a connection device arranged for direct connection to an injection syringe's connection nozzle. As seen with respect to claim 12, this feature is not disclosed in D3, whose air filter is mounted at the outer end of the closure member which is part of a package assembly.

The filter unit of claim 14 is novel, accordingly.

6. Since the subject-matter of the independent claims 1, 12, and 14 is novel, all of claims 1 to 22 meet the novelty requirement of Article 52(1) EPC.

The examining division's statement that dependent claims 9, 10, 13, 15, 16 and 20 to 22 do not meet the inventive step requirement of Article 52(1) EPC was based on the proposition that the subject-matter of the independent claims lacked novelty. Since this is not the case the Board leaves it to the examining division to reconsider the question of inventive step.

Order

For these reasons, it is decided that:

The case is remitted to the department of the first instance to resume the examination on the basis of claims 1 to 22 filed by telefax dated 23 November 2006.

The Registrar The Chairman

V. Commare T. K. H. Kriner