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Datasheet for the decision of 19 November 2007

Case Number: T 1376/06 - 3.2.02

Application Number: 98941952.8

Publication Number: 1009455

IPC: A61M 5/00

Language of the proceedings: EN

Title of invention:
Coding of syringes to monitor their use

Applicant:
Safer Sleep Limited

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 52(4), 56

Keyword:
"Surgical method (no)"
"Inventive step (yes)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1376/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 19 November 2007

Appellant: Safer Sleep Limited
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Representative: Nettleton, John Victor
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 7 April 2006 refusing European application No. 98941952.8 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 7 April 2006 to refuse European patent application No. 98 941 952.8.

The grounds of refusal were that the method claims 1-12, 29, and 33 to 36 of the main request related to methods of surgical treatment excluded by Article 52(4) EPC, and the subject-matter of the apparatus claims of the main and auxiliary requests lacked an inventive step, having regard to documents D1 (US-A-4 943 939) and D9 (US-A-4 863 521).

II. On 9 June 2006 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same day. On 16 August 2006 a statement of grounds of appeal was filed.

The appellant requests that the decision under appeal be set aside and that the application be allowed to proceed on the basis of claims of the main request or the auxiliary request filed on 9 September 2005.

III. Independent claims 1, 13, and 30 of the main request read as follows:

"1. A method of monitoring substance administration, the method including the steps of: establishing first and second sites (2a, 2b) for a predetermined coded substance carrier (S), wherein the code (2c) for the carrier (S1) corresponds to the substance, placing said coded substance carrier (S) in an at least partially loaded condition prior to use in said first site (2a),

placing the coded substance carrier (S) in the second site (2b) after use in an at least partially discharged condition (relative to said at least partially loaded condition), and maintaining said carrier (S) in said second site (2b) for a predetermined period of time, characterised in that the first and second sites are predetermined coded substance sites and the code (2c) for the sites corresponds to the substance.

13. Apparatus for storage and use of at least one predeterminedly coded (S1), loaded carrier (S) administrable substance carrier (S), the apparatus including a support (1) defining at least one site (2) in relation to which the predetermined coded carrier (S) can be positioned, characterized in that said site (2) is a coded site and said site is coded (2c) and adapted to receive said carrier (S), and in that said code (2c) is provided to enable user verification of said carrier (S) relative to said at least one site (2).

30. A package of at least one contained administrable substance for administration in accordance with the method as claimed in any of Claims 1 to 11, said package including apparatus as defined in any one of Claims 13 to 24, and wherein at least one of said first sites (2a) is charged with a loaded, substantially corresponding coded carrier (S) for said administrable substance and means provided between said carrier (S) and said first coded site (2a) for verifying the correct site positioning of said carrier (S) on said site (2a), a second coded site (2b) adapted for verification of site position."

Claims 2 to 12, 14 to 29, and 31 to 36 are dependent claims.

Reasons for the Decision

1. The appeal is admissible.

2. *Amendments*

Claim 1 is based on original claim 1, and additionally specifies that the code for the carrier and the sites corresponds to the substance to be administered. This amendment merely clarifies the correspondence between the substance and the coding, which is the basis of the present application, and complies with Article 123(2) EPC.

Claim 13 is based on original claim 13

Claim 30 corresponds with original claim 29.

3. *Article 52(4) EPC*

Method claim 1 is confined to the technical steps of placing a coded substance carrier on a coded site before and after use thereof to administer the substance. The claim does not include the step of administering the substance, and the claim may not be interpreted so as to include this step implicitly. Therefore, the claim includes purely technical steps practised outside of and not involving a human or animal body.

For these reasons the claimed method is not to be considered a surgical method for the treatment of the human or animal body, which is excluded from patentability by Article 52(4) EPC.

4. *Novelty - claim 1*

4.1 Novelty of the claimed subject-matter was not challenged by the examining division, and the Board sees no reasons for questioning this decision.

5. *Inventive step – claim 1*

5.1 The application relates to a method and apparatus for storage and monitoring the use of administrable substances, particularly for anaesthetics. Previous methods and apparatus for storage and monitoring the use of administrable substances have, in the main, relied upon the skill, alertness and self-imposed systems of practitioners, leading to errors, sometimes with disastrous consequences, especially in emergency or other stressful circumstances.

It is an object of the application to reduce the likelihood of errors in substance administration, by providing a better method and apparatus for storage and monitoring the use of the substance.

The object is achieved by coding a substance carrier, e.g. a syringe or ampoule, the coding corresponding to the substance within it, and also correspondingly coding sites, for example compartments on a tray, so that the carrier before and after administration of the

substance, may be correctly placed on a respective coded site.

This makes keeping track of syringes and ampoules until completion of a procedure simple by providing a visually striking monitor of drug administration. It is possible to check at a glance what has and what has not been administered.

5.2 Documents D1 and D9 indicate neither the technical problem set out in the application, nor the solution as defined in the claims, namely providing a coded carrier and correspondingly coded sites for the carrier.

5.3 The apparatus described in D1 is a Mayo stand for storing and dispensing surgical instruments and not apparatus for storage of a carrier of an administrable substance, such as a syringe or an ampoule. Moreover, there is no suggestion that the surgical instruments in D1 should be coded or that sites on the stand should be coded. The apparatus of D1 comprises a plurality of equivalent instrument holding compartments, and the instruments therein are identified visually and without the use of coding. The instruments are accounted for visually and the accounting is non-specific for the type of instrument.

5.4 The Examining Division acknowledges that there is a difference between the claimed subject-matter and the teaching of D9, which is the provision of substance coding to a site as well as to a substance carrier, but it alleges that such a difference cannot be seen as implying an inventive step since the skilled person would have been able not only to code the carrier but

also the administrable substance belonging to the carrier. The examining division, however, makes this allegation without indicating any passage in D9, or any other document, which suggests the provision of coding to a site and to a carrier.

Coding is provided in D9 by means of bar coding on the substance carriers themselves. D9 provides no teaching or suggestion of additional coding on storage sites.

5.5 Since neither the present technical problem nor its solution are disclosed in the prior art, the subject-matter of claim 1 involves an inventive step, having regard to D1 and D9.

6. *Remittal to the first instance*

In normal circumstances the Board, having examined the facts and arguments of the case, would order grant of a patent should it come to a positive conclusion on an appeal. In the present case, however, the Board is of the view that the application has had the benefit of a perfunctory examination only, and that a more thorough examination is necessary.

For this reason the Board has examined only claim 1 of the present application and only in respect of Articles 52(4), 54 and 56, and decides to remit the case for completion of the examination, particularly as regards the question of Article 52(1) EPC in respect of claims 13 and 30, and in view of the other documents (D2 to D8) cited by the examining division but not commented upon, and Article 123(2) EPC for the dependent claims and the new description pages.

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 for further prosecution on the basis of claims 1 to 36 of the main request filed on 9 September 2005.

The Registrar The Chairman

V. Commare T. Kriner