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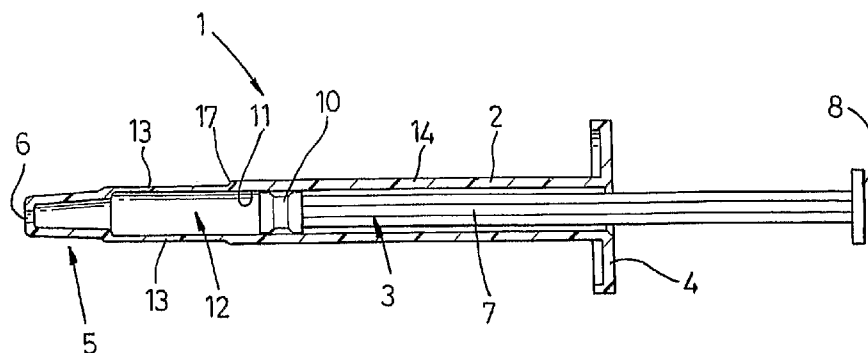
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(54) Title: SYRINGE HAVING A RESILIENT PART IN ORDER TO FACILITATE AN INITIAL ASPIRATION



(57) Abstract: A syringe (1) comprises a barrel (2) with a plunger (3) in slidable and sealing engagement therein, and a needle attached to one end of the barrel (2). The barrel (2) has aspiration means (13) in the form of manually-operable resilient portions (13), which can be operated to cause a pressure differential in the barrel (2), the pressure differential then being used to perform aspiration. The resilient portions (13) are preferably formed by localised reductions (15) of wall thickness in the external surface of the barrel (2).

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SYRINGE HAVING A RESILIENT PART IN ORDER TO FACILITATE AN INITIAL ASPIRATION

This invention relates to a syringe having means to perform aspiration.

A conventional syringe has a barrel with a plunger in slidable and sealing engagement therein, and a needle attached to one end of the barrel. An injection using a conventional syringe is performed by inserting the needle of the syringe into a vial of injectant. The plunger of the syringe is then withdrawn while the user grips the barrel of the syringe with their other hand. This draws the injectant into the barrel of the syringe. The user may then check for any air bubbles in the injectant in the barrel, caused by air being inadvertently drawn into the barrel, and remove them in the usual way through the needle. The injection can then be performed.

The injection is administered by inserting the needle through the skin of a patient. It is necessary to check the position of the needle tip within the patient to ensure the injectant is delivered appropriately, such as to a muscle or into a blood vessel. This is achieved by aspiration of the syringe, which involves withdrawing the plunger a small amount once the needle is within the patient. This will cause the body material adjacent the needle tip to be drawn into the syringe barrel through the needle where the user can view it. Thus, if the injectant is intended for a blood vessel for example, if blood is drawn into the syringe then the needle tip is in the correct position for the injection to be delivered. If blood is not observed, the user would need to find an alternative injection site.

As can be appreciated, the aspiration procedure may be painful for the patient and also potentially hazardous. In particular, as the user is required to pull on the plunger while the needle is within a patient, this can cause unwanted movement of the needle tip, which may be painful. This is particularly so as, due to the seal the plunger needs to have with

the barrel of the syringe, withdrawal of the plunger may require the application of a significant force thereby reducing the chance of keeping the syringe still. The position of the needle tip may also move during aspiration and therefore the injectant may not be delivered to the intended location. Thus, although the user may have thought that an appropriate injection site had been found by aspirating the syringe, the action of aspiration may cause the needle tip to move, which may render the injection ineffective or even dangerous to the health of the patient.

According to the invention, we provide a syringe comprising a barrel having a plunger in slidable and sealing engagement therein, the barrel having aspiration means to allow aspiration of the syringe in use.

This is advantageous as by providing means to effect aspiration on the barrel, the syringe is easy to use and does not require withdrawal of the plunger. Thus, the user of the syringe can hold it by the barrel while they insert the needle in the patient and actuate the aspiration means with the same hand. This allows aspiration to be performed simply and with minimal movement of the syringe. This reduces the chance of pain to the patient and also helps ensure that the injectant is reliably delivered to the intended injection site.

The aspiration means may comprise manually-operable resilient means. Thus, the aspiration means can cause a pressure differential to occur in the barrel, which can be used to perform aspiration. Preferably, the aspiration means comprises at least one manually-operable resilient portion of the barrel. The user can easily apply finger pressure to the manually-operable resilient portion while holding the syringe and inserting the needle into the patient. By applying a squeezing pressure to the barrel, pressure is created within the barrel. Thus, when the user reduces the pressure applied to the manually-operable resilient portion,

the pressure reduction experienced within the barrel draws in body material, such as blood, thereby effecting aspiration.

The barrel may have two manually-operable resilient portions. These are preferably diametrically opposed. As the resilient portions are diametrically opposed, both will naturally be gripped and thus squeezed by the user between finger and thumb. The grip required is consistent with current training of health care workers, and is often known as the 'pencil grip'. This makes the aspiration means particularly effective and easy to use.

Preferably the or each manually-operable resilient portion is formed by a localised reduction in wall thickness of the barrel. The reduction in wall thickness is preferably an external reduction, so as not to affect the seal of the plunger head against the internal surface of the barrel. The wall that forms the or each manually-operable resilient portion must be sufficiently thin to allow a user to easily squeeze the barrel to achieve a pressure change within the barrel. However, it must be thick enough to ensure the syringe barrel has sufficient structural integrity. For example, the hysteresis of the or each manually-operable resilient portion should be such that it does not affect the "feel" of performing the injection or reduce the quality of the seal between the barrel and a head of the plunger as it passes the manually-operable resilient portion or portions of the barrel. Preferably, the wall thickness of the resilient portion is substantially between 20% and 80% of the wall thickness of the remainder of the barrel. As can be appreciated this will depend on the barrel material and size of the syringe and may be 30%, 40%, 50%, 60% or 70% or any other appropriate amount in the range. In a standard syringe of polypropylene material with a wall thickness of 1mm, the resilient portion will have a wall thickness of 0.8mm. Preferably the barrel is of polypropylene, although it may be of ABS or polycarbonate.

A convex ridge may separate the reduced thickness wall portion from the normal thickness wall portion, in order to provide rigidity. The surface of the or each manually-operable resilient portion may be textured, to provide 'feel' for the user, as a physical indication of where to squeeze the barrel. The texture may be provided as a rough surface (as opposed to the smooth surface of the rest of the barrel) or as ridges on the surface. The ridges preferably extend axially.

Preferably, the or each manually-operable resilient portion has a width of between 10% and 40% of the circumference of the barrel and preferably substantially 25%. As can be appreciated the width of the or each resilient portion will depend on at least the wall thickness of the resilient portion and material and size of the barrel and thus could be 15%, 20% or 30%. Further, the length of the or each manually-operable resilient portion may be between 20% and 80% and preferably between 40% and 60% of the longitudinal length of the barrel. However, as above, this depends on at least the wall thickness of the resilient portion and material and size of the barrel.

There now follows by way of example only a detailed description of the present invention with reference to the accompanying drawings in which:

Figure 1 shows a cross-section through a syringe in accordance with the invention;

Figure 2 shows a perspective view of the barrel of a syringe in accordance with the invention; and

Figures 3 to 6 show an embodiment of the invention at different stages of operation.

Figure 1 of the drawings shows an injection device commonly known as a syringe 1. The syringe 1 comprises a barrel 2 and a plunger 3. The barrel 2 has an open proximal end provided with a gripping flange 4 and a distal end 5 having a liquid outlet 6. The liquid outlet 6 can be arranged in a variety of ways as needed to attach a needle; in Figure 1 the needle would be affixed permanently by glue, heat or some other means. A luer slip design, as shown in Figure 2, could also be used. The syringe plunger 3 comprises a rod 7 and a finger plate 8, for gripping the plunger. At the distal end of the rod is a plunger head of reduced diameter, carrying an elastomeric seal 10, which forms a seal with the inside surface 11 of the barrel 2 and defines a chamber 12 to receive injectant (not shown).

The barrel 2 is shown in more detail in Figure 2. The barrel 2 includes aspiration means comprising two diametrically opposed manually-operable resilient portions 13 (only one of which is visible in Figure 2). The manually-operable resilient portions 13 are formed by a portion of the barrel wall of reduced thickness. The reduction of the wall thickness is on the external surface of the barrel 2. Thus, the barrel 2 comprises a normal thickness part 14 and two reduced thickness parts 15, each forming a manually-operable resilient portion, parts 14 and 15 being separated by a slightly convex ridge 16 bridging between the normal wall thickness and the reduced wall thickness, to provide rigidity. Each reduced thickness part 15 is substantially rectangular, and extends from the distal end 5 toward the proximal end of the barrel 2, where it terminates in an arcuate part 17.

The normal thickness part 14 has a thickness of approximately 1mm. Each reduced thickness part 15 has a thickness of approximately 0.8mm. However, depending on the size of the syringe 1, the normal thickness

part 14 may be between 0.5mm and 3mm. Accordingly, each reduced thickness part 15 may be between 0.5mm and 1mm, such as 0.6, 0.7, 0.8 or 0.9mm.

Each reduced thickness part 15 has a width of approximately 25% of the barrel circumference. This may be varied between 10% and 40% depending on the thickness and material and size of the barrel. The length of each reduced thickness part 15 again depends on the thickness and material and size of the barrel, but will normally be between 20% and 80%.

The gripping flange 4 has a pair of diametrically opposed wings enabling the barrel 2 to be gripped between adjacent fingers in use. The portions 13 are formed in line with the wings, so that they do not interfere with the volume markings (not shown) on the barrel 2. These markings are always between the wings.

The portions 13 shown in Figure 2 have a smooth external surface. In a modification (not shown) the external surface of the portions 13 may be textured, to provide a physical indication for the user of where they are. The textured surface may be roughened (in comparison with the smooth external surface of the remainder of the barrel) or be provided by ridges extending axially.

The operation of the syringe 1 is illustrated in Figures 3 to 6. Figure 3 shows the syringe 1 in a state where it is about to draw injectant into the barrel 2. Thus, having the needle (not shown) in a vial (not shown) of injectant, the plunger 3 is withdrawn in the direction of arrow 20 to draw the injectant into the chamber 12 of barrel 2.

Figure 4 shows the plunger 3 withdrawn and the chamber filled with injectant 21. It will be appreciated that more or less injectant can be withdrawn into the chamber 12, according to the amount required. Pressure substantially in the direction of arrows 22 can then be applied to the manually-operable resilient portions 13 as the user grips the syringe barrel 2. As can be seen from Figure 4, the manually-operable resilient portions 13 are resiliently deformed such that the volume of chamber 12 is slightly reduced. The deformation 23 of manually-operable resilient portions 13 is exaggerated for clarity. The needle of the syringe 1 may have been inserted into a patient before pressure is applied to the manually-operable resilient portions 13.

If not inserted already, the needle (not shown) of the syringe 1 is then inserted into a patient. To perform aspiration the user simply has to reduce the gripping pressure applied to the manually-operable resilient portions 13. Accordingly, the manually-operable resilient portions 13 will resile back to their original form as represented by arrows 24 and shown in Figure 5. This causes the volume of chamber 12 to increase, creating a negative pressure in the barrel 2 that draws body material through the needle (not shown) and into the chamber 12, as represented by arrow 25. It will be appreciated that as all the user has to do is reduce the pressure of their grip on the barrel 2 to perform aspiration, the needle will remain steady and the injection can be performed accurately, reliably and safely.

Finally, Figure 6 shows the syringe 1 once the plunger has been pressed in the direction of arrow 26 to urge the injectant 21 out of the barrel 2, as shown by arrow 27, thereby delivering the injectant into the patient's body. The seal 10 is not impeded by the reduced thickness parts 15 as the wall thickness is reduced externally.

CLAIMS

1. A syringe (1) comprises a barrel (2) having a plunger (3) in slidable and sealing engagement therein, characterised in that the barrel (2) has aspiration means (13) to allow aspiration of the syringe (1) in use.
2. A syringe as claimed in claim 1, in which the aspiration means comprises manually-operable resilient means (13).
3. A syringe as claimed in claim 1 or claim 2, in which the aspiration means comprises at least one manually-operable resilient portion (13) of the barrel (2).
4. A syringe as claimed in claim 3, in which the barrel (2) has two manually-operable resilient portions (13).
5. A syringe as claimed in claim 4, in which the two manually-operable resilient portions (13) are diametrically opposed.
6. A syringe as claimed in any of claims 3 to 5, in which the or each manually-operable resilient portion (13) is formed by a localised reduction in wall thickness of the barrel.
7. A syringe as claimed in claim 6, in which the reduction in wall thickness is an external reduction.
8. A syringe as claimed in claim 6 or claim 7, in which the wall thickness of the or each manually-operable resilient portion (13) is substantially between 20% and 80% of the wall thickness of the remainder of the barrel (2).

9. A syringe as claimed in any of claims 3 to 8, in which the or each manually-operable resilient portion (13) has a width of between 10% and 40% of the circumference of the barrel (2).

10. A syringe as claimed in claim 9, in which the or each manually-operable resilient portion (13) has a width of substantially 25% of the circumference of the barrel (2).

11. A syringe as claimed in any of claims 3 to 10, in which the length of the or each manually-operable resilient portion (13) is between 20% and 80% of the longitudinal length of the barrel (2).

12. A syringe as claimed in claim 11, in which the length of the or each manually-operable resilient portion (13) is between 40% and 60% of the longitudinal length of the barrel (2).

13. A syringe as claimed in any of claims 6 to 12, in which a convex ridge (16) separates the reduced thickness wall portion (15) from the normal thickness wall portion (14).

14. A syringe as claimed in any of claims 3 to 13, in which the or each manually-operable resilient portion (13) has a textured external surface.

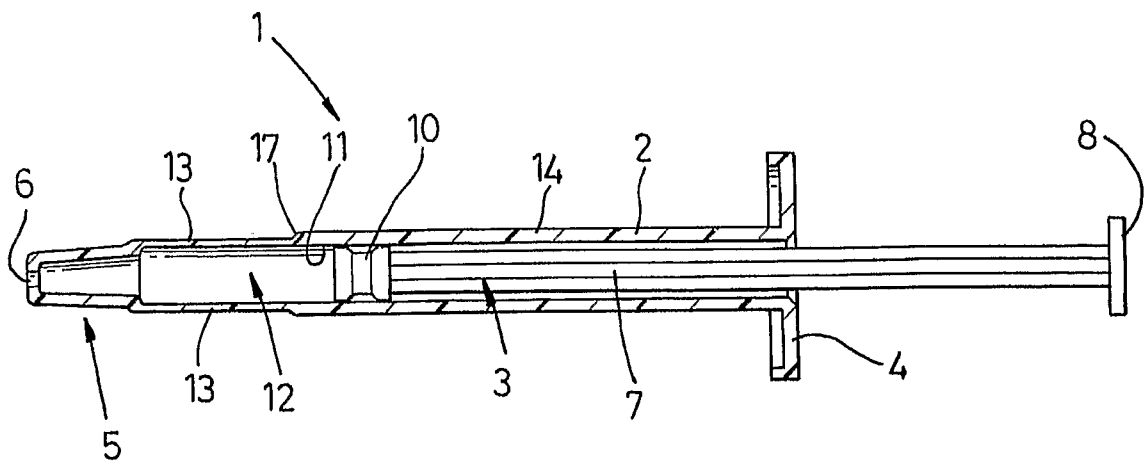


Fig. 1

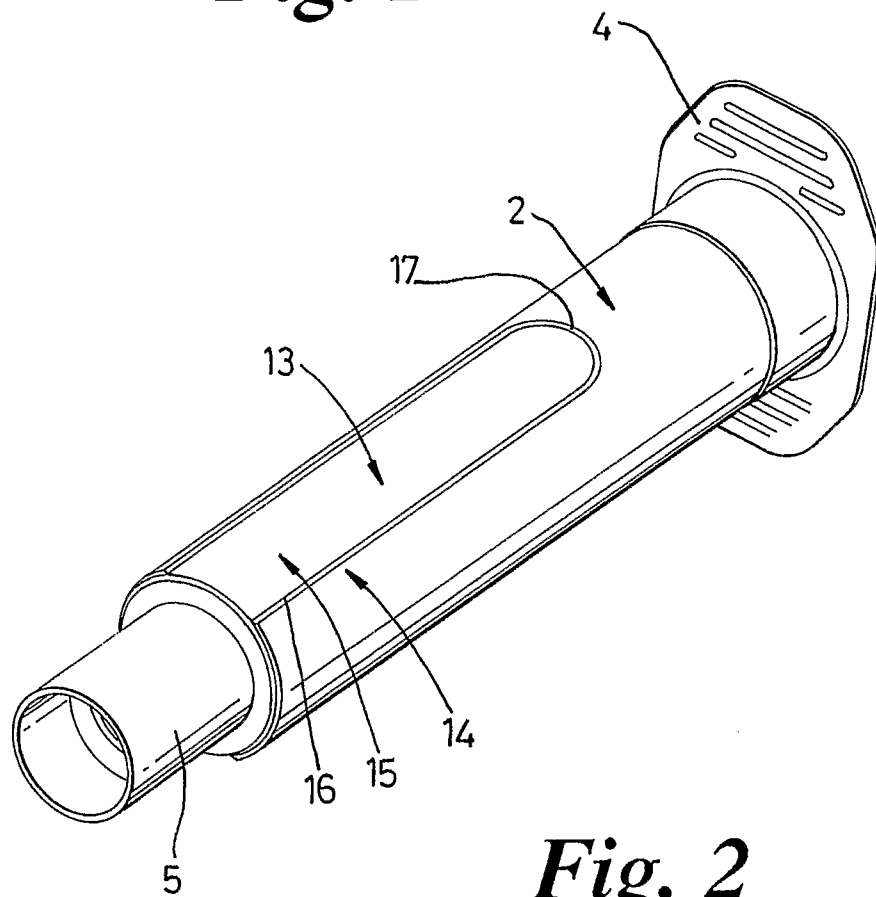


Fig. 2

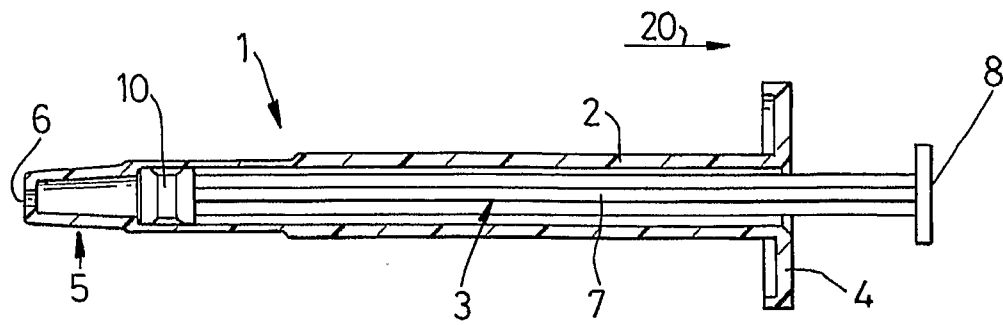


Fig. 3

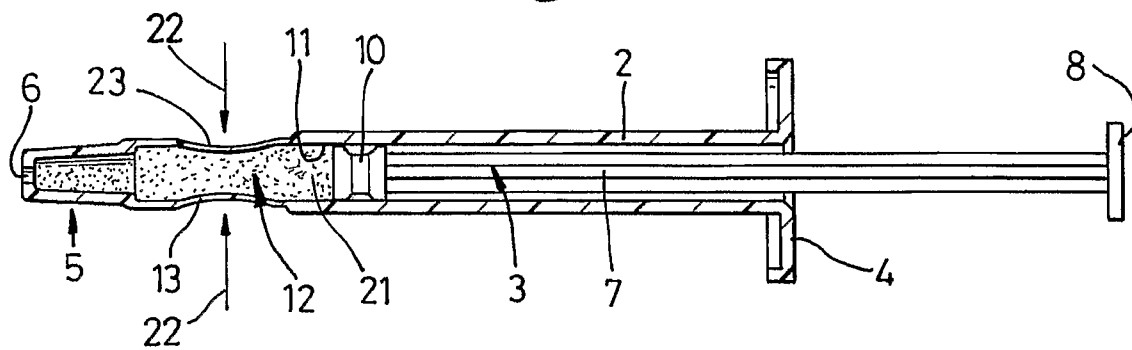


Fig. 4

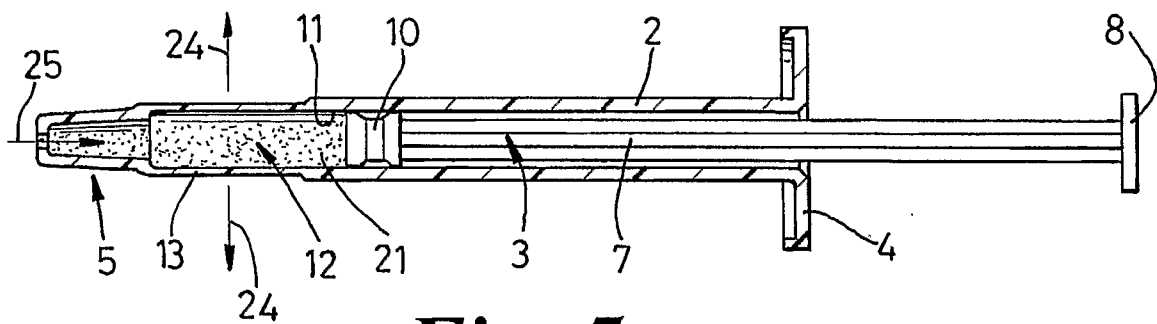


Fig. 5

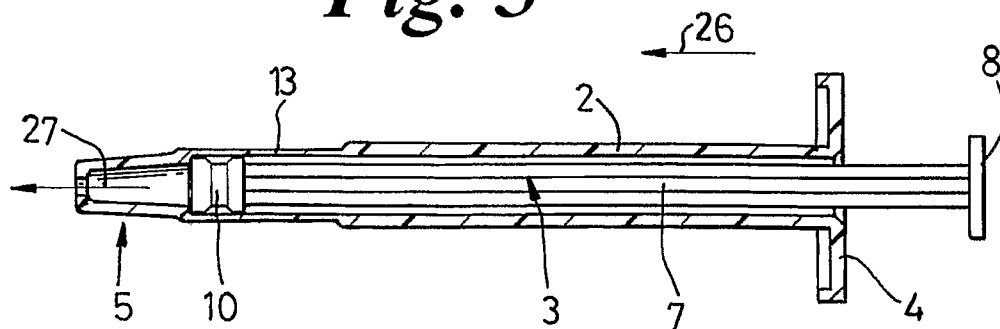


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2006/003666

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/31

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X | US 5 052 403 A (HABER TERRY M [US] ET AL) 1 October 1991 (1991-10-01) the whole document | 1-7, 13, 14 |
| X | US 2 725 057 A (LOCKHART MARSHALL L) 29 November 1955 (1955-11-29) the whole document | 1-5, 14 |
| A | FR 2 659 858 A (OMAROUAYACHE NOUR EDDINE [DZ]) 27 September 1991 (1991-09-27) abstract page 2, line 12 - page 4, line 27 figures 1-7 | 1 |
| A | US 2005/209571 A1 (MCKAY WILLIAM J [US]) 22 September 2005 (2005-09-22) the whole document | 1 |

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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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* & * document member of the same patent family

Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| A | US 6 231 550 B1 (LAUGHLIN JOSHUA D [US]) 15 May 2001 (2001-05-15) abstract ----- | 1 |
| A | EP 1 360 969 A1 (ACHA GANDARIAS PEDRO [ES]) PAGE 65 S L [ES]; SCB S A [ES]) 12 November 2003 (2003-11-12) abstract ----- | 1 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2006/003666

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
|-------------------------------------------|----|---------------------|----------------------------|---------------------|
| US 5052403 | A | 01-10-1991 | NONE | |
| US 2725057 | A | 29-11-1955 | NONE | |
| FR 2659858 | A | 27-09-1991 | NONE | |
| US 2005209571 | A1 | 22-09-2005 | WO 2005089363 A2 | 29-09-2005 |
| US 6231550 | B1 | 15-05-2001 | AU 1802501 A | 12-06-2001 |
| | | | WO 0139820 A1 | 07-06-2001 |
| EP 1360969 | A1 | 12-11-2003 | BR 0116800 A | 03-02-2004 |
| | | | CA 2444538 A1 | 18-07-2002 |
| | | | CN 1496274 A | 12-05-2004 |
| | | | CZ 20032091 A3 | 12-11-2003 |
| | | | WO 02055141 A1 | 18-07-2002 |
| | | | ES 2187333 A1 | 01-06-2003 |
| | | | JP 2004516909 T | 10-06-2004 |
| | | | MA 26268 A1 | 01-09-2004 |
| | | | MX PA03006170 A | 11-12-2003 |
| | | | PL 365341 A1 | 27-12-2004 |
| | | | US 2004073172 A1 | 15-04-2004 |
| | | | ZA 200306067 A | 06-08-2004 |