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(71) Applicant(s):  
**Terence Edward Weston**  
**Swannington Hall, Church Lane, SWANNINGTON,**  
**Norfolk, NR9 5NP, United Kingdom**

**Douglas Arthur Emmott**  
**Pump House, High Road, Swiland, IPSWICH,**  
**Suffolk, IP6 9LB, United Kingdom**

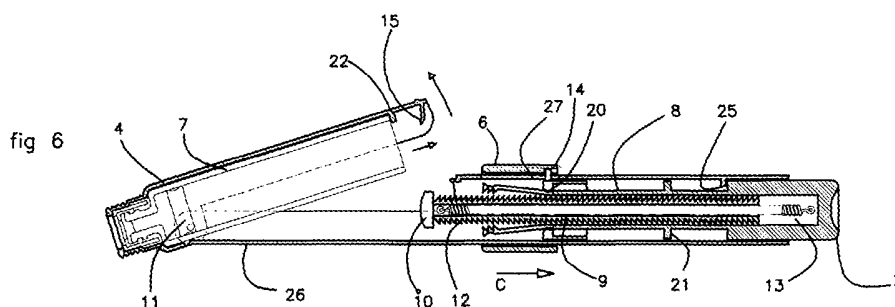
(72) Inventor(s):  
**Terence Edward Weston**  
**Douglas Arthur Emmott**

(74) Agent and/or Address for Service:  
**Terence Edward Weston**  
**Swannington Hall, Church Lane, SWANNINGTON,**  
**Norfolk, NR9 5NP, United Kingdom**

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(54) Abstract Title: **Side loading pen injector**

(57) A side loading pen injector comprises a hinged cartridge cover 7 and a plunger 2 wherein there is a mechanism for the retraction of the plunger. The cover 7 may have a pawl 15 which engages with teeth 12 on the outside of a push rod 9 connected to plunger 2. A collet 6 may be slidable about a middle section of the injector. The collet 6 engages with a peg 28 which causes a collet closer 17 to open, when the cover 7 is opened, pawl 15 is disengaged, causing the plunger 2 to retract under the action of spring 13. The push rod 9 may have an adjustable stroke means for dispensing at least one dose of drugs or a least one dose sequentially from a cartridge. The injector may have a needle, being a passive safety needle attached.



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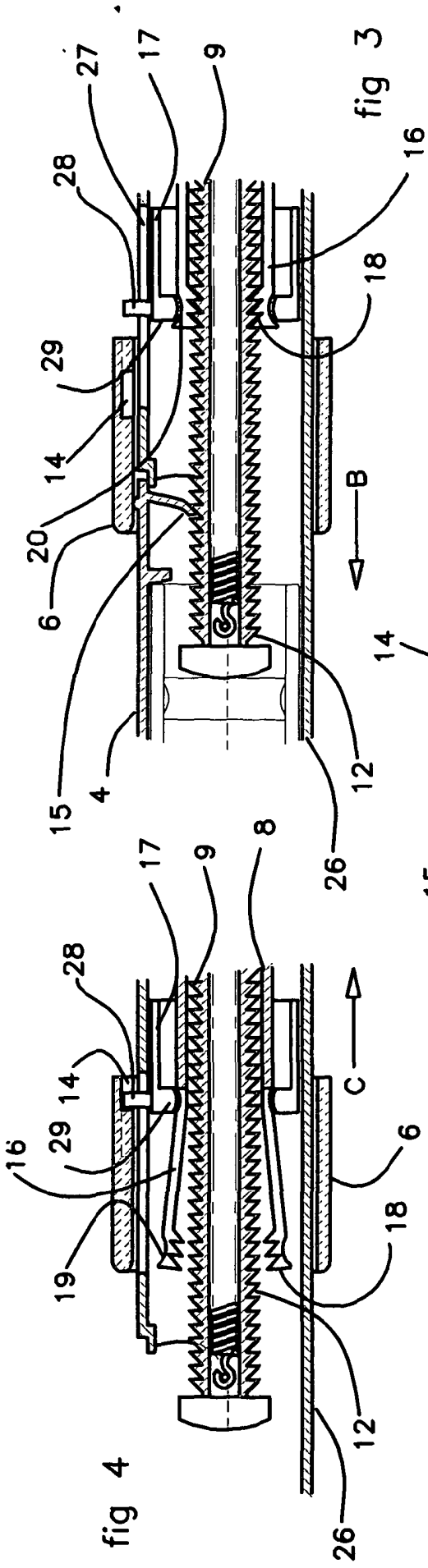


fig 3

fig 4

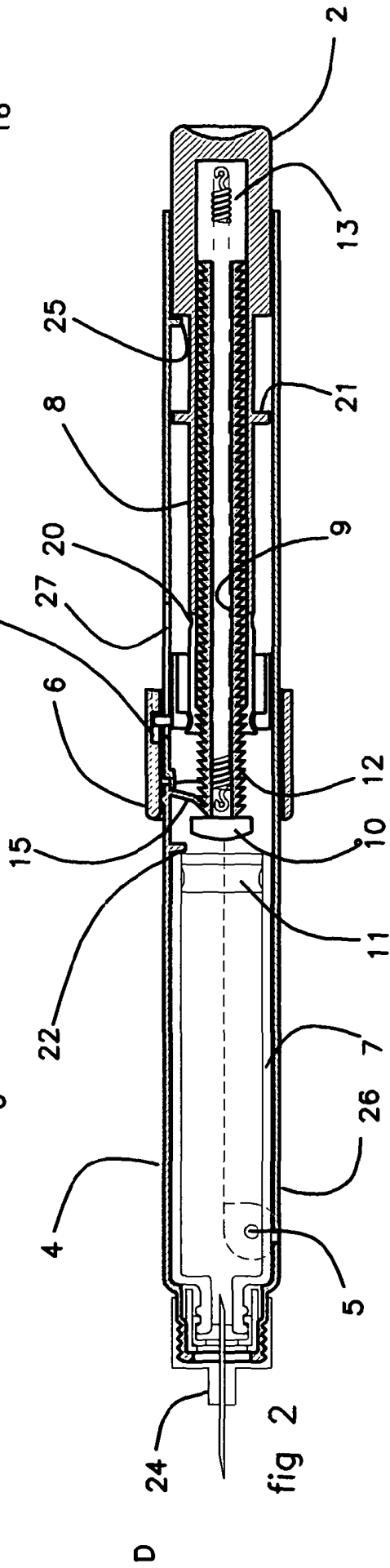


fig 2

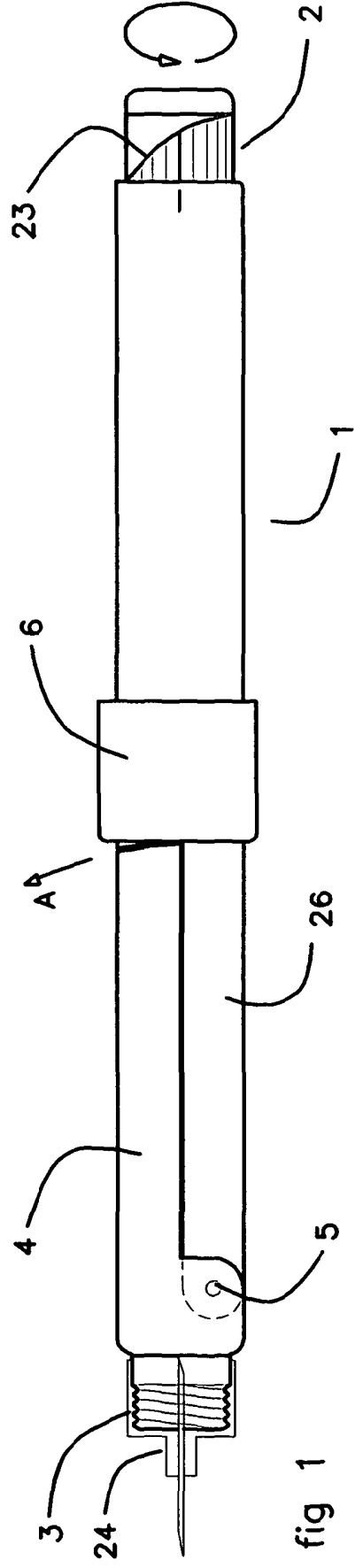


fig 1

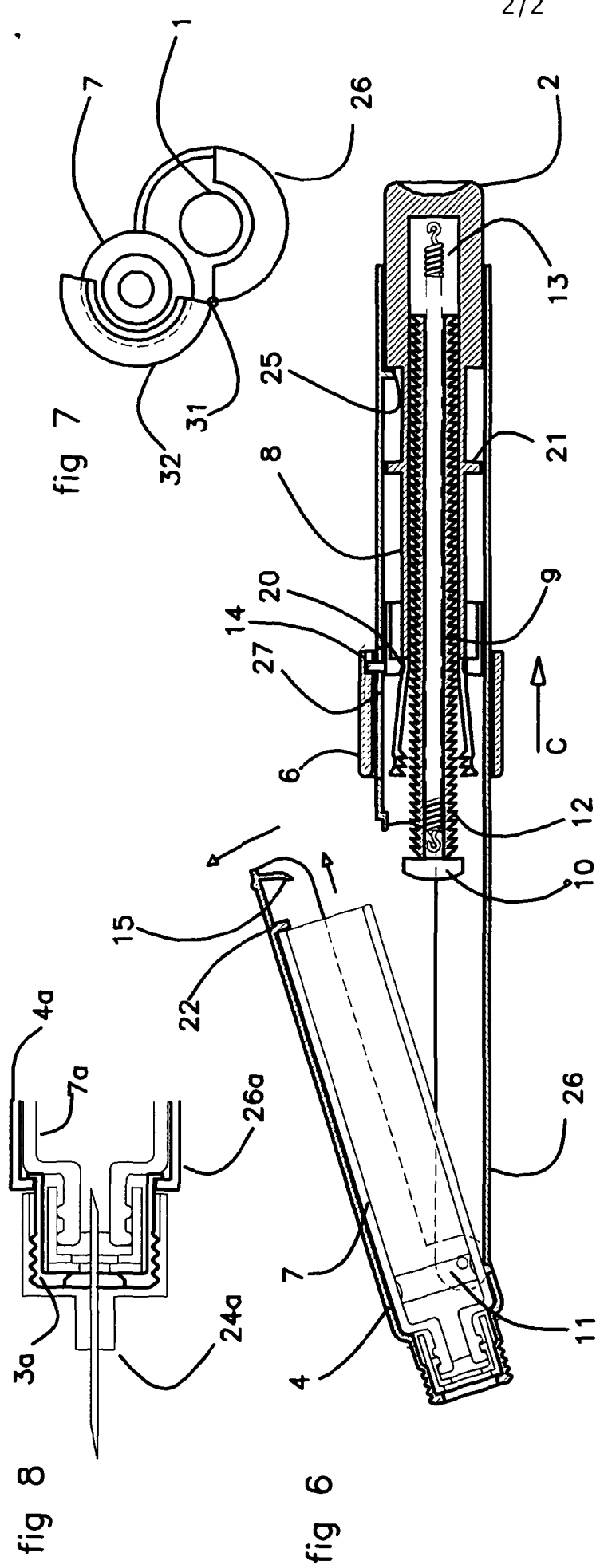


fig 8

fig 6

fig 7

fig 5

## BACKGROUND TO THE INVENTION

5 Pen injectors are pen-shaped devices widely used as a convenient and accurate method of injecting liquid drugs into patients. They are popular with diabetics and others requiring regular injections of drugs, because less skill is required in adjusting the dose. The drug is normally supplied contained in a tubular cartridge – usually made from glass and having a slidable seal at a proximal end, and a piercable septum  
10 at the distal end. (In the present context, proximal means the end nearest to the user, and distal means the end farthest away from the user). Most pen injectors have a manual drive mechanism that advances a rod to push the slidable seal along the drug cartridge, and thus dispense the drug. The drive mechanism usually enables the stroke of the push rod to be adjusted in order to vary the delivered dose, and the drug  
15 cartridge remains installed to enable the user to administer consecutive doses until the cartridge is exhausted. In addition to the manually powered dispensing types of injectors, there are injectors having means for automatic injection, such as those used to treat anaphylactic shock and other emergency conditions. Usually these injectors deliver a fixed dose, and do not have dose adjustment means. Yet another variation  
20 are injectors that allow the dose to be adjusted and inject automatically. Automatic injectors are powered by the stored energy of a spring.

Good practice requires that a new hypodermic needle is attached to the pen barrel for each injection, or in some cases, the drug cartridge itself has a screw thread and the needle is screwed onto the cartridge.. The needle is supplied fixed into a hub, and has  
25 a distal end for piercing the patient's skin, and a proximal end for piercing the septum of the drug cartridge, the hub having a thread for connection to the barrel of the pen or cartridge. When the needle is assembled to the pen, the needle hub first aligns the proximal end of the needle with the centre of the cartridge septum, and by pushing the needle and hub towards the cartridge, the needle pierces the septum. Once the needle  
30 has passed completely through the septum, the hub thread becomes in contact with the pen or cartridge thread, and by twisting the needle hub it screws onto the pen to make a secure connection. Removal of the needle is a reverse procedure.

Prior art pen injectors require the cartridge housing part to be unscrewed from the main body of the pen, so that a cartridge may be assembled therein. Apart from the

inconvenience, a problem arises when users of limited manual dexterity or without sensitivity as regards good assembly practice, damage the screw thread when re-assembling the pen. Again, those with impaired dexterity, such as those suffering from arthritis or Parkinson's Disease, find it quite difficult to manipulate the assembly, and will sometimes fail to secure the hypodermic needle properly. Another drawback of prior art injectors is that the pushrod that urges the drug cartridge piston must be manually adjusted by screwing it back to a zero position; this requires the injector to be partly dismantled for access. Again, this is inconvenient and not particularly easy for some users. The pens are usually paid for by the user, and are relatively expensive, so any damage or inconvenience in the operating procedure will at least cause irritation, and at worst poor compliance and incorrect dosing.

Whilst the present invention discloses embodiments applicable to injection pens, the invention may be applied to other medical dosing devices which employ a prefilled cartridge of the type described herein, such as automatic dosing pumps..

#### DESCRIPTION OF THE INVENTION

The present invention is directed to improve the ergonomics and convenience of pen injectors by providing a pen having a variable or fixed dose dispensing mechanism of any known type, manually or automatically operated, wherein there is means for inserting the drug cartridge into the side of the pen, preferably without dismantling the pen. Another objective is to simplify the push rod re-setting procedure.

In a first embodiment, the pen injector has a hinged panel provided with clip means to temporarily retain a drug cartridge. The hinged panel may be spring-loaded towards the closed position, or be unbiased and have latching means to keep the panel in the closed position. Once the cartridge is assembled onto the panel, the panel is closed, thus aligning the cartridge with the dispensing mechanism. To remove the cartridge, the panel is opened and the cartridge unclipped from the panel. In a second embodiment, the pen again has a hinged panel, which may be simply opened to give access to a chamber into which the drug cartridge is loaded. Again, the hinged panel may be spring-loaded towards the closed position, or be unbiased and have latching means to keep the panel in the closed position.

A third embodiment has at least one longitudinal slot through which the drug cartridge to be pushed into alignment with the dispensing mechanism. When the cartridge is exhausted, it is merely pushed out through a slot. A fourth embodiment has a shuttle which may be partly or fully ejected sideways from the pen barrel. The drug cartridge is inserted into the shuttle, and the shuttle is pushed back into the pen barrel. In all 5 embodiments, a mechanism for driving the cartridge piston may be set to a zero or start position without disassembling the pen. In all embodiments, it is preferred that an automatic plunger retraction mechanism is interlocked with the side-loading means, so that it is not possible to open the access panel or push the drug cartridge out 10 of the pen unless the push rod is fully withdrawn from the cartridge. It may be preferred that the drug cartridge is visible to enable the user to check the contents, and this may be facilitated by providing a window or transparent element in the construction. Again, there is increasing demand to reduce needle-stick injuries, and this specification includes the use of the present invention with safety needles having 15 so-called "passive" protection (i.e., automatic shielding of the needle tip after withdrawal from the patient).

It may be seen that the invention simplifies the pen construction, and greatly simplifies the operating procedures.

The first two embodiments of the invention are now described with reference to the 20 following drawings. For simplicity, like parts are given like annotation. The second embodiment is very similar to the first, the difference being that the first requires the drug cartridge to be clipped to an openable panel, and in the second embodiment, the cartridge is loaded directly into the body of the injector. The description therefore refers to the first embodiment, with references where necessary to identify the 25 differences.

Figure 1 is a side view of the pen injector, and figure 2 is a section through the injector on the centre line. the Figures 3 and 4 show a thread engaging and disengaging mechanism. Figure 5 shows the injector set to dispense a dose from a medicament cartridge. Figure 6 shows how the cartridge may be removed after use, 30 and figure 7 shows an alternative means of loading and unloading a cartridge.

Referring to figure 1, injector 1 comprises a body 26 of approximately cylindrical section, having a cartridge carrier 4 hinged at 5 onto the body 26. A rotary dose

adjusting knob 2 with calibrations 23 is shown on the proximal end of the injector. The distal end of the cartridge carrier 4 has a screwed connector 3 to which a needle 24 may be attached.

Referring to figure 2, a drug cartridge 7 is held temporarily within the carrier 4, being retained by clip means 22. In the second embodiment, the clip means is not required. The dose adjusting knob 2 has an elongated tubular section 8, and is a sliding fit within the body 26. Slidable within the tubular section 8 is a tubular push rod 9. Located inside the tubular push rod 9 is an extension spring 13, which is attached at one end to the inside of the knob 2, and at the other to the distal end of the push rod 9. The spring 13 thus holds the push rod 9 and knob 2 in resilient contact. The push rod 9 has a saw-tooth thread 12, which may be engaged with a matching thread at the distal end of the inside of the tubular section 8. This may be seen more clearly in the enlarged section in figures 3 and 4. The distal end of the tubular section 8 is configured as a collet, sprung radially outwards. In the example shown, this would be achieved by a number of slits extending longitudinally from the open end of tubular section 8. The collet thread 18 may be engaged or disengaged with the thread 12 on the push rod 9 by the action of a collet closer 17; again, this may be seen more clearly in figures 3 and 4. The collet closer 17 is sleeve slidable longitudinally along the bore of the body 26. Collet closer 17 has an internal ridge configured to engage with the detents 19 and 20. Thus, if the collet closer 17 is slid in the direction of arrow B (figure 3), the ridge 29 engages with the detent 20, and will remain engaged to hold the thread 18 of collet 16 closed onto the thread 12 of the push rod 9, until the closer 17 is slid in the opposite direction C as shown in figure 4. This allows the collet 16 to open and disengage the threads 18 from the thread 12 of the push rod 9. The collet closer 17 has a peg 28 extending radially therefrom, which is engageable by the sliding sleeve 6. The sliding sleeve 6 has a switchable action so that it may push or pull the collet closer 17. This mechanism may be one of many types typically employed in retractable ball point pens mechanisms and the like.

When the sleeve 6 is in the position shown in figures 2 and 3, the dose adjusting knob 2 and tubular extension 8 may be rotated, and this unscrews the knob from the push rod 9. The push rod 9 is prevented from rotating by a pawl 15, which is engaged with the saw tooth thread 12 of the push rod 9. As the knob 2 is screwed out, markings 23 on the knob indicate the dose required to be dispensed from the cartridge 7. At the

same time, the spring 13 is stretched, maintaining the components in resilient contact. The injector will then be set as shown in figure 5, which shows the push rod and pad 10 already in contact with the piston 11 in the drug cartridge 7 from a previous injection.

5 By acting on the knob 2 in the direction of arrow D, the knob 2 and tubular section 8 push on push rod to urge the piston 11 along the cartridge to dispense the drug therefrom. During this action, the saw tooth thread behaves a ratchet in conjunction with the pawl 15. The ratchet and pawl maintain the incremental adjustments of the knob 2 and the push rod 9, so that subsequent doses may be delivered until the  
10 cartridge is empty. The markings 23 on the knob 2 relate to the gap X between the abutment 20 on knob 2 and stop 25 on the body 26, dimension X thus controlling the stroke of the piston.

When the cartridge 7 is empty, the sleeve 6 is slid in the direction C. This moves  
15 collet closer to disengage the threads 18 of collet 16 from the saw tooth threads 12, and allows the cartridge carrier 4 to be opened. The initial part of the second action also disengages the pawl 15 from the screw thread 12, and the spring 13 pulls the push rod 9 and the pad 10 towards the knob 2, thus withdrawing the rod and pad from the empty cartridge, and allowing the carrier 4 to be fully opened. The cartridge 7 may  
20 then be withdrawn and replaced by a full cartridge.

Figure 7 shows an alternative opening cartridge carrier 31, hinged at 31 to body 26. Cartridge 7 may be clipped into the carrier 31 or loaded into the body 26 in the second embodiment. The other features of this configuration remain similar to those described.

25 Figure 8 shows a common alternative fixing for the needle. The cartridge 7a has a fixed threaded part 3a to which the needle 24a is attached. The distal end of the body 26a therefore has an aperture through which the thread 3a of the cartridge 7a projects. The sliding sleeve 6 and associated collet operating parts provide an interlocking function, and it is preferred that the sequence of interlock is first to disengage the  
30 thread 18 of the collet 16 from the thread 12 of push rod 9, followed by disengaging the pawl 15 from the thread 12 of push rod 9. This latter action allows the spring 13



to pull the push rod 9 out of the cartridge. Thereafter the hinged panel 4 or 32 (fig.8) may be opened and the cartridge extracted.

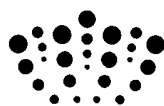
The third and fourth embodiments have not been described in detail, because the construction would be obvious to a skilled person. A similar sliding sleeve and interlocking functions would achieve the same preferred sequence of operation.

The interlocking means disclosed is but one of many that would suffice, and although that used in the present invention has only one component (sleeve 6) operable by the user, further locking buttons and devices may of course be added if necessary.

The main objectives of the invention have been achieved, namely, the drug cartridge may be inserted and removed without dismantling the pen injector, and resetting is achieved also without dismantling. Interlock means prevent the removal of the drug cartridge until the push rod is withdrawn from the cartridge. There are several alternative mechanisms that will provide similar detent and ratchet functions to those described, and these are deemed to form part of this specification. Also there are other devices such as automatic medicament pumps that employ similar cartridges and such devices are included in this specification.

## CLAIMS

- 5 1. A pen injector adapted to allow a drug cartridge to be loaded into the side of the injector and having interlocked and automatic means for retracting the plunger from the cartridge before allowing the cartridge to be removed from the pen injector.
2. A pen injector as in any previous claim having adjustable stroke push rod means for dispensing the drug from the cartridge.
- 10 3. A pen injector as in any previous claim having adjustable stroke push rod means for dispensing more than one dose sequentially from the cartridge.
4. An injector as in any previous claim which has a hypodermic needle attached to the pen injector and proximal end of said needle being in hydraulic connection with the contents of the drug cartridge and the distal end suitable for piercing a patient's skin.
- 15 5. An injector as in any previous claim 1 to 3 adapted to receive a drug cartridge having means to attach a hypodermic needle thereto and proximal end of said needle being in hydraulic connection with the contents of the drug cartridge and the distal end suitable for piercing a patient's skin.
- 20 6. An injector as in claims 4 and 5 wherein the hypodermic needle is a passive safety needle.



**Application No:** GB0821424.9

**Examiner:** Hayley Yates

**Claims searched:** 1-6

**Date of search:** 24 March 2009

**Patents Act 1977: Search Report under Section 17**

**Documents considered to be relevant:**

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-6	EP 0937474 A Becton, Dickinson and Company; see figures 10 and 11 and paragraphs [0021-0022]
A	-	US 3848593 A Baldwin; see figures 1, 9 and 10
A	-	US 5112307 A Haber et al; see figures 13-16 and column 7 line 54 to column 8 line 54
A	-	US 4915701 A Halkyard; see figures 1-3
A	-	US 1012700 A Payne; see figures 1-3
A	-	US 4407283 A Reynolds; see figures

**Categories:**

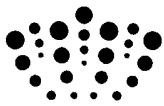
X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

**Field of Search:**

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC<sup>X</sup>:

Worldwide search of patent documents classified in the following areas of the IPC
A61M
The following online and other databases have been used in the preparation of this search report
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**International Classification:**



<b>Subclass</b>	<b>Subgroup</b>	<b>Valid From</b>
A61M	0005/31	01/01/2006
A61M	0005/24	01/01/2006