(19) DANMARK

(10) **DK/EP 2654835 T3**

(12) Oversættelse af europæisk patentskrift

Patent- og Varemærkestyrelsen

(51) Int.Cl.: ***A 61 M 5/20 (2006.01)*** ***A 61 M 5/00 (2006.01)*** ***A 61 M 5/32 (2006.01)***

(45) Oversættelsen bekendtgjort den: **2017-09-04**

(80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2017-05-17**

(86) Europæisk ansøgning nr.: **11802090.8**

(86) Europæisk indleveringsdag: **2011-12-21**

(87) Den europæiske ansøgnings publiceringsdag: **2013-10-30**

(86) International ansøgning nr.: **EP2011073503**

(87) Internationalt publikationsnr.: **WO2012085022**

(30) Prioritet: **2010-12-21 EP 10196068** **2011-01-13 US 201161432254 P**

(84) Designerede stater: **AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR**

(73) Patenthaver: **Sanofi-Aventis Deutschland GmbH, Brüningstraße 50, 65929 Frankfurt am Main, Tyskland**

(72) Opfinder: **HOURMAND, Yannick, 14 The Elms, Haslingfield CB23 1ND, Storbritannien**
BARROW-WILLIAMS, Timothy Donald, 93 Castle Road, St. Albans, Hertfordshire AL1 5DQ, Storbritannien
EKMAN, Matthew, 59 Ecton Avenue, Macclesfield, Cheshire SK10 1RD, Storbritannien

(74) Fuldmægtig i Danmark: **RWS Group, Europa House, Chiltern Park, Chiltern Hill, Chalfont St Peter, Bucks SL9 9FG, Storbritannien**

(54) Benævnelse: **AUTOINJEKTOR**

(56) Fremdragne publikationer:
WO-A1-2009/062508
WO-A2-2010/146358
US-A1- 2007 112 310

DESCRIPTION

Technical Field

[0001] The invention relates to an auto-injector for administering a dose of a liquid medicament.

Background of the Invention

[0002] Administering an injection is a process which presents a number of risks and challenges for users and healthcare professionals, both mental and physical.

[0003] Injection devices (i.e. devices capable of delivering medicaments from a medication container) typically fall into two categories - manual devices and auto-injectors.

[0004] In a manual device - the user must provide the mechanical energy to drive the fluid through the needle. This is typically done by some form of button / plunger that has to be continuously pressed by the user during the injection. There are numerous disadvantages to the user from this approach. If the user stops pressing the button / plunger then the injection will also stop. This means that the user can deliver an underdose if the device is not used properly (i.e. the plunger is not fully pressed to its end position). Injection forces may be too high for the user, in particular if the patient is elderly or has dexterity problems.

[0005] The extension of the button/plunger may be too great. Thus it can be inconvenient for the user to reach a fully extended button. The combination of injection force and button extension can cause trembling / shaking of the hand which in turn increases discomfort as the inserted needle moves.

[0006] Auto-injector devices aim to make self-administration of injected therapies easier for patients. Current therapies delivered by means of self-administered injections include drugs for diabetes (both insulin and newer GLP-1 class drugs), migraine, hormone therapies, anticoagulants etc.

[0007] Auto-injectors are devices which completely or partially replace activities involved in parenteral drug delivery from standard syringes. These activities may include removal of a protective syringe cap, insertion of a needle into a patient's skin, injection of the medicament, removal of the needle, shielding of the needle and preventing reuse of the device. This overcomes many of the disadvantages of manual devices. Injection forces / button extension, hand-shaking and the likelihood of delivering an incomplete dose are reduced. Triggering may be performed by numerous means, for example a trigger button or the action of the needle reaching its injection depth. In some devices the energy to deliver the fluid is provided by a

spring.

[0008] US 2002/0095120 A1 discloses an automatic injection device which automatically injects a pre-measured quantity of fluid medicine when a tension spring is released. The tension spring moves an ampoule and the injection needle from a storage position to a deployed position when it is released. The content of the ampoule is thereafter expelled by the tension spring forcing a piston forward inside the ampoule. After the fluid medicine has been injected, torsion stored in the tension spring is released and the injection needle is automatically retracted back to its original storage position.

[0009] The post-published WO 2010/146358 A2 discloses an auto-injector for a syringe that is suitable for use in the injected delivery of drug to a patient. The auto-injector comprises a housing defining a housing cavity and a needle delivery aperture, the housing cavity arranged for receipt of a syringe. The syringe is movable within the housing cavity from a rest position, in which the needle tip thereof is within the housing to a use position, in which the needle tip protrudes from the needle delivery aperture. The auto-injector further comprises a drive transfer element for transferring axial drive; and a first coupling for coupling said drive transfer element to said syringe barrel of the syringe. The drive transfer element communicates with said plunger of the syringe for transferring axial drive thereto. The first coupling is a friction clutch coupling arranged for decoupling by declutching thereof when the syringe moves to the use position.

[0010] WO 2009/062508 A1 discloses a disposable auto injector having a housing for accommodation of a syringe with a needle movably positioned in the housing between a first position in which the needle is inside the housing and a second position in which the needle protrudes outside the housing, a driver positioned laterally in relation to the syringe and configured for applying a force to the syringe thereby moving the syringe from the first position to the second position, a first injection lock configured in a locked state for preventing syringe movement from the first position to the second position and an injection trigger member configured for releasing the first injection lock to an unlocked state wherein the first injection lock comprises a rotatable release shaft configured for rotation between a first angular position in which it prevents movement of the syringe from the first position to the second position and a second angular position in which position does not prevent movement of the syringe from the first position to the second position.

[0011] US 2007/112310 A1 discloses an injector being automatic in that the needle is inserted into the injection site (e.g., a patient's skin) with user or caregiver assistance, the delivery is automatically initiated upon needle insertion, and the needle is retracted automatically after the end of delivery. Preferably the needle is not seen by the user prior to, during or after injection. Prior to and after injection, the needle is hidden in the device so as to avoid any potential injury or health risk to the user or health care provider. The injector includes a housing and a shield arranged to slide relative to the housing and a driver moving during drug delivery. The housing and shield form a cartridge enclosure. The cartridge is shielded and locked after delivery is completed.

Summary of the Invention

[0012] It is an object of the present invention to provide an improved auto-injector.

[0013] The object is achieved by an auto-injector according to claim 1.

[0014] Preferred embodiments of the invention are given in the dependent claims.

[0015] In the context of this specification, the terms distal and proximal are defined from the point of view of a person receiving an injection. Consequently, a proximal direction refers to a direction pointing towards the body of a patient receiving the injection and a proximal end defines an end of an element that is directed towards the body of the patient. Respectively, the distal end of an element or the distal direction D is directed away from the body of the patient receiving the injection and opposite to the proximal end or proximal direction.

[0016] According to the invention, an auto-injector for administering a dose of a liquid medicament comprises

- a substantially cylindrical housing arranged to contain a pre-filled syringe,
- a syringe retainer slidably arranged with respect to the housing that mounts a pre-filled syringe with an injection needle, a plunger and a stopper for sealing a syringe barrel of the pre-filled syringe,
- a coupling shroud slidably arranged within the housing and releasably coupled to the plunger and
- a single drive means. Upon release, the single drive means is capable of driving the coupling shroud from a first position in the proximal direction. The proximal translatory movement of the coupling shroud with respect to the housing
- translates the syringe retainer in the proximal direction to expose the injection needle of the pre-filled syringe,
- depresses the plunger connected to the stopper into the syringe barrel to expel the dose of medicament and
- advances a needle shroud to a safe position to surround the injection needle after the medicament has been at least partially delivered. The coupling shroud is decoupled from the plunger at a pre-determined second position defined by an aperture formed into the housing.

[0017] The mechanism of the auto-injector is arranged in a manner that a plurality of functions is executed by the single drive means. The injection needle is inserted into the skin of the patient, the plunger is translated to expel the medicament and the needle shroud is moved proximally to provide needle safety after the injection is completed by the action of the spring means. Conventional auto-injectors usually comprise a plurality of spring means to accomplish

these tasks. The auto-injector according to the invention comprises only few parts and is particularly inexpensive to mass-produce. Consequently, the auto-injector is particularly suited as a single-use device that may be disposed after an injection has been carried out.
The coupling shroud is initially coupled to the plunger to translate the syringe retainer proximally, whereby the injection needle is inserted into the skin of the patient, and to depress the stopper into the syringe barrel to expel the medicament. A crucial step for designing the auto-injector with the single drive means is the decoupling of the plunger and the coupling shroud at the proper pre-determined second position, so that the same drive means may be used to advance the needle shroud after the medication has been completely or partially delivered. The pre-determined second position is defined by a longitudinal aperture in the housing.

[0018] In one possible embodiment of the invention, the pre-determined second position defined by the aperture is arranged in a manner that allows for a decoupling of the plunger from the coupling shroud before the stopper reaches a proximal end of the syringe barrel. This ensures that a reliable activation of the safety functions of the auto-injector are activated after the medicament has been at least partially delivered.

[0019] According to the invention, a coupling catch is arranged to abut against a shoulder formed to the plunger as a particularly simple and reliable means to releasably couple the plunger to the coupling shroud. The coupling shroud is moved by the action of the relaxing drive means in the proximal direction and coupled to the plunger connected to the stopper to insert the injection needle before the injection and to expel the medication during the injection.

[0020] The aperture formed into the lateral side of the housing at the second position allows the coupling catch to deflect radially outwards at the second position, so that the coupling shroud is decoupled from the plunger after the medicament is partially or completely delivered.

[0021] Preferably, the single drive means is arranged as a single compression spring. Compression springs are readily available and inexpensive drive means that may be used to cut down on production costs.

[0022] According to the invention, a rotating collar is rotatably arranged within the housing. The rotating collar creates friction to slow down a proximal movement of the needle shroud that is designed to rest onto the skin of the patient during the injection. The rotating collar acts as a dampening element that alleviates the pressure exerted upon the skin of the patient by the single drive means via the needle shroud and thus reduces the risk of injuries like bruises. Furthermore, the modulus of resilience of the single drive means may be chosen to be sufficiently large without having to worry about potential injury risks. Thus, the modulus of resilience of the single drive means is adapted to reliably provide an energy supply for a plurality of actions comprising, in particular, the advancing of the syringe retainer and the needle shroud, the displacement of the stopper to expel the medication and the decoupling of the plunger and the coupling shroud.

[0023] Preferably, the rotating collar comprises a pin that engages a helical recess formed into the needle shroud. The engagement of the helical recess and the pin forces the rotating collar to rotate around the needle shroud when the needle shroud is translated. This in particular dampens a proximal movement of the needle shroud and thus reduces the pressure exerted upon the skin of the patient by generating friction.

[0024] According to another possible embodiment of invention, the auto-injector comprises safety means that are arranged to cooperate with the needle shroud to prevent a release of the drive means when the needle shroud is in an advanced position and hence is not pushed against the skin of the patient at the injection site. This mechanism avoids an early release of the drive means and thus a prematurely expelling of the medicament. Furthermore, injuries resulting from an activation of the drive means when the auto-injector is not or not properly placed onto the skin of the patient are reduced.

[0025] In one possible embodiment of the invention, the safety means comprises an elastic bushing that engages the plunger and/or the coupling shroud. The elastic bushing is firmly attached to a proximal end of the housing and may engage the coupling shroud and/or the plunger to prevent an inadvertent release of the drive means.

[0026] In another possible embodiment of the invention, a release element is hinged to the lateral side of the housing. The safety means comprises a blocking element slidably arranged relative to the housing. Manual actuation of the release element causes the release element to pivot about a hinge to release the drive means. The blocking element is arranged to limit a pivoting movement of the release element when the needle shroud is in an advanced position and hence to prevent an activation of the drive means. The release element is allowed pivot about the hinge when the needle shroud is moved to a retracted position by pressing the needle shroud against the skin surface of the patient receiving the injection.

[0027] Preferably, the blocking element is arranged to block a distal movement of the needle shroud when the release element is manually actuated while the needle shroud is located in the advanced position. The pivoting release element may comprise an inward projection that is pushed radial inwards by manually actuating the release element to block a displacement of the needle shroud from the advanced position. The user is thus forced to perform the sequence of actions necessary to start the injection in the proper order. In particular, the user is forced to first push the needle shroud against the skin of the patient to translate the needle shroud to the retracted position. Subsequently, the release element is manually actuated to release the drive means.

[0028] The auto-injector may preferably be used for subcutaneous or intra-muscular injection, particularly for delivering one of an analgetic, an anticoagulant, insulin, an insulin derivate, heparin, Lovenox, a vaccine, a growth hormone, a peptide hormone, a proteine, antibodies and complex carbohydrates.

[0029] Further scope of applicability of the present invention will become apparent from the

detailed description given hereinafter. However, it should be understood that the detailed description and specific examples, while indicating preferred embodiments of the invention, are given by way of illustration only, since various changes and modifications within the scope of the invention will become apparent to those skilled in the art from this detailed description.

Brief Description of the Drawings

[0030] The present invention will become more fully understood from the detailed description given hereinbelow and the accompanying drawings which are given by way of illustration only, and thus, are not limitive of the present invention, and wherein:

Figures 1A und 1 B
: show two different sectional views of an auto-injector according to a first embodiment of the invention with a hinged release element before an injection,

Figure 2
: an expanded sectional view of the auto-injector according to the first embodiment, wherein the release element is blocked to prevent an inadvertent release of a drive means,

Figure 3
: an expanded sectional view of the hinged release element that is actuated to release the drive means,

Figures 4A and 4B
: two different sectional views of the auto-injector according to the first embodiment after a drug has been delivered,

Figure 5
: an isometric view of a needle shroud,

Figures 6A and 6B
: two different sectional views of the auto-injector according to the first embodiment after an injection has been performed,

Figures 7A and 7B
: two different sectional views of an auto-injector according to a second embodiment of the invention,

Figure 8
: a sectional view of a distal end section of the auto-injector according to the second embodiment of the invention,

Figure 9A and 9B
: two different sectional views of an auto-injector according to a third embodiment of the invention,

Figure 10
: a sectional view of a distal end section of the auto-injector according to the third embodiment of the invention.

[0031] Corresponding parts are marked with the same reference symbols in all figures.

Detailed Description of Preferred Embodiments

[0032] **Figures 1A and 1B** show two sectional views of an essentially cylindrical auto-injector 1 according to a first embodiment of the invention, wherein the sectional plane shown in figure 1A is oriented perpendicularly to the one shown in figure 1B. The auto-injector 1 comprises a housing 2, a proximal needle shroud 3, a syringe retainer 4 adapted to mount and move translatably with a pre-filled syringe 5 within the housing 2, a coupling shroud 6 slidably arranged within the housing 2 and a release element 7 hinged to a lateral side of the substantially cylindrical housing 2 of the auto-injector 1.

[0033] A single drive means 8 is arranged between the distal end of the housing 2 and the coupling shroud 6 to bias the coupling shroud 6 in a proximal direction P towards the skin of a patient receiving an injection.

[0034] According to one possible embodiment of the invention, the drive means 8 is arranged as a single, conventional compression spring.

[0035] The coupling shroud 6 is releasably coupled to a plunger 9 that is connected to a stopper 10 fluid-tightly sealing a distal end of a syringe barrel 11 containing a dose of a medicament M. An inner cavity of the syringe barrel 11 is in fluid communication with an injection needle 12, so that the dose of the medicament M may be expelled through the injection needle 12 by displacing the stopper 10 in the proximal direction P.

[0036] Before the injection, the coupling shroud 6 abuts against a distal end of the release element 7 to releasably retain the coupling shroud 6 in a first position I, wherein the coupling shroud 7 is located at a distal end of the housing 2. The drive means 8 is compressed, so that the coupling shroud 6 is strongly biased in the proximal direction P. The plunger 9 extends from the syringe barrel 11 in a distal direction D and comprises a shoulder 9.1 of increased diameter. The coupling shroud 6 comprises an inwardly protruding coupling catch 6.1 that bears against the shoulder 9.1 so that the plunger 9 and the coupling shroud 6 may be jointly moved in the proximal direction P by the action of the relaxing drive means 8.

[0037] The proximal end of the needle shroud 3 is designed to be pushed against the skin surface of the patient during the injection. Edges of the needle shroud 3 may thus be smoothed to avoid injuries. The needle shroud 3 is slidably arranged within the housing 2 of the auto-injector 1, so that the needle shroud 3 may be pushed from an advanced position PA shown in figures 1A and 1B in the distal direction D. A biasing means 13 bears against the needle shroud 3 and the housing 2 to bias the needle shroud 3 towards the advanced position PA.

[0038] An annular rotating collar 14 engages an outer surface of the needle shroud 3. The rotating collar 14 rotates around an axis of the substantially cylindrical auto-injector 1 when the needle shroud 3 is longitudinally displaced in the proximal and/or the distal direction P, D. The rotating collar 14 acts as a damping means that creates friction to slow down the movement of the needle shroud 3 and to reduce the pressure exerted onto the skin of the patient receiving the injection.

[0039] The release element 7 hinged to the housing 2 works like a see-saw: a proximal section may be pushed radially inwards, whereby the release element 7 pivots about a hinge 15, so that the distal section of the release element 7 moves radially outwards and the coupling shroud 6 is disengaged to release the drive means 8.

[0040] The auto-injector 1 comprises safety means S that prevents an early release of the drive means 8. The safety means S ensures that the needle shroud 3 is pushed against the skin of the person receiving the injection before the drive means 8 may be released.

[0041] According to the first embodiment of the invention, the safety means S comprises a blocking element 16 slidably arranged with the housing 2. When the needle shroud 3 is positioned in the advanced position PA, the blocking element 16 is positioned to prevent a pivoting movement of the release element 7 and thus a release of the coupling shroud 6. A radially outwards protruding blocking projection 16.1 of the blocking element 16 is located opposite to an inward protrusion 7.1 formed to the release element 7. If the proximal section of the release element 7 is pushed inwards, the inward protrusion 7.1 abuts against the blocking projection 16.1 to limit the pivoting movement of the release element 7, so that a release of the coupling shroud 6 and the drive means 8 is prevented.

[0042] Figure 2 shows a proximal section of the auto-injector 1 in a sectional view with the blocking element 16 positioned to prevent an inadvertent actuation of the hinged release element 7 to release the drive means 8.

[0043] A distal end of the needle shroud 3 is clipped to the housing 2 and retained between two inwardly protruding retaining protrusions 2.1 formed into an inner surface of the housing 2. The two retaining protrusions 2.1 are longitudinally displaced from each other to limit the range of axial displacement of the needle shroud 3 with respect to the housing 2. A boss 3.1 formed into an outer surface of the needle shroud 3 bears against an inner surface of the blocking element 16, so that the blocking element 16 may move with the needle shroud 3 in the proximal direction P to deblock the release element 7.

[0044] The blocking projection 16.1 comprises a central indention that forces a user of the auto-injector 1 to perform a sequence of actions necessary to inject the dose of the medicament M in the proper order. If the release element 7 is pushed inwards before the needle shroud 3 is moved proximally from the advanced position PA towards a retracted position PR (see Figure 3) by pushing the needle shroud 3 towards the skin of the patient, the inward projection 7.1 is retained in the central indentation of the blocking projection 16.1, so

that both the longitudinal displacement of the needle shroud 3 and the pivoting movement of the release element 7 is blocked.

[0045] A proper sequence of actions for injecting the dose of the medicament M is described in the following. First, the user pushes the needle shroud 3 against the skin to move the needle shroud 3 distally to the retracted position PR illustrated in figure 3. The blocking element 16 jointly moves with the needle shroud 3 in the distal direction D, so that the release element 7 may be manually actuated to pivot about the hinge 15, whereby the drive means 8 are released.

[0046] Upon release of the drive means 8, the coupling shroud 6 is urged in the proximal direction P. The single and fully compressed drive means 8 drives the coupling shroud 6 and the plunger 9 coupled thereto in the proximal direction P. The coupling shroud 6 first pushes the syringe retainer 4 by means of plunger 9, stopper 10 and the friction between stopper 10 and syringe 11 proximally to insert the injection needle 12 into the skin of the patient and a first clip connection 2.2 formed into a lateral side of the housing 2 latches to an outward protrusion 4.1 of the syringe retainer 4, as illustrated in more detail in figure 4B.

[0047] The syringe retainer 4 and the pre-filled syringe 5 mounted thereto is now locked to the housing 2. The coupling shroud 6 is moved further in the proximal direction P by the action of the relaxing drive means 8, whereby the plunger 9 is depressed into the syringe barrel 11 to expel the dose of the medicament M contained therein through the injection needle 12.

[0048] Figure 4A and 4B show two sectional views of the auto-injector 1 according to the first embodiment of the invention with the plunger 9 fully depressed within the syringe barrel 11. The dose of the medicament M has been delivered beneath the skin of the patient. The coupling shroud 6 is located in an intermediate second position II. The drive means 8 is not yet completely discharged and biases the coupling shroud 6 in the proximal direction P. The shoulder 9.1 engages a ramp of the coupling catch 6.1 to deflect the coupling catch 6.1 in a radial outward direction. An aperture 2.3 is formed into the housing 2 to allow for a radial outward deflection of the coupling catch 6.1, so that the coupling catch 6.1 overcomes the shoulder 9.1 decoupling the coupling shroud 6 from the plunger 9.

[0049] In a possible embodiment of the invention, the aperture 2.3 defining the second position II is located at a longitudinal position along the housing 2 that allows for a full depression of the plunger 9 completely emptying the syringe barrel 11 before the plunger 9 is decoupled from the coupling shroud 6.
Alternatively, the aperture 2.3 defining the second position II may be located at a longitudinal position along the housing 2 that allows for an adjustment space accounting for manufacturing tolerances. The adjustment space is dimensioned as to allow for a reliable decoupling of the plunger 9 from the coupling shroud 6 even if the parts constituting the auto-injector 1 comprise mismatch in mould or are slightly misaligned. In this alternative embodiment, the dose of the medicament M may or may not be completely expelled before the plunger 9 is decoupled from the coupling shroud 6.

[0050] The retaining protrusions 2.1 are elastically supported and may be deflected radially outwards to release the needle shroud 3. The coupling shroud 6 engages a ramp of the retaining protrusions 2.1 and splays the retaining protrusions 2.1 outwards, whereby the needle shroud 3 is released and allowed to move proximally from the retracted position PR towards an extended safe position PS.

[0051] The drive means 8 is still partially loaded when the coupling shroud 6 is located in the second position II. In a possible embodiment of the invention the biasing force of the drive means 8 exerted on the coupling shroud 6 in the second position II is about 10 N.

[0052] The coupling shroud 6 bears against a distal end of the needle shroud 3, so that the needle shroud 3 may be moved to the safe position PS by the action of the further relaxing drive means 8. As the biasing force exerted onto the needle shroud 3 by the drive means 8 may be relatively large and could even bruise the patient, the rotating collar 14 is arranged within the housing 2 to partially absorb the excess energy of the drive means 8 and slow down the proximal movement of the needle shroud 3 by generating friction.

[0053] Figure 5 shows an isometric view of the needle shroud 3. A helical recess 3.2 is formed into a tubular proximal section 3.3 of the needle shroud 3. The proximal section 3.3 of the needle shroud 3 is inserted into the annular rotating collar 14, wherein a pin 14.1 formed to an inner surface of the rotating collar 14 protrudes into the helical recess 3.2 as shown in figure 6A. The linear translatory movement of needle shroud 3 towards the safe position PS thus causes the rotating collar 14 to rotate within the housing 2 around the axis of the auto-injector 1.
Figures 6A and 6B show two different sectional views of the auto-injector 1 according to the first embodiment of the invention after the injection has been performed. The needle shroud 3 is permanently locked to the safe position PS by a second clip connection 2.4 formed into the housing 2. The needle shroud 3 surrounds the injection needle 12 and extends a suitable distance proximally beyond the needle tip to avoid accidental needle stick injuries after the auto-injector 1 has been used.

[0054] Figures 7A and 7B show two different sectional views of an auto-injector 1 according to a second embodiment of the invention before the injection. The sectional plane shown in figure 7A is oriented perpendicularly to the sectional plane shown in figure 7B.

[0055] The needle shroud 3 of the auto-injector 1 according to the second embodiment substantially extends over the axial length of the housing 2. Before the injection, the needle shroud 3 is mounted to the housing 2 by the retaining protrusions 2.1 that protrude into orifices formed into a lateral side of the needle shroud 3. The orifices comprise a longitudinal length that allows the needle shroud 3 to be slid from the advanced position PA to the retracted position PR.

[0056] A retaining catch 2.5 is formed to an inner surface of the housing 2 and protrudes

through an opening formed into the needle shroud 3 to releasably mount the syringe retainer 4 retaining the pre-filled syringe 5. The retaining catch 2.5 comprises a bevelled ramp and is deflectable in a radial outward direction. The retaining catch 2.5 latches to the outward protrusion 4.1 formed to the outer surface of the syringe retainer 4 when the needle shroud 3 is in the advanced position PA.

[0057] The needle shroud 3 abuts against the bevelled ramp of the retaining catch 2.5 when the needle shroud 3 is moved from the advanced position PA in the distal direction D, whereby the retaining catch 2.5 is deflected in a radial outward direction and disengages the outward protrusion 4.1, so that the syringe retainer 4 may be moved in the proximal direction P.

[0058] The release element 7, shown in more detail in figure 8, is arranged as a push button and mounted to a distal end of the housing 2. The release element 7 may be pushed in the proximal direction P to release the drive means 8 when the needle shroud 3 is in the retracted position PR, whereas the release element 7 and thus the release of the drive means 8 is blocked when the needle shroud 7 is in the advanced position PA.

[0059] According to the second embodiment of the invention, the safety means S that prevent the early release of the drive means 8 comprises clips 2.6 that may deflect in a radial outward direction and a bushing 17 locking the plunger 9 before use of the auto-injector 1.

[0060] Before the auto-injector 1 is used, the clips 2.6 formed to the housing 8 latch to the release element 7. (See Figure 7b) The clips 2.6 block the movement of the release element 7 in the proximal direction P, so that a manual actuation of the release element 7 is prevented as long as the needle shroud 3 is in the advanced position PA. A distal movement of the release element 7 is blocked by a first detent 2.7 engaging an inner surface of the release element 7.

[0061] The clip 2.6 comprises a ramp that the needle shroud 3 engages when pushed distally from the advanced position PA to the retracted position PR, whereby the clip 2.6 is deflected radially outwards to disengage the needle shroud 3. The release element 7 may be pushed in the proximal direction P when the needle shroud 3 is in the retracted position PR.

[0062] The plunger 9 comprises a distal end 9.2 of increased diameter that is retained in the bushing 17 firmly attached to a distal end of the housing 2. The bushing 17 comprises an inner surface corresponding to the distal end 9.2 of the plunger 9 that engages the distal end 9.2 in a locked position L to lock the plunger 9 and the coupling shroud 6 coupled thereto to the housing 2 before use of the auto-injector 1. The bushing 17 abuts radially against an annular inner collar 7.2 of the release element 7 in the locked position L shown in figures 7A and 7B. A radial outward deflection of the bushing 17 releasing the plunger 9 is thus prevented.

[0063] Figure 8 shows a sectional view of a distal end section of the auto-injector 1 according to the second embodiment of the invention. The needle shroud 3 is located in the retracted position PR and the release element 7 is pushed in the proximal direction P, so that the bushing 17 disengages the annular inner collar 7.2 of the release element 7. The bushing 17 is

positioned in an unlocked position U and may deflect outwardly to release the plunger 9.

[0064] Furthermore, the bushing 17 acts as a counter bearing for the drive means 8 bearing against the bushing 17 in the distal direction D.

[0065] Figure 9A and 9B show two different sectional views of an auto-injector 1 according to a third embodiment of the invention, wherein the release element 7 is arranged as an outer sleeve extending over a substantial length of the auto-injector 1.

[0066] According to the third embodiment of the invention, the safety means S that prevent the early release of the drive means 8 comprise clips 2.6, second and third detents 2.8, 7.3, a locking catch 6.2 formed to the coupling shroud 6 and the bushing 17 that comprises an inner sleeve 17.1 receiving a lug 7.4, wherein the locking catch 6.2 latches to a collar 17.2 of the inner sleeve 17.1.

[0067] The release element 7 of the third embodiment is gripped by a user to perform the injection. When the needle shroud 3 is in the advanced position PA, the proximal displacement of the release element 7 is blocked by the clips 2.6 in a similar manner as in the second embodiment described herein above.

[0068] Additionally, the release element is releasably retained in position before the injection by the second and the third detents 2.8, 7.3 respectively formed to an outer surface of the housing 2 and to an inner surface of the release element 7, wherein the second and third detents 2.8, 7.3 comprise correspondingly shaped ramps facing each other.

[0069] The bushing 17 of the third embodiment comprises the inner sleeve 17.1 that receives the lug 7.4 formed to an inner surface of the release element 7. A proximal end of the lug 7.4 snugly fits in the central aperture of the inner sleeve 17.1, so that an inward deflection of the inner sleeve 17.1 is prevented.

[0070] The inner sleeve 17.1 comprises a collar 17.2. An inwardly protruding locking catch 6.2 of the coupling shroud 6 latches to the collar 17.2 before use of the auto-injector 1 to releasably retain the coupling shroud 6 in the first position I.

[0071] Figure 10 shows a sectional view of a distal end section of the auto-injector 1 according to the third embodiment of the invention. The release element 7 is actuated and moved in the proximal direction P. The proximal end of the lug 7.4 disengages the inner sleeve 17.1 of the bushing 17, so that the inner sleeve 17.1 may bend radially inwards, whereby the locking catch 6.2 disengages the collar 17.2 and releases the coupling shroud 8 and the drive means 8.

List of References

[0072]

1 auto-injector
2 housing
2.1 retaining protrusion
2.2 first clip connection
2.3 aperture
2.4 second clip connection
2.5 retaining catch
2.6 clip
2.7 first detent
2.8 second detent
3 needle shroud
3.1 boss
3.2 helical recess
3.3 proximal section
4 syringe retainer
4.1 outward protrusion
5 pre-filled syringe
6 coupling shroud
6.1 coupling catch
6.2 locking catch
7 release element

7.1
inward protrusion
7.2
inner collar
7.3
second detent
7.4
lug
8
drive means
9
plunger
9.1
shoulder
9.2
distal end
10
stopper
11
syringe barrel
12
injection needle
13
biasing means
14
rotating collar
14.1
pin
15
hinge
16
blocking element
16.1
blocking projection
17
bushing
17.1
inner sleeve
17.2
collar
M
medicament
S
safety means

I
: first position

II
: second position

PA
: advanced position

PR
: retracted Position

PS
: safe position

L
: locked position

U
: unlocked position

P
: proximal direction

D
: distal direction

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US20020095120A1 **[0008]**
- WO2010146358A2 **[0009]**
- WO2009062508A1 **[0010]**
- US2007112310A1 **[0011]**

Patentkrav

1. Autoinjektor (1) til administrering af en dosis af et væskeformigt medikament (M), som omfatter:
- et i det væsentlige cylindrisk hus (2), der er indrettet til at indeholde en fyldt sprøjte (5),
- en sprøjteholder (4), der er anbragt glidbart i forhold til huset (2), som omfatter en fyldt sprøjte (5) med en injektionskanyle (12), et stempel (9) og en prop (10) til forsegling af sprøjtecylinderen (11),
- en koblingskappe (6), der er glidbart anbragt i huset (2) og frigørligt koblet til stemplet (9), og
- et enkelt drivmiddel (8), der ved frigørelse er i stand til at:
- drive koblingskappen (6) fra en første position (I) i den proksimale retning (P), hvor den proksimale translationsbevægelse af koblingskappen (6) i forhold til huset (2)
- translaterer sprøjteholderen (4) i den proksimale retning (P) til eksponering af injektionskanylen (12) på den fyldte sprøjte (5),
- trykker stemplet (9), der er forbundet til proppen (10), ind i sprøjtecylinderen (11) til udstødning af dosen af medikament (M), og
- fremfører en kanyleafskærmning (3) til en sikker position (PS), så den omgiver injektionskanylen (12), efter medikamenter (M) er blevet mindst delvist fremført,
hvor koblingskappen (6) afkobles fra stemplet (9) i en forudbestemt anden position (II), der defineres af en åbning (2.3), der er formet i huset (2), hvor en koblingspal (6.1) er anbragt, så den støder mod en skulder (9.1), der er formet på stemplet (9), til frigørlig kobling af stemplet (9) til koblingskappen (6), hvor åbningen (2.3) åbner mulighed for, at koblingspalen (6.1) kan afbøje radialt udad til afkobling af koblingskappen (6) fra stemplet (9) i den anden position (II), der er kendetegnet ved, at en roterende krave (14) er roterbart anbragt i huset (2) til frembringelse af friktion til reducering af hastigheden af en proksimal bevægelse af

kanyleafskærmningen (3).

2. Autoinjektor (1) ifølge krav 1,
der er kendetegnet ved, at den forudbestemte anden position (II), der defineres af åbningen (2.3), er anbragt på en måde, der åbner mulighed for afkobling af stemplet (9) fra koblingskappen (3), før proppen (10) når en proksimal ende af sprøjtecylinderen (11).

3. Autoinjektor (1) ifølge et af ovennævnte krav,
der er kendetegnet ved, at det enkelte drivmiddel (8) er indrettet som en enkelt kompressionsfjeder.

4. Autoinjektor (1) ifølge krav 1,
der er kendetegnet ved, at den roterende krave (14) omfatter en stift (14.1), der går i indgreb med en spiralformet indskæring (3.2), der er formet i kanyleafskærmningen (3).

5. Autoinjektor (1) ifølge et af ovennævnte krav,
der er kendetegnet ved, at et sikkerhedsmiddel (S) er anbragt, så det kan samvirke med kanyleafskærmningen (3) til forhindring af frigørelse af drivmidlet (8), når kanyleafskærmningen (3) er i en fremskudt position (PA).

6. Autoinjektor (1) ifølge krav 5,
der er kendetegnet ved, at sikkerhedsmidlet (S) omfatter en bøsning (17), der går i indgreb med stemplet (9) og/eller koblingskappen (6) til forhindring af frigørelse af drivmidlet (8).

7. Autoinjektor (1) ifølge krav 5,
der er kendetegnet ved, at sikkerhedsmidlet (S) omfatter et blokeringselement (16), der er anbragt glidbart i forhold til huset (2), hvor blokeringselementet (16) er anbragt, så det begrænser en drejebevægelse af et frigøringselement (7), der er hængslet til en lateral side af huset (2), når kanyleafskærmningen (3) er i den fremskudte position (PA), og hvor blokeringselementet (16) er anbragt, så det åbner

mulighed for, at frigørelseselementet (7) kan dreje omkring et hængsel (15), når kanyleafskærmningen (3) er i en tilbagetrukket position (PR).

8. Autoinjektor (1) ifølge krav 7,
der er kendetegnet ved, at blokeringselementet (16) er anbragt, så det blokerer en distal bevægelse af kanyleafskærmningen (3), når frigøringselementet (7) aktueres manuelt, mens kanyleafskæmningen (3) er placeret i den fremskudte position (PA).

DRAWINGS

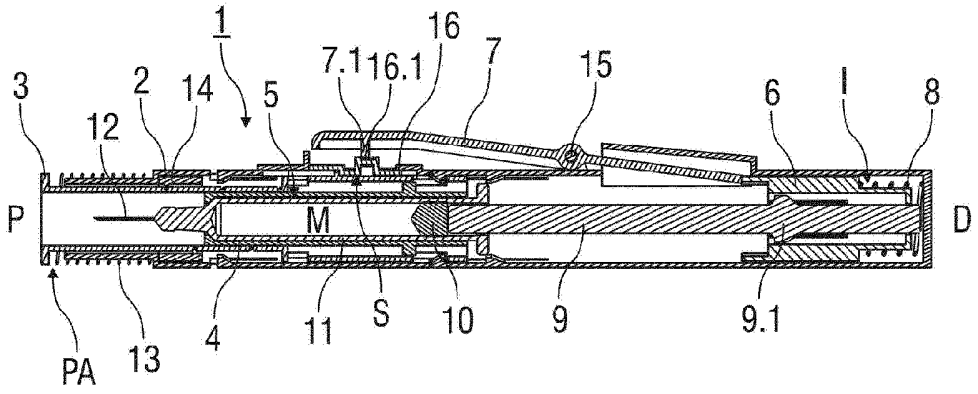

FIG 1A

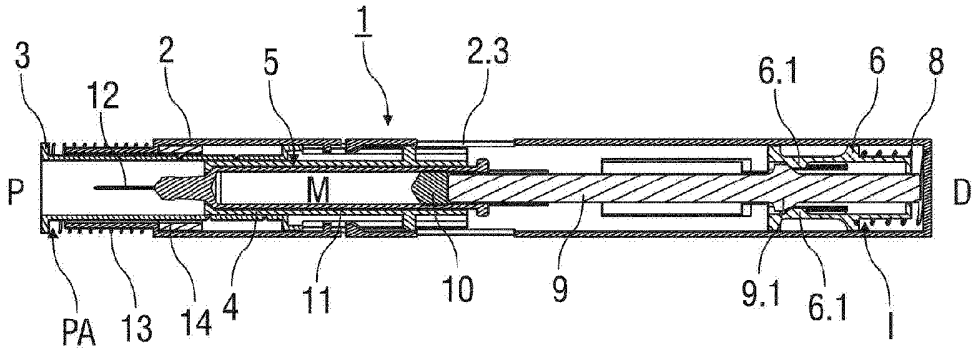

FIG 1B

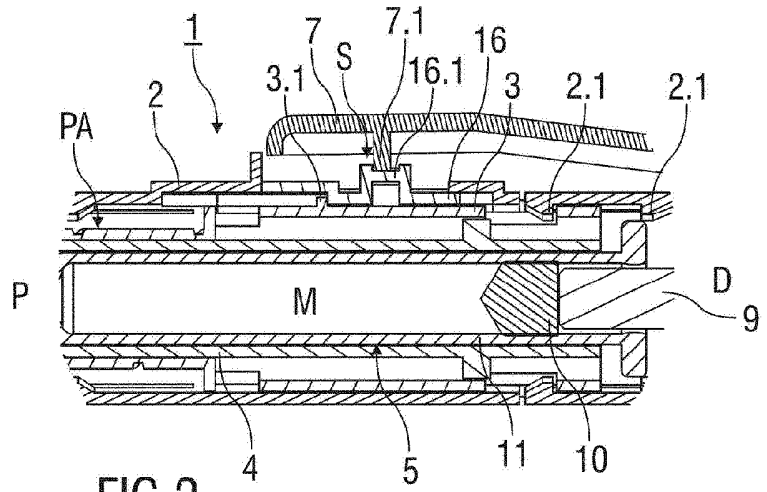

FIG 2

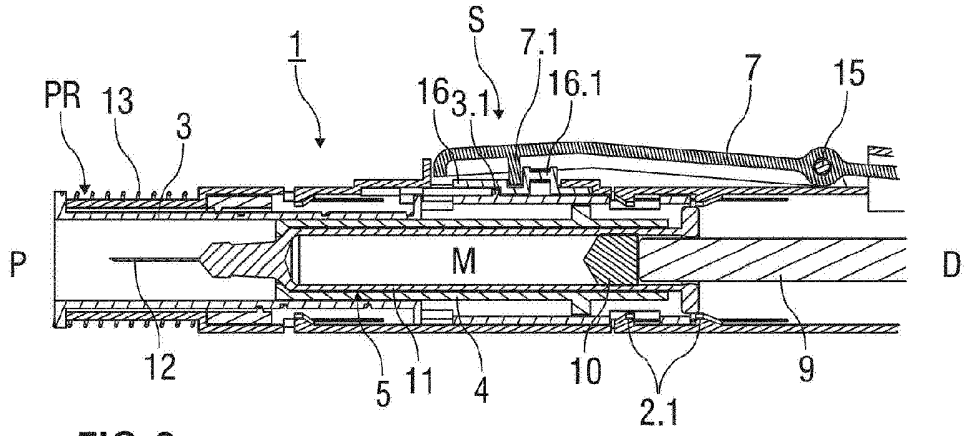

FIG 3

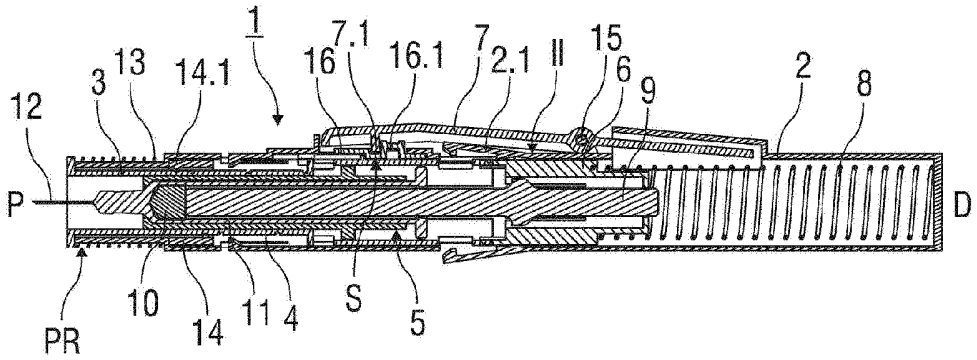

FIG 4A

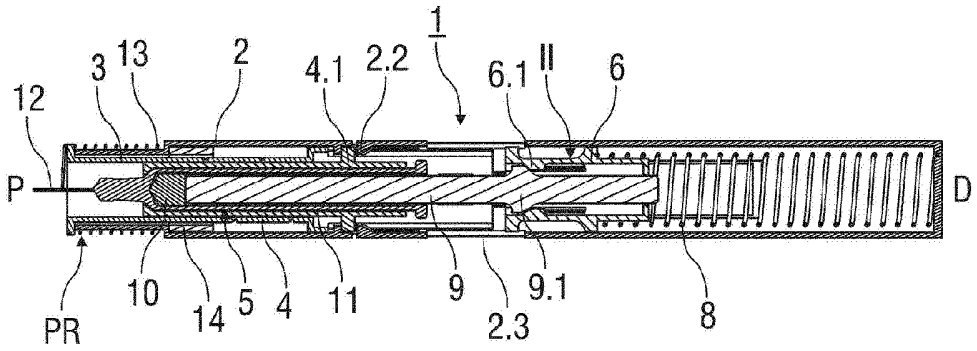

FIG 4B

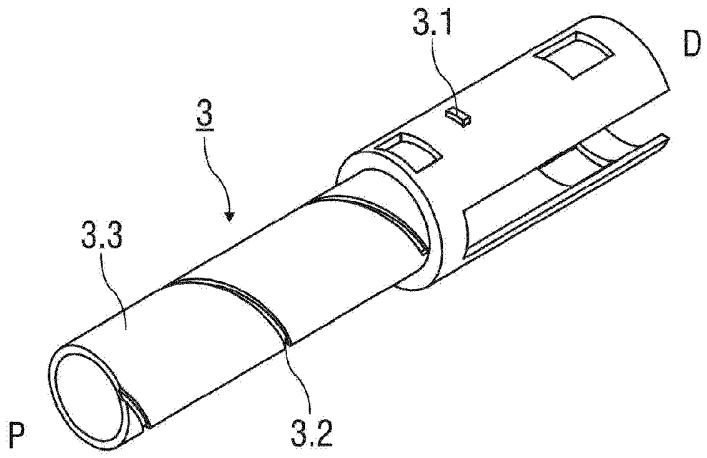

FIG 5

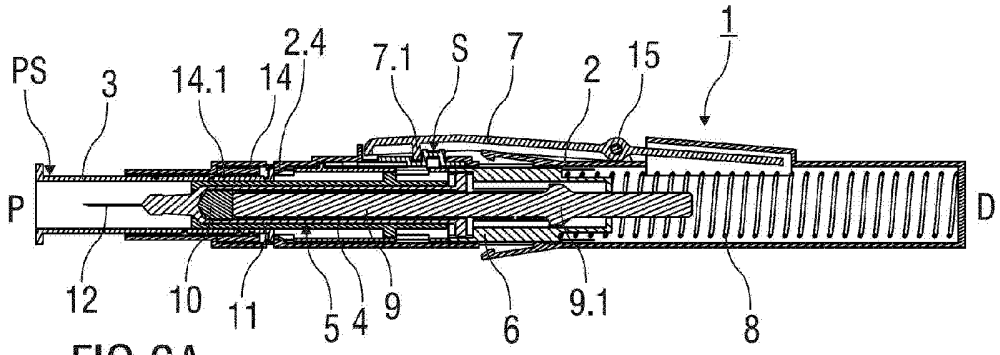

FIG 6A

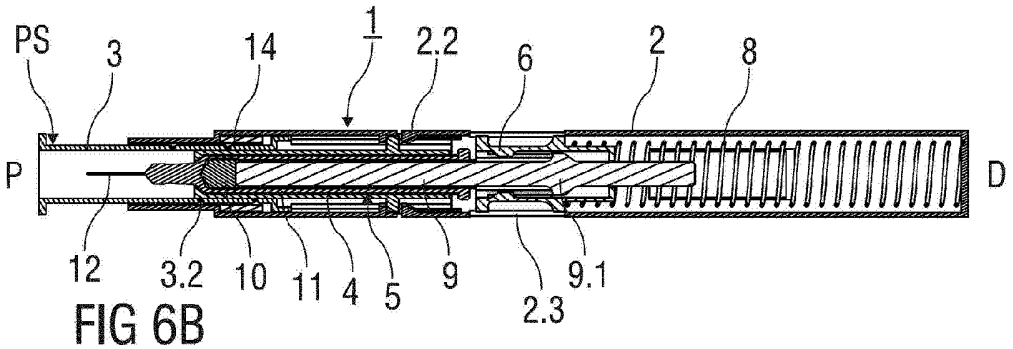

FIG 6B

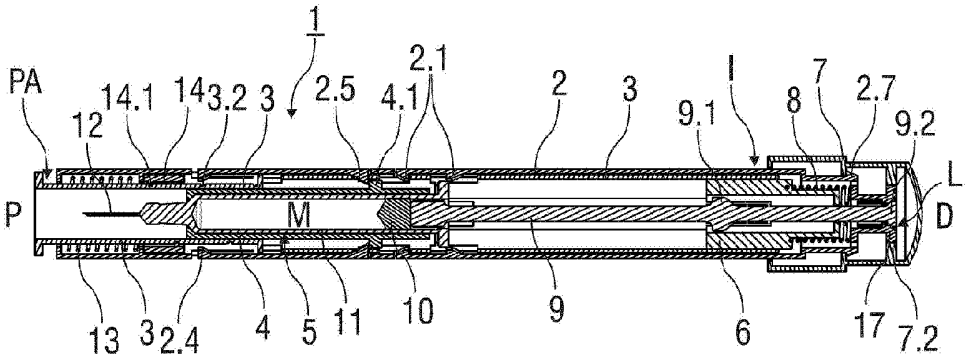

FIG 7A

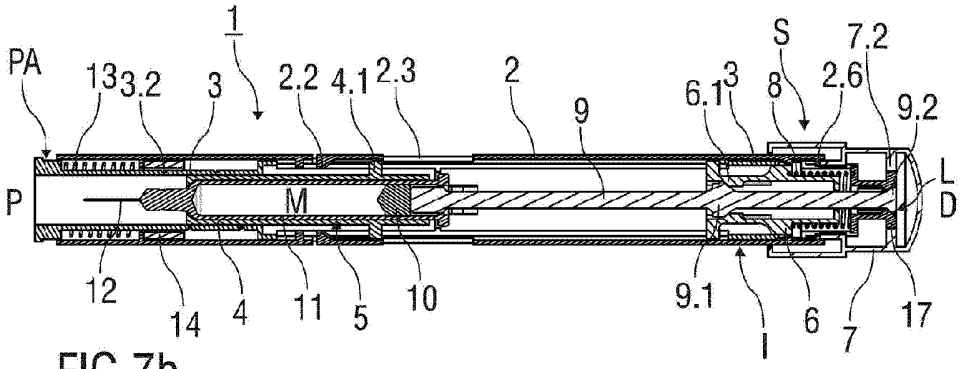

FIG 7b

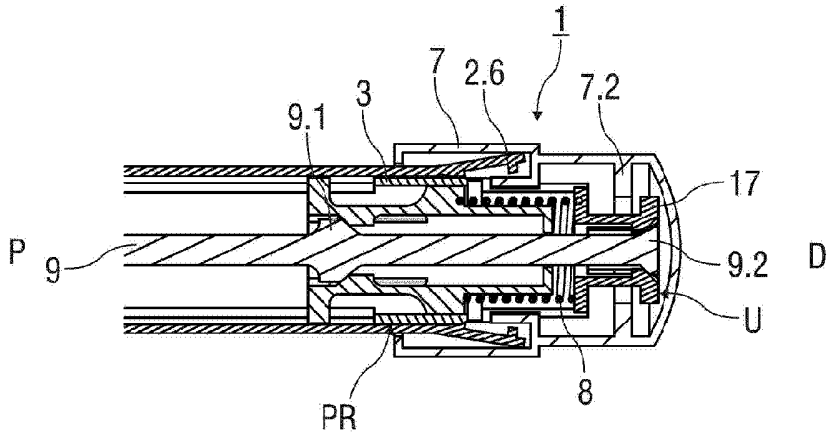

FIG 8

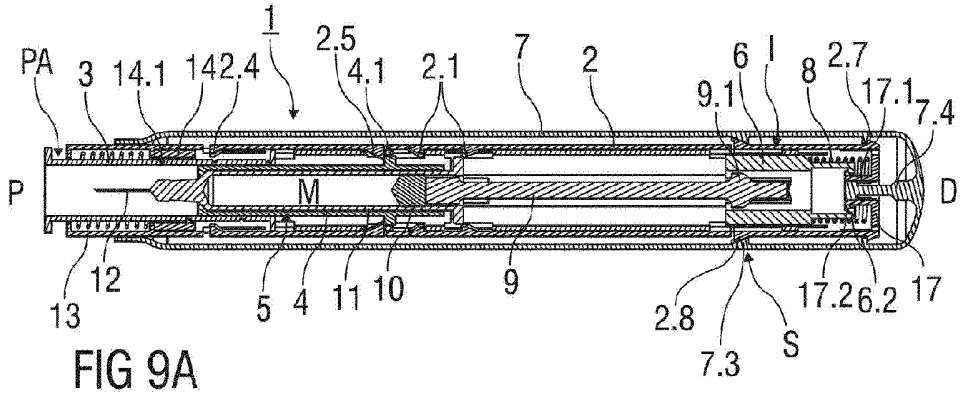

FIG 9A

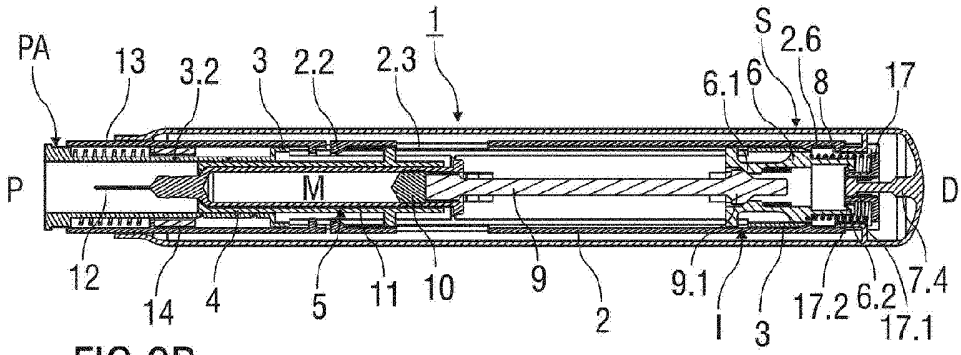

FIG 9B

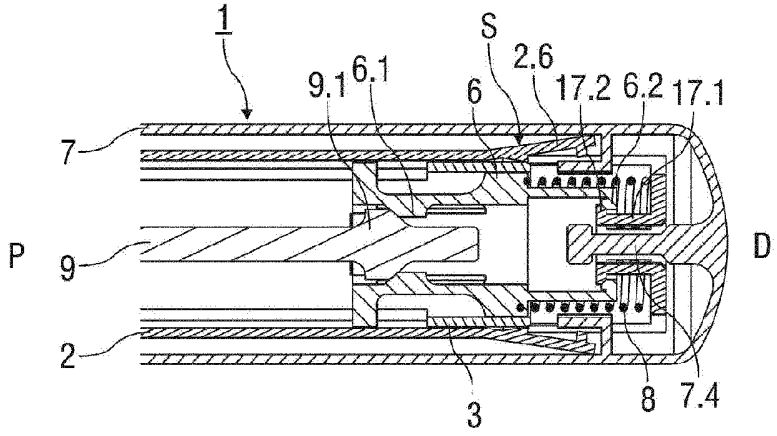

FIG 10