



- (51) International Patent Classification:
A61M 5/315 (2006.01)
- (21) International Application Number:
PCT/US2016/012590
- (22) International Filing Date:
8 January 2016 (08.01.2016)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
62/104,102 16 January 2015 (16.01.2015) US
- (71) Applicant: ELI LILLY AND COMPANY [US/US];
Lilly Corporate Center, Indianapolis, Indiana 46285 (US).
- (72) Inventor: MØLLER, Claus Schmidt; c/o Eli Lilly and
Company, P.O. Box 6288, Indianapolis, Indiana 46206-
6288 (US).
- (74) Agents: PREIN, Edward J. et al.; Eli Lilly and Company,
P.O. Box 6288, Indianapolis, Indiana 46206-6288 (US).

- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: INJECTION DEVICE WITH END OF DOSE MECHANISM



Fig. 1

(57) Abstract: An injection device including a housing defining a central axis. A drive system defines an initial position and an end of stroke position relative to the housing. Axial movement of the drive system expels medicament from a cartridge. A spring mechanism is operably coupled with the drive system and includes first and second spring members. When the drive system is in the end of stroke position, the first spring member moves the second spring member relative to a triggering structure from a first position to a second position as fluid pressure of the medicament is reduced and the injection is completed. When second spring member moves into the second position with the drive system in the end of stroke position, the triggering structure actuates the second spring member to thereby generate a tactile and/or audible signal and indicate that the injection is complete.

WO 2016/114985 A1

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

- *with international search report (Art. 21(3))*

INJECTION DEVICE WITH END OF DOSE MECHANISM

BACKGROUND

[0001] The present invention relates to injection devices such as those used to inject a medicament into the body of a patient.

[0002] Injection devices may be manually driven or have a spring or other mechanism for driving the injection process. One common use of such injection devices is for the injection of insulin in the treatment of diabetes. Many diabetes patients use such injection devices to inject themselves. To facilitate such self-injections, many injection devices have mechanisms which facilitate the setting and delivery of a controlled dose of medicament.

[0003] Many of the injection devices which are capable of setting doses of various sizes provide a means for indicating when the device has reached a zero position in the injection process.

[0004] A visible indication of the progress of the injection may be provided. However, many users, *e.g.*, diabetics, have a reduced sight and because the devices often are used in positions where the display is not visible for the user an additional audible or tactile indication of the progress of the injection can be advantageous.

[0005] An indication of when the mechanical parts have reached the zero/end position is important, as a malfunction in the device or a blocked needle might stop the injection halfway and give the user the impression that the full dose has been injected. This could result in the user receiving an under dose.

[0006] When the zero position has been reached, it is normally recommended that the user wait for 5-6 seconds to allow the pressure, which will have built up in the device during the injection, to decrease by expelling the full dose out through the needle.

[0007] During the injection process, the limited flow through the needle will generally cause a build-up of pressure as the piston of the cartridge is advanced. This pressure will typically result in the compression of the piston and potentially internal parts of the device. After the device has reached the mechanical end or zero position, the cartridge piston will begin to expand as the pressure is reduced by the continued expulsion of medicament through the needle. The device will continue to expel medicament until the cartridge piston and any device parts have fully expanded to their relaxed shape. As a result, it is possible to inject an undersized dose if the needle is removed too quickly after

the device has reached the zero position, *i.e.*, if the needle is removed after the device has reached the zero condition but while the piston and other parts are still expanding.

[0008] The known art includes U.S. Pat. No. 5,391,157 which discloses an end of dose indicator that is operatively associated with the dose knob of an injection syringe.

[0009] U.S. Pat. No. 4,624,659 discloses a syringe with pressure sensing means.

[0010] WO 2006/079481 A1 describes an injection device with an end of dose feedback mechanism. An injection device with a dose delivering mechanism adapted to provide a non-visual, *e.g.*, audible and/or tactile, feedback signal when a set dose has been at least substantially injected is described.

[0011] The known art also includes WO 2013/124139 A1 which discloses an end of dose indicator. WO 99/38554 and WO 2013/077800 A1 also describe injection devices.

[0012] While known devices include many features that facilitate the setting and delivering of desired dosages, further improvements in injection devices which facilitate the delivery of a desired dosage remain desirable.

SUMMARY

[0013] The present invention provides an injection device that generates feedback to the user, *e.g.*, an audible and/or tactile signal, that indicates when the dose has been fully injected and the injection can be terminated by removing the needle from the patient/user.

[0014] The invention comprises, in one embodiment thereof, an injection device for injecting a medicament from a cartridge. The device includes a housing defining a central axis. The cartridge is positionable within the housing. A drive system is coupled with the housing and defines an initial position and an end of stroke position relative to the housing. The drive system is operably couplable with the cartridge wherein axial movement of the drive system from the initial position to the end of stroke position forcibly engages the drive system with the cartridge to expel the medicament from the cartridge. A spring mechanism is operably coupled with the drive system and includes an axially acting spring member and a radially acting spring member. When the drive system is in the end of stroke position relative to the housing, the axially acting spring member repositions the radially acting spring member relative to a triggering structure from a first position to a second position as the fluid pressure of the medicament is reduced and the injection is completed. When the radially acting spring member moves into the second position with the drive system in the end of stroke position, the triggering

structure actuates the radially acting spring member to thereby generate a tactile and/or audible signal.

[0015] In some embodiments, the triggering structure is an opening defined by the device and the radially acting spring member snaps through the opening to generate the tactile and/or audible signal when the radially acting spring member moves into the second position. The movement of the radially acting spring member from the first position to the second position may advantageously include a rotational movement about the central axis. This rotational movement may be generated by the axially acting spring member exerting a force on a drive system member that is engaged with another device member with a helical thread. It is also noted the housing may take the form of a single housing member, or, more conveniently, an assemblage of a plurality of housing members. Moreover, some of these housing members may also perform additional functions. For example, some housing members may define helical threads or grooves that are employed when setting a dose or function as part of the drive system when injecting the dose.

[0016] In some embodiments, the two spring members may be fixed to the spring mechanism with the spring mechanism being a single integral part. In such an embodiment, the spring mechanism may be advantageously formed out of sheet metal.

[0017] When forming the spring mechanism out of sheet metal, the spring mechanism may include a generally cylindrical portion with each of the spring members being formed by a substantially V-shaped portion of the sheet metal. In some embodiments, the radially acting spring member defines an impact feature on its free end wherein the impact feature generates the tactile and/or audible signal when the radially acting spring member moves into the second position by impacting a surface defined by the device.

[0018] The invention comprises, in one embodiment thereof, an injection device for injecting a medicament from a cartridge. The device includes a housing defining a central axis. The cartridge is positionable within the housing. A drive system is coupled with the housing and defines an initial position and an end of stroke position relative to the housing. The drive system is operably couplable with the cartridge wherein axial movement of the drive system from the initial position to the end of stroke position forcibly engages the drive system with the cartridge to expel the medicament from the cartridge. A spring mechanism includes a first spring member operably coupled with the

drive system and a second spring member. When the drive system is in the end of stroke position relative to the housing, the first spring member repositions the second spring member relative to a triggering structure from a first position to a second position as the fluid pressure of the medicament is reduced and the injection is completed. When the second spring member moves into the second position with the drive system in the end of stroke position, the triggering structure actuates the second spring member to thereby generate a tactile and/or audible signal.

[0019] The invention comprises, in another embodiment thereof, an injection device for setting and injecting doses of a medicament from a cartridge. The device includes a housing that interfaces with a user, a dose setting member for setting the dose to be injected, and an actuator or release button for injecting the set dose. The device also includes a drive stem or screw that cooperates with a plunger in the cartridge for expelling the medicament through a needle during the injection. A first spring member is tensed during the injection process. A second spring member is tensed when setting the dose. The first spring member causes the second spring member and a triggering structure to move relative to each other when the pressure of the medicament in the cartridge falls below a predetermined threshold. The relative movement between the second spring member and the triggering structure produces at least one of either an audible or tactile signal.

[0020] By utilizing a first spring member responsive to the medicament pressure in the cartridge and a second spring member to produce the feedback signal, the pressure sensing ability and the quality of the feedback of the device can be optimized separately.

[0021] In another embodiment, the first and the second spring members are fixed together to form a single integral part. This simplifies the handling and assembly of the part into the device. In such an embodiment, the first and the second spring members may be formed out of sheet metal. This allows the part to have a very little material thickness and thereby more easily fit into the device.

[0022] In yet another embodiment, the second spring member is aligned with an opening in the device member by rotational movement of the second spring member and the tension of the second spring member causes it to forcibly move into the opening and thereby produce the audible and/or tactile signal. By using rotational movement to align

the parts, more relative movement between the parts, compared to purely axial movement, is provided.

[0023] The use of a radial acting spring for the second spring member can be advantageous because such a configuration makes it relatively easy to tense/load the spring during the dose setting process.

[0024] As mentioned above, sheet metal may be used to form both an axial acting spring and a radial acting spring. The axial acting spring can be positioned so that it is compressed between an item, *e.g.*, an actuator or release button, which transmits the force applied by the user, and a driver. The driver may take the form of a drive member that both rotates and moves axial during injection and which transmits the force applied by the user to the piston in the cartridge through a chain of intermediate parts which together form a drive system. The sheet metal item can be rotationally fixed to the driver. The radial acting spring arm of the sheet metal item is capable of snapping into or through a hole in a non-axial moving part when the driver is in the zero position. When the injection is ongoing the axial acting spring is compressed a small distance between the item compressed by the user and the driver. At the zero position the item compressed by the user will stop, and when the internal pressure in the cartridge is low enough the axial acting spring will move the driver the remaining distance, which in turn will rotate the driver the remaining angle, and allow the radial acting spring to snap into the hole in the non-axial moving part and make a clicking sound and/or generate a tactile feedback signal.

[0025] The disclosed device provides reliable operation and the illustrated spring mechanism is one that is easily optimized to respond at the desired medicament pressure level and generate the desired audible and/or tactile feedback signal.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] The above mentioned and other features of this invention, and the manner of attaining them, will become more apparent and the invention itself will be better understood by reference to the following description of an embodiment of the invention taken in conjunction with the accompanying drawings, wherein:

[0027] FIG. 1 is a partial exploded view of an embodiment of the injection device.

[0028] FIG. 2 is a partial cross sectional view of the injection device wherein a dosage has been set but not yet injected.

[0029] FIG. 3 is a partial cross sectional view of the injection device wherein the actuator has been partially depressed.

[0030] FIG. 4 is a partial cross sectional view of the injection device wherein the actuator has reached the end of stroke position.

[0031] FIG. 5 is a partial cross sectional view of the injection device after the injection has been fully completed.

[0032] FIG. 6 is a partial and schematic representation of the device and a cartridge holding a medicament.

[0033] Corresponding reference characters indicate corresponding parts throughout the several views. Although the exemplification set out herein illustrates an embodiment of the invention, in one form, the embodiment disclosed below is not intended to be exhaustive or to be construed as limiting the scope of the invention to the precise form disclosed.

DETAILED DESCRIPTION

[0034] An exemplary first embodiment of an injection device is shown in a partial exploded view in FIG. 1. The injection device defines central axis 30 and includes a spring mechanism 1. In the illustrated embodiment, spring mechanism 1 is formed out of sheet metal and includes two spring arms. The spring arms take the form of an axial acting spring arm 5 and a radial acting spring arm 11. Spring mechanism 1 is axially and rotationally fixed within a connector 2 in such a way that the tube shaped body 6 of spring mechanism 1 is concentrically arranged within connector 2. Connector 2 has an opening 9 through which the radial acting arm 11 of the spring item 1 can operate. An actuator 3 is rotationally fixed to connector 2 via radially extending ribs 14 on actuator 3 and grooves 15 in the connector 2. Actuator 3 is capable of moving axially relative to the connector 2 a small distance between an upper and a lower extreme position. The lower surface of the actuator 3 is in contact with the spring arm 5. When the actuator moves axially toward spring mechanism 1 it will tense or load the spring arm 5. Spring arm 5 biases actuator 3 toward its upper extreme position when no axial load is applied to actuator 3. Connector 2 engages a mechanism housing 4 via helical thread segments 12 on connector 2 and corresponding helical thread cuts 13 in mechanism housing 4. The mechanism housing 4 also includes a triggering structure in the form of an opening 10 through which the radial acting spring arm 11 can operate when the opening 9 in the

connector 2 and the opening 10 in the mechanism housing 4 are aligned. Connector 2 cooperates with a screw or threaded stem 28 to push piston 42 and thereby expel a medicament 44 of a cartridge 40 through a needle 36. For example, connector 2 may be threadedly engaged with threaded stem 28 such that when connector 2 is axially advanced by the application of a force to actuator 3, threaded stem 28 will be axially advanced together with connector 2.

[0035] It is noted that actuator 3, spring member 5, connector 2 and stem 28 together with any other device members in the chain of parts, which transmit a force applied by the user to piston 42 in the cartridge together form the drive system of the device.

[0036] With reference to FIG. 2, a dose is set on the illustrated injection device by rotating a dose selector 22, which is rotationally secured to actuator 3 and thereby to connector 2 during dose setting. After setting the dose, the device is ready to inject. The dose setting mechanism may take the form of a mechanism as disclosed in U.S. Pat. No. 8,864,721 B2 entitled GEARING MECHANISM FOR A DOSE DELIVERY DEVICE by Møller, the entire disclosure of which is hereby incorporated herein by reference.

[0037] In FIG. 2, connector 2 has been rotated and moved up relative to the mechanism housing 4, *i.e.*, actuator 3 has been moved axially away from mechanism housing 4. Spring mechanism 1 has been moved axially and is no longer disposed within mechanism housing 4. Actuator 3 is in its upper extreme position and the spring arm 5 is at a pretensioned condition and is not under an external load. Radial spring arm 11 is protruding radially outward through opening 9 in connector 2. The free end of radial spring arm 11 defines a head 8, which is in contact with the inner surface of dial 20 in FIG. 2. Spring mechanism 1, which includes spring arm 11, moves axially and rotationally with connector 2.

[0038] FIG. 3 illustrates the condition where a user has pushed actuator 3 axially downward to housing mechanism 4 and into the lower extreme position of actuator 3. In the movement from FIG. 2 to FIG. 3, spring arm 5 has been compressed by the application of a force on actuator 3. Any further depression of actuator 3 will axially move connector 2 and cause connector 2 and actuator 3 to rotate within mechanism housing 4 as they move axially.

[0039] FIG. 4 illustrates the condition where actuator 3 has been further pushed to an “end of stroke” position defined by dial 20. This position defines the limit of axial

movement for actuator 3. In FIG. 4, actuator 3 has just reached this position and, as a result, most, but not the full dose, of the medicament has been injected and spring arm 5 is still compressed. Connector 2 and spring mechanism 1, which are fixed together, have not yet moved to the position which defines the “end of injection.” The internal parts of the injecting mechanism of the device forming the drive system are under a compressive force, which exceeds the spring force of the axial acting spring arm 5. Most notably, the medicament is experiencing a relatively high pressure and generates a reactive force, which is sufficient to compress spring arm 5. The user will maintain pressure on actuator 3 in this condition until the injection is completed. Alternatively, a mechanical or electromechanical mechanism could be used to maintain actuator 3 in the position shown in FIGS. 4 and 5 until the injection is completed.

[0040] As can also be seen in FIG. 4, connector 2 has been axially advanced within mechanism housing 4 such that opening 9 and radial acting spring arm 11 mounted therein are disposed within mechanism housing 4. The V-shape and orientation of spring arm 11 facilitate its introduction into mechanism housing 4. As radial acting spring arm 11 is introduced into the interior of mechanism housing 4, spring arm 11 is biased radially inward toward axis 30. As a result, spring arm 11 now bears against the interior surface of mechanism housing 4.

[0041] FIG. 5 illustrates the condition wherein the full dose has been injected. In the time period that has elapsed between FIG. 4 and FIG. 5, the remaining dosage of the medicament has been expelled through the needle. As the remaining dosage is expelled from the cartridge, the pressure of the medicament decreases and the compressive axial force acting on spring arm 5 correspondingly decreases. When the pressure and corresponding axial force is reduced below threshold value, spring arm 5 expands. Because actuator 3 is being maintained in the position shown in FIGS. 4 and 5, as spring arm 5 expands it axially moves connector 2 the remaining axial distance to the “end of injection” position. Because connector 2 and mechanism housing 4 are engaged via helical threads, this final movement of connector 2 is helical relative to mechanism housing 4, having both an axial and a rotational component. Spring mechanism 1 is secured to connector 2 with spring arm 11 mounted in opening 9 and, thus, spring mechanism 1 and spring arm 11 are moved helically in this final movement together with connector 2.

[0042] This final rotational movement of connector 2 about axis 30 aligns opening 9 in connector 2 with opening 10 in mechanism housing 4 and thereby allows radial acting spring arm 11 to snap radially outwardly through opening 10 and cause impact head 8 to forcibly impact the inner surface of dial 20. The contact between head 8 and dial 20 generates a sound and/or a tactile signal informing the user that the full amount of the dose has been injected and that the needle can be retracted.

[0043] While the illustrated embodiment employs a single spring mechanism 1 that includes both an axial acting spring member 5, which is responsive to the pressure in cartridge 40, and a radial acting spring member 11 for generating a tactile and/or audible signal, alternative embodiments may employ different arrangements. For example, the two spring members can be separate parts, which are not directly connected but are instead operably coupled through intermediate parts of the device.

[0044] Various other modifications may also be employed wherein, when the drive system is in its end of stroke position, a first member responsive to the pressure of the medicament in cartridge 40 moves a second member from a first position to a second position as the injection is completed and the pressure of the medicament decreases. The disclosed first member, namely spring arm 5, is disposed in the drive system and, from a design and assembly perspective, it will generally be most convenient for this first member responsive to the medicament pressure to be disposed in the drive system. Moreover, while the illustrated embodiment is a spring member, alternative embodiments may take a different approach, for example, employing a resiliently compressible foam member or other mechanism responsive to a change in the force exerted on the cartridge plunger.

[0045] Alternative embodiments of the second member, which is part of a signal mechanism and generates an audible or tactile signal when it moves into its second position, may also be employed. For example, instead of moving a spring member as the pressure in the cartridge changes, the spring member could be stationary and the triggering structure that interacts with the spring could be moved in response to the change in medicament pressure. For example, a part having a triggering structure in the form of an opening into which the spring snaps to generate the tactile and/or audible signal could be moved relative to a spring member in response to a change in the medicament pressure. Other suitable forms of triggering structures, *e.g.*, ratchet teeth

across which the spring member is moved, could also be employed to generate the end of dose signal.

[0046] Returning now to a discussion of the illustrated embodiment, when setting a new dose, connector 2 will be rotated and axially displaced in mechanism housing 4 to return it to its original position depicted in FIG. 2. When rotating connector 2 to set the new dose, a slanted surface on head 8 will engage and slide across a slanted surface on the edge of opening 10 to thereby bias spring arm 11 radially inwardly until it is contained within the interior of mechanism housing 4. It is noted that head 8 may be advantageously formed by bending small tabs of sheet metal that are integral with spring arm 11. Alternatively, a separate material, such as a polymeric material, could be used to form head 8.

[0047] Further rotation of connector 2 in the dose setting process will cause the radial acting spring arm 11 to move radially outward once again as it moves axially past the upper edge of the mechanism housing 4. Spring arm 11 may advantageously be flexible in a transverse direction so that if head 8 catches on a side edge of opening 10 when rotating connector 2 relative to mechanism housing 4, spring arm 11 may bend sideways until spring arm 11 is biased radially inward into the interior of mechanism housing 4 and is free of the opening 10 whereafter it will return to its intended orientation. In this regard, it is noted that when head 8 is advancing in the opposite direction during the final phase of the injection process, it will be advantageous for head 8 to cross an abrupt edge when it encounters opening 10 so that it will snap outwardly quickly and generate an audible sound and/or tactile signal. If head 8 moved radially outwardly along a gently sloped surface, it would be less likely to generate an audible sound or tactile signal when it contacted dial 20. A sloped surface could be used, however, if dial 20 included an opening to allow head 8 to protrude outwardly to the exterior of the device and thereby provide for a tactile signal. Still other alternative configurations could be employed to provide for an audible or tactile signal.

[0048] FIG. 6 is a schematic representation of the end of the injection device opposite actuator 3. As schematically depicted in FIG. 6, a medicament cartridge 40 is held within a cartridge housing 32. Threaded stem 28 is coupled with a piston 42 disposed in cartridge 40. Cartridge housing 32 includes a threaded end 34 for engagement with a double-ended needle assembly 36. As can be seen in FIGS. 4 and 5, cooperating helical

threads and grooves engage dial 20 with cartridge housing 32. In the illustrated embodiment, connector 2 is concentrically disposed in mechanism housing 4, which, in turn, is concentrically disposed in dial 20 which is concentrically disposed within cartridge housing 32. Although dial 20 performs a dose setting function, it also functions as a housing member along with cartridge housing 32 and mechanism housing 4.

[0049] While this invention has been described as having an exemplary design, the present invention may be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles.

WHAT IS CLAIMED IS:

1. An injection device for injecting a medicament from a cartridge, the injection device comprising:
 - a housing defining a central axis, the cartridge being positionable within the housing;
 - a drive system coupled with the housing and defining an initial position and an end of stroke position relative to the housing, the drive system being operably couplable with the cartridge wherein axial movement of the drive system from the initial position to the end of stroke position forcibly engages the drive system with the cartridge to expel the medicament from the cartridge; and
 - a spring mechanism operably coupled with the drive system, the spring mechanism including an axially acting spring member and a radially acting spring member, wherein, when the drive system is in the end of stroke position relative to the housing, the axially acting spring member repositions the radially acting spring member relative to a triggering structure from a first position to a second position as a fluid pressure of the medicament is reduced and the injection is completed, and, when the radially acting spring member moves into the second position with the drive system in the end of stroke position, the triggering structure actuates the radially acting spring member to thereby generate a tactile and/or audible signal.
2. The injection device of claim 1 wherein the triggering structure is an opening defined by the device and the radially acting spring member snaps through the opening to generate the tactile and/or audible signal when the radially acting spring member moves into the second position.
3. The injection device of claims 1 or 2 wherein movement of the radially acting spring member from the first position to the second position comprises a rotational movement about the central axis.
4. The injection device of claims 1 through 3 wherein the axially acting spring member and the radially acting spring member are fixed to the spring mechanism and the spring mechanism is a single integral part.
5. The injection device of claim 4 wherein the spring mechanism is formed out of sheet metal.

6. The injection device of claim 5 wherein the spring mechanism includes a generally cylindrical portion and each of the spring members are formed by a substantially V-shaped portion of the sheet metal.

7. The injection device of claims 1 through 6 wherein the radially acting spring member defines an impact feature on its free end, the impact feature generating the tactile and/or audible signal when the radially acting spring member moves into the second position by impacting a surface defined by the device.

8. An injection device for injecting a medicament from a cartridge, the injection device comprising:

a housing defining a central axis, the cartridge being positionable within the housing;

a drive system coupled with the housing and defining an initial position and an end of stroke position relative to the housing, the drive system being operably couplable with the cartridge wherein axial movement of the drive system from the initial position to the end of stroke position forcibly engages the drive system with the cartridge to expel the medicament from the cartridge; and

a spring mechanism including a first spring member operably coupled with the drive system and a second spring member, wherein, when the drive system is in the end of stroke position relative to the housing, the first spring member repositions the second spring member relative to a triggering structure from a first position to a second position as a fluid pressure of the medicament is reduced and the injection is completed, and, when the second spring member moves into the second position with the drive system in the end of stroke position, the triggering structure actuates the second spring member to thereby generate a tactile and/or audible signal.

9. The injection device of claim 8 wherein the triggering structure is an opening defined by the device and the second spring member snaps through the opening to generate the tactile and/or audible signal when the second spring member moves into the second position.

10. The injection device of claims 8 or 9 wherein movement of the second spring member from the first position to the second position comprises a rotational movement about the central axis.

11. The injection device of claims 8 through 10 wherein the first spring member and the second spring member are fixed to the spring mechanism and the spring mechanism is a single integral part.

12. The injection device of claim 11 wherein the spring mechanism is formed out of sheet metal.

13. The injection device of claim 12 wherein the spring mechanism includes a generally cylindrical portion and each of the spring members are formed by a substantially V-shaped portion of the sheet metal.

14. The injection device of claims 8 through 13 wherein the second spring member defines an impact feature on its free end, the impact feature generating the tactile and/or audible signal when the second spring member moves into the second position by impacting a surface defined by the device.

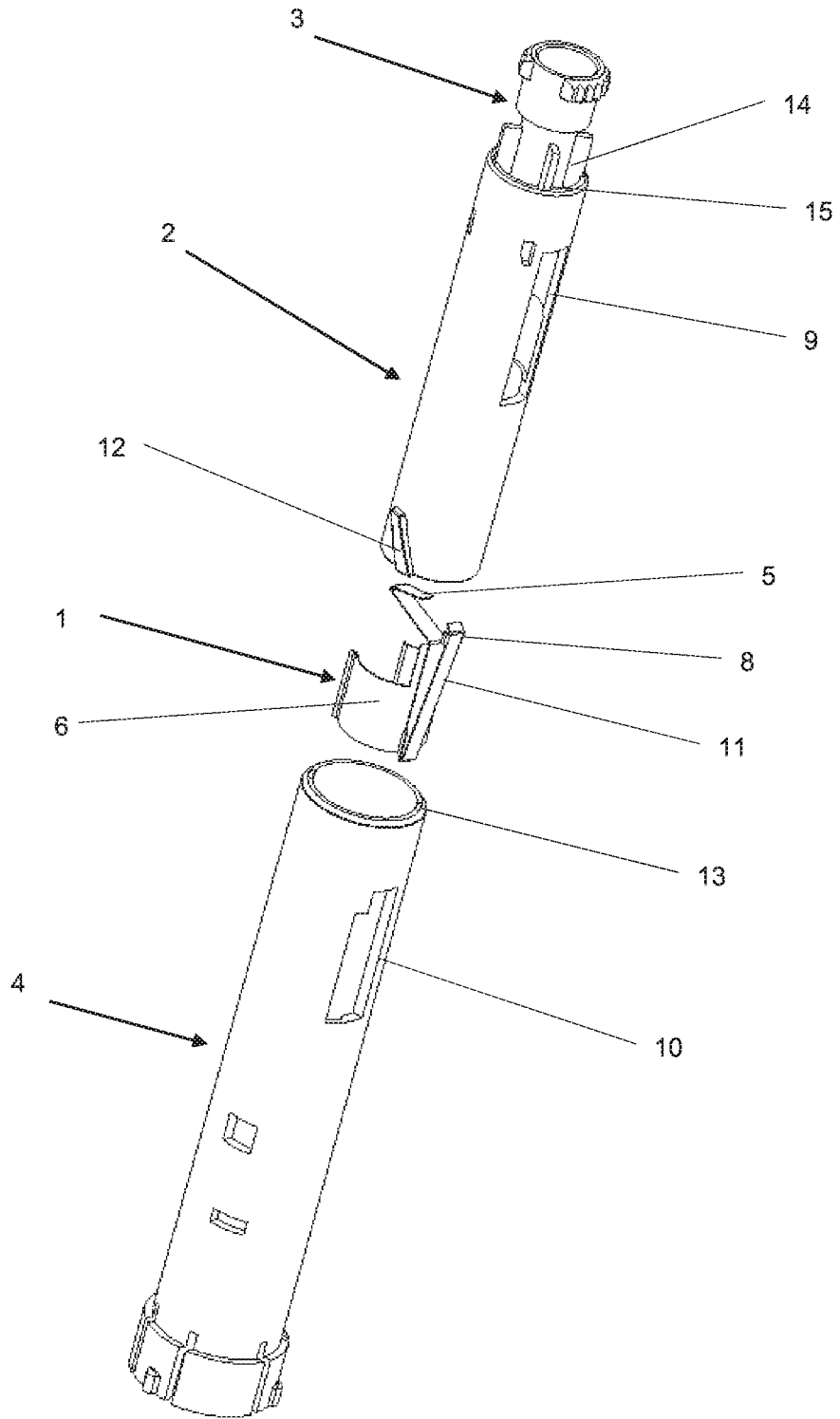


Fig. 1

2 / 3

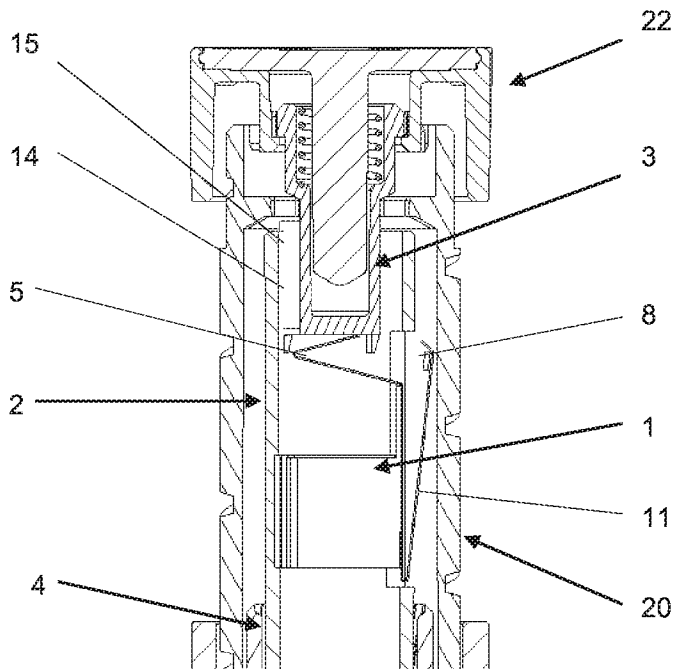


Fig. 2

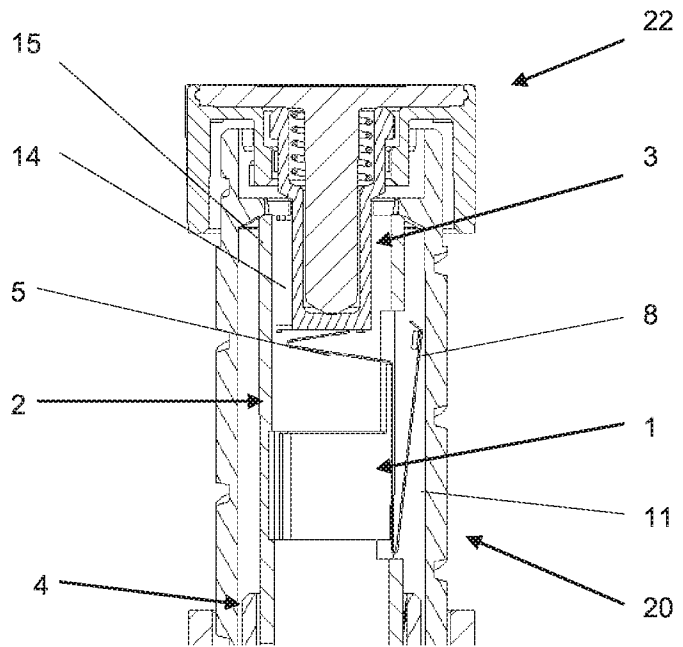


Fig. 3

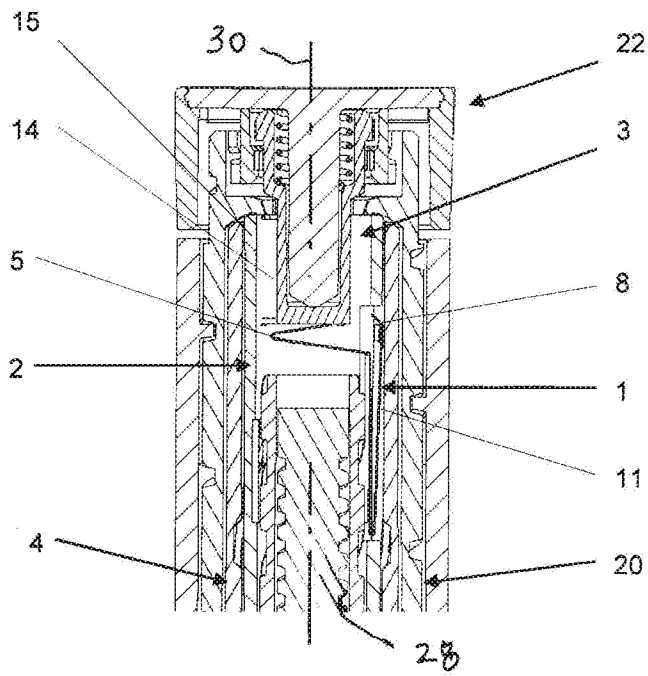


Fig. 4

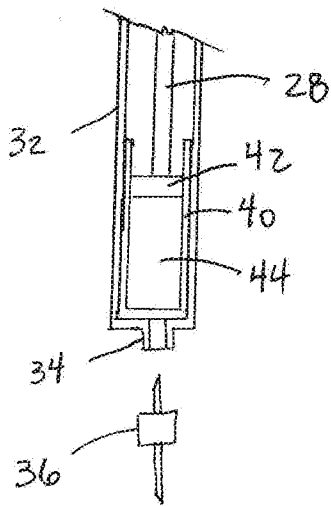


FIG. 6

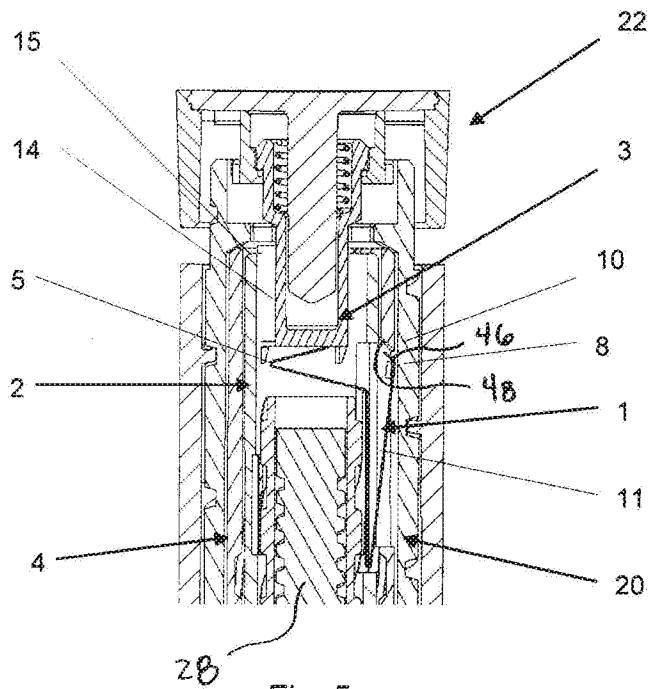


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No PCT/US2016/012590

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M5/315 ADD.				
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				
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 practicable, search terms used) EPO-Internal, WPI Data				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X	WO 2014/195270 A1 (NOVO NORDISK AS [DK]) 11 December 2014 (2014-12-11) page 10, line 34 - page 13, line 2; figures 1-7 -----	1-14		
A	WO 2014/139916 A1 (SANOFI AVENTIS DEUTSCHLAND [DE]) 18 September 2014 (2014-09-18) page 17, line 33 - page 18, line 30; figures 1-3 -----	1-7		
A	WO 2010/139635 A1 (SANOFI AVENTIS DEUTSCHLAND [DE]; PLUMPTRE DAVID [GB]) 9 December 2010 (2010-12-09) figures 1-8 -----	6		
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.				
* Special categories of cited documents : <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="width: 50%; border: none; vertical-align: top;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> </td> </tr> </table>			<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>
<p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>			
Date of the actual completion of the international search 11 April 2016		Date of mailing of the international search report 18/04/2016		
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Diamantouros, S		

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/US2016/012590

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2014195270 A1	11-12-2014	CN 105246530 A	13-01-2016
		EP 3003434 A1	13-04-2016
		WO 2014195270 A1	11-12-2014

WO 2014139916 A1	18-09-2014	CN 105025965 A	04-11-2015
		EP 2968784 A1	20-01-2016
		JP 2016509900 A	04-04-2016
		US 2016008549 A1	14-01-2016
		WO 2014139916 A1	18-09-2014

WO 2010139635 A1	09-12-2010	AU 2010255810 A1	22-12-2011
		CA 2762954 A1	09-12-2010
		CN 102458520 A	16-05-2012
		DK 2437813 T3	05-10-2015
		EP 2437813 A1	11-04-2012
		HK 1168309 A1	08-01-2016
		IL 216482 A	31-10-2013
		JP 5782432 B2	24-09-2015
		JP 2012528623 A	15-11-2012
		US 2010324497 A1	23-12-2010
		US 2012157930 A1	21-06-2012
		WO 2010139635 A1	09-12-2010
