devices, in order to reset the dose setting mechanism, the spindle that advances in a distal direction during dose injection must somehow be retracted back into the dose setting mechanism. Certain known methods of retracting this spindle back into the dose setting mechanism to a restart or an initial position are known in the art. As just one example, certain known reset mechanisms require a user to turn back or push back (retract) the spindle or some other portion of the dose setting mechanism. Resetting of known dose setting mechanisms have certain perceived disadvantages. One perceived disadvantage is that the pen device user has to disassemble the device to either remove an empty cartridge or somehow reset the device. As such, another perceived disadvantage is that such devices have a high number of parts and therefore such devices are typically complicated from a manufacturing and from an assembly standpoint. For example, certain typical resettable pen type devices are not intuitive as to how a user must replace an empty cartridge or how a user is to reset the device. In addition, because such resettable devices use a large number of components parts, such resettable devices tend to be large and bulky, and therefore not easy to carry around or easy to conceal.

There is, therefore, a general need to take these disadvantages associated with resetting issues into consideration in the design and development of resettable drug delivery devices. Such desired drug delivery devices would tend to reduce the number of component parts and also tend to reduce manufacturing costs while also making the device less complex to assemble and manufacture. Such desired devices would also tend to simplify the steps required for a user to reset a dose setting mechanism while also making the device less complex and more compact in size.

SUMMARY

According to an aspect, a drug delivery device is provided comprising a housing, a number sleeve, a button, a spindle not rotating during dose setting and rotating during injection, a driver engaged with the spindle via a groove, wherein the driver follows a helical path when setting a dose and a helical path in an opposite direction when delivering the dose, and a clutch engaged with the button such that the button is rotationally coupled with the driver during dose setting and decoupled during dose delivery.

According to an aspect, a dose setting mechanism is provided which is configured to be secured to a cartridge holder for use as a drug delivery device, the dose setting mechanism comprising: a tubular shaped housing extending from a distal end to a proximal end, the distal end configured to be secured to a cartridge holder; a dial sleeve positioned within the tubular shaped housing, a button positioned near the proximal end of the cylindrically shaped housing, a rotatable spindle that rotates during administration of a dose, a driver threadedly engaged with the spindle, wherein the driver rotates in a first direction when setting a dose and rotates in a second direction that is opposite the first direction when delivering the set dose, and a clutch engaged with the button such that the button is rotationally coupled with the driver during dose setting and decoupled during dose delivery.

According to an aspect, a dose setting mechanism is provided for use with a drug delivery device, the dose setting mechanism comprising: a housing portion, the housing portion extending from a distal end to a proximal end; a dose dial grip operably positioned near the proximal end of the housing portion, wherein rotation of the dose dial grip causes a dose to be set by the dose setting mechanism; an axially moveable push button configured to initiate an administration of a set dose, the axially moveable push button operably disposed adjacent the dose dial grip; a rotatable dial sleeve, the rotatable dial sleeve comprising a surface configured to be in threaded engagement with the housing portion; a rotatable spindle, the rotatable spindle comprising at least one thread that is provided along at least a portion of an outer surface of the spindle, the spindle configured so that it does not rotate and does not move in an axially direction when the dose setting member is rotated to set a dose, and the spindle configured to rotate and move axially during the administration of the set dose; a driver that drives the spindle in a distal direction during the administration of the set dose, the driver comprising a thread that is in threaded engagement with the spindle; and a clutch engaged with the button such that the button is rotationally coupled with the driver during dose setting and decoupled during dose delivery; wherein when the dose is set, the dose dial grip rotates to set a dose that is viewable by way of a window provided by the housing, while the dose dial grip does not move in an axial direction, the axially moveable push button does not

rotate and does not move in an axial direction; the dial sleeve rotates, and the driver rotates.

According to an aspect, a method of setting a dose with a dose setting mechanism, where the dose setting mechanism comprises, a housing, a dose dial grip, a button, a piston rod not rotating during dose setting and rotating during injection, a driver engaged with the piston rod via a groove, wherein the driver follows a helical path when setting a dose and a helical path in an opposite direction when delivering the dose, and a clutch engaged with the button such that the button is rotationally coupled with the driver during dose setting and decoupled during dose delivery, wherein the method comprises the steps of rotating a dose dial grip in a first direction; causing a driver to rotate in the first direction; translating the driver along a piston rod in a proximal direction, a proximal movement of the driver representative of a dose set by the dose setting mechanism; establishing a selected dose after the dose dial grip and the driver have been rotated in the first direction; providing a scale arrangement along an outer surface of a rotatable dial sleeve; causing the dial sleeve to rotate along with the dose setting button and the driver; and viewing the scale arrangement representative of the selected dose through a window of the drug delivery device wherein the scale arrangement of the dial sleeve is only visible by way of the window.

According to an exemplary arrangement, a dose setting mechanism for a drug delivery device comprises an outer housing and an inner housing having an external groove and a helical groove. The inner housing guides the driver to dispense a dose set by the dose setting mechanism. A dial sleeve may be disposed between the outer and inner housing and is rotatably engaged with the inner housing. When a dose is set, the dial sleeve is rotated with respect to both the outer housing and the inner housing. The dial sleeve is translated away from both the outer housing and the inner housing.