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(54) **DIAL-DOWN MECHANISM FOR WIND-UP PEN**

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(57) **ABSTRACT**

The present invention relates to a dial-down mechanism for an injection device comprising a torsion spring for assisting injection of a dose of medicament from the injection device, the dial-down mechanism comprising dial-up cam arranged to receive and engage with a dial-up key, wherein the dial-up cam and the dial-up key are adapted to, upon rotation of a dose setting member in a first direction, cooperate to strain the torsion spring of the injection device, and a dial-down cam arranged to receive and engage with a dial-down key, wherein the dial-down cam and the dial-down key are

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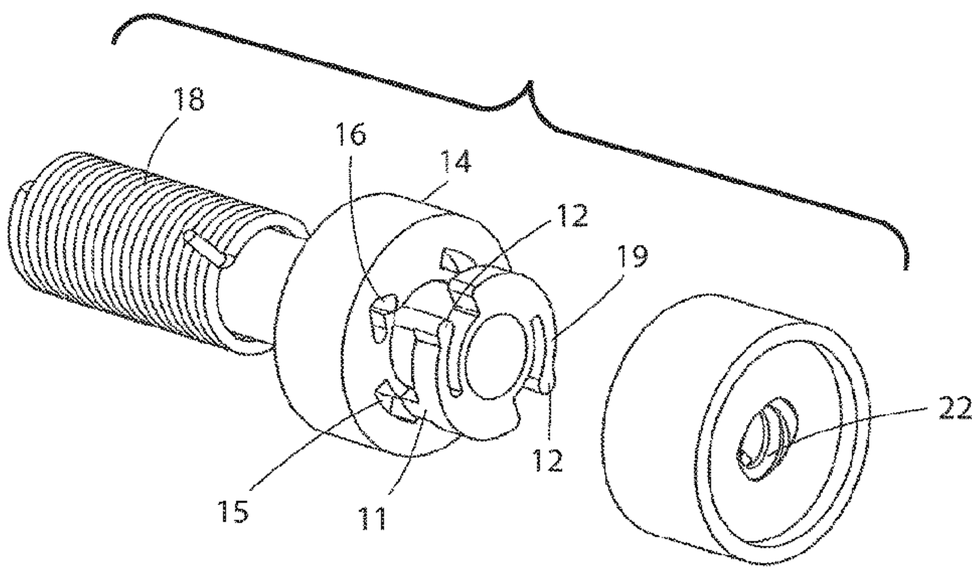

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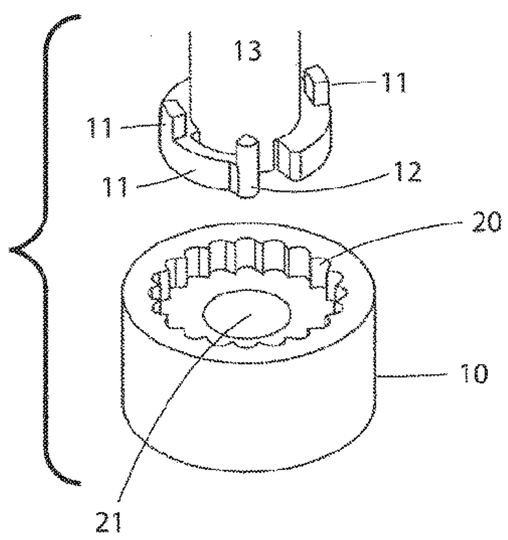

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adapted to, upon rotation of the dose setting member in a second direction, cooperate to release the torsion spring of the injection device, the second rotation direction being opposite to the first rotation direction.

11 Claims, 5 Drawing Sheets

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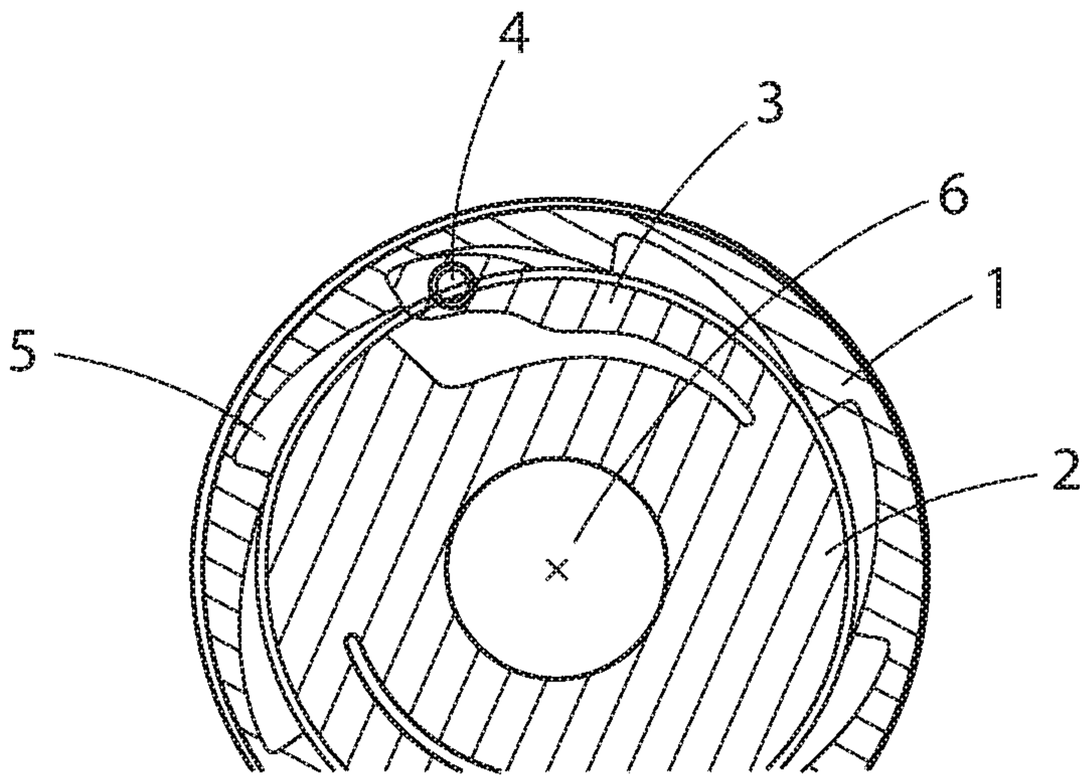

Fig. 1A Amended

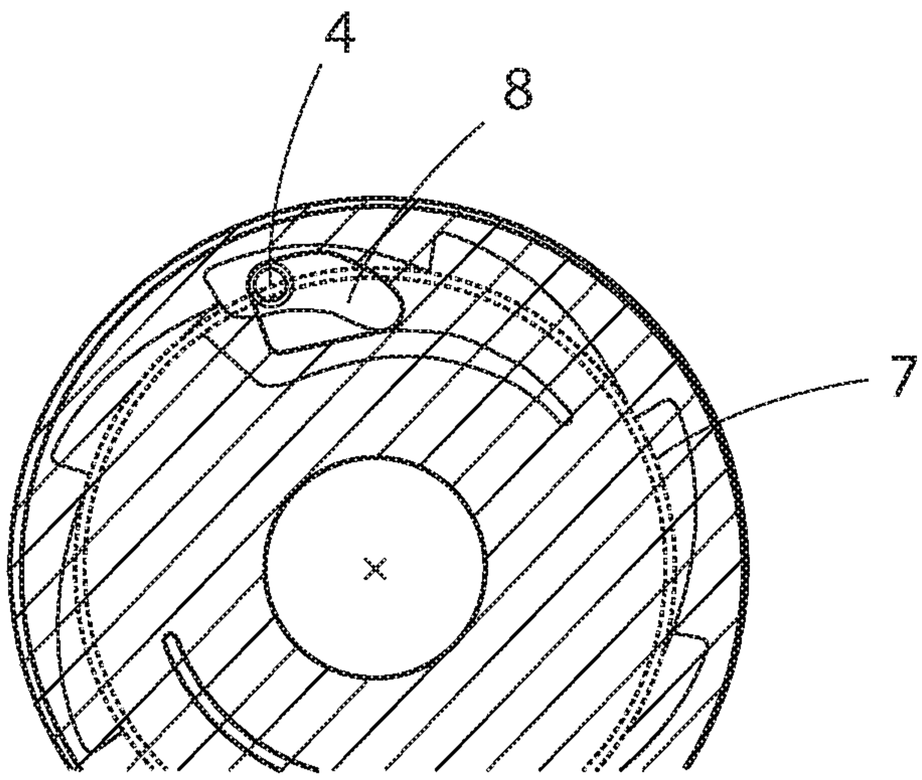

Fig. 1B Amended

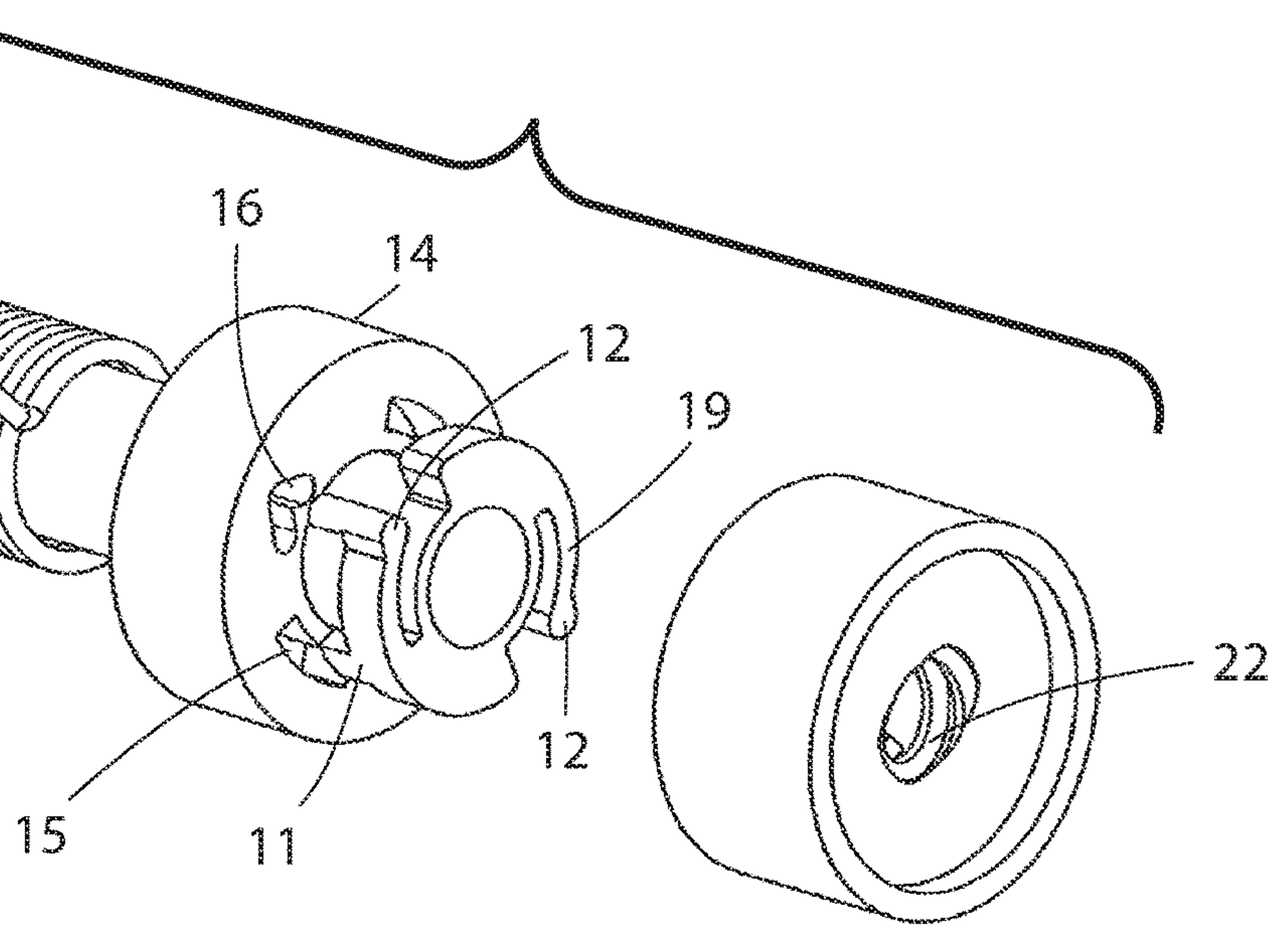

Fig. 2A Amended

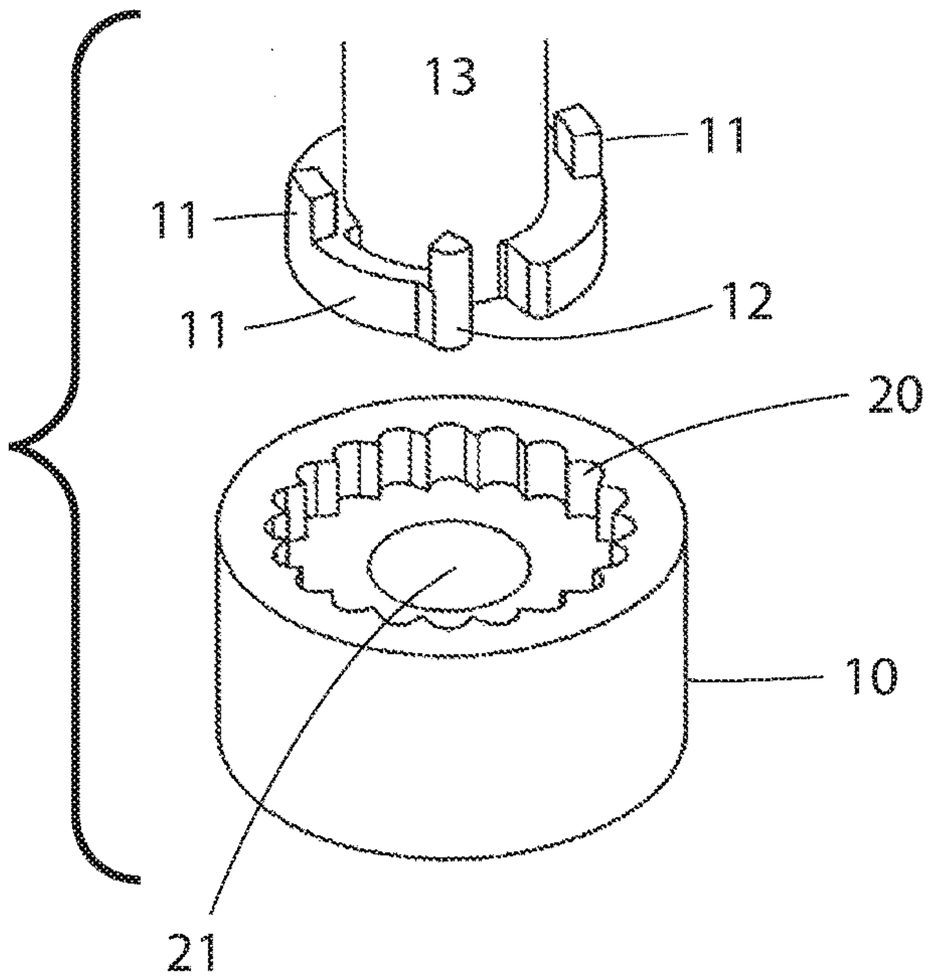

Fig. 2B Amended

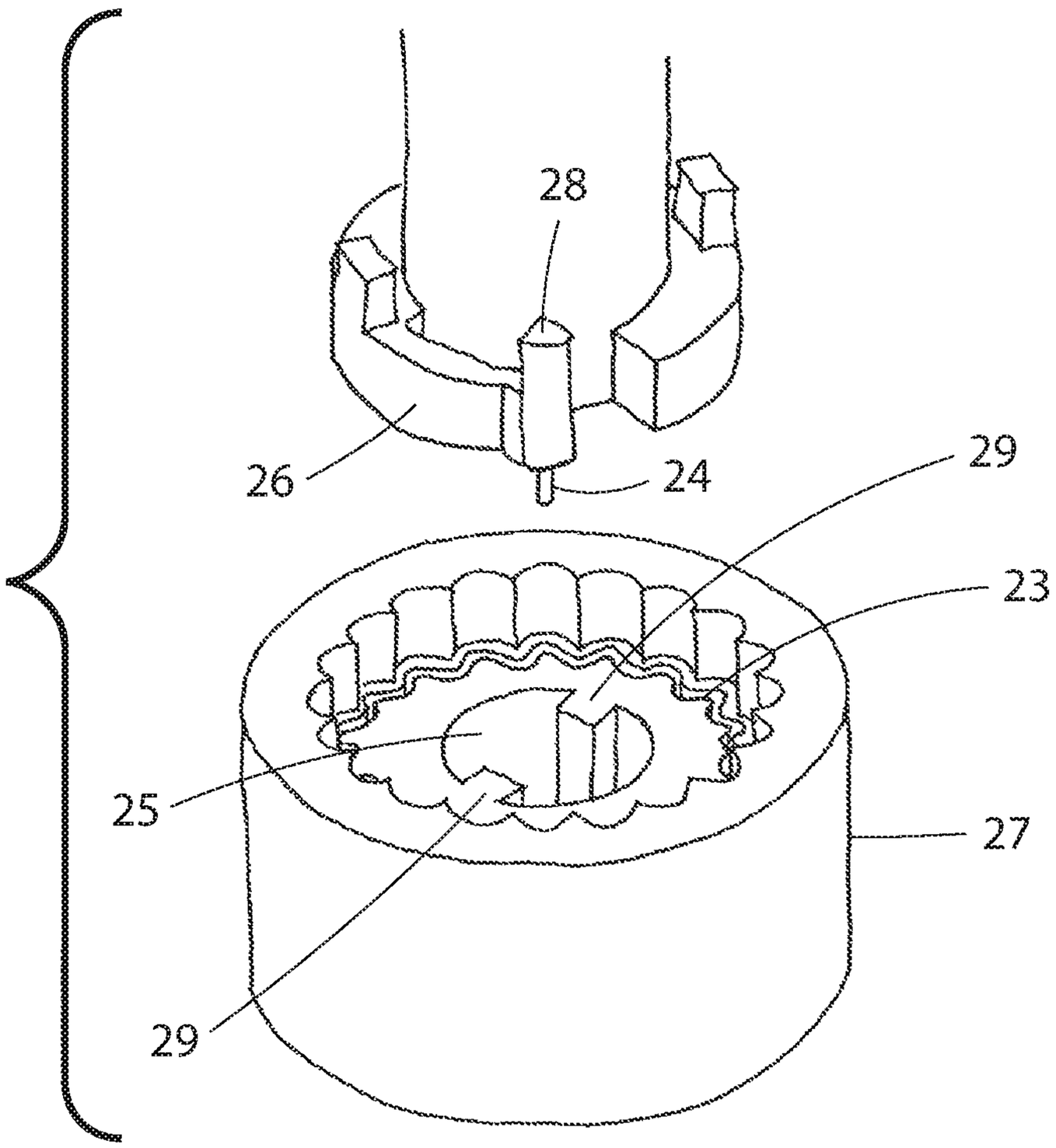

Fig. 3 Amended

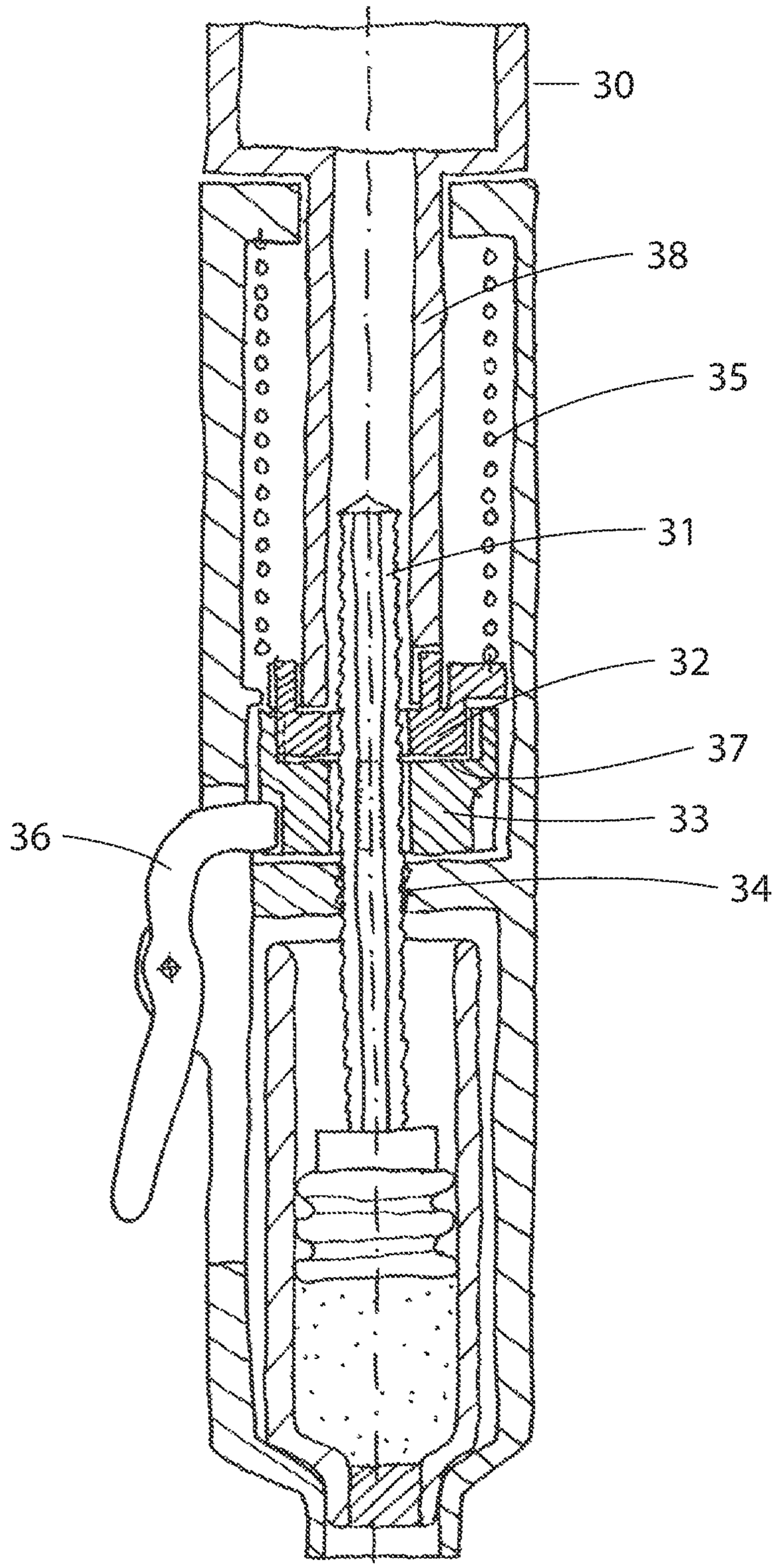

Fig. 4 Amended

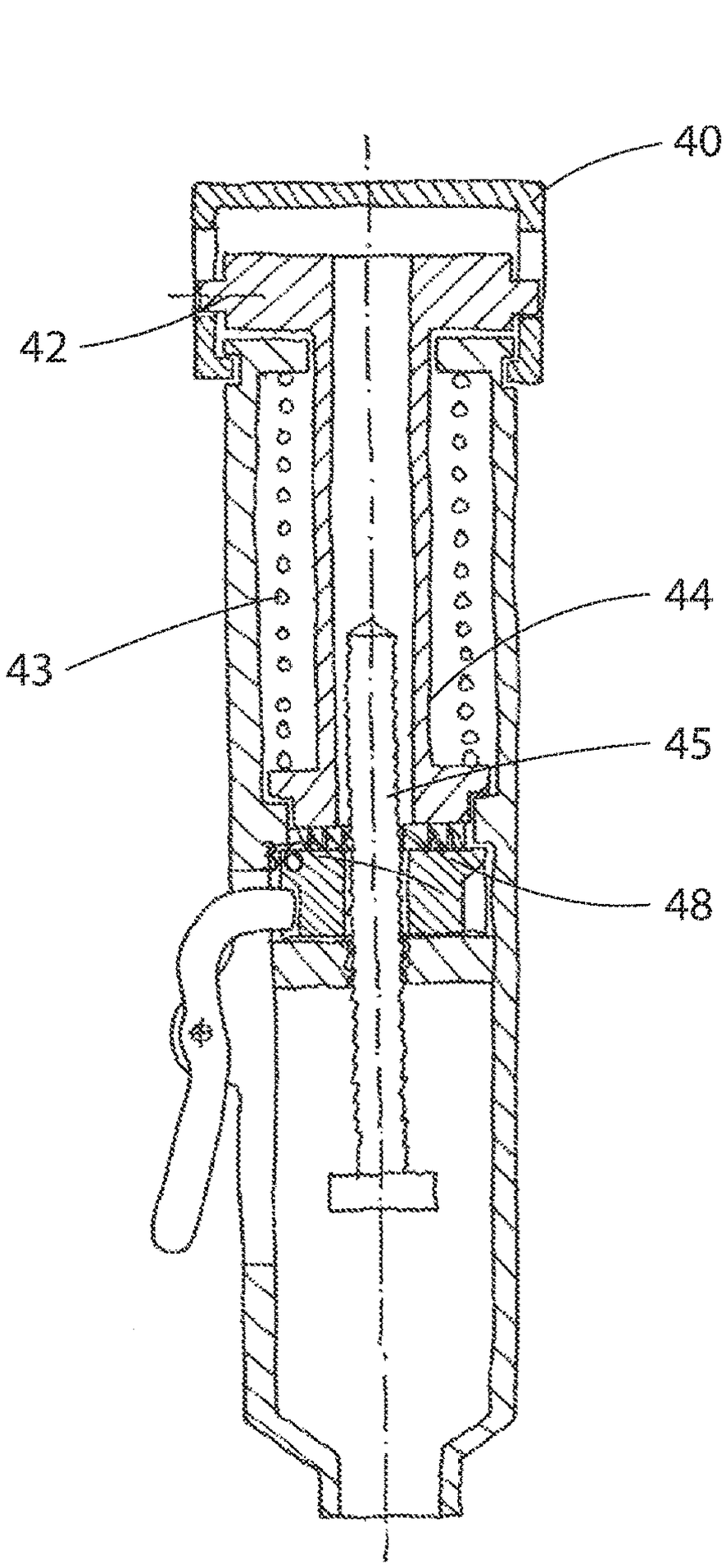

FIG. 5A Amended

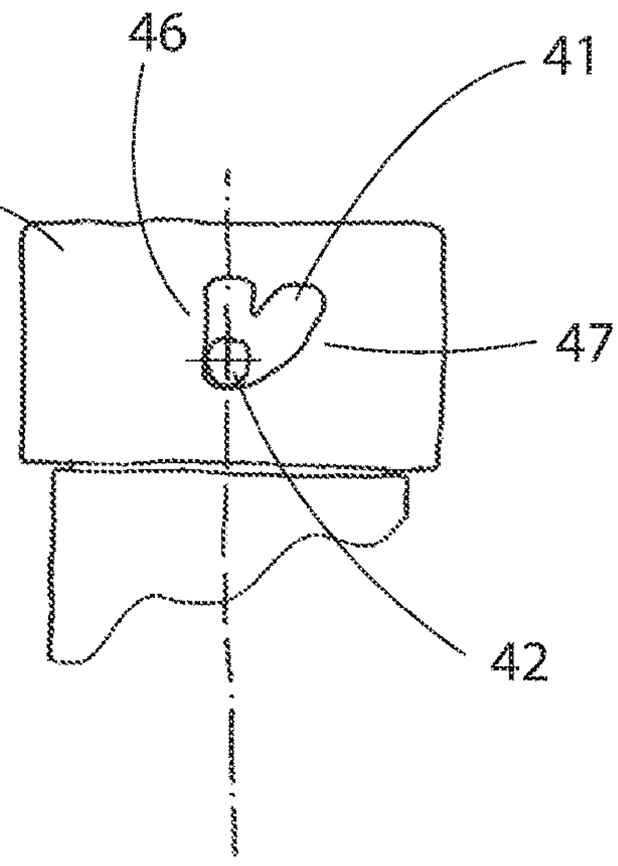

FIG. 5B Amended

DIAL-DOWN MECHANISM FOR WIND-UP PEN

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

CROSS-REFERENCE TO RELATED APPLICATIONS

[This application is a 35 U.S.C. § 371 national stage application of International Patent Application PCT/EP2005/011285 (published as WO 2006/045526), filed Oct. 20, 2005, which claimed priority of European Patent Application 04077900.1, filed Oct. 21, 2004; this application further claims priority under 35 U.S.C. § 119 of U.S. Provisional Application 60/626,270, filed Nov. 9, 2004.] *This application is a Divisional Reissue of U.S. application Ser. No. 13/431,019, filed Mar. 27, 2012, which is an Application for Reissue of U.S. Pat. No. 7,686,786, issued Mar. 30, 2010 (U.S. application Ser. No. 11/665,486, filed Oct. 11, 2007), which is a 35 U.S.C. §371 national stage application of International Patent Application PCT/EP2005/011285 (published as WO2006/045526), filed Oct. 20, 2005, which claimed priority of European Patent Application 04077900.1, filed Oct. 21, 2004; this application further claims priority under 35 U.S.C. §119 of U.S. Provisional Application 60/626,270, filed Nov. 9, 2004, incorporated herein by reference.*

FIELD OF THE INVENTION

The present invention relates to a dial-down mechanism for automatic wind-up pens. In particular, the present invention relates to integrated axial and radial dial-down mechanisms for wind-up pens.

BACKGROUND OF THE INVENTION

In known injection devices, such as wind-up pens, based on torsion springs, the use of dial-down mechanisms rely on that the user of the injection device applies a force to a rotatable dose setting member of the injection device. The force must be applied in order to axially withdraw the dose setting member a certain distance to release the dose setting member from a toothing mechanism or ratchet positioned within the body of the injection device. By releasing the dose setting member from this toothing mechanism the dose setting member can be reversed by rotation and set at a new and lower dose.

An example of a known wind-up pen applying a torsion spring may for example be found in U.S. Pat. No. 5,104,380. However, the pen suggested in U.S. Pat. No. 5,104,380 does not offer a dial-down mechanism. A dial-down mechanism is provided in WO 02/053214. However, the proposed solution in WO 02/053214 involves a linear spring.

It is a disadvantage of known torsion spring-based dial-down systems that the user must apply a force to withdraw the dose setting member a certain axial distance and, at the same time, adjust the angular position of the dose setting member. Especially for persons having reduced motoric skills or reduced finger strength, such as children, elderly people or disabled people this is a rather complicated procedure.

US 2004/199117 discloses a medication delivery pen including an arrangement where incorrect dosage settings may be corrected by a user via a dial-back feature that enables the user to reset the dose amount without expelling medication and without having to dial a dose knob to an extended, reset position. The medication delivery pen of US 2004/199117 is a so-called manual pen where the injection of a medicament from the pen is driven by a force purely provided by the user of the pen. Thus, the injection of a medicament is not assisted by any resilient member, such as a spring, and the dial-down arrangement disclosed in US 2004/199117 is not arranged to maintain a resilient member in a given strained position.

It is an object of the present invention to provide a dial-down mechanism for automatic wind-up pens. Automatic wind-up pens are here to be understood as pens having a resilient member, such as a spring, to assist injecting a medicament from an injection device.

SUMMARY OF THE INVENTION

The above-mentioned object is complied with by providing, in a first aspect, a dial-down mechanism for an injection device comprising a torsion spring for assisting injection of a dose of medicament from the injection device, the dial-down mechanism comprising

- dial-up cam arranged to receive and engage with a dial-up key, wherein the dial-up cam and the dial-up key are adapted to, upon rotation of a dose setting member in a first direction, cooperate to strain the torsion spring of the injection device, and
- a dial-down cam arranged to receive and engage with a dial-down key, wherein the dial-down cam and the dial-down key are adapted to, upon rotation of the dose setting member in a second direction, cooperate to release the torsion spring of the injection device, the second rotation direction being opposite to the first rotation direction.

Generally speaking the dial-down mechanism may be implemented as a radial dial-down mechanism or as an axial dial-down mechanism. In the radial dial-down mechanism the dial-down key or keys are arranged to move in the radial direction of the mechanism. This may also be the radial direction of the injection device. In the axial dial-down mechanism, the dial-down key or keys are arranged to move in the axial direction of the injection device.

Also it should be noted that the dial-up key or keys, and the dial-down key or keys may be different keys—i.e. physically separated keys. However, it may also be that the dial-up and dial-down key is constituted by the same key. Thus, it may be that the mechanism according to the present invention comprises only a single key which is used for both dial-up and dial down.

The dial-up and dial-down cams may be arranged as openings or indentations in an outer surface part of a disc-shaped cam member. The cam member may, alternatively, also be shaped as a substantially cylindrical member. In particular, the dial-up and dial-down cams may be arranged in a substantially plane surface part of the cam member. This substantially plane surface part may be substantially perpendicular to an axial direction of the disc or cylindrical shaped cam member. The cam member may be a hollow construction, or alternatively, the cam member may be a solid construction.

In both the radial and the axial mechanism, the dial-up cam may form a curved track, such as part of a circular, elliptical or parabolic track. The dial-down cam may form part of a V-shaped track, or alternative, it may have a rectangular shape.

The dial-down mechanism may comprise a first and a second dial-up cam. Furthermore, the dial-down mechanism may comprise a first and a second dial-up key, wherein the first dial-up key may be adapted to engage and cooperate with the first dial-up cam, and wherein the second dial-up key may be adapted to engage and cooperate with the second dial-up cam.

The dial-down mechanism may further comprise a first and a second dial-down cam, and a first and a second dial-down key. The first dial-down key may be adapted to engage and cooperate with the first dial-down cam, whereas the second dial-down key may be adapted to engage and cooperate with the second dial-down cam.

It may also be that the dial-up and dial-down cams form part of regions of the same track. Furthermore, the dial-up and dial-down keys may be constituted by the same key, said key being adapted to engage and cooperate with dial-up and dial-down cams of the same track.

In the axial mechanism, the dial-up and dial-down cams may be arranged as cams having an axial component parallel to an axial direction of the injection device. The dial-up and dial-down cams may be arranged on an outer and curved surface part of a substantially cylindrical cam member. This substantially cylindrical cam member may be the dose setting member of the injection device, or it may be a separate component cooperating with the dose setting member of the injection device.

In the axial mechanism, the dial-up cam may be substantially parallel to an axial direction of the injection device. In order to be able to release an associated ratchet from a toothing the dial-down cam may form an angle, such as around 45 degrees, to the dial-up cam.

In a second aspect, the present invention relates to an axially arranged dial-down mechanism for an injection device, the dial-down mechanism comprising

a rotatable member adapted to be rotated when a dose to be injected from the injection device is set, the rotatable member comprising a dial-up cam and a dial-down cam, wherein the dial-up cam is adapted to receive and engage with a key of a ratchet of the injection device during dose setting during dial-up, and wherein the dial-down cam is adapted to receive and engage with the key during dial-down,

wherein the dial-up cam is substantially parallel to an axial direction of the injection device.

In this second aspect of the present invention the dial-up and dial-down cams may form part of regions of the same track. The dial-up and dial-down keys may be constituted by the same key, said key being adapted to engage and cooperate with dial-up and dial-down cams of the same track.

In a third aspect, the present invention relates to a medication delivery device, such as a handheld medication delivery device, comprising a dial-down mechanism according to the first aspect of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will now be described in further details with reference to the accompanying figures, wherein

FIG. **1** shows the principle of a radial dial-up and dial-down mechanism where the keys on the flexible arm are used for both dial-up and dial-down,

[FIG. **2** shows] *FIGS. 2A and 2B show* a radial dial-up/dial down mechanism with separate keys for dial-up and dial-down, *where FIG. 2A shows torsion spring 18 and disc 14 over ratchet 13 (not labeled) and adjacent to nut 10 (not labeled), and FIG. 2B also shows ratchet 13 adjacent nut 10.*

FIG. **3** shows a radial dial-up/dial down mechanism with separate keys for dial-up and dial-down where the movements of the dial-down key is determined by a track in the nut,

FIG. **4** shows an injection device having an integrated radial dial-down mechanism, and

[FIG. **5** shows] *FIGS. 5A and 5B show* an injection device having an integrated axial dial-down mechanism, *where FIG. 5A shows a cross-section of an injection device, and FIG. 5B shows a partial front or side elevation view of the same injection device.*

While the invention is susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and will be described in detail herein. It should be understood, however, that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION

The dial-down mechanism according to the present invention may be implemented as an axial or a radial mechanism. Both of these mechanisms may be integrated into an injection device, such as an injection pen.

A radial solution is shown in FIG. **1**. FIG. **1**a shows a rotatable inner part **2** biased against a fixed outer part **1**. The biasing force is provided by a torsion spring (not shown) in the counter-clockwise direction. The inner part **2**, which is rotatable around a center axis **6**, has one or more flexible arms **3** adapted to engage with the edges **5** in the fixed outer part **1**. FIG. **1**b shows the arrangement of FIG. **1**a with a rotatable disc **7** (hatched region) placed on top of the inner part **2** and outer part **1**. The disc **7** has an opening **8**. The edges defining the opening **8** constitute dial-up and dial-down cams. A pick-up key **4** attached to, or integrated with, the flexible arm **3** operates as a cam follower when the disc **7** is rotated relative to the outer part **1**.

The system illustrated in FIG. **1** is operated in the following manner:

When a dose is to be set (dial-up), the inner part **2** is rotated in the clockwise direction whereby the flexible arm **3** will move from one edge **5** to the neighboring edge or edges—depending on the angle of rotation. The inner part **2** is driven by disc **7**—thus, when disc **7** is rotated the inner part **2** rotates with it. During rotation in the clockwise direction, the pick-up key **4** moves in and out along the radial direction.

When the disc **7** is rotated in the counter clockwise direction (dial-down direction) the pick-up key **4**, and thereby the flexible arm **3**, is lifted out of its engaging position with the edge **5** of the outer part **1**. When the arm **3** is fully disengaged from the edge **5** the inner part **2** may be rotated in the counter clockwise direction relative to the outer part **1**. It is a characteristic of the system shown in FIG. **1** that the pick-up key **4** is used for both dial-up (increasing a dose) and dial-down (resetting or reducing a dose).

It should be noted that the directions of rotation could be reversed so that dial-up is achieved by rotating the inner

portion **2** in the counter clockwise direction. In such a configuration dial-down could be achieved by rotating disc **7** in the clockwise direction.

[FIG. **2** shows**]** *FIGS. 2A and 2B show* an exploded drawing of the radial embodiment of the dial-down mechanism according to the present invention. The main difference compared to the embodiment shown in FIG. **1** is that the embodiment of **[**FIG. **2]** *FIGS. 2A and 2B* applies different pick-up keys for dial-up (pick-up key **11**) and dial-down (pick-up key **12**). The dial-up key **11** engages with track **15** of the disc **14**, whereas dial-down key **12** engages with track **16** of the disc **14**. Tracks **15** and **16** are formed as through-going openings or indentations in a planar surface of the disc **14**. The dial-up tracks **15** take the form of curved tracks whereas the dial-down tracks **16** are V-shaped. An obvious alternative to the V-shape is a rectangular shape. It should be noted that the general idea is that the dial-up tracks **15** should be capable of transferring a momentum to a torsion spring **18**. In the same manner, the dial-down tracks **16** should be capable of releasing the dial-down keys (and thereby release energy) in case the disc **14** is rotated just a few degrees relative to the nut **10**.

The dial-down keys **12** are integrated with the flexible arms **19**. These arms are fabricated of a resilient material such as for example plastic. The flexible arms **19** with integrated dial-down keys **12** form an integral part of the ratchet **13**. Thus, the ratchet including arms and dial-down keys may preferably be fabricated of the same material, such as of plastic. In order to bias the dial-down keys **12** against the teeth **20** of the nut **10** a torsion spring **18** is arranged coaxially with the ratchet **13**. An opening **21** is provided in the center part of the nut **10**. The side wall of this opening is provided with threads **22** which are adapted to engage with a threaded outer surface of a piston rod (not shown).

FIG. **3** shows another radial embodiment according to the present invention. In this embodiment, the movement of the arm **26** is controlled by a track **23** in the nut **27**. The track **23** is engaged by the track/cam follower **24** which precisely guides the dial-down key **28** from one tooth to the neighboring tooth during dial-down. In contrast to FIG. **2** the opening **25** in the center of the nut **27** is provided with a track follower **29**. This track follower is adapted to engage with a track in the outer surface of a piston rod (not shown).

FIG. **4** shows an injection device having a radial dial-down mechanism according to the present invention. Among other components the injection device shown in FIG. **4** shows a dose setting member **30**, a piston rod **31** having a threaded outer surface and a drive track arranged in the axial direction of the piston rod, a nut **32**, a torsion spring **35**, a drive member **33**, the threaded portion **34** of the housing, a lease mechanism **36**, a toothing mechanism **37**, and ratchet **38**.

A dose is set by rotating the dose setting member **30** and the nut **32** whereby the torsion spring **35** is strained. The dose setting member **30** is prevented from returning to its initial position due the toothing mechanism **37** positioned between the nut **32** and the drive member **33**. In case the user wants to reduce a preset dose, the dose setting member **30** is simply rotated in the opposite direction. The interaction between ratchet **38** and nut **32** during dial-down is described in connection with FIG. **2**.

[FIG. **5** shows**]** *FIGS. 5A and 5B show* an injection device having an axial dial-down mechanism according to the present invention. Among other components the injection device shown in FIG. **[5]** *5B* comprising a dose setting member **40**, an opening **41** defining dial-up and dial-down cam surfaces, a cam follower **42**, a torsion spring **43**, a ratchet **44**, and a piston rod **45**. The general idea behind the axial dial-down mechanism is to use the torsion spring **43** to both drive and rotate the piston rod **45** and to ensure that the upper and lower parts of the toothing **48** remain together.

When a dose is to be set, the cam follower **42** engages with cam surface **46**. As a result the torsion spring **43** is strained because the ratchet **44** is prevented from reversing due to the toothing **48**. During dial-up the ratchet **44** will move up and down along cam surface **46** as the upper and lower parts of the toothing **48** rotate relative to each other. In case of dial-down the cam surface **47** will lift and thereby release the upper part of the toothing from the lower part of the toothing thereby the ratchet **44** is allowed to rotate an angle corresponding to one tooth.

The invention clamed is:

1. A dial-down mechanism for an injection device comprising a torsion spring (**18**) for assisting injection of a dose of medicament from the injection device, the dial-down mechanism comprising

dial-up cam (**15**) arranged to receive and engage with a dial-up key (**11**), wherein the dial-up cam (**15**) and the dial-up key (**11**) are adapted to, upon rotation of a dose setting member in a first direction, cooperate to strain the torsion spring (**18**) of the injection device, and

a dial-down cam (**16**) arranged to receive and engage with a dial-down key (**12**), wherein the dial-down cam (**16**) and the dial-down key (**12**) are adapted to, upon rotation of the dose setting member in a second direction, cooperate to release the torsion spring (**18**) of the injection device, the second rotation direction being opposite to the first rotation direction,

wherein the dial-up and dial-down cams form part of regions of the same track,

further comprising an arm wherein the dial-up and dial-down keys are both located on the same arm, said keys being adapted to engage and cooperate with dial-up and dial-down cams of the same track.

2. A dial-down mechanism according to claim **1**, wherein the dial-up cam (**15**) forms part of a curved track.

3. A dial-down mechanism according to claim **2**, wherein the curved dial-up cam (**15**) forms part of a circular, elliptical or parabolic track.

4. A dial-down mechanism according to claim **1** comprising a first and a second dial-up cam.

5. A dial-down mechanism according to claim **4** comprising a first and a second dial-up key, wherein the first dial-up key is adapted to engage and cooperate with the first dial-up cam, and wherein the second dial-up key is adapted to engage and cooperate with the second dial-up cam.

6. A dial-down mechanism according to claim **1**, wherein the dial-down cam (**16**) forms part of a V-shaped track.

7. A dial-down mechanism according to claim **1** comprising a first and a second dial-down cam.

8. A dial-down mechanism according to claim **7** comprising a first and a second dial-down key, wherein the first dial-down key is adapted to engage and cooperate with the first dial-down cam, and wherein the second dial-down key is adapted to engage and cooperate with the second dial-down cam.

9. A medication delivery device comprising a dial-down mechanism according to claim **1**.

10. A medication delivery device according to claim **9**, wherein the medication delivery device is a handheld medication injection pen.

11. A method for using a wind up injection pen, the method comprising the steps of

rotating a first element in a first direction, the direction being a dial up direction;

causing a second element to be rotated in the same direction as the first element;

straining a torsional spring;

moving an arm that is in engagement with one edge to a neighboring edge, wherein when the arm is engaged with an edge it prevents the torsional spring from unwinding;

rotating the first element in a second direction opposite the first direction;

moving a pick-up key and radially lifting the arm out of engagement with an edge and when the arm is fully disengaged from an edge allowing the second rotatable element to rotate in the second direction and allowing the strain on the spring to be decreased.

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