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(54) **DRUG DELIVERY DEVICE AND METHOD OF MANUFACTURING A DRUG DELIVERY DEVICE**

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(71) Applicant: **SANOFI-AVENTIS DEUTSCHLAND GMBH**, Frankfurt am Main (DE)

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None
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(72) Inventors: **Michael Harms**, Frankfurt am Main (DE); **Steffen Raab**, Frankfurt am Main (DE)

(56) **References Cited**

U.S. PATENT DOCUMENTS

(73) Assignee: **Sanofi-Aventis Deutschland GMBH**, Frankfurt am Main (DE)

533,575 A 2/1895 Wilkens
2,461,481 A * 2/1949 Roehr A61M 5/24
604/201

(Continued)

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FOREIGN PATENT DOCUMENTS

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CA 2138528 C 12/1998
CA 2359375 A1 7/2000

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Related U.S. Patent Documents

OTHER PUBLICATIONS

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Primary Examiner — Glenn K Dawson
(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

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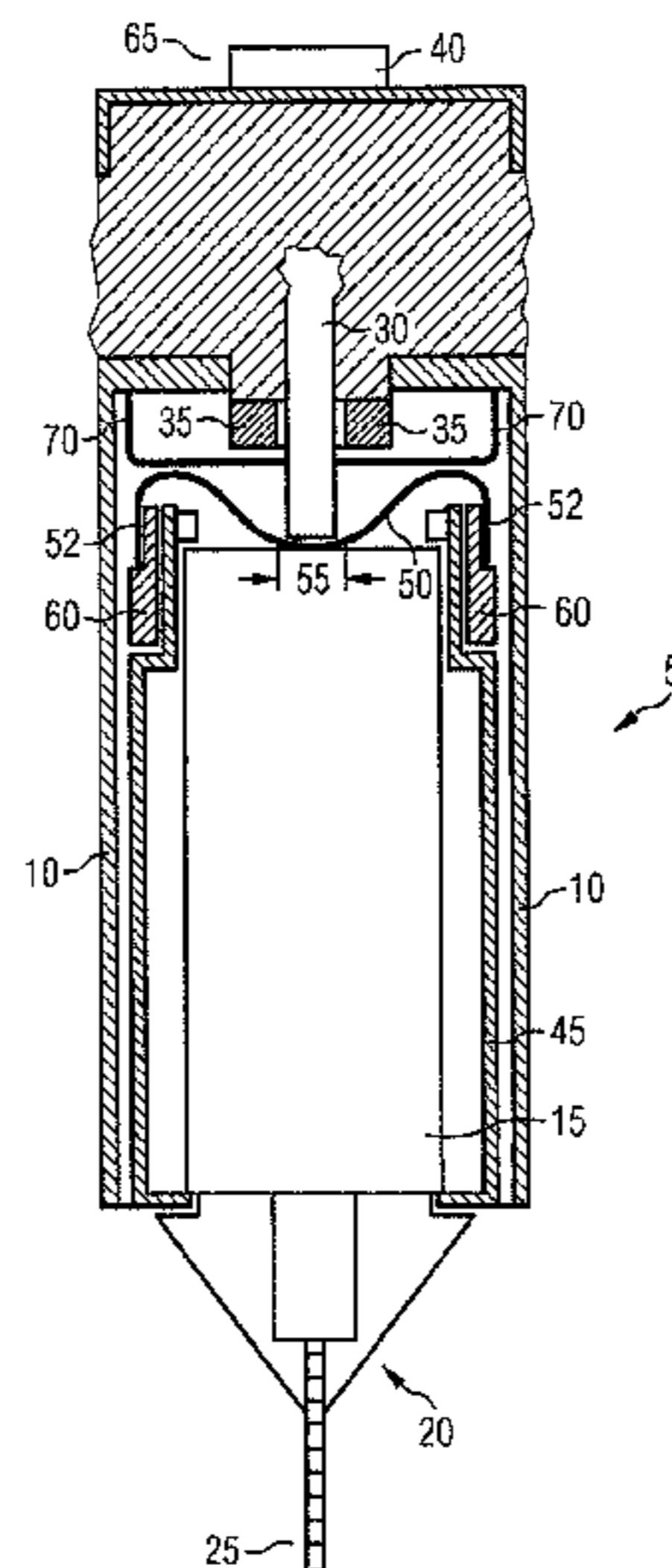
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(57) **ABSTRACT**

The present invention relates to drug delivery device and a method of manufacturing a drug delivery device with a housing having a proximal end and a distal end, a cartridge adapted to accommodate a drug, a cartridge retaining member adapted to retain the cartridge, the cartridge retaining member being secured to the housing, and a spring washer being arranged within the housing so as to exerting a force on the cartridge and securing the cartridge against movement with respect to the cartridge retaining member and against movement with respect to the housing.

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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,742,948	A	7/1973	Post et al.	A61M 5/2033 604/139
4,490,142	A *	12/1984	Silvern	A61M 5/344 604/241
4,865,591	A	9/1989	Sams	
4,931,043	A *	6/1990	Ray	A61M 5/3151 604/218
5,092,842	A	3/1992	Bechtold et al.	
5,226,895	A	7/1993	Harris	
5,226,896	A	7/1993	Harris	
5,279,586	A	1/1994	Balkwill	
5,304,152	A	4/1994	Sams	
5,320,609	A	6/1994	Haber et al.	
5,378,233	A	1/1995	Haber et al.	
5,383,865	A	1/1995	Michel	
5,391,157	A	2/1995	Harris et al.	
5,480,387	A	1/1996	Gabriel et al.	
5,505,704	A	4/1996	Pawelka et al.	
5,582,598	A	12/1996	Chanoch	
5,626,566	A	5/1997	Petersen et al.	
5,674,204	A	10/1997	Chanoch	
5,688,251	A	11/1997	Chanoch	
5,807,346	A	9/1998	Frezza	
5,820,602	A	10/1998	Kovelman et al.	
5,851,079	A	12/1998	Horstman et al.	
5,891,106	A	4/1999	Butuzov et al.	
5,921,966	A	7/1999	Bendek et al.	
5,957,896	A	9/1999	Bendek et al.	
5,961,495	A	10/1999	Walters et al.	
6,004,297	A	12/1999	Steenfeldt-Jensen et al.	
6,095,572	A *	8/2000	Ford	F16L 37/248 210/198.2
6,193,698	B1	2/2001	Kirchhofer et al.	
6,221,046	B1	4/2001	Burroughs et al.	
6,235,004	B1	5/2001	Steenfeldt-Jensen et al.	
6,248,095	B1	6/2001	Giambattista et al.	
6,361,687	B1 *	3/2002	Ford	F16L 37/107 210/198.2
6,425,532	B1 *	7/2002	Popp	F02M 47/046 239/124
6,562,006	B1	5/2003	Hjertman et al.	
6,585,685	B2	7/2003	Staylor et al.	
6,613,023	B2	9/2003	Kirchhofer et al.	
6,699,224	B2	3/2004	Kirchhofer et al.	
6,899,698	B2	5/2005	Sams	
6,932,794	B2	8/2005	Giambattista et al.	
6,936,032	B1	8/2005	Bush, Jr. et al.	
7,169,132	B2	1/2007	Bendek et al.	
7,241,278	B2	7/2007	Moller	
7,337,796	B2	3/2008	Choate et al.	
7,678,084	B2	3/2010	Judson et al.	
7,850,662	B2	12/2010	Veasey et al.	
8,092,420	B2 *	1/2012	Bendek	A61M 5/2448 604/207
8,187,233	B2	5/2012	Harms et al.	
9,078,970	B2 *	7/2015	Harms	A61M 5/24
9,132,237	B2 *	9/2015	Harms	A61M 5/24
9,180,250	B2 *	11/2015	Teucher	A61M 5/24
9,375,535	B2 *	6/2016	Veasey	A61M 5/31543
2001/0007338	A1 *	7/2001	Popp	F02M 47/046 239/132.5
2001/0039394	A1 *	11/2001	Weston	604/72
2002/0052578	A1	5/2002	Moller	
2002/0120235	A1	8/2002	Enggaard	
2003/0050609	A1	3/2003	Sams	
2004/0035491	A1	2/2004	Castellano	
2004/0059299	A1	3/2004	Moller	

2004/0097883	A1	5/2004	Roe	
2004/0210199	A1	10/2004	Atterbury et al.	
2004/0254526	A1	12/2004	Weston	
2004/0267207	A1	12/2004	Veasey et al.	
2005/0113765	A1	5/2005	Veasey et al.	
2005/0267422	A1	12/2005	Kriesel	
2006/0153693	A1	7/2006	Fiechter et al.	
2007/0005021	A1	1/2007	Kohlbrener et al.	
2007/0016143	A1	1/2007	Miller et al.	
2007/0021718	A1	1/2007	Burren et al.	A61M 5/24 604/110
2007/0142789	A1	6/2007	Fisher et al.	
2009/0275916	A1	11/2009	Harms et al.	
2011/0306939	A1 *	12/2011	Harms	A61M 5/24 604/208
2012/0191049	A1 *	7/2012	Harms	A61M 5/24 604/232
2017/0119971	A1 *	5/2017	Marsh	A61M 5/3157
2017/0128673	A1 *	5/2017	Marsh	A61M 5/31583
2017/0136182	A1 *	5/2017	Marsh	A61M 5/20
2017/0136186	A1 *	5/2017	Marsh	A61M 5/3157
2017/0151392	A1 *	6/2017	Marsh	A61M 5/20
2017/0340830	A1 *	11/2017	Wieselblad	A61M 5/31551
2017/0340835	A1 *	11/2017	Jones	A61M 5/31583

FOREIGN PATENT DOCUMENTS

DE	10 2004 053529	5/2006
DE	10 2005 032 705	11/2006
EP	0496141 A1	7/1992
EP	0897729 A2	2/1999
EP	0937471	8/1999
EP	0937476	8/1999
EP	1776975 A2	4/2007
EP	1974761	10/2008
EP	2346552 B1	8/2012
GB	743839	5/1954
GB	743839	1/1956
JP	H06-7741 U	2/1994
JP	H11-514242 A	12/1999
RU	2004256	12/1993
RU	2060736	5/1996
TW	201019980 A	6/2010
WO	93/07922 A1	4/1993
WO	93/24160 A1	12/1993
WO	WO 95/21645	8/1995
WO	96/17640	6/1996
WO	99/038554	8/1999
WO	01/010484	2/2001
WO	02/30495 A2	4/2002
WO	02/092153 A2	11/2002
WO	03/080160 A1	10/2003
WO	WO 2004/062715	7/2004
WO	WO 2005/032449	4/2005
WO	2006/084876 A1	8/2006
WO	2008/008694	1/2008
WO	2010/043533 A1	4/2010
WO	2010/139635	12/2012

OTHER PUBLICATIONS

New Zealand Examination Report for NZ App. No. 592172, dated Apr. 16, 2012.
 Russian Office Action for RU App. No. 2011119019, dated Aug. 23, 2013.
 Singapore Written Opinion and Search Report for SG App. No. 201102565-7, dated Apr. 18, 2013.
 Canadian Examination Search Report for CA App. No. 2740331, dated Jul. 13, 2015.
 Japanese Office Action for JP App. No. 2011-530486, dated Oct. 8, 2013.
 Russian Decision on Grant for RU App. No. 2011119019, dated Aug. 19, 2014.
 Taiwan Search Report for TW Patent Application No. 098134224, dated Jan. 23, 2015.
 Extended European Search Report for EP App. No. 12160352.6, dated May 2, 2012.

(56)

References Cited

OTHER PUBLICATIONS

International Preliminary Report on Patentability for corresponding PCT application No. PCT/EP2009/063075.

Boker's Inc., Wave Spring Washers [online] [retrieved on Sep. 30, 2015]; Retrieved from the Internet: <URL:https://www.bokers.com/wave_spring_washers.asp>.

Wikipedia, Washer (hardware) [online] [retrieved on Sep. 30, 2015]; Retrieved from the Internet: <URL:https://en.wikipedia.org/wiki/Washer_(hardware)>.

Beitz, W., et al., "Taschenbuch für den Maschinenbau," Dubbel-Handbook of Mechanical Engineering, pp. G55-G57, 1997.

'bokers.com' [online], "Wave Spring Washers", retrieved on Sep. 30, 2015, retrieved from: URL<http://www.bokers.com/wave_spring_washers.asp>, 1 page.

"Beitz and Grote", "Dubbel, Pocketbook for mechanical engineering", 1997, 16 pages.

Wikipedia [online], "Washer (hardware)", Aug. 21, 2004, [retrieved on Sep. 30, 2015], retrieved from: URL<https://en.wikipedia.org/wiki/Washer_(hardware)>, 7 pages.

Wilhelm Becker, "Technical springs and punched and bent parts", 2007, 20 pages (with English Translation).

"Pen-injectors for medical use—Part 1: Pen-injectors—Requirements and test methods," International Standard, reference No. ISO 11608-1:2000(E), first edition Dec. 15, 2000, 32 pages.

International Preliminary Report in International Application No. PCT/EP2009/063075, dated Nov. 4, 2010, 8 pages.

International Search Report and Written Opinion in International Application No. PCT/EP2009/063075, dated Jan. 25, 2010, 9 pages.

Barrett, "Fastener Design Manual," NASA Reference Publication 1228, Published Mar. 1990, 2 pages.

Beitz and Grote, "Taschenbuch für den Maschinenbau," Dubbel, Published 1997, G55-G57, 5 pages.

Indian Pre Grant Opposition Brief in Application No. 2423/CHENP/2011, dated Apr. 25, 2019, 35 pages (Exhibits excluded).

International Search Report for corresponding PCT application No. PCT/EP2009/063075.

European Search Report for EP App. No. 12160352, completed Apr. 17, 2012.

* cited by examiner

FIG 1

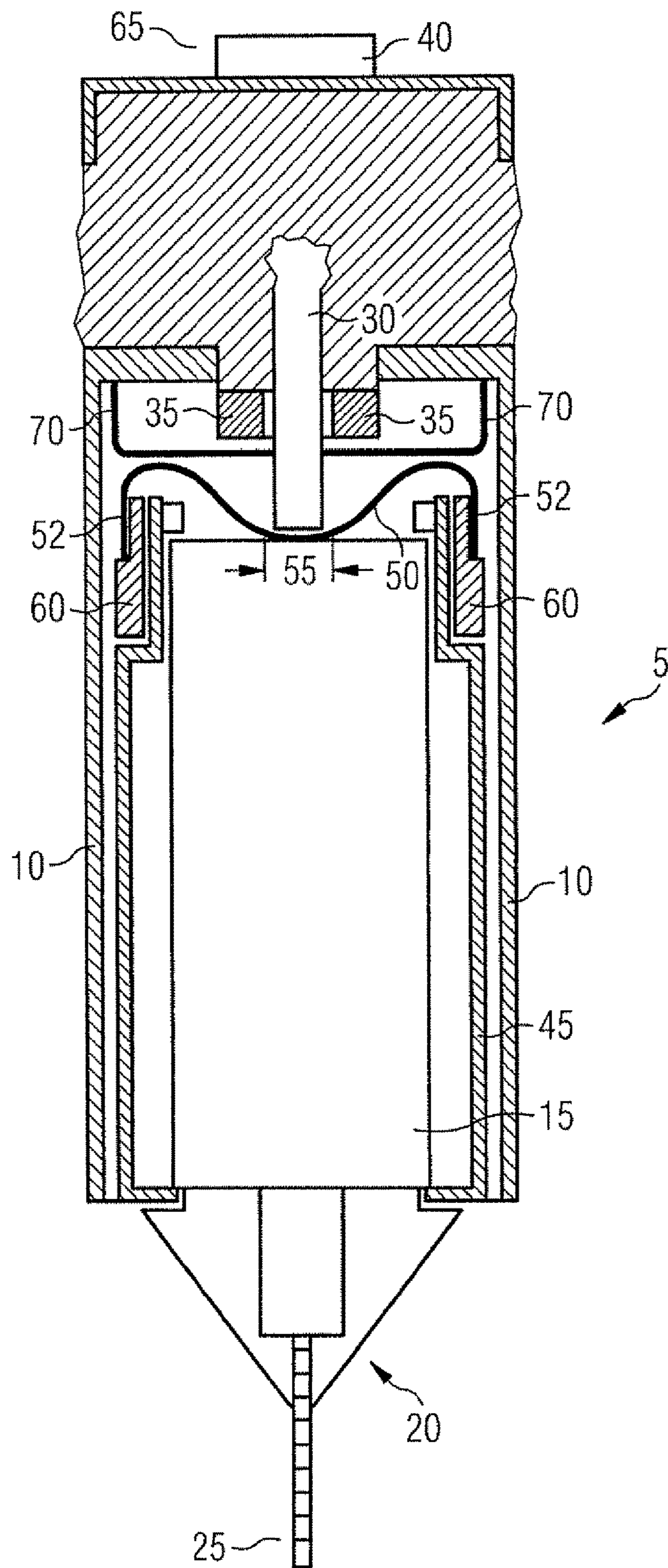


FIG 2

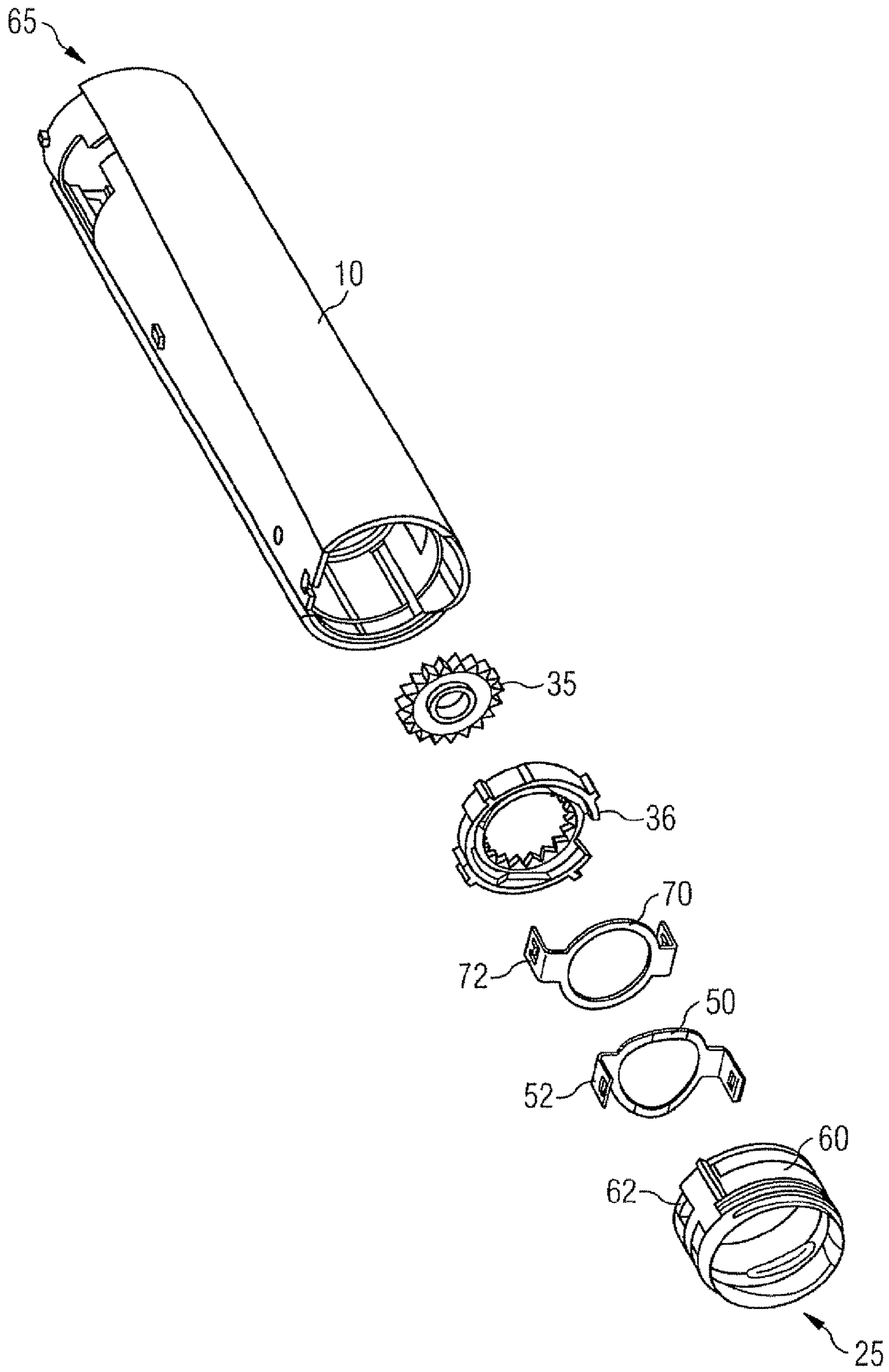


FIG 3

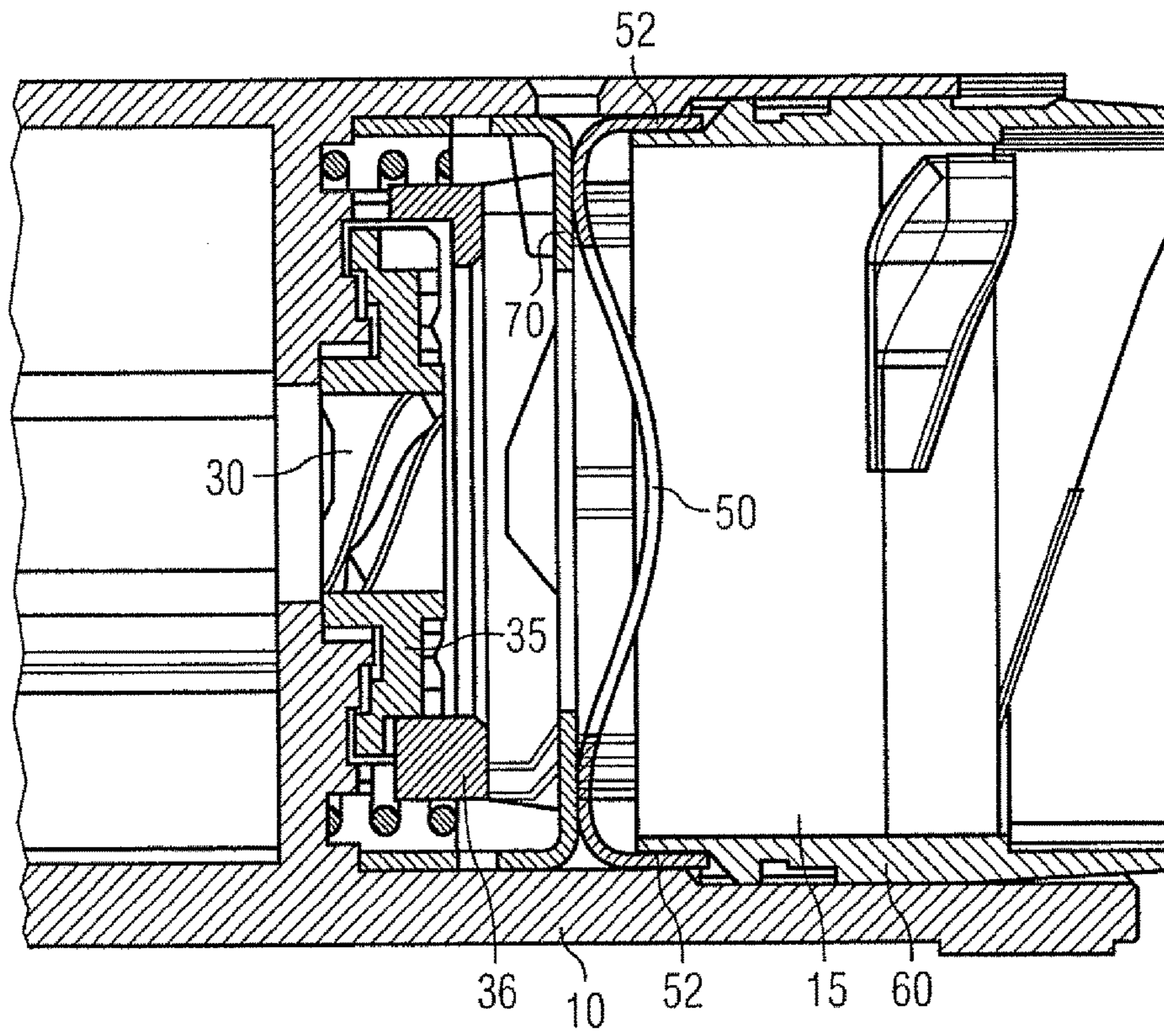


FIG 4

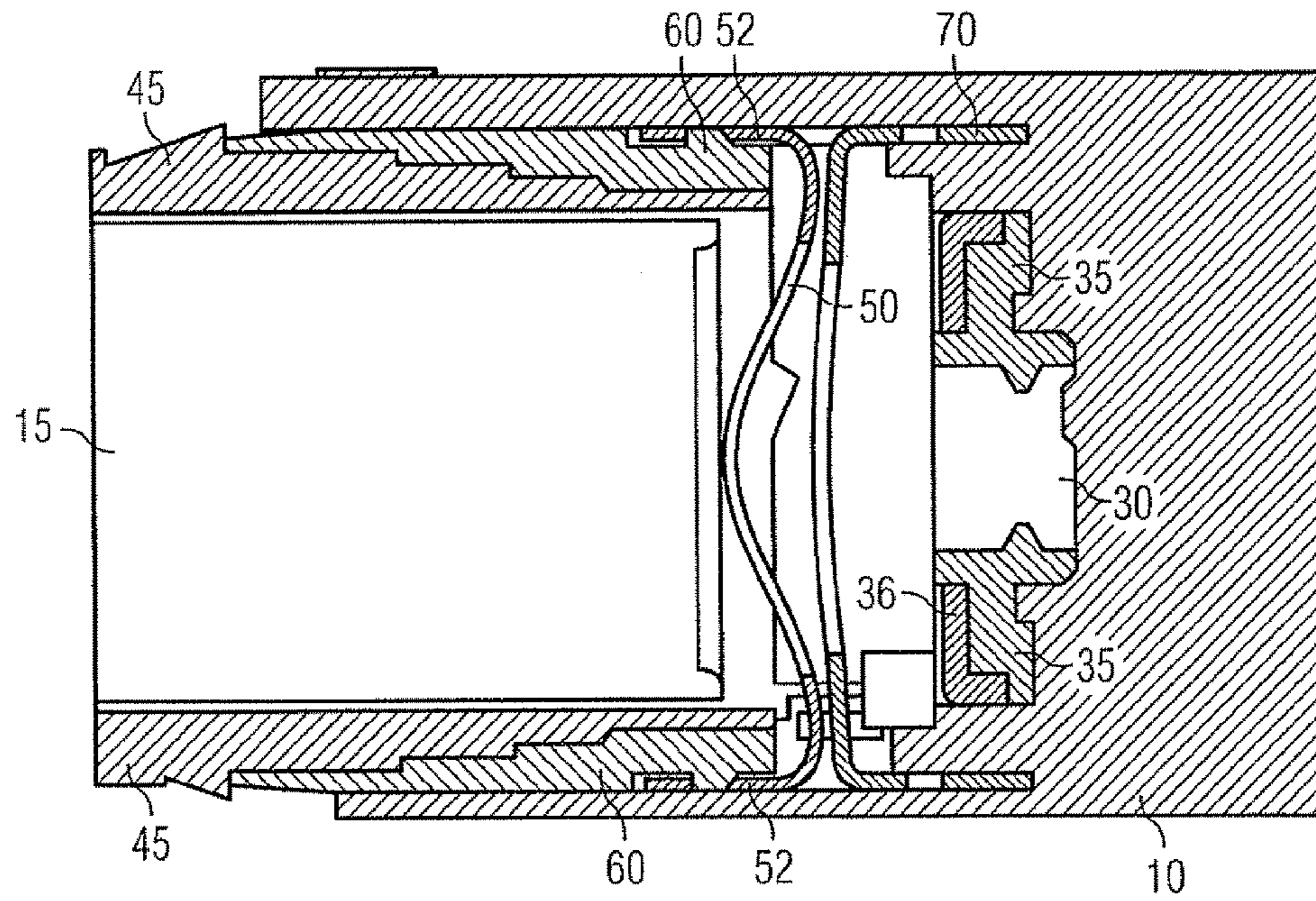


FIG 5

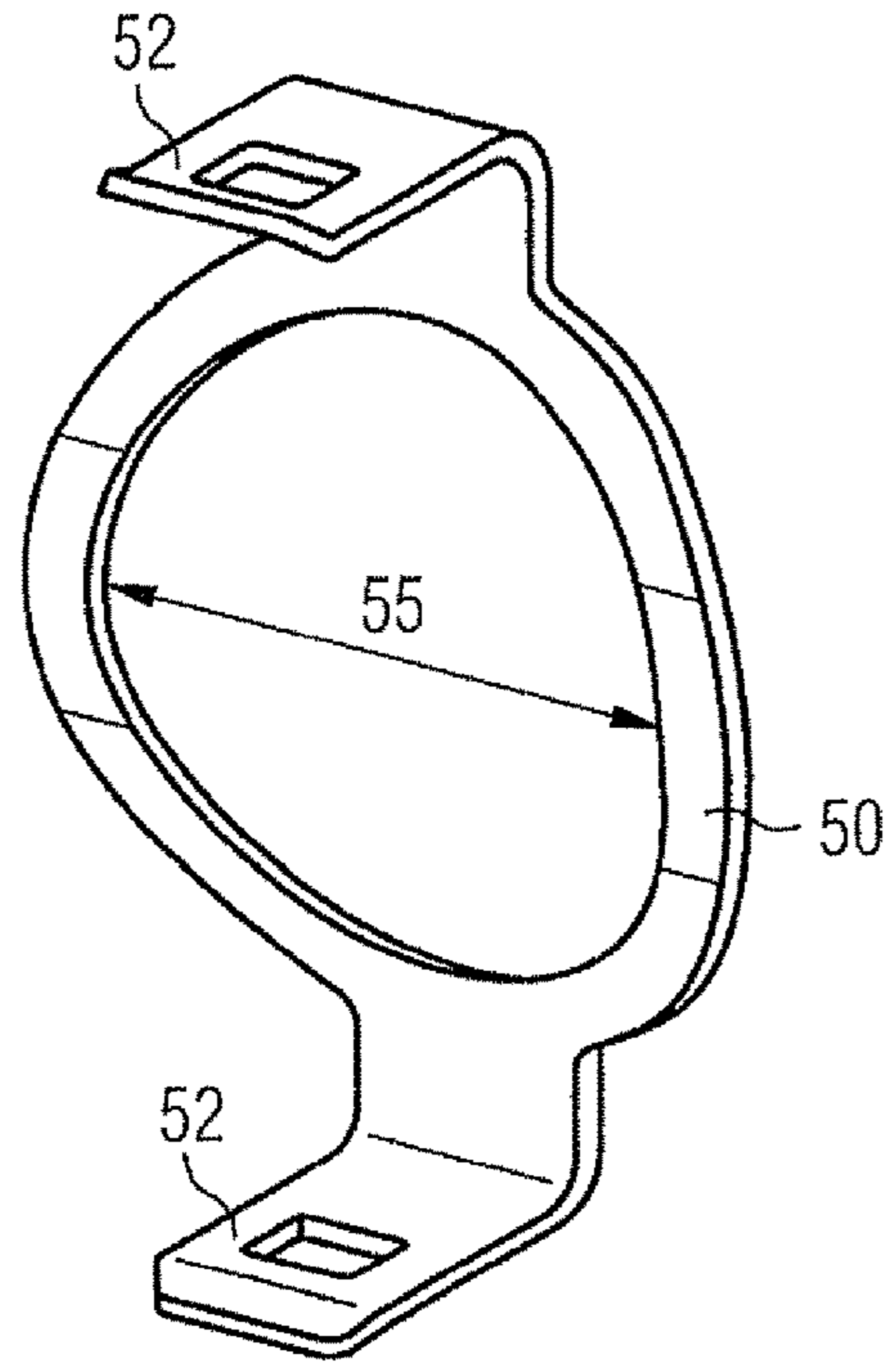
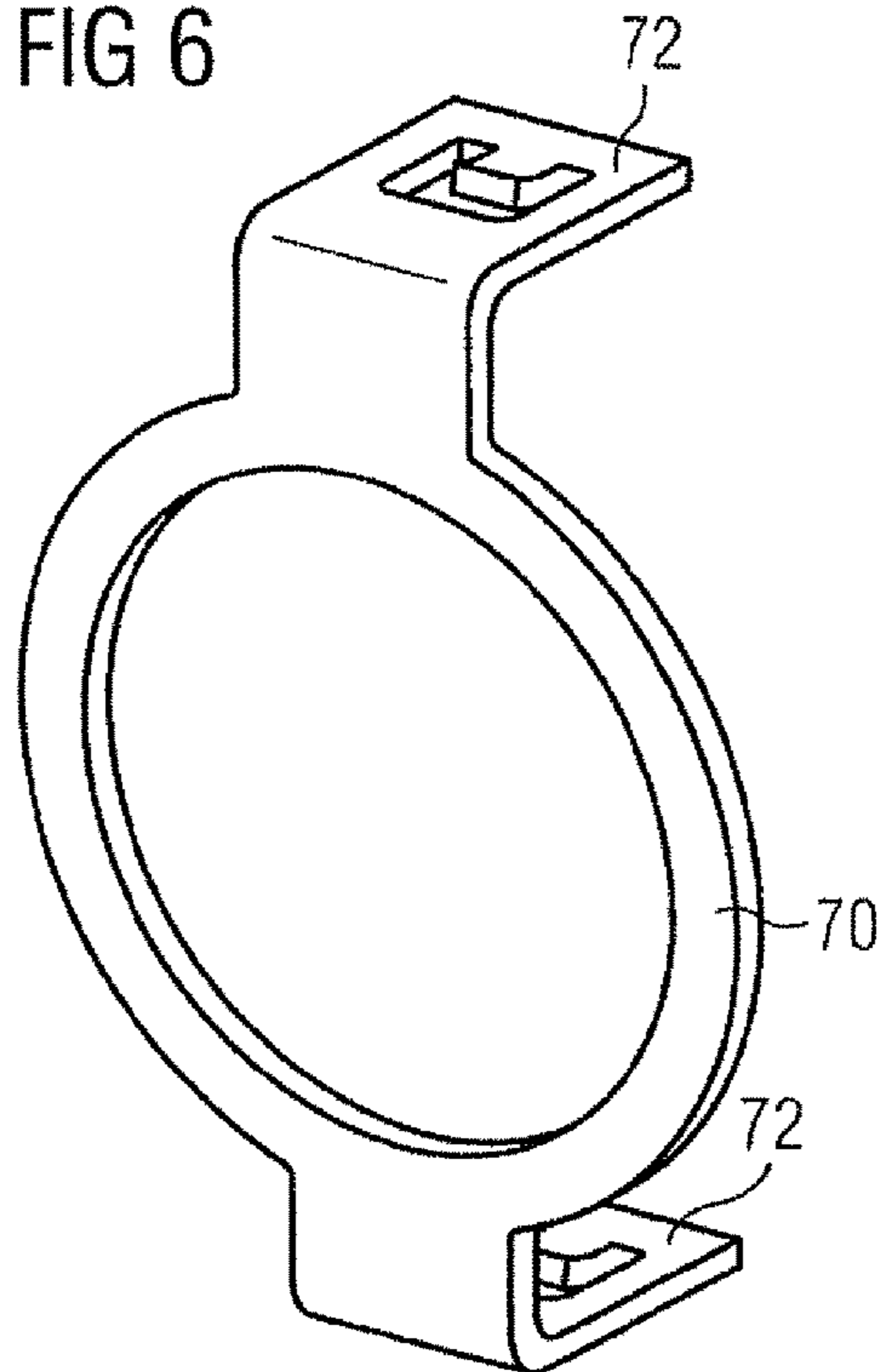


FIG 6



**DRUG DELIVERY DEVICE AND METHOD
OF MANUFACTURING A DRUG DELIVERY
DEVICE**

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

The present application is a U.S. National Phase Application pursuant to 35 U.S.C. § 371 of International Application No. PCT/EP2009/063075 filed Oct. 8, 2009, which claims priority to European Patent Application No. 08017889.0 filed on Oct. 13, 2008. The entire disclosure content of these applications are herewith incorporated by reference into the present application.

TECHNICAL FIELD

The present invention relates to a drug delivery device and a method of manufacturing a drug delivery device. Drug delivery devices are used for the administration of a drug, for example insulin, heparin or growth hormones. Some devices are configured to deliver a plurality of doses. Additionally some devices are configured to allow setting of different dose sizes which are to be delivered. Here it is important that the size of the dose can be precisely set and the set dose can be reliably delivered.

BACKGROUND

In US 2007/0021718 A1 a syringe is shown having a spring which is arranged between a housing insert and a driving element. The spring may serve as compensation for longitudinal tolerances in order to support a medical container in an injection device.

In U.S. Pat. No. 3,742,948 a syringe is shown having a pressure member constructed as a cup spring. The pressure member includes resilient lugs which bear on the upper edge of the liquid container with their free end.

Further medication delivery devices are known from the documents WO 2005/032449 A1 and DE 10 2004 053529 A1.

It is an aim of the present invention to provide for an improved drug delivery device. In particular, a drug delivery device should be provided, which allows for improved operability with respect to dosage control and/or improved reproducibility of the dosage in connection with different cartridges.

SUMMARY

For this aim, a drug delivery device comprises a housing with a proximal end and a distal end, a cartridge adapted to accommodate a drug, a cartridge retaining member adapted to retain the cartridge, the cartridge retaining member being secured to the housing, and a spring washer being arranged within the housing so as to exert a force on the cartridge and secure the cartridge against movement with respect to the cartridge retaining member and, preferably, against movement with respect to the housing.

In a drug delivery device of this kind movement of the cartridge with respect to the housing and/or the cartridge retaining member is reduced or even avoided on account of the spring washer, which exerts the force on the cartridge.

5 The spring washer can reduce play between cartridge and housing and/or between cartridge and cartridge retaining member. This is, for example, particularly advantageous when cartridges with different lengths are to be used in the drug delivery device. Thus, the drug delivery device may be
10 a reusable device. Manufacturing tolerances in cartridge lengths can thus be compensated by means of the spring washer. Consequently, during operation of the drug delivery device, axial movement of the cartridge in the cartridge retaining member can be reduced or even prevented and
15 dose accuracy can be increased. The spring washer allows securing the cartridge within the cartridge retaining member without requiring much space. Consequently a very compact drug delivery device can be formed.

In a further embodiment, the spring washer is arranged so as to abut the cartridge, preferably on a side of the cartridge that faces the proximal end of the housing.

The spring washer may keep the cartridge fixed in the cartridge retaining member by abutting the cartridge, preferably on a side of the cartridge that faces the proximal end
25 of the housing. Accordingly, axial movement of the cartridge with respect to the cartridge retaining member is reduced or even prevented.

The spring washer may exert a force on the cartridge in the distal direction. The spring washer may be loaded or
30 biased so as to exert the force on the cartridge.

In a further embodiment, the spring washer is fixed to the housing. In particular, the spring washer may be secured to the housing so as to prevent relative axial movement between spring washer and housing in that region in which
35 the spring washer is secured to the housing.

According to this embodiment, the counter force when the spring washer exerts a force on the cartridge acts on the housing with the spring washer being held at its axial position.

In one embodiment, the drug delivery device comprises a piston rod for dispensing a dose of the drug from the device when the piston rod is driven in the distal direction and the spring washer comprises an opening, the opening being
45 arranged so as to allow the piston rod to run through the opening.

In this example, the spring washer can easily be implemented together with conventional drug delivery mechanisms, which utilize a piston rod or the like. Accordingly, the manufacturability of the drug delivery device is facilitated as
50 no significant design changes must be performed.

According to a further embodiment, the spring washer is curved in an axial and/or a radial direction. The axis may extend between the proximal end and the distal end of the housing.

55 Loading the spring washer and exerting a force on the cartridge is facilitated by shaping the spring washer in this way.

In a further embodiment, the spring washer is a Belleville type spring washer.

60 Spring washers of this kind can be easily implemented in the drug delivery device.

In one embodiment, the spring washer is fixed to a sleeve member of the housing, preferably a threaded sleeve member of the housing.

65 According to this embodiment, the spring washer may be implemented in a conventional housing of a drug delivery device, without performing significant design changes on

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the housing. The (threaded) sleeve member may simultaneously be used to secure the cartridge retaining member to the housing, e.g. by means of an inner thread.

In one embodiment, the drug delivery device comprises a further washer, the further washer preferably being arranged on the proximal side of the spring washer. The further washer is preferably arranged to be abutable by the spring washer.

In one embodiment, the further washer is arranged to limit the loading distance of the spring washer.

During insertion of the cartridge, a force in the proximal direction may be exerted on the spring washer, e.g. when (releasably) securing the cartridge retaining member with the cartridge being retained therein to the housing. In order to prevent the spring washer from being permanently plastically deformed, the further washer can be arranged on the proximal side of the spring washer. The further washer may limit the distance by which the spring washer may be deformed.

In one embodiment, the further washer is a disk washer or a spring washer. If the further washer is a spring washer, it preferably has a higher strength as compared to the spring washer that exerts the force on the cartridge. If the spring washer is loaded by a given force, the risk of overloading the spring washer, e.g. in the region of plastic deformation, can be reduced by providing a further spring washer of higher spring strength.

In one embodiment, the further washer is arranged to limit deformation of the spring washer to elastic deformation. In this example, the spring characteristics of the spring washer can be conserved as no plastic, i.e. non-elastic, deformation takes place.

According to a further embodiment, the further washer is curved in an axial and/or a radial direction. Preferably, the curvature of the further washer corresponds to or resembles the curvature of the spring washer.

In this example, the curvature of the further washer may be adapted to the curvature of spring washer in that region in which the further washer and the spring washer overlap as seen along the axial direction. This allows for a smooth abutment of the spring washer and the further washer.

For the above mentioned aim, a method of manufacturing a drug delivery device comprises the steps of: providing a housing with a proximal end and a distal end, providing a cartridge adapted to accommodate a drug, providing a cartridge retaining member adapted to retain the cartridge, arranging a spring washer within the housing and securing the cartridge retaining member to the housing, thereby loading the spring washer so as to exert a force on the cartridge and to secure the cartridge against displacement, in particular against axial displacement, with respect to the cartridge retaining member.

For the above mentioned aim, a spring washer is used to secure a cartridge which contains a drug in a cartridge retaining member of a drug delivery device against displacement, preferably against axial displacement, with respect to the cartridge retaining member.

Other features will become apparent from the following detailed description when considered in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 schematically shows a simplified cross sectional side view of a drug delivery device according to an embodiment;

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FIG. 2 schematically shows an exploded perspective view of a drug delivery device according to an embodiment;

FIG. 3 schematically shows a detailed cross sectional side view of a part of a drug delivery device according to an embodiment;

FIG. 4 schematically shows a detailed cross sectional side view of a part of a drug delivery device according to an embodiment;

FIG. 5 schematically shows a side view of a spring washer according to an embodiment; and

FIG. 6 schematically shows a side view of a further washer according to an embodiment.

DETAILED DESCRIPTION

In FIG. 1 an embodiment of a drug delivery device 5 is shown, which is an injector for a liquid medication. The drug delivery device may be configured to deliver a plurality of, preferably user-settable, doses of a drug. The drug delivery device may be a pen-type device. The drug delivery device 5 comprises a housing 10, wherein a cartridge 15 containing a medical product (drug) is located. A needle unit 20 is located at the distal end 25 of the drug delivery device 5. Needle unit 20 may be secured against movement with respect to the housing. Through needle unit 20 the medical product can be injected into a patient.

It should be noted that the description of the drug delivery device 5 as shown in FIG. 1 is merely illustrative.

The drug delivery device as shown in FIG. 1 further comprises a cartridge retaining member 45 which is (releasably) secured to the housing 10. The cartridge retaining member 45 is adapted to retain the cartridge 15 within the drug delivery device 5. The cartridge retaining member 45 can be configured such that the cartridge 15 can be replaced by a user after it has been emptied.

Delivery of the medical product can be performed by means of a piston rod 30 or the like, which can be moved into the distal direction with respect to the cartridge 15. A piston (not explicitly shown) which is retained in the cartridge and seals the cartridge on the proximal end side may be moved in the distal direction with respect to the cartridge by the piston rod. Due to the moving piston, a dose of medical product may be delivered from the cartridge. Piston rod 30 may be threadedly engaged with a (lead screw) nut 35. During operation of the device, nut 35 is secured against rotational movement with respect to the housing 10 by lock nut 36 (cf. FIGS. 2 and 4) which may engage nut 35. Accordingly the piston rod may rotate and translate with respect to the housing when driven in the distal direction. Lock nut 36 and nut 35 may be held in engagement while cartridge retaining member 45 is secured to the housing 10. When the cartridge retaining member is released from the housing 10, nut 35 and lock nut 36 may disengage thereby allowing for rotation of the nut 35 with respect to housing 10. In order to reset the device, e.g. before securing a new and unused cartridge to the housing, piston rod 30 can then be screwed back into its initial position without such a movement being prevented due to engagement of nut 35 and lock nut 36. Thus, resetting of the device is facilitated.

Furthermore, the piston rod 30 is expediently connected to a drive mechanism (not explicitly shown), e.g. a mechanical or electrical drive mechanism, and to a dose setting mechanism (not explicitly shown). Drive mechanism and dose setting mechanism are configured to set a dose of the medical product and to move the piston in the distal direc-

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tion such that the set dose is dispensed from the cartridge when a dispense button 40 of the drug delivery device is pressed.

When the cartridge 15 has been inserted into the cartridge retaining member 45 and the cartridge retaining member 45 has been secured to the housing, movement of the cartridge 15 in the distal direction is prevented by the cartridge retaining member 45. The cartridge 15 may abut the cartridge retaining member distally.

On the proximal side of the cartridge 15, a spring washer 50 is arranged within the housing 10. Spring washer 50 exerts a force on the cartridge 15 in the distal direction and secures the cartridge 15 against movement with respect to the cartridge retaining member 45 and against movement with respect to the housing 10. The loaded spring washer may hold the cartridge and the cartridge retaining member in permanent abutment on the distal end side of the cartridge 15. As shown in FIG. 1, the spring washer 50 is arranged in abutment with the cartridge 15 on the side of the cartridge which faces the proximal end 65 of the housing 10. Furthermore, the spring washer 50 comprises an opening 55 so as to allow the piston rod 30 to pass through spring washer 50 and to drive delivery of the medical product from the cartridge 15.

The spring washer 50 is fixed to the housing 10 in order to allow for the force to be exerted on the cartridge 15. In order to allow easy manufacturing of the drug delivery device 5, a (threaded) sleeve member 60 can be provided. The spring washer may be fixed to the sleeve member 60, e.g. by fixing elements 52 of the spring washer. The fixing elements 52 may extend in the axial direction. The spring washer may be fixed to the sleeve member 60 on an outer surface of the sleeve member. The sleeve member is fixed to the housing. Spring washer 50 may be fixed to sleeve member 60 by a snap-fit, for example. Sleeve member 60 and/or spring washer 50 is expediently secured against rotational and/or axial movement with respect to the housing. Of course, axial movement of the spring washer 50 for loading the spring washer or during relaxing of the spring washer is allowed. However, the region(s) in which the spring washer 50 is fixed to the housing 10, e.g. fixing elements 52, preferably do not rotate and/or do not move axially during operation of the drug delivery device.

The spring washer 50 may be provided with one, or a plurality of positioning elements. The respective positioning element may serve for keeping the spring washer 50 in a determined orientation, preferably in a predetermined angular orientation, with respect to the housing 10. For example, the fixing elements 52 may serve as positioning elements. The respective positioning element may cooperate with the housing or an element axially and rotationally locked to the housing for keeping the spring washer 50 in the predetermined orientation.

The respective positioning element/fixing element may be oriented axially. The respective positioning element/fixing element may extend from the outer circumference of the spring washer. Two positioning elements/fixing elements may be oppositely disposed. For example, the positioning elements/fixing elements may be arranged and/or axially guided within a respective guide slot (not explicitly shown). The guide slot may be axially and/or rotationally secured to the housing. The guide slot may be axially limited, preferably distally and/or proximally, such that axial movement of the spring washer 50 with respect to the housing 10 may be restricted. The guide slot in cooperation with the positioning elements/fixing element which runs in the slot may rotationally lock the spring washer 50 with respect to the housing 10.

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Embodying a helical pressure spring to be rotationally locked with respect to a housing would be considerable more difficult than it is for a spring washer, as the helical spring is usually considerably deformed, in particular in the angular direction, under the influence of an external force. The spring washer may keep its shape in the angular direction even under the influence of considerable forces. Provision of a drug delivery device with accurately aligned parts is facilitated when applying a spring washer which is provided with according positioning elements/fixing elements.

The cartridge retaining member 45 can be secured to the housing 10 via a threaded connection provided between sleeve member 60 and cartridge retaining member 45. Sleeve member 60 is preferably provided with an inner thread for this purpose.

Exerting a force on the cartridge 15 in the distal direction can be performed by loading the spring washer 50 in the proximal direction when the cartridge retaining member 45 with the cartridge is mounted to the housing 10, e.g. by screwing the cartridge retainer into sleeve member. Thus, when the cartridge moves into abutment with the spring washer 50 and spring washer 50 is moved further in the proximal direction together with the cartridge, the spring washer is loaded and exerts a force on the cartridge in the distal direction.

The drug delivery device 5 of the embodiment depicted in FIG. 1 eliminates axial movement of cartridge 15 with respect to the housing 10 and with respect to the cartridge retaining member 45. This is for example advantageous when cartridges 15 with different lengths are used in the drug delivery device 5. It is, for example, possible to compensate for length differences, which may result from manufacturing tolerances between different cartridges or which may be the properties of different cartridge types, e.g. between 0.2 and 2 mm, by applying a spring washer. Consequently, during operation of the drug delivery device 5 axial movement of the cartridge 15 in the cartridge retaining member 45 is prevented and precision of drug delivery is improved.

It should be noted that different configurations of the spring washer 50 regarding its position within the housing 10 can be used for preventing axial movement of the cartridge. For example it is also possible to fix the spring washer 50 to the cartridge retaining member 45 or directly to the housing 10.

In order to ensure that the spring washer is kept in the range of elastic deformation, a further washer 70 can be arranged on the proximal side of the spring washer 50. The further washer 70 can be a disk washer or a spring washer having a higher strength as compared to the spring washer 50.

The further washer 70 limits the movement of the spring washer 50 such that the spring washer 50 is not plastically deformed. Thus, the geometry of the relaxed, i.e. unloaded, spring washer 50 and, in particular, its spring strength remain constant. As shown in FIG. 1, the further washer can be shaped like a disk. It is, however, also conceivable that the further washer has a curvature corresponding to the one of the spring washer 50.

The spring washer may contain metal or may be of metal. The respective spring washer may be made of steel, for example. The spring washer 50 preferably has a spring constant D which is smaller than the spring constant D of the further spring washer 70.

Preferably, the further washer 70 is secured against rotational movement with respect to the housing 10. The further

washer does not have to be secured to the housing against axial movement. Rather, the spring washer **50** may limit distal movement of the further washer. An abutment element (not explicitly shown) may limit proximal movement of the further washer with respect to the housing. However, axial movement of the further washer **70** is expediently limited so as to allow the spring washer **50** to abut the further washer **70** and the further washer to abut the housing **10** before the spring washer is plastically deformed.

The embodiment of FIG. **1** is now further explained with reference to FIG. **2**. FIG. **2** is an exploded view of the drug delivery device **5** which shows several parts of the drug delivery device **5** in a side view before the parts are inserted into the housing **10**. In FIG. **2**, the (threaded) sleeve member **60** is shown which has holding means **62** for holding the spring washer **50**. The spring washer **50** has two fixing elements **52**, e.g. hook shaped, in order to fix the spring washer **50** to the sleeve member **60**, for example by the respective fixing element **52** interacting with the respective holding means **62**.

Furthermore, in FIG. **2** the (lead screw) nut **35** and the lock nut **36** are shown. The further washer **70** also includes fixing members **72**, for securing the further washer against rotational and/or axial movement with respect to the housing **10**. The elements shown in FIG. **2** fit into housing **10**. The sleeve member **60** may be laser welded to housing **10**, for example. As it is immediately apparent from FIG. **2**, the spring washer **50** allows securing the cartridge **15** with respect to the housing **10** and within the cartridge retainer without requiring too much space. In particular, spring washer **50** is a lot more space saving than a helical coil spring of equal spring strength. Consequently a very compact drug delivery device **5** can be formed.

With reference to FIG. **3** a further embodiment of the drug delivery device **5** is shown. FIG. **3** shows a detailed view of the spring washer **50** and the further washer **70**. As shown in FIG. **3**, the further washer **70** can be configured as a disk shaped washer.

Making now reference to FIG. **4** a further embodiment is shown. According to this embodiment the further washer **70** is also formed as a spring washer. The further washer **70** is curved in an axial and/or radial direction in a way that corresponds to or resembles the curvature of the spring washer **50**.

In FIG. **5** a detailed view of spring washer **50** is shown. The spring washer **50** is curved in axial and/or radial direction and includes fixing elements **52**. Fixing elements **52** may be arranged oppositely with respect to one another. The spring washer can be a Belleville type spring washer.

Making now reference to FIG. **6** the further washer **70** is shown in more detail. The further washer **70** is provided as a disk like washer with fixing members **72** arranged on two opposite sides.

A method of manufacturing the drug delivery device **5** includes the steps of providing a housing with a proximal end and a distal end, providing a cartridge adapted to accommodate a drug, providing a cartridge retaining member adapted to retain the cartridge, arranging a spring washer within the housing and securing the cartridge retaining member to the housing, thereby loading the spring washer so as to exert a force on the cartridge and to secure the cartridge against displacement, in particular against axial displacement, with respect to the cartridge retaining member.

Other implementations are within the scope of the following claims. Elements of different implementations may be combined to form implementations not specifically described herein.

The invention claimed is:

1. A drug delivery device comprising:

a housing with a proximal end and a distal end,
a cartridge adapted to accommodate a drug,
a cartridge retaining member adapted to retain the cartridge, the cartridge retaining member releasably secured to the housing, and
a spring washer arranged within the housing so as to exert a force on the cartridge and to secure the cartridge against movement with respect to the cartridge retaining member,
wherein the spring washer has at least two fixing elements configured to axially and rotationally fix the spring washer relative to the housing.

2. The drug delivery device according to claim **1**, wherein the spring washer is biased so as to exert the force on the cartridge in the distal direction.

3. The drug delivery device according to claim **1**, wherein the spring washer is secured against axial movement with respect to the housing.

4. The drug delivery device according to claim **1**, wherein the drug delivery device comprises a piston rod for dispensing a dose of the drug from the device when the piston rod is driven in the distal direction and wherein the spring washer comprises an opening, the opening being arranged so as to allow the piston rod to run through the opening.

5. The drug delivery device according to claim **1**, wherein the spring washer is curved in an axial [and/or radial] direction.

6. The drug delivery device according to claim **1**, wherein the spring washer is a Belleville type spring washer.

7. The drug delivery device according to claim **1**, wherein the spring washer is fixed to a threaded sleeve member of the housing.

8. The drug delivery device according to claim **1**, wherein the spring washer being fixed to the housing comprises the spring washer fixed to a threaded sleeve member of the housing and the threaded sleeve member fixed to the housing.

9. The drug delivery device according to claim **1**, wherein the at least two fixing elements comprise two oppositely disposed fixing elements which extend in the axial direction.

10. The drug delivery device according to claim **1**, wherein the at least two fixing elements are further configured as positioning elements, which keep the spring washer in a determined orientation.

11. The drug delivery device according to claim **1**, comprising a further washer, the further washer being arranged on the proximal side of the spring washer.

12. The drug delivery device according to claim **11**, wherein the further washer is a disk washer or a further spring washer having a higher strength as compared to the spring washer.

13. The drug delivery device according to claim **11**, wherein the further washer is arranged to limit the loading distance of the spring washer.

14. The drug delivery device according to claim **11**, wherein the further washer is arranged to limit deformation of the spring washer to elastic deformation.

15. The drug delivery device according to claim **11**, wherein the further washer is curved in an axial [and/or radial] direction so as to correspond to a curvature of the spring washer.

16. A method of manufacturing a drug delivery device comprising:

providing a housing with a proximal end and a distal end,
providing a cartridge adapted to accommodate a drug,

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providing a cartridge retaining member adapted to retain the cartridge and be releasably secured to the housing, arranging a spring washer within the housing and releasably securing the cartridge retaining member to the housing, thereby loading the spring washer so as to exert a force on the cartridge and to secure the cartridge against displacement with respect to the cartridge retaining member, 5
 wherein the spring washer has at least two fixing elements configured to axially and rotationally fix the spring washer relative to the housing. 10

17. *A drug delivery device comprising:*
a housing with a proximal end and a distal end,
a cartridge adapted to accommodate a drug,
a cartridge retaining member adapted to retain the cartridge, the cartridge retaining member is secured to the housing, and 15
a spring washer arranged within the housing so as to exert a force on the cartridge and to secure the cartridge against movement with respect to the cartridge retaining member,

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wherein the spring washer has at least two fixing elements configured to axially and rotationally fix the spring washer relative to the housing.

18. *A drug delivery device comprising:*
a housing with a proximal end and a distal end,
a cartridge configured to accommodate a drug,
a cartridge retaining member configured to accept and retain the cartridge, the cartridge retaining member is secured to the housing, and
a spring washer comprising at least two fixing elements configured to fix the spring washer from movement with respect to the housing, where the spring washer is positioned axially within the housing so as to exert a force on the cartridge to secure the cartridge against movement with respect to the cartridge retaining member, where the fixing elements allow axial loading of the spring washer when the cartridge retaining member is secured to the housing.

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : RE47,614 E
APPLICATION NO. : 14/934406
DATED : September 24, 2019
INVENTOR(S) : Michael Harms and Steffen Raab

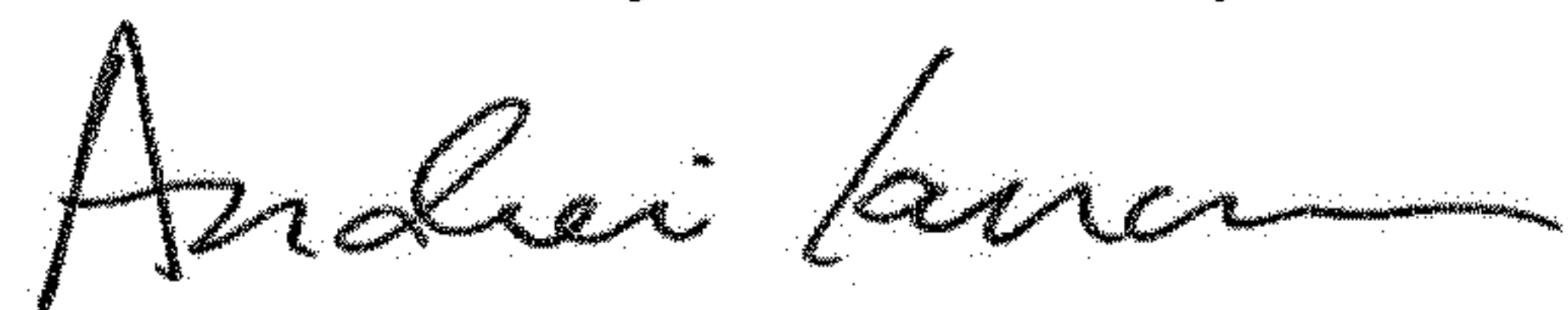
Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Item (57), Column 2, Line 2 under "ABSTRACT", before "method", delete "and"

Signed and Sealed this
Eleventh Day of February, 2020



Andrei Iancu
Director of the United States Patent and Trademark Office

(12) **INTER PARTES REVIEW CERTIFICATE** (3291st)

United States Patent
Harms et al.

(10) **Number:** **US RE47,614 K1**
(45) **Certificate Issued:** **Oct. 27, 2023**

(54) **DRUG DELIVERY DEVICE AND METHOD
OF MANUFACTURING A DRUG DELIVERY
DEVICE**

(71) Applicants: **Michael Harms; Steffen Raab**

(72) Inventors: **Michael Harms; Steffen Raab**

(73) Assignee: **SANOFI-AVENTIS
DEUTSCHLAND GMBH**

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The results of IPR2019-01657 are reflected in this inter partes review certificate under 35 U.S.C. 318(b).

INTER PARTES REVIEW CERTIFICATE
U.S. Patent RE47,614 K1
Trial No. IPR2019-01657
Certificate Issued Oct. 27, 2023

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AS A RESULT OF THE INTER PARTES
REVIEW PROCEEDING, IT HAS BEEN
DETERMINED THAT:

Claims **1-18** are found patentable.

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