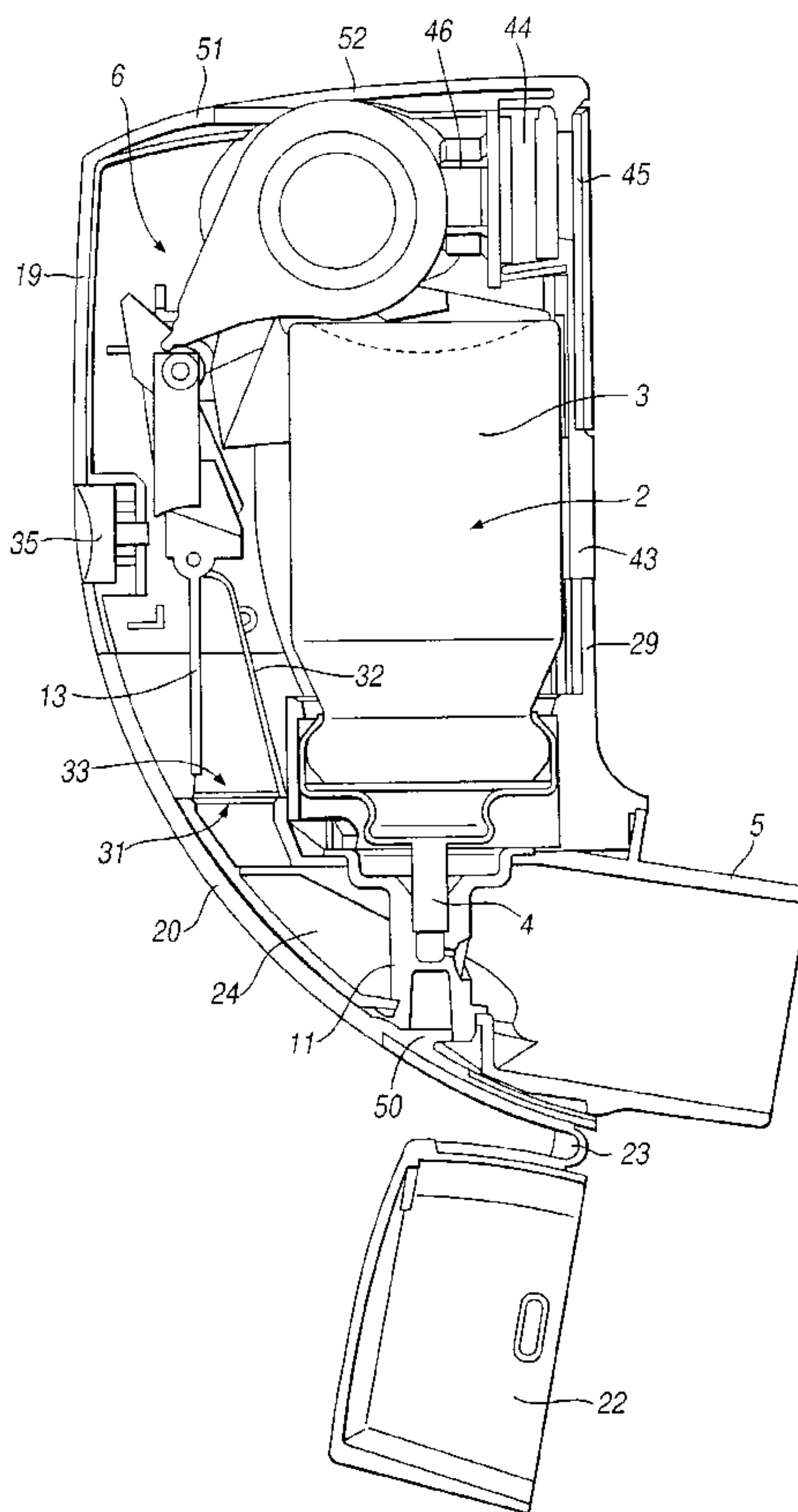




(86) Date de dépôt PCT/PCT Filing Date: 2001/03/16
 (87) Date publication PCT/PCT Publication Date: 2001/09/27
 (85) Entrée phase nationale/National Entry: 2002/08/29
 (86) N° demande PCT/PCT Application No.: SE 2001/000561
 (87) N° publication PCT/PCT Publication No.: 2001/070317
 (30) Priorité/Priority: 2000/03/18 (0006529.2) GB

(51) Cl.Int.⁷/Int.Cl.⁷ A61M 15/00
 (71) Demandeur/Applicant:
ASTRAZENECA AB, SE
 (72) Inventeurs/Inventors:
JANSEN, ROB, GB;
KNUDSEN, LARS, DK;
VILSTRUP, HENRIK, DK
 (74) Agent: FETHERSTONHAUGH & CO.

(54) Titre : INHALATEUR
 (54) Title: INHALER



(57) **Abrégé/Abstract:**

A breath-actuated inhaler for delivery of a medicament by inhalation from a canister (2) which is compressible to deliver a dose of medicament. The inhaler comprises a housing (1) for holding a canister (2) and including a mouthpiece (5) for delivery of a dose of medicament from a canister (2) held in the housing; and an actuation mechanism (6) for compressing a canister (2) held in the housing (1) in response to inhalation at the mouthpiece (5). The housing includes two separable portions (19, 20). The first

(57) **Abrégé(suite)/Abstract(continued):**

housing portion (19) mounts the actuation mechanism (6). The second housing portion (20) houses the mouthpiece (5) and a duct (24) shaped to direct an inhalation flow from the mouthpiece (5) to the first housing portion (19) for triggering the actuation mechanism (6). The duct (24) and the mouthpiece (5) are integrally formed and separable from the second housing portion (20).

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
27 September 2001 (27.09.2001)

PCT

(10) International Publication Number
WO 01/70317 A1(51) International Patent Classification⁷: **A61M 15/00**

(21) International Application Number: PCT/SE01/00561

(22) International Filing Date: 16 March 2001 (16.03.2001)

(25) Filing Language: English

(26) Publication Language: English

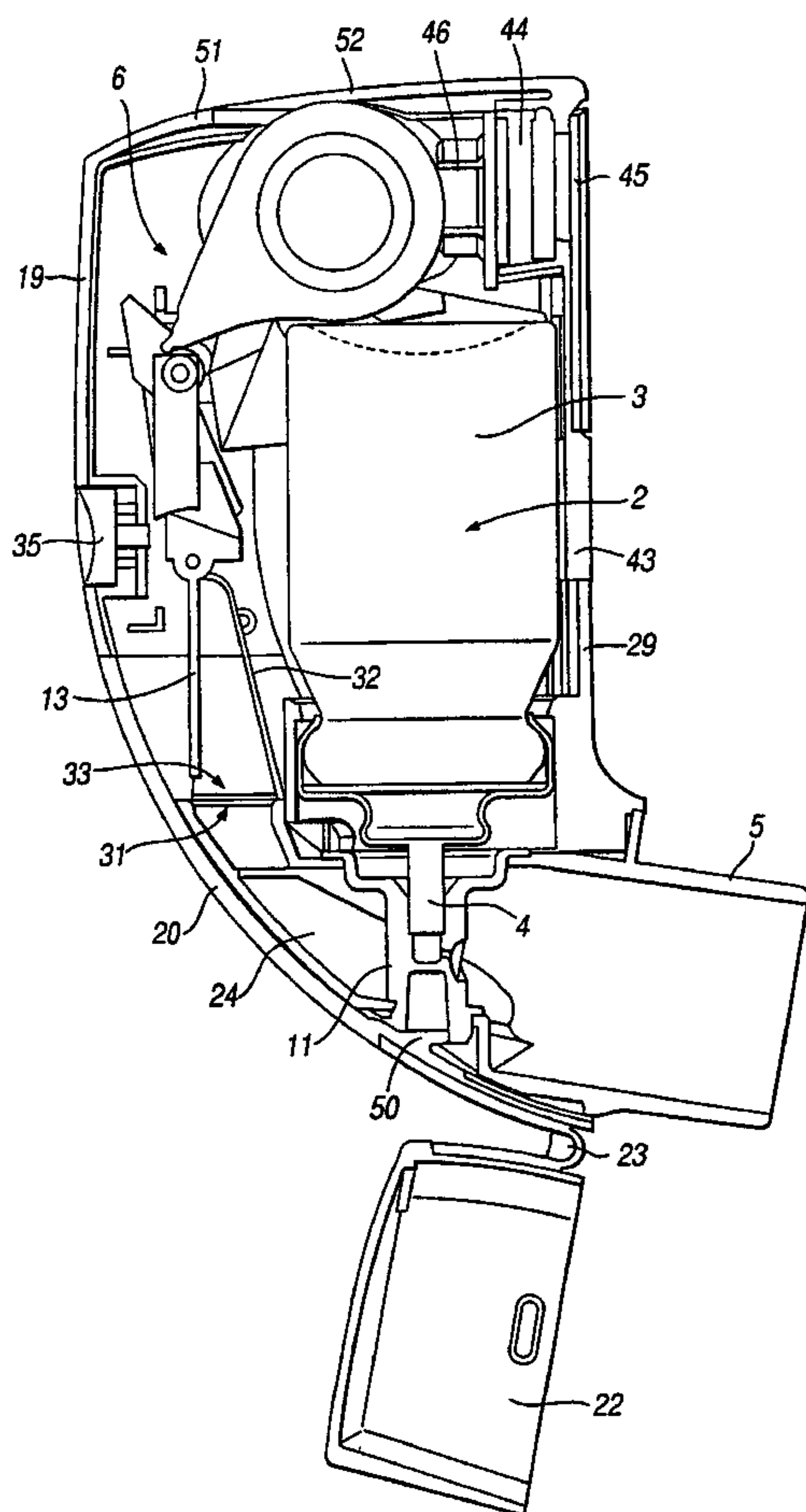
(30) Priority Data:
0006529.2 18 March 2000 (18.03.2000) GB(71) Applicant (for all designated States except US): **ASTRAZENECA AB** [SE/SE]; S-151 85 Södertälje (SE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **JANSEN, Rob** [GB/GB]; AstraZeneca R & D Charnwood, BakewellRoad, Loughborough, Leics. LE11 5RH (GB). **KNUDSEN, Lars** [DK/DK]; Bang & Olufsen Medicom a/s, Gimsinglundvej 20, DK-7600 Struer (DK). **VILSTRUP, Henrik** [DK/DK]; Bang & Olufsen Medicom a/s, Gimsinglundvej 20, DK-7600 Struer (DK).(74) Agent: **ASTRAZENECA AB**; Global Intellectual Property, S-151 85 Södertälje (SE).(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European

[Continued on next page]

(54) Title: INHALER



(57) Abstract: A breath-actuated inhaler for delivery of a medicament by inhalation from a canister (2) which is compressible to deliver a dose of medicament. The inhaler comprises a housing (1) for holding a canister (2) and including a mouthpiece (5) for delivery of a dose of medicament from a canister (2) held in the housing; and an actuation mechanism (6) for compressing a canister (2) held in the housing (1) in response to inhalation at the mouthpiece (5). The housing includes two separable portions (19, 20). The first housing portion (19) mounts the actuation mechanism (6). The second housing portion (20) houses the mouthpiece (5) and a duct (24) shaped to direct an inhalation flow from the mouthpiece (5) to the first housing portion (19) for triggering the actuation mechanism (6). The duct (24) and the mouthpiece (5) are integrally formed and separable from the second housing portion (20).

WO 01/70317 A1

-1-

INHALER

The present application relates to a breath-actuated inhaler for delivery of medicament from a canister.

Inhalers are commonly used to deliver a wide range of medicaments. The inhaler holds a canister of medicament which is actuatable, for example by compression, to deliver a dose of medicament. A very simple, known type of inhaler consists of a plastic shell including a mouthpiece and a nozzle block for holding the valve stem of the canister and directing medicament delivered from the canister out of the mouthpiece. The body of the canister is exposed to allow the user to actuate the canister by compressing the canister body against the shell of the inhaler. This type of inhaler is commonly known as a press-and-breathe inhaler.

The present invention relates to a inhaler provided with an actuation mechanism for actuating the canister. In particular, the mechanism is breath-actuated, ie. arranged to actuate the canister in response to inhalation at the mouthpiece. Typically a breath-actuated inhaler includes a loading mechanism for loading a resilient loading element with an actuation force for compression of the canister. A triggering mechanism may be provided to hold the resilient loading element against compression of the canister, the triggering mechanism releasing the resilient loading element upon inhalation.

Inhalers with an actuation mechanism may be designed to be reusable. An expired canister may be removed and replaced by a fresh canister. Consequently such a reusable inhaler will have a longer lifetime and higher usage than a simple press-and-breathe inhaler which is cheap and typically supplied new with each canister.

According to the present invention, there is provided a breath-actuated inhaler for delivery of a medicament by inhalation from a canister which is compressible to deliver a dose of medicament, the inhaler comprising:

a housing for holding a canister and including a mouthpiece for delivery of a dose of medicament from a canister held in the housing; and

an actuation mechanism for compressing a canister held in the housing in response to inhalation at the mouthpiece,

-2-

wherein the housing includes two separable portions, the first portion mounting the actuation mechanism and the second portion housing the mouthpiece and a duct shaped to direct an inhalation flow from the mouthpiece to the second portion for triggering the actuation mechanism.

5 The high usage of an inhaler having an actuation mechanism can cause a number of different problems. For example the duct may become dirty which is undesirable because of the risk of contamination when the user inhales. Similarly, the duct can become clogged up which is undesirable because it may restrict the inhalation flow required to actuate the inhaler and risk the mechanism failing to
10 operate upon inhalation. Another problem which can occur is that the mouthpiece becomes progressively damaged by the user's teeth when the mouthpiece is inserted in the mouth. However, the present invention allows the mouthpiece and/or duct to be replaced and/or removed for cleaning because the second portion holding these elements is separable from the first portion which mounts the actuation mechanism.

15 Preferably, the duct is separable from the second portion of the housing. This is particularly advantageous because it allows the duct to be replaced whilst retaining the second portion of the housing. This is advantageous because it minimises the number of parts which need to be replaced. Also, separation of the duct from the second portion of the housing facilitates cleaning of the duct.

20 Advantageously, the duct and the mouthpiece are an integrally formed. This allows the duct and mouthpiece to be replaced together. For example, the integral duct and mouthpiece may be supplied with each new canister.

 The present invention is advantageously applied to an inhaler wherein the first portion of the housing has a flow inlet for receiving said inhalation flow and the
25 duct is shaped to direct the inhalation flow to the flow inlet.

 Desirably, the actuation mechanism includes a vane responsive to said inhalation flow for triggering the actuation mechanism and the first portion of the housing houses a further duct shaped to direct inhalation flow from the flow inlet to the vane. Thus the duct housed in the second portion of the housing and the further
30 duct together define a composite duct from the mouthpiece to the vane. This allows the inhalation flow to be controlled by the shape of the duct which is important to

-3-

allow proper operation of the actuation mechanism.

To allow better understanding, an inhaler which embodies the present invention will now be described by way of non-limitative example with reference to the accompanying drawings, in which:

5 Fig. 1 is a side view of the inhaler;

Fig. 2 is a cross-sectional view of the inhaler illustrating the housing and duct;

Fig. 3 is a side view of the duct;

Fig. 4 is a side view of the canister and duct assembled together;

10 Fig. 5 is an exploded view of the canister, collar and duct;

Fig. 6 is a cross-sectional view of the canister and duct assembled together;

Fig. 7 is a view from the side and rear of the actuation mechanism;

Fig. 8 is a view from the rear of the spindle;

15 Fig. 9 is a view from the side, rear and above showing the arrangement of the resilient loading element;

Fig. 10 is a schematic view of the cam surfaces formed on the spindle;

Fig. 11 is a view from the side and rear of the triggering mechanism;

Fig. 12 is a side view of the triggering mechanism;

Fig. 13 is a side view of the locking mechanism;

20 Fig. 14A to 14F are graphs showing the angular positions of the elements of the actuation mechanism during its operation sequence; and

Figs. 15 to 22 are views of the actuation mechanism in various states during its operation sequence with views from opposite sides being suffixed by the letters A, B respectively.

25 As illustrated in Fig. 1, the inhaler has a housing 1 comprising an upper portion 19 and a lower portion 20. As illustrated in the cross-sectional view of Fig. 2, the upper housing portion 19 is a hollow shell which holds a canister 2 of medicament having a generally cylindrical body 3 held with its axis in a predetermined direction, vertical in Fig. 2. The upper housing portion 19 houses an
30 actuation mechanism for actuating the canister 2 which will be described in more detail below.

-4-

The interior of the upper housing portion 19 is open to the atmosphere by means of air inlets 51 formed in the upper wall 52 of the upper housing portion 19. The location of the air inlets 51 minimises occlusion by the users hand which will normally grip the sides of the housing 1 and not cover the upper wall 52.

5 The canister 2 is compressible to deliver a dose of medicament. In particular the canister 2 has a valve stem 4 which is compressible relative to the body 3 to deliver a dose of medicament from the valve stem 4. The canister is of a known type including a metering chamber which captures a defined volume the medicament from the body 3 of the canister 2. This volume of medicament is delivered as a
10 metered dose from the valve stem 4 on compression of the valve stem 4 relative to the body 3. The valve stem 4 is weakly biased outwardly by an internal valve spring (not shown) to reset the canister 2 after compression for refilling the metering chamber.

The lower housing portion 20 is a hollow shell connected to the upper
15 housing portion 19 by a sliding joint (not shown) which allows the lower portion 20 to be separated in the direction of the arrow in Fig. 1 by the user gripping textured surfaces 21 formed on the upper and lower housing portions 19 and 20. A cap 22 is hinged to the lower housing portion 20 by a flexible joint 23 to cover and uncover a mouthpiece 5 protruding from the lower housing portion 20.

20 As shown in Fig. 2, the lower housing portion 20 houses a duct 24 which is integrally formed with the mouthpiece 5, as illustrated in isolation in Fig. 3.

The duct 24 is assembled with a canister 2 as shown in Figs. 4 to 6. The duct 24 receives a nozzle block 11 in an opening 25. The valve stem 4 of the canister is received in the nozzle block 11 which is arranged to direct a dose of medicament
25 delivered from the valve stem 4 out of the inhaler through the mouthpiece 5. The duct 24 and nozzle block 11 are separately formed. This allows each to be manufactured and subsequently assembled. This produces manufacturing and logistical savings because it facilitates different nozzle block designs being incorporated with a single duct design and vice versa.

30 A collar 26 is permanently connected to the canister 2. The collar 26 includes an annular retaining ring 27 permanently fitted around a necked portion 28

-5-

of the canister body 3. The retaining portion 27 prevents removal of the collar 26 from the canister such that the collar 26 is removed and replaced together with the canister 2. However, the retaining portion 27 and the canister 2 have a small degree of relative movement along the axis of the canister 5 to allow compression of the canister body 2 towards the valve stem 4.

The collar 26 further includes a front panel 29 integrally formed with the retaining ring 27. When the canister 2 is inserted in the housing 1, the front panel 29 of the collar 26 closes an opening formed between the upper housing portion 19 and the lower portion 20 and therefore forms a part of the outer wall of the housing 1. Accordingly, the presence or absence of the front panel 29 provides a visual indication to the user of whether or not a canister 2 has been inserted in the canister, because the collar 26 is permanently connected to the canister 2.

A pair of catch arms 30 integrally formed with the front panel 29 of the sides of the collar 26 catch the interior surface of the upper housing portion 19 to hold the collar 26 and the canister 2 in the upper housing portion 19.

The lower housing portion 20 has a stud 50 which locates the end of the nozzle block 11 as shown in Fig. 2 to hold the lower housing portion 20 and the duct 24 in place relative to one another. However, the lower housing portion 20 is not retained on the duct 24, so may be removed from the upper housing portion 19 leaving the canister 2 inserted in the upper housing portion 19 and the duct 24 held on the canister 2 by the valve stem 4 being inserted in the nozzle block 11. The duct 24 and nozzle block 11 may subsequently be slid off the valve stem 4 for cleaning or replacement. The canister 2 and collar 26 may be slid out from the upper housing portion 19 after depression of the catch arms 30. Subsequently a replacement canister 2 and collar 26 may be inserted.

Typically a new duct 24 and nozzle block 11 will be provided to the user with each new canister 2 so that the duct 24 and mouthpiece 5 are regularly replaced to prevent damage or dirt building up over time. The duct 24 has an opening 31 at its end opposite from the mouthpiece 5.

As shown in Fig. 2, the upper housing portion 19 holds a flap duct 32 which extends from a flow inlet 33 to a flap 13 which forms part of the triggering

-6-

mechanism for the actuation mechanism as described in detail below. Therefore the duct 24 housed in the lower housing portion 19 and the flap duct 32 together define a composite duct shaped to direct the inhalation flow from the mouthpiece 5 to the flap 13. The composite duct formed by the duct 24 and the flap duct 32 is shaped to control the flow to the flap 13 to provide appropriate flow characteristics for proper operation of the flap 13.

The inhaler is further provided with an actuation mechanism 6. To assist understanding, a general description of the overall structure and operation of the actuation mechanism 6 will first be given.

10 An actuation force for compressing the canister 2 is stored in a resilient loading element in the form of a torsion spring 7. To load the torsion spring 7, the actuation mechanism 6 includes a loading mechanism consisting of a loading member in the form of a rotatable spindle 8 and two contact members in the form of buttons 9 which protrude from the housing as shown in Fig. 1. Depression of the
15 buttons 9 towards one another, relative to the housing 1, drives the loading member 8 to load the torsion spring 7 through a cam arrangement between the buttons 9 and spindle 8.

The torsion spring 7 biases compression of the canister 2 by engaging a canister engagement member in the form of a lever 10 which depresses the body 3 of
20 the canister towards the stem 4 held in the nozzle block 11.

To allow storage of the actuation force in the torsion spring 7 after loading, the actuation mechanism 6 includes a triggering mechanism. This includes a locking lever 12 which holds the canister engagement lever 10 against compression of the canister 2. To release the canister engagement lever 10, the triggering mechanism
25 further includes a vane in the form of a flap 13 which in a rest state holds the locking lever 12 in place. Inhalation at the mouthpiece 5 moves the flap 13 to release the locking member 12. This in turn releases the canister engagement lever 10 allowing the torsion spring 7 to drive compression of the canister 2.

The actuation mechanism 6 further includes a locking mechanism which
30 locks the spindle 8 after loading of the torsion spring 7, thereby holding the torsion spring 7 in its loaded state before triggering and locking the canister in its

-7-

compressed state after triggering.

The locking mechanism includes a catch 14 which, in a locking position, catches the spindle 8 and holds the torsion spring 7 in its loaded state. The locking mechanism further includes an intermediate member 15. A resilient biasing element
5 in the form of a spring 16 is provided between the catch 14 and the intermediate member 15 to bias the catch 14 towards its locking position. The spring 16 allows deflection of the catch 14 by the spindle 8 during loading of the torsion spring 7.

Prior to inhalation the intermediate member 15 is held in place by the canister engagement lever 10. Upon inhalation at the mouthpiece 5, the flap 13
10 engages the intermediate member 15 to hold it in place. After compression by the canister engagement lever 10, the canister 2 is locked in its compressed state by the catch 14 of the locking mechanism holding the spindle 8 in place.

When the level of inhalation at the mouthpiece falls below a predetermined threshold, the flap 13 releases the intermediate member 15 to unload the biasing
15 element 16 which in turn allows the catch 14 to release the spindle 8. After release by the catch 14, the spindle 8, torsion spring 7 and canister engagement lever 10 move upwardly and the canister resets.

Now there will be given a detailed description of the actuation mechanism 6, the entirety of which is illustrated in Fig. 7 and parts of which are illustrated in Figs.
20 8 to 13.

The loading mechanism is illustrated in Fig. 8 and consists of a rotatable spindle 8 and two contact members in the forms of buttons 9 at both ends. The spindle 8 is rotatably mounted in the upper housing portion 19 about an axis orthogonal to the axis of the cylindrical body 3 of the canister 2. The spindle 8 has a
25 pair of cam surfaces 8a disposed on opposite sides of the rotational axis of the spindle 8. The buttons 9 are mounted in the housing to be movable in a movement direction parallel to the rotational axis of the spindle 8. The buttons 9 each have a pair of inwardly projecting cam followers 9a which each engage a respective cam surface 8a of the spindle 8. The cam arrangement of the cam surfaces 8a and the cam
30 followers 9a between the spindle 8 and the buttons 9 causes depression of the buttons 9 to drive rotation of the spindle 8.

-8-

As illustrated in Fig. 9, the torsion spring 7 which forms the resilient loading element is disposed with its coils 7a encircling a central cylindrical surface 8b of the spindle 8. A catch arm 8c protrudes radially from the spindle 8. A first leg 7b of the torsion spring 7 is restrained by the catch arm 8c so that the movement of the spindle 8 driven by the buttons 9 loads the torsion spring 7.

As illustrated schematically in Fig 10, the cam surfaces 8a have a non-linear shape which causes the gearing ratio of the amount of driven movement of the spindle 8 to the amount of movement of the buttons 9 to be a non-linear function of the rotational position of the spindle 8. The major portion 8b of each cam surface 8a is shaped with increasing pitch to compensate for the increased reactive loading force applied by the torsion spring 7 to the spindle 8 as the buttons 9 are depressed. In particular, they are shaped such that the necessary force applied to the buttons is substantially constant so the user feels a linear resistance. As the torsion spring 7 has a linear spring constant, this is achieved by shaping the major portion 8b of each cam surface 8a such that the gearing ratio is inversely proportion to the rotational position of the spindle 8.

Optionally, the outermost portion of the cam surfaces 8a which are contacted by the cam followers 9a during the initial portion of the driven movement of the spindle may have a decreased pitch, for example as illustrated by the dotted lines 8e. This is to reduce the gearing ratio relative to the subsequent major portion 8b. In this way the user initially feels a low resistance to movement of the buttons 9. This improves the feel perceived by the user and also assists the user in applying force.

Another option is to provide the final portion of the cam surface 8a with a detent, for example as illustrated by the dotted lines 8d. When the end of the cam followers 9a reach the detent 8d, the cam surface 8a of the spindle 8 no longer exerts a force urging the buttons outwardly on the buttons 9. At this position the detent 8d is urged by the torsion spring 7 against the side of the cam followers 9a and therefore holds the buttons 9 in their innermost position. This prevents the buttons 9 from loosely sliding back and forth after the torsion spring 7 has been loaded.

As shown in Fig. 9, the torsion spring 7 engages a canister engagement lever

-9-

10 which is pivotally mounted to the interior of the housing about an axis 10a. The
canister engagement lever 10 is generally U-shaped with two parallel sides 10b
connected by a cross piece 10c. A bar 10d extending between the two sides 10b
bears on the body 5 of the canister 2. A mount 10e formed on the cross-piece 10c is
5 engaged by the second leg 7c of the torsion spring 7, whereby loading of the torsion
spring 7 biases the lever 10 to compress the canister 2. The canister engagement
lever 10 is biased upwardly by a reset spring (not shown), which may be arranged as
a torsion spring on the axis 10a, but this is weaker than the torsion spring 7.

The torsion spring 7, spindle 8 and canister engagement lever 10 are all
10 rotatable about axis orthogonal to the cylindrical axis of the body 5 of the canister 2.
This provides a simple and reliable loading mechanism particularly because of the
arrangement of the torsion spring 7 with its coils 7a encircling the spindle 8. Some
or all of these elements could alternatively be linearly movable in a plane parallel to
the cylindrical axis of the body 5 of the canister 2 to achieve a loading mechanism
15 which is equally simple to construct. However rotatable elements are preferred from
the point of view of reliability in repeated use of the actuation mechanism 6.

On the other hand, the movement of the buttons in a direction orthogonal to
the cylinder axis of the body 3 of the canister 2 assists the user in application of force
to the loading mechanism. As typical for inhalers, the housing 1 extends in the
20 direction of the cylindrical axis of the body 3 of the canister 2, so may be easily held
in the palm of a hand with the buttons 9 protruding from either side. Thus the
buttons 9 are easily depressed between a finger and thumb. Alternatively a single
button could be provided allowing loading in a similar manner by the user pressing
the button and the housing on the opposite side to the button. Either configuration
25 also allows loading by laying the inhaler on a surface and applying force for example
with the palm of a hand. This facilitates loading by a user with limited finger control
or movement, for example a chronic arthritis sufferer.

The actuation member mechanism 6 includes a triggering mechanism as
illustrated in Figs. 11 and 12 which allows storage of the actuation force in the
30 torsion spring 7 after loading.

The triggering mechanism includes a locking lever 12 which is pivotably

-10-

mounted on an axle 17 extending across the interior of the housing 1. The locking lever 12 has a notch 12a adjacent the axle 17. In a reset state shown in Fig. 12, the notch 12a holds a protrusion 10f protruding from the cross-piece 10c of the canister engagement lever 10, thereby holding the lever 10 against compression of the
5 canister 2. The locking lever 12 is weakly biased towards the position shown in Figs. 11 and 12 by a reset spring 34 arranged as a torsion spring on the axle 17.

The triggering mechanism further includes a vane in the form of a flap 13 which is rotatably mounted on an axle 18 extending across the interior of the housing 1. The flap 13 biased by a reset spring (not shown), which may be arranged as a
10 torsion spring on the axle 18, towards the position shown in Fig. 12. The flap 13 has a locking lever engagement surface 13a which protrudes from a block 13b positioned above the axle 18. In the position shown in Fig. 12, the engagement surface 13a engages a contact surface 12b formed on the end of the locking lever 12 distal from the axle 17 to hold the locking lever 12 in place holding the canister engagement
15 lever 10.

The flap 13 is disposed in the composite duct formed by the duct 24 and the flap duct 32 extending from the mouthpiece 5 with a flap portion 13c extending across the composite duct at the opposite end from the mouthpiece 5, where the duct opens into the interior of the housing 1. Therefore, the flap 13 is responsive to
20 inhalation at the mouthpiece 5.

Inhalation of the mouthpiece draws the flap portion 13c into the flap duct 32 (clockwise in Fig. 2 and anticlockwise in Fig. 12). Such rotation of the flap 13 allows the locking lever engagement surface 13a to move out of contact with the contact surface 12b of the locking lever 12.

25 The upper housing portion 19 also mounts a button 35 disposed adjacent the flap 13 above the axle 18 so that depression of the button 35 rotates the flap 13 in the same direction as inhalation at the mouthpiece 5. Therefore, the button 35 allows the actuation mechanism 6 to be manually released without inhalation at the mouthpiece 5, for example to allow actuation of the canister 2 for testing.

30 When the canister engagement lever 10 is loaded by the torsion spring 7, release of the locking lever 12 by the flap 13 allows the canister engagement lever 10

-11-

to be driven to compress the canister 2. The protrusion 10f deflects the locking lever 12 (anticlockwise in Fig. 12) as the canister engagement lever 10 passes.

As illustrated in Fig. 13, the actuation mechanism 6 further includes a locking mechanism for locking the spindle 8 after loading of the torsion spring 7.

5 The locking mechanism comprises a catch 14 and an intermediate member 15 which are both pivotally mounted on the axle 17, adjacent the locking lever 12. Before compression of the canister 2, the intermediate member 15 is held in the position illustrated in Fig. 13 by the cross-piece 10c of the canister engagement lever 10 contacting a first contact surface 15a adjacent the axle 17. A resilient biasing
10 element in the form of a torsion spring 16 is connected between the catch 14 and the intermediate member 15 and loaded to bias the catch 14 towards its locking position shown in Fig. 13.

The catch 14 has a notch 14a adjacent the axle 17 for engaging the arm 8c of the spindle 8 after rotation to the position illustrated in Fig. 13 where the torsion
15 spring 7 is loaded. In this position, the loading provided by the spring 16 prevents release of the spindle 8 and thereby holds the torsion spring 7 in its loaded state. Before loading, the arm 8c of the spindle 8 is positioned above the end 14b of the catch 14 distal from the axle 17. When the spindle 8 is driven downwards by depression of the buttons 9, the arm 8c of the spindle engages the end 14b of the
20 catch 14 and deflects the catch 14 by compressing the spring 16 to allow passage of the arm 8c of the spindle 8.

The flap 13 further includes a stud 13d protruding from the block 13b on the opposite side of the axle 18 from the locking lever engagement surface 13a. Upon inhalation at the mouthpiece 5, the flap 13 moves to the position illustrated in Fig. 13
25 where the stud 13d engages a second contact surface 15b of the intermediate member 15 distal from the axle 17. Prior to this point, the stud 13d does not contact the second contact surface 15b but the intermediate member 15 has been held in place by the canister engagement lever 10. Movement of the flap 13 triggers the triggering mechanism to release the canister engagement member 10 which moves downwards
30 out of contact with the intermediate member 15. However, the stud 13d catches the contact surface 15b and so continues to hold the intermediate member 15 with the

-12-

spring 16 loaded. Accordingly, the catch 14 remains in its locking position locking the spindle 8 by engagement of the arm 8c of the spindle 8 in the notch 14a of the catch 14.

Subsequently, when the level of inhalation of the mouthpiece falls below a predetermined threshold, the flap moves out of contact with the intermediate member 15 (clockwise in Fig. 13). The level of the predetermined threshold at which the flap 13 releases the intermediate member 15 is controlled by the shape of the second contact surface 15b of the intermediate member 15.

After release by the flap 13, the intermediate member 15 is driven by spring 16 which unloads (clockwise in Fig. 13). Such unloading of the spring 16 reduces the force by which the catch 14 is biased towards its locking position. Accordingly, the force of the torsion spring 7 acting on the canister engagement lever 10 is sufficient to force the catch arm 8c of the spindle 8 out of the notch 14a. Accordingly, the spindle 8, the torsion spring 7 and canister engagement lever 10 are able to move upwardly biased by the reset spring acting on the canister engagement lever 10, thereby allowing the canister to reset.

The sequence of operation of the actuation mechanism 6 will now be described with reference to Figs. 14 to 22. Fig. 14A to 14F are graphs showing the angular positions of the various elements of the actuation mechanism 6. In particular, Fig. 14A illustrates the angular position of the flap 13; Fig. 14B illustrates the angular position of the locking lever 12; Fig. 14C illustrates the angular position of the canister engagement lever 10; Fig. 14D illustrates the angular position of the intermediate member 15; Fig. 14E illustrates the angular position of the catch 14; and Fig. 14F illustrates the angular position of the spindle 8. Various states and positions of the actuation mechanism 6 are labelled by the letters A to R in Figs. 14 and Figs. 15 to 22 illustrate the actuation mechanism 6 in some of these states with the views from opposite sides being suffixed by the letters A and B, respectively.

The sequence commences in state A as shown in Figs. 15 in which the torsion spring 7 has been loaded by depression of the buttons 9 and the spindle 8 is locked by the catch 14. In state A, the canister engagement lever is 10 held by the locking lever 12. The inhaler may be stored with the actuation mechanism 6 in state

-13-

A.

At position B, the user starts to inhale. The flap 13, being responsive to such inhalation, starts to move. The shape of the contact surface 12b allows the locking lever 12 to start moving slowly. The actuation mechanism 6 is now in state
5 C illustrated in Figs. 16.

At position D, the locking lever engagement surface 13a of the flap 13 releases the contact surface 12b of the locking lever 12. Accordingly, the canister engagement member 10 under the loading of the torsion spring 7 starts to rotate downwards deflecting the locking lever 12 against its reset spring as the projection
10 10f moves out of the notch 12a. The actuation mechanism is now in state E illustrated in Figs. 17.

At position F, the canister engagement lever 10 moves out of contact with the first contact surface 15a at the intermediate member 15 which therefore starts to move under the biasing of spring 16. However, the intermediate member 15 only
15 moves a short way because at position G it is caught by the flap 13, in particular by the bar 13d of the flap 13 contacting the second contact surface 15b. This contact stops the movement of the flap 13 and the intermediate member 15.

The movement of the canister engagement lever 10 compresses the body 3 of the canister 2 relative to the stem 4 held in the nozzle block 11, thereby causing
20 the canister 2 to deliver a dose of medicament. The nozzle block 11 directs the dose of medicament out of the mouthpiece at which the user is inhaling. The actuation mechanism 6 is now in state H illustrated in Figs. 18.

When the level of inhalation starts to fall, at position I the flap 13 under the biasing of its reset spring starts to move back closing the duct. This movement of
25 the flap 13 causes the intermediate member 15 to move slightly due to the shape of the second contact surface 15b.

When the level of inhalation falls below the predetermined threshold, at position J the bar 13d of the flap 13 moves out of contact with the second contact surface 15b. This releases the intermediate member 15. Under the action of the
30 spring 16, the intermediate member 15 moves to unload the spring 16. The actuation mechanism 6 is now in state K illustrated in Figs. 19.

-14-

At position L the load on the catch 14 from the spring 16 reduces to the extent that the catch 15 can no longer hold the spindle 8. The force of the torsion spring 7 forces the arm 8c of the spindle 8 upwards and out of engagement with the notch 14a of the catch 14. This forces the catch 14 backwards. The actuation
5 mechanism 6 is now in state M illustrated in Figs. 20.

At position N, the torsion spring 7 reaches its neutral, unloaded position, so there is no load between the canister engagement lever 10 and the spindle 8. Thereafter the canister engagement lever 10 and the torsion spring 8 are moved under the action of the reset spring biasing the canister engagement lever 10.

10 At position O, the canister engagement lever 10 contacts the first contact surface 15a of the intermediate member 15 and forces it backwards. The actuation mechanism is now in state P illustrated in Figs. 21. This loads the spring 16 and pushes the catch 14 towards its locking position until the catch 14 contacts the arm 8c of the spindle 8 which has now passed out of the notch 14a.

15 At position Q, the projection 10f of the canister engagement lever 10 moves into the notch 12a of the locking lever 12 which snaps back into its locking position under the action of its reset spring. The actuation mechanism 6 is now in state R in Figs. 22. In state R, the canister is reset and ready to be compressed again for
20 delivery of the next dose, but the actuation mechanism 6 is relaxed with the torsion spring 7 unloaded. The rotation of the spindle 8 has forced the buttons 9 outwards to the position illustrated in Figs. 22. The actuation mechanism 6 is ready to be loaded once again by compression of the buttons 9. The user is instructed to do this immediately after inhalation, so that the canister may be stored in a state ready to be used simply by inhaling at the mouthpiece 5.

25 When the user depresses the buttons 9 at position S, this drives the spindle 8 downwards. The arm 8c of the spindle 8 deflects the catch 14 slightly against the loaded spring 16 until the arm 8c moves into the notch 14a. This allows the spring 16 to snap the catch 14 into its locking position.

-15-

CLAIMS

1. A breath-actuated inhaler for delivery of a medicament by inhalation from a canister which is compressible to deliver a dose of medicament, the
5 inhaler comprising:
- a housing for holding a canister and including a mouthpiece for delivery of a dose of medicament from a canister held in the housing; and
 - an actuation mechanism for compressing a canister held in the housing in response to inhalation at the mouthpiece,
- 10 wherein the housing includes two separable portions, the first portion mounting the actuation mechanism and the second portion housing the mouthpiece and a duct shaped to direct an inhalation flow from the mouthpiece to the second portion for triggering the actuation mechanism.
- 15 2. An inhaler according to claim 1, wherein the duct and the second portion of the housing are separately formed.
3. An inhaler according to claim 1 or 2, wherein the duct is separable from the second portion of the housing.
- 20 4. An inhaler according to any one of the preceding claims, wherein the duct and the mouthpiece are an integrally formed.
5. An inhaler according to any one of the preceding claims, wherein
25 the duct houses a nozzle block arranged to direct a dose of medicament delivered from a canister held in the inhaler out of the mouthpiece.
6. An inhaler according to claim 5, wherein the nozzle block and duct are separately formed.
- 30 7. An inhaler according to any one of the preceding claims, wherein

-16-

separation of the first and second portions of the housing allows replacement of the canister.

8. An inhaler according to any one of the preceding claims, wherein
5 the duct holds a nozzle block for holding the valve stem of the canister and directing medicament delivered from the canister out of the mouthpiece.

9. An inhaler according to any one of the preceding claims, wherein
the first portion of the housing has a flow inlet for receiving said inhalation flow and
10 the duct is shaped to direct the inhalation flow to the flow inlet.

10. An inhaler according to claim 9, wherein the actuation mechanism
includes a vane responsive to said inhalation flow for triggering the actuation
mechanism and the first portion of the housing houses a further duct shaped to direct
15 inhalation flow from the flow inlet to the vane.

11. An inhaler constructed and arranged to operate substantially as
hereinbefore described with reference to the accompanying drawings.

1/12

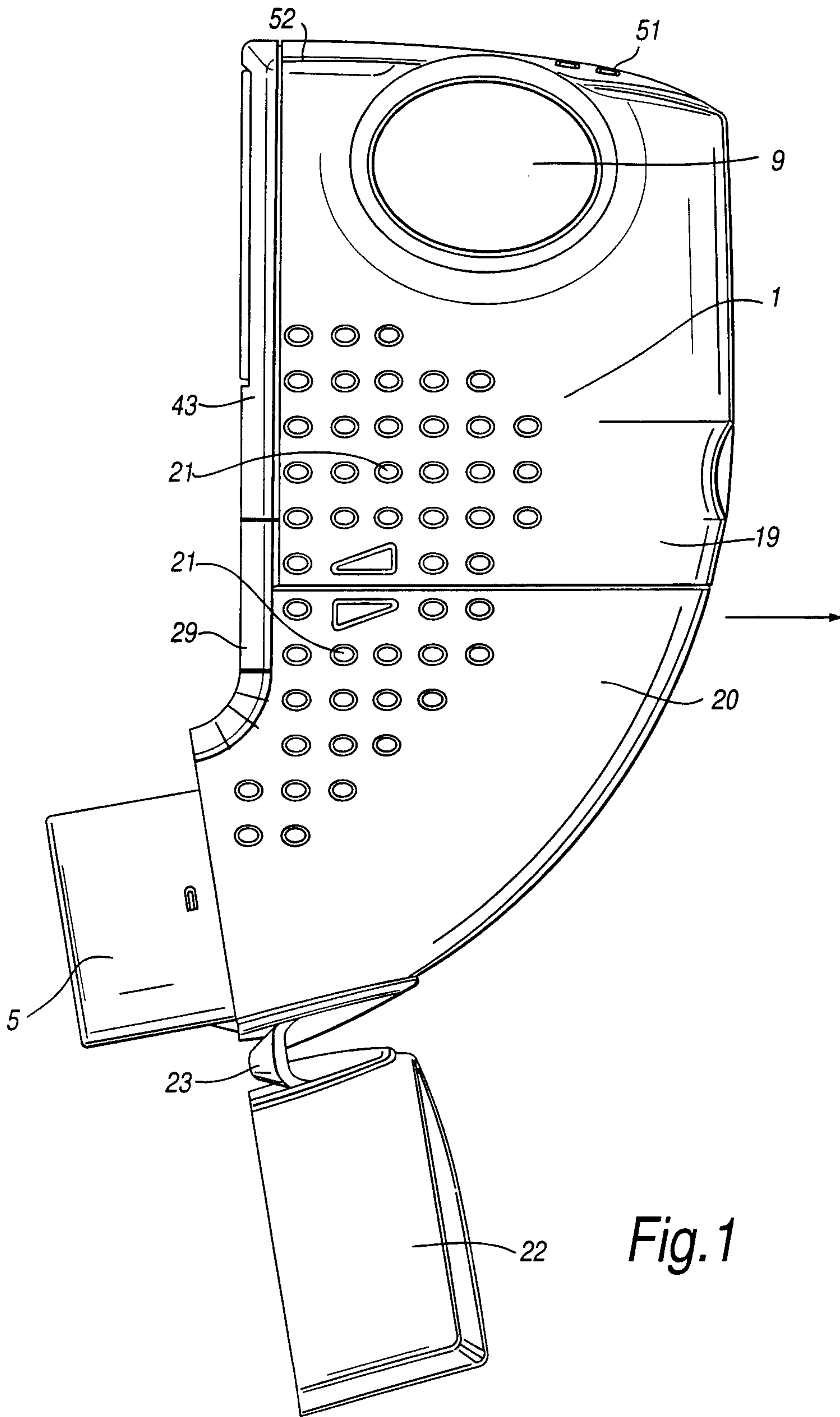
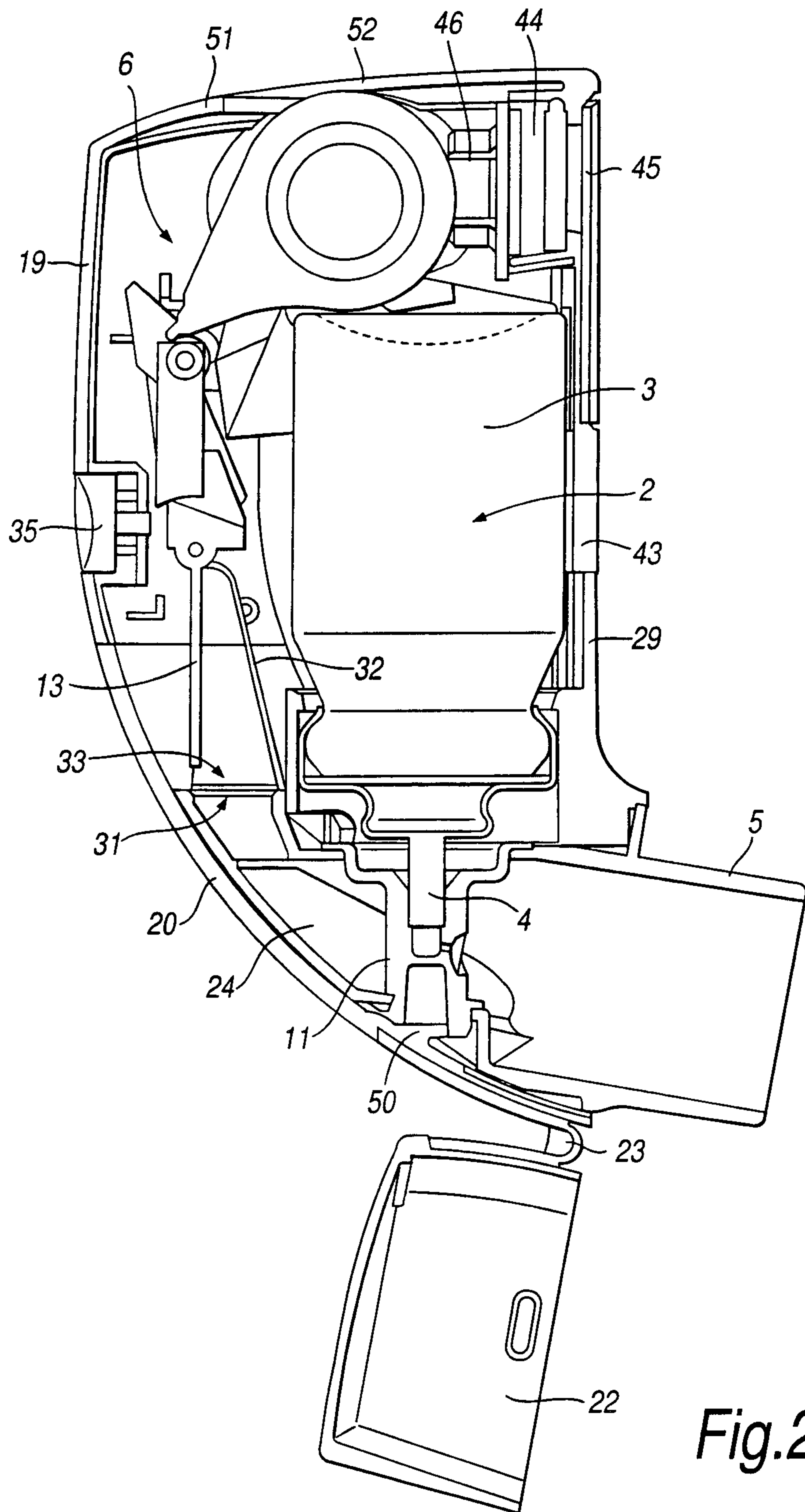


Fig. 1

2/12



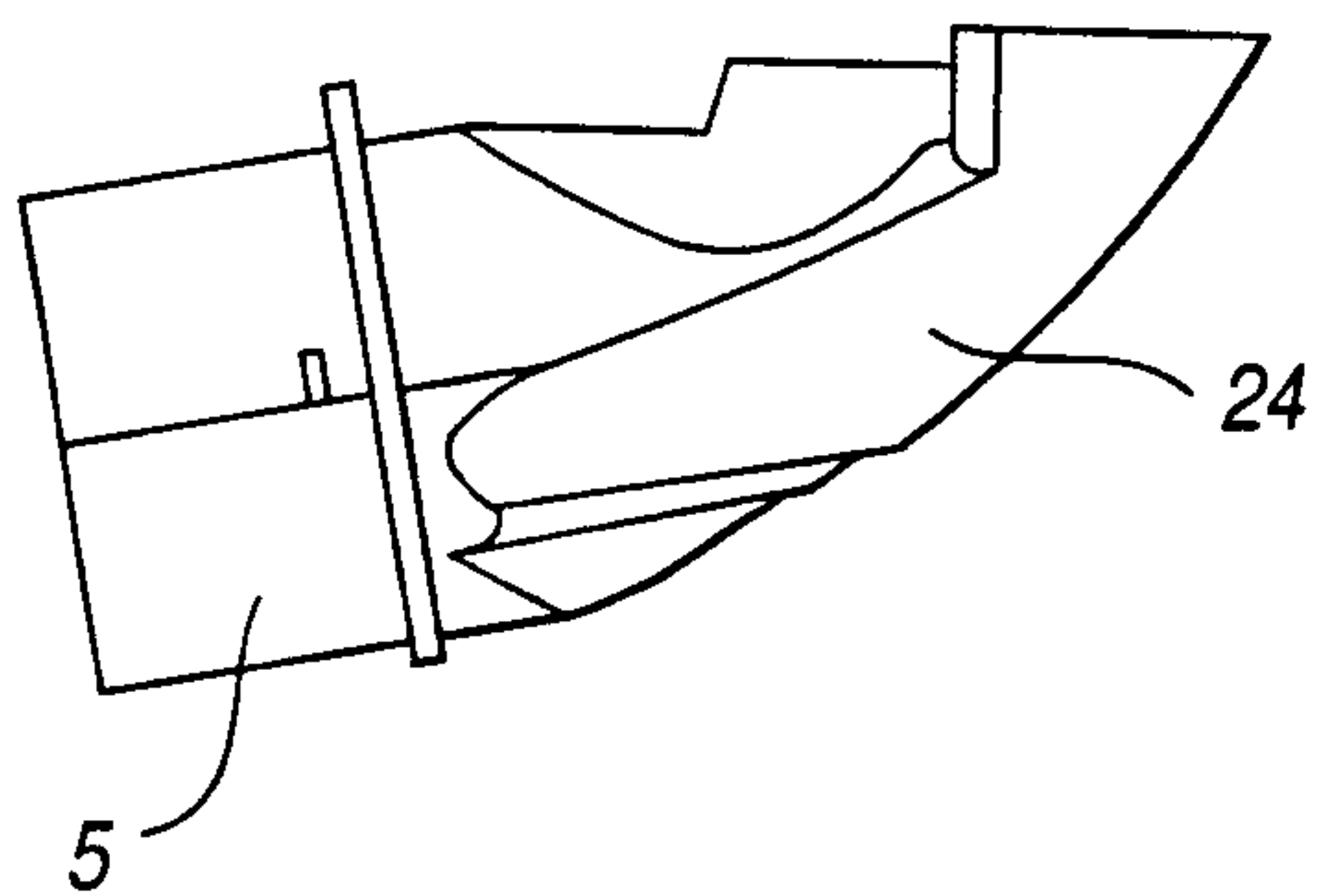


Fig.3

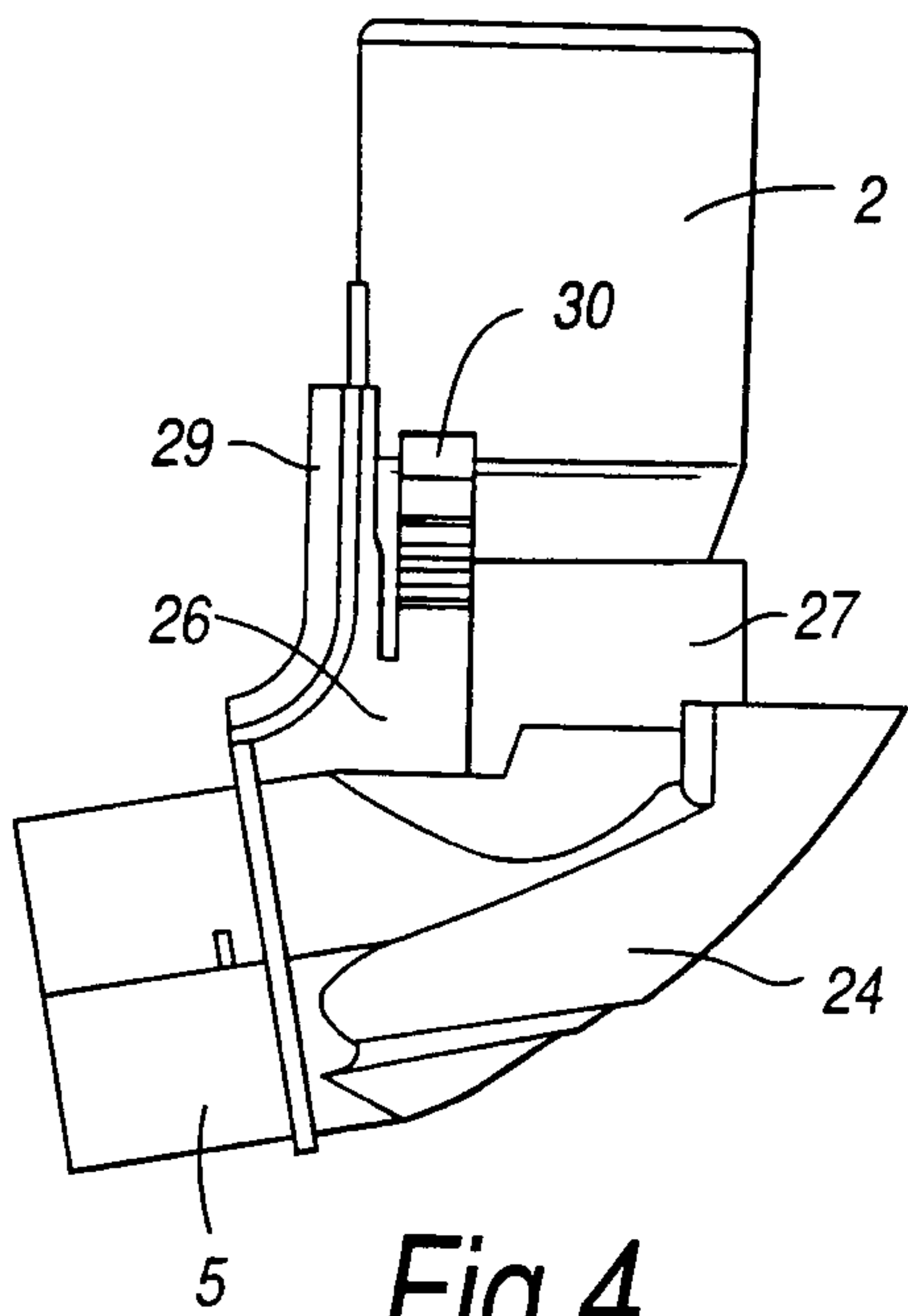
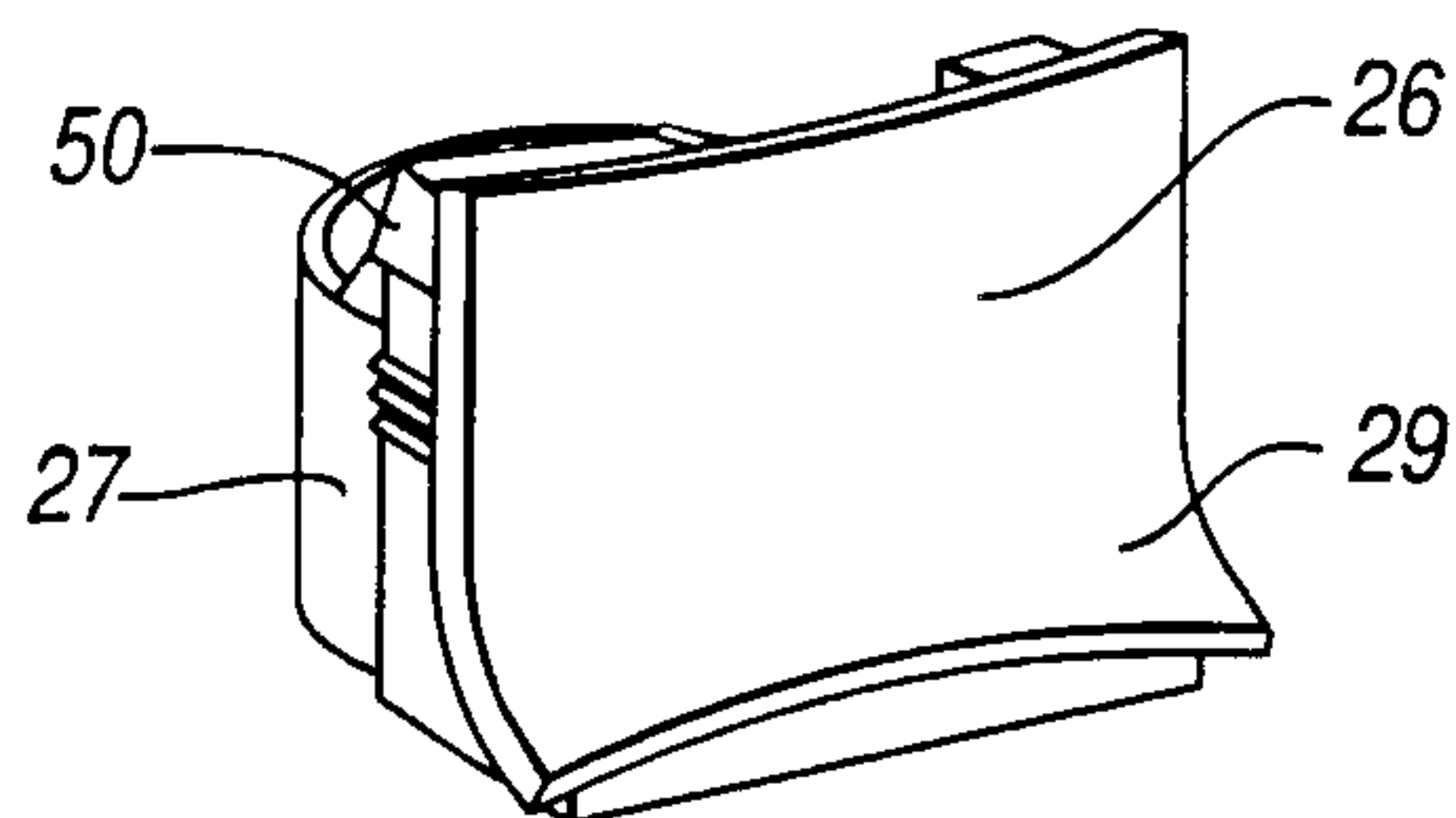
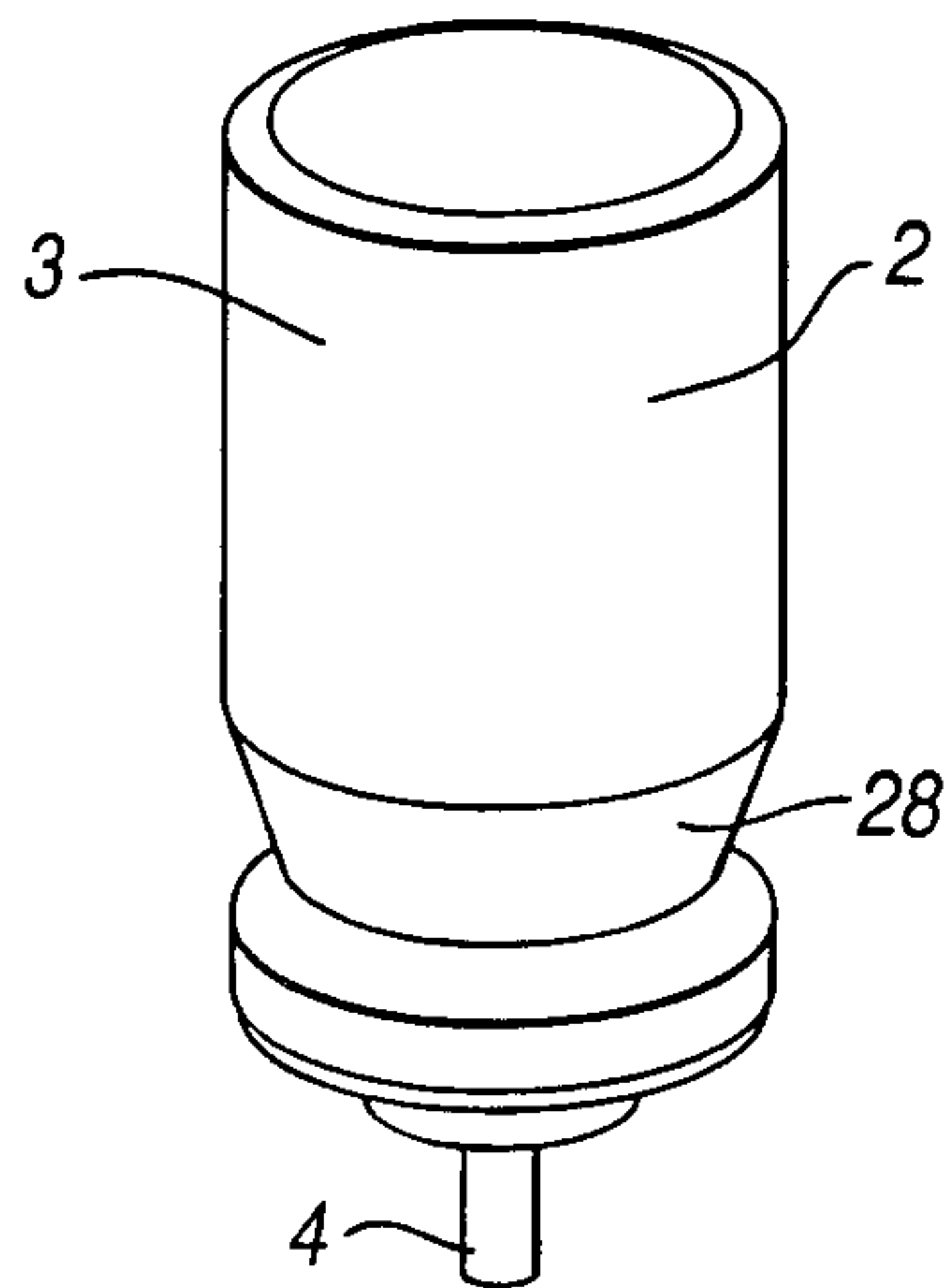


Fig.4

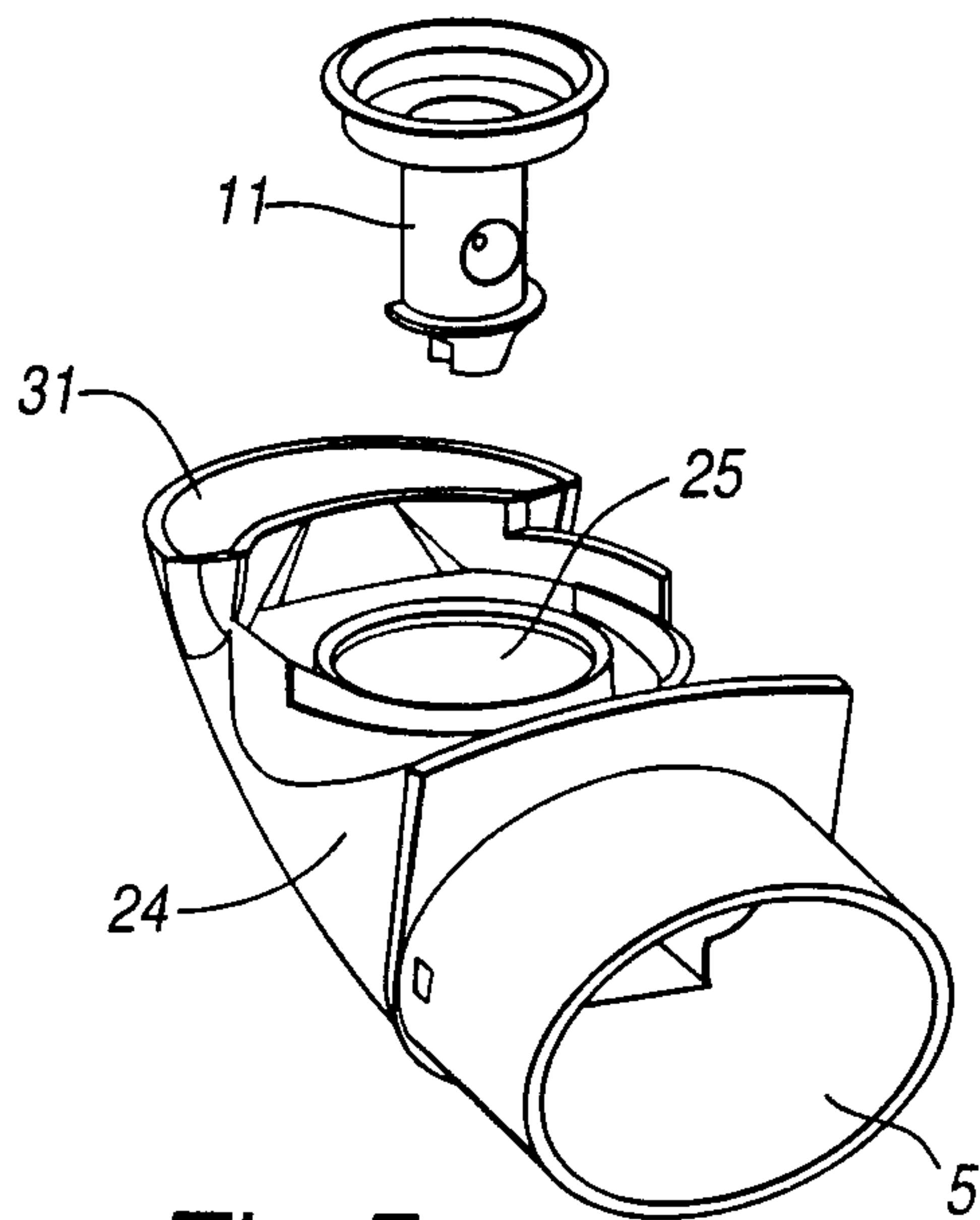


Fig.5

4/12

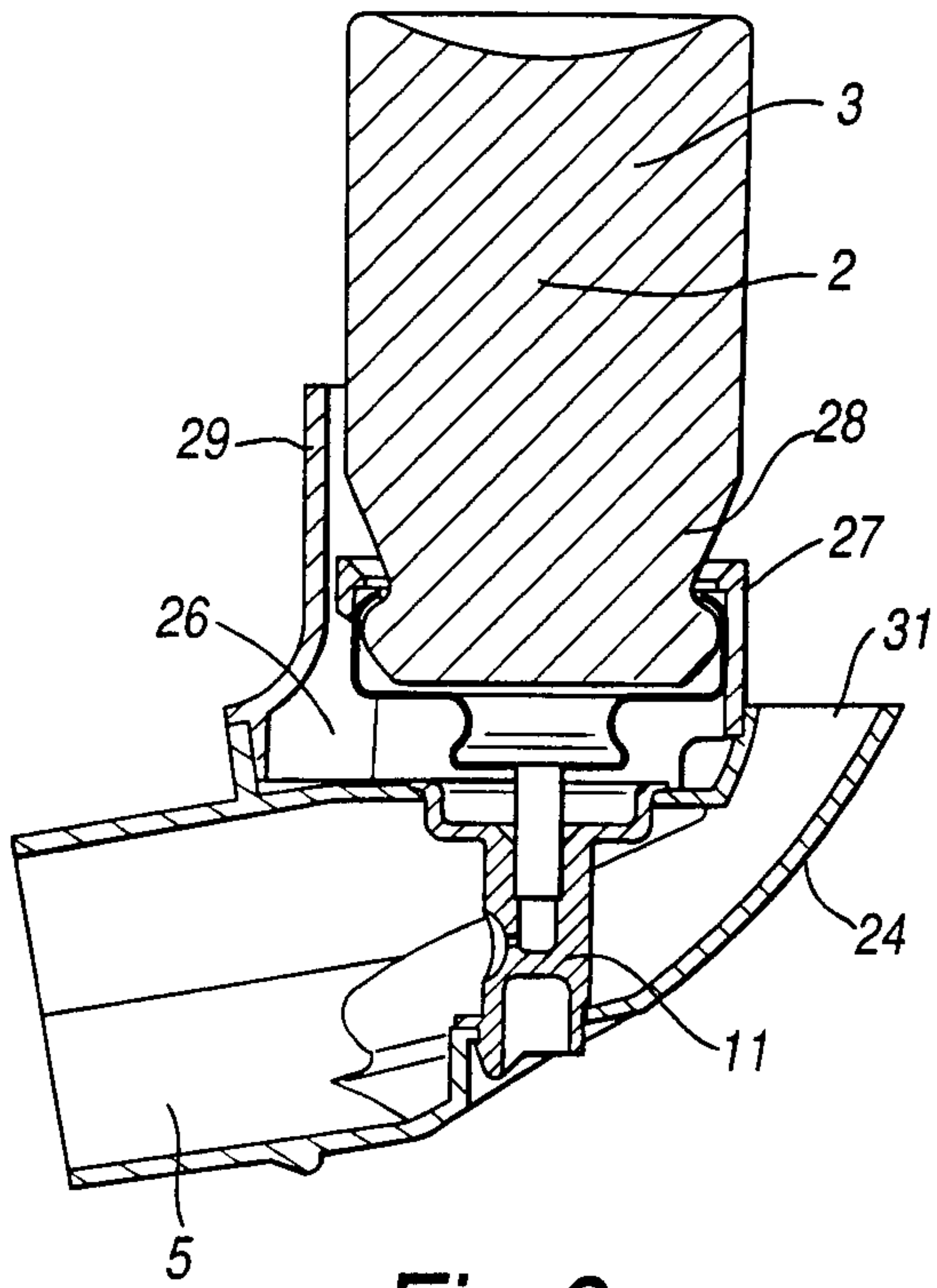


Fig. 6

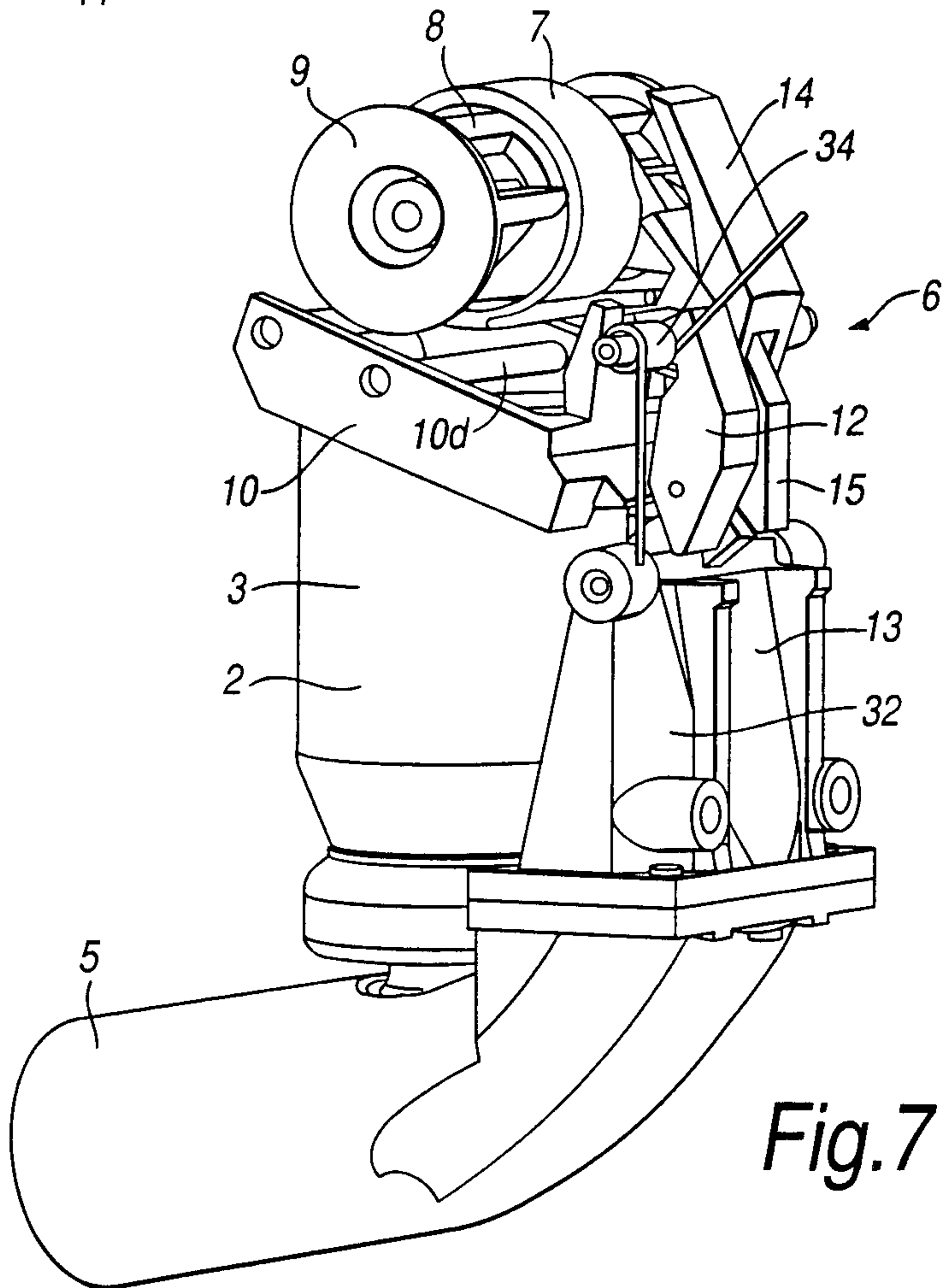


Fig. 7

5/12

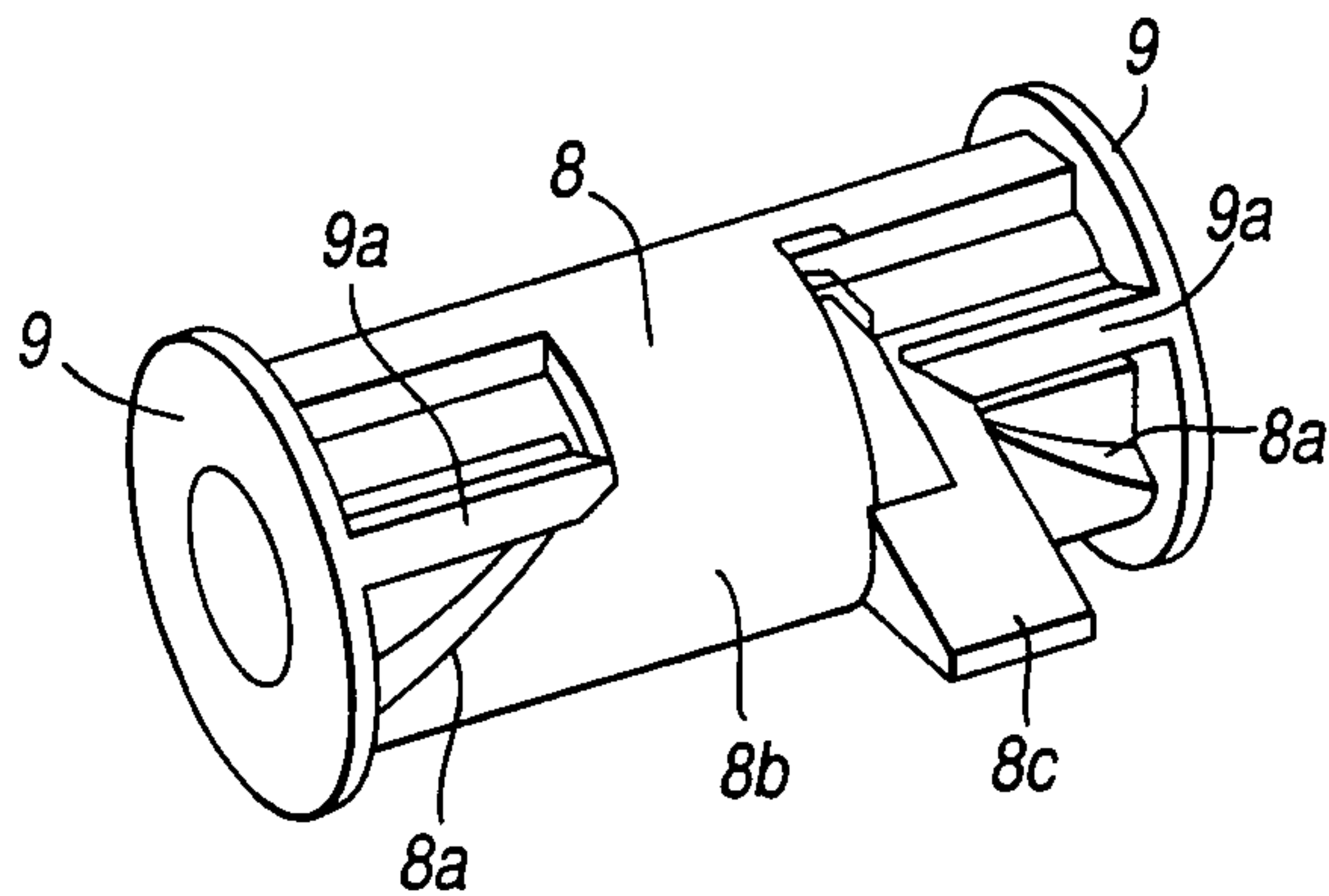


Fig. 8

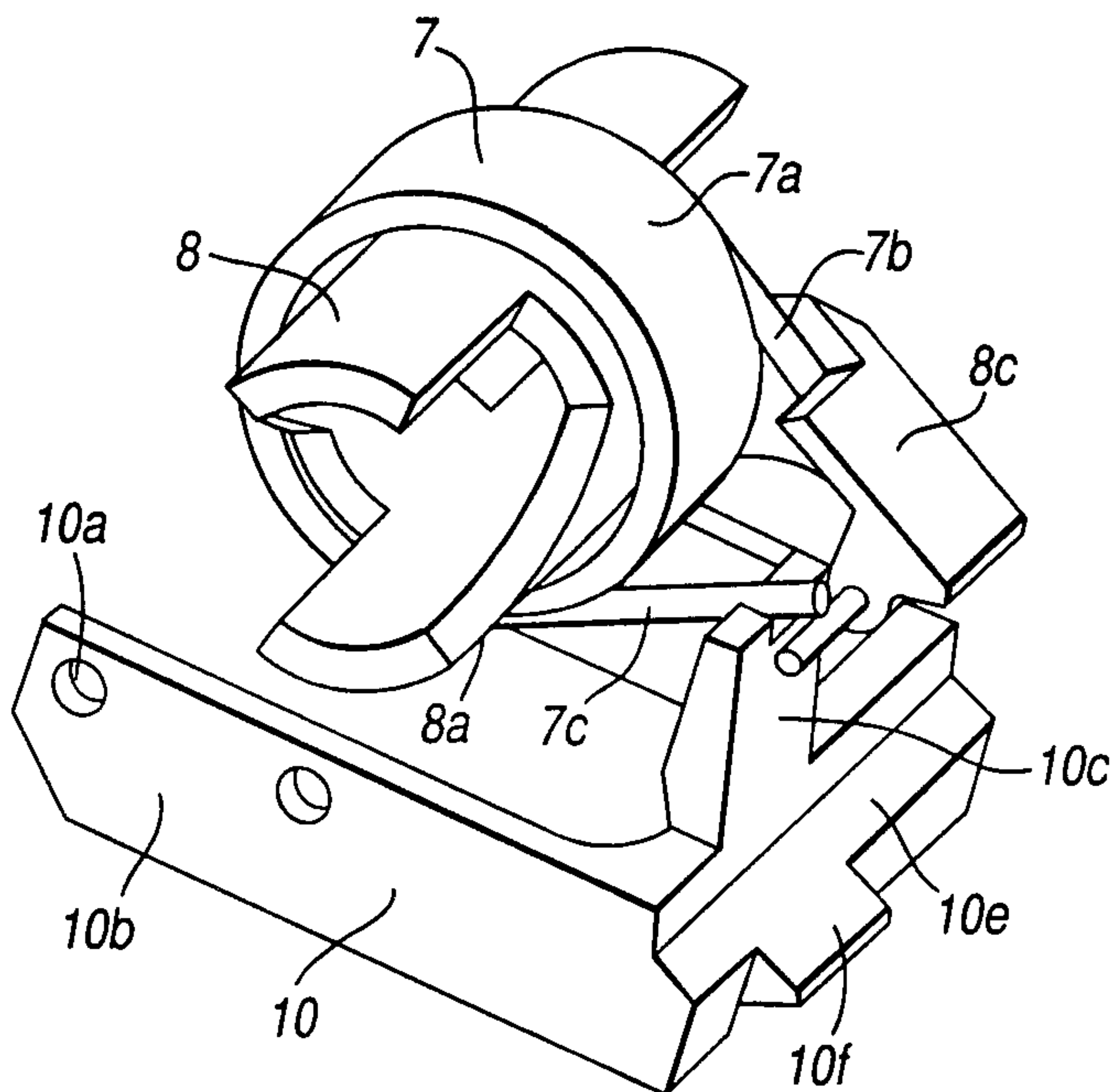


Fig. 9

6/12

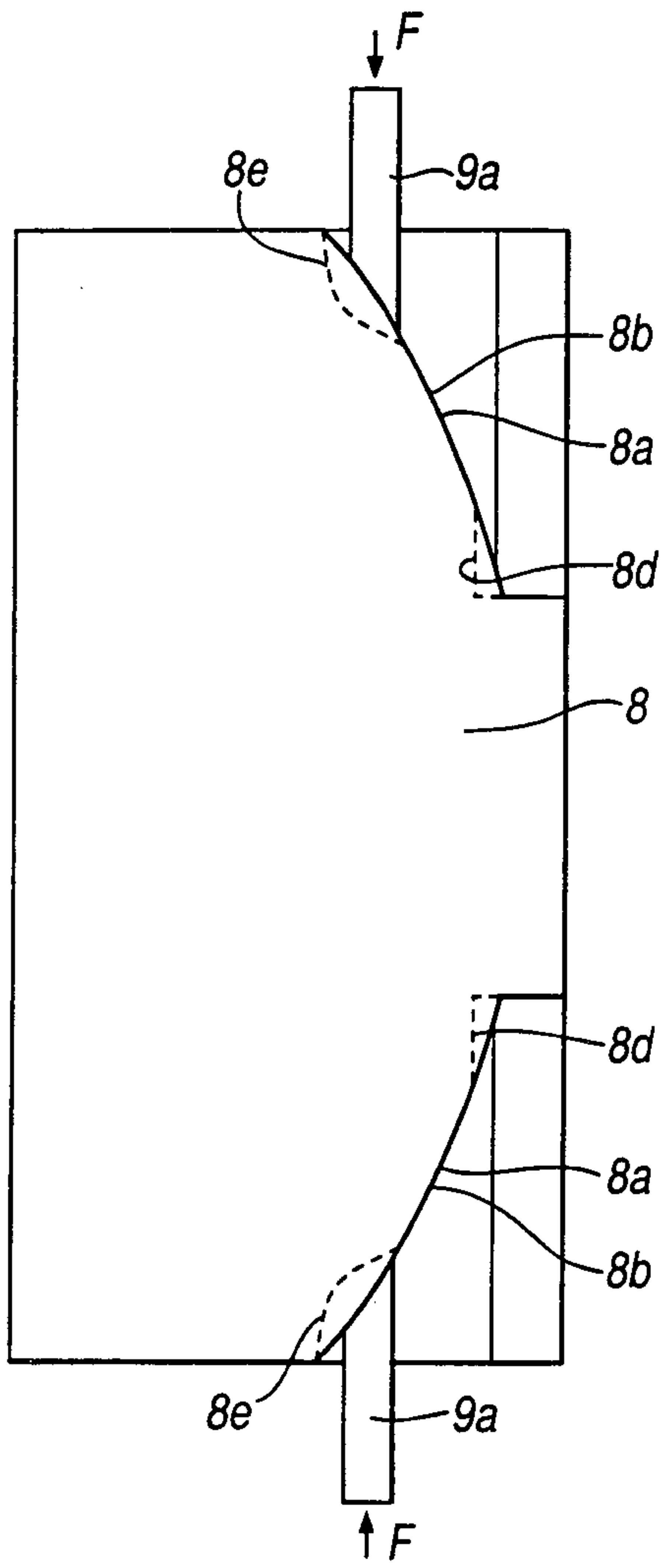


Fig. 10

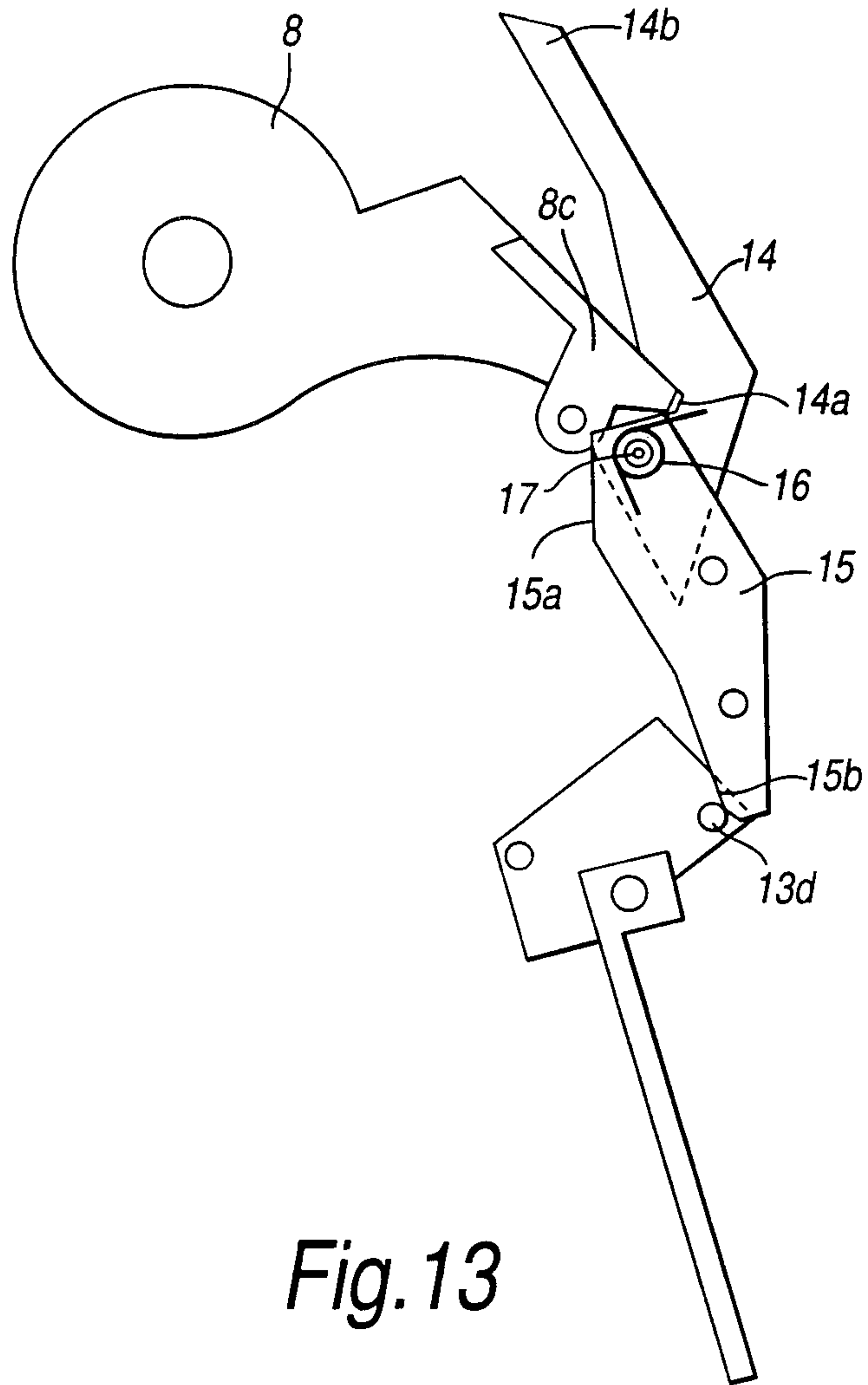


Fig. 13

7/12

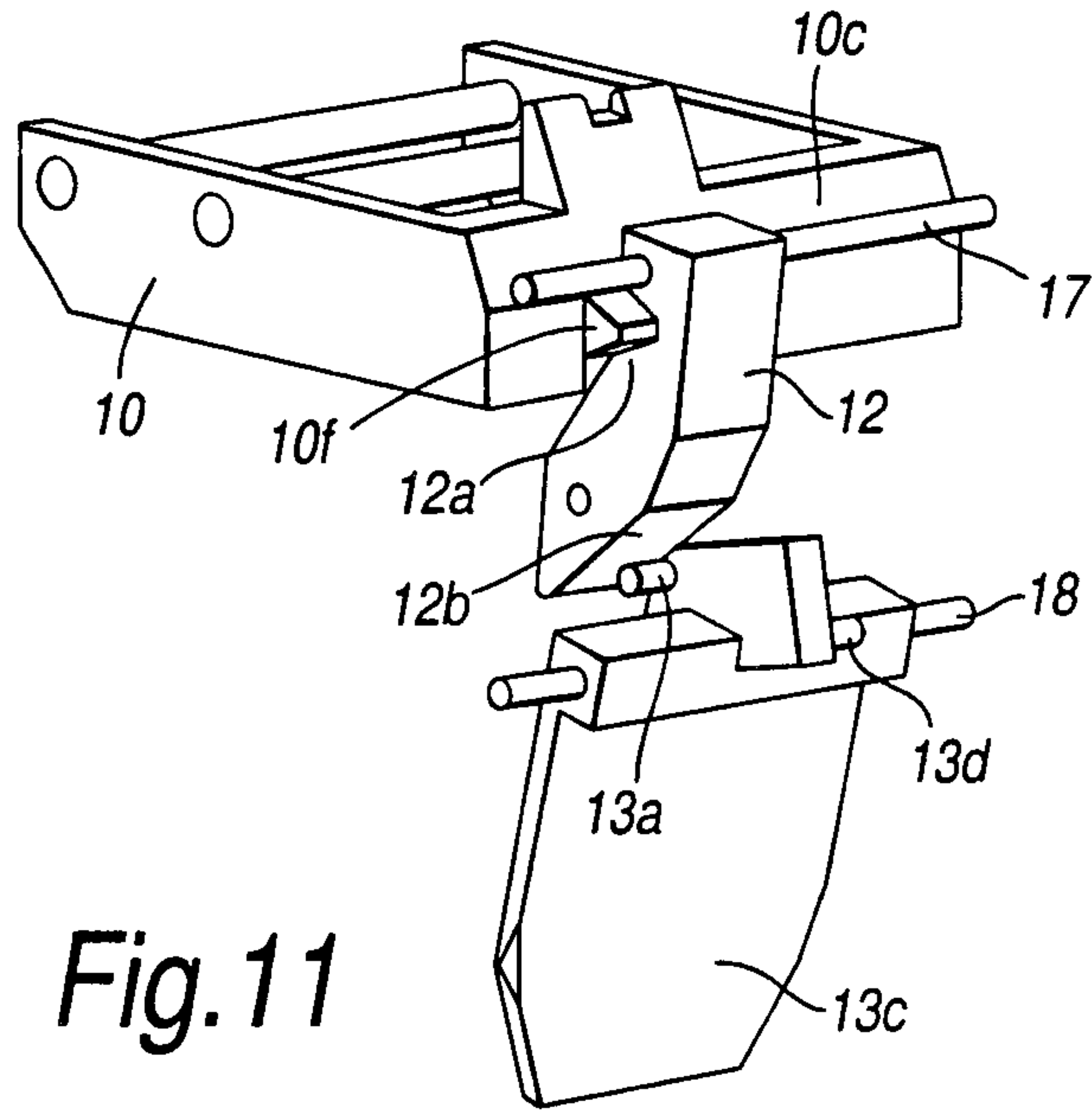


Fig. 11

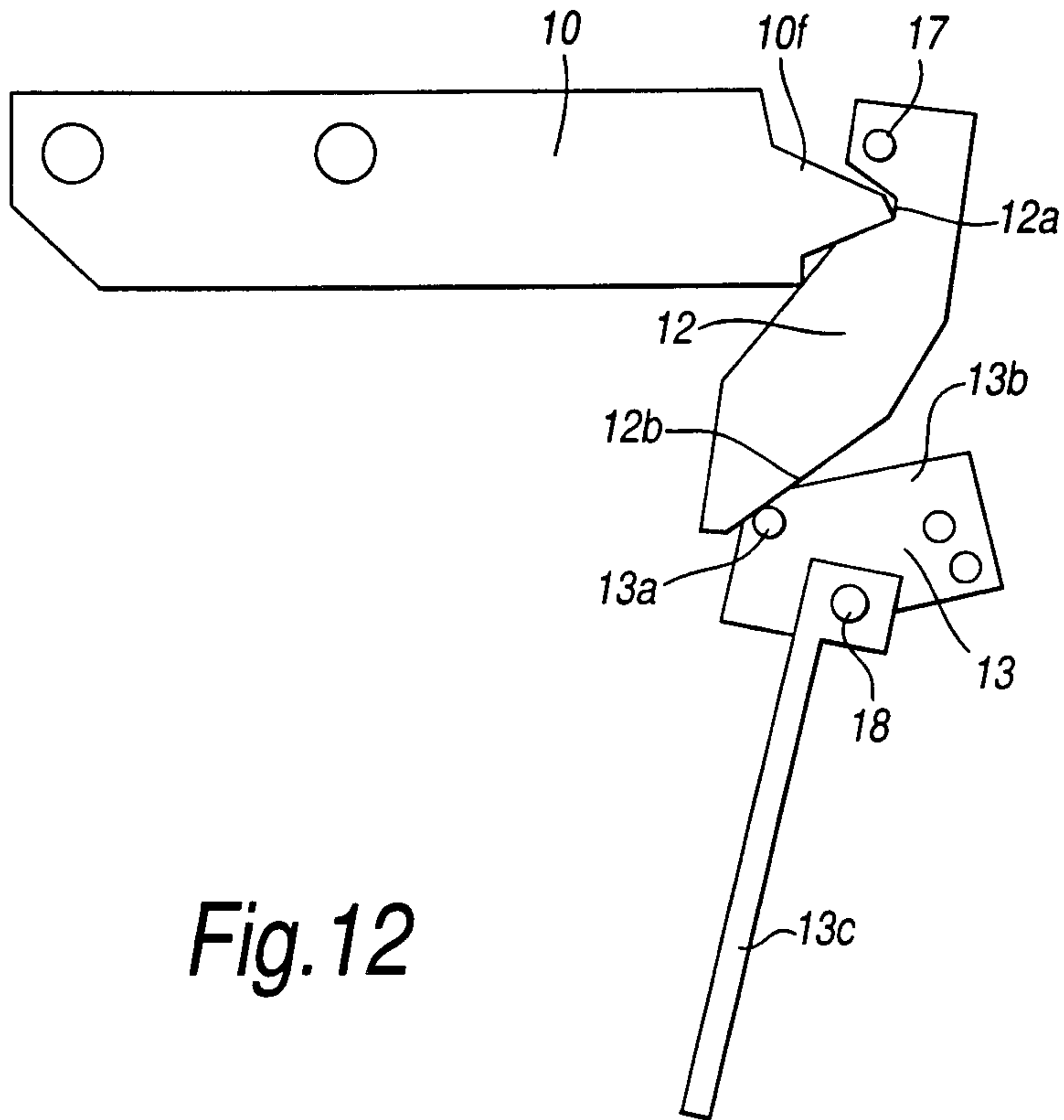


Fig. 12

8/12

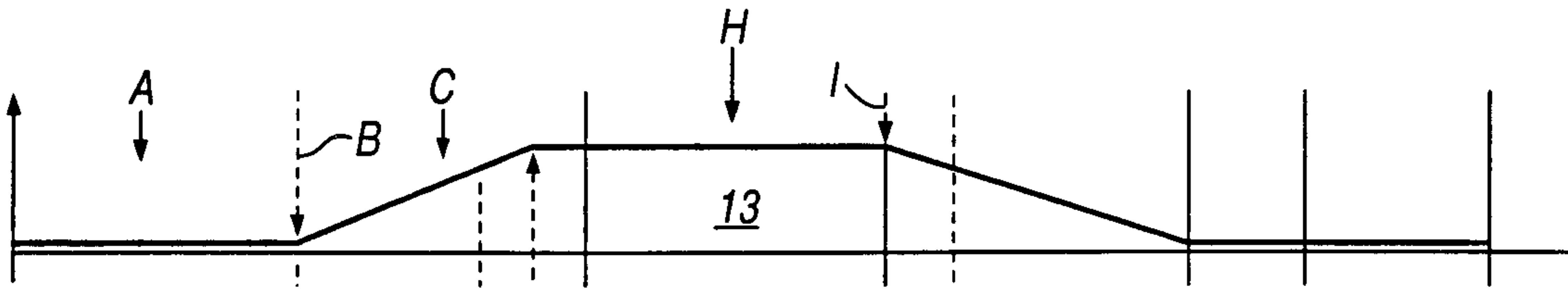


Fig. 14A

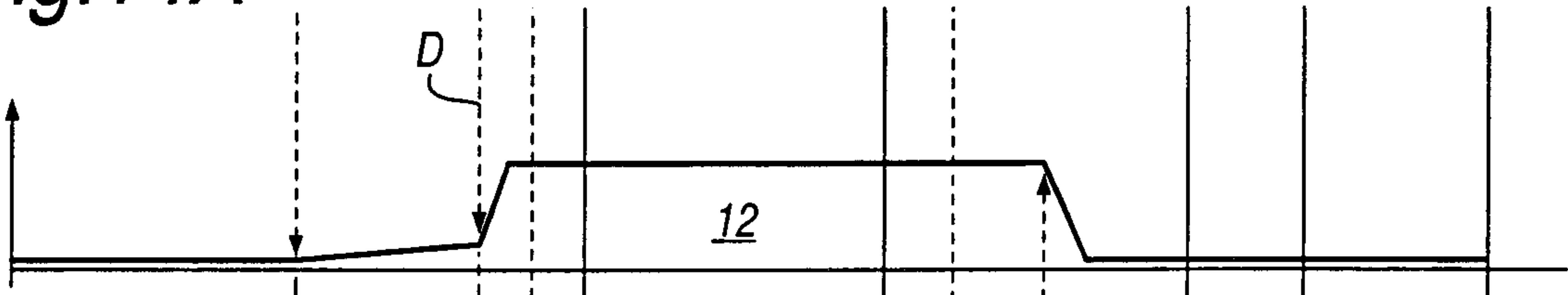


Fig. 14B

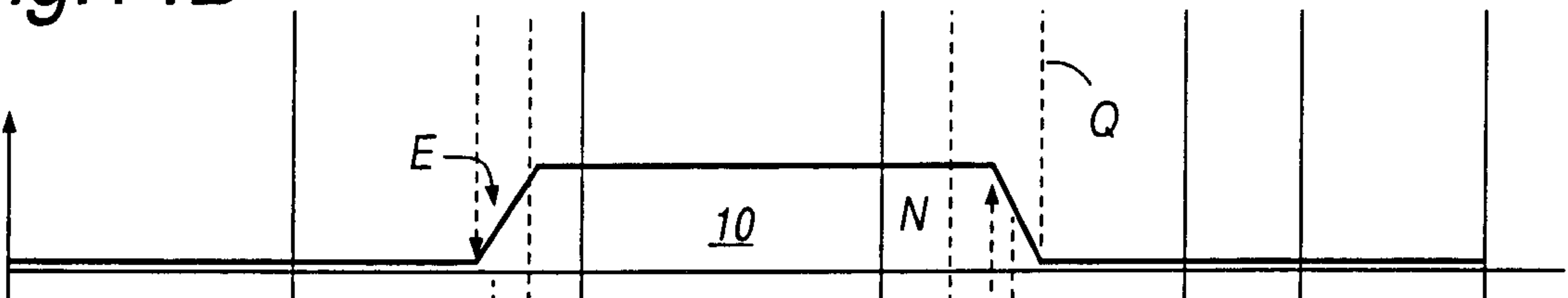


Fig. 14C

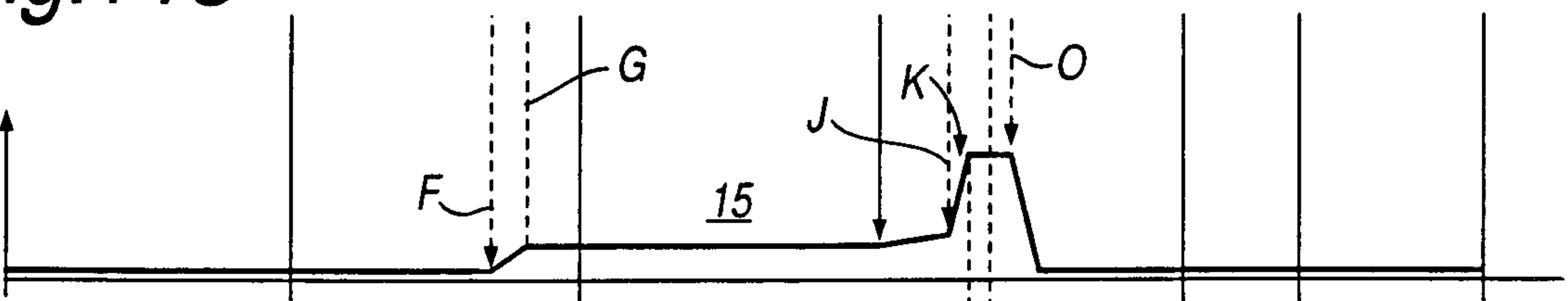


Fig. 14D

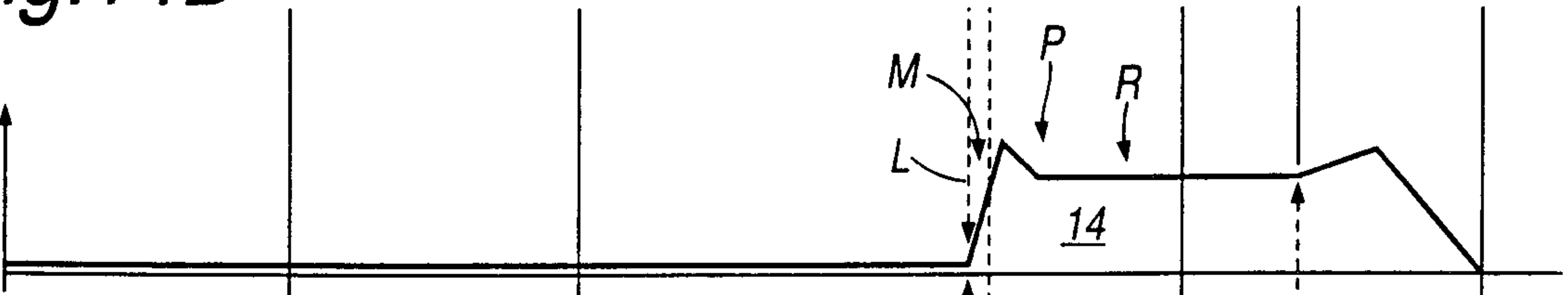


Fig. 14E



Fig. 14F

9/12

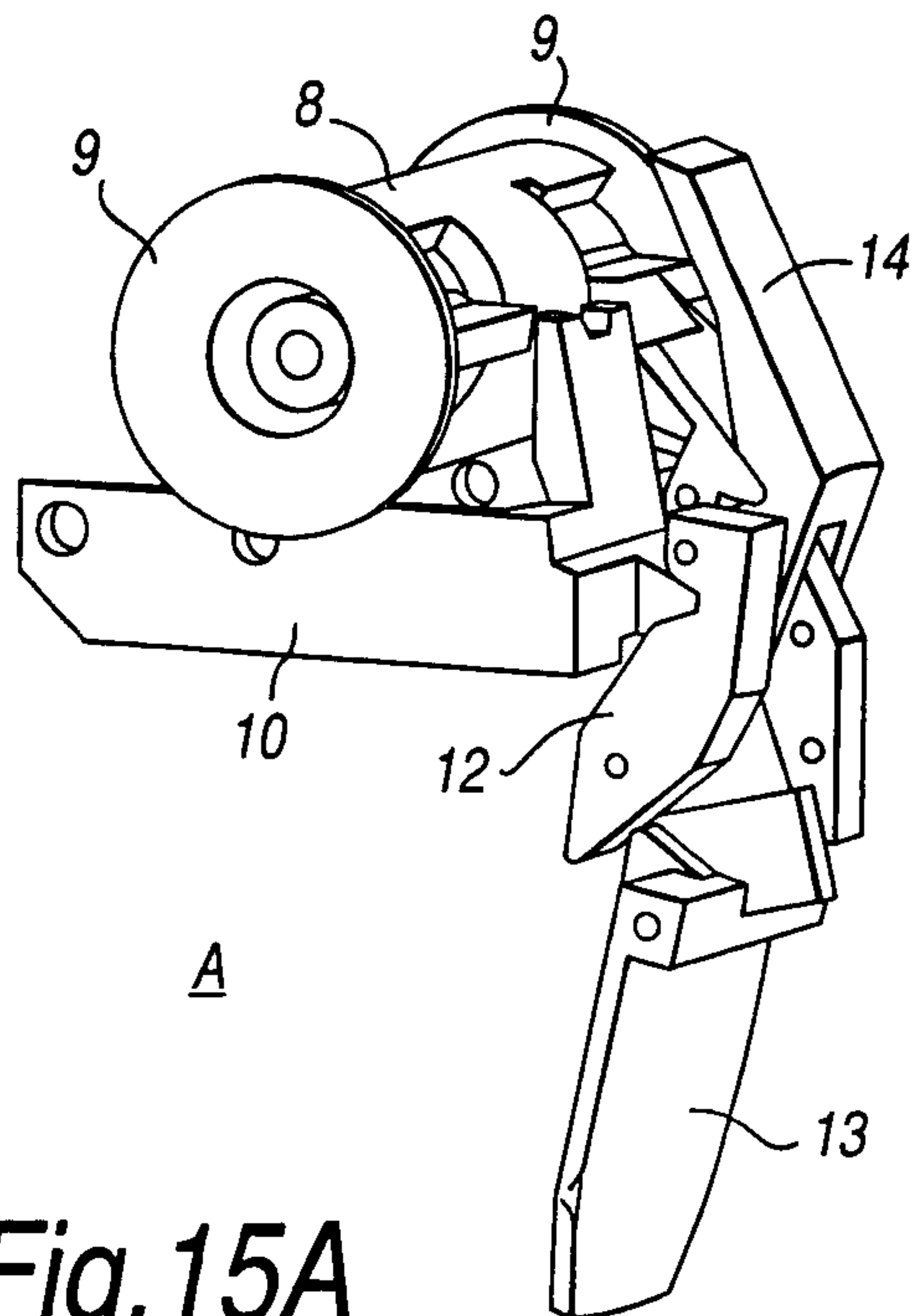


Fig. 15A

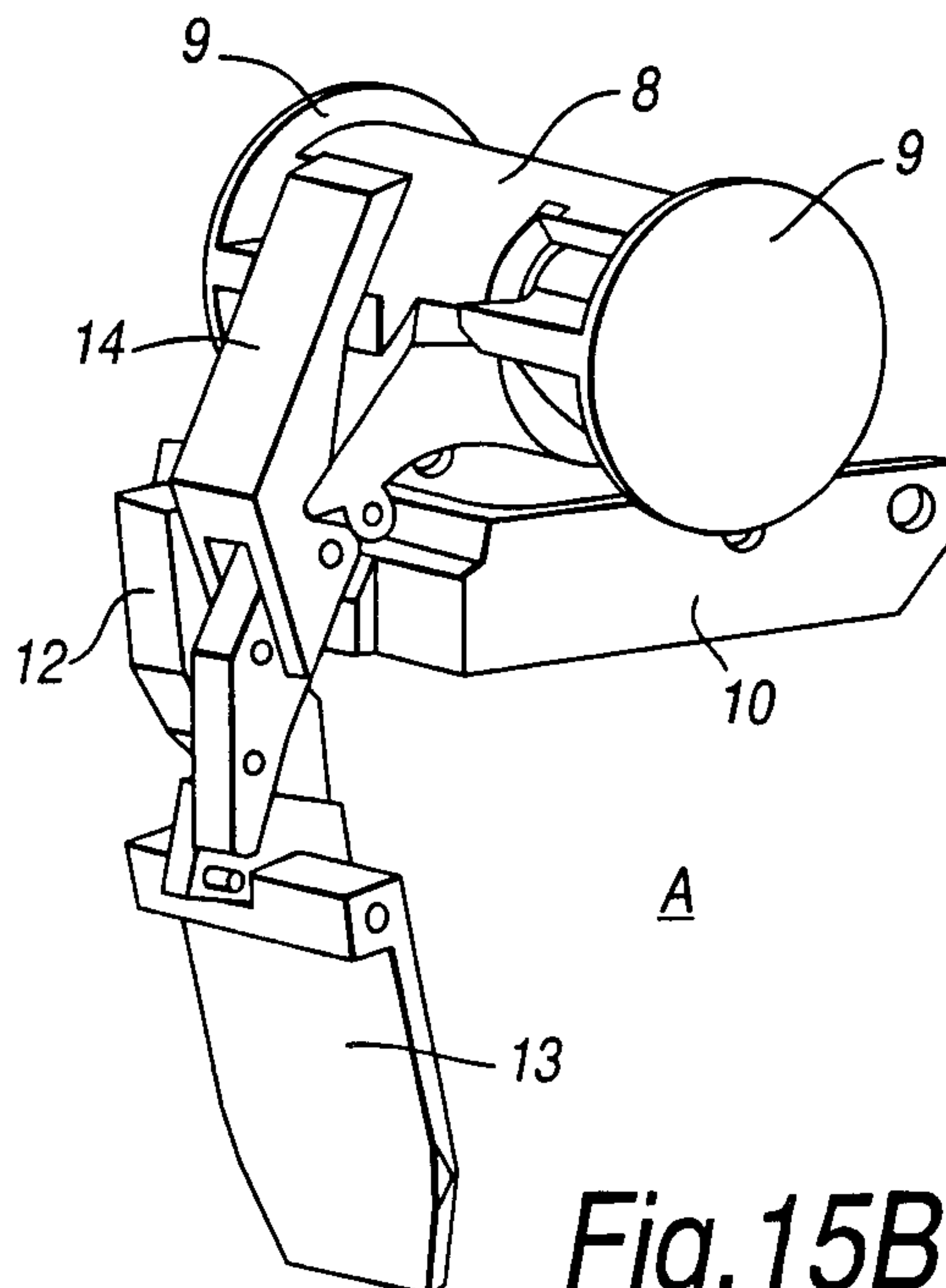


Fig. 15B

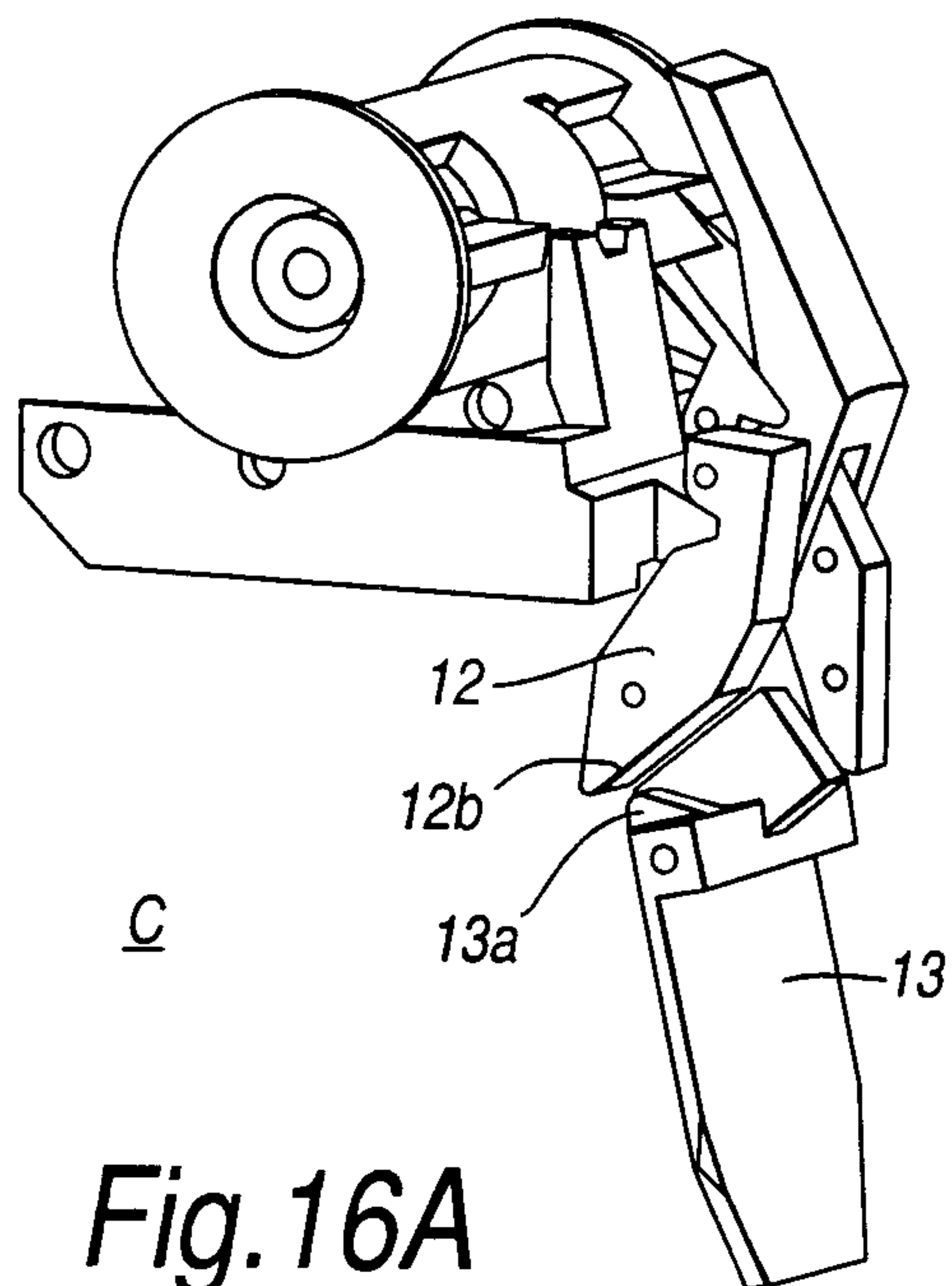


Fig. 16A

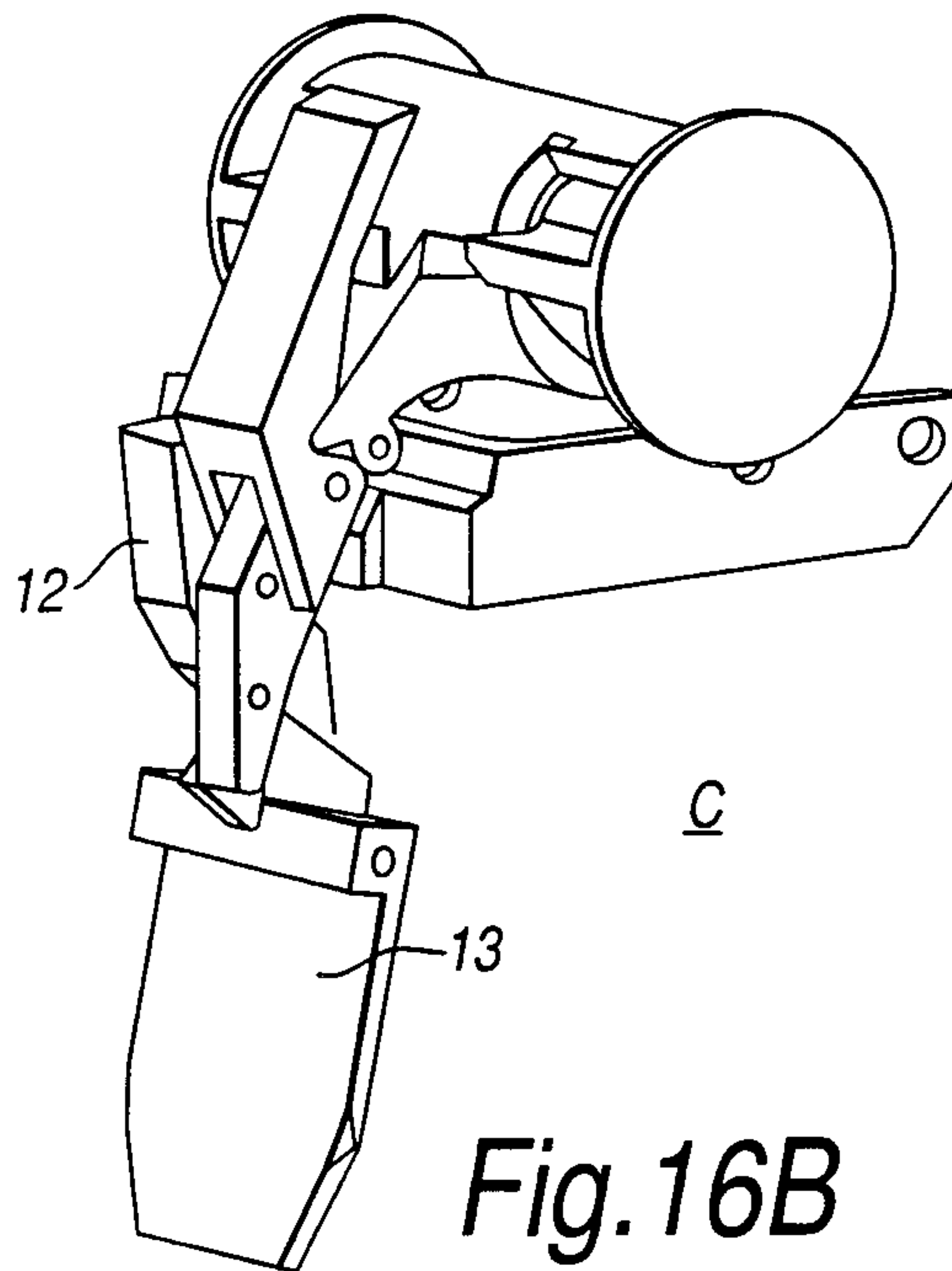
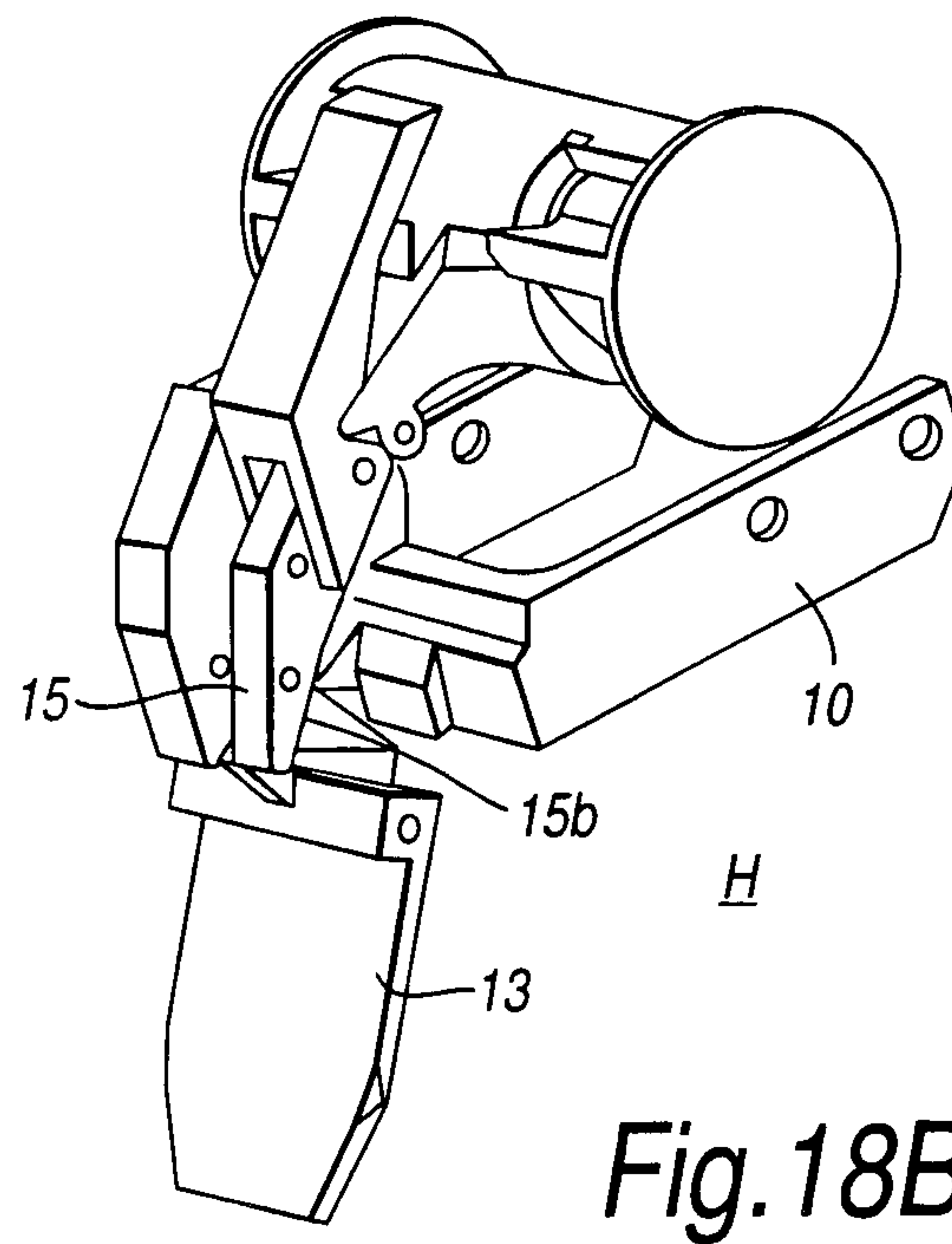
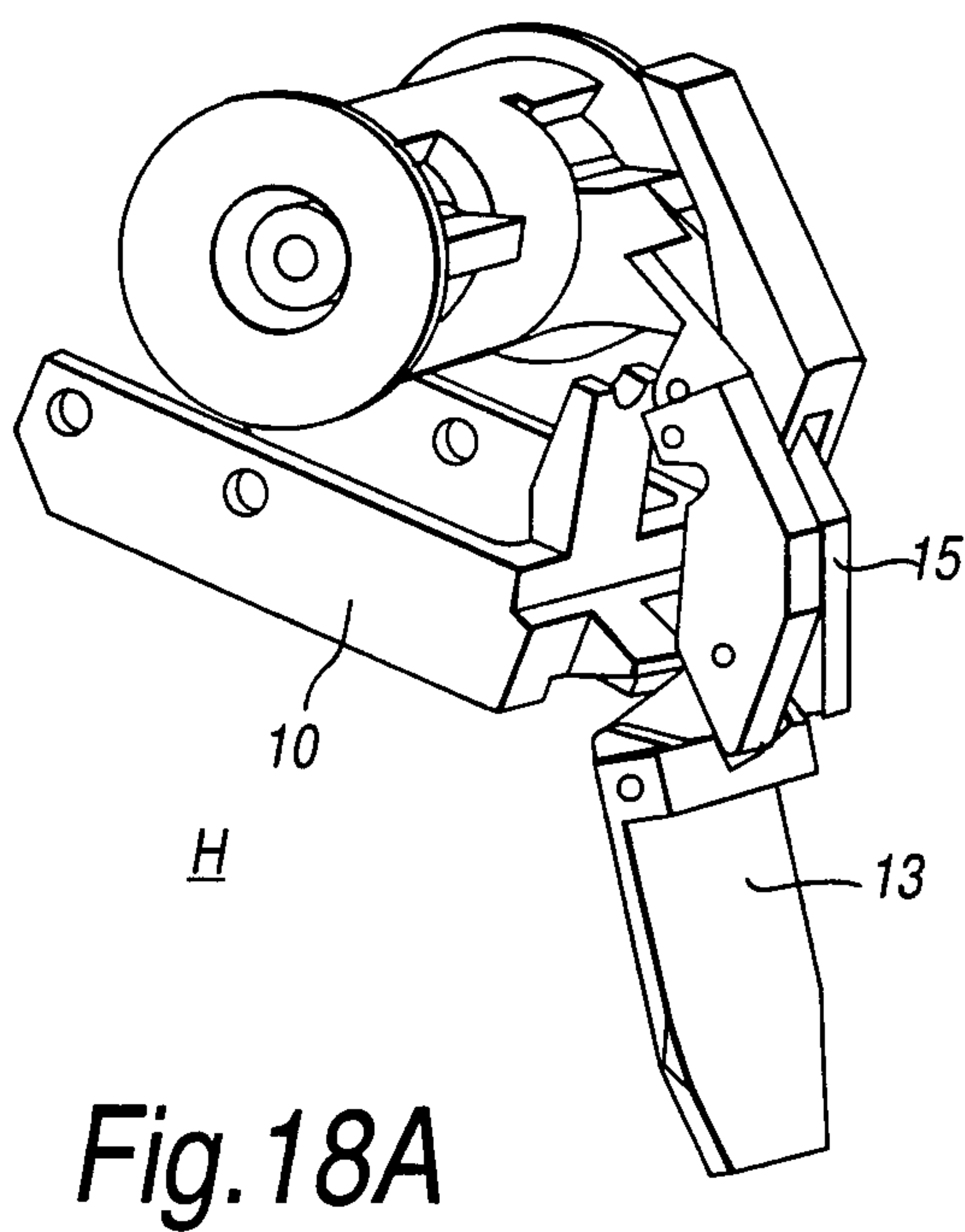
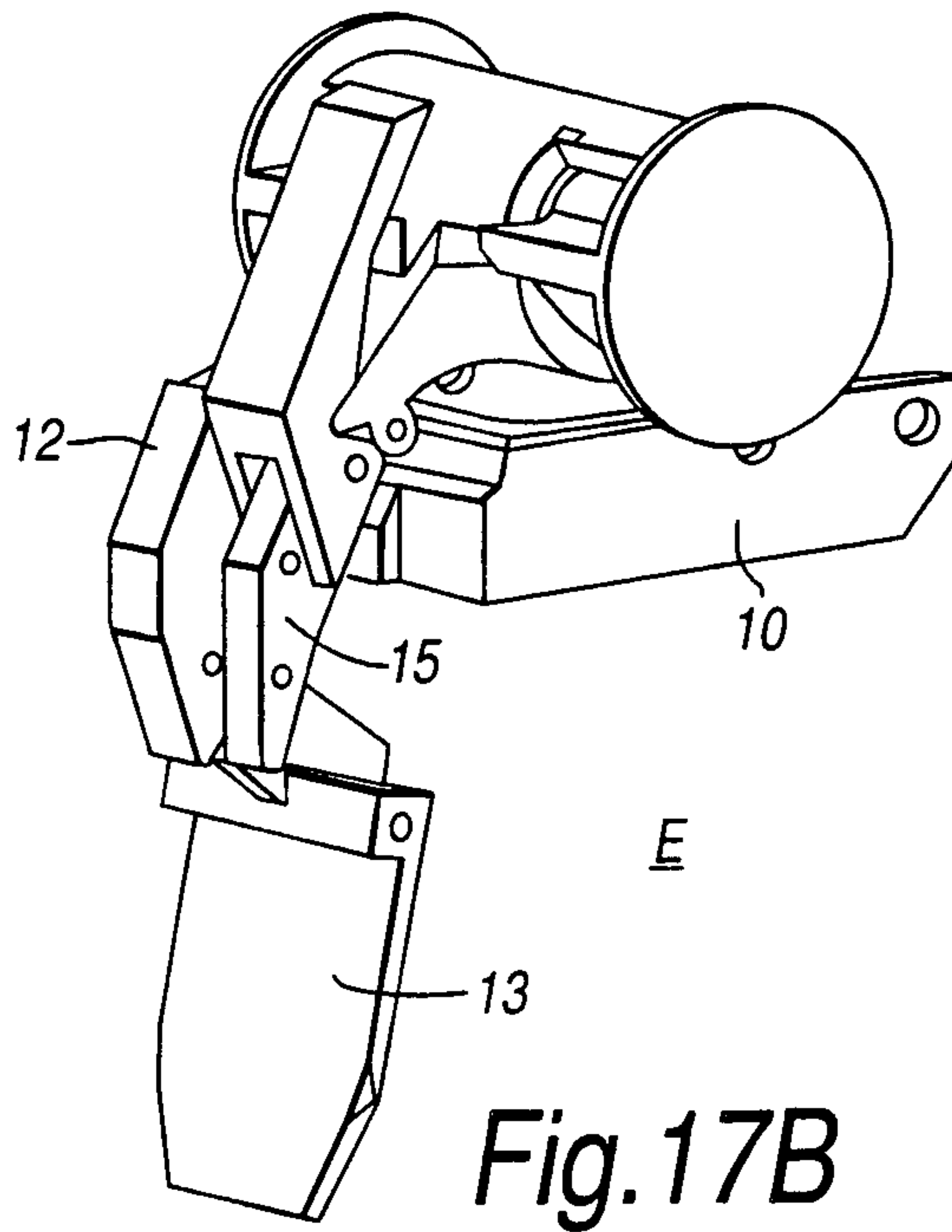
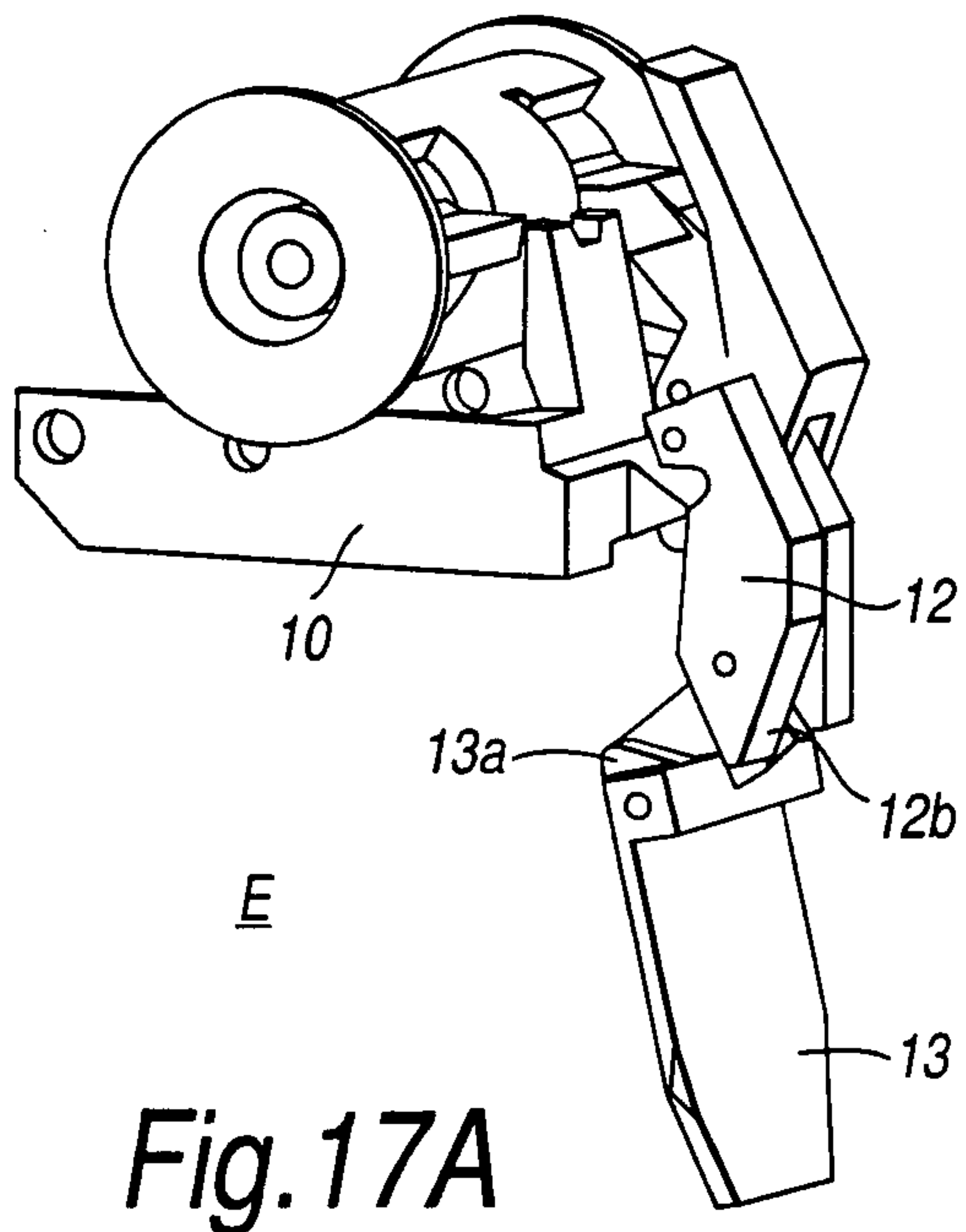
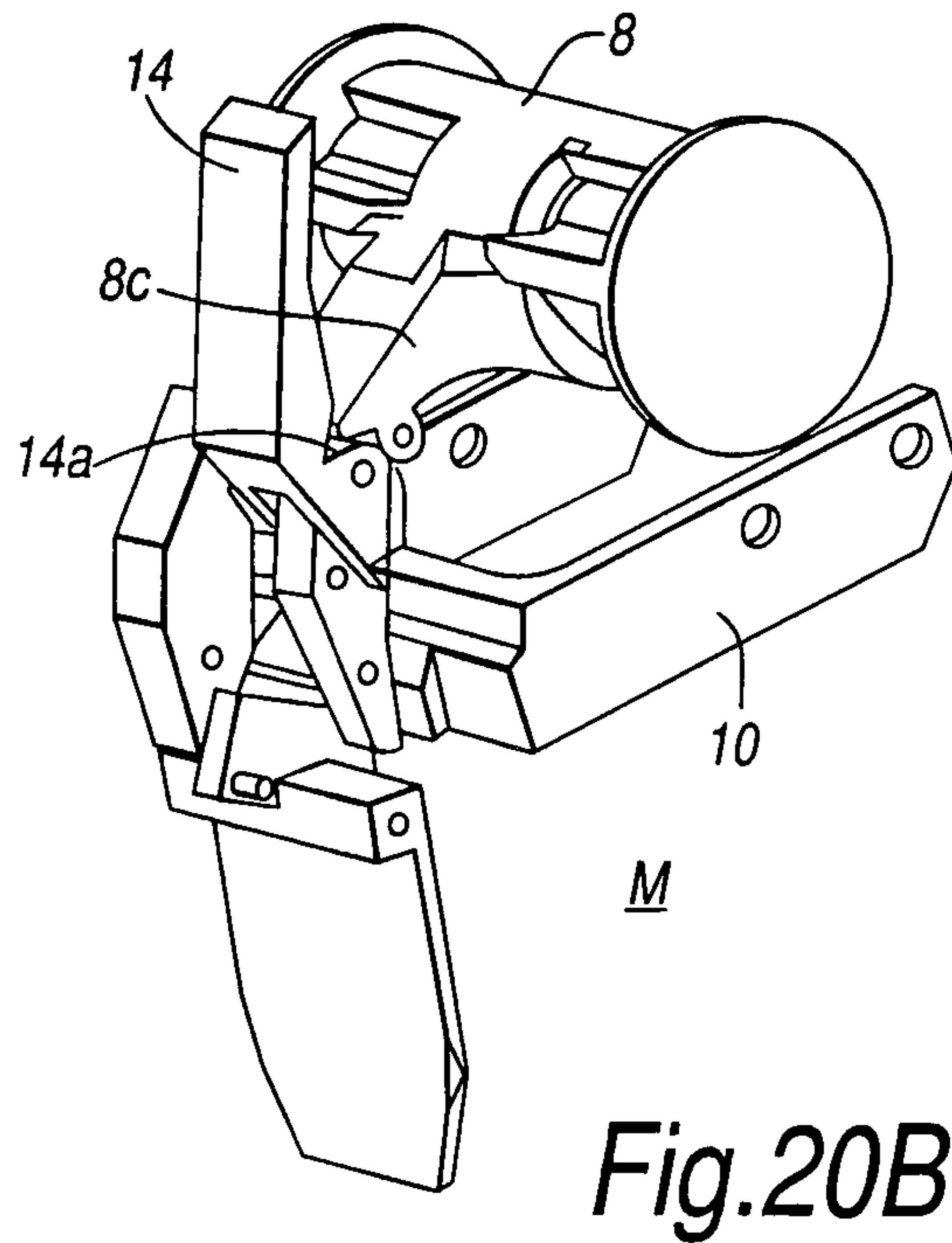
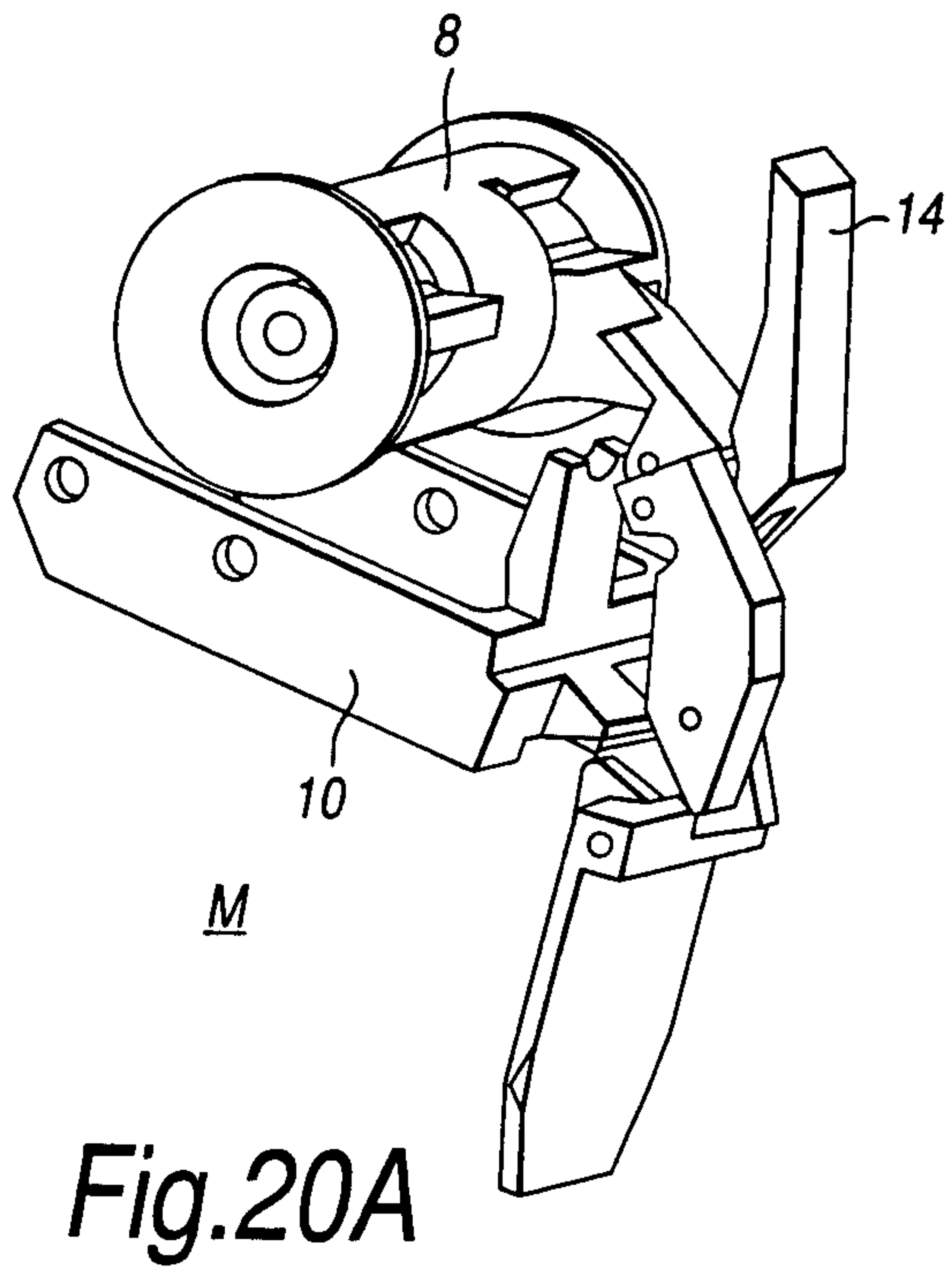
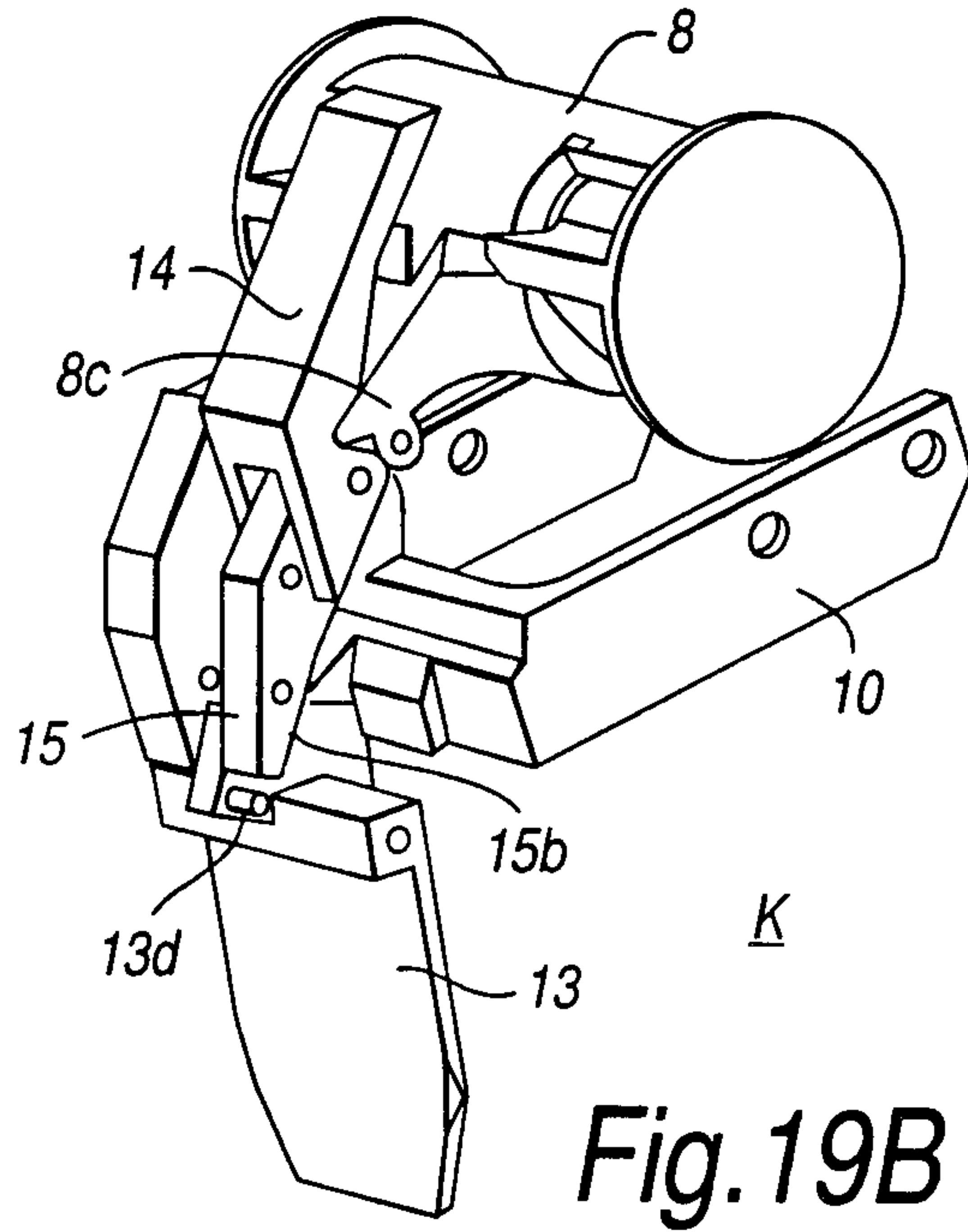
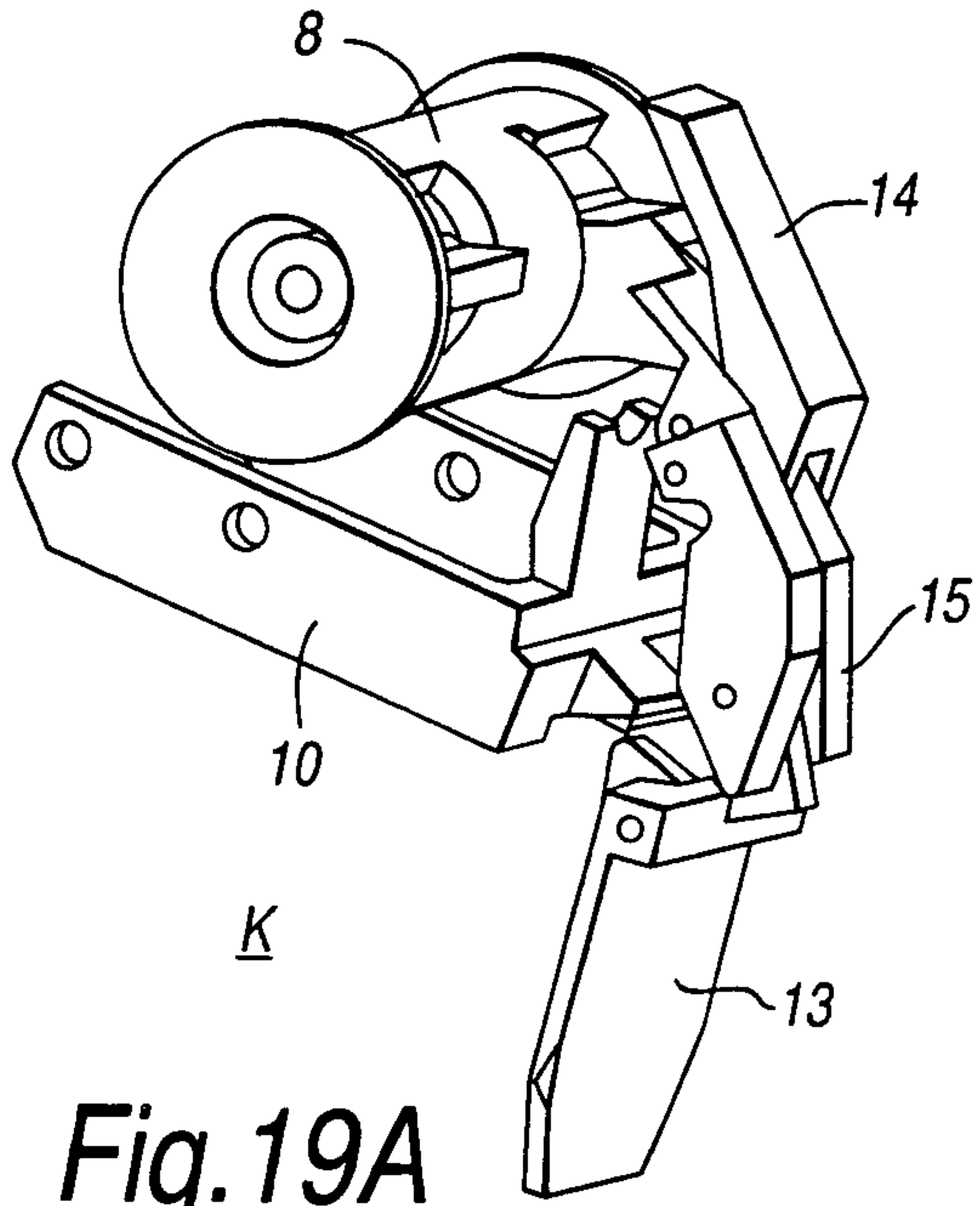


Fig. 16B

10/12



11/12



12/12

