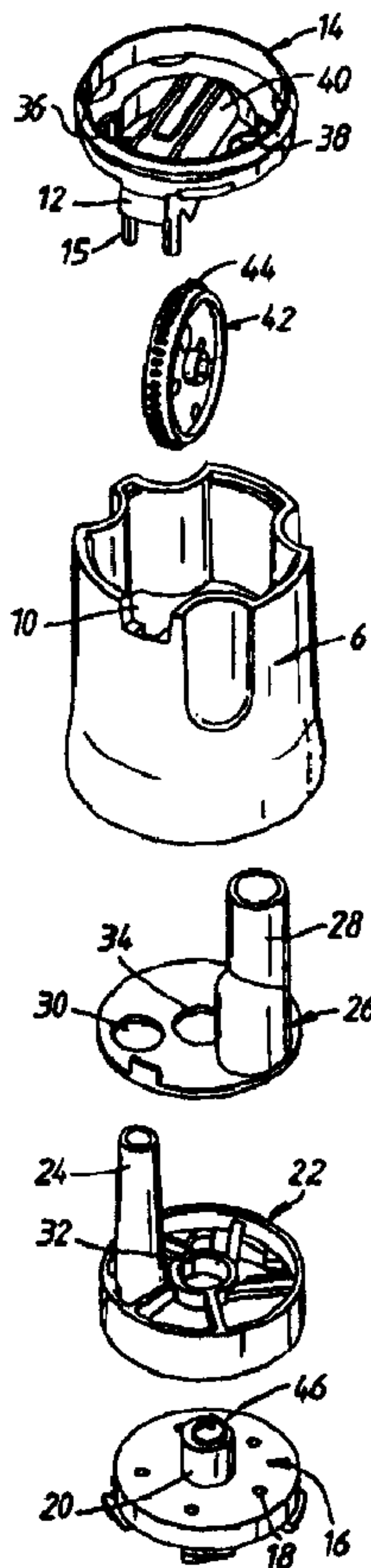




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(54) Titre : DISPOSITIF D'INHALATION  
 (54) Title: INHALATION DEVICE



(57) Abrégé/Abstract:

An inhaler for administering powder by inhalation and a method of constructing the same, the inhaler comprising: an inhaler body (6) having an opening (10) therein; an indicating wheel (42) disposed in the inhaler body (6) for providing an indication as to the

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

usage of the inhaler, the indicating wheel (42) being disposed such that at least part thereof is visible through the opening (10) and so as to be rotatable in a diametrical plane containing the central axis of the inhaler body (6); a divider (14) substantially closing one end of the inhaler body (6); and a storage unit (26) disposed in the inhaler body (6), the storage unit (26) comprising a storage chamber (28) for storing powder for inhalation; characterized in that the inhaler body (6) and the divider (14) are formed as a single integral unit of an opaque material and in that the storage unit (26) is formed of a transparent material and has a portion (12) which substantially fills the opening (10).



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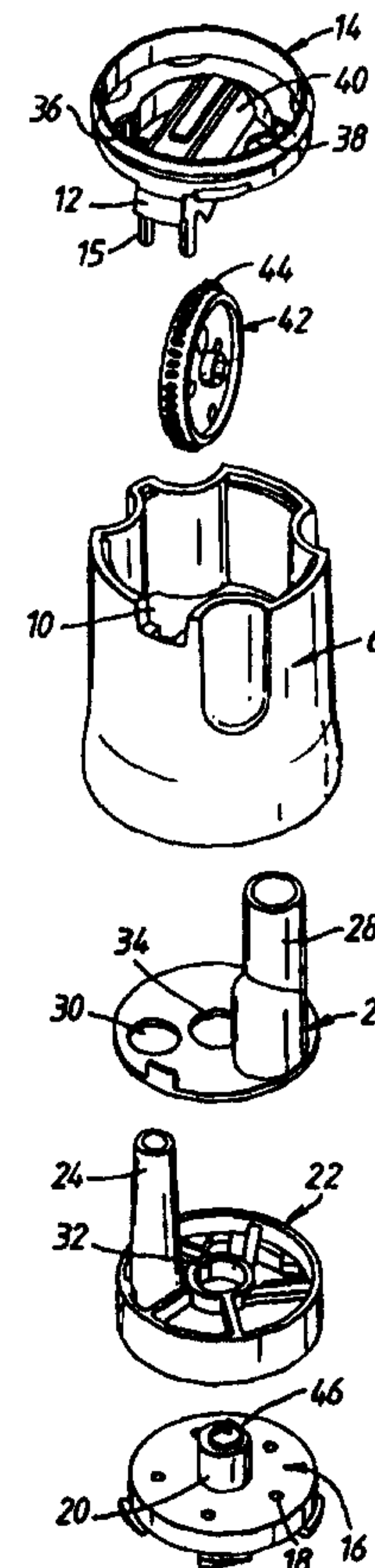
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<p>(21) International Application Number: PCT/SE98/00458</p> <p>(22) International Filing Date: 13 March 1998 (13.03.98)</p> <p>(30) Priority Data: 9700938-5                      14 March 1997 (14.03.97)                      SE</p> <p>(71) Applicant (for all designated States except US): ASTRA AKTIEBOLAG [SE/SE]; S-151 85 Södertälje (SE).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): DAGSLAND, Allan [SE/SE]; Musseronvägen 13, S-374 40 Karlshamn (SE). VIRTANEN, Risto [FI/FI]; Torenvägen 10 C, FIN-01900 Nurmijärvi (FI).</p> <p>(74) Agent: ASTRA AKTIEBOLAG; Patent Dept., S-151 85 Södertälje (SE).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>

(54) Title: INHALATION DEVICE

## (57) Abstract

An inhaler for administering powder by inhalation and a method of constructing the same, the inhaler comprising: an inhaler body (6) having an opening (10) therein; an indicating wheel (42) disposed in the inhaler body (6) for providing an indication as to the usage of the inhaler, the indicating wheel (42) being disposed such that at least part thereof is visible through the opening (10) and so as to be rotatable in a diametrical plane containing the central axis of the inhaler body (6); a divider (14) substantially closing one end of the inhaler body (6); and a storage unit (26) disposed in the inhaler body (6), the storage unit (26) comprising a storage chamber (28) for storing powder for inhalation; characterized in that the inhaler body (6) and the divider (14) are formed as a single integral unit of an opaque material and in that the storage unit (26) is formed of a transparent material and has a portion (12) which substantially fills the opening (10).



## INHALATION DEVICE

The present invention relates to a powder inhaler for administering powder by inhalation.

5 A number of powder inhalers are known which use different systems for introducing a dose of powder into an air stream. Typically, the powder is inhaled into the lungs of a patient in order to treat, for example, asthma.

Examples of such powder inhalers are disclosed in WO-A-86/05991 and EP-A-0237507;  
10 claim 1 being characterized over the disclosures of WO-A-86/05991. These inhalers include a flow path, which comprises an inhalation channel and a mouthpiece comprising an air chamber and an outlet nozzle, through which a stream of air is drawn during inhalation by a user, and means for introducing powder into the inhalation channel. During  
15 inhalation, air is first drawn into and through the inhalation channel so as to pick up powder. The stream of air containing powder is then drawn through the air chamber and out of the outlet nozzle of the mouthpiece.

Figure 1 illustrates one such powder inhaler. The inhaler comprises a mouthpiece 2 comprising an air chamber (not illustrated) and an outlet nozzle 4, an inhaler body 6 and a  
20 rotatable grip portion 8 for operating a dosing mechanism for providing doses of powder for inhalation. The inhaler body 6 is provided with an opening 10 which is filled with a window 12 through which an indicating wheel 42 is visible so as to provide an indication as to the usage of the inhaler.

25 Figure 2 illustrates in exploded view component parts disposed within and to the inhaler body 6. The inhaler body 6 is capped with a divider 14 which is fixed thereto and separates the air chamber in the mouthpiece 2 from a major part of the inhaler body 6. For aesthetic reasons the inhaler body 6 is an opaque moulding. The divider 14 is a transparent  
30 moulding which has a depending tongue 15, a part of which forms the window 12. When the inhaler is assembled, the only part of the divider 14 which is visible is the part of the

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tongue 15 forming the window 12, and thus the overall appearance of the inhaler is unaffected.

Within the inhaler body 6 are housed the component parts of the dosing mechanism. These  
5 component parts include a dosing unit 16 which comprises a plurality of dosing means 18  
and has a central axial shaft 20, an inhalation unit 22 which comprises an inhalation  
channel 24 and a storage unit 26 which comprises a storage chamber 28 for storing powder.  
The above-mentioned component parts of the dosing mechanism are assembled by passing  
the inhalation channel 24 through an opening 30 in the storage unit 26 and passing the shaft  
10 20 through central openings 32, 34 in the inhalation unit 22 and the storage unit 26  
respectively. When so assembled, the upper ends of the inhalation channel 24 and the  
storage chamber 28 pass respectively through first and second openings 36, 38 in the  
divider 14.

15 In use, powder is transferred from the storage chamber 28 to one of the dosing means 18,  
and, with rotation of the dosing unit 16, the one dosing means 18 provides a dose of  
powder to the inhalation channel 24. On inhalation by a user the powder is drawn up  
through the air chamber and out of the outlet nozzle 4 of the mouthpiece 2.

20 As illustrated in Figures 2 and 3, the divider 14 further comprises supporting means 40 for  
rotatably supporting an indicating wheel 42. The indicating wheel 42 has a plurality of  
teeth 44 disposed around the periphery thereof which engage with a spiral groove or  
protrusion 46 on the end face of the shaft 20 of the dosing unit 16. The supporting means  
40 is configured to align the indicating wheel 42 such that a part of the periphery thereof is  
25 disposed adjacent the inner surface of the window 12.

In use, as the dosing unit 16 is rotated, the spiral groove or protrusion 46 engages with one  
or more of the teeth 44 on the indicating wheel 42 so as to rotate the same. In this way, by  
providing a coloured marking on the periphery of the indicating wheel 42, it is possible to  
30 provide the user with a visible indication at the window 12 as to the usage of the inhaler.

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Although the above-described known powder inhaler functions quite adequately, it is an aim of the present invention to provide a powder inhaler of improved construction.

5 Accordingly, the present invention provides an inhaler for administering powder by inhalation, comprising: an inhaler body provided with a window; a divider substantially closing one end of the inhaler body and being integrally formed therewith; an indicating wheel disposed in the inhaler body for providing an indication as to the usage of the inhaler, the indicating wheel being disposed such that at least part thereof is visible through  
10 the window and so as to be rotatable in a diametrical plane containing the central axis of the inhaler body; and a storage unit disposed in the inhaler body, the storage unit comprising a storage chamber for storing powder for inhalation; characterized in that the inhaler body includes an opening through which at least part of the indicating wheel is visible, in that the inhaler body and the divider are formed of an opaque material and in  
15 that the storage unit is formed of a transparent material and includes a portion which substantially fills the opening and provides the window.

Preferably, the inhaler further comprises an inhalation unit disposed in the inhaler body, the inhalation unit having an inhalation channel through which powder is in use inhaled. In a  
20 preferred embodiment the inhalation unit and the storage unit are formed as a single integral unit.

Preferably, the inhaler further comprises a dosing unit disposed in the inhaler body so as to be rotatable about the central axis thereof for introducing a dose of powder into the  
25 inhalation channel, the dosing unit having a central shaft co-axial with the central axis of the inhaler body, the central shaft having an end face with a spiral groove or protrusion and the indicating wheel having a toothed periphery for engaging the spiral groove or protrusion.

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In a preferred embodiment the indicating wheel is rotatably supported by the storage unit and the divider is constructed as a substantially flat member so as to minimize the risk of powder accumulating on the upper surface thereof.

5 Preferably, the inhaler body includes an air inlet in a side wall thereof, the air inlet allowing air to be drawn to the dosing unit and through the inhalation channel. In a preferred embodiment the inhaler body includes a recess in the side wall thereof in which the air inlet is provided.

10 Medicaments suitable for administration by the powder inhaler of the present invention are any which may be delivered by inhalation and include, for example,  $\beta$ 2-adrenoreceptor agonists, for example, salbutamol, terbutaline, rimiterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol, formoterol, clenbuterol, procaterol, broxaterol, picumeterol, TA-2005, mabuterol and the like, and their  
15 pharmacologically acceptable esters and salts; anticholinergic bronchodilators, for example, ipratropium bromide and the like; glucocorticosteroids, for example, beclomethasone, fluticasone, budesonide, tipredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone and the like, and their  
20 pharmacologically acceptable esters and salts; antiallergic medicaments, for example, sodium cromoglycate and nedocromil sodium; expectorants; mucolytics; antihistamines; cyclooxygenase inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists; phospholipase-A2 (PLA2) inhibitors; platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic medicaments; tranquilisers; cardiac glycosides; hormones; antihypertensive medicaments; antidiabetic medicaments; antiparasitic  
25 medicaments; anticancer medicaments; sedatives; analgesic medicaments; antibiotics; antirheumatic medicaments; immunotherapies; antifungal medicaments; antihypotension medicaments; vaccines; antiviral medicaments; proteins; polypeptides and peptides, for example, peptide hormones and growth factors; polypeptide vaccines; enzymes;

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endorphins; lipoproteins and polypeptides involved in the blood coagulation cascade; vitamins; and others, for example, cell surface receptor blockers, antioxidants, free radical scavengers and organic salts of N,N'-diacetylcystine.

5 Preferred embodiments of the present invention will now be described hereinbelow by way of example only with reference to the accompany drawings, in which:

Figure 1 illustrates a perspective view of a known powder inhaler;

10 Figure 2 illustrates in exploded view component parts of the inhaler of Figure 1;

Figure 3 illustrates component parts of the inhaler of Figure 1;

15 Figures 4 and 5 illustrate component parts of a powder inhaler in accordance with a first embodiment of the present invention;

Figure 6 illustrates a component part of a powder inhaler in accordance with a second embodiment of the present invention;

20 Figures 7 and 8 illustrate component parts of a powder inhaler in accordance with a third embodiment of the present invention;

Figure 9 illustrates a component part of a powder inhaler in accordance with a fourth embodiment of the present invention;

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Figures 10 and 11 illustrate component parts of a powder inhaler in accordance with a fifth embodiment of the present invention;

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Figures 12 and 13 illustrate component parts of a powder inhaler in accordance with a sixth embodiment of the present invention; and

Figures 14 and 15 illustrate indicating wheels for use with the powder inhalers of any of  
5 Figures 7 to 13.

Structurally, the powder inhalers in accordance with the preferred embodiments of the present invention have many features in common with the above-described known powder inhaler. For this reason, and in order to avoid unnecessary duplication of description, only  
10 the structural differences will be described in detail and reference is made to the preceding description of the known powder inhaler.

Figures 4 and 5 illustrate respectively a body part 48 and a storage unit 26 of a powder inhaler in accordance with a first embodiment of the present invention.

15

This inhaler is a modification of the above-described known powder inhaler. This inhaler differs from the above-described known powder inhaler in comprising a body part 48 which is a single part moulded from an opaque material that comprises both the inhaler body 6 and the divider 14. As in the above-described known powder inhaler, the inhaler  
20 body 6 includes the opening 10 through which the indicating wheel 42 is visible. This inhaler further differs from the above-described known powder inhaler in that the storage unit 26 is formed from a transparent material and comprises a tongue 50, one part, in this embodiment the distal end, of which is shaped and dimensioned such that when the storage unit 26 is fitted in the inhaler body 6 that part of the tongue 50 fills the opening 10 so as to  
25 provide the window 12. As in the above-described known powder inhaler, the indicating wheel 42 is rotatably supported to the underside of the divider 14 such that at least a part of the periphery of the indicating wheel 42 is visible through the window 12. In a preferred embodiment one or both of the inhalation unit 22 and the storage unit 26 are formed together with the inhaler body 6 as a single integral unit.

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Figure 6 illustrates a structural unit 52 of a powder inhaler in accordance with a second embodiment of the present invention.

This inhaler is a modification of the inhaler of the above-described first embodiment. This inhaler differs from the inhaler of the above-described first embodiment in that the inhalation unit 22 and the storage unit 26 are replaced by a structural unit 52 which is a single part moulded from a transparent material. The structural unit 52 comprises the tongue 50, a part of which fills the opening 10 so as to provide the window 12. Again, as in the inhaler of the above-described first embodiment, the indicating wheel 42 is rotatably mounted to the underside of the divider 14.

Figures 7 and 8 illustrate respectively a body part 48 and a storage unit 26 of a powder inhaler in accordance with a third embodiment of the present invention.

This inhaler is a modification of the inhaler of the above-described first embodiment. In this embodiment the body part 48 differs in that the peripheral wall of the inhaler body 6 includes a recess 54 in a side of which is provided the opening 10 and the storage unit 26 differs in that the tongue 50 is oriented substantially radially so as to align with the opening 10 in the recess 54.

Figure 9 illustrates a structural unit 52 of a powder inhaler in accordance with a fourth embodiment of the present invention.

This inhaler is a modification of the inhaler of the above-described third embodiment. In this embodiment the inhalation unit 22 and the storage unit 26 of the inhaler of the above-described third embodiment are replaced by a structural unit 52 which is a single part moulded from a transparent material.

Figures 10 and 11 illustrate respectively a body part 48 and a structural unit 52 of a powder inhaler in accordance with a fifth embodiment of the present invention.

This inhaler is a modification of the inhaler of the above-described fourth embodiment. In this embodiment the body part 48 differs in that a lower section of the recess 54 in the inhaler body 6 is cut away to provide an opening 56 into the inhaler body 6 and the structural unit 52 differs in that the lower end of the inhalation channel 24 is provided with a lateral opening 58. During inhalation by a user, air is drawn through the opening 56 in the recess 54 and then the lateral opening 58 in the inhalation channel 24 where a dose of powder is entrained, which powder is then drawn up the inhalation channel 24 into and through the air chamber and out of the outlet nozzle 4 of the mouthpiece 2.

10

Figures 12 and 13 illustrate respectively a body part 48 and a structural unit 52 of a powder inhaler in accordance with a sixth embodiment of the present invention.

This inhaler is a modification of the inhaler of the above-described fifth embodiment. This inhaler differs from the inhaler of the above-described fifth embodiment in that the structural unit 52 includes the supporting means 40 for rotatably supporting the indicating wheel 42 instead of the divider 14 and in that the divider 14 is formed with a substantially flat top surface. In this way, the risk of powder accumulating at this top surface is minimized. This is of particular importance where the top surface of the divider 14 forms the lower wall of the air chamber of the mouthpiece 2.

In any of the inhalers of the above-described third to sixth embodiments the indicating wheel 42 may be disposed such that a side surface thereof is visible through the opening 10 in the recess 54 in the inhaler body 6. In order to improve visibility, one of the side surfaces of the indicating wheel 42 can be formed as a conical surface, with the surface of the cone enclosing an angle of from 10° to 30°, preferably about 15°, with the rotational plane of the indicating wheel 42. The indicating wheel 42 may have indications on the surface of the cone, for instance numeric indications of increasing or decreasing value, for indicating the number of times the inhaler has been operated or the number of times it may still be operated. Alternatively, or additionally, the indicating wheel 42 may have a

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circumferential band of changing width along its length, such that the width visible through the window 12 is representative of the number of doses delivered. Suitable indicating wheels are illustrated in Figures 14 and 15. Colour changes may also be used to indicate the number of doses delivered. Such colour changes may also be applied in conjunction  
5 with the indications described hereinabove. For instance, by using numerals of different colour, or by using a band, the colour of which changes along its length.

In each of the above-described embodiments the storage chamber 28 is crescent-shaped in plan view and thereby provides an increased storage capacity. It will be understood,  
10 however, that the storage chamber 28 may be formed as a cylinder as in the above-described known powder inhaler.

Finally, it will be understood by a person skilled in the art that the present invention is not limited to the described embodiments but can be modified in many different ways within  
15 the scope of the appended claims.

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CLAIMS:

1. An inhaler for administering powder by inhalation, comprising:

an inhaler body provided with a window;

5 a divider substantially closing one end of the inhaler body and being integrally formed therewith;

an indicating wheel disposed in the inhaler body for providing an indication as to the usage of the inhaler, the indicating wheel being disposed such that at least part  
10 thereof is visible through the window and so as to be rotatable in a diametrical plane containing a central axis of the inhaler body; and

a storage unit disposed in the inhaler body, the storage unit comprising a storage chamber for storing powder  
15 for inhalation;

characterized in that the inhaler body includes an opening through which at least part of the indicating wheel is visible, in that the inhaler body and the divider are formed of an opaque material and in that the storage unit is  
20 formed of a transparent material and includes a portion which substantially fills the opening and provides the window.

2. The inhaler according to claim 1, further comprising an inhalation unit disposed in the inhaler body,  
25 the inhalation unit comprising an inhalation channel through which powder is in use inhaled.

3. The inhaler according to claim 2, wherein the inhalation unit and the storage unit are formed as a single integral unit.

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4. The inhaler according to claim 2 or 3, further comprising a dosing unit disposed in the inhaler body so as to be rotatable about the central axis thereof for introducing a dose of powder to the inhalation channel, wherein the dosing unit has a central shaft co-axial with the central axis of the inhaler body, the central shaft having an end face with a spiral groove or protrusion and the indicating wheel having a toothed periphery for engaging the spiral groove or protrusion.
5. The inhaler according to any of claims 1 to 4, wherein the storage unit further comprises supporting means for rotatably supporting the indicating wheel.
6. The inhaler according to any of claims 1 to 5, wherein the storage chamber has an arcuate cross-section.
7. The inhaler according to any of claims 1 to 6, wherein the inhaler body includes an air inlet in a side wall thereof, the air inlet allowing air to be drawn to the dosing unit and through the inhalation channel.
8. The inhaler according to claim 7, wherein the inhaler body includes a recess in the side wall thereof in which the air inlet is provided.
9. The inhaler according to any of claims 1 to 8, wherein the inhaler body is substantially cylindrical.
10. The inhaler according to any one of claims 1 to 9, further comprising said powder.
11. The inhaler according to claim 10, wherein said powder comprises a medicament selected from:  $\beta$ 2-adrenoreceptor agonists; anticholinergic bronchodilators; glucocorticosteroids; antiallergic medicaments; expectorants; mucolytics; antihistamines; cyclooxygenase

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inhibitors; leukotriene synthesis inhibitors; leukotriene antagonists; phospholipase-A2 (PLA2) inhibitors; platelet aggregating factor (PAF) antagonists and prophylactics of asthma; antiarrhythmic medicaments; tranquilisers; cardiac glycosides; hormones; antihypertensive medicaments; antidiabetic medicaments; antiparasitic medicaments; anticancer medicaments; sedatives; analgesic medicaments; antibiotics; antirheumatic medicaments; immunotherapies; antifungal medicaments; antihypotension medicaments; vaccines; antiviral medicaments; proteins; polypeptides and peptides; polypeptide vaccines; enzymes; endorphines; lipoproteins and polypeptides involved in the blood coagulation cascade; vitamins; cell surface receptor blockers; antioxidants; free radical scavengers; or organic salts of N,N'-diacetylcystine.

12. The inhaler according to claim 10, wherein said powder comprises a medicament selected from: salbutamol or a pharmaceutically acceptable salt or ester thereof; terbutaline or a pharmaceutically acceptable salt or ester thereof; rimiterol or a pharmaceutically acceptable salt or ester thereof; fenoterol or a pharmaceutically acceptable salt or ester thereof; reproterol or a pharmaceutically acceptable salt or ester thereof; adrenaline or a pharmaceutically acceptable salt or ester thereof; pirbuterol or a pharmaceutically acceptable salt or ester thereof; isoprenaline or a pharmaceutically acceptable salt or ester thereof; orciprenaline or a pharmaceutically acceptable salt or ester thereof; bitolterol or a pharmaceutically acceptable salt or ester thereof; salmeterol or a pharmaceutically acceptable salt or ester thereof; formoterol or a pharmaceutically acceptable salt or ester thereof; clenbuterol or a pharmaceutically acceptable salt or ester thereof; procaterol or a pharmaceutically

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acceptable salt or ester thereof; broxaterol or a  
pharmaceutically acceptable salt or ester thereof;  
picumeterol or a pharmaceutically acceptable salt or ester  
thereof; TA-2005 or a pharmaceutically acceptable salt or  
5 ester thereof; mabuterol or a pharmaceutically acceptable  
salt or ester thereof; ipratropium bromide; beclomethasone  
or a pharmaceutically acceptable salt or ester thereof;  
fluticasone or a pharmaceutically acceptable salt or ester  
thereof; budesonide or a pharmaceutically acceptable salt or  
10 ester thereof; tipredane or a pharmaceutically acceptable  
salt or ester thereof; dexamethasone or a pharmaceutically  
acceptable salt or ester thereof; betamethasone or a  
pharmaceutically acceptable salt or ester thereof;  
fluocinolone or a pharmaceutically acceptable salt or ester  
15 thereof; triamcinolone acetonide or a pharmaceutically  
acceptable salt or ester thereof; mometasone or a  
pharmaceutically acceptable salt or ester thereof; sodium  
cromoglycate; or nedocromil sodium.

13. The inhaler according to claim 10, wherein said  
20 powder comprises formoterol or a pharmaceutically acceptable  
salt or ester thereof.

14. The inhaler according to claim 10, wherein said  
powder comprises budesonide or a pharmaceutically acceptable  
salt or ester thereof.

25 15. The inhaler according to claim 10, wherein said  
powder comprises formoterol or a pharmaceutically acceptable  
salt or ester thereof and budesonide or a pharmaceutically  
acceptable salt or ester thereof.

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PATENT AGENTS



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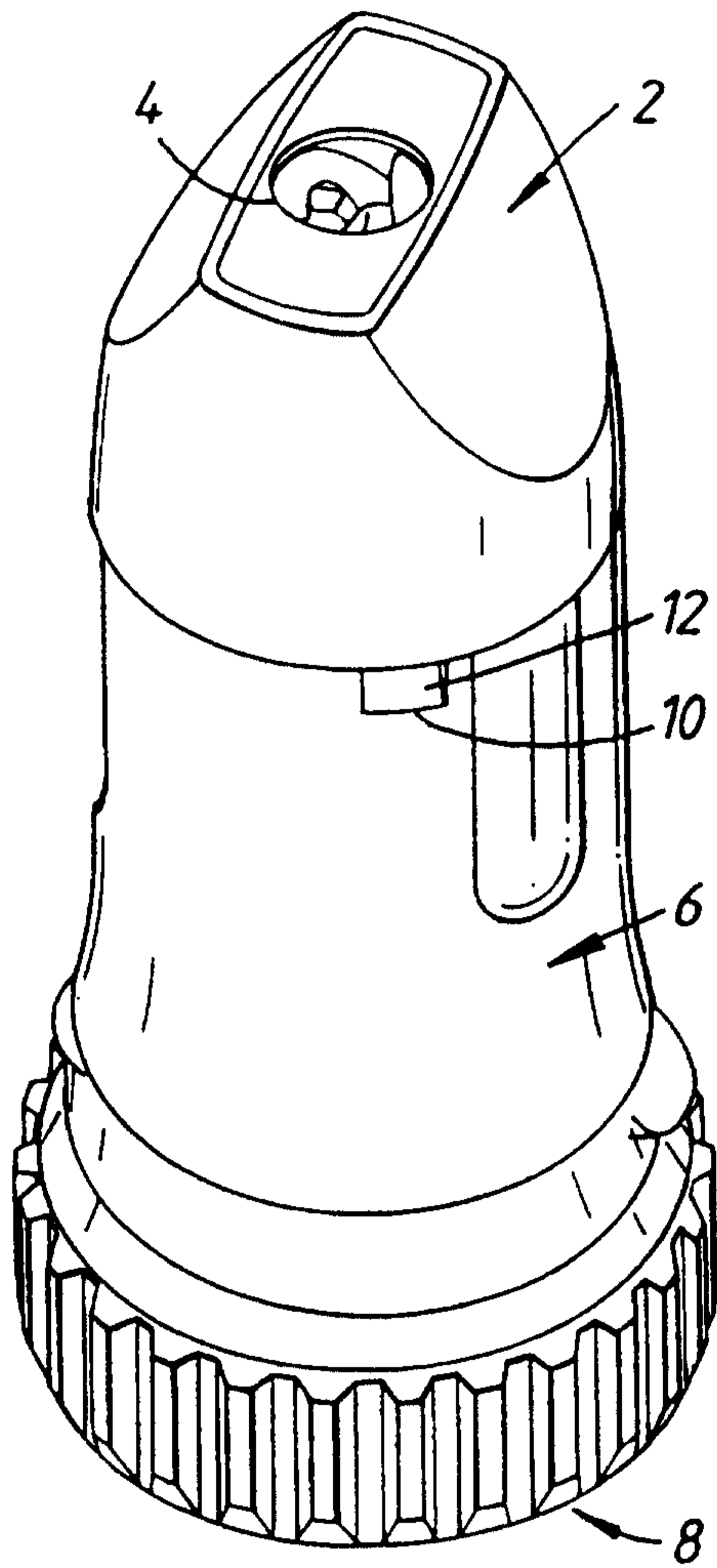


Fig. 1

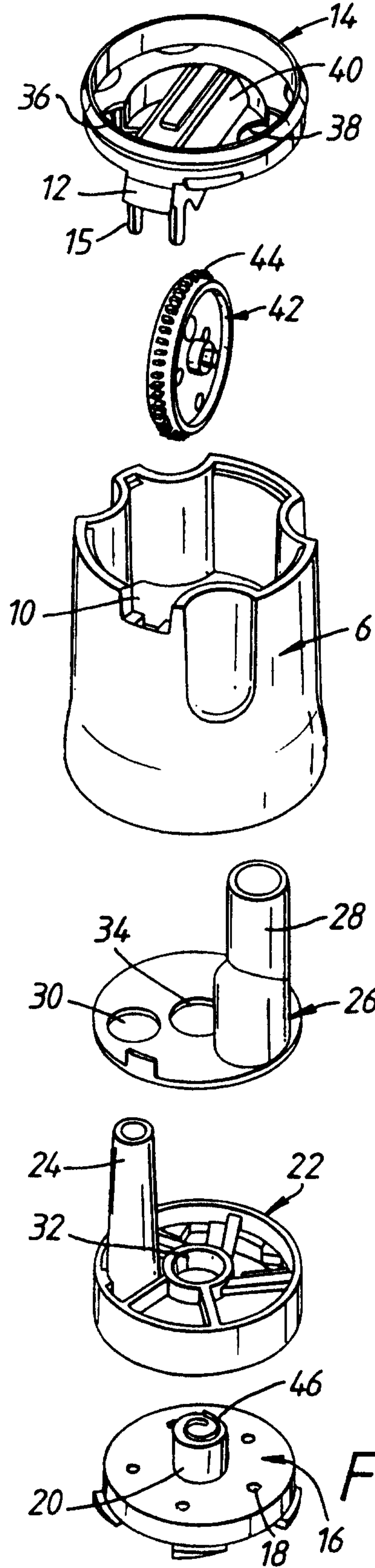


Fig. 2

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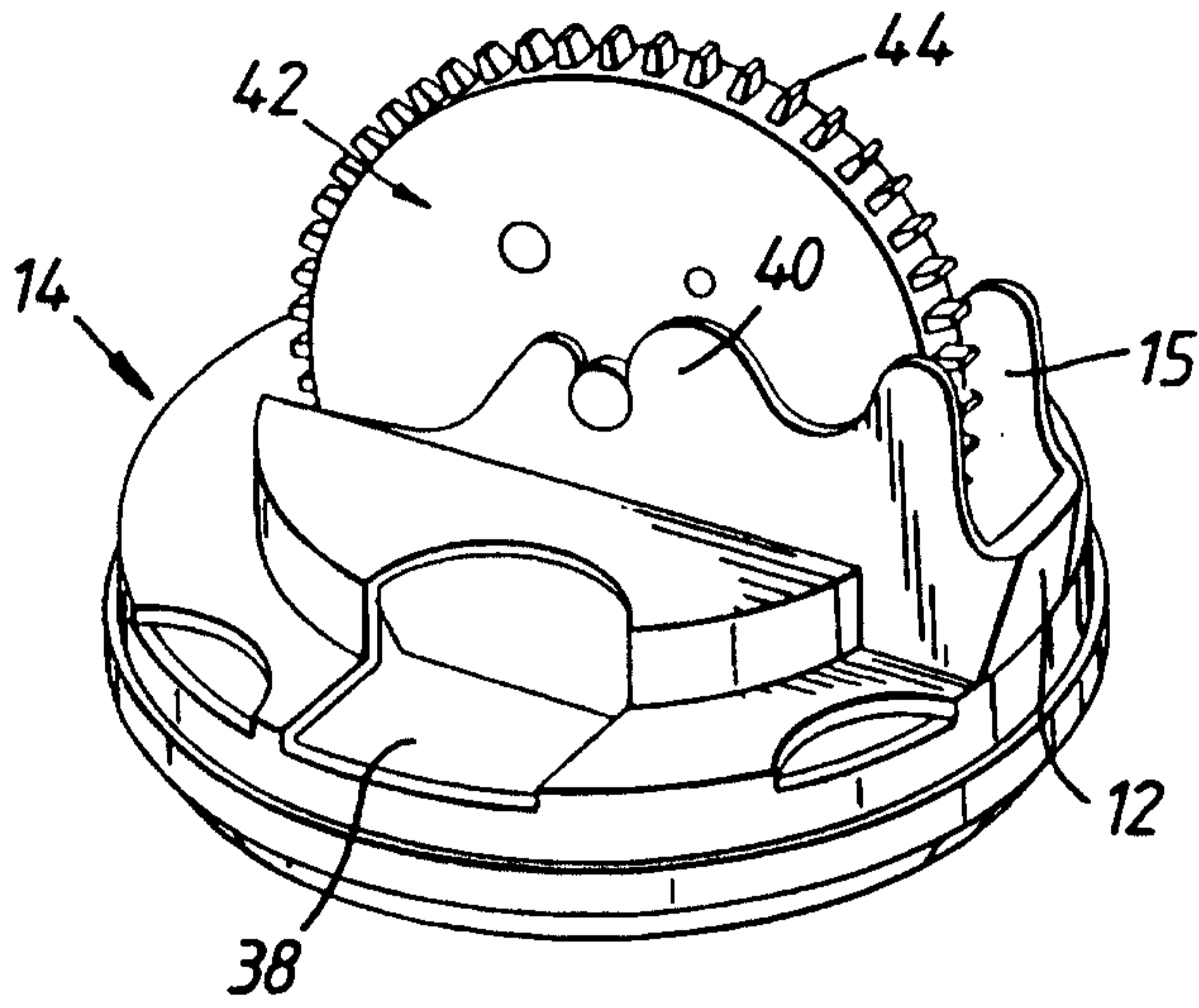


Fig. 3

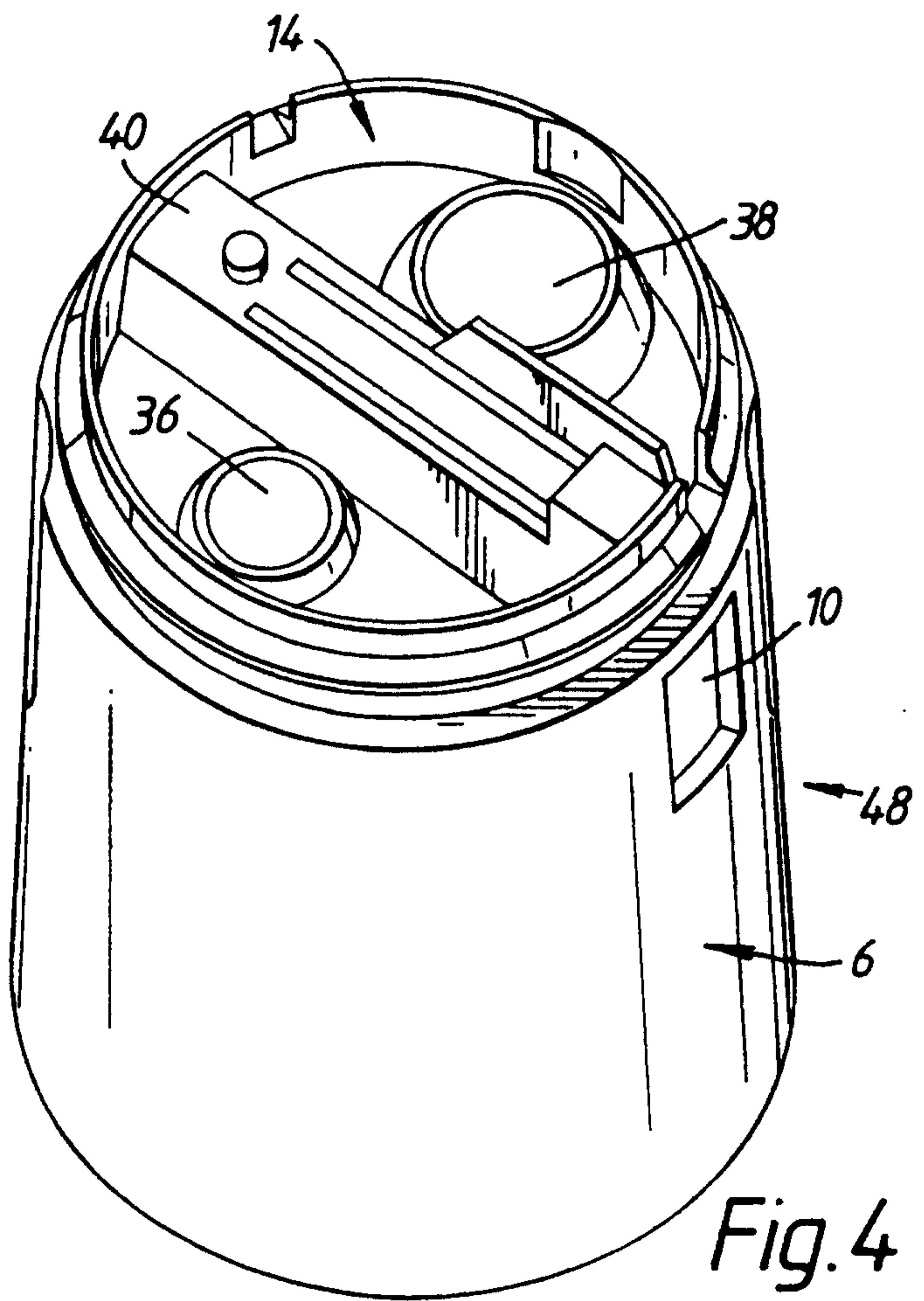


Fig. 4

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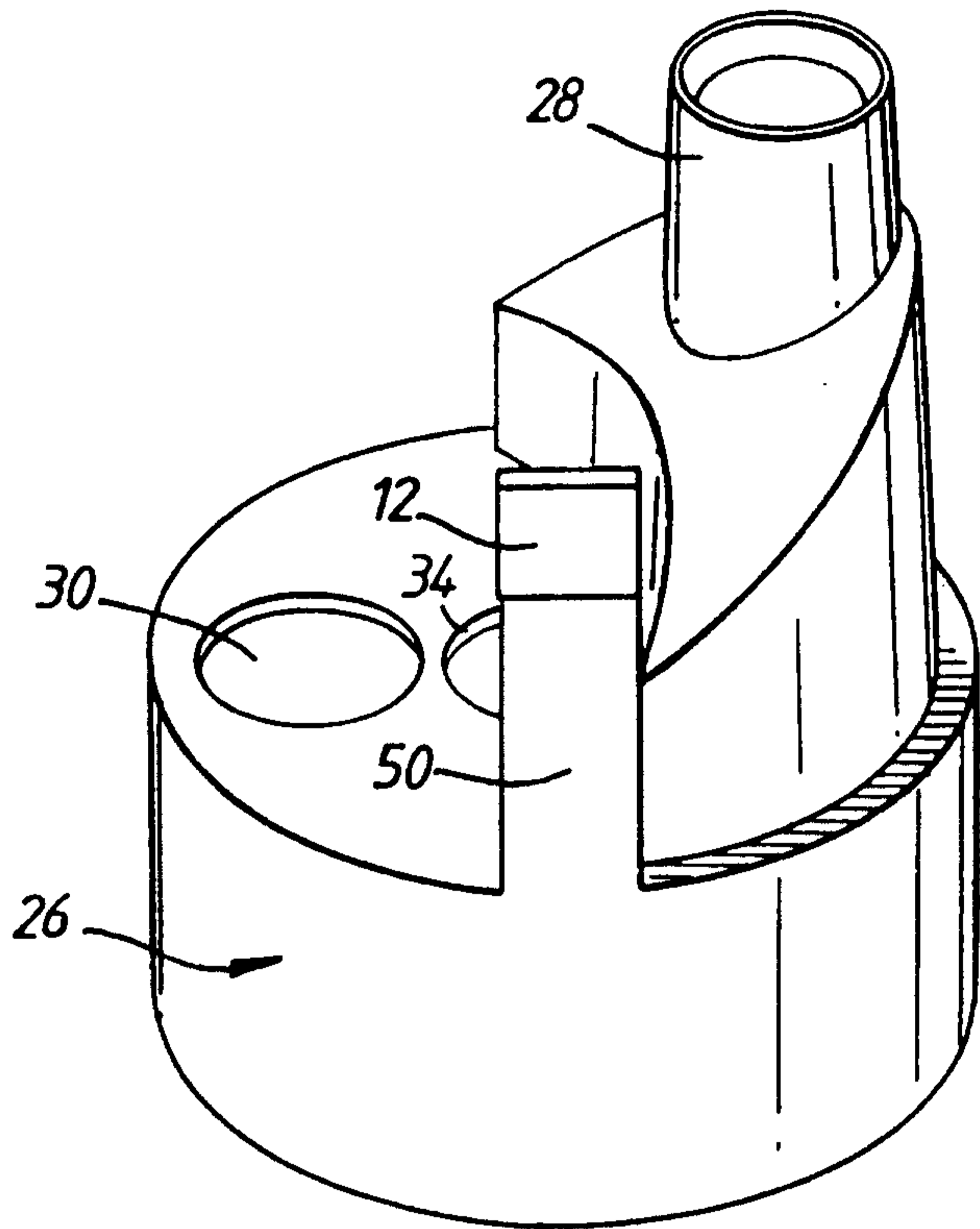


Fig. 5

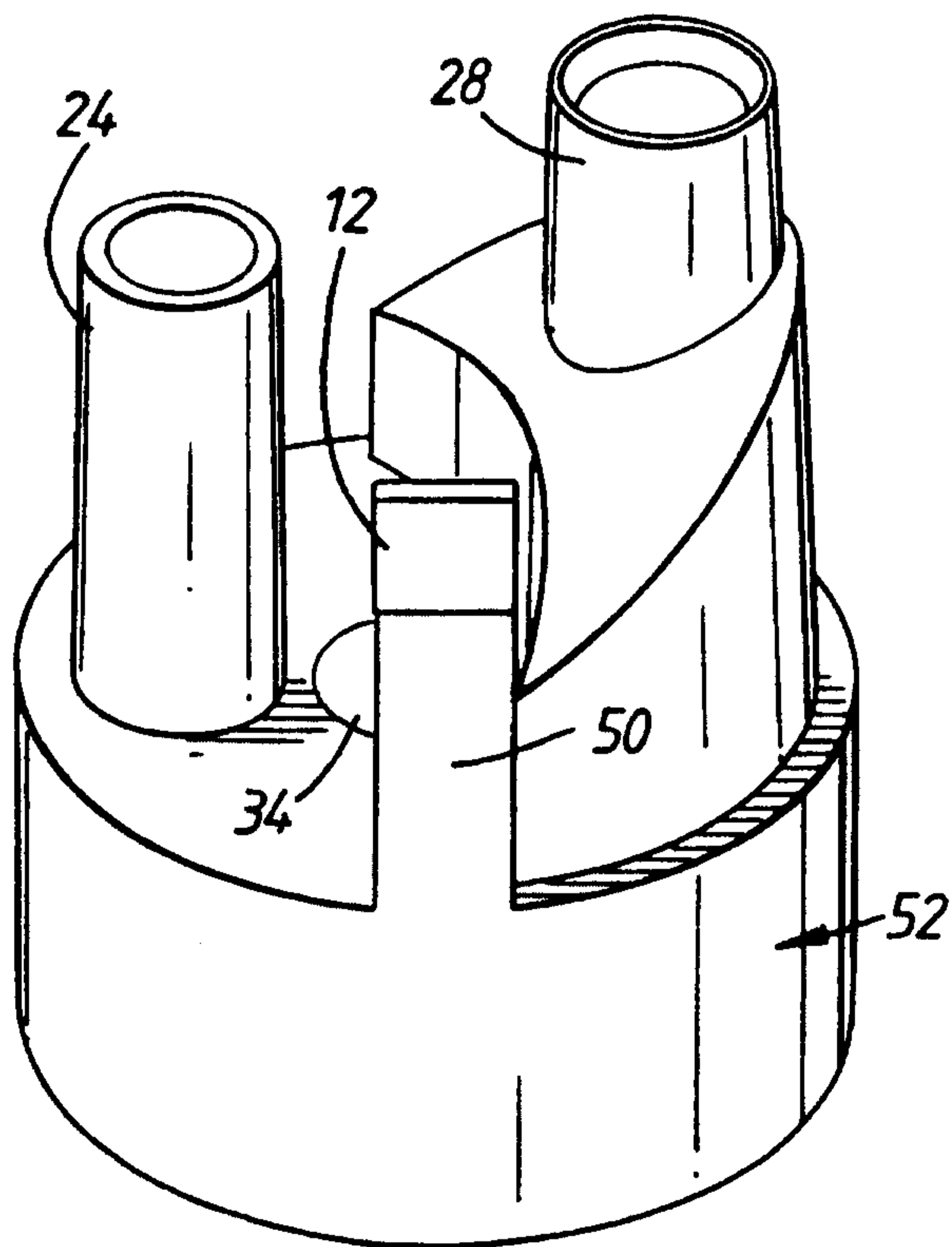


Fig. 6

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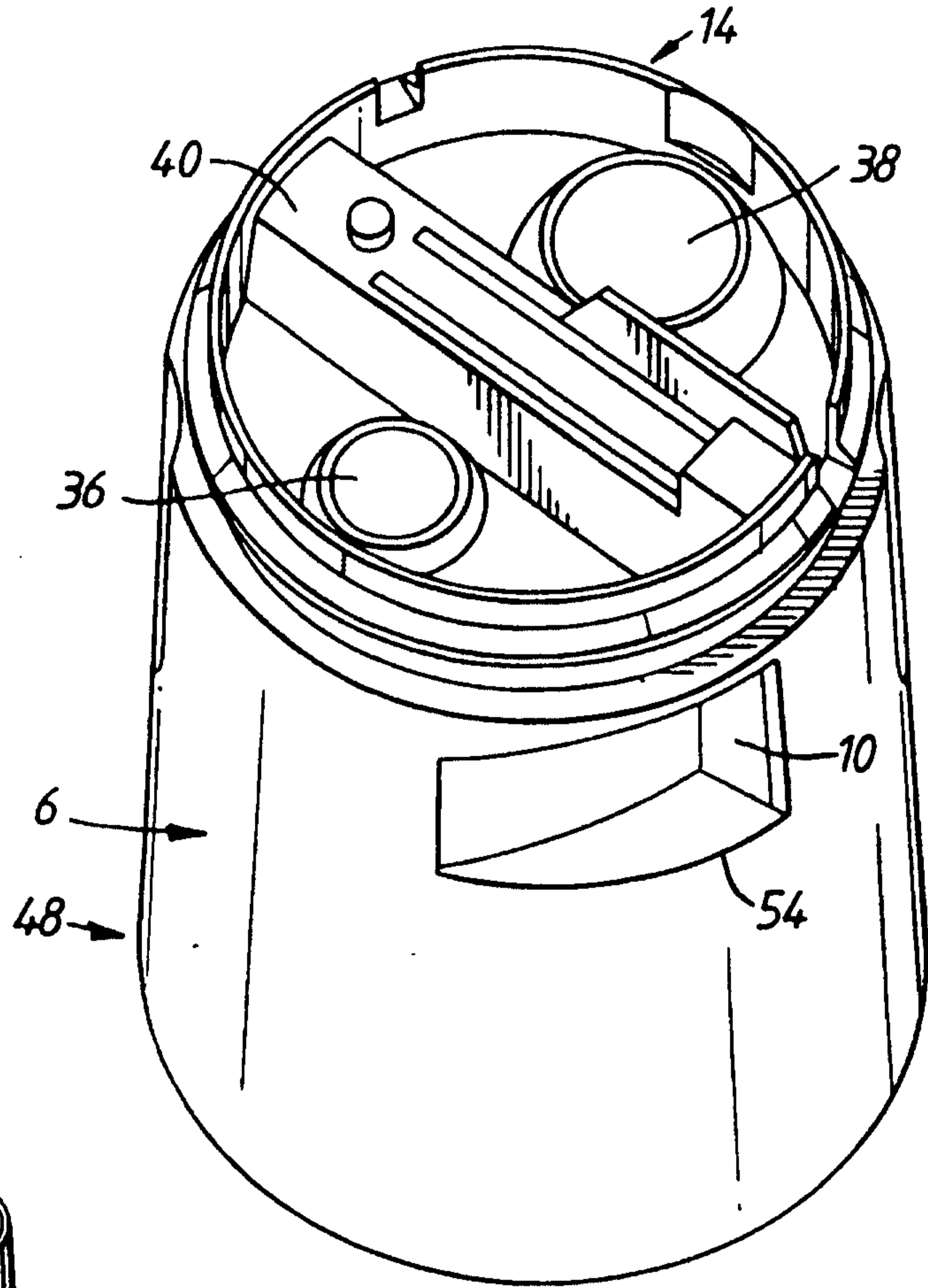


Fig. 7

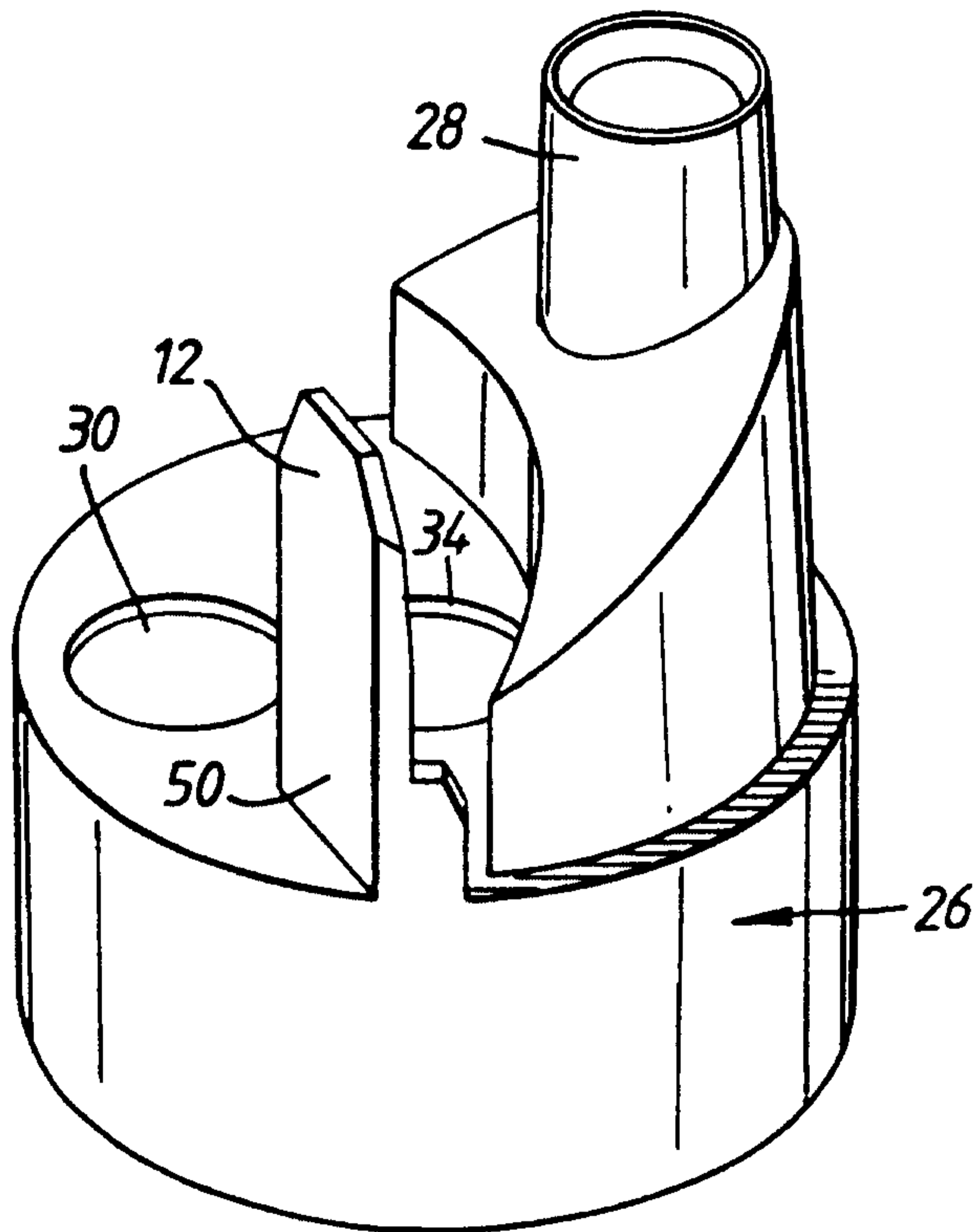


Fig. 8

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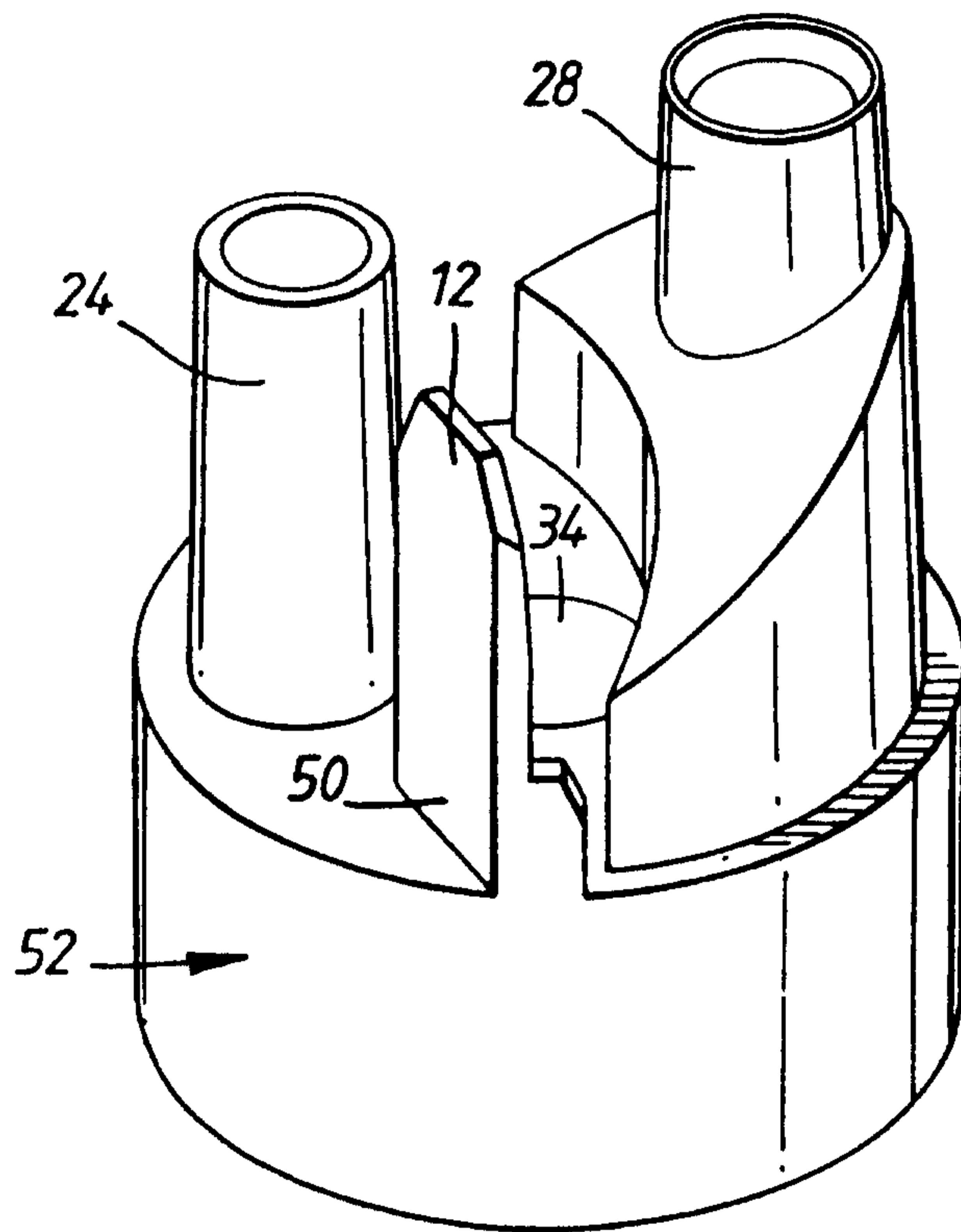


Fig. 9

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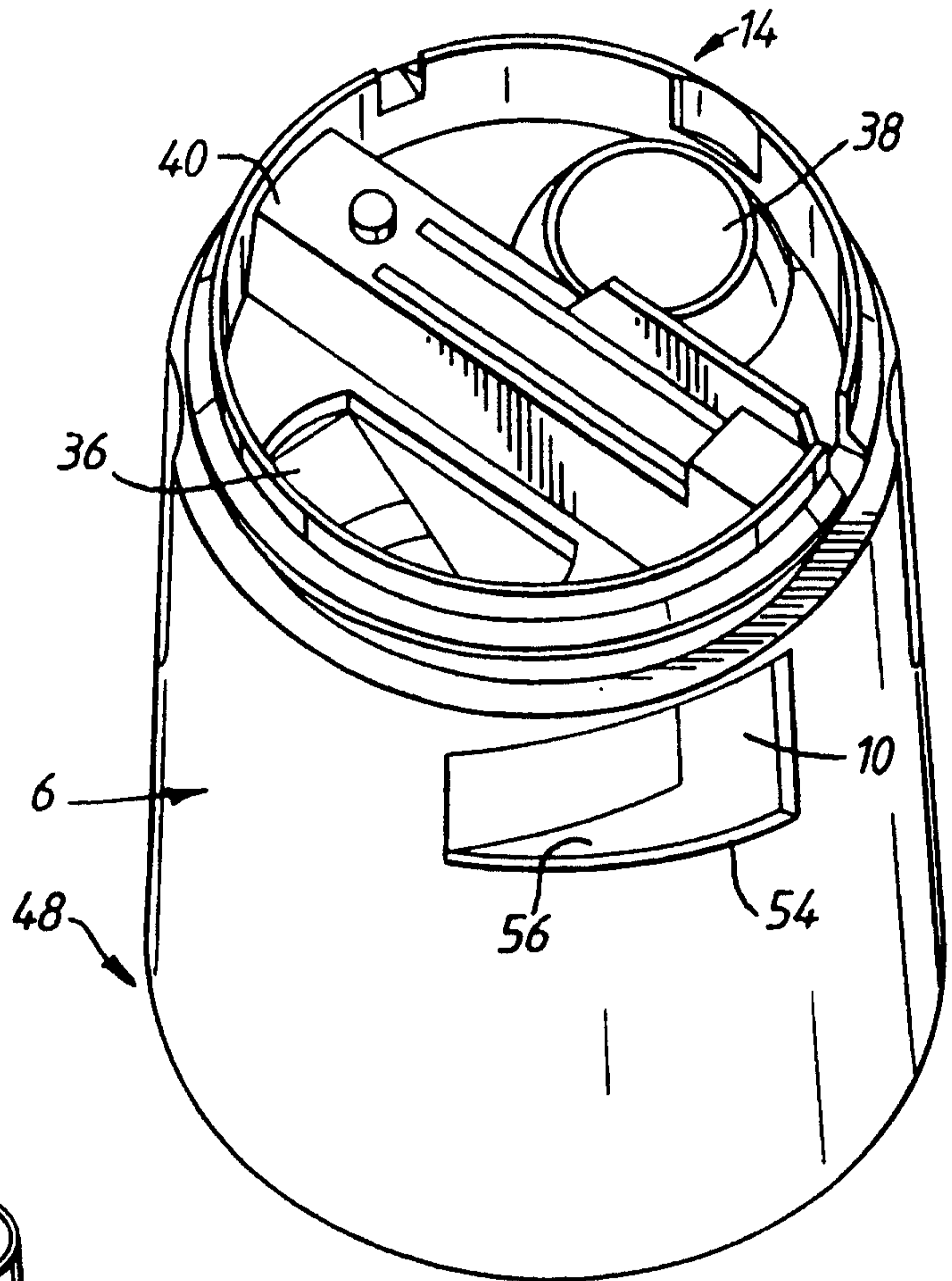


Fig. 10

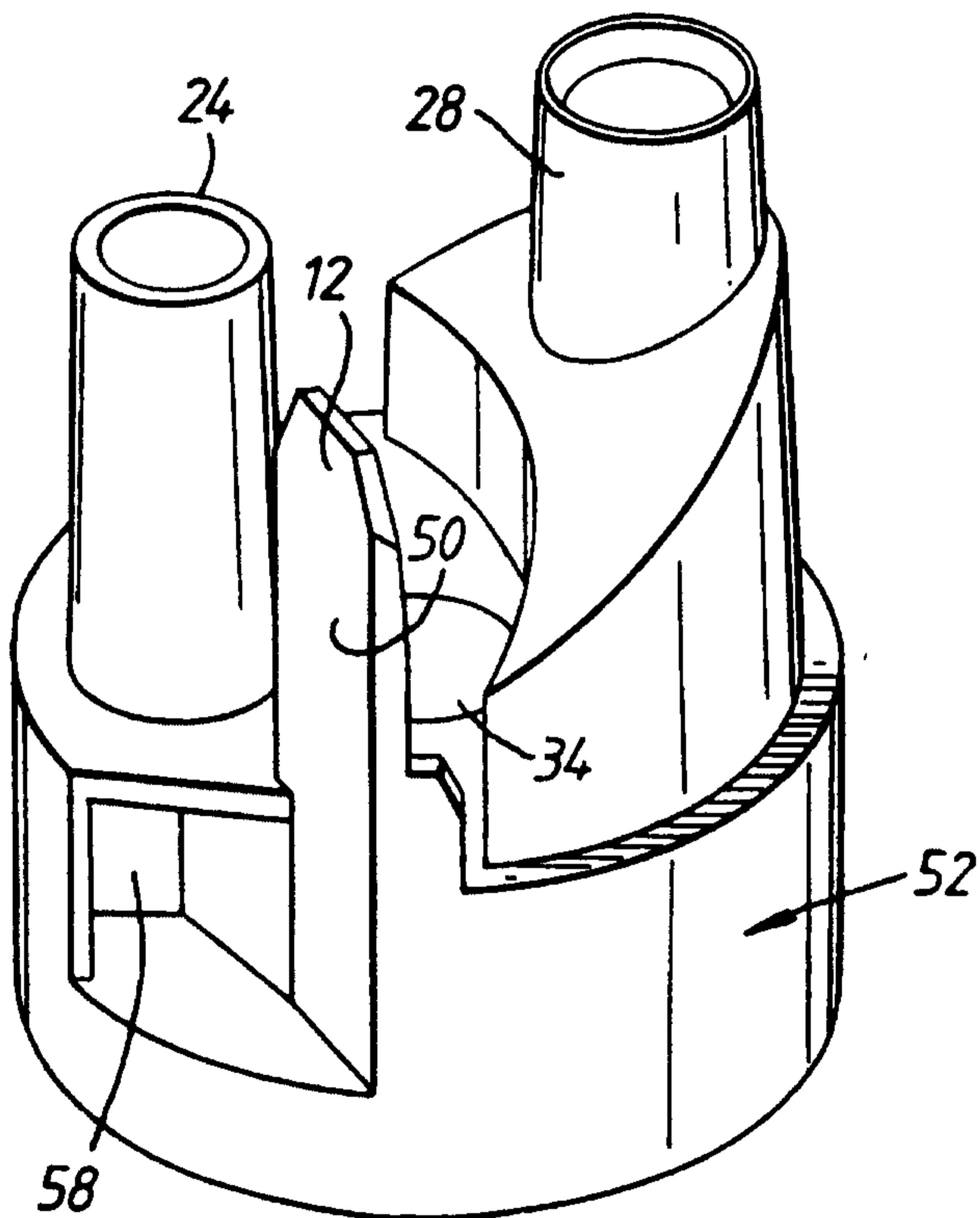


Fig. 11

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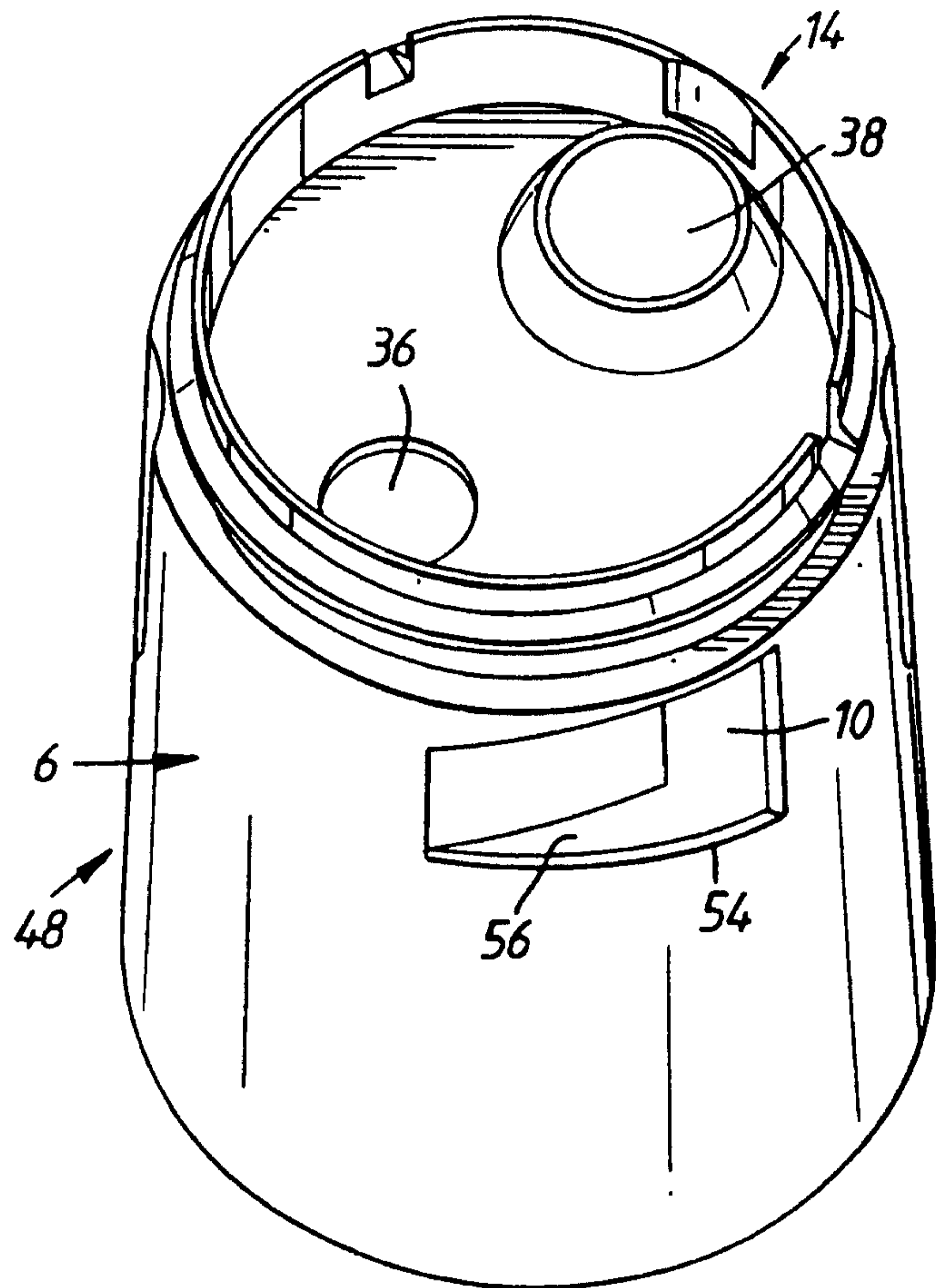


Fig. 12

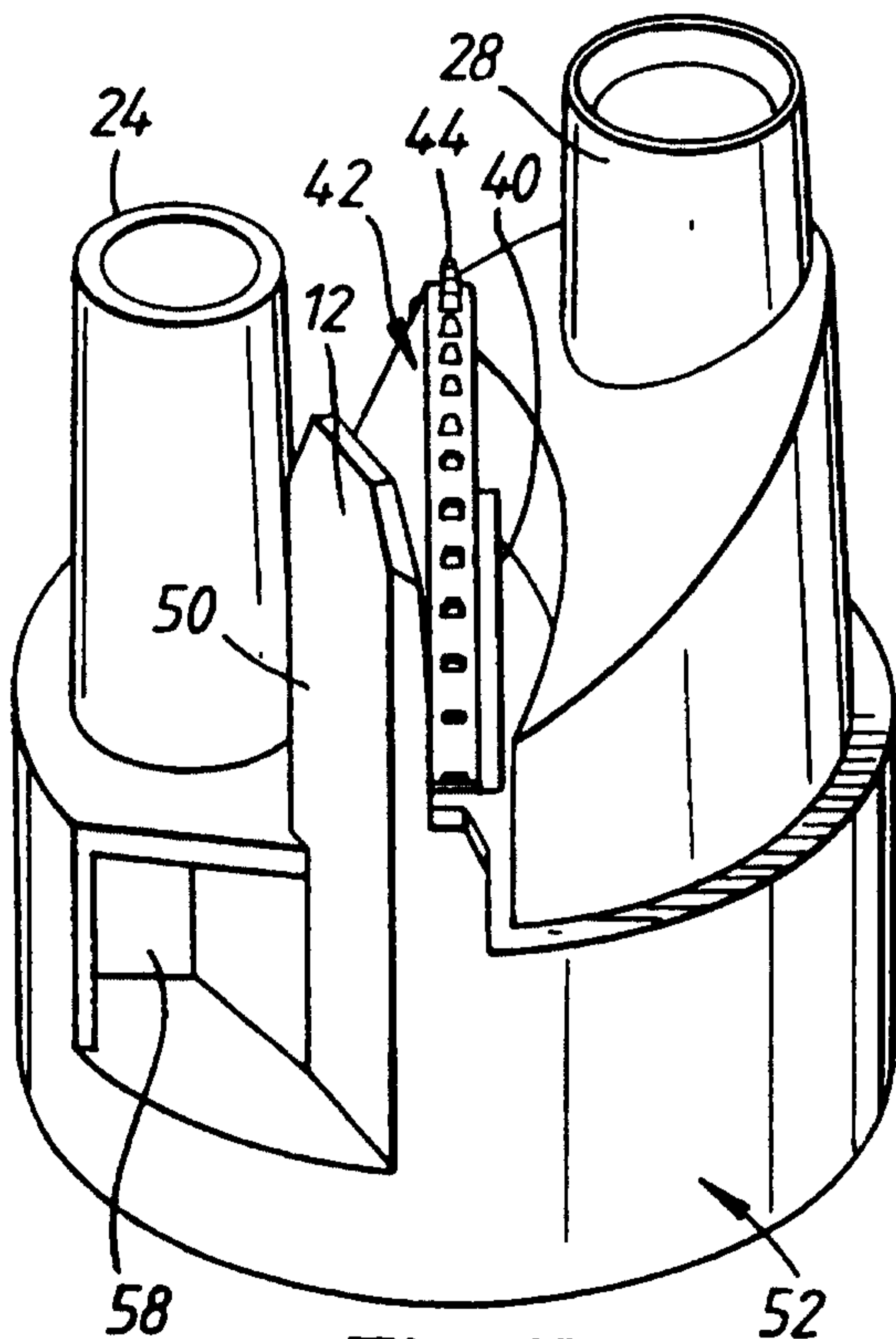


Fig. 13

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