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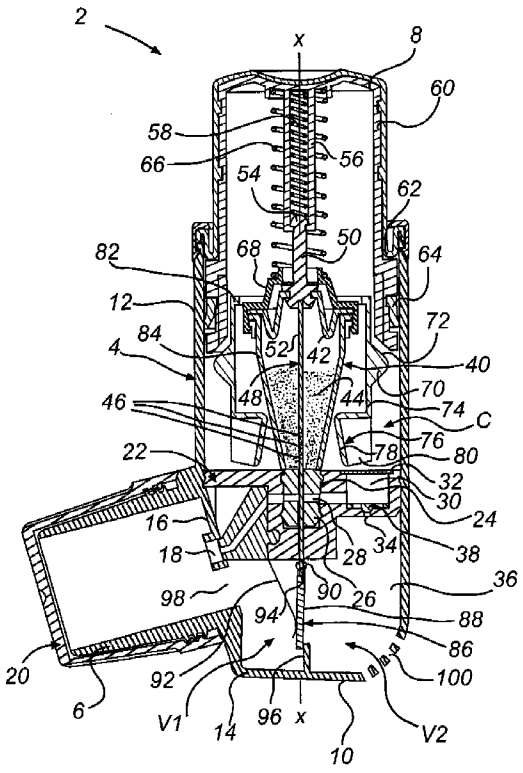

Fig. 1a

(57) Abstract: The invention relates to an inhaler for powdered substance. The inhaler comprises a transfer member which is displaceable in a substance storing chamber and which comprises at least one dosing chamber for taking up substance from the substance storing chamber. The transfer member can being latched by an inhalation-triggered release mechanism which, upon inhalation by a user, unlatches the transfer member, thereby enabling it to move the dosing chamber to a flow passage.

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Breath-triggered inhaler

Technical field

The present invention relates to an inhaler for powdered substance, which comprises a mouthpiece or nasal adaptor through which substance is inhalable by a user.

Background of the Invention

There are different types of inhalers on the market. A pressurized Metered Dose Inhaler (pMDI) releases a fixed dose of substance in aerosol form. A powder inhaler generally releases a dose of powdered substance entrained in an air stream. Powder inhalers commonly require a priming procedure to place a dose of powder ready for the user to take. International patent applications PCT/EP2007/052172 and PCT/EP/2007/052178 (AstraZeneca AB) illustrate examples of powder inhalers.

In Figs. 27-37 of US 6,029,661 a powder inhaler is disclosed. The inhaler has an agglomerator (e.g. blades) for transferring a quantity of dry powder medicament from a medicament reservoir to a dosage chamber. A spring is provided for biasing the dosage chamber towards a position in register with a pressure outlet. An inhalation activated assembly releases the dosage chamber in response to user inspiratory airflow through an inhalation airway passageway to afford movement of the dosage chamber to the registered position under the bias of the spring.

Summary of the Invention

The present invention is based on the insight that one and the same component may be used for transferring a substance from a substance storage chamber to a flow passage for delivery of the substance to a user. Thus, the present invention avoids using a separate component (as in US 6,029,661) for transferring the substance from a medicament reservoir to another component which in turn is moved in response to a user's inhalation. Instead, the inventors of the present invention have realized that the actual component that transfers the substance from a reservoir may be latched and then released in response to a user's inhalation so as to provide the substance to the flow path leading to the user.

According to at least one aspect of the invention, an inhaler for powdered substance is provided, such as a pharmaceutical substance or a plurality of pharmaceutical substances which are provided separately or in mixture. The inhaler comprises an inhalation interface in the form of a mouthpiece or nasal adaptor through which substance is inhalable by a user. A flow passage is in fluid communication with the mouthpiece or nasal adaptor. The inhaler further comprises a substance storing chamber for holding the substance. A transfer member is displaceable in the substance storing chamber and comprises at least one dosing chamber for taking up substance inside the substance storing chamber. The transfer member is displaceable between a substance-keeping position, in which the dosing chamber keeps the substance, and a substance-evacuating position, in which the dosing chamber presents the substance to the flow passage. The transfer member is latched in the substance-keeping position by an inhalation-triggered release mechanism which, when a user inhales through the mouthpiece or nasal adaptor, unlatches the transfer member, thereby enabling it to move to the substance-evacuating position.

Thus, unlike the prior art inhaler of US 6,029,661 in which the dosage chamber receives the substance outside the reservoir, the present dosing chamber can be arranged to travel from inside the actual substance storing chamber to the flow passage.

The inhalation effort required by the user for triggering the release mechanism may be chosen depending on e.g. age of user and type of therapy. The inspiratory air flow threshold to be overcome may be chosen by appropriate design of e.g. inertia and resistive force acting upon the release mechanism.

According to at least one example embodiment of the invention, the transfer member comprises a rod which is displaceable in its longitudinal (lengthwise) direction. Thus, a dose will be taken up from the substance storing chamber and then, in response to inhalation be moved substantially in a straight uncurved direction to the flow passage. The dosing chamber may be incorporated as an integral part of the rod. However, it would also be conceivable to have a separate dosing chamber which is connected to the rod. In either case, the straight movement from the substance storing chamber is achievable.

Although the above-described example embodiment discusses a rod which is displaceable in its longitudinal direction, a rotational displacement or pivoting

displacement of the rod would also be conceivable depending on the configuration and placement of the storing chamber and the flow passage. Furthermore, instead of or as a complement to a rod, the transfer member may comprise component shapes, such as polygonal or circular. For instance, a rotatable wheel may take up the substance from the storing chamber and then, after unlatching by the release mechanism, rotate to present the substance to the flow passage. Thus, it should be understood that the general idea of using a latchable transfer member for moving a dose from a substance storing chamber to the flow passage can be implemented in various configurations.

Even though gravitational force may be used for making the transfer member drop to its substance-evacuating position when unlatched by the release mechanism, it may be desirable to use some other force which is less dependent of the spatial orientation of the inhaler. Thus, according to at least one example embodiment of the invention, the inhaler comprises a biasing mechanism adapted to bias the transfer member towards the substance-evacuating position. The biasing mechanism could be activated electronically or mechanically. The biasing mechanism could provide the force by a manually maintained pressure, e.g. the user pressing and keeping his/her finger on the biasing mechanism so as to provide the force urging the transfer member to the substance-evacuating position. Rather than keeping a manual pressure, the biasing mechanism may have some kind of latch for maintaining the bias on the transfer member even after the user has let go of the biasing mechanism. The biasing mechanism may suitably comprise a spring acting on the transfer member.

According to at least one example embodiment of the invention, the dosing chamber is located inside the substance storing chamber when the transfer member is latched by the release mechanism in said substance-keeping position and biased towards the substance-evacuating position by the biasing mechanism. Thus, when the inhaler is primed, i.e. in a loaded state ready for inhalation, the substance is kept safely inside the substance storing chamber, or more specifically, the substance is kept inside the dosing chamber which in turn is located inside the substance storing chamber. This arrangement reduces the risk of contamination. Furthermore, the inhaler may be provided with a feature that allows the biasing of the biasing mechanism to be cancelled if a user changes his/her

mind and does not want to use the inhaler at present. The substance will then still be kept safe in the substance storing chamber. In the inhaler disclosed in US 6,029,661 the substance is moved out of the medicament reservoir and cannot be moved back if the user changes his/her mind.

Although the above-described example embodiment discusses the dosing chamber being located in the substance storing chamber when the inhaler has been primed, an alternative would be to arrange said substance-keeping position of the transfer member in such way that the dosing chamber is located in an intermediate conduit or the like between the storing chamber and the flow passage, which could still provide a safely shielded location. Thus, the priming could comprise introducing substance into the dosing chamber, displacing the transfer member so that the dosing chamber is moved from the substance storing chamber to said intermediate conduit (the transfer member becomes latched after said displacement) and biasing the transfer member towards the substance-evacuating position. Alternatively, the transfer member may be displaced only a short distance before becoming latched so that the dosing chamber, even though moved, still remains located inside the substance storing chamber.

As mentioned previously, the biasing mechanism may be configured in various ways. According to at least one example embodiment of the invention, the biasing mechanism comprises an actuator which is movable towards the transfer member and a spring which is compressible between the actuator and the transfer member, whereby movement of the actuator towards the transfer member, when the transfer member is latched in the substance-keeping position, causes the transfer member to become spring-loaded. Other alternatives to providing a spring between the actuator and the transfer member are conceivable. For instance, there could be provided a hydraulic arrangement, such as comprising a piston movable in a cylinder, for transmitting the biasing force. While a simple linear movement of the actuator towards the transfer member is readily envisaged, there may also be alternatives, such as rotating the actuator (e.g. like a tightening screw).

According to at least one example embodiment of the invention, the actuator, when actuated, is adapted to create an overpressure in a pressurizable space which comprises the flow passage. In response to a user's inhalation, the breath-triggered release mechanism

will cause the overpressure to be released, thereby evacuating the substance from the dosing chamber when the transfer member is in the substance evacuating position.

The pressurizable space, including the flow passage, may be closed in various ways for maintaining the overpressure. For instance, a valve may be provided. Suitably, the actual transfer member may act as or be part of a closure. Thus, according to at least one example embodiment of the invention, said transfer member in its substance-keeping position extends through the flow passage to close said pressurizable space and to maintain the overpressure until the transfer member is unlatched by the inhalation-triggered release mechanism. As the transfer member is unlatched, it will be displaced to the substance-evacuating position. In that position the dosing chamber presents the substance to the flow passage and the overpressure. The release of the overpressure causes a propellant stream to entrain the substance and deliver it to the mouthpiece or nasal adaptor. Suitably, in the substance-evacuating position of the transfer member, the dosing chamber will be located within the flow passage so as to form part of the flow path. This may be arranged in various ways, one of which being designing the dosing chamber as a cross hole through the transfer member so that the propellant stream will be led through the transfer member to entrain the substance.

According to at least another example embodiment of the invention, said pressurizable space does not comprise the flow passage but is instead arrangable in fluid communication with the flow passage. The overpressure is released by the release mechanism and the fluid communication between the pressurizable space and the flow passage becomes open. This may suitably be accomplished by a valve between the flow passage and the pressurizable space, the valve being movable between a closed position for closing said pressurizable space and an open position for releasing the overpressure in the pressurizable space. The valve may be latched in the closed position by an inhalation-triggered release mechanism which, when a user inhales through the mouthpiece or nasal adaptor, unlatches the valve, thereby enabling the overpressure to be released and evacuate the substance from the dosing chamber.

Although the overpressure in the pressurizable space according to the above-described embodiments could have a release mechanism which is triggered separately from

the release mechanism for unlatching the transfer member, the inhaler may suitably use one and the same triggering for releasing the overpressure and unlatching the transfer member. A common triggering may facilitate the timing for entraining the substance into the flow caused by the released overpressure.

Furthermore, the overpressure in the above-described example embodiments may suitably be an air overpressure, whereby a stream of air entrains the substance in the dosing chamber. However, other alternative propellants are also conceivable, such as another gas, e.g. a HFA (Hydro Fluoro Alkane) or a CFC (Chloro Fluoro Carbon).

The actuator has hitherto been described as being used for one or two functions, namely for urging the transfer member towards the substance evacuating position and/or for creating an overpressure in the pressurizable space. In addition, to these functions, the actuation of the actuator may also be used for promoting substance to enter the dosing chamber. Thus, according to at least on example embodiment of the invention, the actuator, when actuated, causes at least a wall portion of the substance storing chamber to move towards the transfer member so that substance is urged into the dosing chamber, while the transfer member remains unmovable in the substance-keeping position. Although the use of the actual substance storing chamber wall for promoting substance to enter into the dosing chamber may be advantageous, alternative example embodiments could include other promoting means. For instance, the actuator could be connected to one or more pushers inside the storing chamber, wherein the substance would be pushed into the dosing chamber upon actuation of the actuator. Although the above-described example embodiments encompass the actuator to be involved in three different functions, an alternative would be to provide two or three separate actuators for said functions.

The inhaler may have several suitable locations for arranging the inhalation-triggered release mechanism. The transfer member could be latched in various ways, e.g. having protrusions or indentations mating with complementary features of the release mechanism. Another example could be that the release mechanism comprises a gripping means which may be closed and open for latching and releasing the transfer member. Yet another example could be that the release mechanism simply stands in the way of the transfer member, preventing it from further displacement until the release mechanism is

out of the way. The latter alternative may suitably be used for a transfer member which comprises a rod, however, that alternative and other alternatives may also be used for otherwise designed transfer member. Likewise, the transfer member which comprises a rod may also be used with otherwise designed release mechanisms.

According to at least one example embodiment of the invention, the storing chamber is located on one side of the flow passage and the release mechanism is located on the other side of the flow passage, wherein the transfer member extends through the flow passage. In the case of the transfer member comprising a rod, the actual rod could extend through the flow passage.

For the case in which the transfer member extends through the flow passage, the release mechanism may suitably comprise an abutment surface for receiving one end of the transfer member and latching the transfer member in the substance-keeping position. Although the abutment surface may simply be a surface which stands in the way of the travel direction of the transfer member and suitably mating with an end portion of the transfer member, the abutment surface could alternatively engage with other portions and features of the transfer member as mentioned previously.

According to at least one example embodiment of the invention, the release mechanism is displaceable from a latching state, in which the transfer member is latched in the substance-keeping position, to a releasing state, in which the transfer member is enabled to move to the substance-evacuating position, wherein the release mechanism comprises a return spring for urging the release mechanism to the latching state. The return spring may be provided in various configurations. One example is a leaf spring, another example is a coil spring.

Although the above-described example embodiment discusses a spring for urging the release mechanism to the latching state, other means for returning the release mechanism may be provided. For instance, various types of elastic bodies, hydraulic means or pneumatic means are conceivable alternatives, or some other components that can at least temporarily store energy developed when the release mechanism moves from the latching state to the releasing state. Furthermore, another alternative would be to manually affect the release mechanism to return to its latching state.

According to at least one example embodiment of the invention, the release mechanism comprises a movable member being movable from a relaxed position, in which the release mechanism is kept in the latching state, to an energized position in which the release mechanism is caused to be displaced to the releasing state, wherein a first side of the movable member partly defines a first volume which is in fluid communication with said mouthpiece or nasal adaptor, wherein, when a user inhales through said mouthpiece or nasal adaptor, an underpressure is established in said first volume causing the movable member to move from the relaxed position to the energized position. In the case of the release mechanism having a return spring or the like, the energizing force on the movable member will work against the force of the return spring. Thus, the design of the return spring and the movable member should be suitably balanced so that when a user inhales above a certain airflow threshold, the force of the return spring is overcome by the movable member and causes the release mechanism to unlatch the transfer member.

According to at least one example embodiment of the invention, the movable member is a diaphragm which is flexed to the energized position upon inhalation by a user. Suitably, the release mechanism comprises a pivotable rocker having an abutment surface for latching the transfer member, wherein the diaphragm is operatively connected to the rocker so that, when the diaphragm is flexed, the rocker is pivoted to said releasing state of the release mechanism.

According to at least one example embodiment of the invention, said movable member is a flap which is pivoted to the energized position upon inhalation by a user.

According to at least one example embodiment of the invention, a second side of the movable member, opposite to said first side, partly defines a second volume which is in fluid communication with the atmosphere surrounding the inhaler. When the movable member is moved in response to the underpressure in the first volume, air will be allowed to flow into the second volume on the other side of the movable member, thereby keeping the second volume at atmospheric pressure even if the second volume is increased upon movement of the movable member, thus avoiding counteracting the movement caused by the underpressure in the first volume. The second volume may be small or, alternatively,

even infinitesimal if the movable member would form part of the exterior wall portion of the inhaler housing.

Although the above-described example embodiments discuss a defined volume in which underpressure is created to cause movement of the movable member, an alternative or a complement would be to provide an extra flow channel through which the inspiratory flow may propagate and impart its kinetic energy to a movable member which causes the release mechanism to be displaced to its releasing state.

As previously mentioned, the dosing chamber may be designed as a cross hole of the transfer member. Additionally, the transfer member may have several dosing chambers consecutively located at the transfer member, which during a dispensing action are successively presented to the flow passage and are, piece by piece, evacuatable by an overpressure in the flow passage. In the case of the transfer member comprising a rod, the dosing chambers, suitably in the form of cross holes, would be positioned after each other in the travel direction of the rod, i.e. in its longitudinal extension. The rod may have a circular cross section or polygonal cross section. Suitably, a part of the transfer member, or the actual rod itself, is designed as a flat bar. A flat bar may be advantageous if means are provided for urging substance into the dosing chamber, wherein such means would easily land against the flat bar surface.

As previously mentioned, at least part of the storing chamber wall may be moved towards the transfer member to urge substance into the dosing chamber. According to at least one example embodiment of the invention, the storing chamber wall, consisting of an elastic material, curves in the direction towards the transfer member when the inhaler is actuated. Suitably, the substance storing chamber wall, at least in the dosing chamber region, curves into contact with the transfer member. Press pieces may be provided for curving of the substance storing chamber wall. The press pieces may be provided with cheeks which have impinging surfaces which, in a fully in-turned position of the press pieces, are positioned parallely to the broadside wall surfaces of the transfer member, if comprising a flat bar. Suitably, the inhaler may comprise an inhaler housing and an action button protruding from the top side of the inhaler housing, the action button being displaceable against a return spring, which action button via bevels, pivots the press pieces

in the direction towards the transfer member. The previously described actuator of the biasing means may suitably incorporate such an action button, which may be manually depressible. Thus, when the actuator comprises such an action button, the inhaler may establish an overpressure when the action button is displaced in the inhaler housing, which overpressure, through the displacement of the transfer member, is used in the flow passage for the discharge of substance. After depression, the action button may be latched at least until the user inhales, the action button may then become automatically or manually unlatched and return to its starting position, enabling other components to return to their respective starting position as well.

The inhaler may contain various substances, such as drugs and/or bioactive agents to be inhaled.

The bioactive agent may be selected from any therapeutic or diagnostic agent. For example it may be from the group of antiallergics, bronchodilators, bronchoconsitrictors, pulmonary lung surfactants, analgesics, antibiotics, leukotrine inhibitors or antagonists, anticholinergics, mast cell inhibitors, antihistamines, antiinflammatories, antineoplastics, anaesthetics, anti-tuberculars, imaging agents, cardiovascular agents, enzymes, steroids, genetic material, viral vectors, antisense agents, proteins, peptides and combinations thereof.

Examples of specific drugs which can be incorporated in the inhaler according to the invention include mometasone, ipratropium bromide, tiotropium and salts thereof, salemeterol, fluticasone propionate, beclomethasone dipropionate, reproterol, clenbuterol, rofleponide and salts, nedocromil, sodium cromoglycate, flunisolide, budesonide, formoterol fumarate dihydrate, Symbicort™ (budesonide and formoterol), terbutaline, terbutaline sulphate, salbutamol base and sulphate, fenoterol, 3-[2-(4-Hydroxy-2-oxo-3H-1,3-benzothiazol-7-yl)ethylamino]-N-[2-[2-(4-methylphenyl)ethoxy]ethyl]propanesulphonamide, hydrochloride. All of the above compounds can be in free base form or as pharmaceutically acceptable salts as known in the art.

Combinations of medicaments may also be employed, for example formoterol/budesonide; formoterol/fluticasone; formoterol/mometasone;

salmeterol/fluticasone; formoterol/tiotropium salts; zafirlukast/formoterol, zafirlukast/budesonide; montelukast/formoterol; montelukast/budesonide; loratadine/montelukast and loratadine/zafirlukast.

Further combinations include tiotropium and fluticasone, tiotropium and budesonide, tiotropium and mometasone, mometasone and salmeterol, formoterol and rofleponide, salmeterol and budesonide, salmeterol and rofleponide, and tiotropium and rofleponide.

Brief description of the drawings

Figs. 1a-1d illustrate the operation of an example embodiment of the invention.

Figs. 2a-2d illustrate the operation of another example embodiment of the invention.

Fig. 3 illustrates a further example embodiment of the invention.

Detailed description of the drawings

In order to clarify the description, terms such as “up”, “upwardly”, “down”, “downwardly”, “vertical”, “horizontal”, etc. are sometimes used: these terms are not limiting and serve merely to facilitate understanding of the drawings.

Figs. 1a-1d illustrate the operation of an example embodiment of the invention. Even though the general inventive concept may be used without a propellant, the illustrated example embodiment operates with a propellant in the form of air.

Beginning with Fig. 1a, a vertical section through an inhaler 2 for powdered substance is illustrated. The inhaler 2 comprises a cylindrical housing 4 from which a substantially radially projecting mouthpiece 6 originates.

The inhaler 2 comprises an actuator in the form of an action button 8 arranged at the top of the housing 4 and an opposite surface 10 at the bottom of the housing 4, a general geometrical housing axis x extending therebetween. By displacement of the action button 8 along the axis x in the direction towards the opposite surface 10, a substance output becomes obtainable.

The housing 4 is formed as a hollow cylindrical body, with a circular horizontal projection in the shown embodiment. Also other shapes, different from this shape with a circular horizontal projection, are conceivable, for example elliptical or multi-cornered/-angled shapes.

The circular-cylindrical external inhaler housing 12 is closed at the base by an inhaler bottom 14, which forms the opposite surface 10 for the actuation of the inhaler 2. At the side opposite to this bottom 14, the housing 4 is openly designed.

In the base region of the housing 4, the mouthpiece 6 protrudes therefrom in a substantially radial orientation, more specifically in the shown example embodiment, with the inclusion of an acute angle of about 75 to 80° to the inhaler axis *x*, which mouthpiece 6 is substantially formed as a hollow cylinder body with an orifice pointing axially outwards with regard to the orientation of the mouthpiece 6. A mouthpiece bottom 16, arranged in the transition region from the housing 4 to the mouthpiece 6, has a central opening 18.

When the inhaler 2 is not in use, the mouthpiece 6 may be covered by a cover, in this example illustrated as a screw cap 20. When the inhaler 2 is to be used, the user removes the screw cap 20.

As an alternative to the illustrated example embodiment, it would be conceivable to provide a nasal adaptor instead of the mouthpiece 6. Suitably, instead of sloping downwardly like the illustrated mouthpiece 6, such a nasal adaptor would slope upwardly in relation to the vertical inhaler axis *x*, thus with the inclusion of an angle to the longitudinal axis *x* from about 45°.

Returning to the illustrated example embodiment in Fig. 1a, the housing 4 is divided transversely to the axis *x* by a support 22 attached to the internal wall of the housing 4 on the level of the transition from the housing 4 to the mouthpiece 6. The disc-shaped solid support 22 has a central recess 24, in which a sealing element 26 consisting of a thermoplastic material is inserted. This sealing element 26 is positioned in the recess 24 in a plug-like manner.

The sealing element 26 is provided with a flow passage, in this example embodiment an airflow passage 28, which is orientated substantially linearly transversely to the axis *x*, which airflow passage 28, on both sides, is continued going through the

support 22. The airflow passage 28 extends on one side of the sealing element 26 through the support 22 to the central opening 18 of the mouthpiece bottom 16. In the opposite direction, with regard to the sealing element 26, the airflow passage 28 goes, with a widening of its cross-section, to an upper housing section separated by the support 22. The airflow passage orifice 30 is formed on the broad surface of the support 22, which is turned towards the upper housing section, whereby this passage orifice 30 is covered by a filter element 32.

Consequently, the airflow passage 28 is divided into a passage section on the mouthpiece side and a section on the housing side. In the latter one, the filter-covered passage orifice 30 is formed. Furthermore, in this section, an after-flow opening 34 is provided, which is opposite the passage orifice 30 and forms a connection between the on-the housing-side section of the airflow passage 28 and the lower space 36 formed under the support 22. This after-flow opening 34 is covered by an air inlet valve 38 which is switched such that the after-flow opening 34 is only opened upon an airflow from the lower space 36 through the airflow passage 28 in the direction of the upper housing section. In the opposite airflow direction, the valve 38 closes this after-flow opening 34.

The airflow passage 28, particularly in the region of the sealing element 26 and the section turned to the mouthpiece 6, is designed essentially smaller than the free cross-section of the mouthpiece 6. Thus, the diameter of the internal space of the mouthpiece 6 corresponds to about ten to thirty times the diameter of the airflow passage, the latter of which is tapered, particularly from the sealing element 26 in the direction of the opening 18 on the mouthpiece side, in the region of a slopingly downward-extending section, for the forming of a nozzle-type duct.

The sealing element 26 merges, in one piece and materially homogeneous, into a funnel-shaped substance storing chamber 40 facing the upper housing section, the substance storing chamber 40 having upwards, i.e. in the direction of the housing opening at the front side, a widening cross-section. The substance storing chamber 40 consists also of a thermoplastic elastomer or another rubber-type material.

The upper end of the substance storing chamber 40, having an expanded diameter, is sealed off by a rolling bellows 42 forming a cover of the substance storing chamber 40.

A micronized powdered substance 44 is stored in the substance storing chamber 40, which substance 44 is inhaled in a portioned output by means of the exemplified arrangement.

Dosing chambers 46 are provided for the portioned output of the substance 44, three in the illustrated example embodiment. The size of each dosing chamber 46 defines the output substance quantity.

The dosing chambers 46 are formed as cross holes of a centrally along the axis *x* extending transfer member 48, herein illustrated as comprising a connector 50 attached to the upper end portion of a rod 52 formed as a flat bar. The cross holes go through the broad side wall surfaces of the flat bar, whereby this in cross-section has a width/length ratio from 1:5 to 1:20. In the shown embodiment, a flat bar thickness of about 0.5 mm is chosen, with a crosswise measured length of about 3 to 3.5 mm. The diameter of the cross holes is chosen, such that a formed dosing chamber 46 hosts from 0.05 mg to 0.1 mg.

The rod 52, with the dosing chambers 46, goes through the substance storing chamber 40 centrally in the direction of extension of the axis *x*. At the bottom of the substance storing chamber 40, the rod 52 further goes through the sealing element 26 with the crossing of the airflow passage 28 formed therein, as a result of this embodiment, by means of the rod 52, a closure of the airflow passage 28 is firstly attained.

In the hereto opposite direction, the transfer member 48 comprising the rod 52 extends upwardly via the substance storing chamber 40, with the passing through the rolling bellows 42, which is attached to the connector 50 of the transfer member 48.

The dosing chambers 46, evenly spaced to each other and consecutively located in the longitudinal extension of the rod 52, are, in an initial position of the inhaler 2 according to the view of Fig. 1a, positioned in the lower third of the substance storing chamber 40, surrounded by the stored substance 44.

The distance between the dosing chambers 46 corresponds substantially approximately to the diameter of a cross hole forming a dosing chamber.

The connector 50 extending upwardly from the substance storing chamber 40 has a mushroom-shaped head 54. This is captured by towing arms 56 formed on the underside of

the action button 8. Between the towing arms 56, a biasing coil spring 58 extends from the action button 8 to the head 54 of the connector 50.

The action button 8 extending substantially transversely to the inhaler axis *x* merges into a cylindrical section formed concentrically with the axis *x* and with a pot-shaped wall 60 which, with its opening, is downwardly dipping into the housing 4. The external diameter of the wall 60 is adapted to the internal diameter of the cylindrical housing section 12. The action button 8 is with its wall 60 insertable into the housing 4 when guided through the cylindrical section 12, with stop limitation in every end position.

The movement area of the action button 8 is sealed off by a rolling bellows 62 which rolls into a gap between the action button 8 and the housing 4.

In the region of free end of the action button wall 60, which free end extends into the housing 4, a circumferential nut is provided in the external mantle wall, for housing a piston ring 64 consisting of an elastomeric material, which for sealing goes towards the inner wall of the cylindrical housing section 12.

The initial position of the action button 8 according to the view of Fig. 1a, is supported by a return coil spring 66 acting on the underside of the action button 8, which spring 66 surrounds the connector 50 of the transfer member 48 and the towing arms 56 of the action button 8, and is supported at its other side by a holder 68 which holds the upper portion of the substance storing chamber 40 and its associated covering rolling bellows 42. In this initial position, the two concentric coil springs 58, 66 are in their relaxed uncompressed state.

In the path of displacement of the action button wall 60 come wedge-shaped connecting protrusions 70 with upwardly pointing bevels 72 of two diametrically opposite supporting arms 74 which support radially inwardly projecting press pieces 76 in the lower free end region.

The arms 74 and the radially inwardly pointing impinging surfaces 78 of the press pieces 76 forming cheeks 80 extend in a horizontal projection respectively in a cross-section through the inhaler 2 parallelly spaced to a broadside surface of the rod 52. Correspondingly, the impinging surfaces 78 are positioned turned to the broadside surface of the rod 52, whereby the impinging surfaces 78 are evenly formed.

Particularly the arms 74, further particularly the hinge region 82 on the circular annular support are, with regard to the choice in material and/or with regard to the material thickness, chosen such that a radial pivoting about the hinge region 82 in the direction of the axis *x* is allowed. The resilient properties of the chosen plastic material are used for the self-acting return of the arms 74 to the original position.

The length of the arms 74, measured in the axial direction, is chosen such that the press pieces 76, provided on the end side, extend approximately at the level of the lower third of the storing chamber 40.

When a user pushes the action button 8, it is slidingly lowered into the housing 4 along the axis *x*, as illustrated in Fig. 1b. The housing 4 and, conditioned by the sealing via the piston ring 64, the pot shaped action button 8 form a compressed-air cylinder *C*, in which, in connection with the lowering of the action button 8, an air overpressure is produced. The internal underside of the action button 8 forms hereby a piston surface.

Thereto, in connection with the downward movement, the connecting protrusions 70 are impinged via the front edge of the wall 60 provided with a chamfer, which with a further lowering of the action button 8 results in a pivoting of the arms 74 about the hinge region 82. As a result of this, the press pieces 76 pivot, in a radial and inward direction, around a radius to the hinge region 82 with the curving of the substance storing chamber wall 84 to the filling position according to the view of Fig. 1b, in which the impinging surfaces 78 reach to parallel orientation to each other and to the broadside surfaces of the rod 52, in which position, at the intermediate position of the storing chamber wall sections, substance portions are pushed into the dosing chambers 46. The substance, present on both sides of the dosing chamber openings in the initial position of the inhaler 2, is pushed into the cross holes by means of the substance storing chamber wall 84 and the press pieces 76 acting on this, whereupon, particularly with a micronized powdered substance, a self-retaining in the dosing chambers 46 is provided.

The curving of the substance storing chamber wall 84 for the pushing of substance 44 into the dosing chambers 46 is supported by the air overpressure produced in the compressed-air cylinder *C* in connection with this procedure.

Even though not shown in the drawings, the action button 8 could be held in the depressed position by a latching means. Alternatively, the user could keep his finger on the depressed action button 8.

As the action button 8 is pushed downwardly the biasing coil spring 58 will become compressed and exert a downwardly-directed force on the transfer member 48. However, at this stage, due to a latching inhalation-triggered release mechanism arrangement 86, the transfer member 48 will remain in this substance-keeping position and the dosing chambers 46 will be kept safely inside the substance storing chamber 40.

In the illustrated example embodiment, the inhalation-triggered release mechanism 86 comprises a movable member, herein shown as a flap 88, which is mounted to a circular bearing 90 around which it can pivot. The inhalation-triggered release mechanism 86 further comprises a blade spring 92 urging the flap 88 towards the latching state shown in Figs. 1a-1b. The bearing 90 is provided with a bore which, in the latching state, is in register with a recess in the mounted end portion of the flap 88. The rod 52 extends through the bore and to the bottom of the recess which forms an abutment surface 94. The abutment surface 94 thus prevents the rod 52 from being displaced under the force of the biasing spring 58.

In this latching state, the flap 88 extends from the circular bearing 90 substantially along the axis *x* and its free end portion is pressed by the blade spring 92 against a projection 96 from the inhaler bottom 14. In this latching state the flap 88, the projection 86 and the inhaler housing define a first volume *V1* on the mouthpiece-side of the flap 88 and a second volume *V2* on the opposite side of the flap 88. The first volume *V1* is in fluid communication with the mouthpiece 6 via a first opening 98 and the second volume *V2* is in fluid communication with the atmosphere surrounding the inhaler 2 via a second grille-formed opening 100.

When the user inhales through the mouthpiece 6, an underpressure is established in the first volume *V1* and causes the flap 88 to pivot around the circular bearing 90 towards the mouthpiece 6 against the force of the blade spring 92. This is illustrated in Fig. 1c. The flap 88 could in its relaxed state completely separate the first volume *V1* from the second volume *V2*, and as the flap 88 starts opening due to the underpressure, the air will also be

enabled to flow from the second volume *V2* to the first volume *V1* across the flap 88 for further assisting the pivoting of the flap 88. Alternatively, the flap 88 may only partially separate the two volumes *V1*, *V2*, wherein, when a user inhales the underpressure and the flow from the second volume *V2* will together cause the flap 88 to open. The pivoting of the flap 88 results in that the recess with its abutment surface 94 is displaced from being in register with the bore, thereby presenting the release mechanism 86 in a releasing state. In this releasing state, the rod 52 can under the force of the biasing spring 58 (and gravity) move downwardly along the axis *x*.

As illustrated in Fig. 1d, in connection with the downward displacement of the rod 52 after the dosing chamber filling, the filled dosing chambers 46 successively go in overlap to the airflow passage 28. Until then, the airflow passage 28 has been slidingly closed by the closing solid portion of the rod 52, enabling the producing of the overpressure in the pressurizable space which comprises the compressed-air cylinder *C* and the on-the housing-side section of the airflow passage 28. When a dosing chamber 46 reaches the airflow passage 28 (the substance-evacuating position of the transfer member 48), the so formed valve is temporarily opened. The cross hole forming the dosing chamber 46 becomes part of the airflow passage 28. The produced air overpressure causes a blow-type exhaustion of the portioned substance from the dosing chamber 46 to jet this portion into the mouthpiece 6. Since the transfer member 48 in the illustrated example embodiment is provided with three dosing chambers 46, it will consequently have three substance-evacuating positions.

According to the arrangement of three consecutively provided dosing chambers 46 in the shown example embodiment, the result is, in dependency of the force of the biasing spring 58, a fast momentary compressed-air supported ejection of the substance portion.

By terminating a pushing contact of the action button 8 or releasing it if latched, the action button 8, together with the guided transfer member 48, will return to the initial position under the force produced by the return coil spring 66. The arms 74 having the press pieces 76 are also released and, due to the resilient properties of the chosen material, pivot back to the original position illustrated in Fig. 1a.

In connection with the return-displacement of the action button 8 and the therewith following enlargement of the volume of the compressed-air cylinder *C*, air is fed in. This via the after-flow opening 34 and at least said second opening 100, suitably with a through flow of moisture absorbing material (not shown) at the corresponding opening of the air inlet valve 38.

Conditioned by the funnel-shaped design of the substance storing chamber 40, the substance material 44 slides self-actingly after the outer force on the storing chamber wall 84 by means of the press pieces 76 has terminated, whereby through the influence of the storing chamber wall 84 through the curving, such a moving-up of substance is supported by flex leveling.

With the exception of the elements having sealing properties and the substance storing chamber 40, and if applicable also with the exception of the construction part having resilient properties with arms 74 and press pieces 76, the inhaler 2, particularly the housing 4 and the action button 8 with the wall 60 and the holder 68 with the support 22, may consist of a plastic material, further particularly of a hard-plastic material. Also the transfer member 48 can comprise such a hard-plastic material. Suitably, with regard to this, the rod 52 may be made of a metallic material.

Figs. 2a-2d illustrate the operation of another example embodiment of the invention. Features in Figs. 2a-2d which correspond to the features illustrated in Figs. 1a-1d are represented by the same reference signs. The example embodiment of Figs. 2a-2d is similar to the one shown in Figs. 1a-1d, however, the release mechanism is different. In this example embodiment the release mechanism 110 comprises a diaphragm 112 which can be flexed between a relaxed position (Figs. 2a-2b) and an energized position (Figs. 2c-2d). The diaphragm 112 is fastened in a support structure 114 and sealingly separates a first volume *V1* from a second volume *V2*. The first volume *V1* is in fluid communication with the mouthpiece 6 via a first opening 116 and the second volume *V2* is in fluid communication with the atmosphere surrounding the inhaler 2 via a second opening 118. The second volume *V2* is illustrated as substantially smaller than the first volume *V1* and could in theory be infinitesimal. While for illustrative purposes the second opening 118 has

been provided at the bottom of the inhaler 2, it could alternatively be placed on the side of the inhaler 2.

Since the diaphragm 112 completely seals off the second volume *V2*, air inflow openings 120 are formed in the mouthpiece wall evenly distributed along a periphery line, thereby enabling an airflow through the mouthpiece 6 as the user inhales.

The diaphragm 112 is operatively connected to a pivotable rocker 122 . The rocker 112 comprises an abutment surface 124 for contacting the end of the rod 52. A coil spring 126 is operatively connected to the rocker 122 for returning the rocker 122 to its original position after it has been pivoted.

The operation of the inhaler 2 is as follows: After removing the screw cap 20 (Fig. 2a), the user will push the action button 8, thereby filling the dosing chambers 46, creating the overpressure in the compressed air-cylinder *C* and on-the-housing section of the airflow passage 28, and biasing the transfer member 48 against the abutment surface 124 of the rocker 122 (Fig. 2b). Next, the user inhales through the mouthpiece 6, thereby creating an underpressure in the first volume *V1* which causes the diaphragm 112 to flex upwardly to its energized position. The flexing of the diaphragm 112 causes the rocker 122 to pivot around its pivot point (Fig. 2c). The force involved in this motion sequence must overcome the spring force acting on the rocker 122 caused by the return coil spring 126. When the rocker 122 has pivoted, its abutment surface 124 no longer prevents the transfer member 48 to be displaced downwardly, whereby, correspondingly to the example embodiment in Figs. 1a-1d, the dosing chambers 46 are sequentially placed in the airflow passage 28 and the substance is evacuated by the overpressure (Fig. 2d).

In connection with the return-displacement of the action button 8 and the therewith following enlargement of the volume of the compressed-air cylinder *C*, air is fed in via the after-flow opening 34 and said first opening 116, suitably with a through flow of moisture absorbing material (not shown) at the corresponding opening of the air inlet valve 38. The components are thus enabled to return to their original position of Fig. 2a.

Fig. 3 illustrate a further example embodiment of the invention. Features in Fig. 3 which correspond to the features illustrated in Figs. 1a-1d and Figs. 2a-2d are represented by the same reference signs. Similarly to the release mechanism illustrated in Figs. 2a-2d,

the release mechanism 130 in this example embodiment of Fig. 3 comprises a diaphragm 132 and a return coil spring 134 operatively connected to a pivotable rocker 136. An arm 138 is attached to the rocker 136 and presents an abutment surface 140 to the end of the rod 52. A linking element 142 extends between the arm 140 and a valve stem 144. The valve stem 144 is in turn connected to a valve 146 which rests against a valve seat 148 as illustrated in Fig. 3.

Unlike the example embodiments illustrated in Figs. 1a-1d and Figs. 2a-2d, when the action button 8 is pushed down in the example embodiment of Fig. 3, due to the valve 146 closing against the valve seat 148, the overpressure will only be created in the compressed-air cylinder *C* and thus not in the airflow passage 28.

In operation of the inhaler 2 illustrated in Fig. 3, when a user inhales, the diaphragm 132 is flexed upwardly and causes the rocker 136 to pivot. According to the example embodiment shown in Fig. 3, the rocker 136 will pivot counterclockwise and bring along the arm 138 in that motion. This results in that the abutment surface 140 of the arm 138 moves away from and unlatching the rod 52, thereby enabling the rod 52 to be displaced downwardly and allow the dosing chambers 46 to come into register with the airflow passage 28. At the same time, as the arm 138 is pivoted, the connected linking element 142 will also pivot and drive the valve stem 144 upwardly, i.e. in direction towards the valve 146, thus lifting the valve 146 from the valve seat 148. Fluid communication between the compressed-air cylinder *C* and the airflow passage 28 becomes established and the overpressure is released and propagated along the airflow passage 28 where it will entrain the substance in the dosing chambers 46 for delivery to the user via the mouthpiece 6.

The drawings have been provided for non-limiting illustrative purposes. Consequently, alternative embodiments are conceivable. For instance, the illustrated transfer member could instead of a rod comprise another geometrically-shaped component as previously discussed. Also, other types of release mechanisms may be provided than those illustrated in the drawings. For instance instead of a release mechanism comprising a flap or a diaphragm, it would be conceivable to use other movable members such as a sliding piston.

Likewise, other types of biasing mechanisms may be provided instead of the illustrated one which comprises an action button and spring. Furthermore, the size and number of dosing chambers may be varied, and a mechanism may be provided for adjusting how many of the dosing chambers will be presented to the flow passage during firing of the inhaler.

CLAIMS

1. An inhaler for powdered substance, comprising

a mouthpiece or nasal adaptor through which substance is inhalable by a user,

a flow passage in fluid communication with the mouthpiece or nasal adaptor,

a substance storing chamber,

a transfer member which is displaceable in the substance storing chamber and which comprises at least one dosing chamber for taking up substance inside the substance storing chamber, the transfer member being displaceable between a substance-keeping position in which the dosing chamber keeps the substance and a substance-evacuating position in which the dosing chamber presents the substance to the flow passage, the transfer member being latched in the substance-keeping position by

an inhalation-triggered release mechanism which, when a user inhales through the mouthpiece or nasal adaptor, unlatches the transfer member, thereby enabling it to move to the substance-evacuating position.

2. The inhaler as claimed in claim 1, wherein the transfer member comprises a rod which is displaceable in its longitudinal direction.

3. The inhaler as claimed in any one of claims 1-2, comprising a biasing mechanism adapted to bias the transfer member towards the substance-evacuating position.

4. The inhaler as claimed in claim 3, wherein, when the transfer member is latched by the release mechanism in said substance-keeping position and biased towards the substance-evacuating position by the biasing mechanism, the dosing chamber is located inside the substance storing chamber.

5. The inhaler as claimed in claim 4, wherein the biasing mechanism comprises an actuator which is movable towards the transfer member and a spring which is compressible between the actuator and the transfer member, whereby movement of the actuator towards

the transfer member, when the transfer member is latched in the substance-keeping position, causes the transfer member to become spring-loaded.

6. The inhaler as claimed in claim 5, wherein the actuator, when actuated, is adapted to create an overpressure in a pressurizable space which comprises or which is arrangable in fluid communication with the flow passage, the overpressure being released by the release mechanism when a user inhales through the mouthpiece or nasal adaptor, thereby evacuating the substance from the dosing chamber when the transfer member is in the substance-evacuating position.

7. The inhaler as claimed in claim 6, comprising a valve which is movable between a closed position for closing said pressurizable space and an open position for releasing the overpressure in the pressurizable space, the valve being latched in the closed position by said inhalation-triggered release mechanism which, when a user inhales through the mouthpiece or nasal adaptor, unlatches the valve, thereby enabling the overpressure to be released and evacuate the substance from the dosing chamber.

8. The inhaler as claimed in claim 6, wherein said pressurizable space comprises said flow passage and wherein said transfer member in its substance-keeping position extends through the flow passage to close said pressurizable space and to maintain the overpressure until the transfer member is unlatched by the inhalation-triggered release mechanism.

9. The inhaler as claimed in any one of claims 5-8, wherein the actuator, when actuated, causes at least a wall portion of the substance storing chamber to move towards the transfer member so that substance is urged into the dosing chamber, while the transfer member remains unmovable in the substance-keeping position.

10. The inhaler as claimed in any one of claims 1-9, wherein the storing chamber is located on one side of the flow passage and the release mechanism is located on the other side of the flow passage, wherein the transfer member extends through the flow passage.

11. The inhaler as claimed in claim 10, wherein the release mechanism comprises an abutment surface for receiving one end of the transfer member and latching the transfer member in the substance-keeping position.

12. The inhaler as claimed in any one of claims 1-11, wherein the release mechanism is displaceable from a latching state, in which the transfer member is latched in the substance-keeping position, to a releasing state, in which the transfer member is enabled to move to the substance-evacuating position, wherein the release mechanism comprises a return spring for urging the release mechanism to the latching state.

13. The inhaler as claimed in claim 12, wherein the release mechanism comprises a movable member being movable from a relaxed position, in which the release mechanism is kept in the latching state, to an energized position in which the release mechanism is caused to be displaced to the releasing state, wherein a first side of the movable member partly defines a first volume which is in fluid communication with said mouthpiece or nasal adaptor, wherein, when a user inhales through said mouthpiece or nasal adaptor, an underpressure is established in said first volume causing the movable member to move from the relaxed position to the energized position.

14. The inhaler as claimed in claim 13, wherein said movable member is a diaphragm which is flexed to the energized position upon inhalation by a user.

15. The inhaler as claimed in claim 14, wherein the release mechanism comprises a pivotable rocker having an abutment surface for latching the transfer member, wherein the diaphragm is operatively connected to the rocker so that, when the diaphragm is flexed, the rocker is pivoted to said releasing state of the release mechanism.

16. The inhaler as claimed in claim 13, wherein said movable member is a flap which is pivoted to the energized position upon inhalation by a user.

17. The inhaler as claimed in any one of claims 13-16, wherein a second side of the movable member, opposite to said first side, partly defines a second volume which is in fluid communication with the atmosphere surrounding the inhaler.

18. The inhaler as claimed in any one of claims 1-17, wherein said at least one dosing chamber is designed as a cross hole of the transfer member.

19. The inhaler as claimed in any one of claims 1-18, wherein the transfer member has several dosing chambers consecutively located at the transfer member, which during a dispensing action successively are presented to the flow passage and are, piece by piece, evacuatable by an overpressure in the flow passage.

20. The inhaler as claimed in any one of claims 1-19, wherein a part of the transfer member is designed as a flat bar.

21. The inhaler as claimed in any one of claims 1-20, wherein the storing chamber wall, consisting of an elastic material, curves in the direction towards the transfer member when the inhaler is actuated.

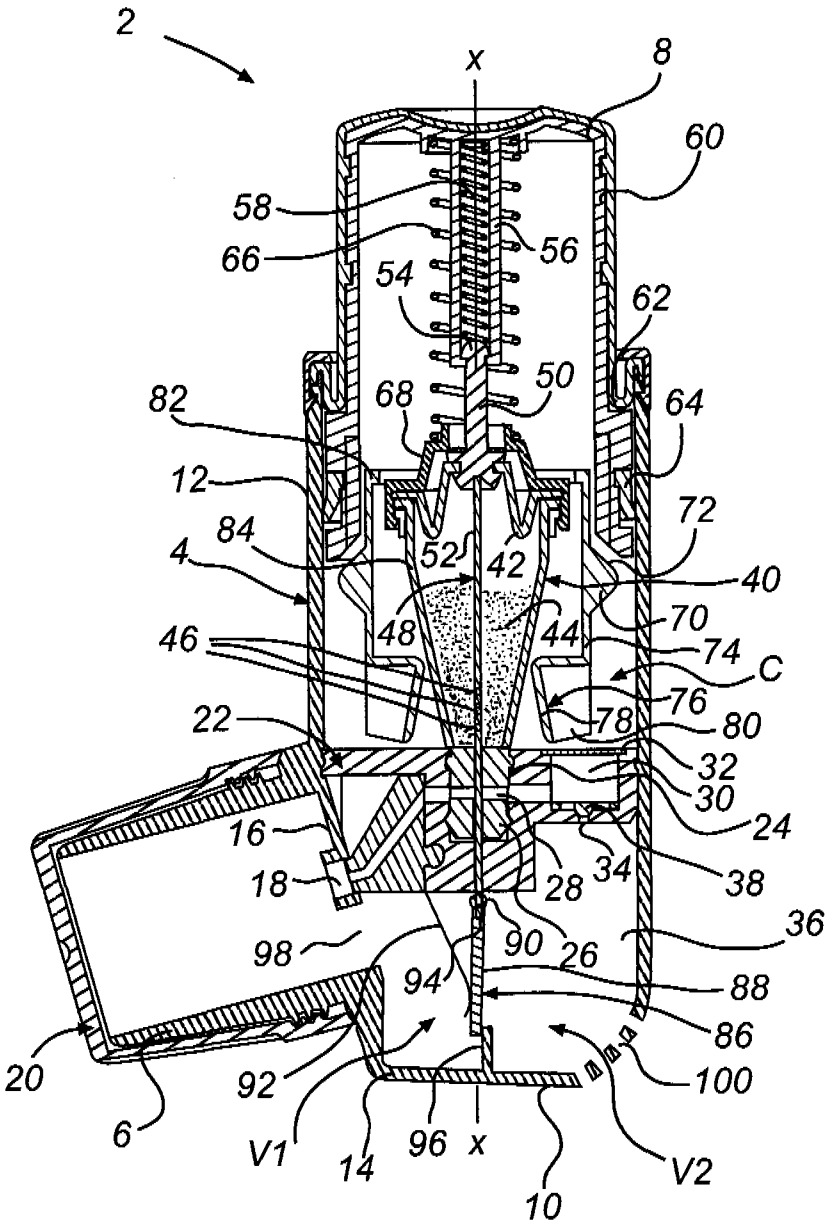
22. The inhaler as claimed in claim 21, wherein the storing chamber wall, at least in the dosing hole region, curves into contact with the transfer member.

23. The inhaler as claimed in any one of claims 21-22, wherein press pieces are provided for curving of the storing chamber wall.

24. The inhaler as claimed in claim 23, wherein the press pieces are provided with cheeks which have impinging surfaces which, in a fully in-turned position of the press pieces, are positioned parallelly to the broadside wall surfaces of the transfer member.

25. The inhaler as claimed in any one of claims 23-24, wherein the inhaler comprises an inhaler housing and an action button protruding from the top side of the inhaler housing, the action button being displaceable against a return spring, which action button via bevels, pivots the press pieces in the direction towards the transfer member.

26. The inhaler as claimed in claim 25, wherein the inhaler establishes an overpressure when the action button is displaced in the inhaler housing, which overpressure, through the displacement of the transfer member, is used in the flow passage for the discharge of substance.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44
74
46
C
76
22
78
80
32
30
24
16
34
38
18
28
36
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88
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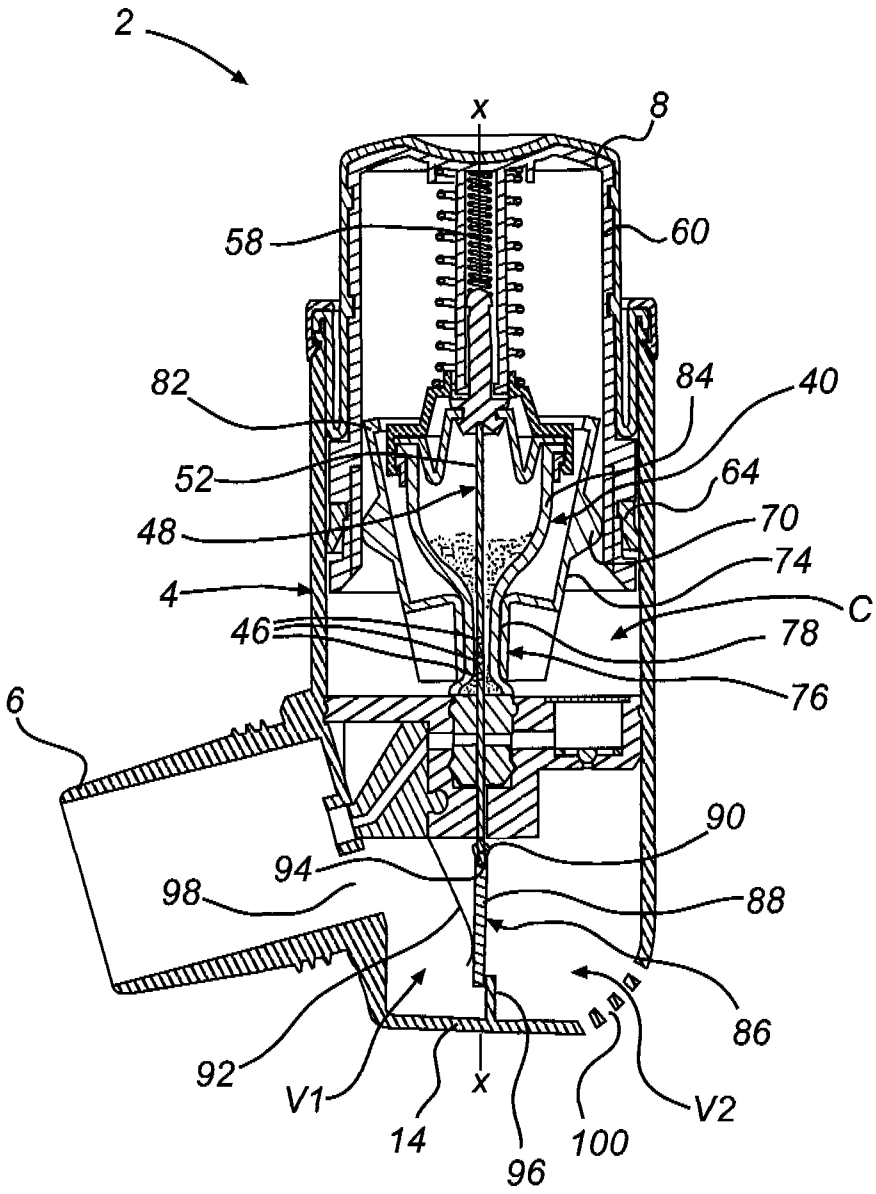
20
92
100
6
V1
14
96
x
10
V2

Fig. 1a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82
84
40
52
64
48
70
74
4
C
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90
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98
88
86
92
V1
x
V2
14
96
100

Fig. 1b

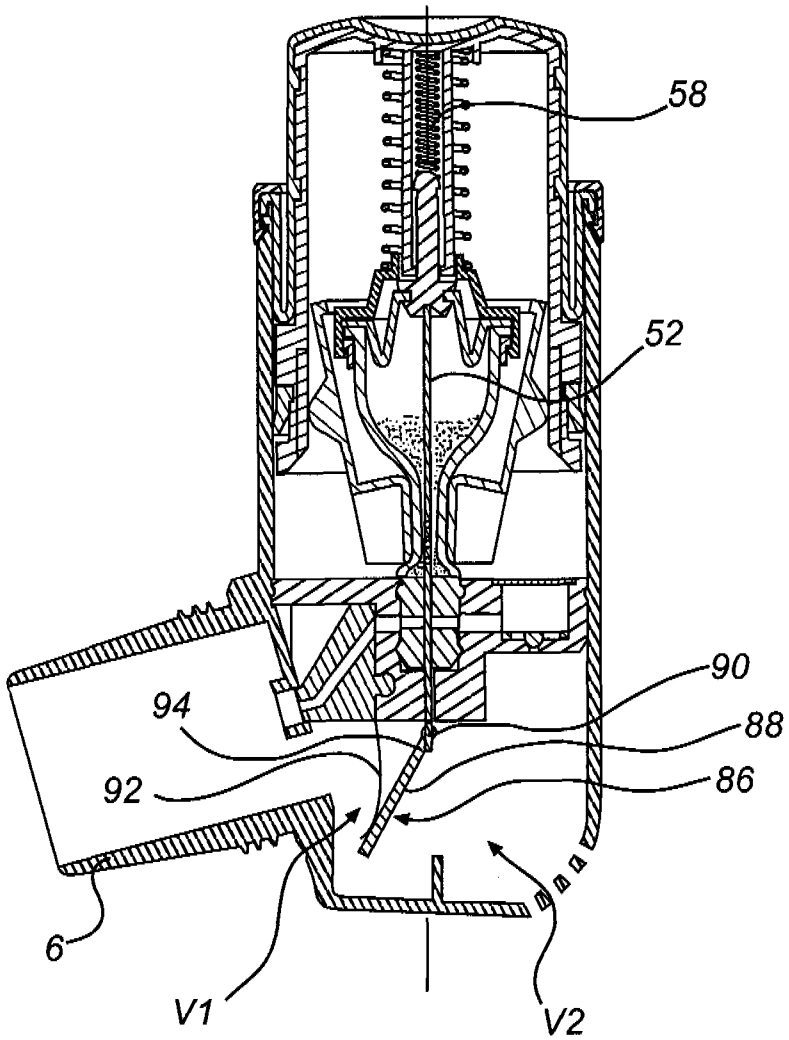

Fig. 1c

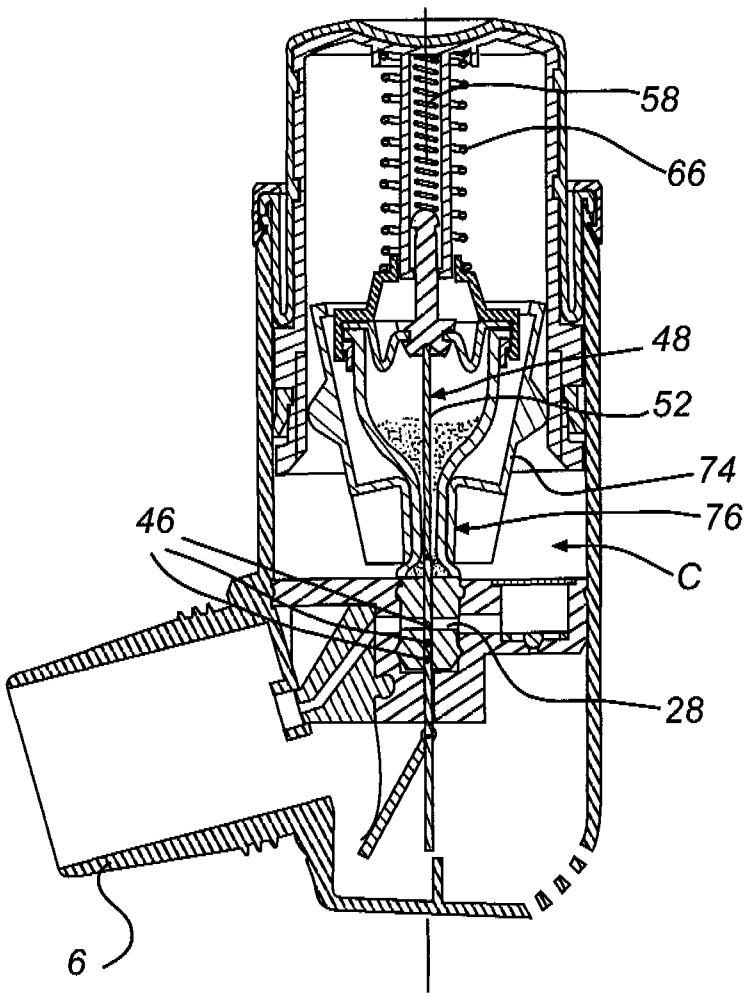

Fig. 1d

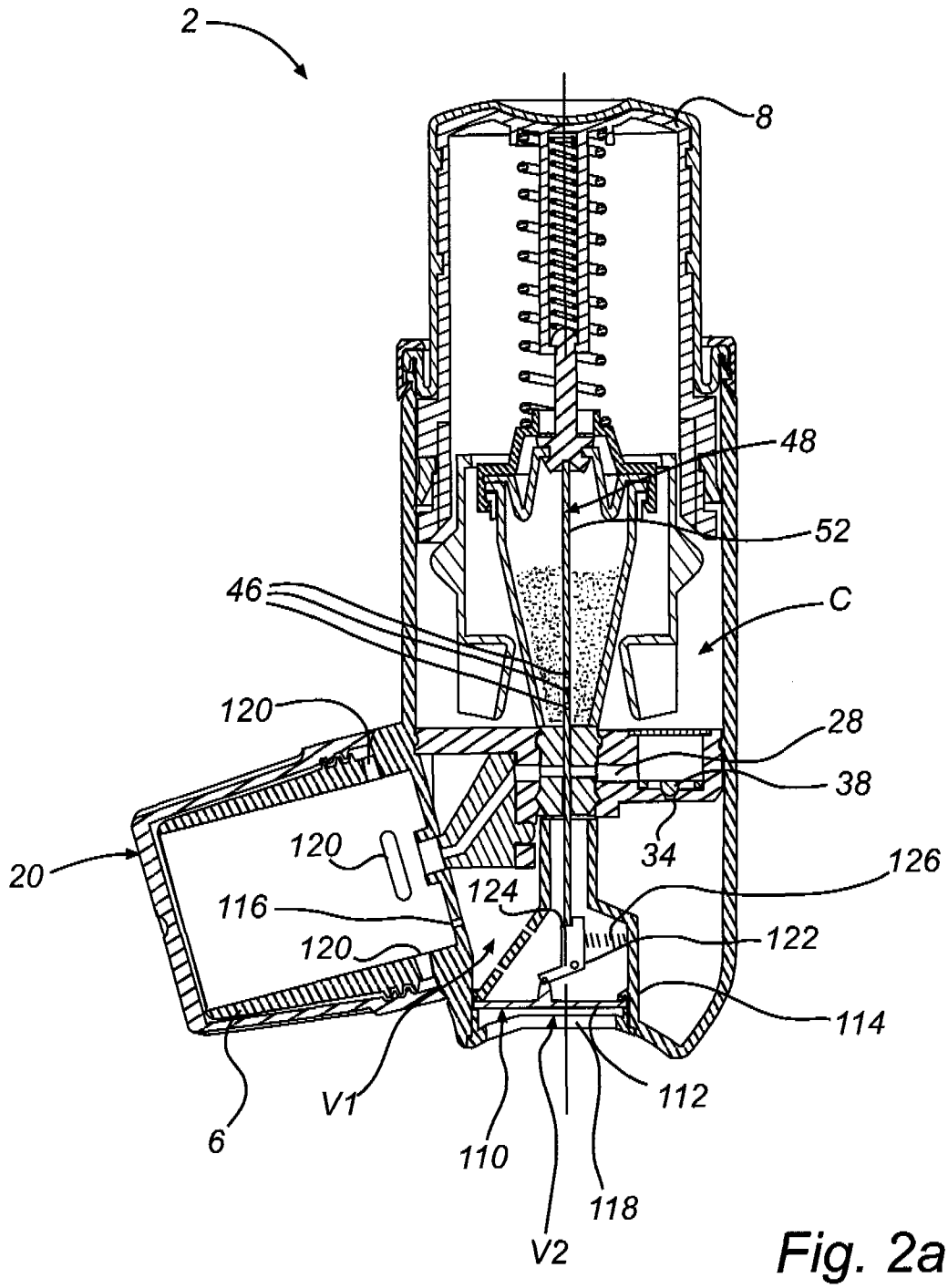
2
8
48
52
46
C
120
28
38
120
34
126
20
116
124
120
122
114
V1
112
6
110
118
V2

Fig. 2a

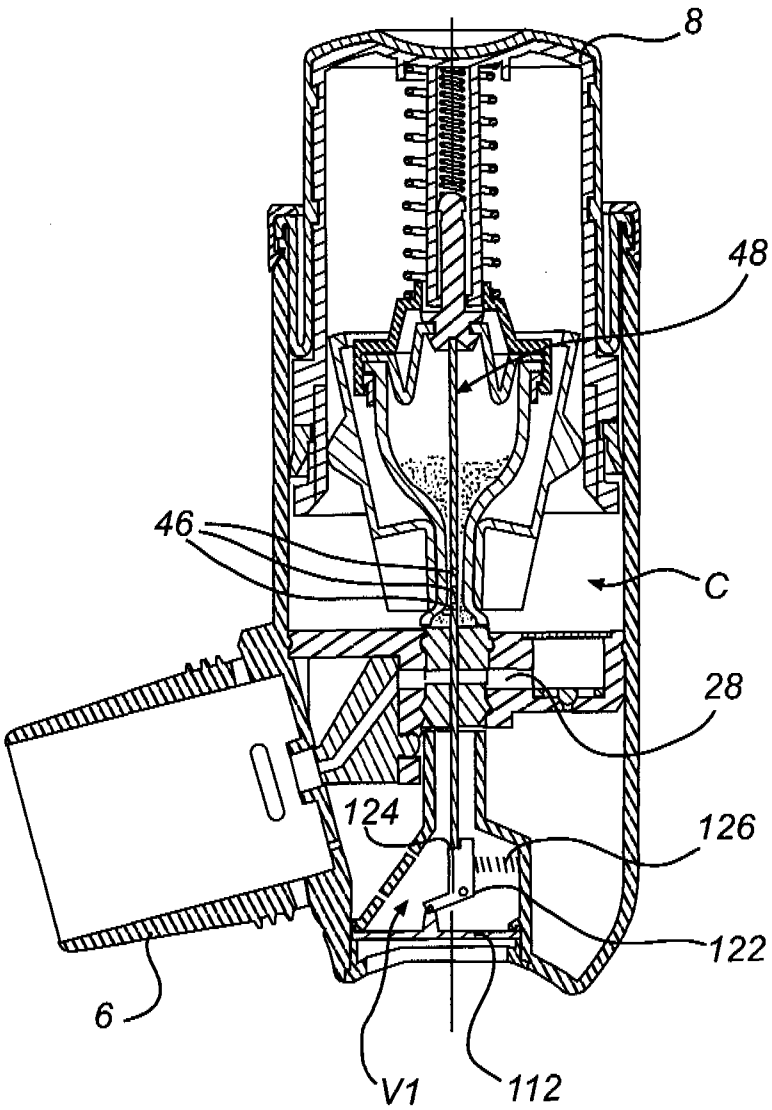

Fig. 2b

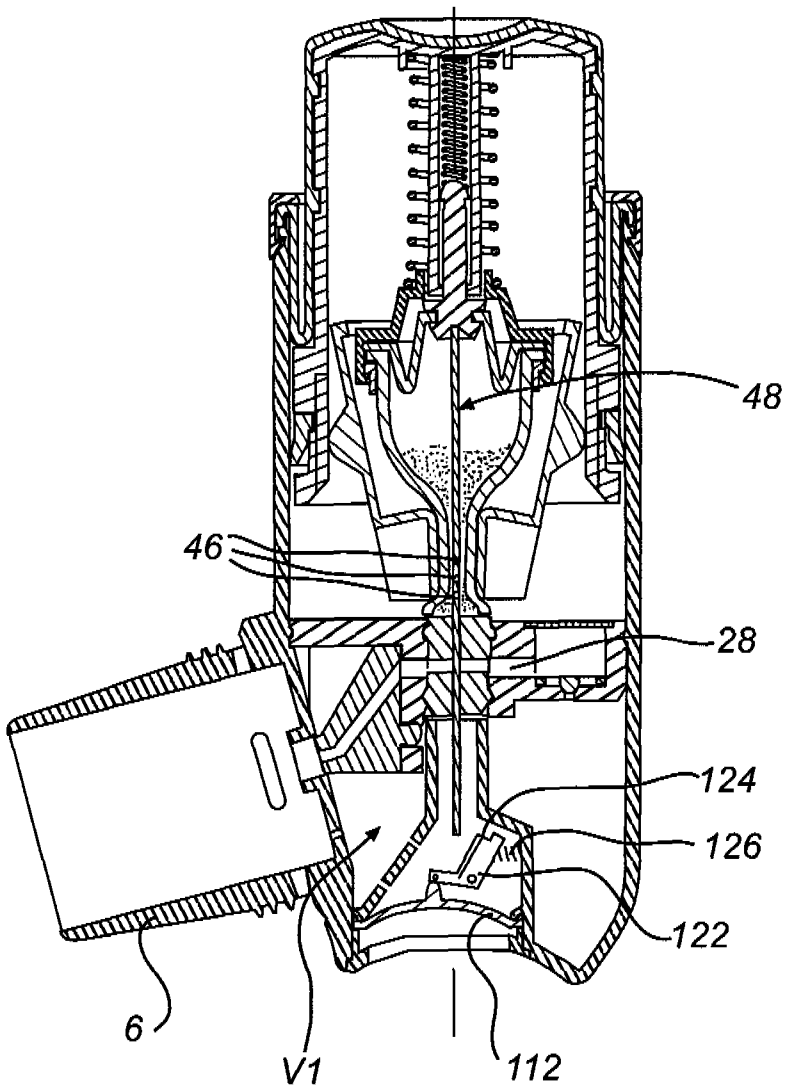

Fig. 2c

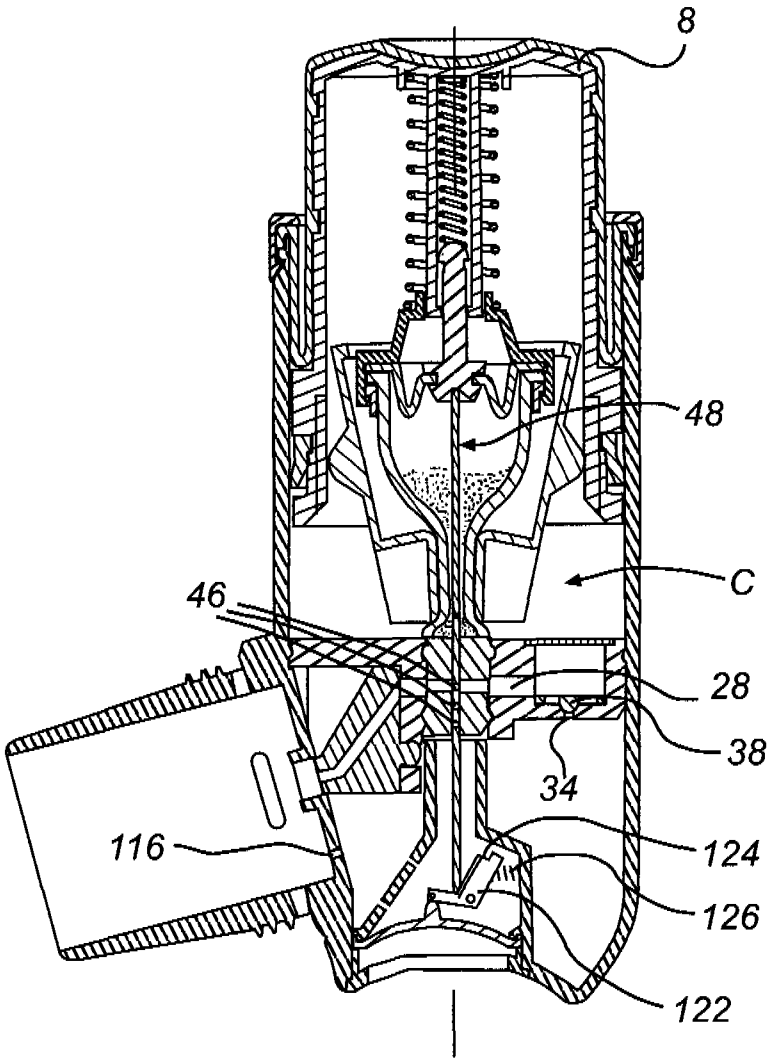

Fig. 2d

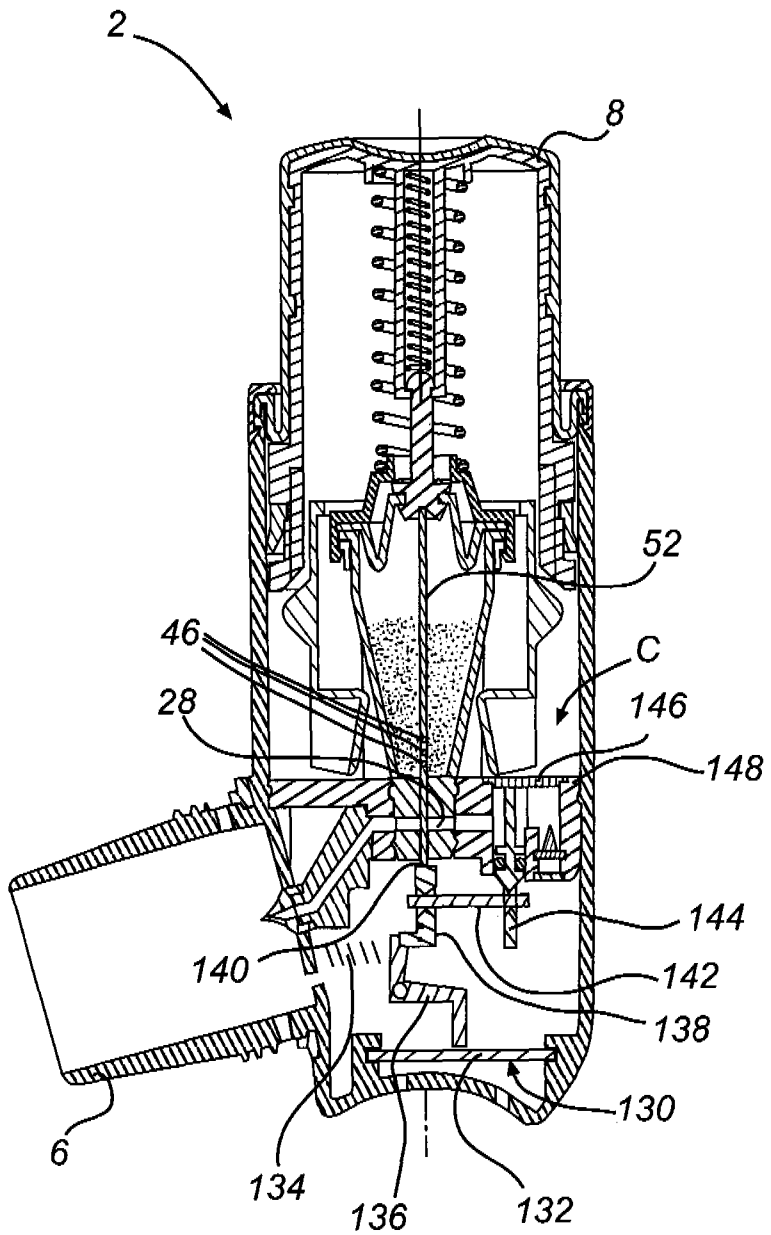

Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2008/050946

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006021546 A1 (VON SCHUCKMANN, A.), 2 March 2006 (02.03.2006), figures 2-5, abstract, paragraphs (0050)-(0053)	1,2,18-20
A	--	3-17,21-26
A	WO 2007009872 A1 (VON SCHUCKMANN, A.), 25 January 2007 (25.01.2007), abstract, figures	1-26
	--	
A	US 6029662 A (C. MARCON), 29 February 2000 (29.02.2000), column 8, line 54 - column 9, line 47, abstract, figures	1-26
	--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance
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"P" document published prior to the international filing date but later than the priority date claimed
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 October 2008	29 -10- 2008
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Nina Jansson / MRo Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2008/050946

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2006062449 A1 (ERNST HÖRLINS INGENJÖRSBYRÅ AB), 15 June 2006 (15.06.2006), abstract, figures, paragraphs (0052)-(0060) --	1-26
A	US 5349945 A (A.C.L. WASS ET AL), 27 Sept 1994 (27.09.1994), column 6, line 31 - line 59, abstract, figures -- --------	1-26

International patent classification (IPC)

A61M 15/00 (2006.01)

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Use the application number as username.
The password is **XTACUAHCWP**.

Paper copies can be ordered at a cost of 50 SEK per copy from PRV InterPat (telephone number 08-782 28 85).

Cited literature, if any, will be enclosed in paper form.

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				CN	101048187	A	03/10/2007
				DE	102004041524	A	02/03/2006
				EP	1791584	A	06/06/2007
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