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NOTICE OF ENTITLEMENT

We, **Rhone-Poulenc Rorer Limited**, the applicant/Nominated Person in respect of Application No. 80655/91 state the following:-

The Nominated Person is entitled to the grant of the patent because the Nominated Person derives title to the invention from the inventors by assignment.

The Nominated Person is entitled to claim priority from the applications listed in the declaration under Article 8 of the PCT because the Nominated Person made the applications listed in the declaration under Article 8 of the PCT, and because those applications were the first applications made in a Convention country in respect of the invention.

DATED this TWENTY NINTH day of MARCH 1993

.....

a member of the firm of
DAVIES COLLISON
CAVE for and on behalf
of the applicant(s)

(DCC ref: 1552632)

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(71) Applicant(s)
RHONE-POULENC RORER LIMITED

(72) Inventor(s)
JOHN RICHARD CALVERT; ROBERT STANLEY COOK; MICHAEL ANTHONY HOBBS; ANN-MARIE LEIGHTON; GORDON THOMAS SIMPKIN; ROY TRUNLEY; ANTHONY DOUGLAS WEST

(74) Attorney or Agent
DAVIES COLLISON CAVE , 1 Little Collins Street, MELBOURNE VIC 3000

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(57) Claim

1. An inhaler which comprises a chamber defined by (a) first and second generally parallel spaced opposed walls defining a median plane of said chamber mid-way therebetween, and between which parallel spaced walls of a medicament-containing capsule can fit with its longitudinal axis generally parallel to said first and second walls but in any angular orientation, and (b) at least one peripheral further wall; an exhaust nozzle through which air can be exhausted from said chamber by inhalation; at least one air inlet arranged in relation to the exhaust nozzle to generate in the chamber during inhalation an airflow rotating about an axis generally perpendicular to said first and second walls; and holding means in the inhaler in association with means operable from outside the closed chamber for opening a capsule while held in the holding means, wherein the holding means are effective to hold a said capsule having a length greater than the minimum spacing between said first and second walls and less than a minimum dimension of the cross-section of said chamber when viewed parallel to said axis of rotation and are configured to hold a said capsule having a

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diameter less than said minimum spacing between the first and second walls; wherein the holding means are effective to hold said capsule with the longitudinal axis of the capsule perpendicular to said axis about which the inhalation air rotates and substantially coincident with the median plane of said chamber.

CORRECTED VERSION *

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under INID Numbers (72) "Inventors; and" and (75) "Inventors/Applicants (for US only)", replace "LEIGHTON, Anne-Marie" by "LEIGHTON, Ann-Marie"

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(71) Applicant *(for all designated States except US)*: RHONE-POULENC RORER LIMITED [GB/GB]; Rainham Road South, Dagenham, Essex RM10 7XS (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)* : CALVERT, John, Richard [GB/GB]; COOK, Robert, Stanley [GB/GB]; HOBBS, Michael, Anthony [GB/GB]; LEIGHTON, Ann-Marie [GB/GB]; SIMPKIN, Gordon, Thomas [GB/GB]; TRUNLEY, Roy [GB/GB]; WEST, Anthony, Douglas [GB/GB]; Rhone-Poulenc Rorer Limited, Rainham Road South, Dagenham, Essex RM10 7XS (GB).

(74) Agents: BARLOW, Roy, James et al.; J. A. Kemp & Co., 14, South Square, Gray's Inn, London WC1R 5LX (GB).

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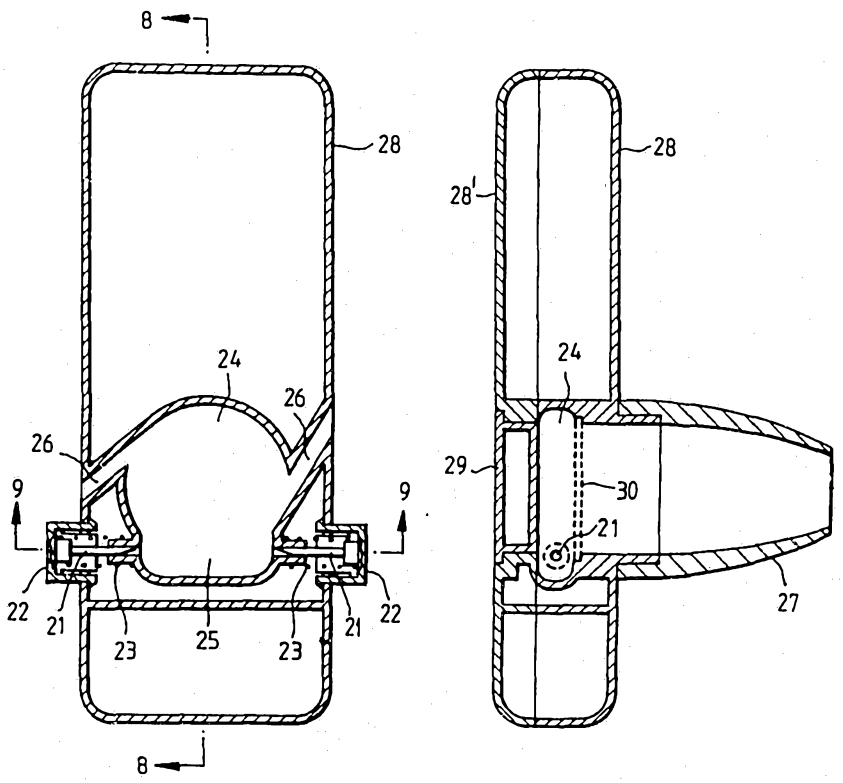
(57) Abstract

An inhaler for inhaling pulverulent medicament from within a capsule comprises a chamber (24) within which the capsule is positioned with its longitudinal axis in the median plane of the chamber and thus generally parallel to the front (29) and rear walls (30) of the chamber, where the spacing between said front and rear walls is just greater than the diameter of the capsule and the diameter of the chamber is larger than the capsule's length. The device includes pins (21) serving as opening means to pierce the ends of the capsule while it is seated in a recess (25). Air inlets (26), chamber (24) and mouthpiece (27) are in such a spatial relation as to create a swirling or vortexing movement of the airflow which allows good capsule's emptying and powders to be finely dispersed. Chamber and mouthpiece inner walls can be of antistatic material.



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Inhaler

The present invention relates to an inhaler for the inhalation of a medicament, usually pulverulent, from a capsule.

Various forms of inhaler are already known, and among these are the ones in which the capsule is pierced, usually at the ends, in order to allow the medicament to be withdrawn during inhalation, and those in which the cap portion of the capsule is removed from the body portion in order to allow the medicament to be extracted.

Extraction of the medicament usually occurs as a result of the inhaled airstream passing over or through the capsule.

With both of the above types of inhaler, it is known to allow the airstream passing through the inhaler to adopt a vortical configuration which results in the pierced capsule or the separated capsule cap and body portions tumbling in the airstream.

It is a disadvantage of virtually all of the known inhalers that not all of the medicament is withdrawn from the capsule or the separated capsule cap and body portions, and this is frequently because the capsule portions or the capsule as a whole can become lodged in the inhaler in a position where either the extraction effect of the inhalation air is unable to operate effectively or the capsule or capsule cap and body portions can become prevented from tumbling freely by a mechanical constraint.

It is an object of the present invention to provide an inhaler in which the disadvantages mentioned above are eliminated.

In accordance with the present invention there is provided an inhaler which comprises a chamber defined by (a) first and second generally parallel spaced opposed walls defining a median plane of said chamber mid-way therebetween, and between which parallel spaced walls of a medicament-containing capsule can fit with its longitudinal axis generally parallel to said first and second walls but in any angular orientation, and (b) at least one peripheral further wall; an exhaust nozzle through which air can be exhausted from said chamber by inhalation; at least one air inlet arranged in relation to the exhaust nozzle to generate in the chamber during inhalation an airflow rotating about an axis generally perpendicular to said first and second walls; and holding means in the inhaler in association with means operable from outside the closed chamber for opening a capsule while held in the holding means, wherein the holding means are effective to hold a said capsule having a length greater than the minimum spacing between said first and second walls and less than a minimum dimension of the cross-section of said chamber when viewed parallel to said axis of rotation and are configured to hold a said capsule having a diameter less than said minimum spacing between the first and second walls; wherein the holding means are effective to hold said capsule with the longitudinal axis of

the capsule perpendicular to said axis about which the inhalation air rotates and substantially coincident with the median plane of said chamber.

In order that the present invention may more readily be understood the following description is given, merely by way of example, reference being made to the accompanying drawings, in which:-

FIGURE 1 is a side elevational view of an inhaler in accordance with the present invention;

FIGURE 2 is a transverse sectional view of the inhaler of Figure 1;

FIGURE 3 is a sectional view taken on the line 3-3 of Figure 2, with the capsule in position ready for opening by the opening means;

FIGURE 4 is a view similar to Figure 3 but showing the inhaler slightly later during the operating cycle in which the capsule has just been opened;

FIGURE 5 is a view, again similar to Figure 3, but this time showing the two separated capsule portions in the chamber being tumbled to remove the contained medicament;

FIGURE 6 is an underneath plan view showing the

rear casing, with an optional hinged cover to facilitate loading of a capsule to be opened;

FIGURE 7 is a sectional view of an alternative embodiment of inhaler of the pin-piercing type;

FIGURE 8 is a sectional view of the inhaler of Figure 7, taken on the line 8-8 of Figure 7;

FIGURE 9 is a sectional view taken on the line 9-9 of Figure 7;

FIGURE 10 is a sectional view of a third embodiment of inhaler;

FIGURE 11 is a sectional view taken on the line 11-11 of Figure 10;

FIGURE 12 is a sectional view taken on the line 12-12 of Figure 10;

FIGURE 13 is an elevational view of a further embodiment of inhaler in which the capsule is pierced by opening pins;

FIGURE 14 is a top plan view of the device of Figure 13;

FIGURE 15 is a section on the line 15-15 of Figure 13, showing the device in the capsule-receiving configuration;

FIGURE 16 is a view corresponding to Figure 15 but showing the device in the configuration in which the capsule has just been ruptured;

FIGURE 17 is a section taken on the line 17-17 of Figure 13 but when in the configuration in which the capsule has just been ejected into the inhalation chamber;

FIGURE 18 is a section taken on the line 18-18 of Figure 15;

FIGURE 19 is a section taken on the line 19-19 of Figure 16; and

FIGURE 20 is a section taken on the line 20-20 of Figure 17.

Referring now to the drawings, Figure 1 shows a mouthpiece nozzle 1 on a plate 2 forming one wall of a

capsule-emptying chamber 3 (Figure 2).

The opposite wall of the chamber 3 is defined by a rear casing panel 4 which is removable in order to allow a capsule 5 to be inserted into the inhaler ready for opening. The two parts of the device are held together by means of a bayonet system to be described later.

In register with the air passage 6 centrally within the mouthpiece nozzle 1 is a grid 7 which is preferably anti-static by virtue of a high electrical conductivity and/or low surface resistivity, and/or high surface electrostatic dissipativity, through which grid the inhalation air passes but through which fragments of the capsule casing are unable to pass, and hence unable to enter the respiratory tract of the user.

Figure 2 shows an important characteristic of the present invention in that the cross-section of the capsule 5 is only slightly smaller than the minimum spacing between the planar right hand chamber wall (defined by the panel 2 and the screen 7) and the planar left hand chamber wall (defined by the rear casing panel 4) with the result that both the capsule body 5a and the capsule cap 5b are prevented from adopting any other orientation than one in which their axes of symmetry are parallel to the planes of the left hand and right hand chamber walls.

It will of course be appreciated that the chamber 3 is defined not only by the left hand and right hand walls 4 and 7, respectively, but also by transversely extending walls such as the partition 8 shown in Figure 2.

Figure 1 illustrates an air inlet 9 which is one of several such inlets of the inhaler.

Figure 3 shows a sectional view taken on the line 3-3 of Figure 2, and illustrates not only the above-mentioned air inlet opening 9, but also two further air inlets 10 and 11, the functions of which will be described below.

Figure 3 again shows the capsule 5 in position

ready for opening, with the capsule cap portion 5b held between an arcuate baffle 12 and an anvil 13. Alternatively the capsule could be positioned in the same manner except that the body portion 5a is squeezed between the baffle 12 and anvil 13 and the cap portion 5c will be removed by a knife 14 (Figure 4).

In this position the capsule 5 has its longitudinal axis in the median plane of the chamber, i.e. the plane perpendicular to the axis of symmetry and located mid-way between the panels 2 and 4. The capsule is inserted into this position by sliding in a direction perpendicular to the plane of the paper of Figure 3, either with the rear casing panel 4 removed from the rest of the inhaler or by insertion through an optional insertion port to be described below with reference to Figure 6.

Figure 3 also shows a capsule holding anvil 13 moulded integrally with the mouthpiece panel 2. Likewise, the arcuate baffle 12 is integrally moulded with the panel 2.

Rotatable relative to the arcuate baffle 12, by virtue of being moulded integrally with the rear casing panel 4, is an opening knife 14 which rotates in the clockwise direction during operation of the inhaler from the loading configuration to the inhalation configuration, so as to flick the capsule body portion 5a away from the cap portion 5b, as shown in Figure 4 at the instant of separation of the capsule portions 5a and 5b.

Behind the opening knife 14 is a guide member 15 which, at the instant when a capsule ejector 16 also carried by the rear casing panel 4 ejects the capsule cap portion 5b from between the baffle 12 and the anvil 13, as shown in Figure 5, cooperates with the anvil 13 to define a passage along which the portion of the capsule which has just been ejected from between the anvil 13 and the baffle 12 must pass towards the inhalation chamber 3. This guiding action prevents the ejected capsule portion from being jammed. It

will also be appreciated that the trailing wall 19 on which the guide member 15 is formed also provides a near seal with the baffle 12, having the result that the majority of the inhalation air sweeps generally tangentially into the chamber 3 by way of the inlet orifices 9 and 10, although the additional air inlet orifice 11 does allow a purge stream to pass along an arcuate passage 17 between the arcuate baffle 12 and an outer wall 18 of the inhaler, in order to purge the spacing between the baffle 12 and the anvil 13 of any medicament which may have been spilt there as a result of the opening operation. The existence of this purge stream through the air inlet 11 therefore further enhances the degree of emptying of the medicament from the inhaler as a whole. The various inlets 9, 10 and 11 thus contribute to the creation of a vortical airflow in the chamber 3.

It will of course be appreciated that there are three important criteria of the device in accordance with the present invention:-

(i) the pressure drop across the loaded inhaler, between inlet 9 or 10 and the inhalation mouthpiece 1 should be as low as possible;

(ii) there is a need for as near perfect as possible delivery of the medicament from within the capsule in order to allow the medicament to enter the inhalation airstream; and

(iii) there is equally a need for as high as possible a degree of emptying of the device as a whole, because the efficiency of delivery of the medicament depends not only upon the medicament being removed from the capsule but also upon the medicament actually reaching the respiratory tract of the user during inhalation.

The final position, shown in Figure 5, when the inhaler is in the relative rotational positioning of its two major parts where the capsule has been opened and released into the spinning chamber 3 for capsule emptying, is the

only one in which the various air inlets 9, 10 and 11 all communicate with the interior of the device by means of the corresponding inlet gaps 9a, 10a and 11a respectively. In all other positions they are closed in that the ports are not aligned until the capsule has been opened.

Figure 6 shows an alternative embodiment of the device in which the rear casing panel 4a includes a capsule insertion port with a hinged or push fit cover 20 which can be opened to facilitate insertion of a capsule 5 in order to allow the device to be loaded without the need to separate the mouthpiece 1 and its panel 2 from the rear casing panel 4. However, these portions will nevertheless normally need to be separated at the end of the operating cycle in order to allow the spent capsule body and cap portions to be removed and permit cleaning of the device by the user.

The bayonet system, mentioned above, for holding the two parts of the device together comprises a pin 17 on the exterior of the skirt of the mouthpiece member engageable in an axially extending slot 18 (Figure 1) in the skirt of the rear panel part. This slot opens into a groove 19 running round the skirt of the rear panel over approximately 80° of arc of the rear panel part, so as to permit rotation of the rear panel part relative to the mouthpiece part without axial separation of these two parts.

In order to minimise the extent to which the released powdered medicament can agglomerate on the surface of the air passage through the inhaler, the panels 2, 4 and the partition 8 which define the chamber portion 3 may be formed of a polymer with a low surface resistivity, thereby having anti-static properties. Preferably the material defining the inside wall of the chamber 3 is a polymer having a surface resistivity less than 10^{12} Ohms or more preferably less than 10^{8} Ohms. In the present embodiment, the entire device is formed of the same polymer of low surface resistivity, but if desired the chamber-defining walls may be provided with an inner lining of the polymer of

low surface resistivity.

There are various additives known to increase the anti-static properties of polymers, for example by increasing the electrical conductivity or reducing the surface resistivity, or enhancing the static dissipativity properties. One possibility is to incorporate carbon or steel filler, often in the form of fibres, into the polymer used for manufacture of those components to be given enhanced anti-static properties. This enhances the electrical conductivity and/or lowers the surface resistivity. Alternatively non-fibrous chemical additives, often blended into the moulding polymer in chip form prior to the moulding process, may be used to lower the surface resistivity in the moulded product. The product Pebax manufactured by the company Atochem of France is a polyether block amide product which may be obtained in an anti-static grade by use of such additives. Alternative materials for this application include the Atmer range of polypropylenes, containing antistatic additives, manufactured by ICI.

Another possibility is for the moulded component to be coated with an electrically conducting layer which thus reduces the surface resistivity.

Preferably the surface resistivity is less than 10^{12} Ohms, and more preferably it is less than 10^{8} Ohms.

More preferably the mouthpiece in any of the embodiments may have at least its inner wall formed of such a polymer of low surface resistivity.

As with the embodiments to be described below, the embodiment of Figures 1 to 6 is formed by injection moulding. The above-mentioned polymeric material of low surface resistivity is itself capable of injection moulding to form the relevant parts of the device, or the whole of it.

Turning now to Figure 7, there will be seen an alternative embodiment of the inhaler in accordance with the present invention in that in this case the capsule is not

opened by separation of its cap and body portions, but is instead pierced by pins in order to allow extraction of the contents by a combination of pneumatic action, centrifugal action, and impact of the pierced capsule with the lateral wall of the swirling chamber.

Figure 7 shows two capsule piercing pins 21 operated by respective buttons 22 which are biased outwardly by means of helical compression springs 23.

For this purpose the chamber 24, having a peripheral wall 24a adjoining flat end walls defined by a grid 30 and a wall of a plug 29 to be described below, also has in its peripheral wall a recess 25 defined by a bulge 25a in the wall 24a able to accommodate the capsule while it is in the median plane of the relatively flat chamber.

The chamber furthermore includes two air inlets 26 which clearly generate a swirling motion in the chamber, about an axis which is generally centrally of the main chamber and extends perpendicular to the plane of the paper in Figure 7, as air is aspirated through the mouthpiece nozzle 27 shown in Figure 8 and 9.

The operation of the inhaler shown in Figures 7, 8 and 9 is relatively straightforward and is as follows.

Firstly, the inhaler is opened by separating the right hand body portion 28 from the left hand body portion 28' shown in Figure 8, so that a capsule can be inserted in the recess 25 of the chamber 24.

The push-buttons will at this stage be biased to their outward positions so that the two needles 21 are retracted from the capsule-receiving bulge 25a in the chamber wall.

The device is then re-assembled by joining the body portions 28 and 28' in the Figure 8 configuration, with some detent means (not shown) in order to hold the two halves together in the assembled configuration.

Up to now the capsule is closed and the operator does not have to fiddle with either a pierced capsule or a

capsule whose cap portion has been separated from its body portion.

The operator then simply squeezes the two push-buttons 22 inwardly, in order to cause the needles 21 to rupture the ends of the capsule in the recess 25, and then to release those push-buttons so that they can be biased outwardly again by the compression springs 23. The capsule is then free in the recess 25 ready for entrainment when inhalation starts.

The user then simply inhales through the mouthpiece 27 of Figures 8 and 9 to generate the necessary swirling airstream into the chamber 24 through the inlets 26, and this same swirling action will detach the capsule from the recess 25 in which it is a loose fit, and will cause the capsule to rotate rapidly about the above-mentioned axis of rotation of the vortical swirling airflow in the chamber 24.

The fact that the capsule is of a length shorter than the diameter of the chamber 24 means that it is able to be spun around its transverse axis in the vortical airflow, and yet at the same time because its length is nearly equal to that diameter it is able to contact the peripheral wall of the chamber 24 so as to sustain impacts which remove the pulverulent medicament from within the capsule by a percussive action.

This degree of impact with the walls of the chamber 24 is enhanced by the presence of the recess 25 which gives the chamber 24 a generally non-symmetrical or eccentric appearance, resulting in random and rapidly occurring impacts which augment the centrifugal emptying of the spinning capsule shell.

When the inhalation is complete, the medicament will almost completely have been emptied from the capsule, and indeed from the chamber 24 by being exhausted through the air-pervious grid 30 defining one of the opposed flat walls of the chamber 24 (the other wall being defined by a closure plug 29).

The inhaler can then either be opened immediately in order to remove the spent capsule, or opened only when the next inhalation is to be carried out.

Provided the inhaler is kept dry, and if the material chosen for all of the embodiments of the inhaler in accordance with the invention is one which has relatively low electrostatic attraction for the powder in the capsule, the inhaler will not need regular cleaning when used by the same patient (i.e. other than for considerations of hygiene).

The embodiment of Figures 10, 11 and 12 is similar in many ways to that of Figures 7, 8 and 9 but differs in the means for opening the capsule.

Those components of the device of Figures 10, 11 and 12 which correspond identically to those of Figures 7, 8 and 9 are denoted by the same reference numerals and will be described only briefly, if at all, in the following description.

Figure 10 shows that the capsule, in its opening position, is now aligned with a diameter of the chamber 24, but still has its longitudinal axis in the median plane of the chamber 24, i.e. in the plane which lies mid-way between the planar front and rear walls of the chamber as viewed in Figure 10 (the left hand and right hand walls as viewed in Figure 11). Again, the planar left hand wall is formed by a separate plug 29, and the planar right hand wall 30 is formed by a grid which serves to prevent the capsule and/or any fragments released upon perforation by the opening pins, from entering the respiratory tract of the user during inhalation. In the present embodiment the grid 30 is of a material which is electrically conductive or is otherwise anti-static. Preferably the material used is a conductive polymer. However, the grid may be of a metal such as stainless steel.

In this embodiment the pins 31 for opening the capsule are carried by a single push-button assembly 32

which is guided by a guide peg 33 and an extended guide peg 34 the end of which has a small diameter extension 35 to act as a latch release as will be described shortly.

Again a compression spring 36 is provided in order to bias the push-button 32 to its outward position in which the two pins 31 are retracted from their respective guide ducts 37.

In order to allow the capsule to enter its opening recess, in which position it is illustrated in Figure 10, an ejector slide 38 is mounted centrally within the body of the inhaler and is slidable axially under the control of an operating handle 39 (Figure 11). In order to hold the ejector in the retracted position shown in Figure 10, it includes a latch pip 40 which engages in an aperture 41 where it remains until ejected by the small diameter extension 35 serving as the latch release portion of the guide pin 34 for the push-button 32. Once the latch has been released, a compression spring 42 urges the ejector axially along the body of the inhaler to eject the capsule from the diametrically extending recess into the main chamber 24, and at the same time the end-of-travel position of the ejector 38 is such that a concave arcuate leading surface 43 of the ejector fits flush with the peripheral wall of the chamber 24 in order to ensure that the capsule will not be able to re-enter that capsule-opening recess during subsequent tumbling in the vortical airstream upon inhalation. It will however impact against the edges of a recess 25 which in this embodiment serves only to provide an irregularity to the peripheral wall of the swirling chamber to provoke ejection of the powdered medicament from the capsule by percussive action.

Figure 10 shows, in broken lines, the location of a slot 44 (see also Figure 11) in the front casing 45 of the inhaler, to allow the operating handle 39 of the ejector 38 the degree of travel required for movement between the capsule-accepting position shown in Figure 10 and the

capsule-ejecting position (which is not shown in the drawings). It should be noted that the plane of section for Figure 11 is taken centrally of the slot 44.

The operation of the device shown in Figure 10, 11 and 12 will now be described.

Firstly the operating handle 39 of the ejector 38 is drawn to the position shown in Figures 10 and 11, in order to free the capsule-opening recess.

Then the front body portion 45 is removed from the rear body portion 46 of the inhaler in order to allow insertion of the capsule into the capsule-opening recess.

The two body portions 45 and 46 are then fastened together again to close the chamber 24 ready for the capsule-opening operation.

It will of course be appreciated that throughout the above three operations the push-button 32 is held in its extended position shown in Figure 10, by virtue of the compression spring 36.

The push-button 32 is now inserted in order to drive the two pins 31 into the capsule ends, and at the end of that insertion stroke the latch release extension 35 of the guide pin 34 will contact the latch pip 40 to release the latch and allow the ejector 38 to be driven forwardly to eject the capsule, under the action of the compression spring 42.

With the capsule now positioned in the chamber 24, the user places his or her lips over the mouthpiece nozzle 27 and inhales in order to generate the swirling motion airstream within the chamber 24, giving rise to ejection of the medicament from within the capsule, by the three-fold actions of pneumatic suction, centrifugal flinging, and percussive impact with the peripheral walls 24a, 25a of the chamber 24.

The user has an indication that the capsule has been fully opened by the piercing operation in that unless the push-button 32 is inserted fully, to a position which

will correspond to adequate rupturing of the capsule ends by the needles 31, the latch release extension 35 of the pin 34 will not displace the latch pip 40 from its aperture 41 and hence the ejector will not be released to eject the capsule. The user will be aware of this by the fact that the operating handle 39 of the ejector 38, also serving as an indicator, will not have displaced from the position shown in Figures 10 and 11. Only when this indicator has moved in order to signal ejection of the capsule should the operator embark on the inhalation step.

Although in the above description it has been indicated that the embodiments of Figures 7 to 9 and Figures 10 to 12 both rely on separation of the front and rear body portions in their entirety in order to allow insertion of a new capsule (and, incidentally, removal of the spent capsule from the last use), it will of course be understood that other arrangements are possible.

In Figures 10 to 12, the body portion 46 may only extend down as far as the end of the inhalation chamber nearest the capsule opening means 31-34.

Alternatively, in both embodiments of pin opening device (Figures 7 to 9 and Figures 10-12), the plug 29 or the mouthpiece 27 and grid 30 section shown can be made to be removed in order to provide for access to the chamber 24 to allow removal of the spent capsule and equally insertion of a fresh capsule in either the capsule-opening recess 25 of Figure 7 or the capsule-opening recess in which the capsule is shown as being positioned in Figure 10. For this purpose the plug 29 or the mouthpiece and grid section may be provided with any suitable means for enabling it to be removed, and the design of such means will be within the capability of the skilled expert in the art. Possibilities include screw threading on the plug 29 and the recess into which it fits, or a hinge, for example a thin film hinge, to attach the plug 29 to the body of the inhaler.

It will be appreciated that each of the three

embodiments described in the present application has the feature of the capsule being opened in the inhaler, while oriented with its major axis in the median plane of the chamber in which the swirling inhalation airflow will cause the capsule to tumble to discharge its contents. In the embodiment of Figures 1 to 6 this opening operation relies on physical separation of the capsule body from the capsule cap while positioned to one side of the chamber, in a position almost tangential to the airflow which is generated during inhalation; in the embodiment of Figures 7 to 9 the opening position is again almost tangential to the airflow in the chamber, but opening is effected by axially moving penetrating pins at each end of the capsule; and in the embodiment of Figures 10 to 12 the capsule is positioned diametrally of the chamber and opening is effected by transverse (i.e. radial) movement of pins but again operating at each end of the capsule.

It will be appreciated that in the embodiments of Figures 7 to 9 on the one hand and Figures 10 to 12 on the other hand, although the capsule is opened by penetration at each end there is no question of airflow having to pass directly through the capsule as the sole means of removing the pulverulent contents. The development of the present invention has revealed that such a system would give too high a pressure drop across the inhaler during the inhalation operation for a person with a disability of the respiratory function to inspire the contents efficiently, and bearing in mind that the capsule inhalation treatment is intended for those with some disability of the respiratory function it is important to keep the pressure drop at a minimum, while aiming for as near as possible total removal of the contents during the inhalation. The present invention achieves such high efficiency of removal of the medicament from not only the capsule but also the inhalation device as a whole, by (i) allowing random impact of the capsule ends with the walls of the chamber, and by (ii)

ensuring that the axis of symmetry of the capsule or of the individual separated capsule cap and body parts during the tumbling operation remains generally parallel to the median plane of the chamber so as to give the best possible centrifugal action, and equally the optimum pneumatic suction on the interior of the capsule, during the inhalation operation. If the capsule were able to tumble into a different orientation where the axis of symmetry becomes anything other than parallel to the median plane of the chamber, the degree of suction will be attenuated, or at least less reliable in strength. It is a feature of the inhalers disclosed in the present application that the contents of the capsule can be efficiently entrained in the airstream even at the relatively low airflow rates likely to be associated with users with impaired respiratory functions.

There are various alternative possibilities for the configuration of the chamber, and it is felt that the adoption of a chamber in which the shape is not fully cylindrical as shown in Figure 10 is preferable in that this will give rise to an increased likelihood of percussive impact on the walls of the recess 25 to tap the contents of the capsule clear of the ruptured capsule shell and capsule body and cap portions.

For the embodiments of Figures 7 to 9 and 10 to 12 it is desirable for the axial length of the chamber 24 (the minimum spacing between the front and the rear flat walls of the chamber) to be less than the axial length of the capsule, and preferably less than it by a margin sufficient to ensure that there is no likelihood of the capsule being trapped in an inclined position. For the embodiment of Figures 1 to 6 it is preferable for the axial length of the chamber to be less than the axial length of the cap portion (this being shorter than the body portion) of the capsule, for the same reason.

There are known inhalers using recesses formed in

the opposed walls which have been described herein as the front and rear walls of the chamber, where the capsule is held clear of the median plane of the chamber during capsule opening, or is even inserted in a capsule-opening recess with the longitudinal axis of the capsule parallel to the axis of rotation of the swirling airflow during inhalation. Those constructions may result in a possibility for the capsule to become lodged in the capsule opening recess during the tumbling action, with the resultant holding of the capsule and impeding of the capsule-emptying action during inhalation. It is considered an important optional feature of the present invention that the front and rear walls of the chamber are generally flat without such depressions, so that the likelihood of the capsule becoming caught during inhalation is reduced if not negligible.

For the same reason the ejector 38 has the concave leading surface 43 which closes off the capsule-opening recess, thereby removing the possibility of the rounded ends of the capsule becoming caught against the sharp edges of the capsule-opening recess, leading to the likelihood of the capsule jamming during inhalation.

As indicated above, the material used for the walls defining at least the swirling chamber, and preferably also the mouthpiece, may in all embodiments of the inhaler in accordance with the present invention be one which is not likely to generate a high electrostatic charge which would cause the released pulverulent medicament to adhere to the surface of the body of the inhaler rather than passing outwardly through the mouthpiece nozzle.

Figure 13 shows a further embodiment of inhaler in which the capsule is to be opened by piercing with pins at its ends. This inhaler 60 has the mouthpiece 61 in the preferred embodiment hinged at 62 to the body portion 63 in which the inhalation chamber and the capsule opening means are defined. Alternative means of detaching the mouthpiece from the body of the inhaler may be employed; for example, unscrewing, or twisting by means of a bayonet pin or pins

and arcuate slot may be provided for.

The capsule opening means is rotary in action and comprises a rotor having a recess 69 (Figure 15) to receive the capsule to be opened and a pusher member to eject the pierced capsule from the recess 69, and the rotor itself is driven by a disc-like control wheel 64 operated manually. In a first, capsule-receiving position (illustrated in more detail in Figure 15) the capsule-receiving recess 69 in the rotor is in register with a capsule insertion opening 65 in the body 63.

The inhalation chamber is positioned at the right hand end of the body 63, close to the point of junction between the body and the mouthpiece 61, and one of the air inlet openings 66 to that inhalation chamber can be seen in Figure 14.

Figure 15 is a sectional view taken on the line 15-15 of Figure 13 and shows the mouthpiece clipped in its operative position by catch engagement between a projection 67 of the body and a corresponding projection 68 of the mouthpiece.

Figure 15 also shows the capsule 5 in position in the capsule-receiving recess 69 in register with the capsule-inserting opening 65.

An arcuate wire clip 70 having a sharpened bent end portion coaxial with the capsule 5 is secured to the end of the rotor 71 by projections 72 which trap the wire clip to rotate with the rotor.

A cam 73 cooperates with the wire 70 in a manner which will be more readily evident from Figures 18 and 19, to drive the bent end portion of the wire clip axially into the capsule 5 held in the recess 69 to pierce the capsule.

It will of course be appreciated that there are in fact two such wires 70, one at each end of the rotor 71.

Figure 16 shows the rotor 71 after rotation in the anti-clockwise direction through 180° to bring the capsule 5 with its axis passing through the cam 73.

As shown in Figure 19, in this position the sharpened end 74 of the bent portion 75 of the wire clip 70 has been pressed into the end of the capsule 5 by the operation of the cam 73 of the body 63 as the rotor 71 rotates.

Comparing Figures 18 and 19 will show that in the Figure 18 "capsule-receiving" position the wire clip 70 is not flat against the rotor but is in fact helical relative to the rotor end wall and that as the rotor rotates towards the Figure 19 position the point where the cam 73 bears against the back of the wire clip 70 gradually moves around the clip towards the bent end portion 75.

Figures 18 and 19 show that there is a similar cam 73' operating on the wire clip 70' at the opposite end of the rotor 71, in the same manner as described above for the cam portion 73.

Figure 17 is a sectional view taken on the line 17-17 of Figure 13 and shows the pusher member 76 within the rotor 71 to eject the capsule 5 into the inhalation chamber 77 after a further 90° of rotation of the rotor 71.

This pusher member 76 is biased in a radially outward direction by means of a helical compression spring 78.

Figure 17 also shows that, in common with the embodiments of Figures 1 to 6, 7 to 9 and 10 to 12, the inhalation chamber 77 is again defined by a generally flat right hand wall formed by the preferably electrically conductive grid 79 of the mouth piece 61 and a left hand wall 80 having an aperture through which a part of the circumference of the rotor 71 may project, but which is generally flat particularly when the capsule pusher member 76 is in the radially outermost position shown in Figure 17.

The dimension of the inhalation chamber between and perpendicular to the two flat walls 80 and 79 is again less than the axial length of a capsule 5 but greater than the diameter of the transverse cross-section of the capsule 5.

The airflow pattern through the inhalation chamber 77 can be best appreciated from Figure 20 which shows an inlet opening 81 entering the chamber 77 generally tangentially and the inlet opening 66 of Figure 14 which also leads into an opening generally tangentially of the chamber 77.

Figure 20 also shows the capsule pusher member 76 of the rotor 71 and the recesses 85 at opposite sides of the swirling chamber 77 to provoke percussive ejection of the medicament from the capsule.

In operation of the device shown in Figures 13 to 20, the operating disc 64 is first of all rotated to the Figure 15 position with the inhalation chamber 77 clear of the debris of any previous capsule. This clearance of the chamber 77 can be achieved by swinging the mouthpiece 61 aside by means of the hinge 62.

The capsule 5 is then pressed through the insertion opening 65 and into the recess 69 against the action of the compression spring 78 and the disc 64 is then rotated firstly to trap the capsule 5 behind the cylindrical wall of the body 63 and then further to bring the rotor 71 to the Figure 16 configuration where the end domes of the capsule cap portion and capsule body portion have been ruptured.

Further rotation of the disc 64 to bring the rotor to the Figure 17 configuration will suffice to prepare the device for inhalation.

At this point the mouthpiece is inserted in the mouth of a patient and the patient inhales so that the air entering through the inlet ports 66 and 81 causes a swirling motion in the inhalation chamber 77 and rotates the capsule 5 rapidly about a transverse axis, in order to eject the pulverulent medicament from the capsule by a combined centrifugal action, a suction action, and a percussive action as the capsule strikes the peripheral wall of the chamber 77.

Then, in order to prepare the device for the next

use, the mouthpiece is swung aside and the spent capsule removed, following which the disc 64 is then rotated by a further 90° from the Figure 17 position to the Figure 15 position to bring the capsule-receiving recess 69 into register with the capsule-insertion opening 69.

Although in each of the above embodiments the first, and second walls of the chamber, namely the opposed walls which together constrain the capsule or each separated capsule portion to maintain its axis of symmetry parallel to the median plane of the chamber are shown throughout as flat, it is of course possible for these walls to be other than truly flat, while still maintaining a shape sufficiently close to the flat shape for allowing the desired capsule-constraining action to be effected. Where the walls are not flat, it is the minimum spacing between these walls which is related to the dimensions of the capsule.

In the embodiment of Figures 1 to 6, the spacing between these first and second opposed walls defined by the rear casing panel 4 and the grid 7 is less than the axial length of the capsule body portion 5a and less than the axial length of the capsule cap portion 5b.

In the embodiments of Figures 7 to 9 and 10 to 12 the spacing between these first and second opposed walls is less than the total axial length of the capsule. This preferred feature guards against any possibility of the capsule becoming jammed in an oblique configuration where the roughness of the grid might assist in holding the capsule and preventing it from rotating freely in the swirling airstream.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

The claims defining the invention are as follows:-

1. An inhaler which comprises a chamber defined by (a) first and second generally parallel spaced opposed walls defining a median plane of said chamber mid-way therebetween, and between which parallel spaced walls of a medicament-containing capsule can fit with its longitudinal axis generally parallel to said first and second walls but in any angular orientation, and (b) at least one peripheral further wall; an exhaust nozzle through which air can be exhausted from said chamber by inhalation; at least one air inlet arranged in relation to the exhaust nozzle to generate in the chamber during inhalation an airflow rotating about an axis generally perpendicular to said first and second walls; and holding means in the inhaler in association with means operable from outside the closed chamber for opening a capsule while held in the holding means, wherein the holding means are effective to hold a said capsule having a length greater than the minimum spacing between said first and second walls and less than a minimum dimension of the cross-section of said chamber when viewed parallel to said axis of rotation and are configured to hold a said capsule having a diameter less than said minimum spacing between the first and second walls; wherein the holding means are effective to hold said capsule with the longitudinal axis of the capsule perpendicular to said axis about which the inhalation air rotates and substantially coincident with the median plane of said chamber.

2. An inhaler according to claim 1, wherein said capsule opening means comprises means for physically separating the cap portion of the capsule from the body portion of the capsule whereupon said separated cap and body portions are able to tumble in the chamber during inhalation.

3. An inhaler according to claim 2, wherein the minimum spacing between said first and second walls of the chamber is less than the length of said capsule cap portion, measured in a longitudinal direction, and than the longitudinal length of said capsule body portion.

4. An inhaler according to claim 1, wherein said holding means comprise a recess in the inhaler in association with the means for opening a capsule while held in the recess with the longitudinal axis of the capsule perpendicular to said axis of airflow rotation; and in that the chamber is non-circular and is able to allow the capsule to rotate freely about its transverse axis under the influence of the inhaled airstream and to impact against said at least one further wall in order to increase the likelihood of ejection of the medicament from within the capsule.

5. An inhaler according to claim 1 or 4, wherein said means for opening the capsule comprise means for rupturing the capsule to permit discharge of the contents of the capsule while the capsule spins in the rotational airflow during inhalation.

6. An inhaler according to claim 5, wherein the minimum spacing between said first and second walls of the chamber is less than the length, measured in a longitudinal direction, of the capsule to be held by said recess during opening by said opening means and to be tumbled in said chamber during inhalation.

7. An inhaler according to claim 6, wherein the minimum spacing between said first and second walls is less than the axial length of the cylindrical part of a said capsule.

8. An inhaler according to any one of claims 5 to 7, wherein said capsule holding means are arranged to receive the capsule in a position with its longitudinal axis generally tangentially of the chamber, while the capsule opening means are being operated, whereupon the capsule is released for extraction from said holding means by the subsequent vortical inhalation airstream.

9. An inhaler according to any one of claims 5 to 7, wherein the capsule holding recess extends in a direction generally collinear with a diameter of said chamber, and said rupturing means comprise means for piercing the ends of a capsule received in said recess with its longitudinal axis extending in a direction collinear with a diameter of the chamber, and further including means for ejecting the thus pierced capsule from said recess into the chamber for tumbling during subsequent inhalation.

10. An inhaler according to claim 9, wherein said capsule ejector includes a capsule-ejecting end face which smoothly conforms to the said at least one further wall when the ejector is in a position corresponding to displacement of the capsule having been achieved.

11. An inhaler according to any one of claims 1 to 7, and further including means for closing said air inlets until inhalation is required, and wherein said capsule opening means are effective to open the capsule only while said air inlets are closed.

12. An inhaler according to any one of claims 1 to 7, wherein the exhaust nozzle is eccentric in relation to said chamber, whereby the capsule spins in the inhalation airflow with random collisions against the further walls of said chamber.

13. An inhaler according to any one of claims 4 to 7, wherein said chamber is generally circular but rendered not strictly circular by virtue of said recess extending tangentially of the generally circular chamber for receiving the capsule to be ruptured by said rupturing means.

14. An inhaler according to claim 1, wherein the capsule opening means comprise a recess extending generally in a direction collinear with a diameter of said chamber, and said capsule opening means comprise means for piercing the ends of an elongate capsule received in said recess with its longitudinal axis extending in a direction collinear with a diameter of the chamber, and further including means for ejecting the thus pierced capsule from said recess into the

chamber for tumbling during subsequent inhalation.

15. An inhaler according to any one of claims 4 to 7, wherein said capsule opening means comprise a capsule-receiving rotor rotatable about an axis parallel to the median plane of said chamber, and having a capsule recess to receive a capsule with its longitudinal axis parallel to the axis of rotation of said rotor, and capsule-rupturing pins carried by said rotor and driven to rupture said capsule during rotation of the rotor between a capsule-receiving position and a capsule-releasing position when the capsule is released into said chamber.

16. An inhaler according to claim 15, wherein said capsule-rupturing pins comprise bent end portions of arcuate wires at opposite ends of said rotor, with said arcuate wires extending generally around the axis of rotation of said rotor and said bent pin-defining end portions coaxial with said capsule-receiving recess, and in that said inhaler further includes stationary cams which engage said arcuate portions to drive the capsule-rupturing end portions axially of the capsule-receiving recess.

17. An inhaler according to any one of claims 1 to 7, wherein the chamber has walls defined by an anti-static member having a surface resistivity of less than 10^{12} Ohms.

18. An inhaler constructed and adapted to operate substantially as hereinbefore described with reference to, and as illustrated in Figures 1 to 6, Figures 7 to 9, Figures 10 to 12, and Figures 13 to 20 of the accompanying drawings.

DATED this 16th day of June, 1994.

RHONE-POULENC RORER LIMITED
By Its Patent Attorneys
DAVIES COLLISON CAVE

Fig.1

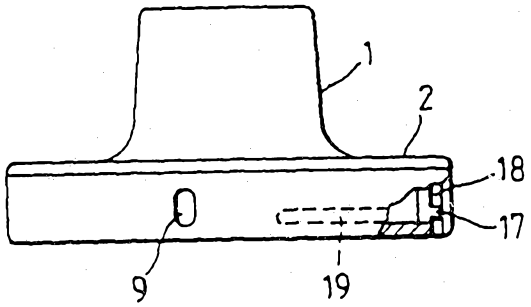


Fig.2

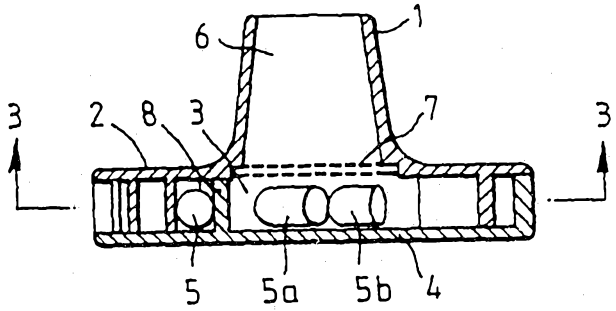


Fig.6

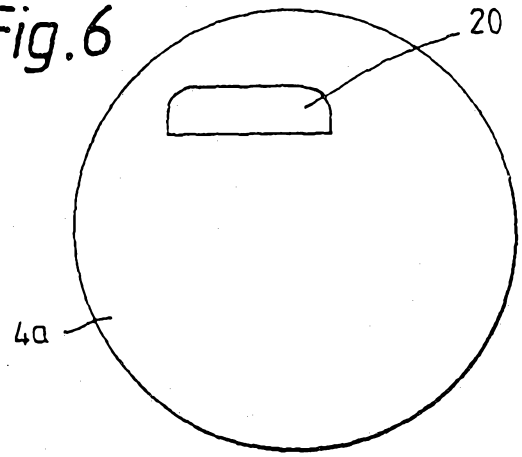


Fig.3

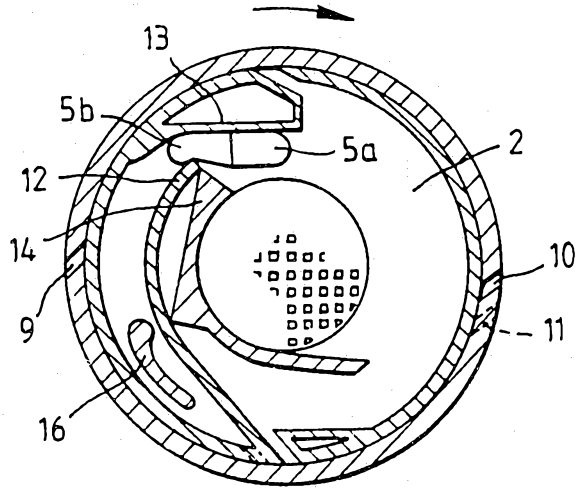


Fig.4

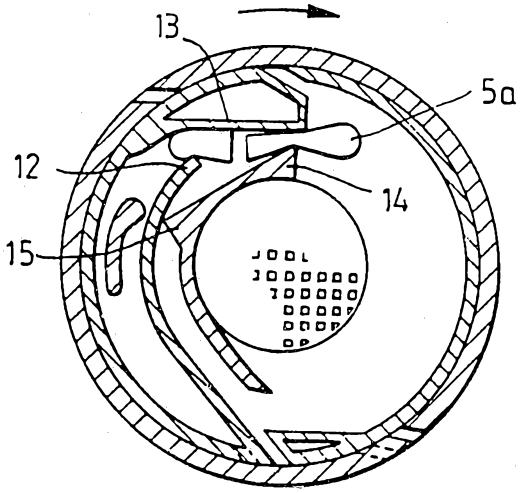


Fig.5

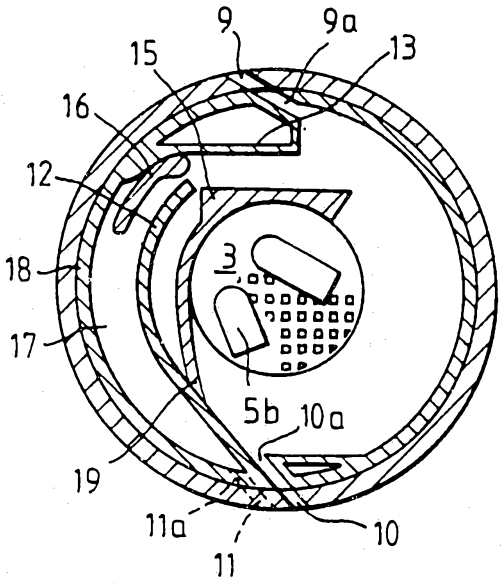


Fig.7

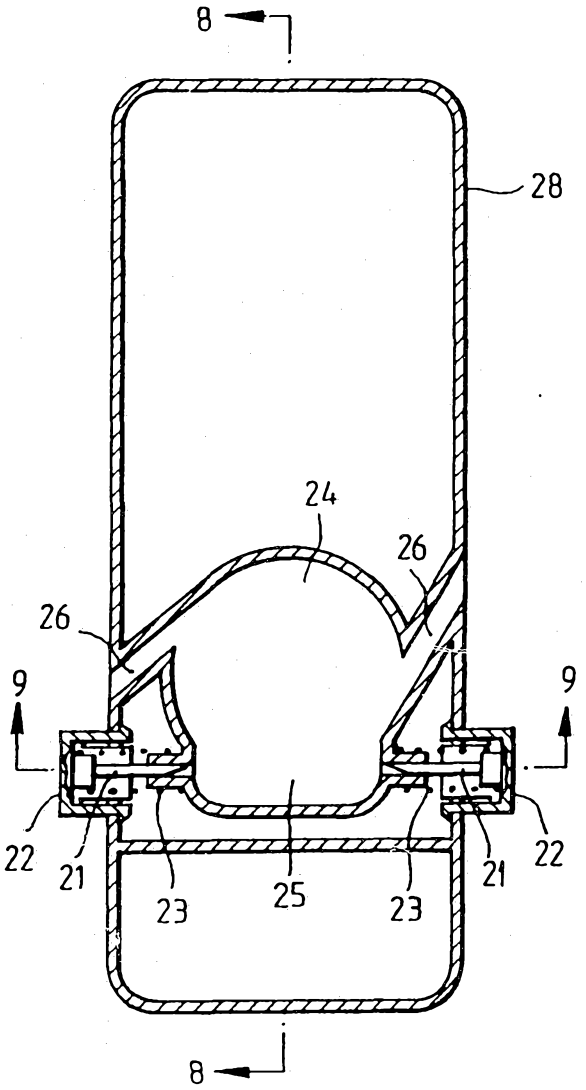


Fig.8

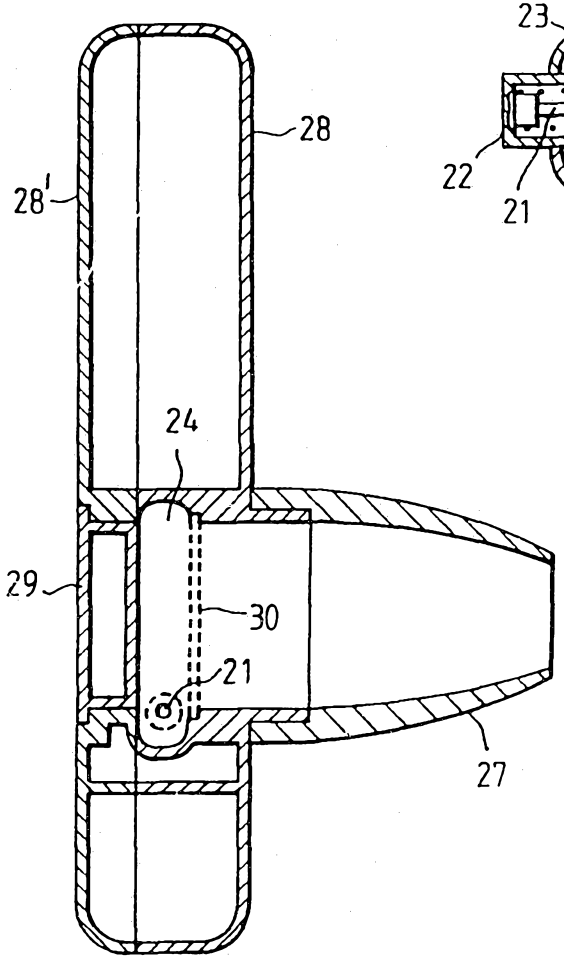


Fig.9

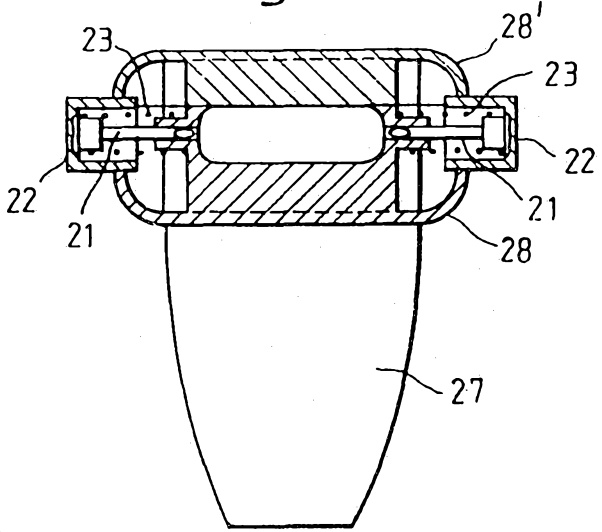


Fig.10

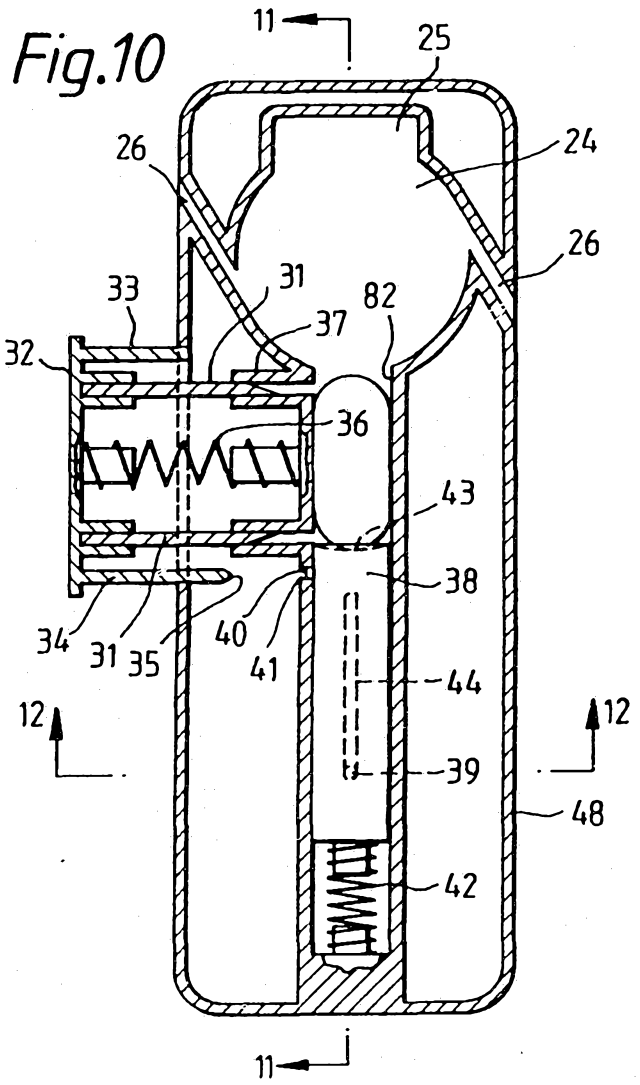


Fig.11

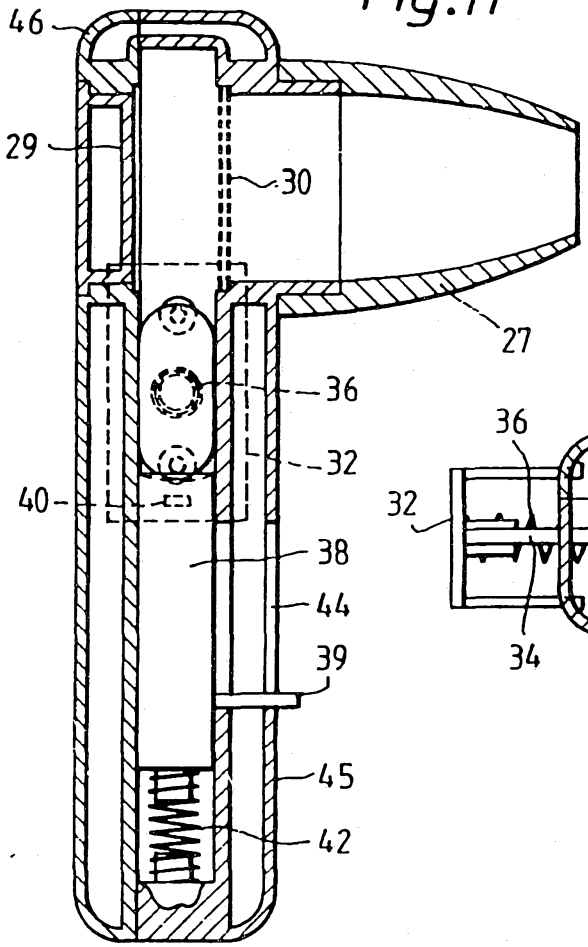


Fig.12

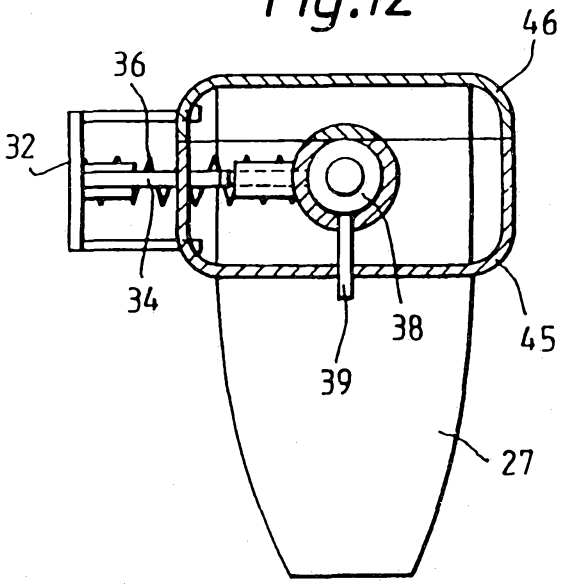


Fig. 13

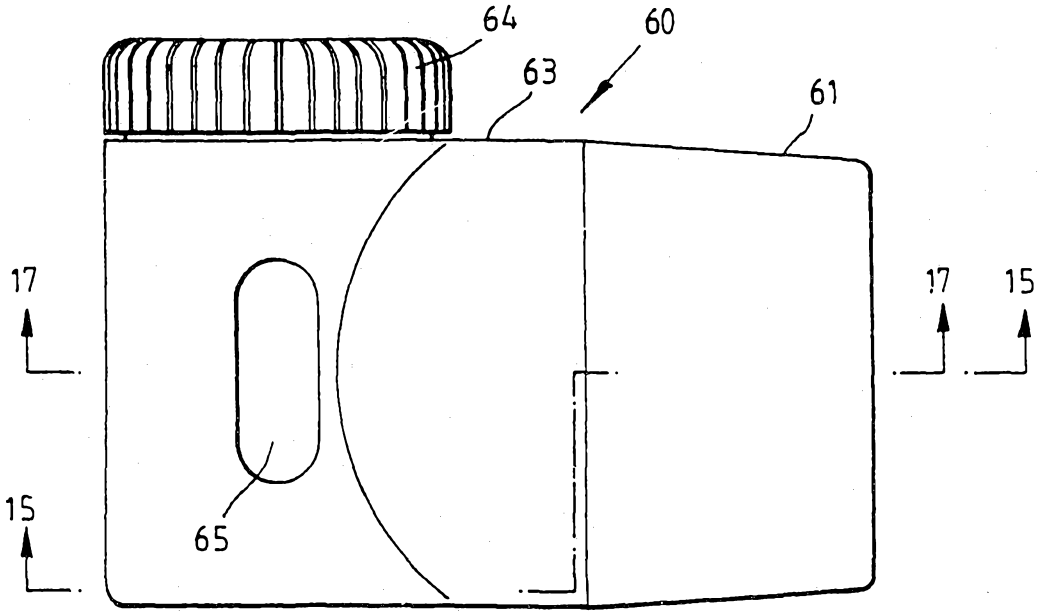


Fig. 14

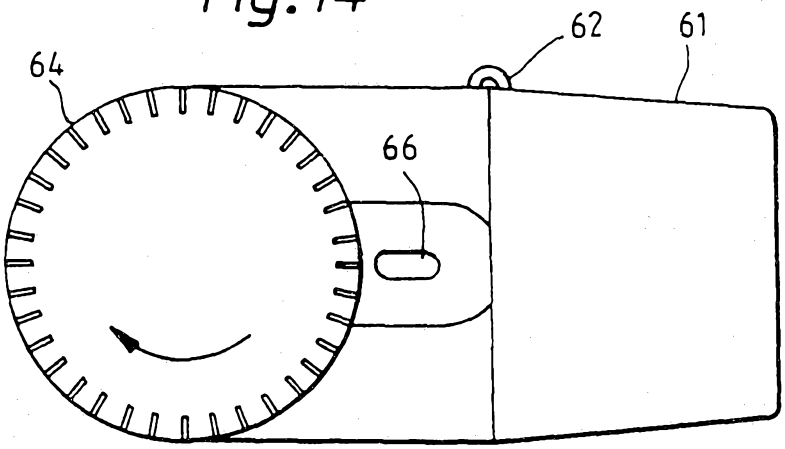


Fig.15

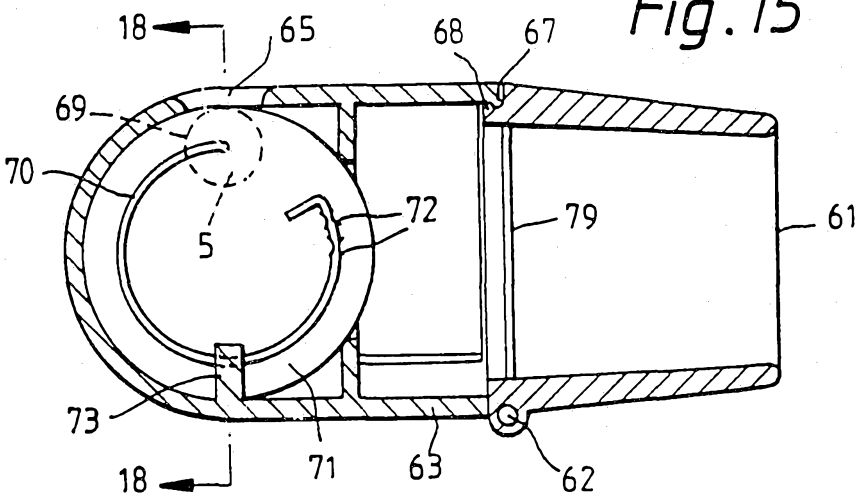


Fig.16

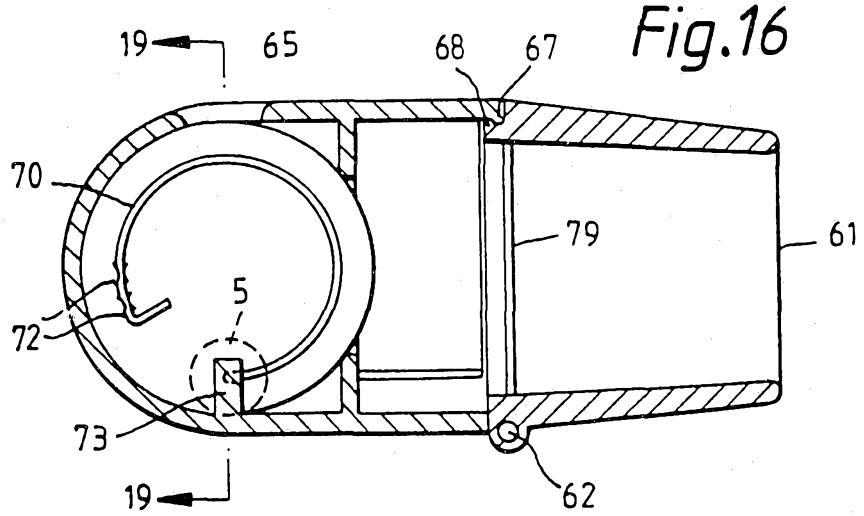


Fig.17

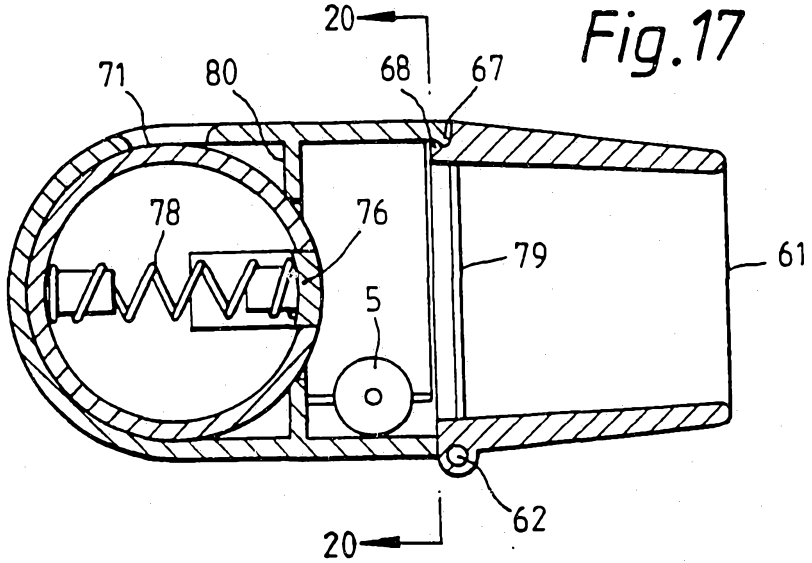


Fig.18

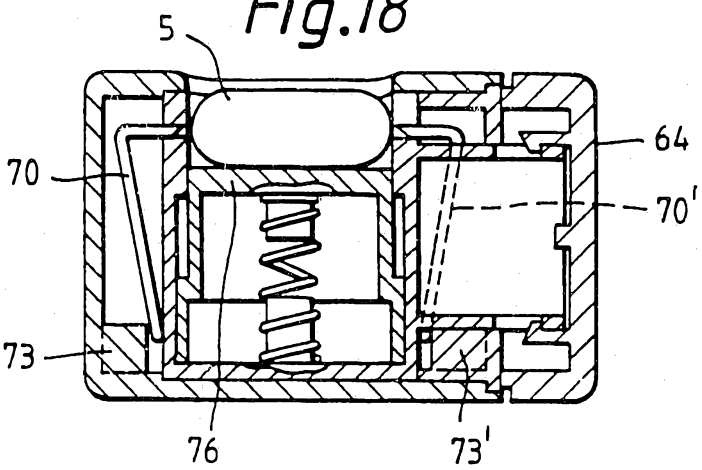


Fig.19

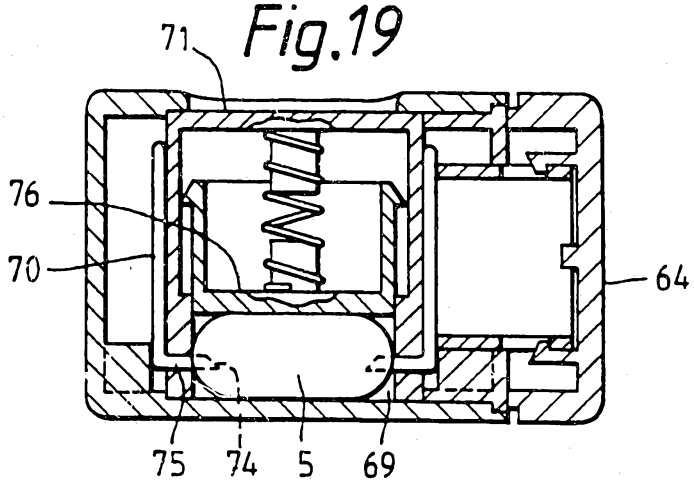
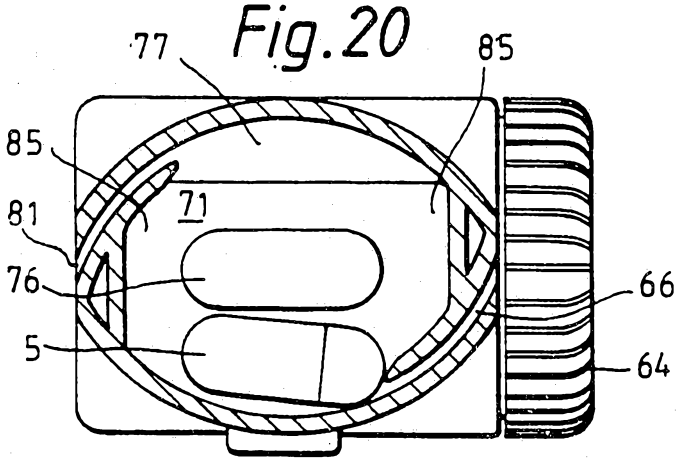


Fig.20



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 91/00958

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl.5 A 61 M 15/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl.5	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
A	EP,A,0333334 (HARRIS PHARMACEUTICALS) 20 September 1989, see the whole document	1

° Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
11-09-1991	23.07.92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	Els Vonk

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB91/00958

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for ne following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please see form PCT/ISA/206 sent on 23.10.91

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1, 2, 3, 5, 10-12, 15, 18.

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9100958 SA 48440

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 27/12/91
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A- 0333334	20-09-89	AU-A- 3293189	06-09-89
		WO-A- 8907464	24-08-89