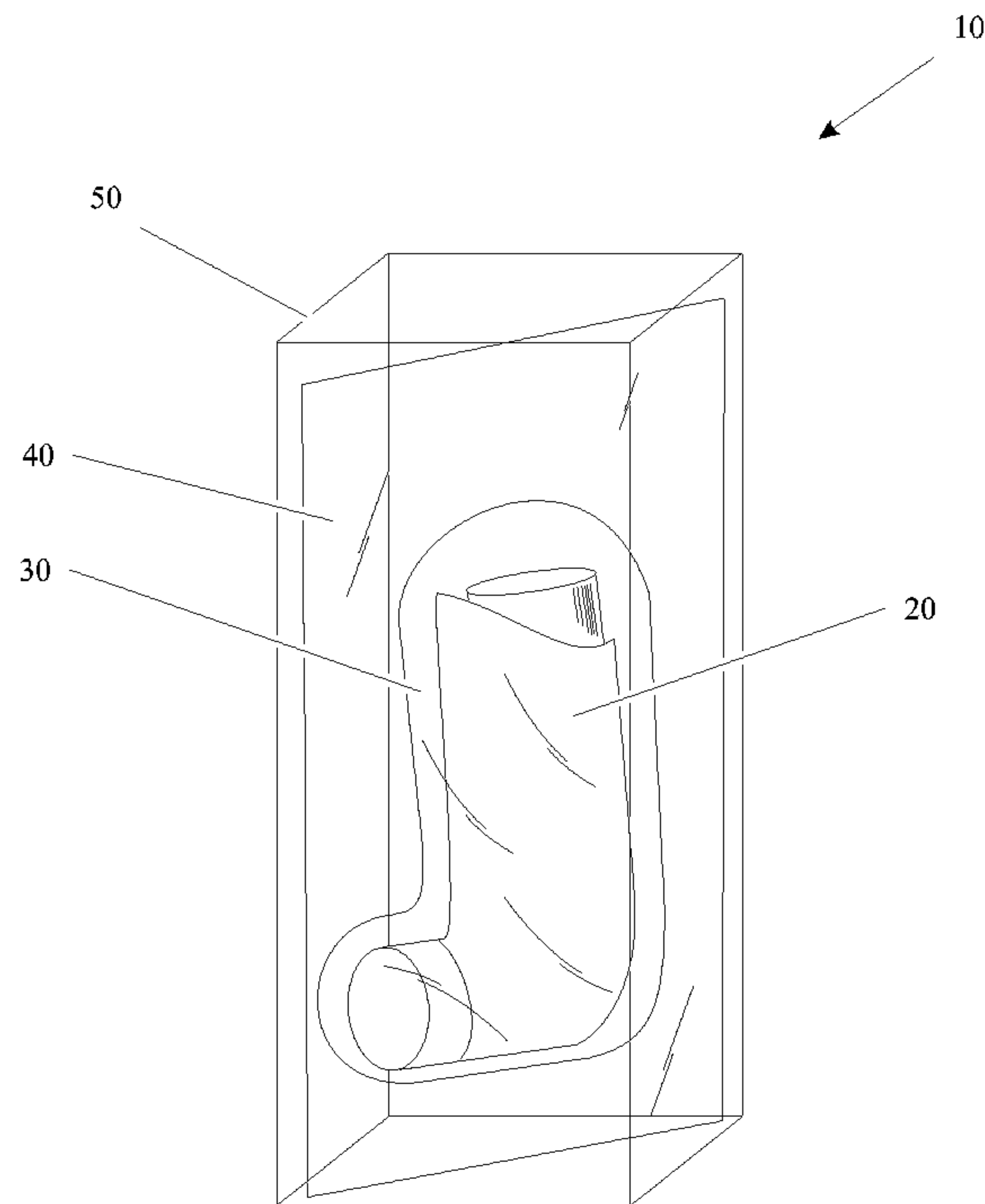




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(57) **Abrégé/Abstract:**

A package with a protective enclosure containing a dispensing device, wherein the protection enclosure comprises at least one rigid enclosure member.



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(54) Title: PACKAGE FOR A DISPENSING DEVICE

(57) Abstract: A package with a protective enclosure containing a dispensing device, wherein the protection enclosure comprises at least one rigid enclosure member.

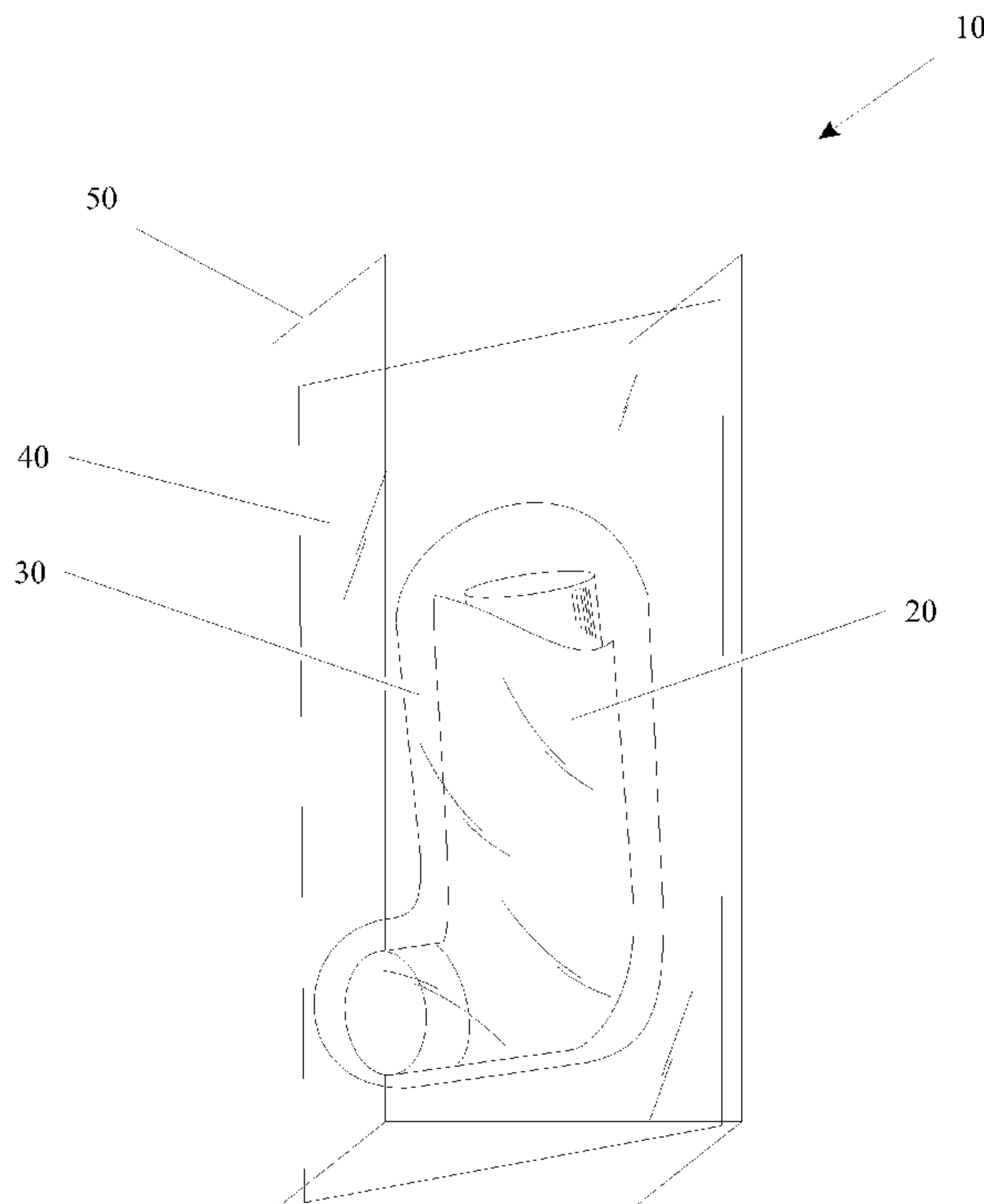


Fig. 2

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PACKAGE FOR A DISPENSING DEVICE

The field of the invention

The present invention relates to a package for a dispensing device, more in detail the invention relates to a package for a drug-dispensing device such as an inhaler and especially a pressurized metered dose inhaler (hereinafter referred to as a "pMDI"). The invention does, however, embrace other dispenser types, for example a dry powder inhaler (DPI), or nasal inhalers, as will be appreciated by the reader skilled in the inhaler art.

Background of the Invention

pMDIs are well known in the art of inhalation devices. It is therefore not necessary to describe the construction and operation of a pMDI other than in bare essentials.

A pMDI comprises a canister unit and a housing. The housing is generally tubular and formed of a plastic material, for instance by moulding. The canister unit comprises a canister having one open end, typically made from a metal such as aluminium. The open end of the canister is sealingly capped by a metering valve assembly. The valve assembly includes a hollow dispensing member, usually in the form of a valve stem, which projects from the open end of the canister. Actuation of the metering valve assembly results in a metered dose of the aerosol formulation being dispensed from the canister through the valve stem.

In use, the sealed canister contains a pressurised medicinal aerosol formulation. The formulation comprises the medicament and a fluid propellant, and optionally one or more excipients and/or adjuvants. The medicament is typically in solution or suspension in the formulation.

The housing comprises an internal passageway having an open end. A nozzle block, is arranged to receive the valve stem from the canister unit, and to direct the dispensed metered dose to a mouth piece (or nasal piece). In use, a patient in need of a metered dose of the medicinal aerosol formulation concurrently inhales on the mouthpiece and actuates the canister unit. The inspiratory airflow produced by the patient entrains the metered dose of the

medicinal aerosol formulation into the patient's respiratory tract.

Dispensing devices are commonly stored in a sealed protection pouch inside a package housing such as a cardboard box or the like. Depending on the type of dispensing device and requirements related thereto, the protection pouch may be arranged to keep the dispensing device protected from moisture, contamination, and/or dust. The protection pouch is commonly made from a thin flexible material such as plastic film, coated paper, metal foil, laminates thereof or the like. Mechanical protection of the dispensing device is mainly provided by the package housing. Moreover, the dispensing device and the protection pouch are normally free to move about inside the package housing.

It has been concluded that current protection pouch designs may be susceptible to punctures due to fatigue failure in the materials and due to impacts from sharp edges on the inhaler. Fatigue failure frequently occurs at crease points in the pouch, where the material is worn and work hardened during vibration. The pouch material punctures in the lower portion of the pouch, generally close to the sides and at evident fold points in the foil. This failure is caused by the vertical movement of the pouch and contents within the product carton during handling, transport, etc, whereby the foil pouch e.g. flexes at natural folds.

WO 2006/003386 discloses a package for a dispenser in the form of an inhaler, comprising a support said to be arranged to suspend the dispenser in order to avoid unintentional actuation. Several types of suspension arrangements are proposed, all said to be arranged to allow a controlled suspended movement of the inhaler inside the package. However, there are no specific provisions for avoiding punctures of the sealed pouch.

Summary of the Invention

The object of the invention is to provide a new package with a protective enclosure containing a dispensing device which overcomes the drawbacks of the prior art. This is achieved by the package as defined in the independent claims.

One advantage of the present package is that the risk for punctures of the protection enclosure is vastly lowered, compared to conventional packages with soft protection pouches.

Aspects of the invention comprises:

- A package with a protective enclosure containing a dispensing device, wherein the protection enclosure comprises at least one rigid enclosure member.
- A package wherein the rigid enclosure member is provided with a recess formed to house a section of the dispensing device.
- A package wherein the recess has a shape that resembles the shape of the dispensing device.
- A package wherein the recess is formed to house the full dispensing device therein, and the protective enclosure further comprises an essentially flat enclosing lid attached to the rigid enclosure member.
- A package wherein the recess depth is essentially equal to the smallest dimension of the dispensing device.
- A package wherein the recess depth is essentially equal to the largest dimension of the dispensing device.
- A package wherein the protection enclosure is comprised of two rigid enclosure members attached to each other, each provided with a recess formed to house a section of the dispensing device.
- A package wherein each recess has a shape that resembles the shape of a section of the dispensing device.
- A package wherein the dispensing device is an inhaler essentially comprised of an elongated main body with a mouth piece extending in an essentially transverse

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direction, and wherein one recess is formed to house essentially the whole mouth piece.

- A package wherein the two rigid enclosure members are attached to each other in a plane that is essentially parallel with the longitudinal direction of the main body, and diagonal to the extension direction of the mouth piece.
- A package wherein the two rigid members are formed from one sheet of rigid material that is folded or hinged.
- A package comprising at least one support member arranged to support the dispensing device.
- A package wherein the support member is integrally formed in a recess of a rigid enclosure member.
- A package comprising a desiccant member.
- A package wherein the rigid enclosure member is an essentially flat back plate and the protective enclosure further is comprised of a flexible sheet attached to the back plate.
- A package wherein the dispenser is an inhaler
- A package wherein the dispenser is a pMDI.
- A package wherein the protection enclosure is arranged in a box.

Embodiments of the invention are defined in the dependent claims.

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4a

According to one aspect of the present invention, there is provided an inhaler package comprising a protective enclosure containing an inhaler, wherein the protective enclosure comprises: a first rigid enclosure member and a second rigid enclosure member, the first and second rigid enclosure members being attached to each other; a first delimiting member
5 formed on the first rigid enclosure member; and a second delimiting member formed on the second rigid enclosure member; wherein each of the first and second rigid enclosure members defines a recess to house a respective section of the inhaler; wherein the first and second rigid enclosure members comprise first and second opening tabs, respectively; and wherein the first and second delimiting members form a delimited portion, the delimited portion adapted to
10 receive at least one auxiliary feature, the auxiliary feature being selected from a desiccant member, a patient information leaflet, a spare mouth piece, or a spare canister.

Brief Description of the Drawings

The invention will be described in detail below with reference to the drawings, in which:

Fig. 1 is a schematic perspective view of one embodiment of a package according to the present invention.

Fig. 2 is a schematic perspective view of the package of fig. 1 arranged in a box.

Figs. 3a to 3d show one embodiment of a protective enclosure and a package according to the present invention.

Figs. 4a to 4d show one embodiment of a protective enclosure and a package according to the present invention.

Figs. 5a to 5d show one embodiment of a protective enclosure and a package according to the present invention.

Figs. 6a to 6d show one embodiment of a protective enclosure and a package according to the present invention.

Figs. 7a to 7c show one embodiment of a protective enclosure and a package according to the present invention.

Figs. 8a to 8c show one embodiment of a protective enclosure and a package according to the present invention.

Figs. 9a to 9c show one embodiment of a protective enclosure and a package according to the present invention.

Figs. 10a and 10b show one embodiment of a protective enclosure and a package according to the present invention.

Fig. 11 shows an embodiment of a protective enclosure and a package according to the present invention.

Fig. 12 shows an embodiment of a protective enclosure and a package according to the present invention.

Detailed Description of Preferred Embodiments

Fig. 1a is a schematic perspective view of an embodiment of a package 10 for a dispensing device 20, in the form of a pMDI, according to the present invention. The package 10 is comprised of a protective enclosure 30, housing the dispensing device 20 therein. In order to provide enhanced support and protection for the dispenser 20, the protective enclosure 30 comprises at least one rigid enclosure member 40. Throughout this description, the term enclosure member is defined as a member of the protective enclosure that constitutes at least a section of the inner wall of the enclosed protection cavity, as will be evident from the descriptions of the embodiments below. Moreover the term rigid enclosure member refers to a member formed of a material or formed in way, such that it provides structural rigidity to the protective enclosure 30. Hence the, rigid enclosure member 40 may be comprised of any suitable rigid material such as plastic, cardboard, metal, etc, or combinations thereof, or of any flexible material such as paper, rubber, foils and laminates of the above materials. According to one embodiment, the rigid enclosure member 40 is comprised of a plastic sheet or plastic laminate sheet that is given the desired shape by any suitable forming technique. According to another embodiment, the rigid enclosure member 40 is comprised of a metal, e.g. aluminium, that is deep drawn or the like to the desired shape. According to still another embodiment, the rigid enclosure member 40 is comprised of a coated cardboard sheet.

In the disclosed embodiments, with the exception of fig. 11, the package 10 is shown containing one single dispensing device 20. However, the package 10 may be formed to house one or more dispensing devices 20 in one or more enclosures 30. In addition, in some embodiments the enclosure 30 may comprise spaces or areas where auxiliary features, such as a desiccant, a spare mouth piece, a spare medicament canister, or a patient insert, may be added.

In the embodiment of fig. 2, the protective enclosure 30 containing the dispenser is arranged inside a box 50, schematically indicated. The box 50 may be of many different shapes and of different size depending on the dispensing device 20 to be contained therein. Examples of

shapes include classic brick type, tetrahedron type and tube like, as well as any other suitable shape. The box 50 may be comprised of a large selection of materials that provide sufficient rigidity, such as cardboard, plastic, metal etc. The box 50 mainly serves to facilitate handling of the package 10 at the same time as it provides display surfaces whereupon informative and display information can be printed.

As is discussed above, the protection enclosure 30 may be comprised of any suitable barrier materials herein referred to as enclosure materials and as will be discussed more in detail below, parts of the protection enclosure 30 may be comprised of different materials. There are numerous ways of forming the protection enclosure 30 and possible forming processes will not be discussed in full detail herein. Moreover, depending on the enclosure materials, there are numerous ways of closing and if required sealing the protection enclosure 30 such as by heat or friction welding, by use of a suitable adhesive, mechanical lock mechanisms or the like. According to one embodiment, the enclosure material may be coated with a functional layer either before or after forming to the desired shape. Examples of such functional layers are, barrier coatings that reduce the gas and moisture permeability, such as diamond like carbon coating or parylene, radiation protection coatings such as UV filtering coatings etc.

Figs. 3a to 3d show one embodiment of a protective enclosure 31 containing a dispensing device 20 according to the present invention. Fig. 3a shows a front view and fig. 3b a side view of the protective enclosure 31. Fig. 3c shows an unassembled protective enclosure 31 with a dispensing device arranged in position. Fig. 3d shows a top view of the assembled protective enclosure 31 arranged in a box 50 according to fig. 2. As can be seen in fig. 3c, the protective enclosure 31 is formed by two rigid enclosure members 60a and 60b, each having a flat rim 70a and 70b surrounding a recess 80a and 80b formed to house a section of the dispensing device 20, respectively. In the disclosed embodiment, the rigid enclosure members 60a and 60b are shown as one integral member arranged to be folded along the hinge line 90 to be closed. After folding, the two rigid enclosure members 60a and 60b are attached/sealed to each other by any suitable technique as discussed above. However, the rigid enclosure members 60a and 60b could also be provided as independent members and attached/sealed accordingly.

In the disclosed embodiment, each rigid enclosure member 60a and 60b are provided with opening tabs 110a and 110b, respectively. Said tabs 110a and 110b are used to tear the protective enclosure 31 open by separation of the two rigid enclosure members 60a and 60b. In alternative embodiments, the opening procedure might involve cutting or tearing one or both of the rigid enclosure members 60a and 60b.

In the assembled state, the two recesses 80a and 80b form a protection cavity 100 adapted for containing the dispensing device 20. In the disclosed embodiment, the two recesses 80a and 80b are of essentially complementary shape, and the protection cavity 100 has a shape that resembles the shape of the dispensing device 20. As will be shown more in detail below, the recesses 80a and 80b may be of many different shapes and need not to be of complementary shape. The protection cavity 100 may be of any shape that allows enclosure about the dispensing device. Figs. 4a to 4d shows a similar embodiment to that of figs. 3a to 3d wherein the protective enclosure 32 comprises enclosure members 60a and 60b with recesses 80a and 80b that are not formed to resemble the dispensing device 20. The protection cavity 100 is instead of general box shape with rounded corners and thus of a large volume compared to the size of the dispensing device 20. In the disclosed embodiment, the dispensing device 20 is essentially free to move about inside the protection cavity 100, but in other embodiments, the movement may be restricted by different support means and or members. Examples of such support means comprises support members, either as protrusions from the recess walls or as independent members arranged in the protection cavity together with the dispensing device, and will be disclosed in more detail below.

Figs. 5a to 5d shows a similar embodiment to that of figs. 3a to 3d comprising enclosure members 61a and 61b with recesses 81a and 81b. In order to achieve a more firm support of the dispensing device 20 in the protective cavity 100, a plurality of flexible support members 120 are formed in the walls of the recesses. In this embodiment, the flexible support members 120 are arranged to define a diameter being smaller than the dispensing device, and when the protective enclosure 32 is closed, the flexible support members are forced about the outer periphery of the dispensing device so that a slight deformation of the support members 120 is achieved. Said deformation of the support members consequently results in a peripheral retaining action on the dispensing device limiting movement of the dispenser in the protective

cavity. A similar effect can also be achieved by the provision of separate support members of resilient material about the dispensing device, such as a rubber, cardboard or foam ring.

Figs. 6a to 6d shows a similar embodiment to that of figs 5a to 5d comprising rigid enclosure members 62a and 62b with recesses 82a and 82b. In this embodiment, the protective cavity 100 is not shaped so as to resemble the dispensing device 20. Like the embodiment of figs. 4a to 4d, it is of general box shape with rounded corners and thus of a large volume compared to the size of the dispensing device 20. In order to achieve a more firm support of the dispensing device 20 in the protective cavity 100, support members 130a to 130c are formed in the walls of the recesses or potentially separately provided.

Figs. 7a to 7c disclose an embodiment wherein at least one of the rigid enclosure members 63a and 63b is provided with supportive rim 130 extending from its peripheral edge. The supportive rim provides additional support to the protective enclosure 33. In fig. 6a, the protective enclosure 30 is shown freestanding without need for an outer box. However, this embodiment may also be inserted inside a box 50, wherein the supportive rim cooperates with the walls of the box to support the dispensing device in the right position for display purposes and for protecting the same. From figs. 7b and 7c it can be seen that the recesses 83a and 83b are non complementary in order to achieve a wider supportive rim 130 without increasing the over all width of the protective enclosure substantially.

Figs 8a to 8c shows an example of an embodiment, wherein the full depth of the protective enclosure 34 is formed by one recess 84 in a single rigid enclosure member 64. In the disclosed embodiment, the depth of the recess 84 is essentially equal to the smallest dimension of the dispensing device 20, but the depth and shape of the recess may be correlated to any of the inhaler dimensions, as well as essentially uncorrelated to the dispensing device. In the disclosed embodiment, a lid member 140 in the form of a flexible sheet is arranged to close the protective enclosure 34. Said enclosure type may be referred to as a blister pack due to the similarity to a package for medicament tablets and the like. In the disclosed embodiment, the protective enclosure 34 is provided with peel off tabs 111a and 111b respectively. The flexible sheet member is removed by pulling the tab 111b, where after the dispensing device may be removed from the recess 84. In another embodiment, the lid 140 is made of a rigid material and can therefore be referred to as a rigid enclosure member like in

the above embodiments, but without a recess. Moreover, the protective enclosure 34 according to the present invention can be provided with a lid 140 that is non peelable and therefore has to be opened in another way as is discussed above.

Figs. 9a to 9c shows a similar protective enclosure 35 to that of figs 8a to 8b comprising a rigid enclosure member 65 with a deep recess 85 and a lid 145, wherein the depth of the recess 85 is essentially equal to the largest dimension of the dispensing device. In the disclosed embodiment, the protective enclosure 35 is given a shape that resemble the inhaler 20, and the protective enclosure 35 is arranged with the lid 145 as bottom surface, which then serves as a wide stable base/foot. Due to its stable freestanding characteristics, the protective enclosure 35 may be used as a stand alone package 10 without a box. The recess 85 may be given many different shapes which results in new esthetical possibilities when it comes to packages of this type. Like in the previous embodiment, the lid 145 may be of peel off type and provided with a peel off tab 115, but it can also be attached more firmly requiring more invasive methods to open the protective enclosure 35. According to another embodiment, the protective enclosure 35 is formed with the lid 145 as top surface and wherein the recess 85 is formed to house the inhaler 20 in a preferred orientation, e.g. with the valve end downwards.

Figs 10a and 10b shows an embodiment of a protective enclosure 36 comprised of a rigid enclosure member 66a in the form of a flat back plate, and a flexible sheet 66b that is attached closely about the dispensing device 20. The rigid enclosure member 66a provides a rigid back surface that provides support for the dispensing device 20 in that the flexible sheet 66b is arranged to hold the dispensing device firmly to the back plate 66a. The flexible sheet 66b may be arranged about the dispensing device in any suitable way, such as by heat shrinking, vacuum or the like. The flexible sheet 66b may also hold information sheets in place.

In all embodiments of the present invention, the protective enclosure may contain a desiccant member or the like to keep a low moisture level in the long term. In one embodiment, disclosed in fig. 11, a desiccant member 160 is arranged in a delimited portion of the protection cavity 100. In the disclosed embodiment, the desiccant portion of the cavity 100 is formed by delimiting members 170a and 170b. Alternatively, the desiccant member 160 may be placed in the main protection cavity 100 together with the dispensing device 20 or it may be removeably attached to the dispensing device 20. Desiccants used in this field are well

known in the art, eg. silica gel sachets, etc., and therefore not described in more detail herein. Moreover, the protection cavity can be formed to house other auxiliary features in addition or in lieu of the desiccant member 160, e.g. one or more spare mouth pieces, one or more spare canisters, patient information leaflet etc. Such auxiliary features may be arranged in the main cavity 100 or in dedicated sections thereof, like the desiccant portion of fig. 11.

Figs. 12a and 12b show a top view of a package 10, with a protective enclosure 37 containing a dispensing device 20, arranged in a box 50. For illustrative purposes, the dispensing device of figs. 12a and 12b is provided with a wider mouth piece 22 compared to the previously disclosed embodiments. Like in the above embodiments, the disclosed dispensing device 20 is a schematic inhaler, essentially comprised of an elongated main body 21 with a mouth piece 22 extending in an essentially transverse direction from the main body 21. In the embodiment of fig 12a, the protective enclosure 37 is comprised of two rigid enclosure members 67a and 67b with complementary recesses 87a and 87b respectively. In many of the conventional forming techniques suitable for forming protective enclosures according to the present invention, forming of sharp edges in the recesses present a problem with local material thinning. Said material thinning is a result of the large deformations involved. Depending on the material selected for the enclosure member, such local thinning of the material may lead to a weakened structural strength and/or impaired moisture or gas protection. In the embodiment of fig. 12a, the wide mouth piece 22 gives rise to one sharp edge 180a and 180b in each recess 87a and 87b, respectively. Moreover, said sharp edges are preferably formed as close to the rim 181 of the enclosure members 67a and 67b as possible to save package volume, whereby sharp corners 181 are created. In order to reduce the occurrence of sharp edges, the protective enclosure 37 of fig. 12b is comprised of two rigid enclosure members 67a and 67b that are attached to each other in a plane that is essentially parallel with the longitudinal direction of the main body, and diagonal to the extension direction of the mouth piece. The enclosure members 67a and 67b have recesses 87a and 87b respectively, that are non complementary in that essentially the whole mouth piece is housed in the recess 87a and a large portion of the main body is housed in recess 87b. By this diagonal arrangement it has been found that the occurrence of sharp edges 180c in the recesses 87a and 87b in the case of a protection cavity that resembles the shape of an inhaler can be essentially minimized. Moreover, the diagonal enclosure arrangement leads to a more volume efficient package 10 because the rim 70 is placed in the corners of the box 50. A more volume efficient package

leads to savings in the transportation of packages. This arrangement lends strength to the package in that only one corner or edge 180c is produced, thereby reducing areas of thinning or weakness.

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CLAIMS:

1. An inhaler package comprising a protective enclosure containing an inhaler, wherein the protective enclosure comprises:

5 a first rigid enclosure member and a second rigid enclosure member, the first and second rigid enclosure members being attached to each other;

a first delimiting member formed on the first rigid enclosure member; and

a second delimiting member formed on the second rigid enclosure member;

wherein each of the first and second rigid enclosure members defines a recess to house a respective section of the inhaler;

10 wherein the first and second rigid enclosure members comprise first and second opening tabs, respectively; and

wherein the first and second delimiting members form a delimited portion, the delimited portion adapted to receive at least one auxiliary feature, the auxiliary feature being selected from a desiccant member, a patient information leaflet, a spare mouth piece, or a
15 spare canister.

2. The inhaler package of claim 1 wherein each recess has a shape resembling the respective section of the inhaler.

3. The inhaler package of claim 2 wherein the inhaler has an elongated main body and a mouth piece extending in an transverse direction with respect to the main body, and
20 wherein the section of the inhaler housed within the recess defined by one of the two rigid enclosure members comprises the whole mouth piece.

4. The inhaler package of claim 3 wherein the two rigid enclosure members are attached to each other in a plane that is parallel with a longitudinal direction of the main body, and diagonal to the transverse direction in which the mouth piece extends.

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5. The inhaler package of claim 1 wherein the two rigid members are formed from one sheet of rigid material that is folded.
6. The inhaler package of claim 1 further comprising at least one support member arranged to support the inhaler.
- 5 7. The inhaler package of claim 6 wherein the support member is integrally formed in the recess of at least one of the two rigid enclosure members.
8. The inhaler package of claim 1 further comprising one or more auxiliary features selected from a desiccant member, a patient information leaflet, a spare mouth piece, or a spare canister, wherein the auxiliary feature is received in the delimited portion.
- 10 9. The inhaler package of claim 1 wherein the protective enclosure is arranged in a box.
10. The inhaler package of claim 1 wherein the rigid enclosure member is coated with a functional layer comprising a barrier coating reducing gas and moisture permeability of the protective enclosure.
- 15 11. The inhaler package of claim 1 wherein the rigid enclosure member is coated with a functional layer comprising a radiation protection coating.

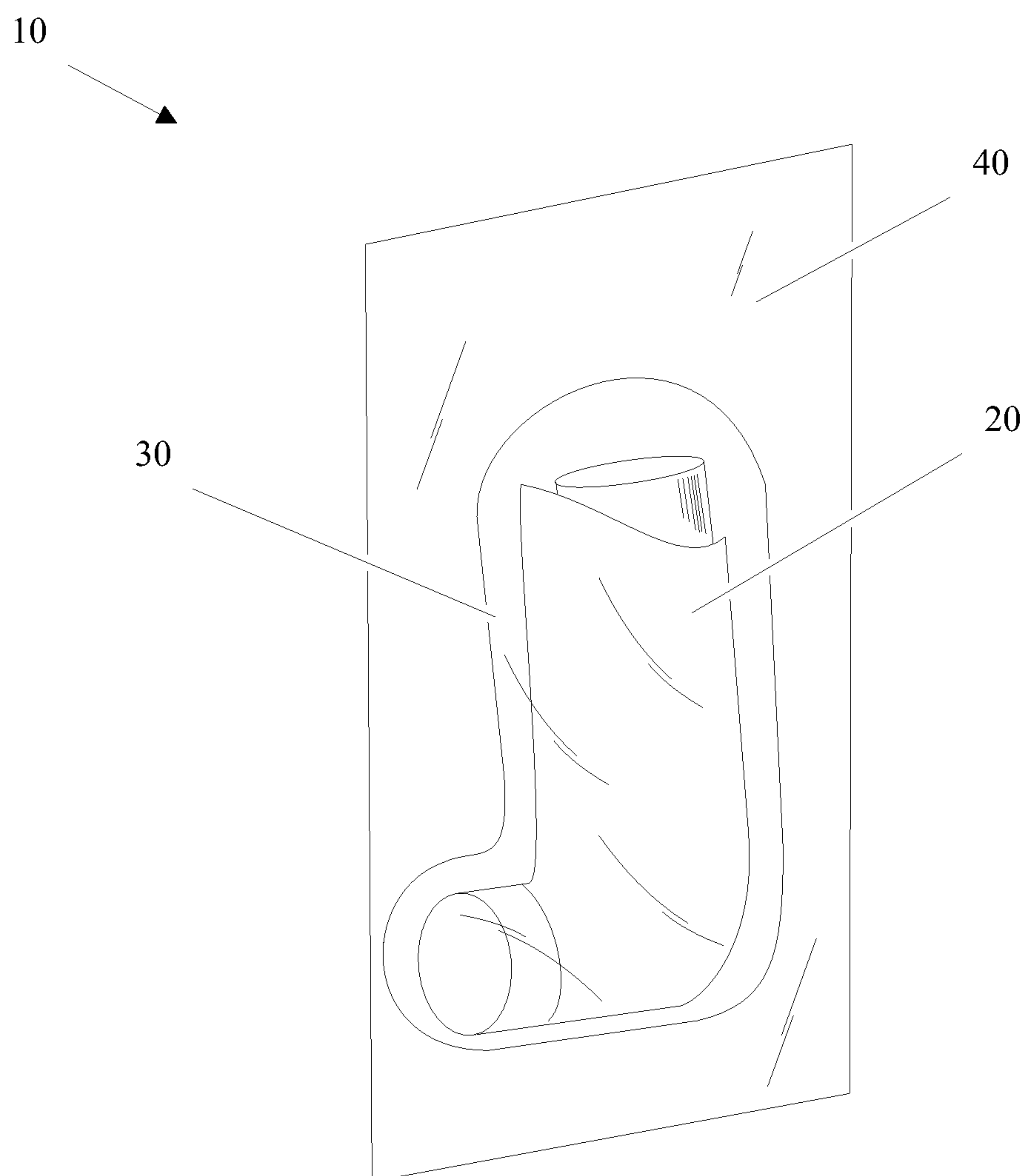


Fig. 1

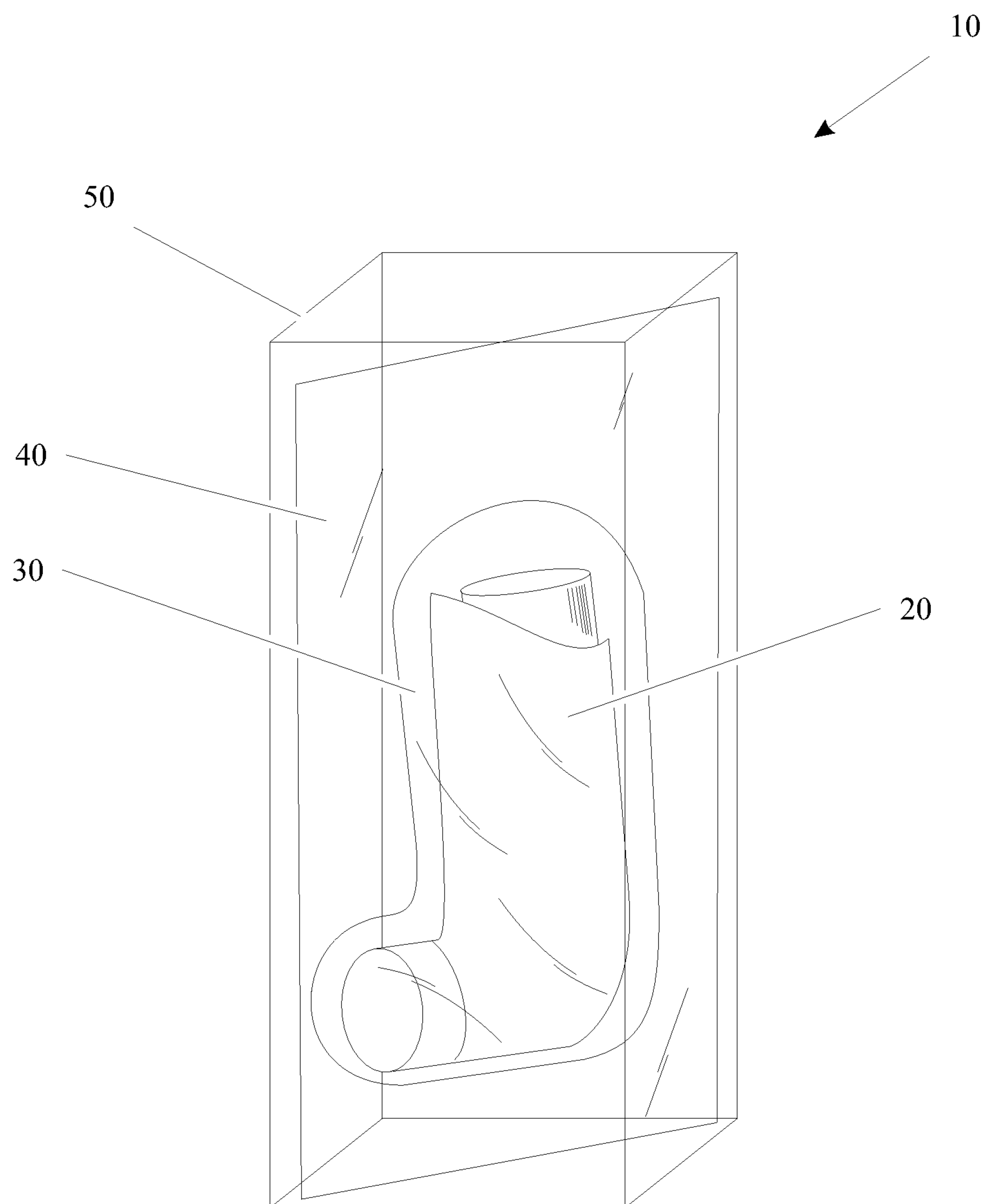


Fig. 2

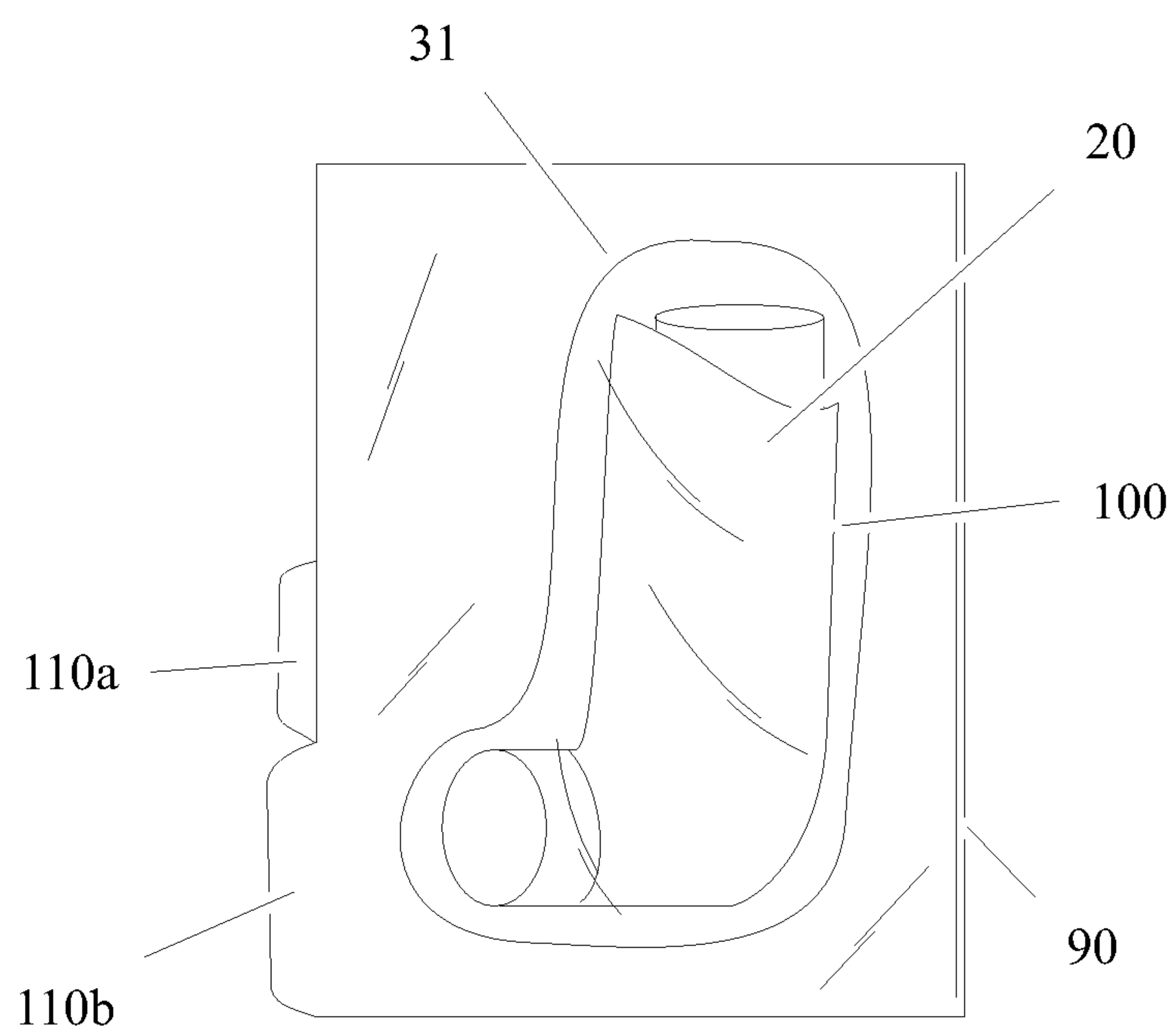


Fig. 3a

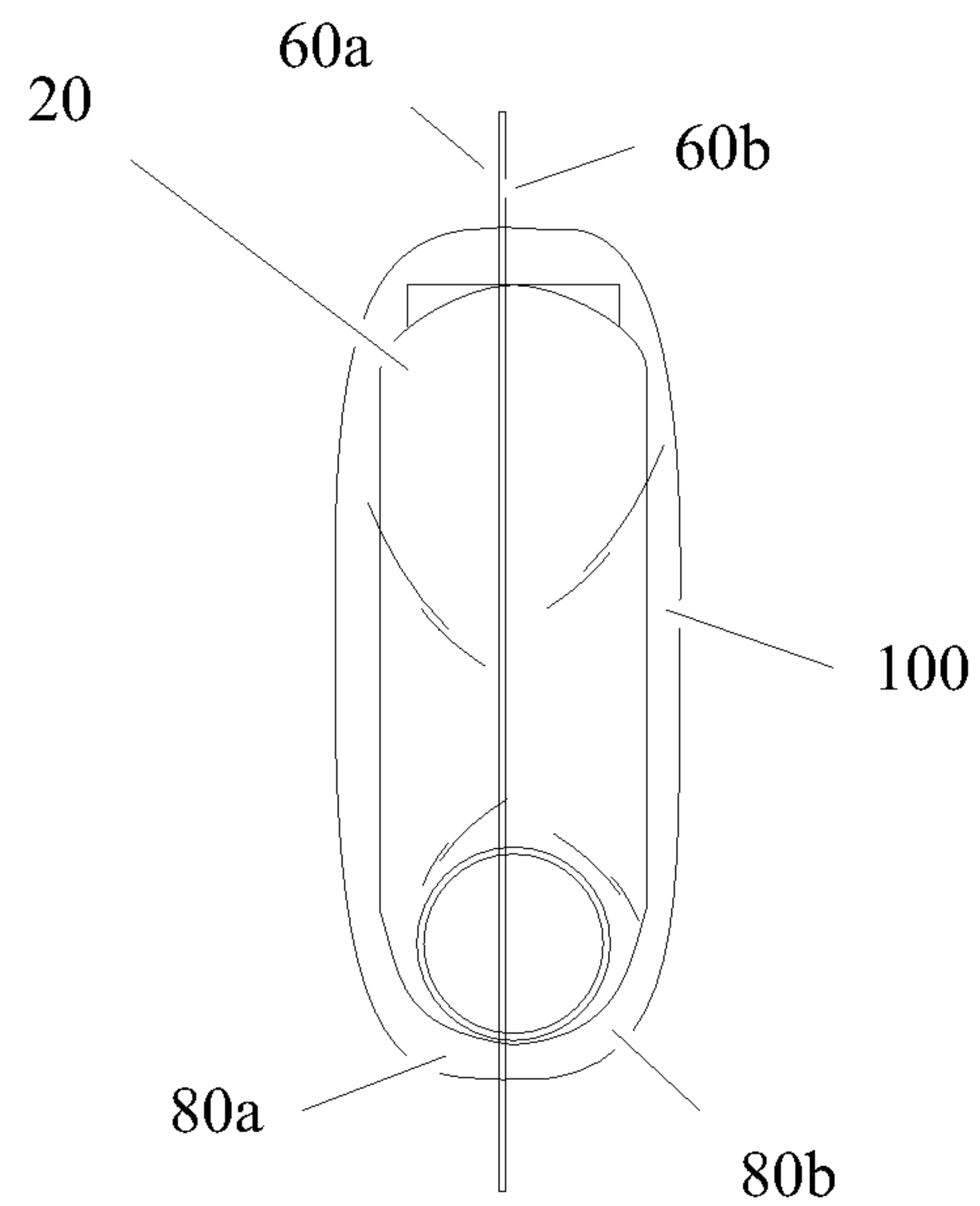


Fig. 3b

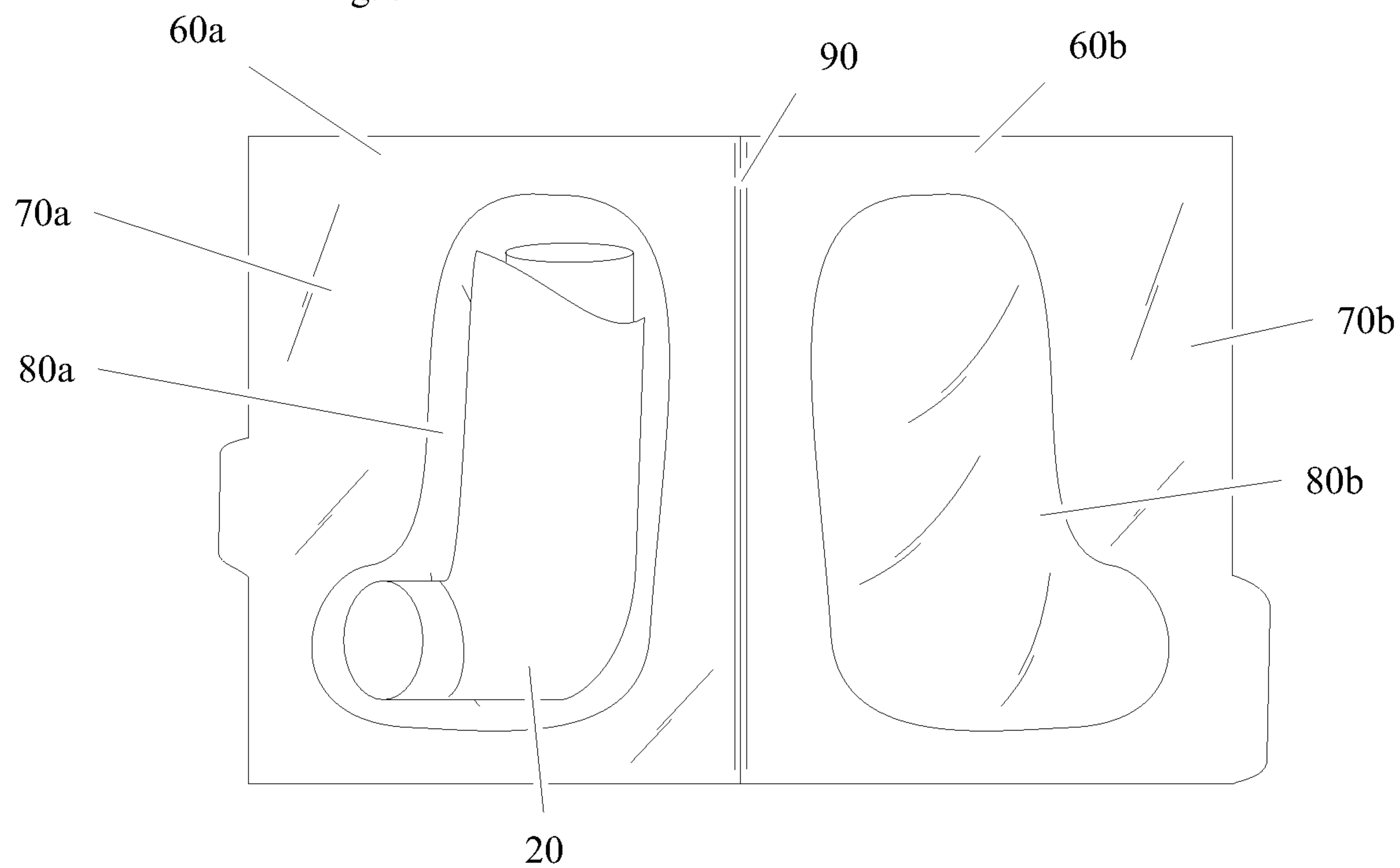


Fig. 3c

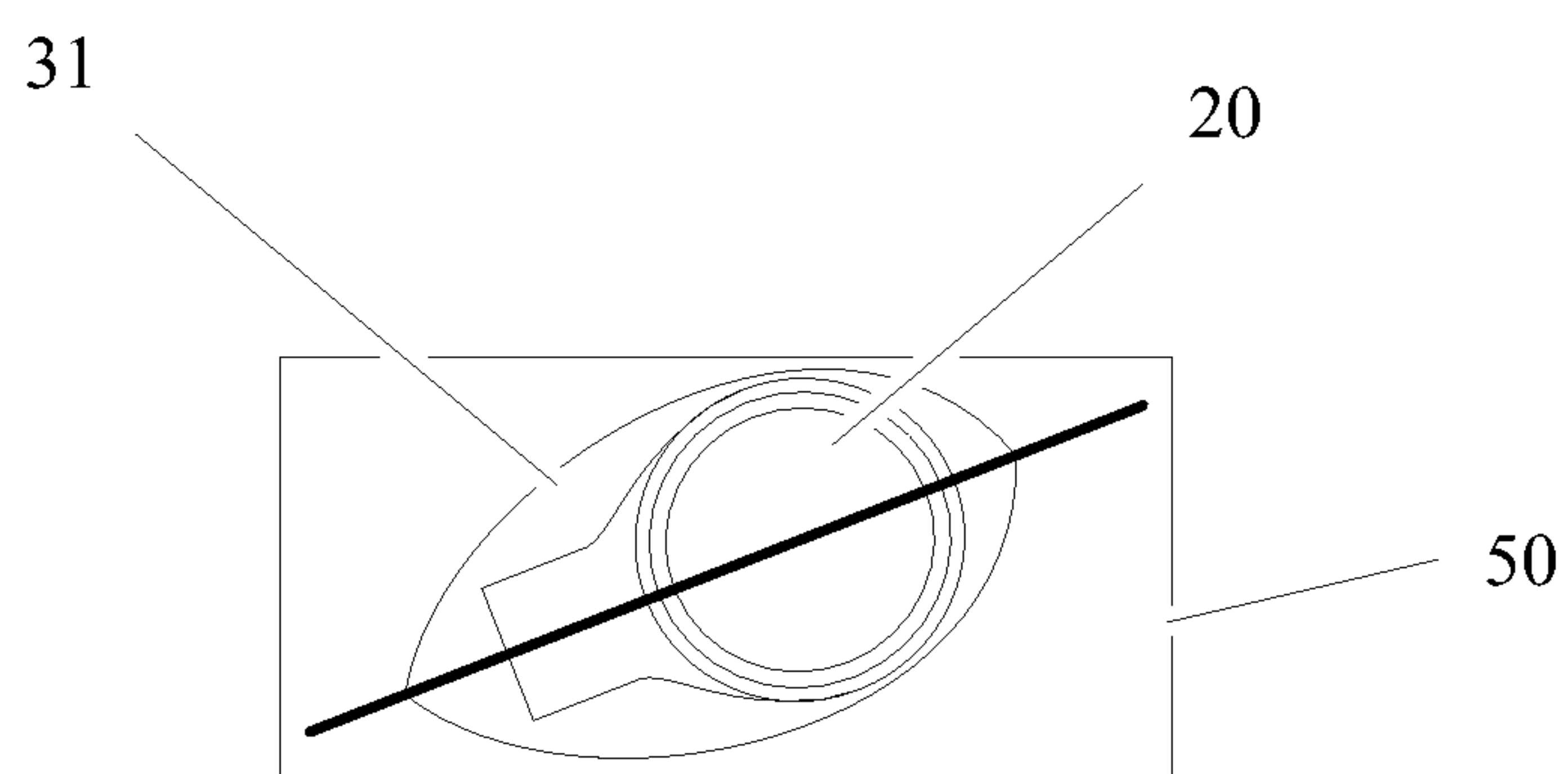


Fig. 3d

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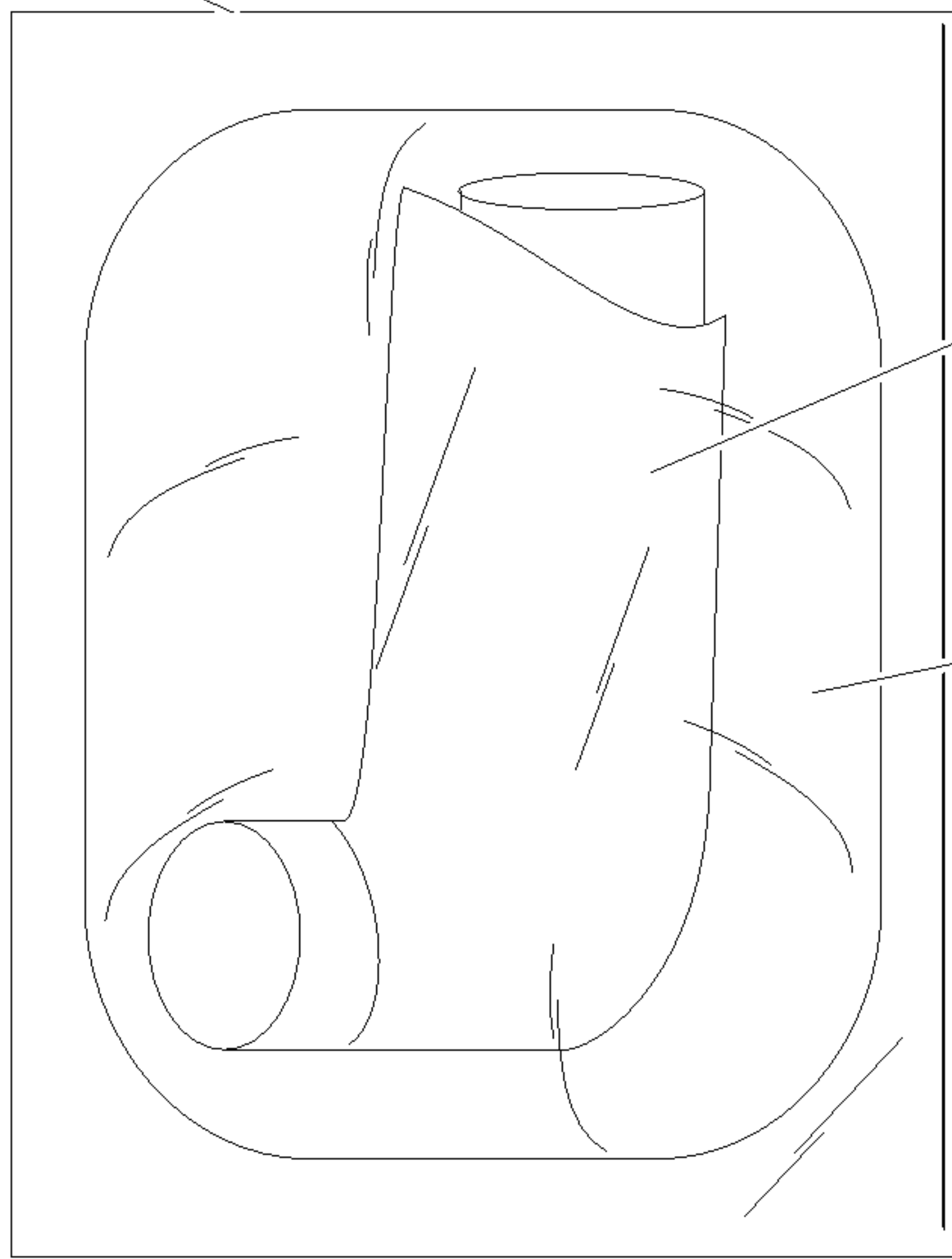


Fig. 4a

60a

60b

20

80a

80b

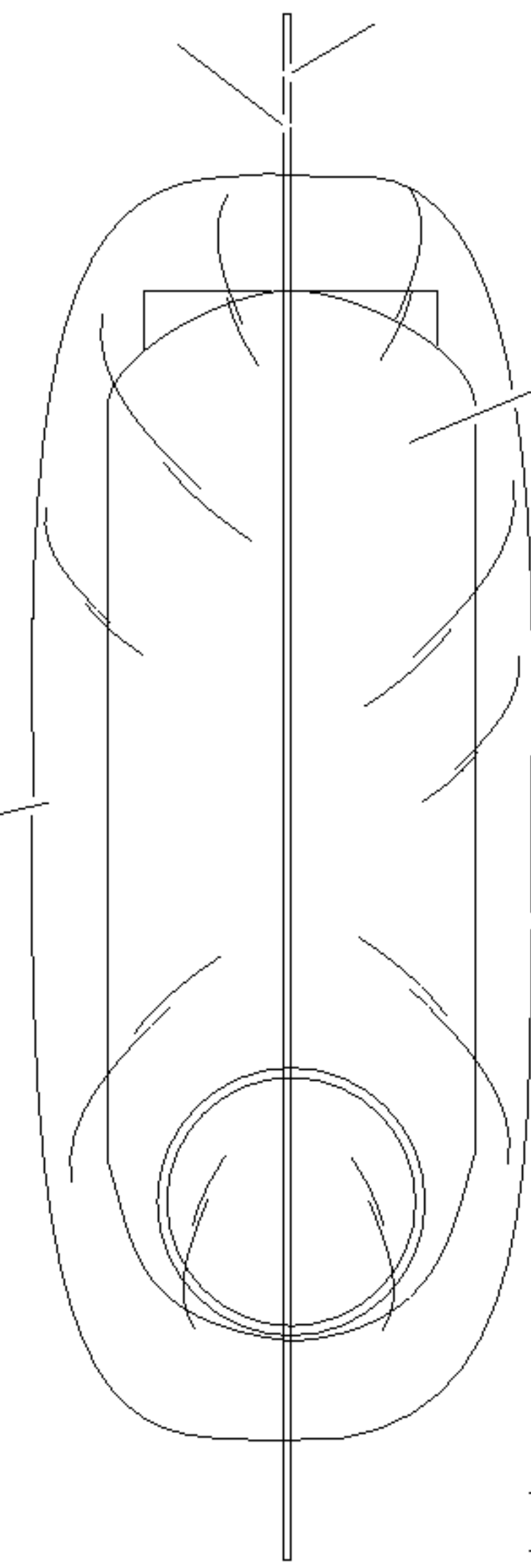


Fig. 4b

60a

80a

60b

80b

70a

70b

20

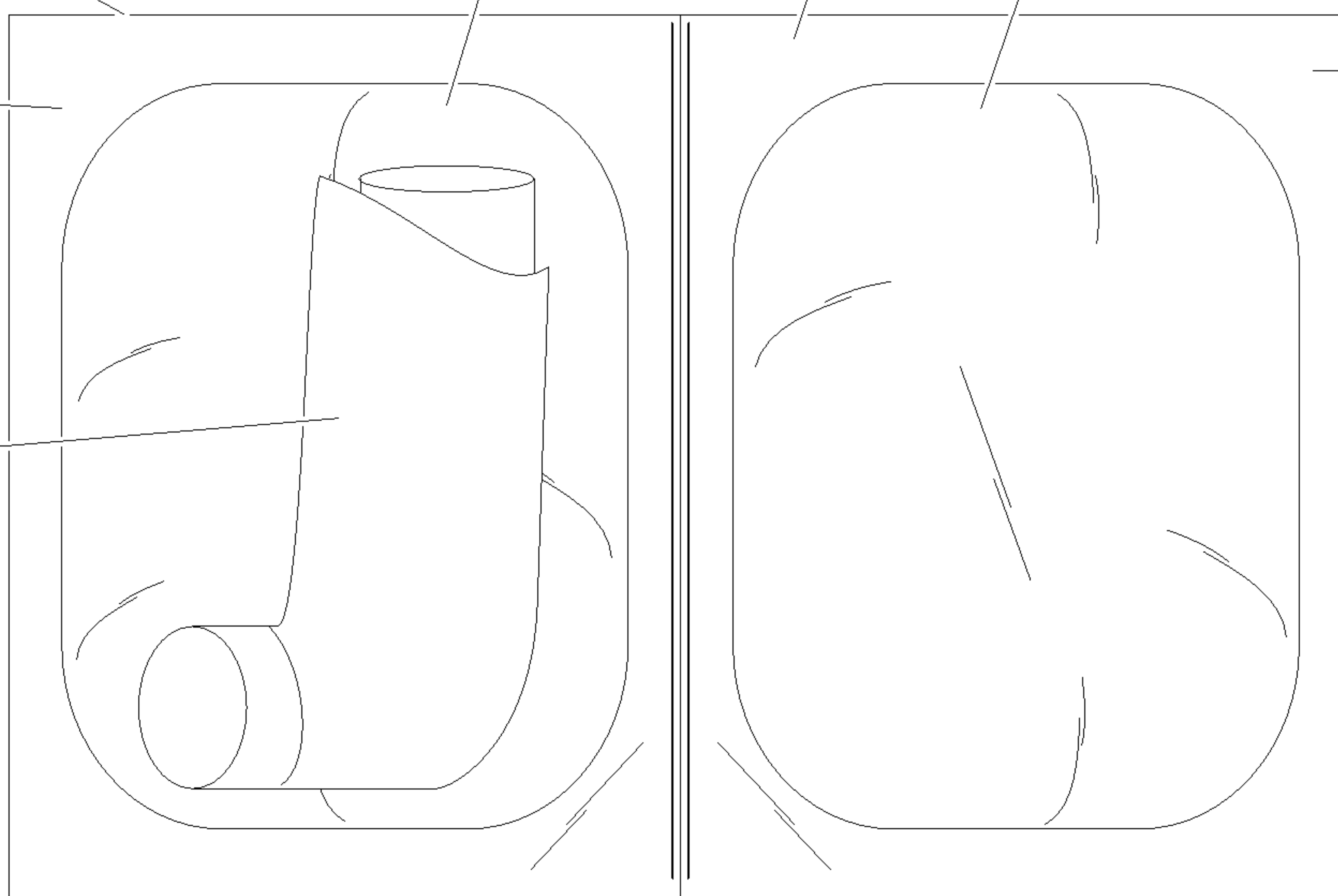


Fig. 4c

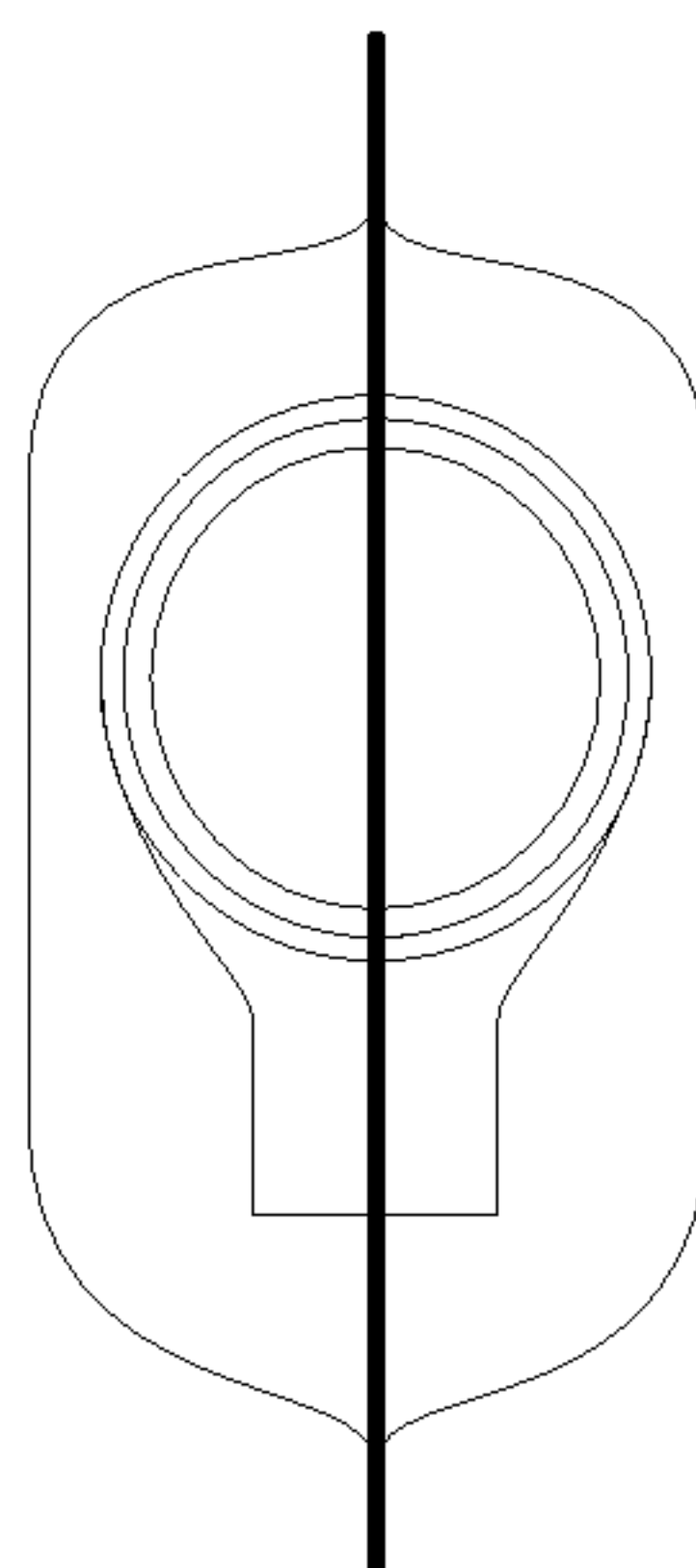


Fig. 4d

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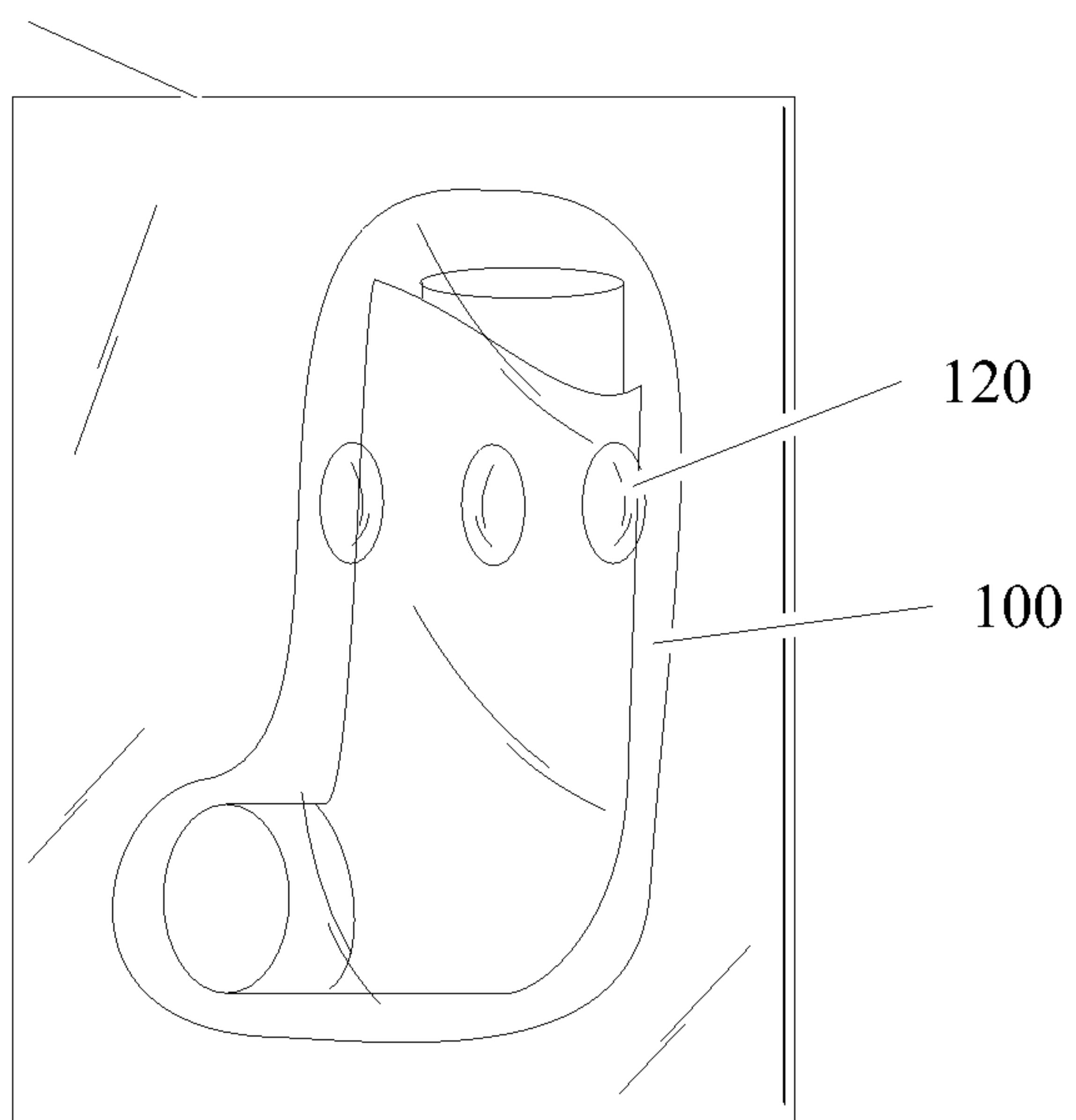


Fig. 5a

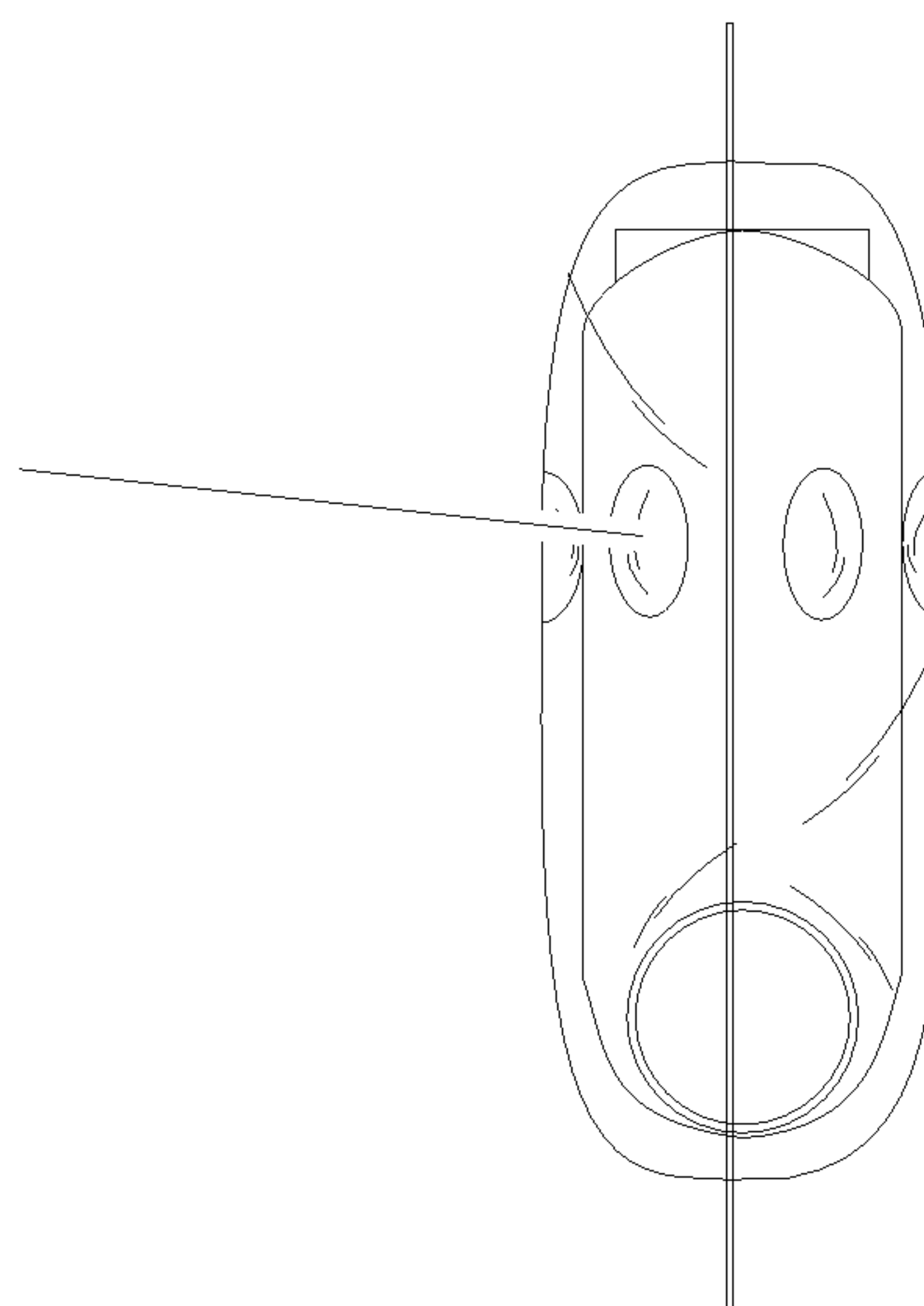


Fig. 5b

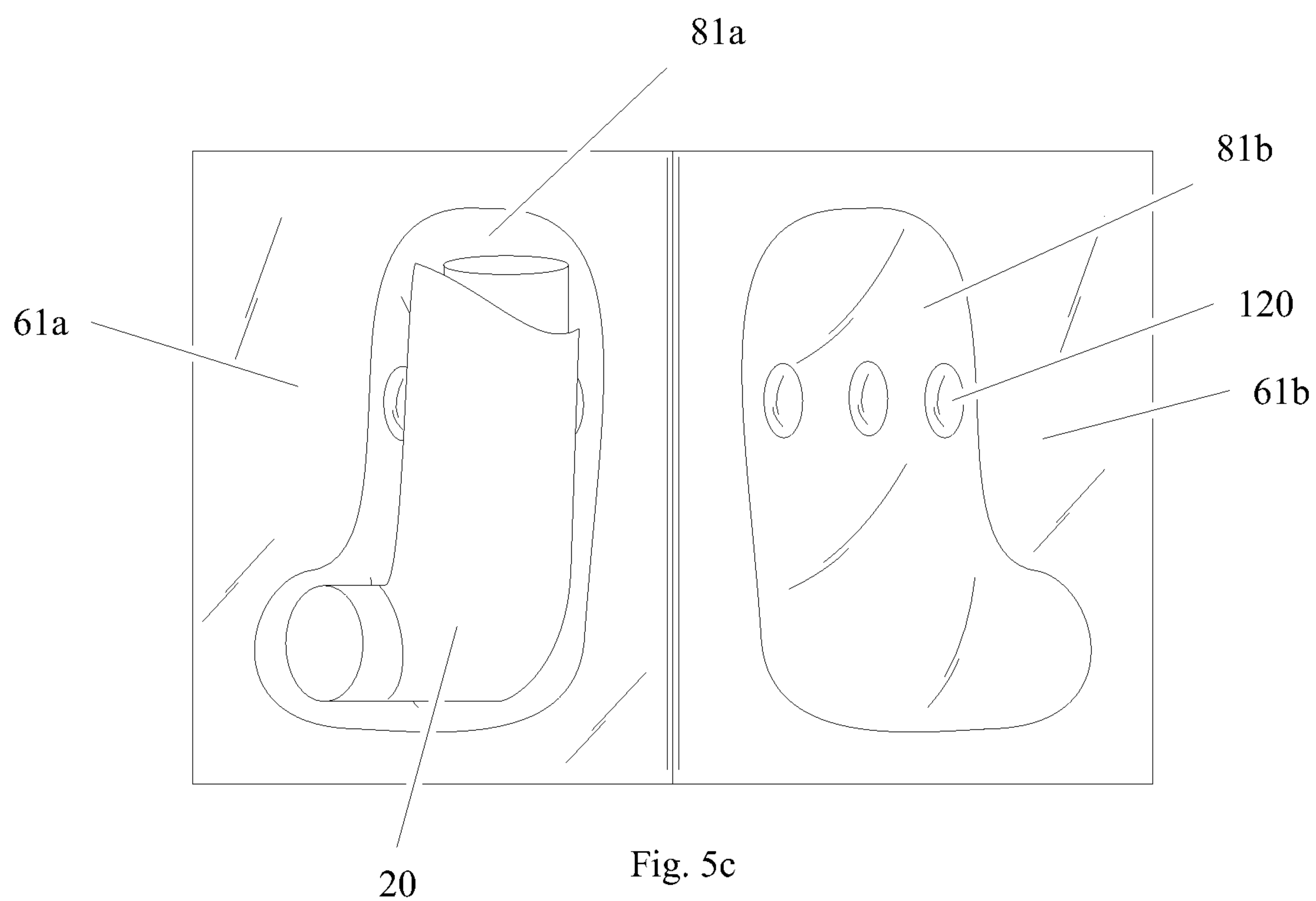


Fig. 5c

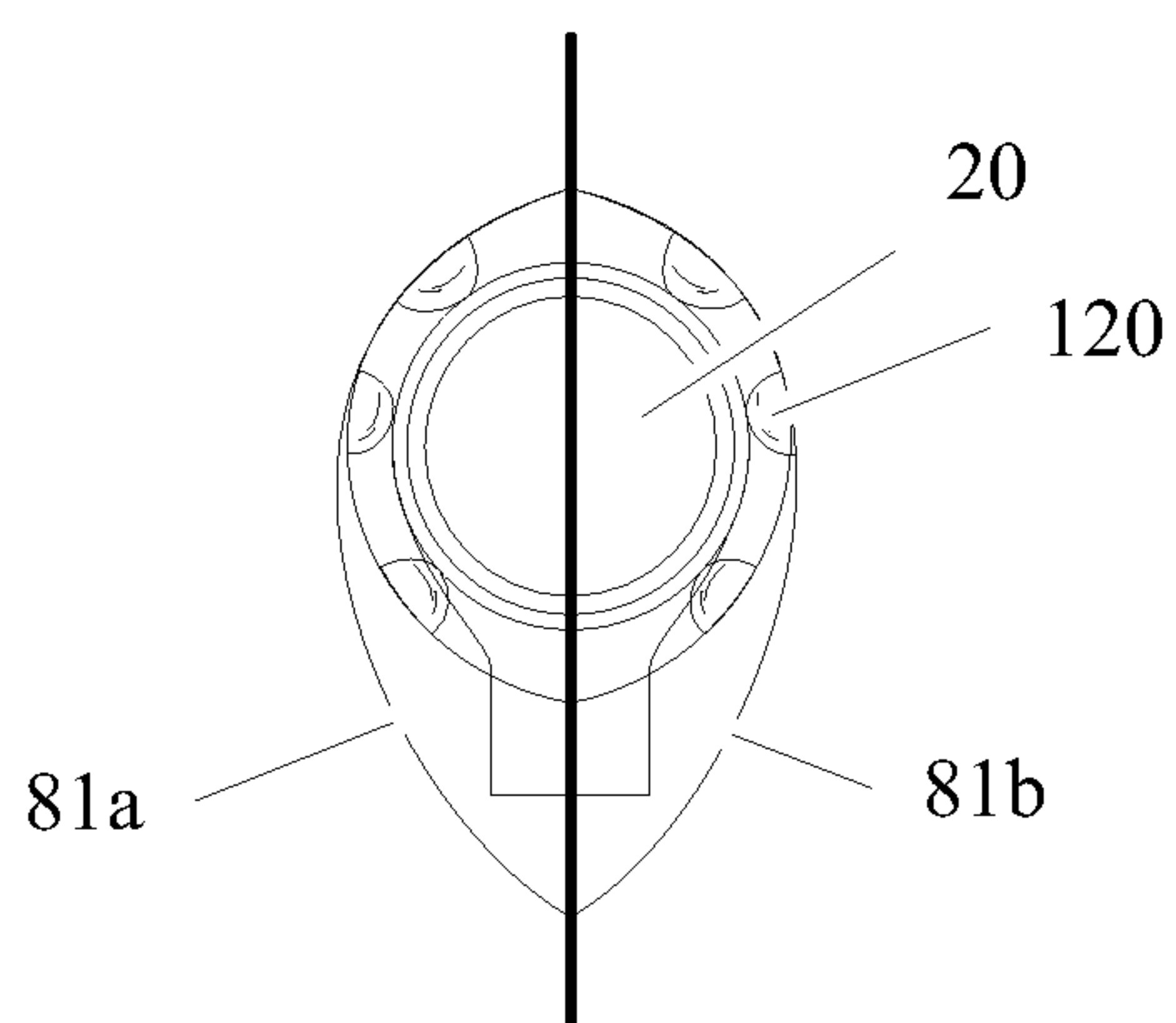


Fig. 5d

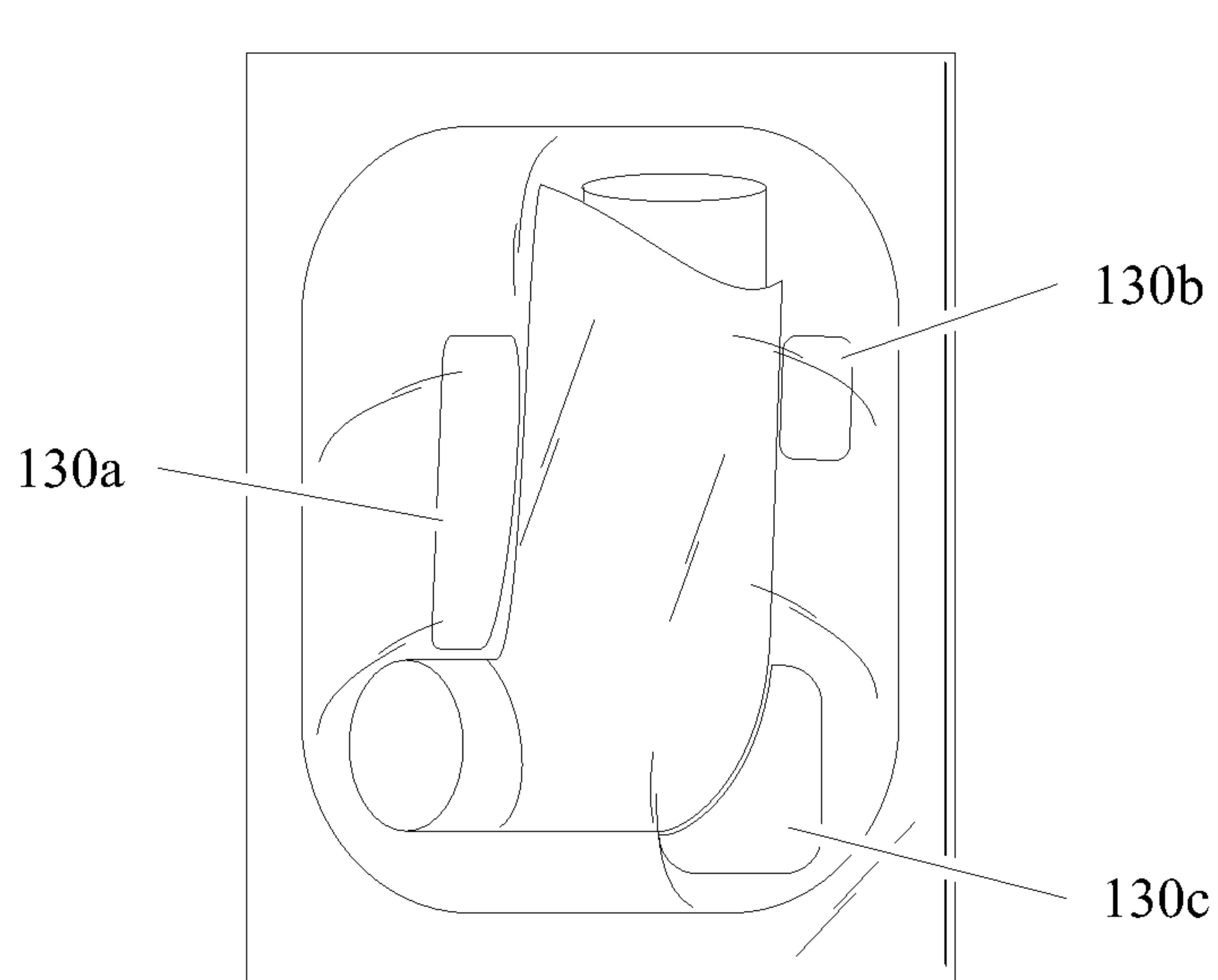


Fig. 6a

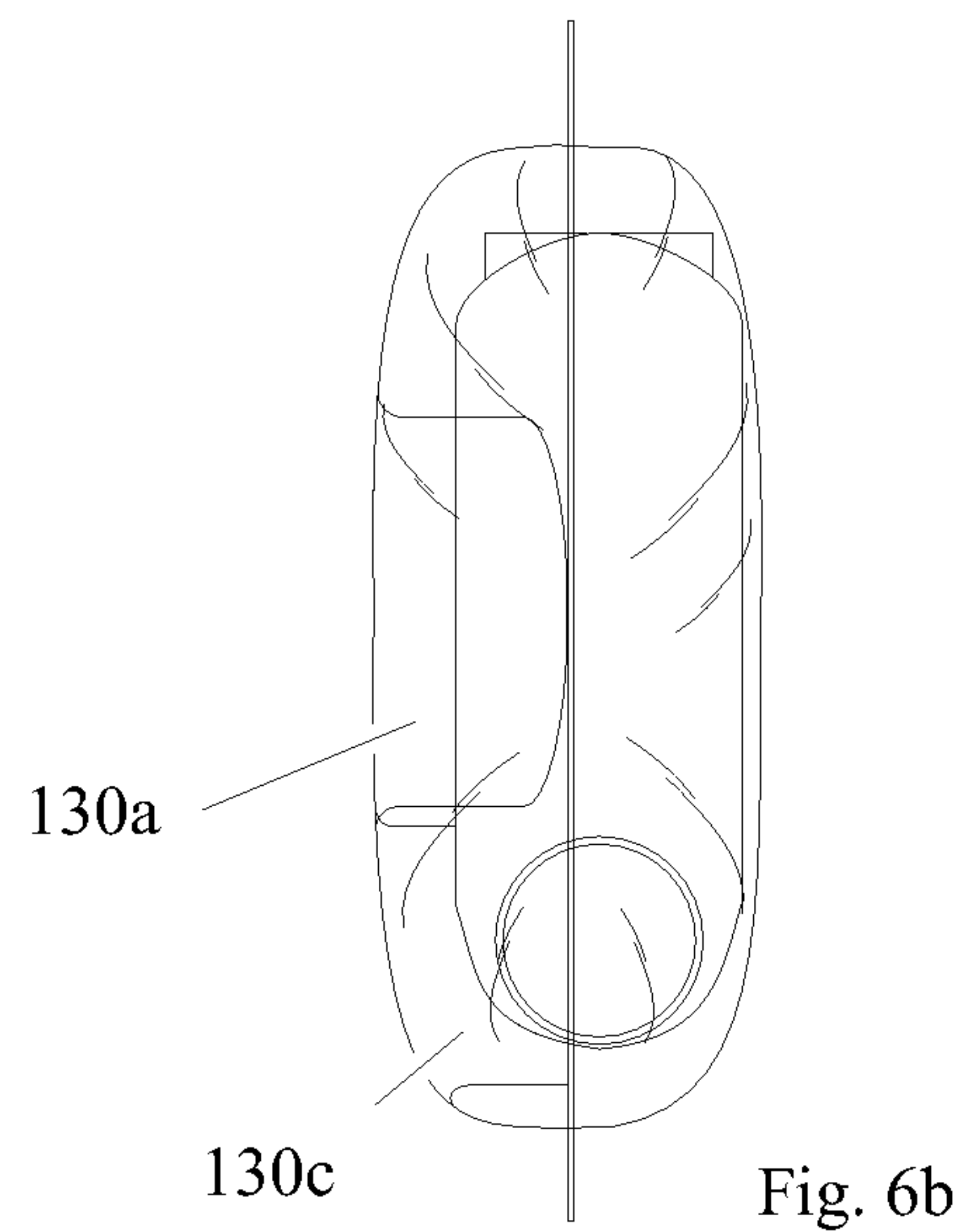


Fig. 6b

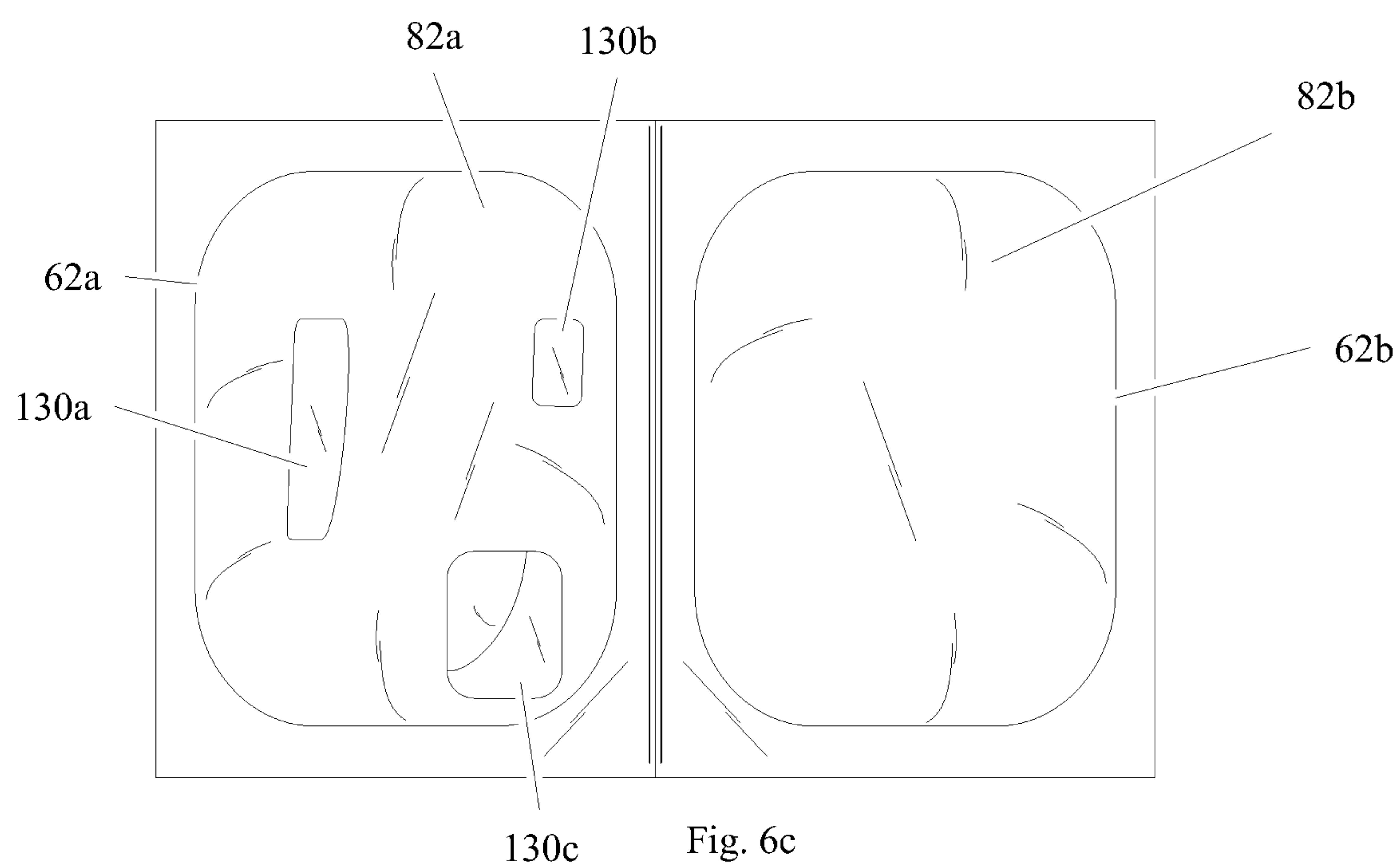


Fig. 6c

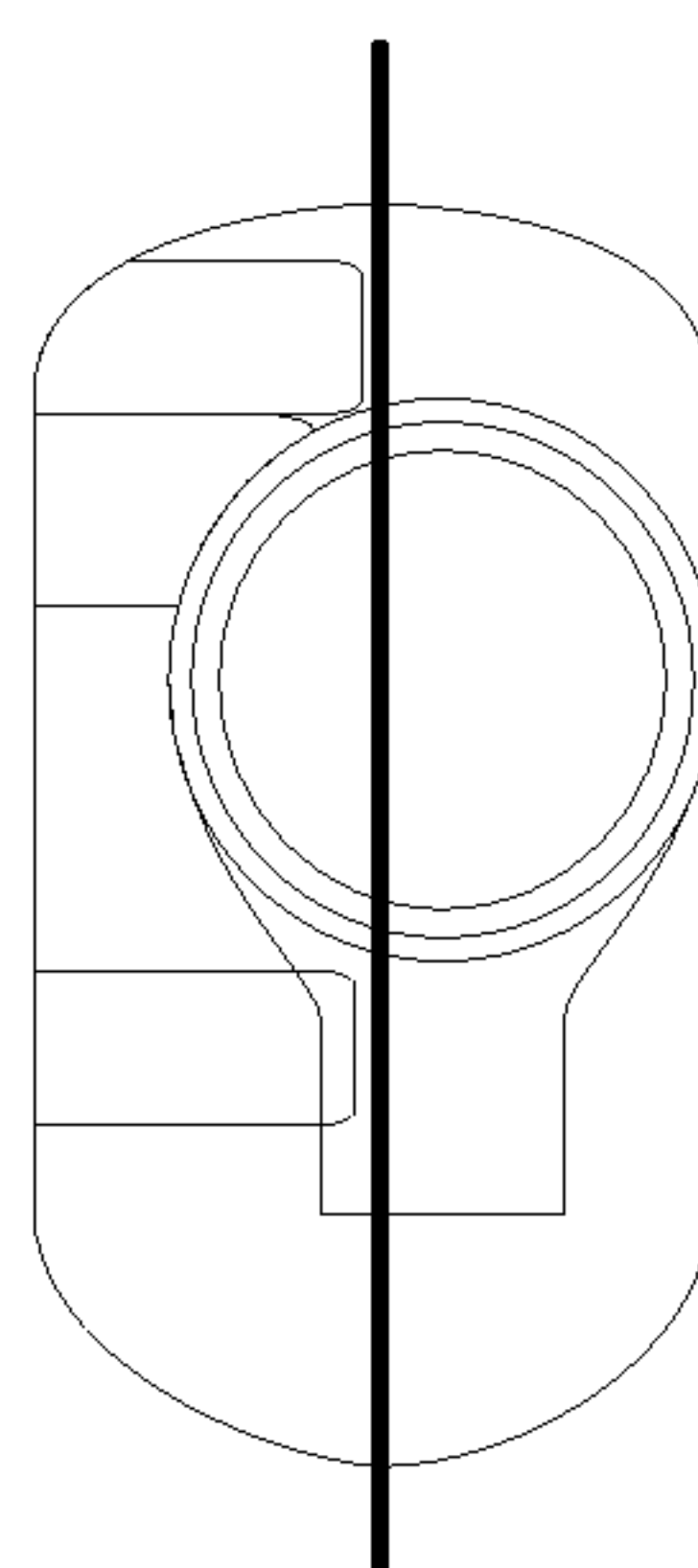


Fig. 6d

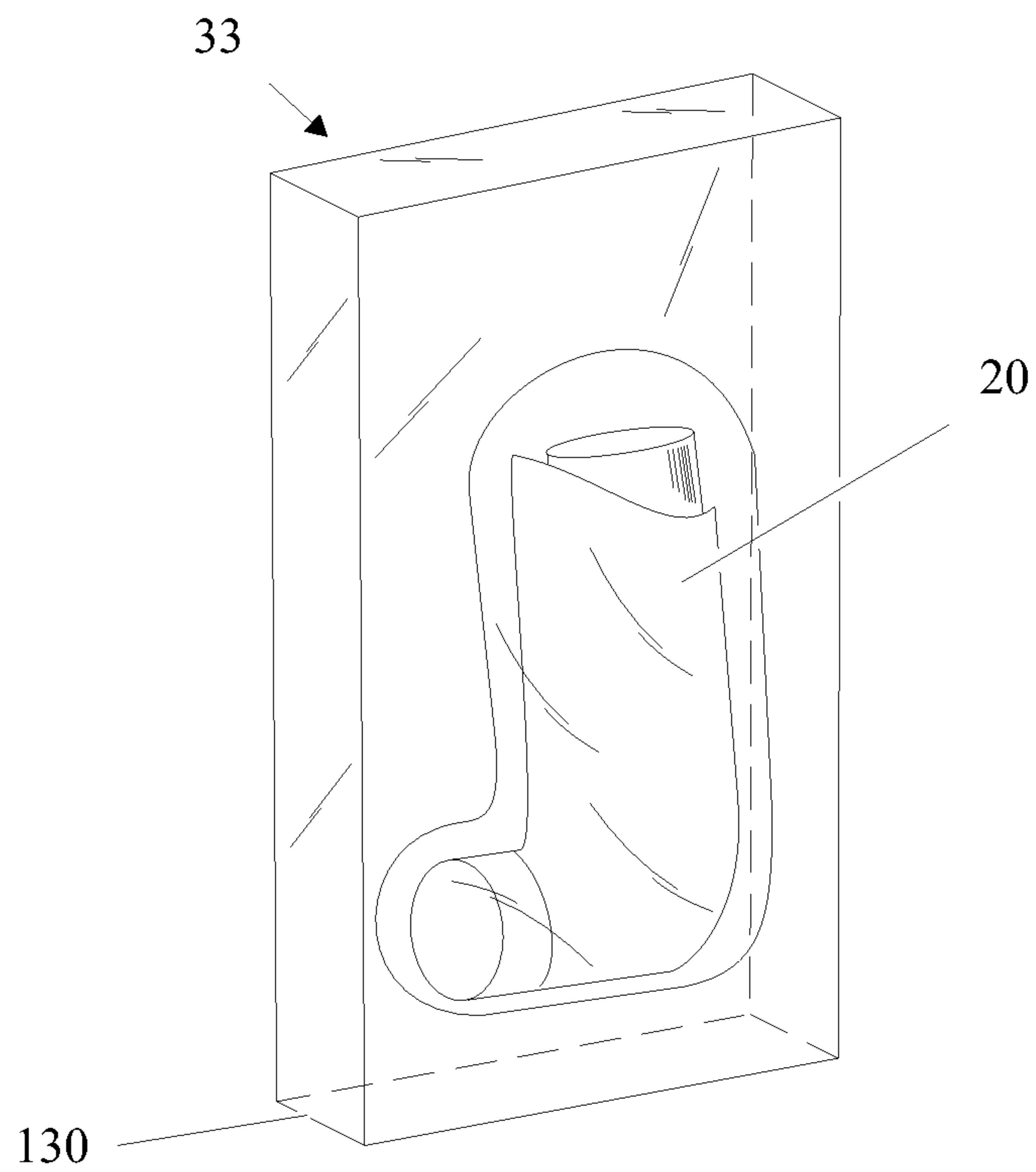


Fig. 7a

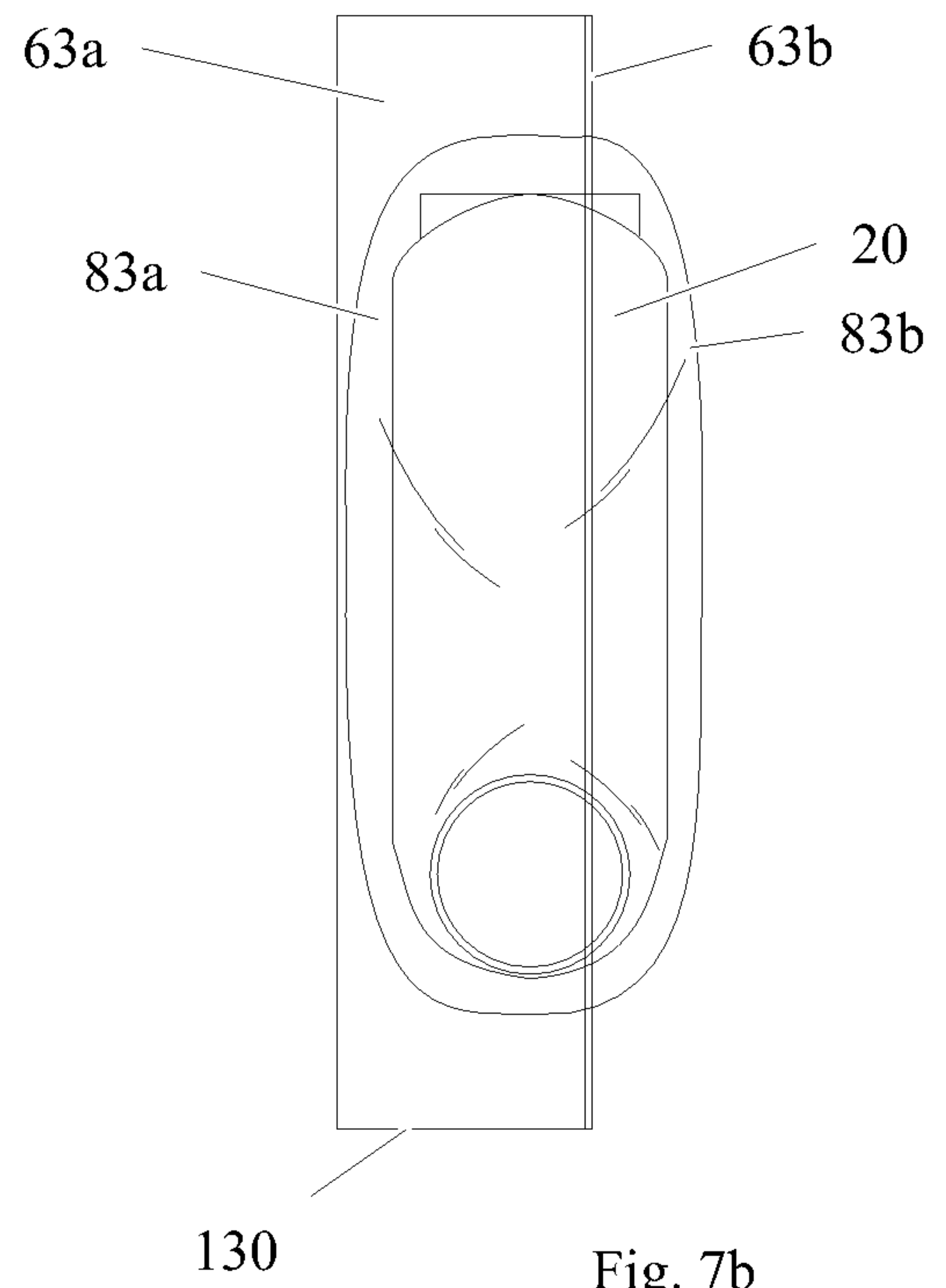


Fig. 7b

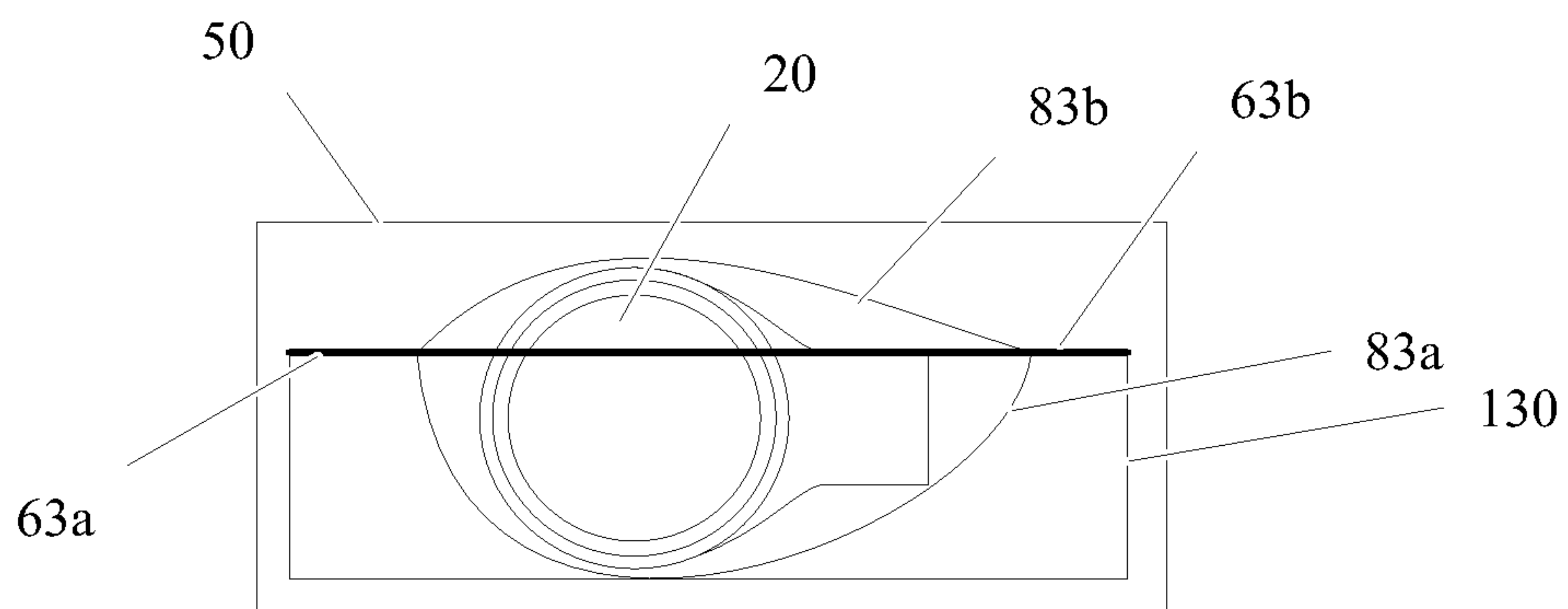


Fig. 7c

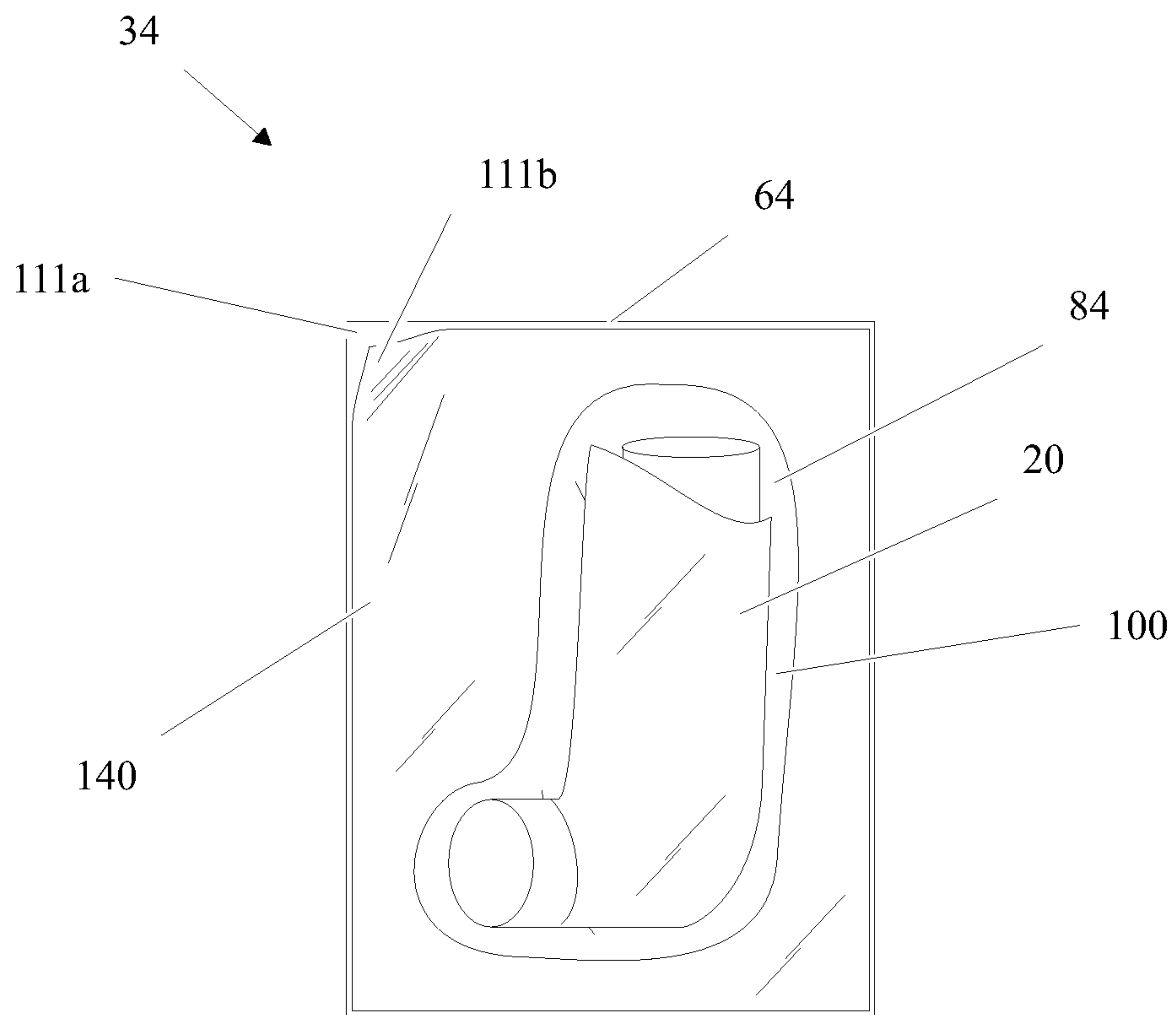


Fig. 8a

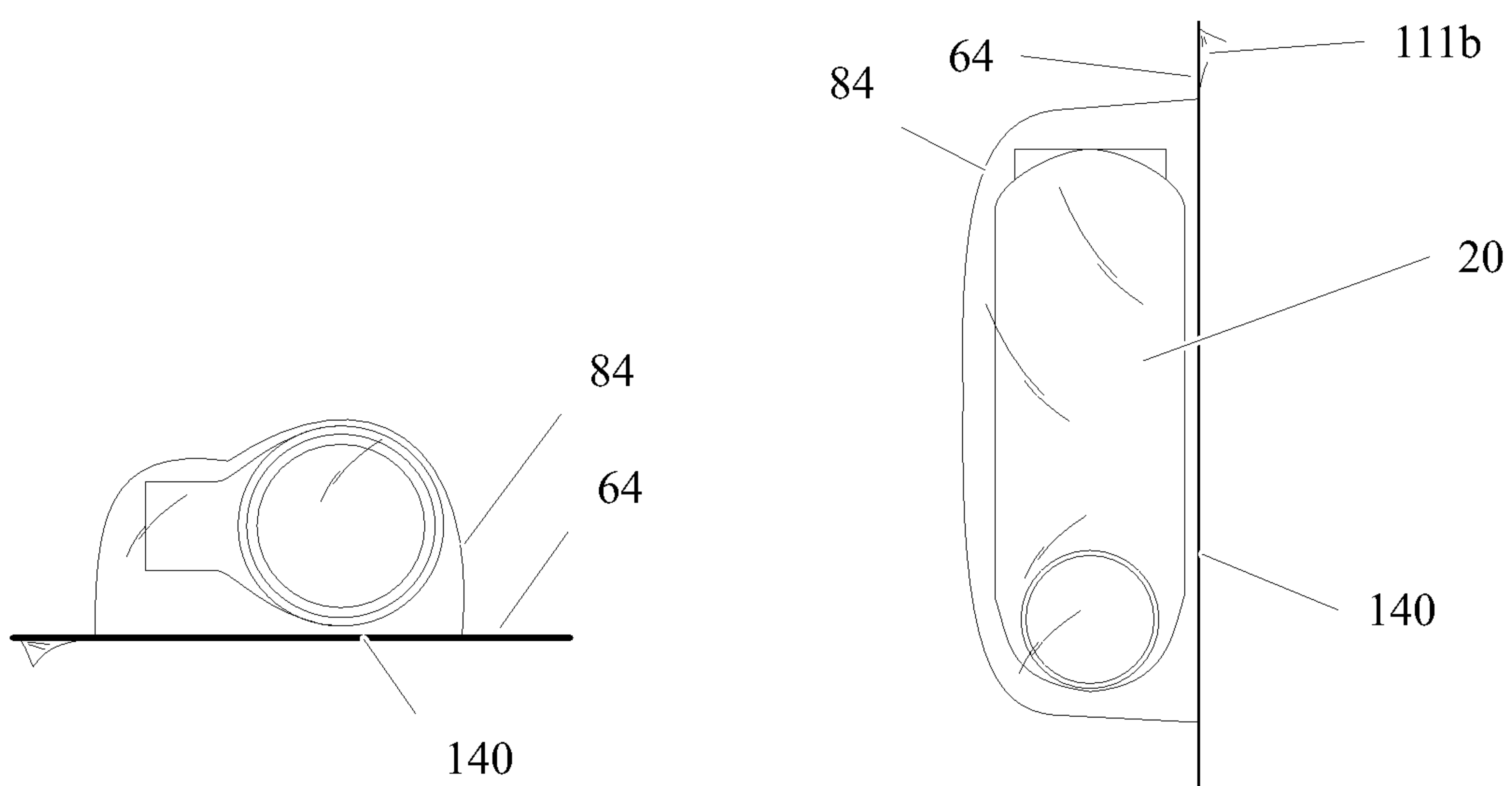


Fig. 8c

Fig. 8b

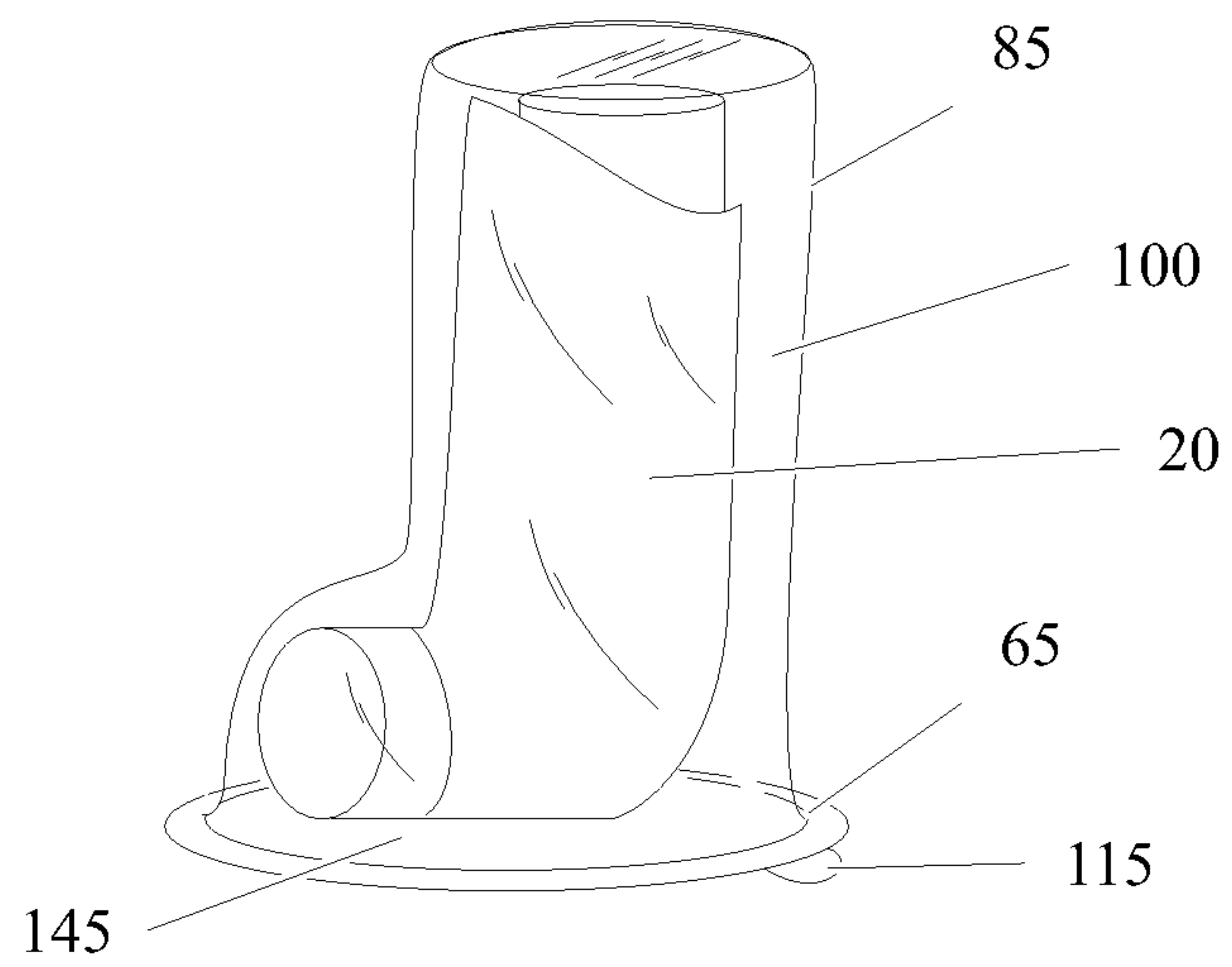


Fig. 9a

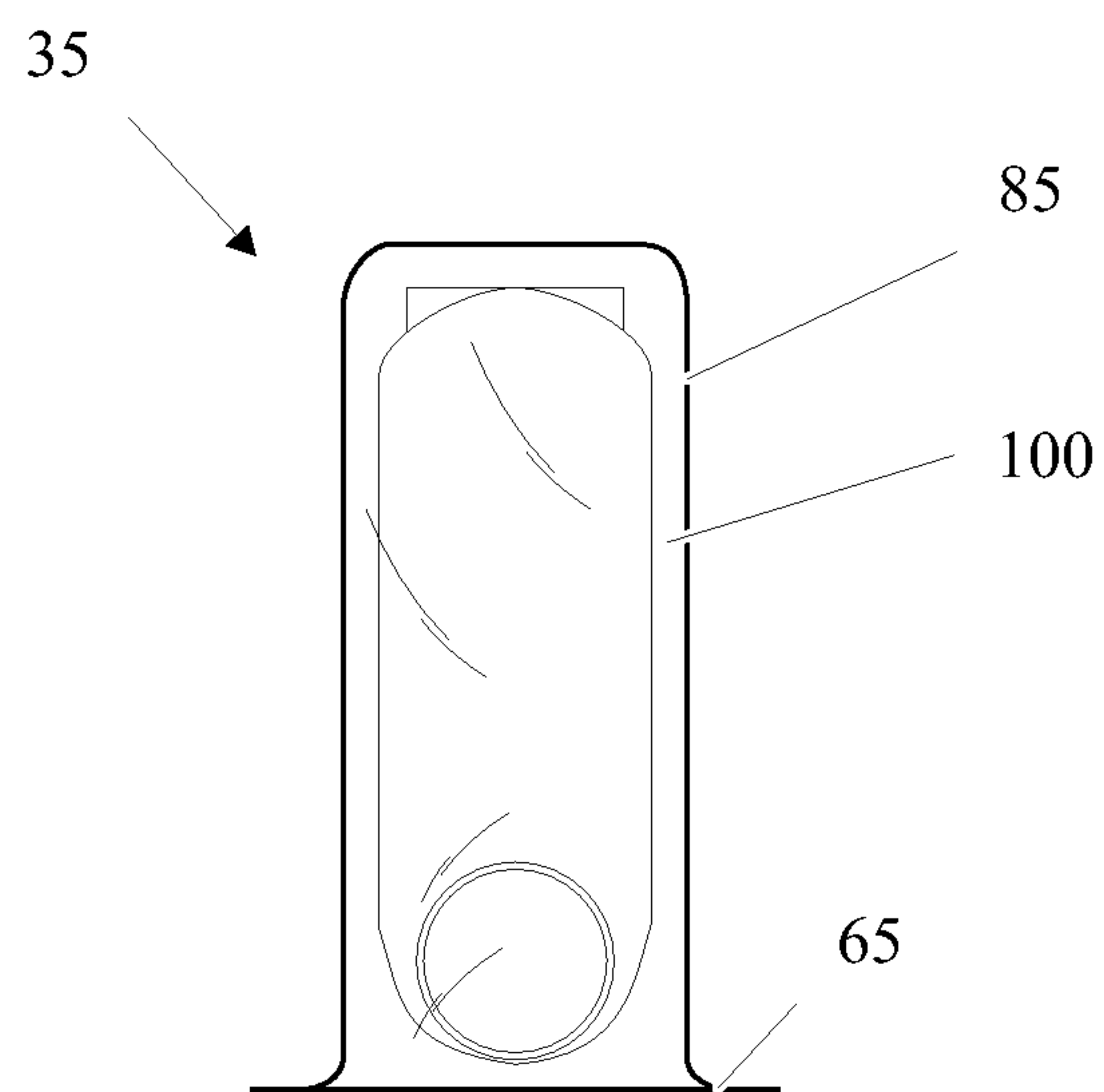


Fig. 9b

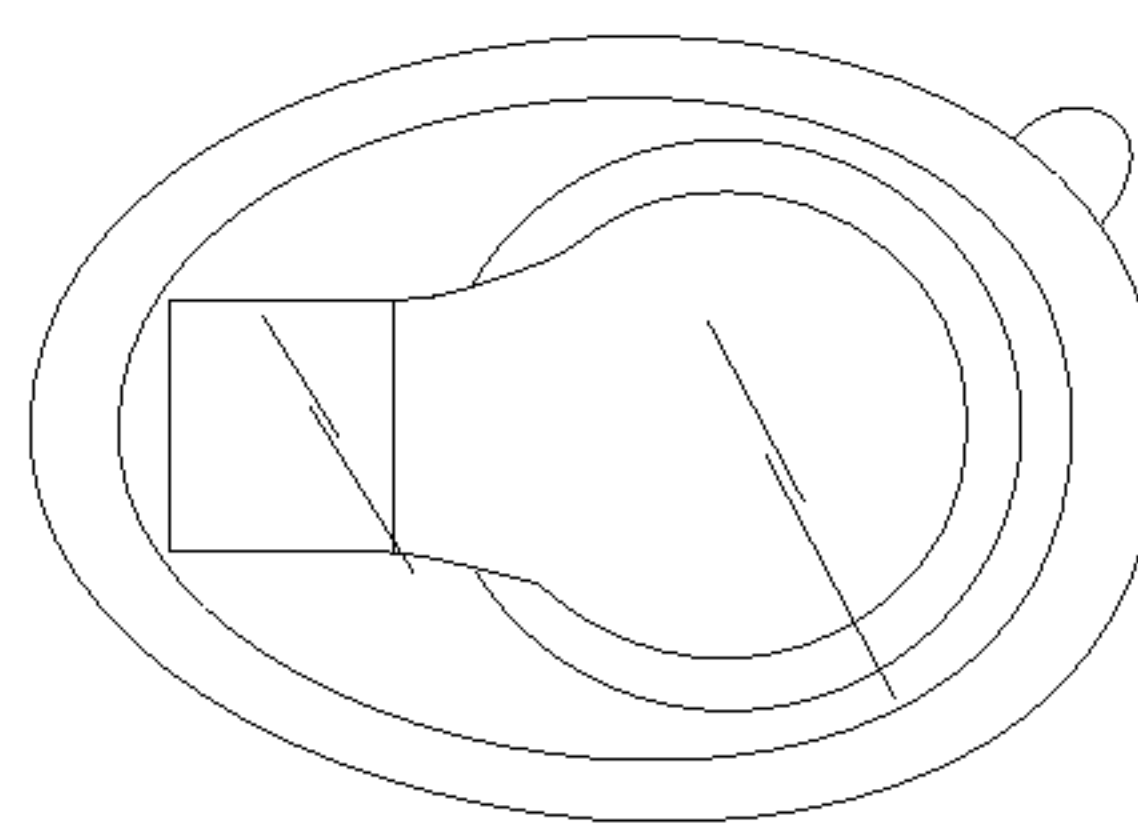


Fig. 9c

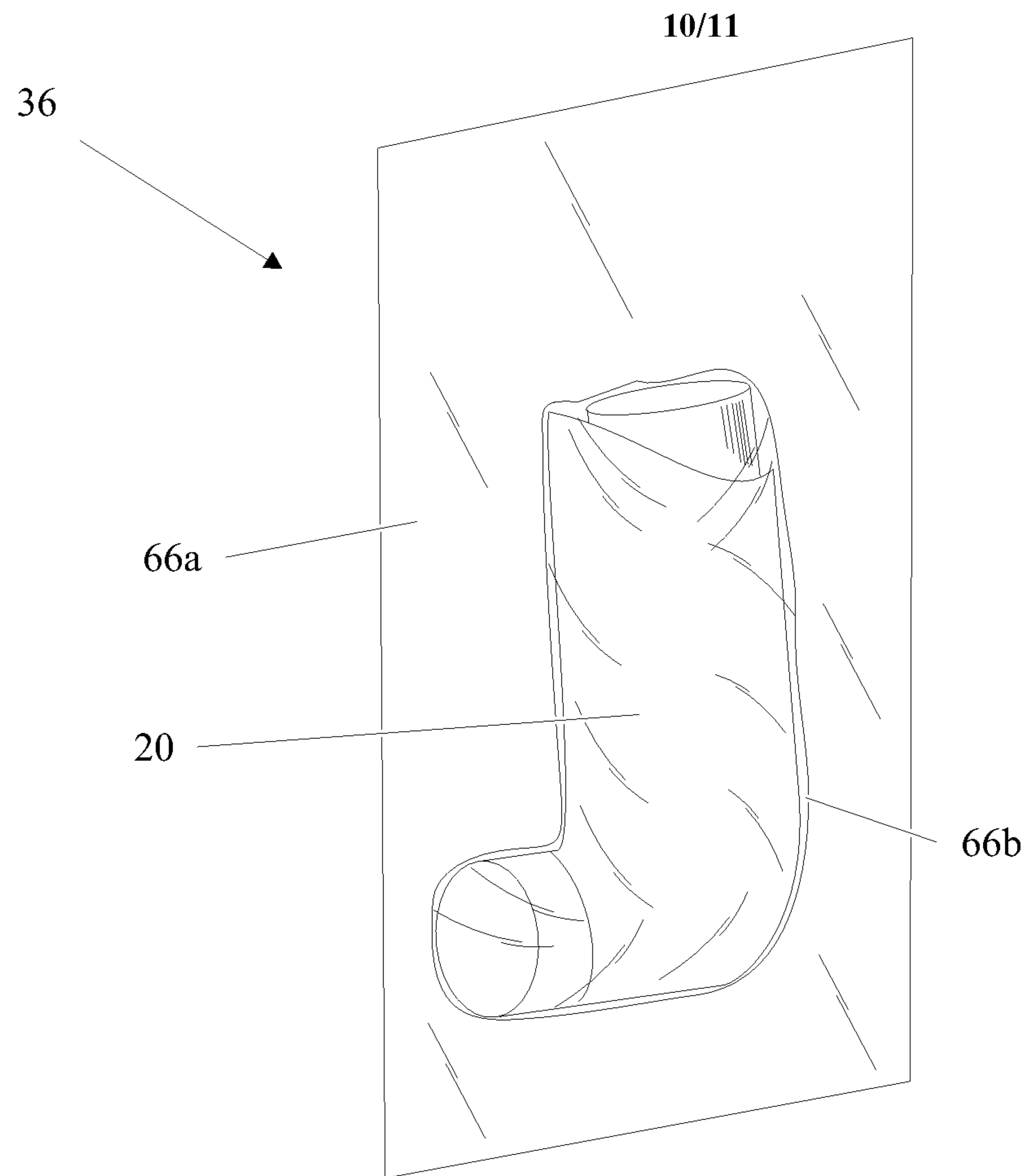


Fig. 10a

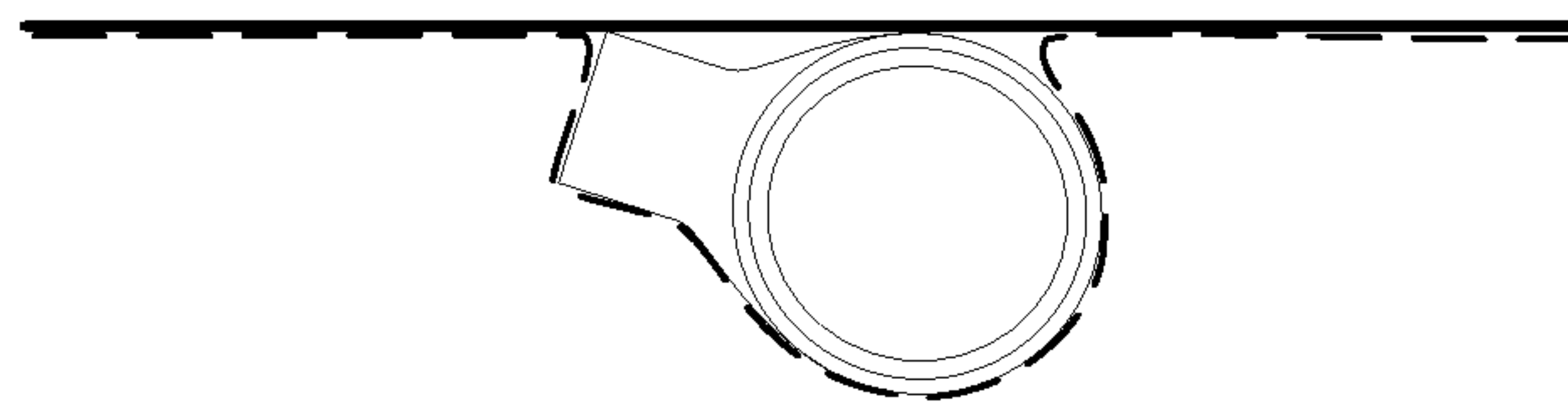


Fig. 10b

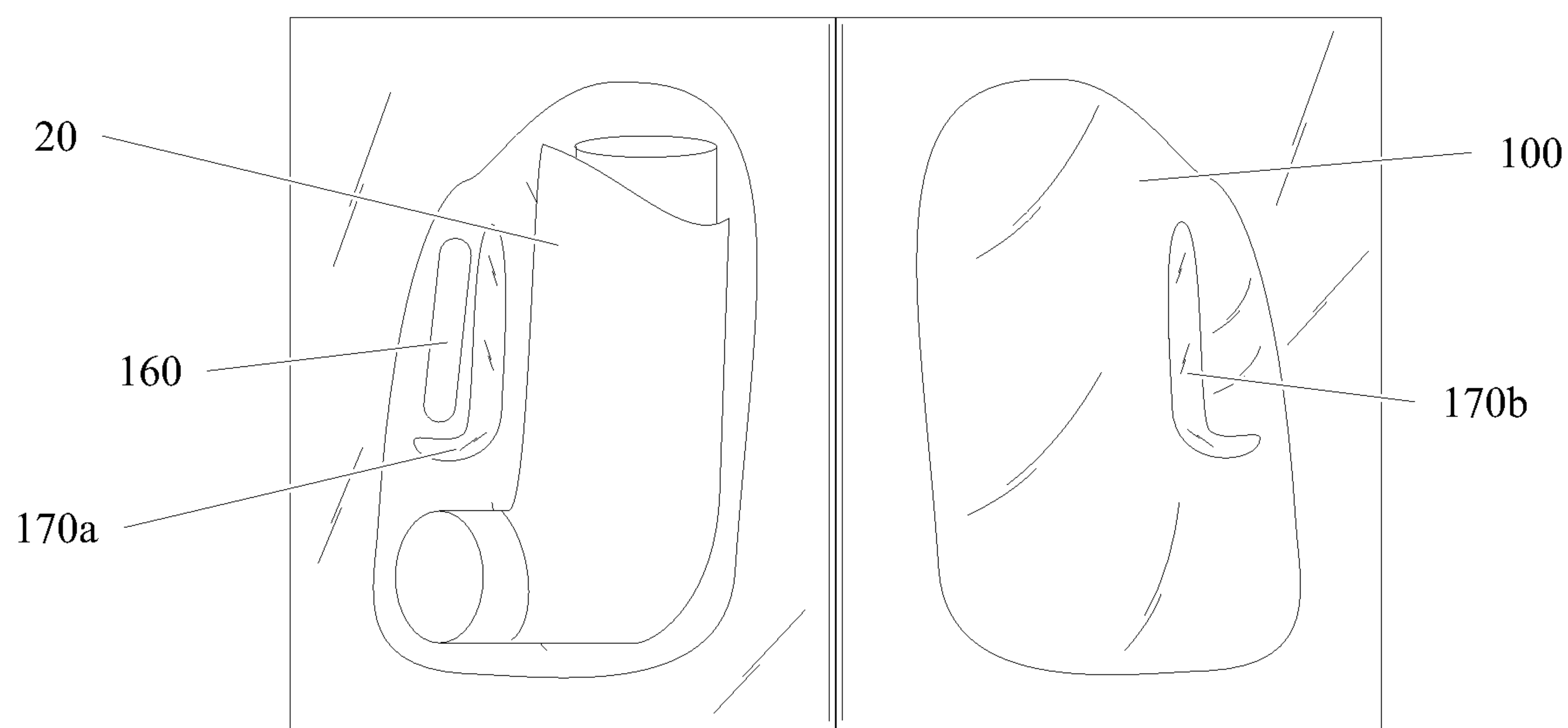


Fig. 11

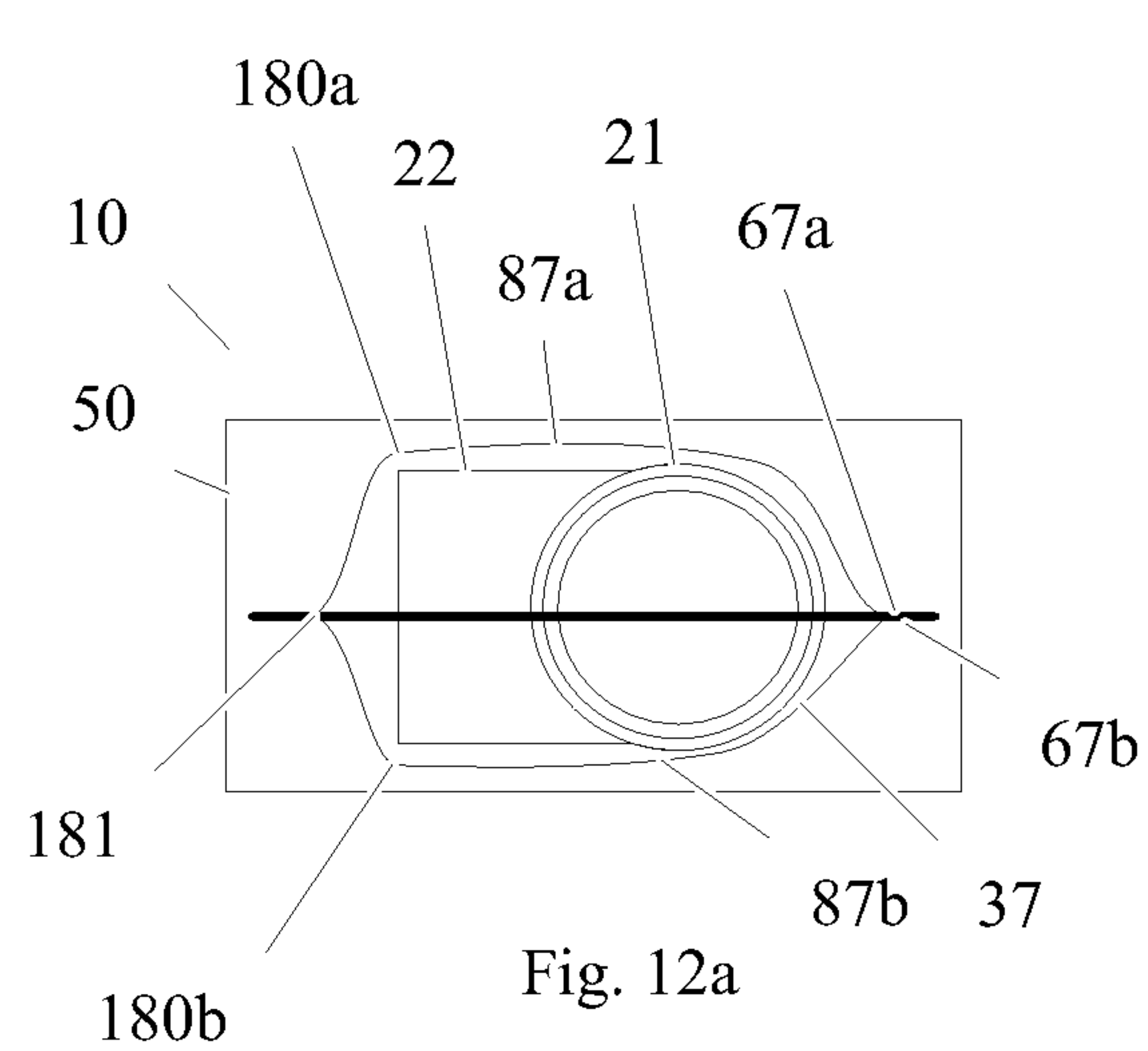


Fig. 12a

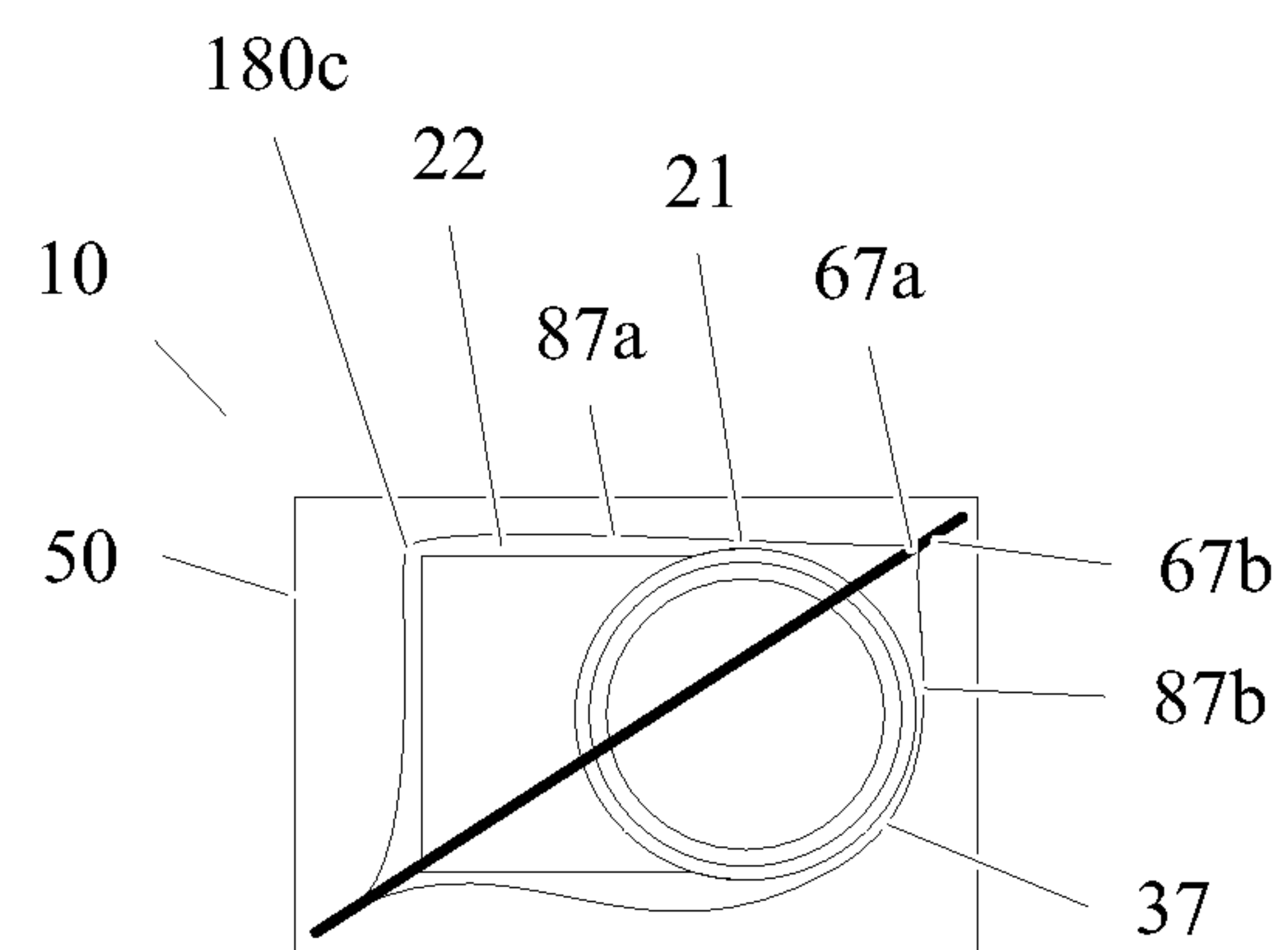
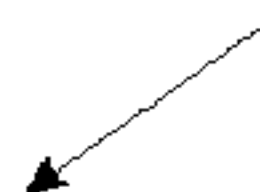
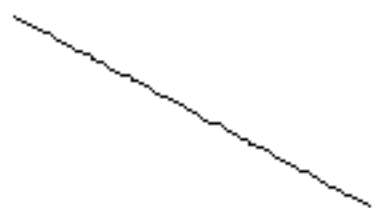


Fig. 12b

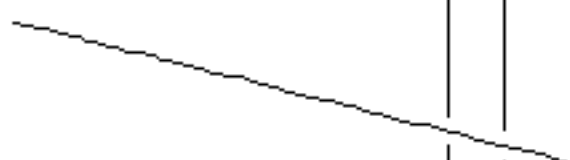
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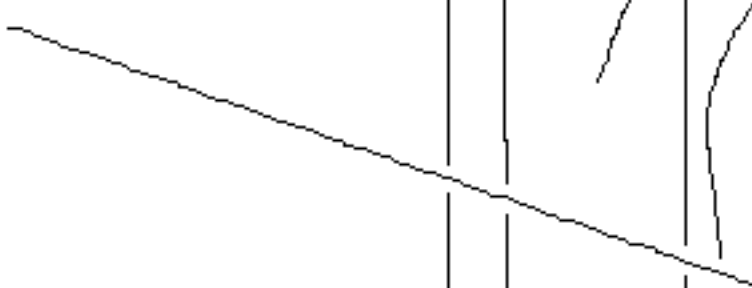
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