

AUSTRALIA
The Patents Act 1952

Trudell Case 35

618789

CONVENTION APPLICATION FOR A PATENT

WE, TRUDELL PARTNERSHIP HOLDING LIMITED, a corporation of the Province of Ontario, Canada, of 926 Leathorne Street, London, Ontario, Canada, N5Z 3M5, and PACKARD MEDICAL SUPPLY LIMITED, a corporation of the Province of Ontario, Canada, of 1220-36th Street North, Leathbridge, Alberta, Canada T1H 5H8, hereby apply for the grant of a Patent for an invention entitled:

"IMPROVED PEDIATRIC ASTHMATIC INHALER"

which is described in the accompanying complete specification.

This application is a Convention application and is based on the Application Numbered 07/164,230 for a patent or similar protection made in United States of America on 19th May, 1988.

Our address for service is: CALLINANS, Patent and Trade Mark Attorneys, of 48-50 Bridge Road, Richmond 3121, Victoria, Australia.

DATED this 27th day of February, 1989.

MO06965 28/02/89

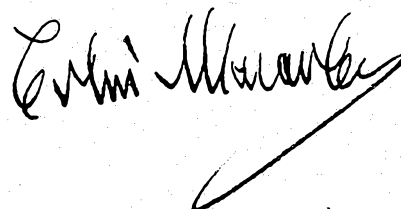
TRUDELL PARTNERSHIP HOLDING LIMITED

and PACKARD MEDICAL SUPPLY LIMITED

By their Patent Attorneys:

CALLINANS

To: The Commissioner of Patents.



COMMONWEALTH OF AUSTRALIA
The Patent Act 1952

DECLARATION IN SUPPORT OF AN APPLICATION FOR A PATENT

In support of the Convention Application made for a patent for an invention entitled:
IMPROVED PEDIATRIC ASTHMATIC INHALER

~~XXX~~, **...I... MITCHELL A. BARAN**.....
of, TRUDELL PARTNERSHIP HOLDING LIMITED, of 926 Leathorne Street, London,
Ontario, Canada N5Z 3M5,

and **...also**.....
of, PACKARD MEDICAL SUPPLY LIMITED, 1220-36th Street North, Leathbridge,
Alberta, Canada T1H 5H8, do solemnly and sincerely declare as follows:

1. We are authorised by TRUDELL PARTNERSHIP HOLDING LIMITED and PACKARD MEDICAL SUPPLY LIMITED the applicants for the patent to make this declaration on their behalf.
2. The basic application as defined by section 141 of the Act was made in the United States of America on the 19th May 1988 by CHRISTOPHER NOWACKI, ALFRED G. BRISSON and EXEQUIEL DELA CRUZ.
3. The basic application referred to in this Declaration was the first application made in a convention country in respect of the invention the subject of the application.
4. CHRISTOPHER NOWACKI, of 1552 Chicamauga Lane, Long Grove, Illinois 60047, United States of America; ALFRED G. BRISSON, of 22358 Timberlea, Kildeer, Illinois 60047, United States of America; and EXEQUIEL DELA CRUZ, of Trail Ridge Road, Arlington Heights, Illinois 60004, United States of America, are the actual inventors of the invention and the facts upon which the applicant is entitled to make the application are as follows:

The applicants are the assignee of the invention and of priority right from the actual inventors.

Declared at this 12th day of September 1991

Signed

Declared at this 12th day of September 1991

Signed

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- (56) Prior Art Documents
AU 268851 23453/62 A61M 16/06
AU 240644 66306/60 A61M 16/06
- (57) Claim

1. A pediatric medication inhaler adaptor comprising an integral mask-like device moulded of flexible plastic material or the like including a first portion of shallow taper adapted to grip a cylinder in which medication is dispersed in the form of a mist, a second portion likewise of shallow taper and extending from said first portion, a third frusto-conical portion of substantially greater taper extending from said second portion and adapted to fit snugly against an infant's face covering the mouth and nose, and having a central through-opening extending through said first, second and third portions, and said third portion having an integral wedge-shaped outward extension for accommodating the infant's nose, an outwardly projecting bubble integral with said second portion, said second portion having a wall of a first thickness and said bubble having a wall of a second thickness that is substantially thinner than the said first thickness of said wall of said second portion for enhanced flexibility, whereby said bubble flexes inwardly upon inhalation by said infant for visual observation by an attendant of such inhalation.

COMPLETE SPECIFICATION

(ORIGINAL)

FOR OFFICE USE

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Accepted:
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Priority:

Related Art:

TO BE COMPLETED BY APPLICANT

Name of Applicant: TRUDELL PARTNERSHIP HOLDING LIMITED and
PACKARD MEDICAL SUPPLY LIMITED

Address of Applicant: 926 Leathorne Street, London, Ontario, Canada, N5Z 3M5,
and 1220-36th Street North, Leathbridge, Alberta, Canada
T1H 5H8, respectively.

Actual Inventors: CHRISTOPHER NOVACKI, ALFRED G. BRISSON and
EXEQUIEL DELA CRUZ

Address for Service: CALLINANS, Patent Attorneys, of 48-50 Bridge Road,
Richmond 3121, Victoria, Australia.

MO 96785-26/02/87
Complete Specification for the invention entitled: "IMPROVED PEDIATRIC ASTHMATIC
INHALER" ..

The following statement is a full description of this invention, including the
best method of performing it known to us:-

IMPROVED PEDIATRIC ASTHMATIC INHALER

Related Patent Application

This application comprises an improvement on and is related to the Asthmatic Medication Inhaler shown in U.S. Patent No. 4,809,692 of Christopher Nowacki, Alfred G. Brisson and Exequiel Dela-Cruz entitled "Pediatric Asthmatic Medication Inhaler". More specifically it relates to an inhaler adaptor.

Background Of The Invention

A person suffering from Asthma may have rather considerable trouble in breathing when suffering from an asthmatic attack, due to the swelling in the bronchii and due to secretion of mucous. There are various anti-asthmatic pills that are effective, which generally are somewhat slow acting. There are also medications available for intravenous treatment which work quite rapidly, but which require administration by skilled medical personnel. For most patients the promptest, immediately available relief is by way of an inhalant. Epinephrine or other suitable asthmatic medication is packaged with a suitable diluent in a small pressurized canister or cartridge which interfits with a mouthpiece. The patient places the mouthpiece in his mouth, and depresses the cartridge, thereby releasing a measured amount of medication which is inhaled through the mouthpiece.

Some patients do not inhale properly, and the mouthpiece may not be completely effective in cooperation with the cartridge to convert the medication into a mist which is deposited in the proper bronchial area to relieve the asthmatic attack. Often there are small droplets, rather than a mist, and this may be compounded by improper inhalation which results in much



IMPROVED PEDIATRIC ASTHMATIC INHALER CONTINUED

of the medication simply going into the throat and stomach where it is ineffective against the asthmatic attack.

5 In the prior U.S. Patent 4,470,412 in the names of Christopher Nowacki and Alfred G. Brisson, there is disclosed a remarkably efficient and low cost inhalation valve in the nature of an extended mouthpiece for a broncho dialator which aids the asthmatic sufferer in properly inhaling, and in breaking up droplets into a mist form. This inhalation valve has achieved extensive commercial success.

The inhalation valve as discussed above is for use by a patient who can take the mouthpiece thereof into his mouth and inhale and exhale through the mouthpiece. Infants, including babies and small children, cannot be relied upon properly to hold the mouthpiece in the mouth, and indeed, the infant's mouth may be too small for the mouthpiece. Furthermore, it cannot be ascertained with certainty under some conditions whether a baby or small child is properly inhaling and exhaling.

U.S. Patent No. 809,692
In ~~application Serial No. 058,683~~, referenced above, there is disclosed a pediatric asthmatic inhaler which includes a mask-like adaptor fitting over the infant's mouth and nose and sealing to the face, whereby breathing by the infant effects proper inhalation, and exhalation through the valve. A whistle-like device is provided in the adaptor which generates sound upon either or both inhalation and exhalation, whereby a party applying the inhalation valve and medication to an infant may be sure that the medication is being breathed in. This prior pediatric asthmatic medication inhaler works satisfactorily under most conditions. However, for an infant, particularly a baby, in which the volume of inhalation or exhalation may be rather small, and wherein the



inhalation or exhalation might also be rather weak, the sound generated is not very loud. Under some circumstances in a noisy environment it may be difficult to hear the sound, and with very low-level respiration the whistle may fail to generate any audible sound. The tapered foam moulding of the inhaler requires
5 a rather expensive mould, and the whistle must be inserted as a separate manufacturing step, or requires sophisticated moulding techniques if the whistle is to be moulded in place.

Objects And Summary of the Present Invention

It is an object of the present invention to provide an improved pediatric
10 asthmatic inhaler adaptor which is less expensive to produce, which provides a more positive indication of inhalation and expiration, and which is longer lasting.

More particularly, it is an object of the present invention to provide
such an inhaler adaptor made of flexible plastic material, and having a "bubble"
of relatively thin, integral construction which is normally convex outwardly upon
15 exhalation or rest, but which deflects inwardly upon inhalation.

Thus according to one aspect of the present invention there is provided
a pediatric medication inhaler adaptor comprising an integral mask-like device
moulded of flexible plastic material or the like including a first portion of shallow
taper adapted to grip a cylinder in which medication is dispersed in the form of
20 a mist, a second portion likewise of shallow taper and extending from said first
portion, a third frusto-conical portion of substantially greater taper extending from
said second portion and adapted to fit snugly against an infant's face covering the
mouth and nose, and having a central through-opening extending through said



first, second and third portions, and said third portion having an integral wedge-shaped outward extension for accommodating the infant's nose, an outwardly projecting bubble integral with said second portion, said second section portion having a wall of a first thickness and said bubble having a wall of a second
5 thickness that is substantially thinner than the said first thickness of said wall of said second portion for enhanced flexibility, whereby said bubble flexes inwardly upon inhalation by said infant for visual observation by an attendant of such inhalation.

According to a further aspect of the invention there is provided a
10 pediatric medication inhaler adaptor as described herein wherein said bubble extends onto said third portion, said third portion having a wall of lesser thickness than said first thickness for enhanced flexibility to adapt to the contours of an infant's face, and further including a rim adjacent the edge of said bubble joining said bubble to said third portion and of greater thickness than said third portion
15 wall for enhanced rigidity at that location. The said inhaler adaptor may have an axial length, said bubble being axially elongated and having a rounded nose at the end thereof on said second portion.

According to another aspect of the invention there is provided a
20 pediatric medication inhaler adaptor as described herein wherein said second portion has a wall of a first thickness, said third portion having a wall of lesser thickness than said first thickness, for enhanced flexibility to conform to an infant's face, and said wedge-shaped extension provided in said third portion of lesser thickness than said third portion wall-thickness for further enhanced flexibility for conforming to an infant's nose and the adjacent portion of its face.

25 According to another aspect of the invention there is provided a pediatric medication inhaler adaptor as described herein wherein said second portion has a wall of a first thickness, said first portion has a wall of thickness greater than said first thickness for enhanced dimensional stability for gripping a



medication dispersing cylinder, and said third portion having a wall of a thickness less than said first thickness for enhanced flexibility for conforming to the face of an infant. The said first portion of the said medication inhaler adaptor may have an open end and the said first portion wall may have an internal taper to said open end to facilitate assembly with a medication dispersing cylinder.

The outwardly projecting bubble is normally convex, and retains its shape upon exhalation or rest. However, upon inhalation, even of a small degree, the bubble will flex inwardly, whereby the adult administering the device may readily observe it visually. The plastic material is of uniform consistency free of bubble. That is, it is not a foam, and thereby it is simpler and quicker in moulding.



~~IMPROVED PEDIATRIC ASTHMATIC INHALER CONTINUED~~

visually. The plastic material is of uniform consistency free of bubbles.
~~I.e., it is not a foam, and thereby it is simpler and quicker in molding.~~

5 The Drawings

The invention will best be understood with reference to the following text when taken in connection with the accompanying drawings wherein:

Fig. 1 is a perspective view of an improved pediatric asthmatic inhaler constructed in accordance with the present invention;

Fig. 2 is a side view thereof;

Fig. 3 is a right end view thereof;

Fig. 4 is a left end view thereof;

Fig. 5 is a longitudinal sectional view taken substantially along the line 5-5 in Fig. 3;

Fig. 6 is a side view of the inhaler as applied to an infant's face and upon inhalation; and

Fig. 7 is a view similar to Fig. 6, but taken upon exhalation.

Detailed Disclosure of the Illustrated Embodiment

As is well known, and as is summarized in prior U.S. Patent 4, 470, 412, a small pressurized canister or cartridge, sometimes referred to as a nebulizer, is charged with epinephrine or other suitable anti-asthmatic medication and a suitable diluent, and under pressure. The cartridge fits into a receiving end of a right angle mouthpiece, the opposite end of which is placed in the asthmatic sufferer's mouth. The cartridge is pressed down, being squeezed between the index finger and thumb underlying the mouthpiece. This causes a valve stem in the cartridge to press against the reaction base in the mouthpiece to discharge a measured quantity of medication into the mouthpiece. The discharge is



IMPROVED PEDIATRIC ASTHMATIC INHALER CONTINUED

5 supposed to be in the form of a mist, but in fact often contains small droplets. The patient inhales and the mist passes into the mouth and hopefully into the bronchial tubes to provide asthmatic relief. The patient is then supposed to hold his breath for a short time, and subsequently to inhale slowly through nearly closed lips. However, as noted heretofore, some of the medication may simply be in the form of droplets rather than mist, and the droplets generally are simply swallowed and do not reach the bronchial tubes to effect their intended purpose.

As is disclosed in detail in the aforesaid prior Patent 4,470,412, the drops can be broken up into a mist, and the patient can be more or less forced to inhale properly through the use of the inhalation valve forming the subject matter of said patent. Only a portion of the valve is shown herein for an understanding in combination with a pediatric adaptor or face mask. Such an inhalation valve 14, is shown fragmentarily in Figs. 6 and 7, and comprises a cylinder 16 preferably molded of a suitable plastic material. The end of the inhalation valve 14 to which the right angle mouthpiece carrying the medication canister is not shown, but this is well-known, and for example is shown in aforesaid U.S. Patent 4,470,412. A resinous plastic or elastomeric diaphragm 44 is disposed adjacent the end of the cylinder 16 and is provided with a horizontal slit 46. A spider (not shown) lies upstream of the diaphragm 44 and backs up the diaphragm so that the diaphragm cannot flex upstream (to the right in Fig. 6) but only downstream upon inhalation. Further details of the diaphragm structure may be seen in aforesaid U.S. Patent 4,470,412, or in ~~copending application 058,683.~~ U.S. Patent No. 4,809,692.

The pediatric asthmatic inhaler, ^{adaptor} of the present invention, ^{comprises} ~~is completed by~~



IMPROVED PEDIATRIC ASTHMATIC INHALER CONTINUED

an adaptor or fitting 36 in the nature of a face mask. The adaptor 36 is molded of a soft plastic material of uniform consistency and density, such as polyethylene. The adaptor 36 is axially open and continuous, and at its entering end has a short section 48 of initially very shallow taper, and which is deformed substantially into cylindrical shape upon encircling and gripping the entering end of the inhalation valve 14. A frustoconical section 50 of slightly greater taper than the section 48 flares outwardly from the section 48. Finally, a face engaging portion 52 flares outwardly from the section 50 at a much shallower angle. The face engaging portion 52 is adapted to engage the face of an infant 54 in sealing engagement so as to prevent ingress or egress of air between the fitting 36 and the face.

The difference in taper between the sections 48 and 50 is so little that there is scarcely any parting line visible, but one is shown at 54 in the drawings to illustrate the difference in taper. There is a definite parting line 56 between the center section 50 and the section or flange 52, although this is not so much a definite line as it is a sharply curved or rolled area.

An upstanding bubble or blister 58 extends radially outwardly from the adaptor or fitting 36, being integral therewith, and has a rounded end or nose 60 terminating substantially at the parting line 54. Except for the nose the blister is slightly less than a semicylinder and terminates at a short cylindrical section 62 of thickened material affording a shape having a certain degree of stability to the rear end of the bubble or blister 58. From the section 62 an extended portion of the flange 52 extends generally radially outwardly at 64 and lies generally over the ridge of the nose of the infant 54, conforming to the shape of the adjacent portion of the face.

IMPROVED PEDIATRIC ASTHMATIC INHALER CONTINUED

Various sections or portions of the adaptor or fitting 36 are of different thicknesses for controlled flexibility. The particular dimensions of a specific example include an inside diameter of the inhalation valve cylinder 16 receiving portion 48 of approximately 35 mm. This and other cross sections being substantially circular. The thickness of this portion is 2.8 mm. The axial length of this section is on the order of 10-12 mm. depending on just where the somewhat indefinite line of demarcation 54 is located.

The intermediate section 50 has an axial length of about 22 or 23 mm. The thickness is approximately 1.8 mm. The internal diameter at the parting line or rule 56 is approximately 40 mm. It should be noted that the first section 48 has an entering internal taper 66 having an axial length of about 10 mm. The thickness of the first portion 48 at the entering end is approximately 2.5 mm.

The final section or flange 52 is approximately 1 mm. in thickness, the axial length is approximately 20 mm., and the exit diameter is approximately 66 mm. The thickness of the bubble or blister 58 and of the flared nosepiece 64 is approximately .3 mm. The thickness of the intermediate strengthening portion 62 is approximately 1.6 mm. at the forward shoulder 62 thereof, and tapers to about .8 mm. at the junction with the flared nosepiece 64, such junction hereinafter being identified by the numeral 70. The bubble 58, including the rounded nose 60 thereof is approximately 21 mm. in length axially of the adaptor or fitting 36 and forwardly of the shoulder 68. The bubble is approximately 20 mm. in width.

As is shown in Figs. 6 and 7 the rear portion or flange 52 adapts by flexing to accommodate fully to the face of the infant 54, even though the adaptor or fitting 36 might be used on infants of rather substantially

IMPROVED PEDIATRIC ASTHMATIC INHALER CONTINUED

different sizes. The flange forms an airtight seal with the face. Thus, when the patient is exhaling, or is resting between breaths, the bubble extends outwardly as shown in Fig. 7. However, when the patient inhales as shown in Fig. 6 the decreased pressure within the adaptor causes the bubble to deflect inwardly as at 72 under the pressure of exterior ambient air as indicated by the arrow 74. It is thus easy for the person administering the medication to observe inhalation, even in a noisy environment. The shiny exterior appearance of the plastic material allows the deflection to be seen even in rather dim light.

Reference has been made to asthmatic medication, but it will be apparent that other medications could be inhaled with the present invention.

The specific example is for illustrative purposes only. Various changes will no doubt occur to those skilled in the art, and will be understood as forming a part of the invention insofar as they fall within the spirit and scope of the appended claims.

The claims defining the invention are as follows:

1. A pediatric medication inhaler adaptor comprising an integral mask-like device moulded of flexible plastic material or the like including a first portion of shallow taper adapted to grip a cylinder in which medication is dispersed in the form of a mist, a second portion likewise of shallow taper and extending from said first portion, a third frusto-conical portion of substantially greater taper extending from said second portion and adapted to fit snugly against an infant's face covering the mouth and nose, and having a central through-opening extending through said first, second and third portions, and said third portion having an integral wedge-shaped outward extension for accommodating the infant's nose, an outwardly projecting bubble integral with said second portion, said second portion having a wall of a first thickness and said bubble having a wall of a second thickness that is substantially thinner than the said first thickness of said wall of said second portion for enhanced flexibility, whereby said bubble flexes inwardly upon inhalation by said infant for visual observation by an attendant of such inhalation.
2. A pediatric medication inhaler adaptor as claimed in claim 1 wherein said bubble extends onto said third portion, said third portion having a wall of lesser thickness than said first thickness for enhanced flexibility to adapt to the contours of an infant's face, and further including a rim adjacent the edge of said bubble joining said bubble to said third portion and of greater thickness than said third portion wall for enhanced rigidity at that location.
3. A pediatric medication inhaler adaptor as claimed in claim 2 wherein said inhaler adaptor has an axial length, said bubble being axially elongated and having a rounded nose at the end thereof on said second portion.
4. A pediatric medication inhaler adaptor as claimed in claim 1 wherein said second portion has a wall of a first thickness, said third portion having a wall of lesser thickness than said first thickness for enhanced flexibility to conform to



an infant's face, and the wedge-shaped extension is of lesser thickness than said third portion wall-thickness for further enhanced flexibility for conforming to an infant's nose and the adjacent portion of its face.

5. A pediatric medication inhaler adaptor as claimed in claim 1 wherein said second portion has a wall of a first thickness, the said first portion has a wall of thickness greater than said first thickness for enhanced dimensional stability for gripping a medication dispersing cylinder, said third portion having a wall with a thickness less than said first thickness for enhanced flexibility for conforming to the face of an infant.

6. A pediatric medication inhaler adaptor as claimed in claim 5 wherein said first portion has an open end, and said first portion wall has an internal taper to said open end to facilitate assembly with a medication dispersing cylinder.

7. A pediatric medical inhaler adaptor as claimed in any one of claims 1 to 5 substantially as hereinbefore described with reference to any one of figures 1 to 7.

D A T E D this 14th day of February 1991

TRUDELL PARTNERSHIP HOLDINGS LIMITED and
PACKARD MEDICAL SUPPLY LIMITED

By their Patent Attorneys:

CALLINAN LAWRIE

