IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFEVAC, LLC,
Petitioner,

v.

DCSTAR INC.,
Patent Owner.

U.S. Patent No. 11,478,575
Issue Date: October 25, 2022
Title: REMOVAL DEVICE FOR REMOVING OBSTRUCTION IN RESPIRATORY TRACT AND CONNECTOR

Inter Partes Review No.: IPR2025-00454

PETITION FOR *INTER PARTES* REVIEW OF PATENT NO. 11,478,575 UNDER 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.107

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Petitioner's Exhibit List

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1002	Select portions of prosecution history of the '575 Patent ("File History")
1003	Declaration of Petitioner's Expert Stanley M. Yamashiro
1004	Chinese Patent Publication CN112932633A ("Zhongnan")
1005	Certified English translation of *EX-1004*
1006	U.S. Patent Application Publication US 2020/0306420 A1 ("Carver")
1007	Korean Patent Publication KR1020200102780A to Jung-Hwan Bae ("Bae")
1008	Korean Patent Publication KR 102229619B ("Yuchang") and
1009	Certified English translation of *EX-1008*
1010	Chinese Patent Publication CN110566698 A ("Changzhon")
1011	Intentionally Left Blank
1012	U.S. Patent No. 9714714 to Daansen et al. ("Daansen")
1013	U.S. Patent Application Publication US 2006/0260617 A1 ("Abolfathi")
1014	Intentionally Left Blank
1015	U.S. Patent No. 5,722,394 to Loescher ("Loescher")
1016	https://web.archive.org/web/20210622105538im_/https://lifevac.net/wp-content/uploads/DSC03001-Bundle-1-1.jpg
1017	Resuscitation of Choking Victims in a Pediatric Population Using a Novel Portable Non-Powered Suction Device: Real-World Data, Laura Levinson Gal, Pamela Pugliesi, Diane Peterman, Pediatrics & Therapeutics Vol. 10 Iss. 4 No: 371 (October 11, 2020).
1018	U.S. Patent No. US 10,052,115 to Lih ("Lih")

I. INTRODUCTION

Pursuant to 35 U.S.C. §§ 311 *et seq*. and 37 C.F.R. §§ 42.1 *et seq*., LifeVac, LLC ("Petitioner") hereby petitions for an *inter partes* review of U.S. Patent No. 11,478,575 ("the '575 Patent"). Petitioner respectfully submits that Claims 1-17 (the "Challenged Claims") of the '575 Patent are unpatentable under 35 U.S.C. §103 in view of the prior art references discussed herein. This Petition demonstrates by a preponderance of the evidence that there is a reasonable likelihood that Petitioner will prevail with respect to at least one of these claims. Accordingly, it is respectfully requested that the Board institute an *inter partes* review of the '575 Patent pursuant to 37 C.F.R. § 42.108.

II. OVERVIEW

The Challenged Claims are unpatentable as obvious over the prior art. The claims are directed to prior art devices and combinations of conventional components that perform conventional functions regarding anti-chocking devices, all of which were well-known in the art of consumer first aid devices.

Specifically, the Claim 1 is directed to a device for removing obstructions from a respiratory tract comprising: (1) a collapsible gasbag (**red**); (2) a connector (**green**) having at least two check valves allowing gas flow in opposite directions; and (3) a face mask (**blue**). The '575 Patent illustrates the device in FIG. 2:

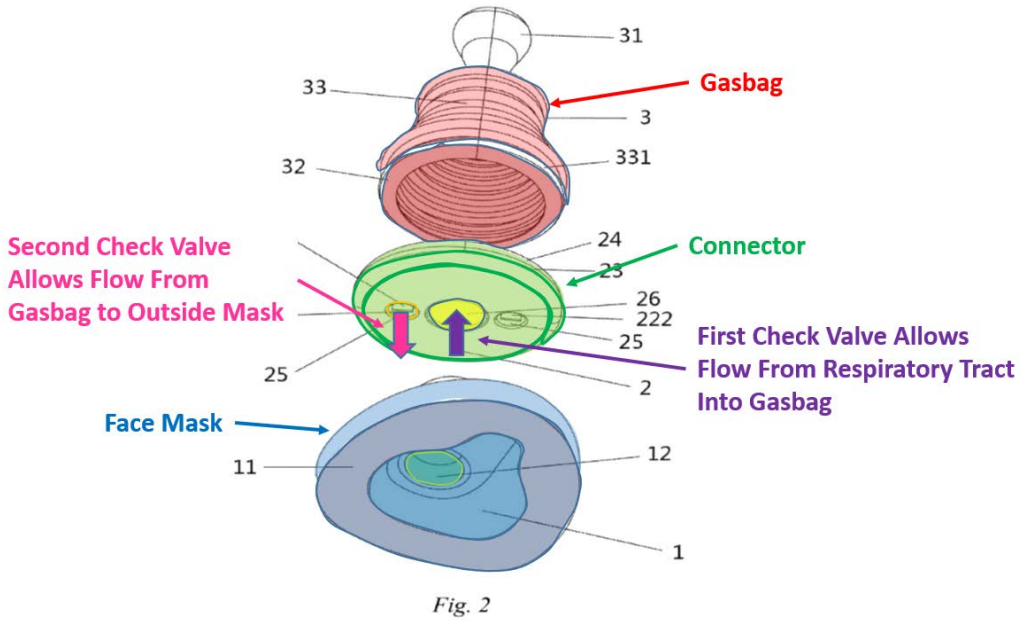


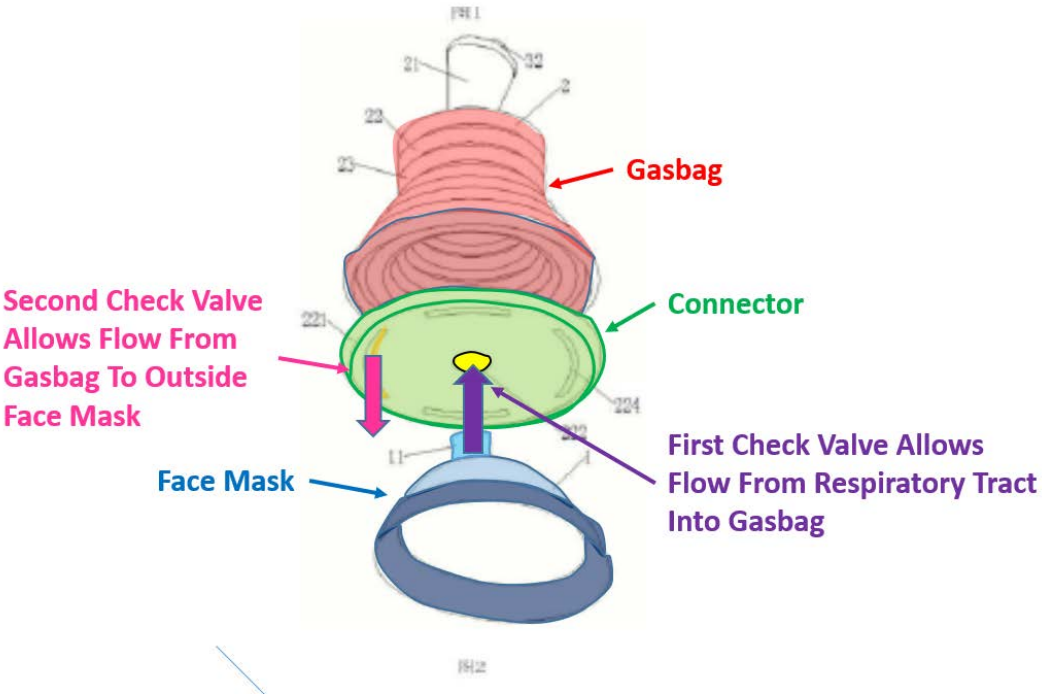
Fig. 2

EX-1001 FIG. 2

However, Zhongnan (*EX-1004*, *EX-1005*)[1] demonstrates that the claimed device for removing an obstruction from a respiratory tract was well known at the time of the ’575 Patent.

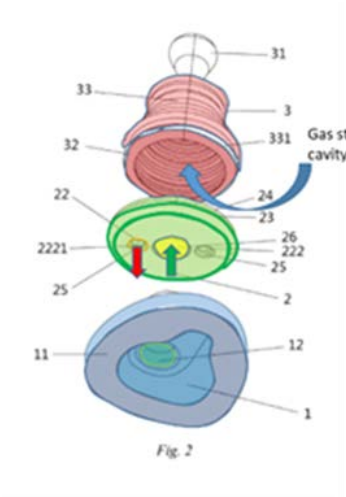
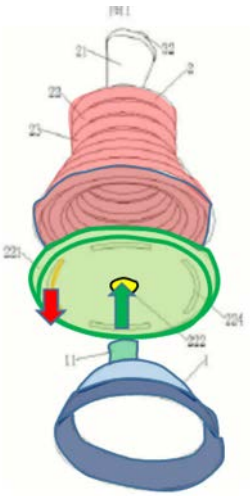
Zhongnan illustrates such a device in FIG. 2:

[1] Citations to Zhongnan and the other foreign language references will be to the English translations.



EX-1005 FIG. 2

Table 1 provides a side-by-side comparison of the devices as well as a listing of the terminology used in each reference for the common elements of the devices:

Table 1	
’575 Patent	Zhongnan
	

Collapsible gas bag (3)	Suction device (2)
Connector (2)	Base Plate (221)
Face mask (1)	Breathing mask (1)
First check valve (21)	One-way inlet valve (226)
Second check valve (25)	One-way exhaust valve (225)
Flexible annular pad (11)	Outer edge

As demonstrated above, Zhongnan discloses a materially identical device to the device of the Challenged Claims with the only variations being the selection of check valve type from among well-known options.

For example, independent Claim 3 recites specific elements of the first check valve (cross-slit check valve), and independent Claim 9 recites specific elements of the second check valve (duckbill check valve). However, as evidenced by the disclosures of Daansen, Yuchang, Loescher and Changzhon, the use of these specifically configured check valves was known generally in the medical device field, and specifically in anti-choking devices. Daansen (*EX-1012*) discloses a cross-slit check valve as recited in Claim 3, and Yuchang (*EX-1009*) discloses a duckbill check valve as recited in Claim 9.

Because these references are directed to the similar or the same problem and utilize the same or similar solutions, these references are naturally combined

together, and each alone or in combination with discloses each limitation recited in the Challenged Claims. *EX-1003* ¶45.

Although Petitioner previously filed a petition for Post Grant Review (PGR) challenging all claims of the '575 Patent (PGR2023-00032), as discussed below in Section VIII.B, the art presented in this Petition was not known nor should have been known to Petitioner at the time of filing PGR2023-00032, and was only located after Petitioner commissioned a specialized foreign language search.

III. GROUNDS FOR STANDING (37 C.F.R. § 42.104(A))

Petitioner certifies that the '575 Patent for which review is sought is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review of the Challenged Claims on the grounds identified herein. 37 C.F.R. § 42.104(a). This Petition is filed pursuant to 37 C.F.R. § 42.106(a).

IV. REASONS FOR THE REQUESTED RELIEF

As explained in §§ II and VI-VIII of this Petition and in the attached Expert Declaration of Stanley Yamashiro, *EX-1003*, the anti-choking device as described and claimed in the '575 Patent, was obvious over the prior art to a person of ordinary skill in the art ("POSA") at the time of the invention.

V. BACKGROUND

A. Summary of the ’575 Patent

The ’575 Patent is directed to a first aid anti-choking device for removing an obstruction in a respiratory tract. *EX-1001* 9:59-60. The ’575 Patent describes the components of the device as “a collapsible gasbag 3, a connector 2 and a facemask 1 which are sequentially connected.” *EX-1001*, 6:5-7; *EX-1003* ¶47.

The ’575 Patent explains that the collapsible gasbag 3 (**red**) includes an internal gas storage cavity, with the top of the bag being sealed, and the bottom of the bag having an opening 32 in communication with the gas storage cavity. A connector 2 (**light green**) is hermetically connected to the opening 32 of the gasbag 3 on an upper side, and to the face mask 1 (**blue**) on the other side. *EX-1001*, 6:10-15; *EX-1003* ¶48.

The ’575 Patent further explains that connector 2 includes a first check valve 21 (**orange**) allowing the flow of air from the interior of the face mask 1 into the gas storage cavity, and one or more second check valves 22 (**gold**) allowing the flow of air from the gas storage cavity to outside the face mask 1. *EX-1001*, 6:49-52; *EX-1003* ¶49.

The ’575 patent illustrates the device in FIG. 3 below:

DESCRIPTION OF REFERENCE NUMERALS IN SPECIFIC IMPLEMENTATIONS

Face mask	1	Collapsible gasbag	3
Flexible annular pad	11	Handle	31
Connecting cylinder	12	Opening	32
Connector	2	Second peripheral side wall	33
First check valve	21	Second check valve	22
Bottom plate	23	First peripheral side wall	24
Peripheral cylinder	25	Central cylinder	26
Stop edge	241	Reinforcement strip	27
Deformed portion	212	First slit	2121
Duckbill portion	222	Second slit	2221
Second base portion	221	Fold	331

EX-1001 5:35-50; *EX-1003* ¶50.

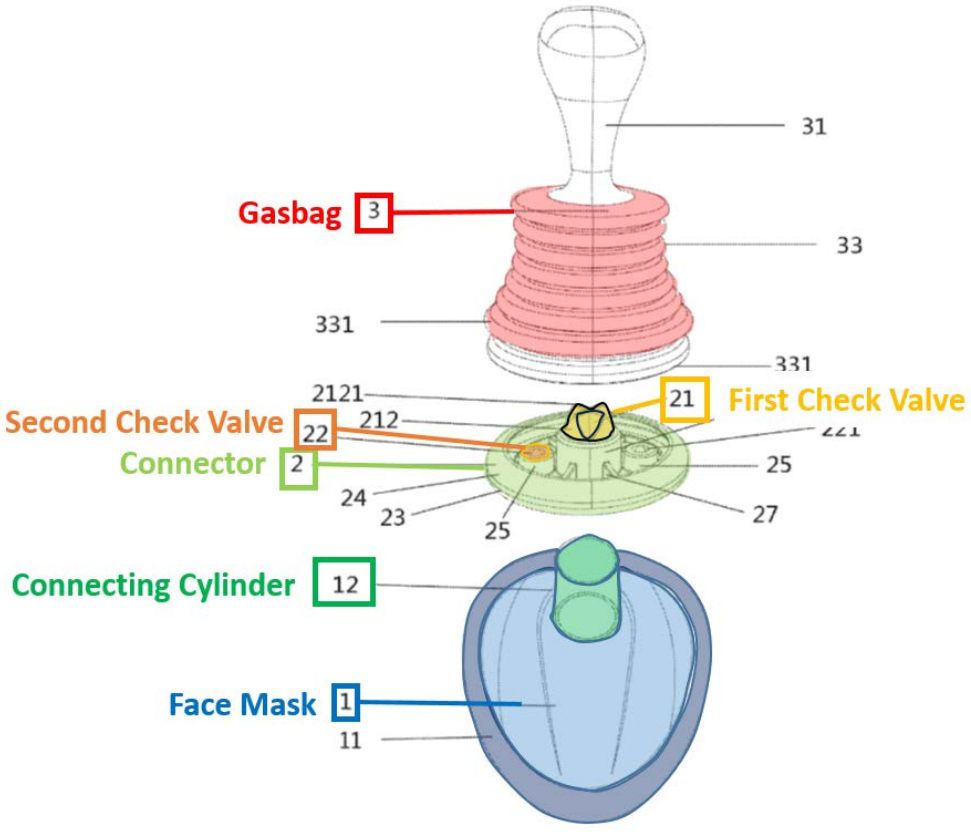


Fig. 3

EX-1001 Fig. 3; *EX-1003* ¶50.

The ’575 Patent explains that when rescuing a choking patient, the flexible annular pad 11 of the face mask 1 is placed to encircle the mouth of the choking patient and is closely attached so as to be connected to the respiratory tract of the patient. The mask 1 must be held to establish and maintain a seal between the mask 1 and the airway. The collapsible gasbag 3 is then repeatedly compressed and stretched until the blockage of the airway is cleared. Compressing gasbag 3 forces air from the internal cavity to outside of mask 1 through second check valve 22 while first check valve 21 prevents air from flowing into the respiratory tract. When the gasbag is stretched, air is drawn from the respiratory tract into the cavity through first check valve 21 while second check valve 22 prevents air from being drawn into the cavity from outside the mask. *EX-1001*, 7:64-8:13; 8:13-28; *EX-1003* ¶51.

The Challenged Claims include four independent claims. Independent Claims 1, 3, and 9 are each directed to:

> *A removal device for removing an obstruction in a respiratory tract, the removal device comprising a collapsible gasbag, a connector and a face mask which are sequentially connected, …*

EX-1001 Preamble of Claims 1, 3, and 9.

Claim 1 specifies that the connector includes two check valves allowing flow in opposite directions:

wherein the connector comprises a bottom plate and the first check valve and the second check valve are arranged on the bottom plate, wherein the first check valve and the second check valve allow gas flow to pass in opposite directions.

EX-1001 Claim 1.

Claim 3 specifies that the connector includes a central cylinder and a first check valve having a cross-slit configuration:

wherein the connector is provided with a bottom plate, the bottom plate being provided with a central cylinder which is vertically through; the first check valve is of a hollowed structure made from an elastic material, and comprises a deformed portion and a first base portion which are connected to each other; the first gas outlet end is composed of at least three first slits provided at a top end of the deformed portion; one end, extending toward the center, of the at least three first slits intersect at the same point, ….

EX-1001 Claim 3.

Claim 9 specifies that the connector includes a peripheral cylinder and a second check valve having a duckbill configuration:

wherein the connector is provided with a bottom plate, the bottom plate being provided with a peripheral cylinder which is vertically through; the second check valve is a duckbill valve, ….

EX-1001 Claim 9.

Claim 13 is directed only to a "connector for a removal device" having the specific configuration recited in Claim 1:

> *A connector for a removal device, the connector comprising a bottom plate, and a first check valve and a second check valve which are arranged on the bottom plate, wherein the first check valve and the second check valve allow gas flow to pass in opposite directions; and the connector is an integrally formed member made from an elastic material*.

EX-1001 Claim 13.

B. Prosecution History

The application that issued as the '575 Patent was filed Aug. 3, 2021, including independent Claim 1 and Claims 2-17 dependent therefrom directed to a device for removing an obstruction in a respiratory tract. *EX-1002* pp.194-198.

On Jun. 8, 2022, a non-final office action issued rejecting Claims 1, 7, and 10-12 as being obvious over Lih (US 10,052,115) in view of Tarrats (US 4,971,053); and Claim 2 over Lih and Tarrats as applied to Claim 1, further in view of Rozinsky (US 7,351,245). Claims 13-17 were allowed and Claims 3-6 and 8-9 were objected to as being dependent from a rejected claim. *EX-1002* pp.99-104.

In response, Applicant amended Claim 1 to specify the connector having two check valves allowing opposite flow while arguing patentability on that basis, and rewrote Claims 3 and 9 into independent form. *EX-1002* p.76.

The Challenged Claims were subsequently allowed on Oct. 25, 2022 and ultimately issued with the '575 Patent. *EX-1002* pp.43-51.

C. Claim Construction

Petitioner proposes that each claim term in the Challenged Claims be given its plain and ordinary meaning, and that no specific construction of any claim term is required because the prior art relied on in this Petition meets each of the claim terms under any reasonable construction.

This interpretation is only applicable to the *inter partes* review sought herein and should not be construed as constituting, in whole or in part, Petitioner's own interpretation of any claim for any other purpose, including any litigation. Accordingly, Petitioners expressly reserve the right to present an interpretation of a claim term in other proceedings, which is different, in whole or in part, from that presented in this Petition.

D. Priority Date of the Challenged Claims

The application that issued as the '575 Patent was filed on Aug. 3, 2021, and makes no claim to an earlier filed application. Thus, the earliest priority date to which the Challenged Claims may be entitled is Aug. 3, 2021.

E. Person of Ordinary Skill in the Art

A POSA in the timeframe of filing the '575 Patent on Aug. 3, 2021, would have been familiar with consumer medical devices in general and would have a

working knowledge of respiratory devices including consumer anti-choking devices. *EX-1003* ¶60.

A POSA would have gained knowledge of these concepts through a mixture of training and work experience, such as by having a Bachelor's degree in Mechanical/Biomedical engineering and two years of experience; or by obtaining a Master's degree in Mechanical/Biomedical Mechanical, but having only one year of experience; or by having no formal education but experience with respiratory devices of at least four years. *EX-1003* ¶61.

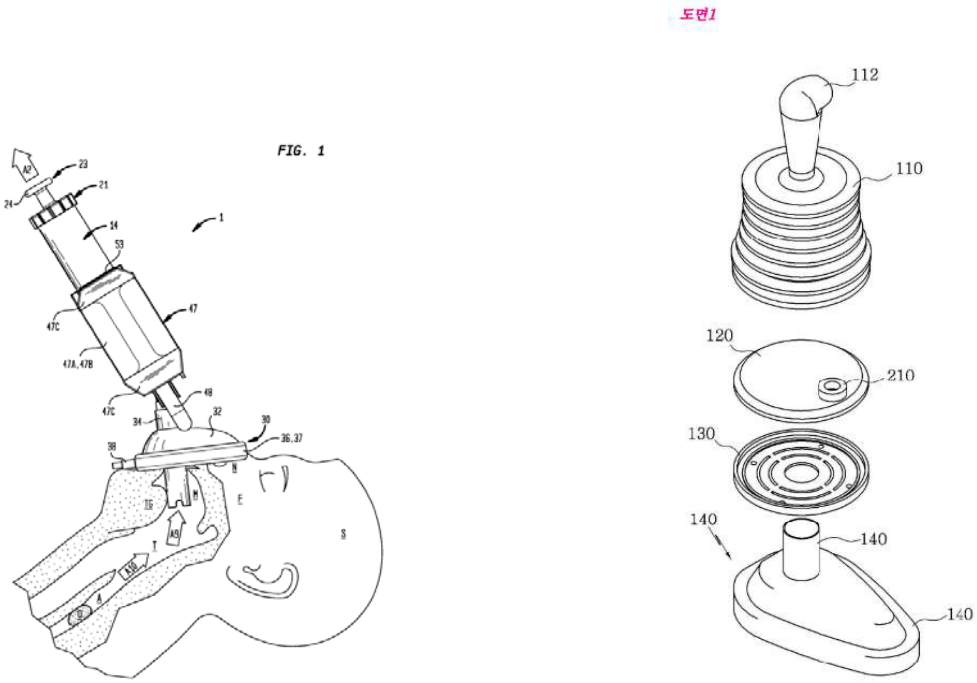
F. State of the Art

The following section describes the state of the art for anti-choking devices as of the priority date of the '575 Patent. *EX-1003* ¶62. The prior art references, and the discussions of what was known to a POSA, provide factual support for the general description of the state of the art at the time of the purported invention, and provide additional motivation to modify or combine references. Accordingly, these references should be considered by the Board.

1. Anti-choking first aid devices

Anti-choking devices for consumer use were well known at the time of the purported invention. The basic concept relies upon creating a pressure differential across the obstruction in the airway such that air in the lungs is at a greater pressure than the upper airway thus forcing the obstruction out of the airway

through the mouth. Unlike the well-known Heimlich maneuver wherein the diaphragm is compressed to increase the pressure in the lungs, consumer anti-choking devices create the pressure differential by evacuating air from upstream of the obstruction in the airway. The evacuation is typically created from a cylinder and plunger configuration wherein air is drawn into the cylinder via movement of the plunger in an upstroke as described in Carver (*EX-1006*) as well as Yuchang, or via the expansion of a collapsible cavity as described by Bae (*EX-1007*) as well as Zhongnan. *EX-1006* [0029], Fig. 1; *EX-1007* Fig. 1, [0032]: *EX-1003* ¶63.



EX-1006, Fig. 1; *EX-1003* ¶63. *EX-1007*, Fig. 1; *EX-1003* ¶63.

2. Prior art check valves

The use of check valves to direct the airflow in the employment of anti-choking devices was well-known. Of particular importance was the need to prevent enhancing the obstruction by forcing the obstruction further into the airway by increasing pressure toward the lungs. It was well-known to use at least two check valves allowing airflow in opposite directions. During compression of the plunger or cavity, a first check valve prevents the flow of air into the airway while a second check valve allows the flow of air to escape out of the face mask. During the expansion stroke of the plunger or airway, the first check valve allows the flow of air from the airway into the plunger or cavity while the second check valve prevents air from being drawn from outside of the face mask. EX-1003 ¶64.

For example, Carver, as well as Yuchang, and Zhongnan demonstrate the well-known use of check valves to control the flow or air during employment of the anti-choking device. The specific types of check valves recited in the Challenged Claims (cross-slit valves in Claim 3 and duckbill valves in Claim 9) were also well-known in medical devices, including anti-choking devices. *EX-1003* ¶65.

For example, Abolfathi discloses a ventilation device that uses a duckbill check valve or a cross-slit check valve for ventilation of the trachea. Specifically, the ventilation device has an expandable cuff that is oriented above the access point through the tracheal wall. A one-way valve (**gold**), specifically, may be

provided in the expandable cuff in order to permit exhalation through the larynx to assist in speech. *EX-1013* Abstract, [0059], FIG. 16B; *EX-1003* ¶66.

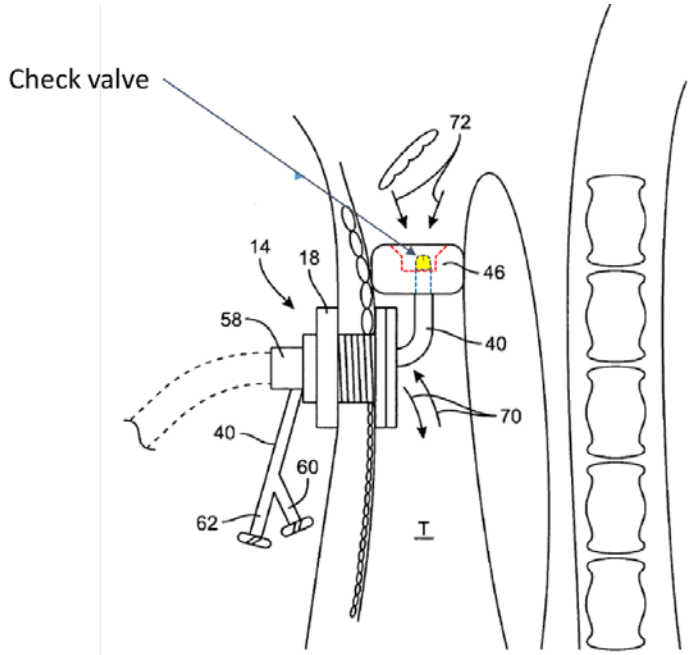


FIG. 4F

EX-1013 FIG. 4F; *EX-1003* ¶66.

A split valve is formed from an elastic material and includes a deformed portion (yellow) and base portion (dark yellow) which are connected to each other; the first gas outlet end is composed of four slits at the top of the deformed portion; each slit extending toward the center, and intersect each other at a common point. A POSA understood that in order for the slits to communicate with the ventilation lumen 268 (blue), a vent hole is provided in the middle of the base portion; and the base portion extends into the top portion of the tube 252 (green). Specifically, the ventilation lumen 268, and an outer side of the base portion is

hermetically connected to tube 252 a lower end of ventilation lumen 268 of the tube 252, is hermetically connected to an upper side of an inflatable cuff in the trachea; the deformation portion is exposed out of the tube 252 and extends into the upper trachea:

> A second valve 274 is provided adjacent the aspiration port 270, and typically includes a duck bill or other *one-way valve structure* permitting air to flow from beneath the cuff 254 to above the cuff. In this way, the patient may exhale and permit to pass upward through the valve 274 to enter the region of the larynx to permit speech. In particular, by covering the ventilation fitting 256 (optionally having removed any ventilator device), the air will have no other place to go, thus will all pass through the valve 274 into the larynx. After the patient is done speaking, the ventilator may be uncovered and/or the ventilation device may be reconnected. Alternatively, **the valve may be a cross-slit valve 275 as shown in FIG. 16B**.

EX-1012 [0059]; *EX-1003* ¶67.

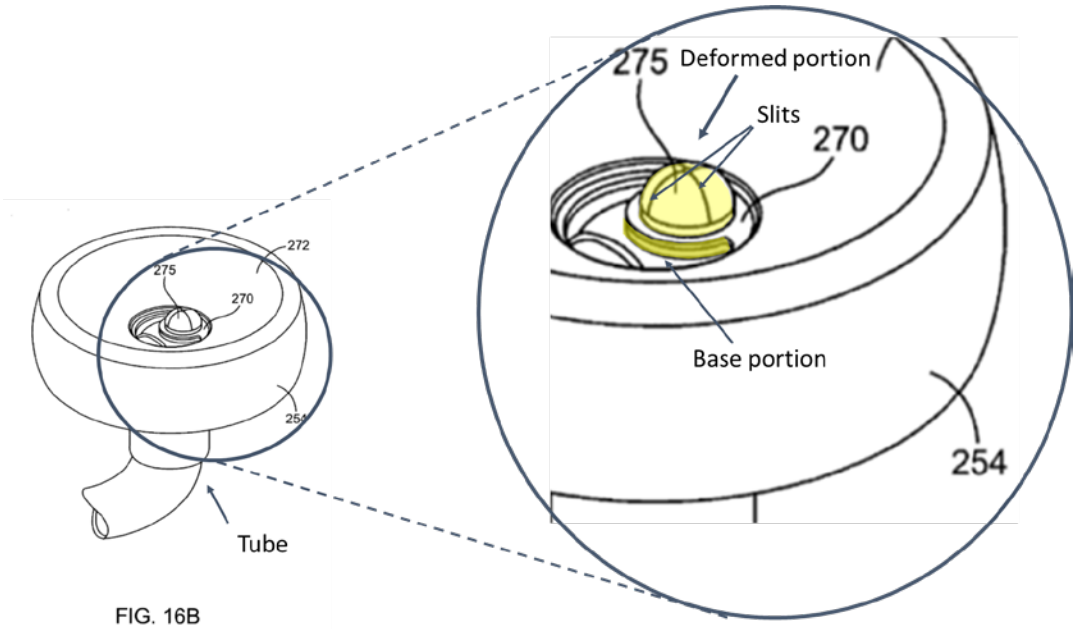


FIG. 16B

EX-1012 FIG. 16B; *EX-1003* ¶67.

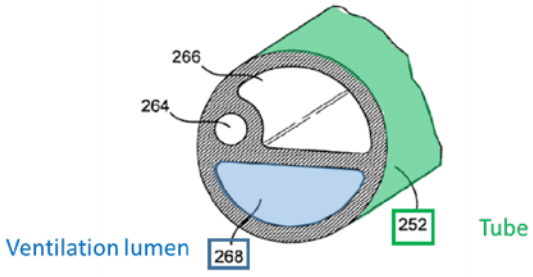


FIG. 15

EX-1012 FIG. 15; *EX-1003* ¶67.

Thus, cross-slit check vales and duckbill valves were well-known for value in assisting ventilation and treated interchangeably. *EX-1003* ¶68.

Cross-slit check valves have many applications given their simple operation and low cost. Daansen discloses a cross-slit check valve 40 used in a fluid

dispenser that operates to allow flow in only one direction. *EX-1012* 5:11-34; *EX-1003* ¶69.

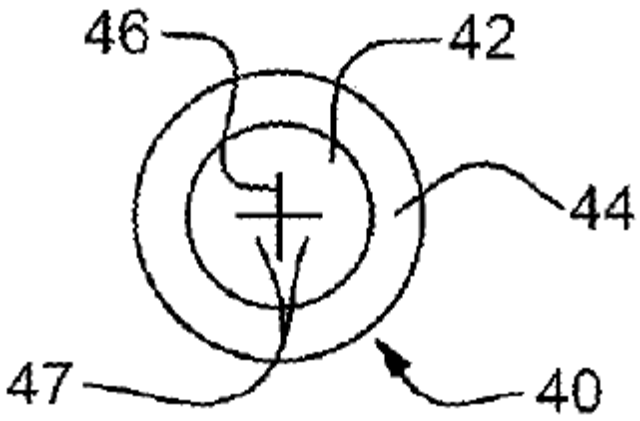
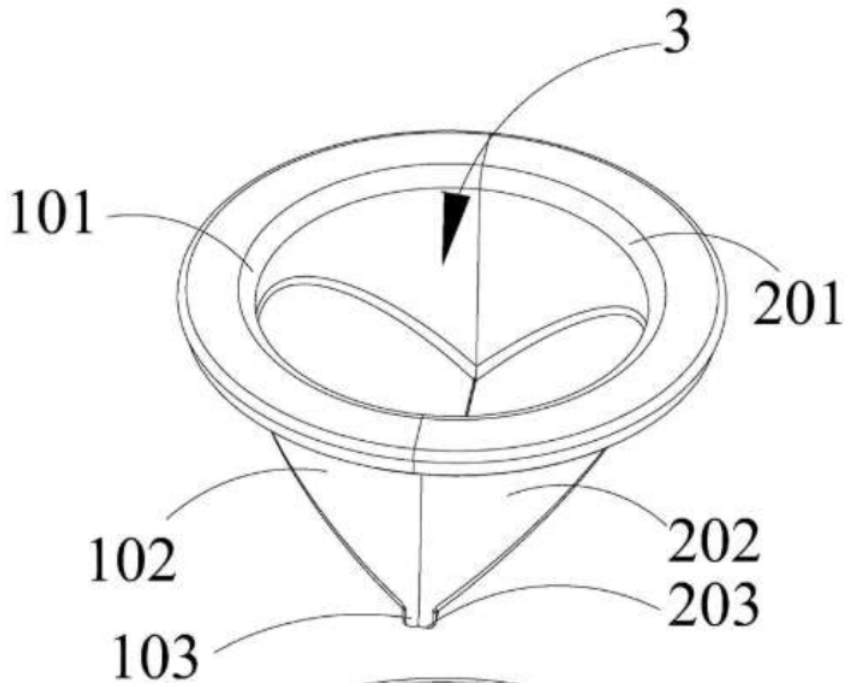


FIG. 2

EX-1012 Fig. 2; *EX-1003* ¶69.

Duckbill check valves were also well-known and perform the same function over many applications. For example, Changzhon, Carver and Loescher disclose duckbill check valves allowing flow in one direction. *EX-1011* Fig. 2, abstract; *EX-1014* [0029]; *EX-1015* 2:12-36, Fig. 2; *EX-1003* ¶70.



EX-1011 Fig. 2; *EX-1003* ¶70.

Thus, the operation and use of cross-slit check valves and duckbill check valves, as well as check valves in general, was well known and understood by a POSA. The choice of the best check valve type for a specific application involves a tradeoff between reliability and flow resistance. If a specific application is limited to use of a single valve a cross-slit check valve would be expected to be the best choice due to lower resistance and pressure drop during flow. If more than one valve can be used net resistance to flow is divided by the number of valves so the higher reliability of duckbill valves would motivate its selection. This is the expected rationale behind valve choice to a POSA. *EX-1003* ¶72.

VI. IDENTIFICATION OF CHALLENGES

A. Challenged Claims

Claims 1-17 of the ’575 Patent are challenged in this Petition.

B. Statutory Grounds for Challenges

The Challenges are set forth in detail below and summarized as follows:

Ground	Claims	Basis	Reference
1	1-2, 7, 13-14	§ 103	Zhongnan
2	3-6, 8-12,15-17	§ 103	Zhongnan in view of Yuchang

C. Prior Art

Chinese Patent Publication CN112932633A (“Zhongnan”) (*EX-1004*) is titled TRACHEAL FOREIGN BODY SUCTION DEVICE AND METHOD and published Jun. 11, 2021 from an application filed Mar. 10, 2021. *EX-1004*. Zhongnan qualifies as prior art under §102(a)1. It was not cited or applied during prosecution of the Challenged Claims, nor was it considered by the Board in PGR2023-00032. *EX-1005* is the certified English translation of Zhongnan, and all citations to Zhongnan are to *EX-1005*.

Korean Patent Publication KR10222961 B1 (“Yuchang”) (*EX-1008*) is titled REMOVAL APPARATUS FOR ESOPHAGEAL FOREIGN SUBSTANCES and published Mar. 18, 2021 from an application filed Jan. 13, 2021. Yuchang qualifies as prior art under §102(a)1. It was not cited or applied during prosecution of the Challenged Claims, nor was it considered by the Board in PGR2023-00032.

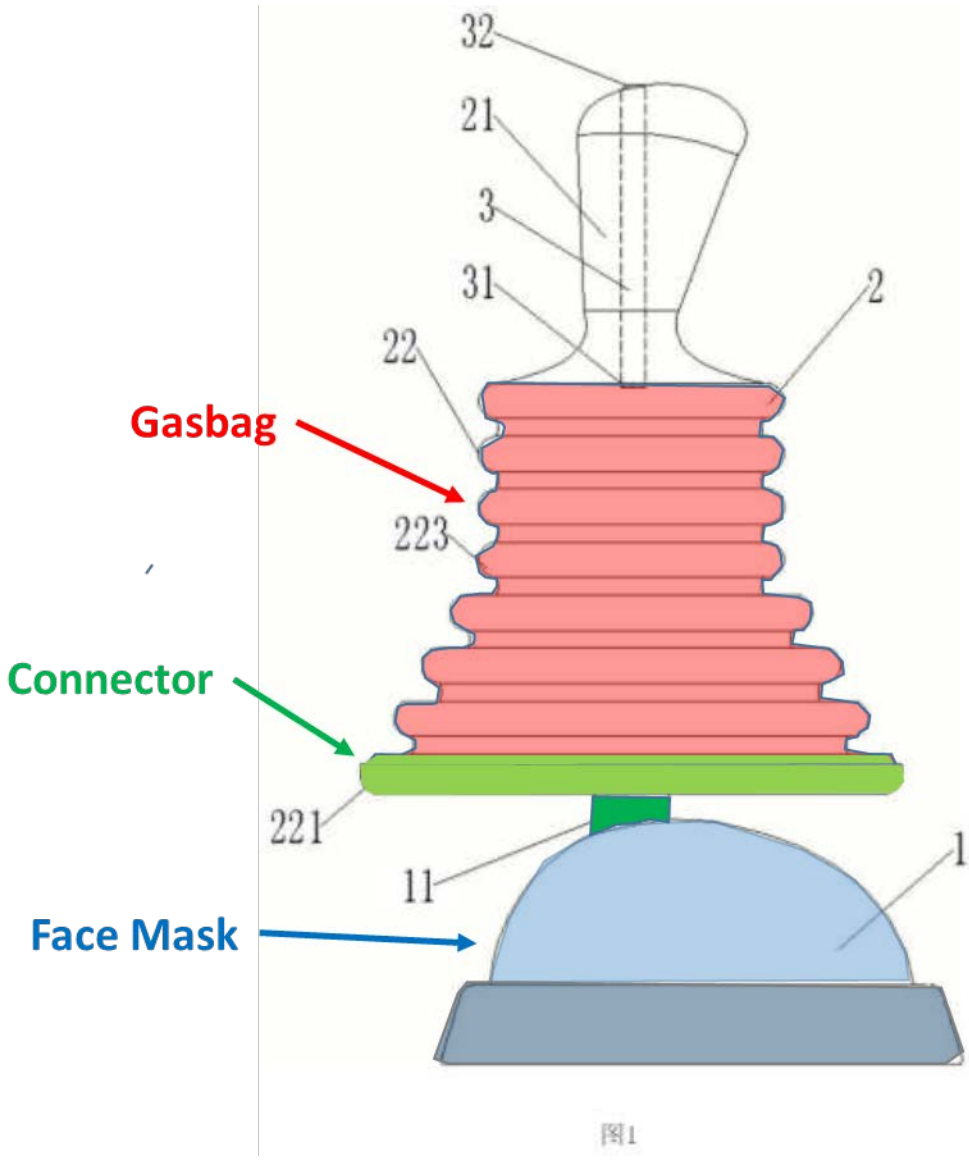
EX-1009 is the certified English translation of Yuchang, and all citations to Yuchang are to *EX-1009*.

VII. IDENTIFICATION OF HOW THE CHALLENGED CLAIMS ARE UNPATENTABLE

A. Challenge 1: Claims 1-2, 7, 13-14 are Unpatentable Over Zhongnan

1. The Zhongnan reference

Zhongnan discloses a tracheal foreign body suction device (*i.e.,* an anti-choking device) and method. Like the anti-choking device of the '575 Patent, the device of Zhongnan includes a collapsible cavity (**red**), a breathing mask (**blue**) and a connector (**green**) having check valves allowing flow in opposite directions between the cavity and mask.

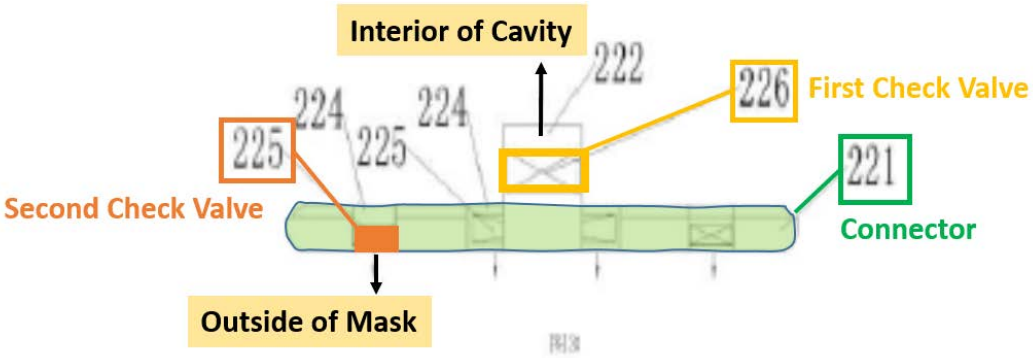


EX-1005 Fig 1; *EX-1003* ¶75.

The breathing mask 1 (face mask) includes a ventilation tube 11 positioned such that one end of the tube is located outside the mask and connected with an aspirator, and the other end of the tube is located inside the mask. *EX-1005* Abstract; *EX-1003* ¶76.

The aspirator includes a handle 21 and a suction cup (collapsible gasbag) below the handle. The suction cup forms an internal cavity with an opening in the bottom. A base plate 221 (connector) is positioned at the opening of the suction cup. *EX-1005* Abstract; *EX-1003* ¶77.

Zhongnan describes that the base plate 221 includes a central connecting tube 222 (central cylinder) that connects at the lower end to ventilation tube 11 (dark green) of the mask, and provides an airway between the interior of the mask and the cavity of the suction cup. *EX-1005* Abstract; *EX-1003* ¶78. A check valve 226 is positioned at the upper end of connecting tube 222 allowing air to flow only in the direction from the interior of the mask into the suction cup. *EX-1005* [0034], [0039]; *EX-1003* ¶78.



EX-1005 FIG. 3; *EX-1003* ¶78.

The base plate 221 also includes a plurality of air outlets 224 around its periphery. A check valve 225 is positioned at each air outlet 224 permitting air to flow only from the cavity of the suction cup to outside the mask. *EX-1005* [0034]; *EX-1003* ¶79.

Zhongnan explains that the anti-choking method using the device includes the following steps:

> S10. attaching the breathing mask to the human face and inserting the ventilation tube into the connecting tube;
> S20. pressing down the handle, driving the cylindrical body to press toward the face; the airflow created inside the cylindrical body flows downward, the one-way exhaust valve opens, the one-way inlet valve closes, and the airflow is discharged through the air outlet, creating a negative pressure inside the cylindrical body;
> S30. pulling up the handle; the one-way exhaust valve closes, and the one-way inlet valve opens; under the effect of the negative pressure, the foreign body in the trachea is suctioned out therefrom.

EX-1005 [0037-0039]; *EX-1003* ¶80.

As set forth in Steps S10 – S30 above, the breathing mask 1 is attached to the face of the choking patient and the ventilation tube 11 of the mask is inserted into the connecting tube 222 of the base plate. The handle 21 may be used to compress the suction cup driving the air out of the cavity. The air outlet check valves/one-way exhaust valves 225 are open allowing air to flow from the cavity to outside the mask through the outlets 224, while the air inlet check valve/one way inlet valve 226 is closed preventing air from flowing into the face mask and airway of the patient. A negative pressure is formed in the cylindrical body. When the handle 21 is pulled up to expand the suction cup, air inlet check valve 226 is open

permitting air to flow from the patient's airway through the mask and into the expanding cavity such that under the action of negative pressure, the foreign body obstructing the airway of the patient is sucked out from the airway. The air outlet check valves/one-way exhaust valves 225 are closed preventing air from outside the mask to be drawn into the cavity. *EX-1005* [0036-0040]; *EX-1003* ¶81.

2. Detailed Application of Zhongnan to the Challenged Claims

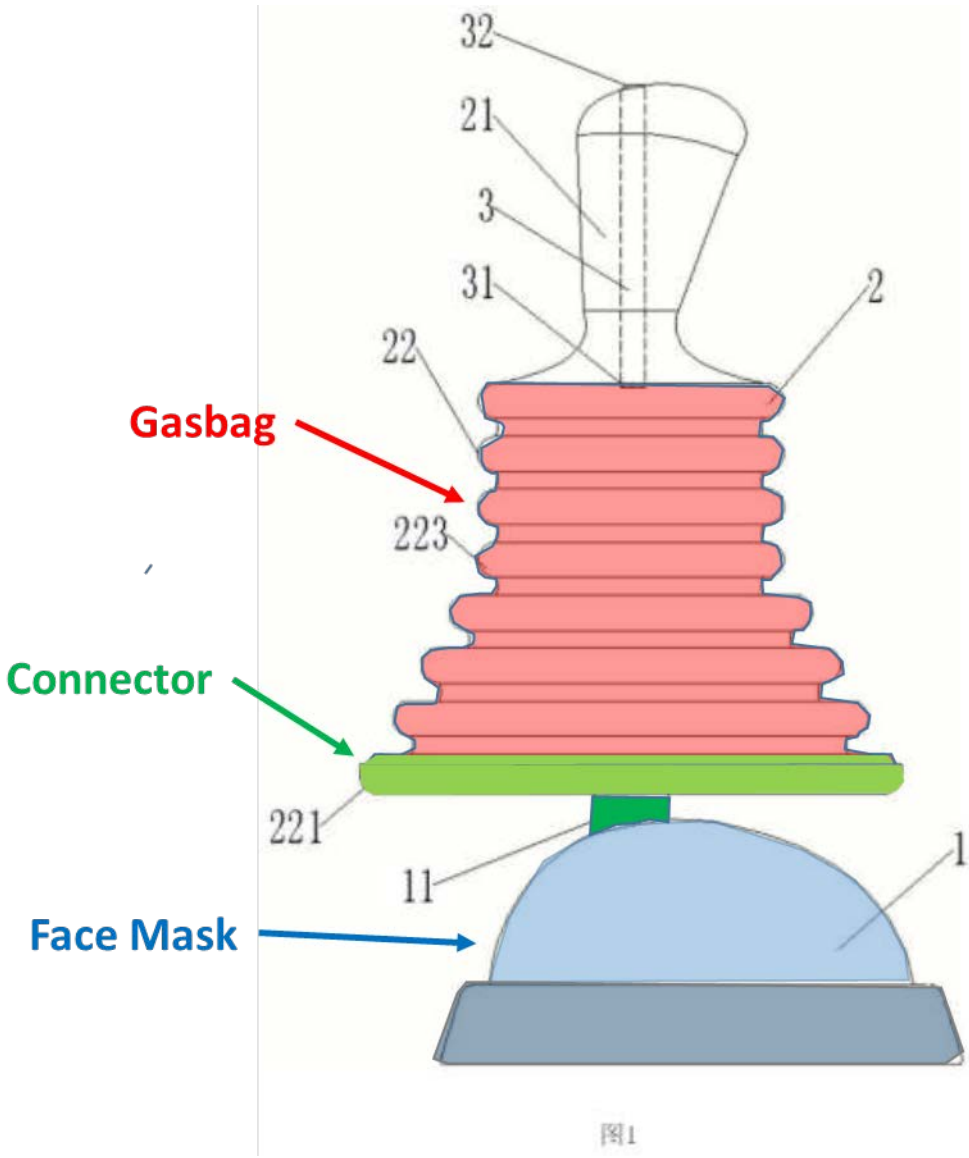
Claim 1

[1.0] A removal device for removing an obstruction in a respiratory tract,

To the extent that the preamble is limiting, Zhongnan discloses a tracheal foreign body suction device [*a removal device for removing an obstruction in a respiratory tract*]:

> The present disclosure provides a tracheal foreign body suction device and method… The present disclosure features the advantages of simple operation and the ability to effectively extract foreign bodies from the trachea, and is applicable to the field of medical devices.

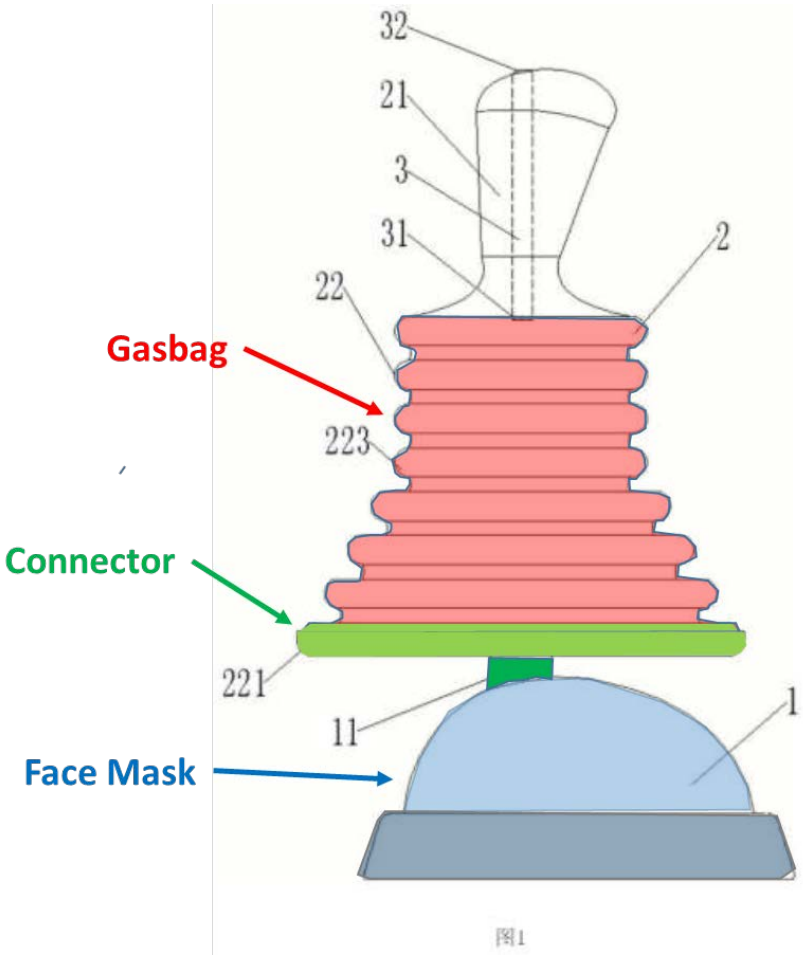
EX-1005 Abstract; *EX-1003* ¶82.



Thus, a POSA understood that Zhongnan discloses element [1.0]. *EX-1003* ¶83.

[1.1] the removal device comprising a collapsible gasbag, a connector and a face mask which are sequentially connected,

Zhongnan discloses that the device includes a suction device [*collapsible gasbag*] (**red**), a base plate [*connector*] (**green**) and a breathing mask [*face mask*] (**blue**) which are sequentially connected. *EX-1003* ¶84.



EX-1005 FIG. 1; *EX-1003* ¶84.

Zhongnan explains:

> The present disclosure provides a tracheal foreign body suction device and method, comprising a breathing mask and a suction device, wherein the breathing mask comprises a ventilation tube, mounted through the breathing mask, with one end of the ventilation tube located outside the breathing mask and connected to the suction device, and the other end

> located inside the breathing mask; the suction device comprises a handle and a suction cup disposed below the handle, wherein the suction cup is a cylindrical body with an open bottom, a base plate is disposed at the open bottom of the cylindrical body.

EX-1005 Abstract; *EX-1003* ¶84.

Thus, a POSA understood that Zhongnan discloses element [1.1]. *EX-1003* ¶85.

[1.2] wherein the collapsible gasbag is internally provided with a gas storage cavity, a top of the collapsible gasbag is sealed, and a bottom of the collapsible gasbag is provided with an opening in communication with the gas storage cavity;

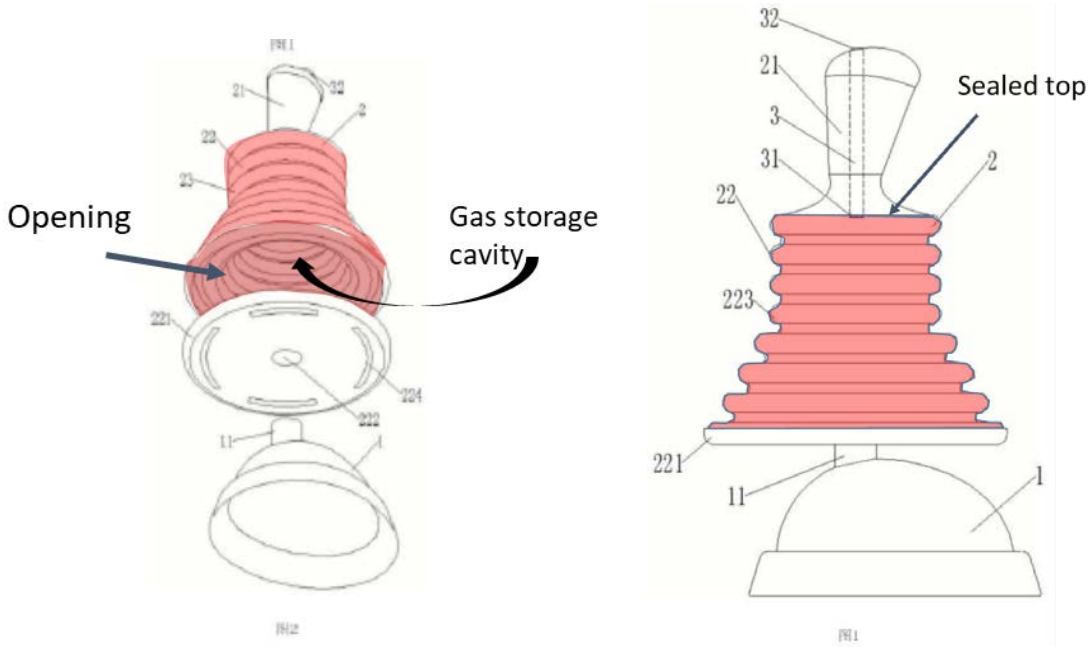
Zhongnan discloses that the suction device/suction cup [*collapsible gasbag*] (**red**) is collapsible and includes an internal cavity for storing air [*internally provided with a gas storage cavity*]. The top of the suction device is sealed by a handle 21 and the bottom is provided with an opening in communication with the interior cavity.

> [T]he suction cup is a cylindrical body with an open bottom,

EX-1005 Abstract; *EX-1003* ¶86.

> with one end of the connecting tube connected to the base plate, the other end extending inward into the cylindrical body and disposed with a one-way inlet valve; and the dimensions of the connecting tube match those of the ventilation tube.

EX-1005 [0007]; *EX-1003* ¶86.



EX-1005 FIGs. 1, 2; *EX-1003* ¶86.

Thus, a POSA understood that Zhongnan discloses element [1.2]. *EX-1003* ¶87.

[1.3] an upper side of the connector is hermetically connected to the opening, and

Zhongnan discloses the upper side of the base plate 221 [*connector*] (**green**) forms a sealed connection [*hermetically connected*] with the opening of the suction device:

a base plate is disposed at the open bottom of the cylindrical body.

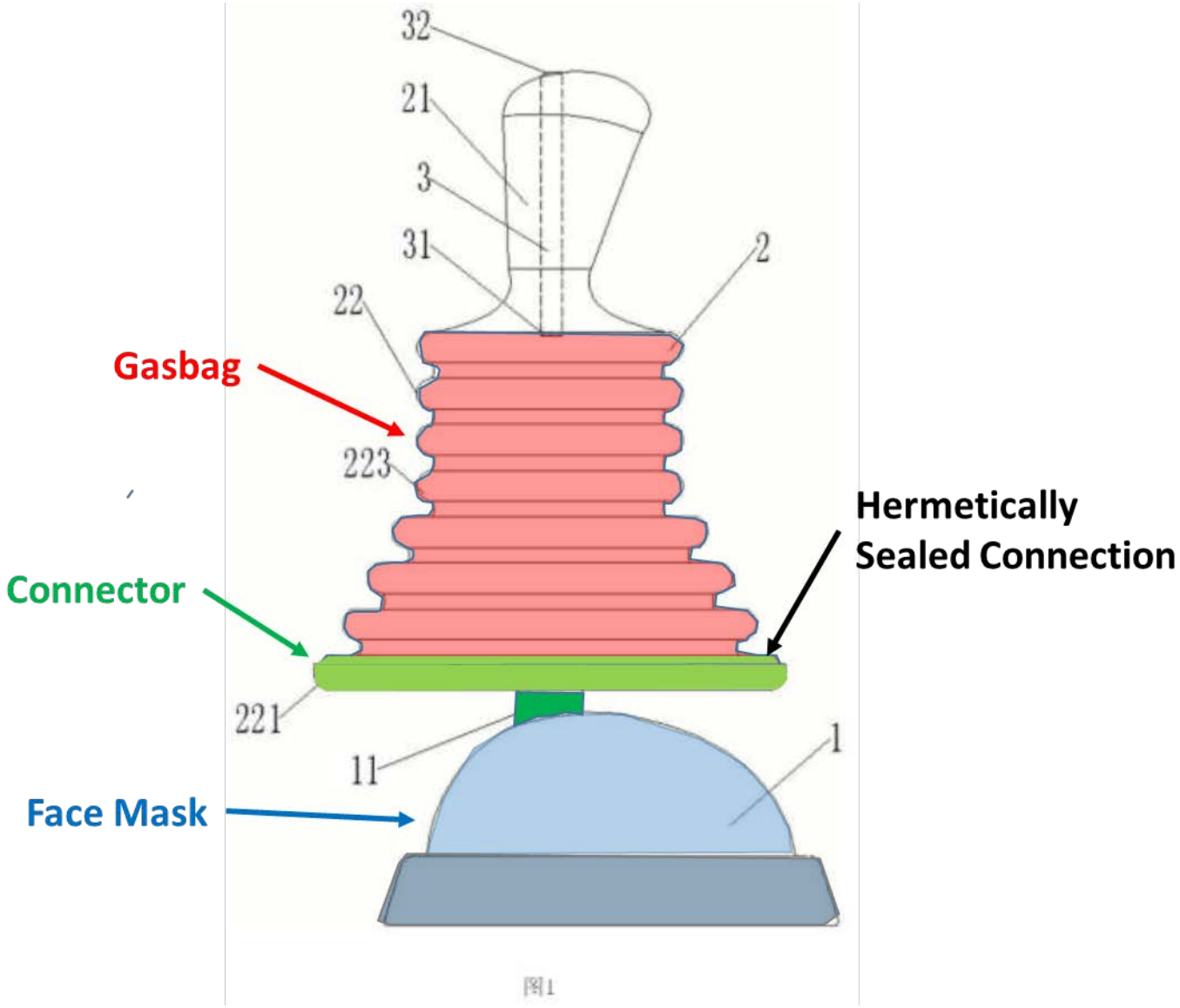
EX-1005 Abstract; *EX-1003* ¶88.

Preferably, the cylindrical body comprises a plurality of grooves arranged sequentially from top to bottom, the groove at the topmost

position is connected to the handle, and the groove at the bottommost position is connected to the base plate.

EX-1005 [0009]; *EX-1003* ¶88.

A POSA understood that in order for the device to operate properly, the connector must be sealed to the gasbag to prevent any leakage of air from the connection between the two as shown below:



EX-1005 FIG. 1; *EX-1003* ¶89.

Thus, a POSA understood that Zhongnan discloses element [1.3]. *EX-1003* ¶90.

[1.4] the connector is provided with a first check valve and a second check valve, a first gas outlet end of the first check valve is in communication with the gas storage cavity, a second gas inlet

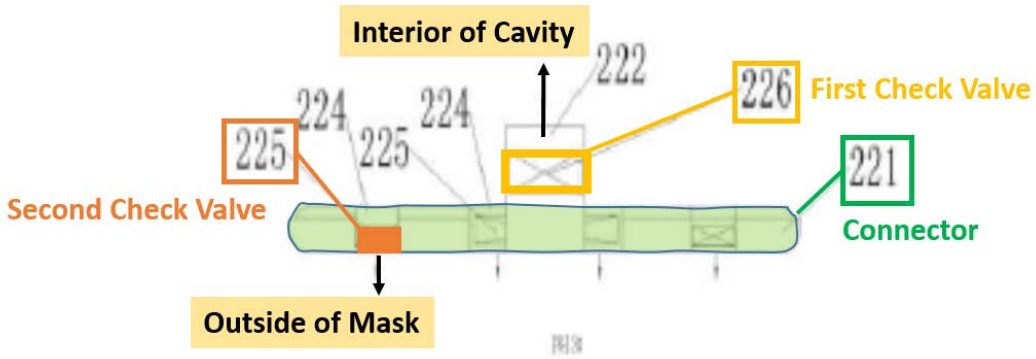
end of the second check valve is in communication with the gas storage cavity, and a second gas outlet end of the second check valve is in communication with the outside; and

Zhongnan discloses that the base plate 221 [*connector*] (**green**) includes an air inlet check valve/one-way inlet valve 226 [*first check valve*] (**gold**) and an outlet one-way valve/one-way exhaust valve 225 [*second check valve*] (**orange**). Air inlet check valve 226 has a first gas outlet end in communication with the interior cavity of the suction device/suction cup 22 [*gas storage cavity*]. The gas inlet end of the outlet one-way valve 225 [*second gas inlet end of the second check valve*] is also in communication with the interior cavity of the suction device 22, and the gas outlet end of the air one-way valve 225 [*second gas outlet end of the second check valve*] is in communication with the outside:

> the base plate is equipped with an air outlet and a connecting tube, a one-way exhaust valve is disposed on the air outlet, with one end of the connecting tube connected to the base plate, the other end extending inward into the cylindrical body and disposed with a one-way inlet valve; and the dimensions of the connecting tube match those of the ventilation tube.

EX-1005 [0007]; *EX-1003* ¶91.

Thus, a POSA understood that the connector included the first and second check valve as shown below:



EX-1005 FIG. 3; *EX-1003* ¶92.

Thus, a POSA understood that Zhongnan discloses element [1.4]. *EX-1003* ¶93.

[1.5] an upper side of the face mask is hermetically connected to a first gas inlet end of the first check valve, and a lower side of the face mask is provided with a flexible annular pad configured to attach to a face,

Zhongnan discloses the upper side of the breathing mask 1 [*face mask*] (**blue**) includes ventilation tube/pipe 11:

> [T]he breathing mask comprises a ventilation tube 11, mounted through the breathing mask 1, with one end of the ventilation tube 11 located outside the breathing mask 1 and connected to the suction device 2, and the other end located inside the breathing mask 1.

EX-1005 [0033]; *EX-1003* ¶93.

Zhongnan further discloses that when the device is in use, the ventilation tube/pipe 11 is inserted into the connecting tube/pipe 222 positioned at the center of the base plate 221 and that the size of the ventilation tube/pipe 11 is matched to

the size of the connecting tube/pipe 222 to form a hermetic connection. One end of the connecting tube/pipe 222 extends inwardly toward the interior cavity of the suction device and is connected to air intake check valve 226 [*first check valve*] such that connecting tube/pipe 222 mates with the gas inlet end of check valve 226 [*first gas inlet end of the first check valve*]:

> S10. attaching the breathing mask to the human face and inserting the ventilation tube into the connecting tube.

EX-1005 [0016]; *EX-1003* ¶94.

> [O]ne end of the connecting tube 222 connected to the base plate 221, the other end extending inward into the cylindrical body and disposed with a one-way inlet valve 226; the dimensions of the connecting tube 222 match the dimensions of the ventilation tube 11.
>
> ***
>
> In this example, the dimensions of the connecting tube 222 match those of the ventilation tube 11, specifically: the diameter of the ventilation tube 11 is slightly larger than that of the connecting tube 222, such that after the connecting tube 222 is inserted into the ventilation tube 11, the outer wall of the connecting tube 222 is in close contact with the inner wall of the ventilation tube 11, thereby improving the airtightness of the suction device.

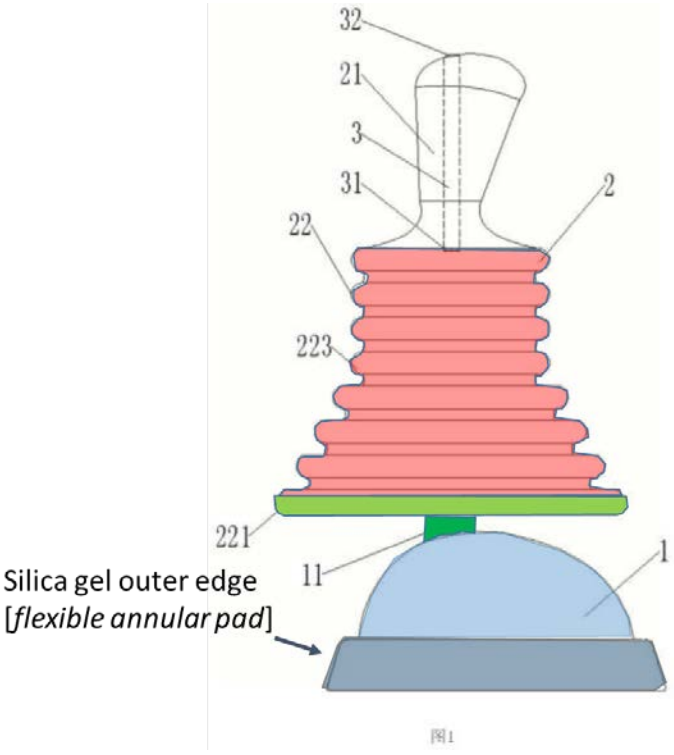
EX-1005 [0034], [0044]; *EX-1003* ¶94.

Thus, a POSA understood that an upper side of the mask 1 is hermetically connected to the gas inlet end of check valve/one-way inlet valve 226. *EX-1003* ¶95.

Zhongnan further discloses that the lower side of the breathing mask 1 [*face mask*] that is placed adjacent the face of a choking patient includes a flexible outer edge of silica gel [*flexible annular pad*] that "shape fits the face" of the patient:

> Specifically, in this example, the outer edge of the breathing mask 1 is made of medical-grade silicone and is shaped to fit the face. Both the breathing mask 1 and the suction device 2 are made of transparent materials, allowing for easy observation of whether the foreign body has been suctioned out.

EX-1005 [0041]; *EX-1003* ¶96.



EX-1005 FIG. 3; *EX-1003* ¶96.

Thus, a POSA understood that Zhongnan discloses element [1.5]. *EX-1003* ¶97.

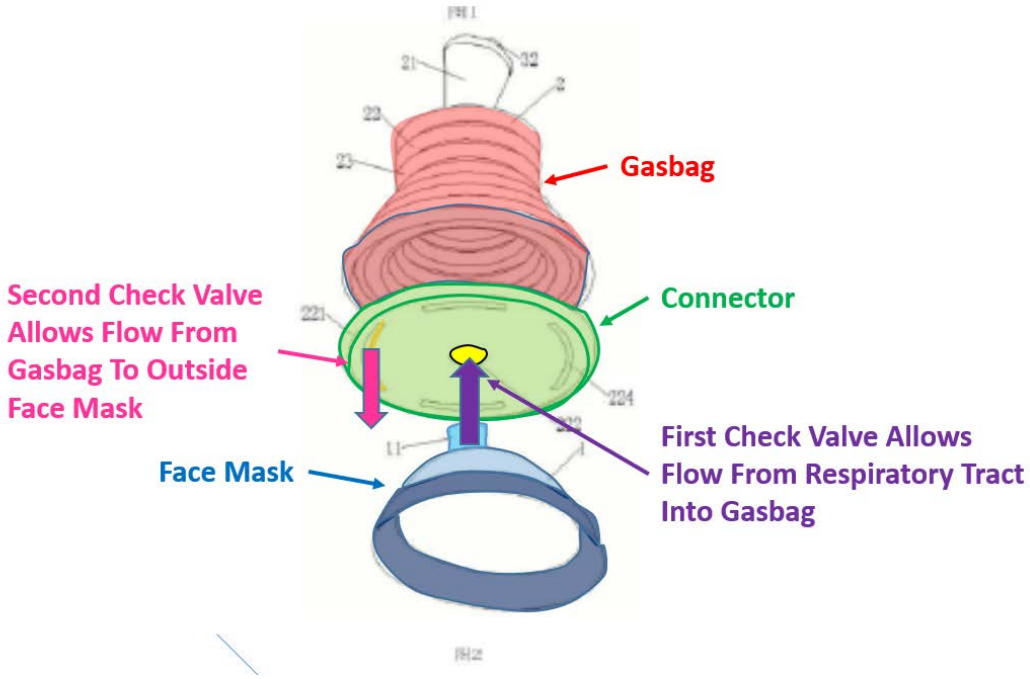
[1.6] wherein the connector comprises a bottom plate and the first check valve and the second check valve are arranged on the bottom plate, wherein the first check valve and the second check valve allow gas flow to pass in opposite directions.

Zhongnan discloses the base plate 221 [*connector*] (**green**) includes a bottom plate and the inlet check valve/one-way inlet valve 226 [*first check valve*] (**gold**) and the outlet one-way valve/one-way exhaust valve 225 [*second check valve*] (**orange**) are arranged on the bottom plate. The inlet check valve 226 allows air flow from inside the mask into the interior cavity of the suction device (**purple arrows**) and the outlet one-way valve 225 allows air flow from the interior of the cavity to outside the mask (**magenta arrows**) to exit the suction device. A POSA understood these air flows are in opposite directions as shown in the annotated figures below:

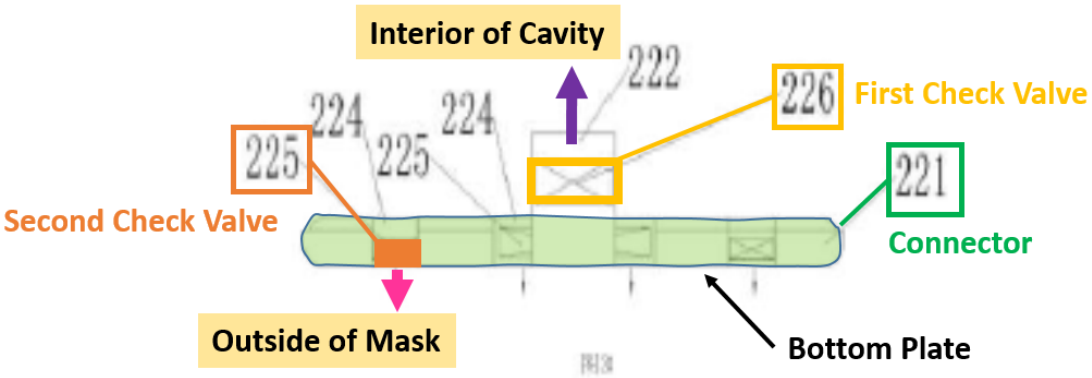
> S20. pressing down the handle, driving the cylindrical body to press toward the face; the airflow created inside the cylindrical body flows downward, the one-way exhaust valve opens, the one-way inlet valve closes, and the airflow is discharged through the air outlet, creating a negative pressure inside the cylindrical body;

S30. pulling up the handle; the one-way exhaust valve closes, and the one-way inlet valve opens; under the effect of the negative pressure, the foreign body in the trachea is suctioned out therefrom.

EX-1005 [0038-0039]; *EX-1003* ¶98.



EX-1005 FIG. 2; *EX-1003* ¶98.



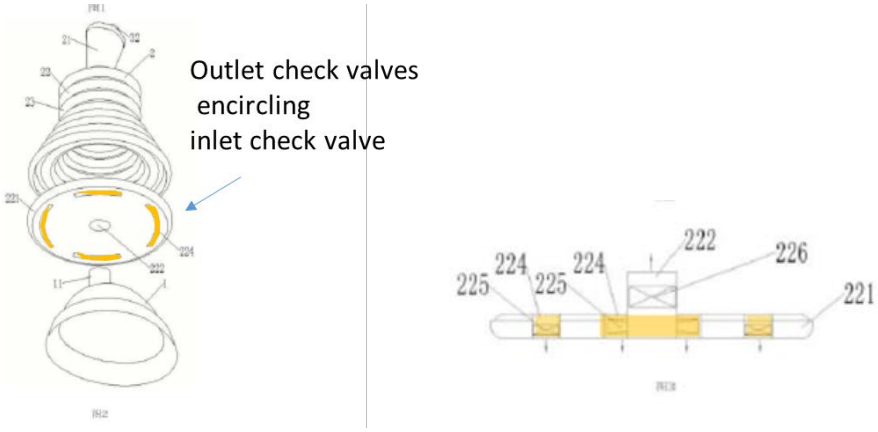
EX-1005 FIG 3; *EX-1003* ¶98.

Thus, a POSA understood that Zhongnan discloses element [1.6]. *EX-1003* ¶99.

Claim 2

> ***The removal device for removing the obstruction in the respiratory tract according to claim 1, wherein the connector is provided with a plurality of second check valves, the plurality of second check valves encircling the first check valve.***

Zhongnan discloses that the base plate 221 [*connector*] includes a plurality of one-way exhaust valves 225 [*second check valves*] positioned at the outlets 224 around the periphery of base plate 221 and encircling the one-way inlet valve 226 [*first check valve*] positioned at the connecting tube/pipe 222 at the center of the base plate 221.



EX-1005 FIGs. 2, 3; *EX-1003* ¶100.

Thus, a POSA understood that Zhongnan discloses the additional limitations recited in Claim 2. *EX-1003* ¶101.

Claim 7

The removal device for removing the obstruction in the respiratory tract according to claim 1, wherein a top wall of the collapsible gasbag is connected to a handle for holding.

Zhongnan discloses a handle 21 at the top of the suction device/cup 22 [*collapsible gasbag*].

> On the basis of Embodiment 1, a cylindrical body of the tracheal foreign body suction device comprises: a plurality of grooves 223 arranged sequentially from top to bottom, the groove 223 at the topmost position is connected to the handle 21, and the groove 223 at the bottommost position is connected to the base plate 221.

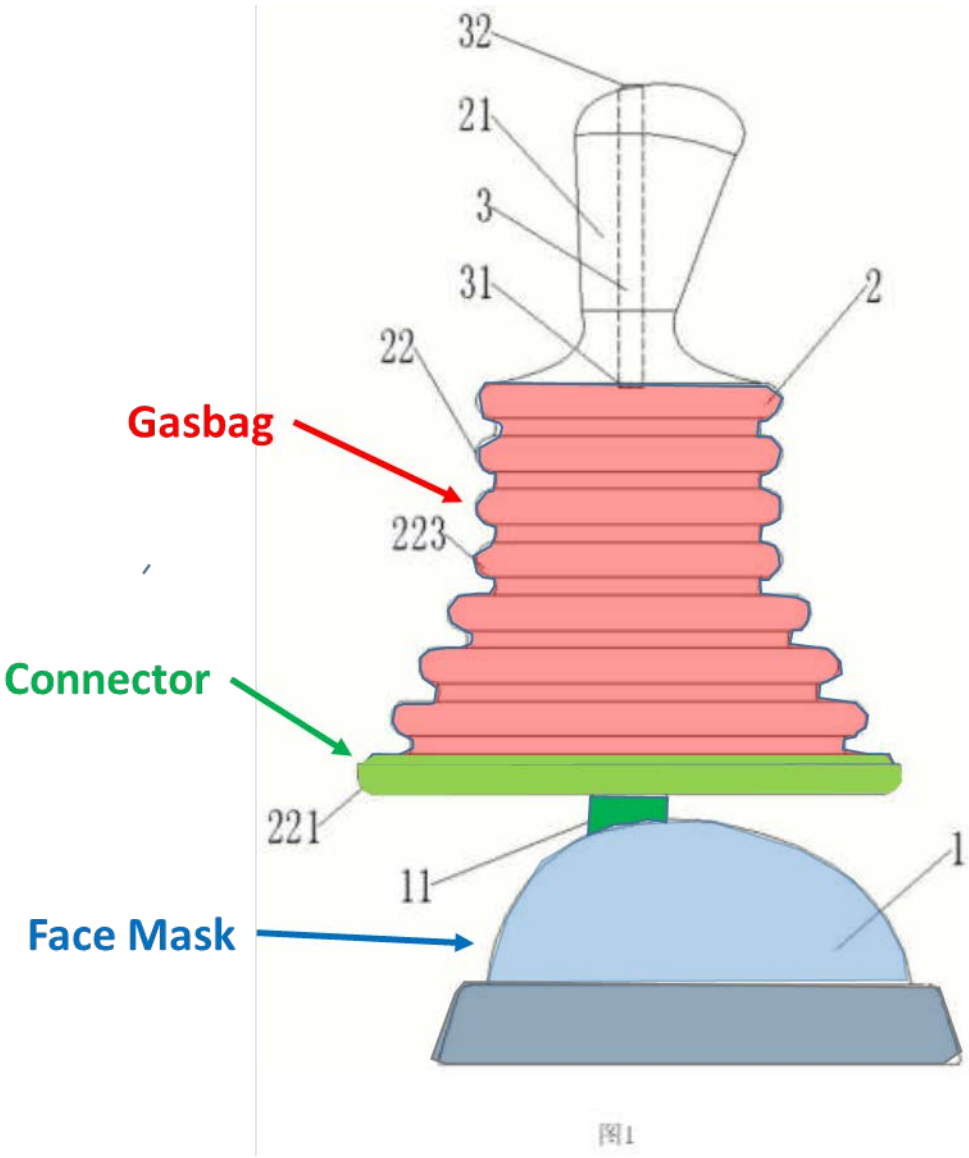
EX-1005 [0050]; *EX-1003* ¶102.

Thus, a POSA understood that Zhongnan discloses the additional limitations recited in Claim 7. *EX-1003* ¶103.

Claim 11

The removal device for removing the obstruction in the respiratory tract according to claim 1, wherein the face mask, the connector and the collapsible gasbag are integral.

Zhongnan discloses the breathing mask 1 [*face mask*], base plate 221 [*connector*] and suction cup 22 [*collapsible gasbag*] are sequentially coupled and are integral in the assembled device. *EX-1003* ¶104.



EX-1005 FIG. 1; *EX-1003* ¶104.

Thus, a POSA understood that Zhongnan discloses the additional limitations recited in Claim 11. *EX-1003* ¶105.

Claim 12

> ***The removal device for removing the obstruction in the respiratory tract according to claim 1, wherein the collapsible gasbag is not provided with a vent hole which is in direct communication with the outside.***

Zhongnan discloses that the suction cup/cylindrical body 22 [*collapsible gasbag*] vents indirectly via the base plate 221 [*connector*] through outlets 224 to the outside:

> a base plate 221 is disposed at the open bottom of the cylindrical body, and the base plate 221 is equipped with an air outlet 224 and a connecting tube 222, a one-way exhaust valve 225 is disposed on the air outlet 224,

EX-1005 [0034]; *EX-1003* ¶106.

A POSA understood that the cylindrical body/suction cup 22 [*collapsible gasbag*] is provided with no vent hole that is in direct communication with the outside. Thus, a POSA understood that Zhongnan discloses the additional limitations recited in Claim 12. *EX-1003* ¶107.

Claim 13

> ***A connector for a removal device, the connector comprising a bottom plate, and a first check valve and a second check valve which are arranged on the bottom plate, wherein the first check valve and the second check valve allow gas flow to pass in opposite directions; and the connector is an integrally formed member made from an elastic material.***

For at least the reasons set forth with respect to element [1.6], Zhongnan discloses "*A connector for a removal device, the connector comprising a bottom plate, and a first check valve and a second check valve which are arranged on the*

bottom plate, wherein the first check valve and the second check valve allow gas flow to pass in opposite directions;" as recited in Claim 13. *EX-1003* ¶108.

In addition, Zhongnan discloses the base plate 221 [*connector*] is an integrally formed member with other elements on the connector:

> Preferably, the base plate and the connecting tube are an integrally formed structure.

EX-1005 [0013]; *EX-1003* ¶109.

Zhongnan, while disclosing portions of the device, such as the gasbag and the facemask are formed from elastic material, does not explicitly disclose the base plate is constructed of such. *EX-1005* [0011], [0014] and [0043]. However, a POSA understood that in order to maintain an airtight seal during operation, the connector would need to flex with the gasbag and the facemask, and thus an elastic material would be used for the connector. *EX-1003* ¶110.

To the extent that PO argues that Zhongnan does not explicitly state that the connector is made from an elastic material, it would have been obvious to a POSA to form the base plate with an elastic material such as plastic. A POSA would have been motivated to make the base plate from an elastic material such as plastic and would have a reasonable expectation of success for the following reasons:

(i) A POSA understood patient face conforming breathing medical devices for hygienic, economic and physical trauma reasons are routinely made of elastic

material that allow flexibility to ensure a proper seal, and furthermore, the elastic nature would improve assembly ease; and

(ii) Zhongnan discloses that the base plate as part of the suction device is preferably made of a transparent material. A POSA understood that plastic can be a relatively economically producible and readily available transparent material, and a POSA would also have been motivated to make the base plate out of an elastic material for its transparent and economic characteristics. *EX-1003* ¶111.

Thus, a POSA understood that Claim 13 is disclosed by, or obvious over Zhongnan. *EX-1003* ¶112.

Claim 14

> ***The connector according to claim 13, wherein the connector is provided with one first check valve and a plurality of second check valves, the plurality of second check valves encircling the first check valve.***

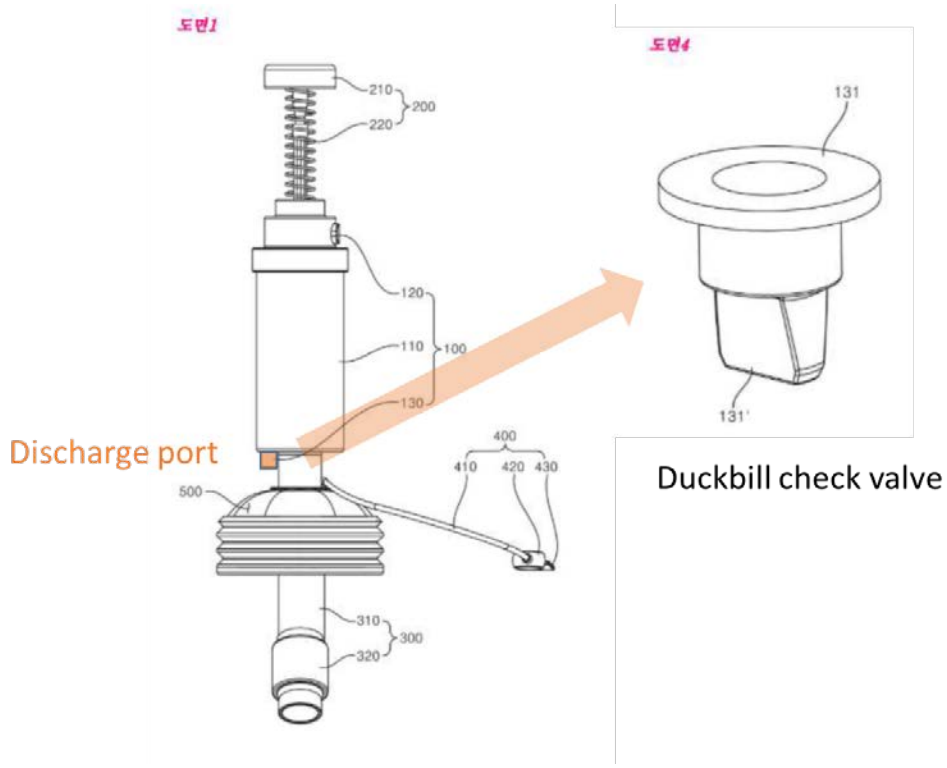
See Claim 2.

B. Challenge 2 Claims 3-6, 8-12, and 15-17 are rendered unpatentable over Zhongnan in view of Yuchang.

1. The Yuchang Reference

Yuchang relates to an anti-choking apparatus for removing foreign substances from the esophagus. The apparatus includes: a case 100 (*i.e.,* cylinder and plunger) for generating vacuum pressure by discharging or introducing air; an insertion tube 300 connected to the bottom of the case 100 and inserted into the

oral cavity of a person whose esophagus is blocked; and a close-fitting mask 500 that is fastened in a structure through which the insertion tube (300) passes, and is in close contact with the surroundings of the oral cavity of the person whose esophagus is blocked. Yuchang discloses that the case includes an air outlet/discharge port 130 (**orange**) which houses a duckbill check valve 131 to discharge air from the case to the outside. *EX-1009*, FIGs. 1, 4, Abstract, [0036]; *EX-1003* ¶114.



EX-1009, Figs. 1, 4; *EX-1003* ¶114.

2. Detailed Application of Zhongnan and Yuchang to the Challenged Claims

Claim 3

[3.0] A removal device for removing an obstruction in a respiratory tract,

See Claim [1.0].

[3.1] the removal device comprising a collapsible gasbag, a connector and a face mask which are sequentially connected,

See Claim [1.1].

[3.2] wherein the collapsible gasbag is internally provided with a gas storage cavity, the top of the collapsible gasbag is sealed, and the bottom of the collapsible gasbag is provided with an opening in communication with the gas storage cavity;

See Claim [1.2].

[3.3] an upper side of the connector is hermetically connected to the opening, and

See Claim [1.3].

[3.4] the connector is provided with a first check valve and a second check valve; a first gas outlet end of the first check valve is in communication with the gas storage cavity, a second gas inlet end of the second check valve is in communication with the gas storage cavity, and a second gas outlet end of the second check valve is in communication with the outside; and

See Claim [1.4].

[3.5] an upper side of the face mask is hermetically connected to a first gas inlet end of the first check valve, and a

lower side of the face mask is provided with a flexible annular pad configured to attach to a face,

See Claim [1.5].

[3.6] wherein the connector is provided with a bottom plate,

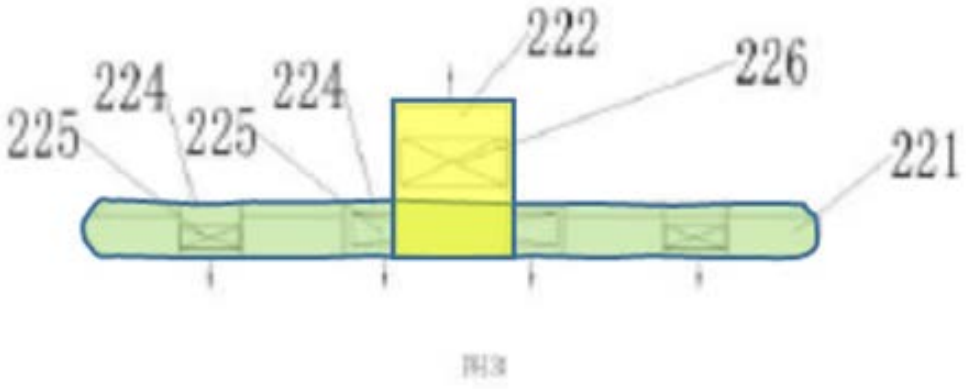
See Claim [1.6].

[3.7] the bottom plate being provided with a central cylinder which is vertically through;

Zhongnan discloses a base plate 221 includes a connecting pipe 222 [*central cylinder*] vertically there through:

> Fig. 3 is a schematic diagram of the base plate of the present disclosure;
>
> In the drawings: 1 represents a breathing mask, 2 represents a suction device, and 3 represents a spotlight;
>
> 11 represents a ventilation tube; 21 represents a handle, 22 represents a suction cup; 31 represents a lamp head, and 32 represents a switch;
>
> 221 represents a base plate, 222 represents a connecting tube, 223 represents a groove, 224 represents an air outlet, 225 represents a one-way exhaust valve, and 226 represents a one-way inlet valve.

EX-1005 [0026-0028]; *EX-1003* ¶122.



EX-1005 Figs. 2, 3; *EX-1003* ¶122.

[3.8] the first check valve is of a hollowed structure made from an elastic material, and comprises a deformed portion and a first base portion which are connected to each other; the first gas outlet end is composed of at least three first slits provided at a top end of the deformed portion; one end, extending toward the center, of the at least three first slits intersect at the same point, and the first gas inlet end is a first vent hole provided in the middle of the first base portion; the first base portion extends into the central cylinder, and an outer side of the first base portion is hermetically connected to an inner side of the central cylinder; a lower end of the central cylinder is hermetically connected to an upper side of the face mask; the deformation portion is exposed out of the central cylinder and extends into the gas storage cavity; when gas flows into the deformation portion through the first vent hole, pressure in the deformation portion gradually increases such that the deformation portion is deformed by expansion, so that the at least three first slits are opened, thereby allowing the gas on the side of the first vent hole to flow into the gas storage cavity; and when the gas flowing into the deformation portion through the first vent hole is reduced or disappears, pressure in the deformation portion is reduced

and even reduced to zero, and the deformation portion shrinks under its own elasticity such that the three first slits are closed, thereby preventing the gas in the gas storage cavity from flowing out of the first vent hole.

Zhongnan, while disclosing an one way inlet valve 226 [*first check valve*], does not disclose a specific type of check valve. However, as discussed in the State of the Art section, the use of a cross-slit check valve [*first check valve*] in association with tracheal respiratory device was well-known. Specifically, the operation of a cross-slit valve is well-known. When gas flows into the deformation portion through the vent hole during an exhale, pressure in the deformation portion gradually increases such that the deformation portion is deformed by expansion, so that the slits are opened, thereby allowing the gas on the lower side of the vent hole to flow into the upper trachea; and when the gas flowing into the deformation portion through the first vent hole is reduced or disappears as during an inhale, pressure in the deformation portion is reduced and the deformation portion shrinks under its own elasticity such that the slits are closed, thereby preventing the gas in the upper trachea from flowing through the vent hole. *EX-1012*; *EX-1003* ¶123.

Thus, it was obvious for POSA to modify the teaching of Zhongnan to use a well-known cross-slit valve would share the same location and perform the identical function of the one way inlet valve taught by Zhongnan. A POSA would have been motivated to select a cross-slit valve because it was a commonly used

type of check valve in medical devices having well known properties of low cost, ease of production, ready availability and reliable operation. Duckbill check valves as discussed earlier are generally more reliable than a 3 or 4 slit check valve, but valve function at the air inlet is not as critical as the outlet because comparable negative pressure can still be generated even if the air inlet valve failed by leaking. This means reliability becomes less of a factor than minimizing flow resistance and pressure which justifies the selection of 3 or 4 slit check valves. A POSA would have also been motivated to make the selection because cross-slit check valves are one of a limited number of check valve types that would meet the cost and function required of the check valves in the device of Zhongnan. *EX-1003* ¶124.

A POSA understood the installation/attachment structure was merely a routine design choice readily within grasp of a POSA, and independent of the function of the check valve. *EX-1003* ¶125.

Further, a POSA would be confident of success in the selection given the ubiquitous and wide ranging use of cross-slit check valves and well known functional characteristics. *EX-1003* ¶126.

Claim 4

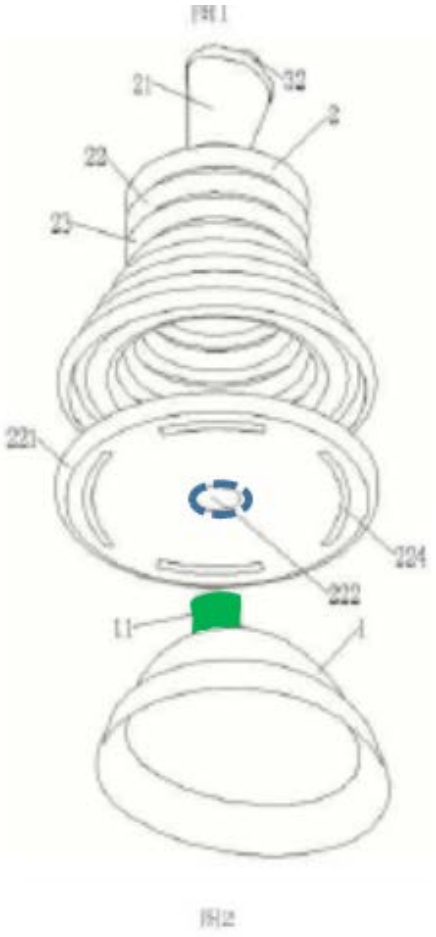
> ***The removal device for removing the obstruction in the respiratory tract according to claim 3, wherein the upper side of the face mask is provided with a connecting cylinder which is vertically through in the middle, the connecting cylinder being***

inserted into the inner side of the lower end of the central cylinder from bottom to top, and an outer side of the connecting cylinder being hermetically connected to the inner side of the central cylinder.

Zhongnan discloses ventilation tube 11 [*connecting cylinder*] (green) on the upper side of the breathing mask inserted vertically through the middle. The ventilation tube/pipe 11 of Zhongnan being inserted into the inner side of the connecting tube 222 [*central cylinder*] (dashed blue) from bottom to top and the interaction of the outside of the ventilation tube and the inside of the connecting pipe form an air seal.

> In this example, the dimensions of the connecting tube 222 match those of the ventilation tube 11, specifically: the diameter of the ventilation tube 11 is slightly larger than that of the connecting tube 222, such that after the connecting tube 222 is inserted into the ventilation tube 11, the outer wall of the connecting tube 222 is in close contact with the inner wall of the ventilation tube 11, thereby improving the airtightness of the suction device.

EX-1005 [0044]; *EX-1003* ¶127.



EX-1005 Fig. 2; *EX-1003* ¶127.

Claim 5

The removal device for removing the obstruction in the respiratory tract according to claim 3, wherein an upper side of the bottom plate is provided with a first peripheral side wall encircling the central cylinder,

an upper end of the first peripheral side wall shrinking inward to form a stop edge;

the collapsible gasbag is provided with a second peripheral side wall made from an elastic material, the second peripheral side wall being provided with a plurality of layers of outwardly convex folds; and the first peripheral side wall covers the lowermost fold

of the second peripheral side wall, and the stop edge covers an upper side of the lowermost fold.

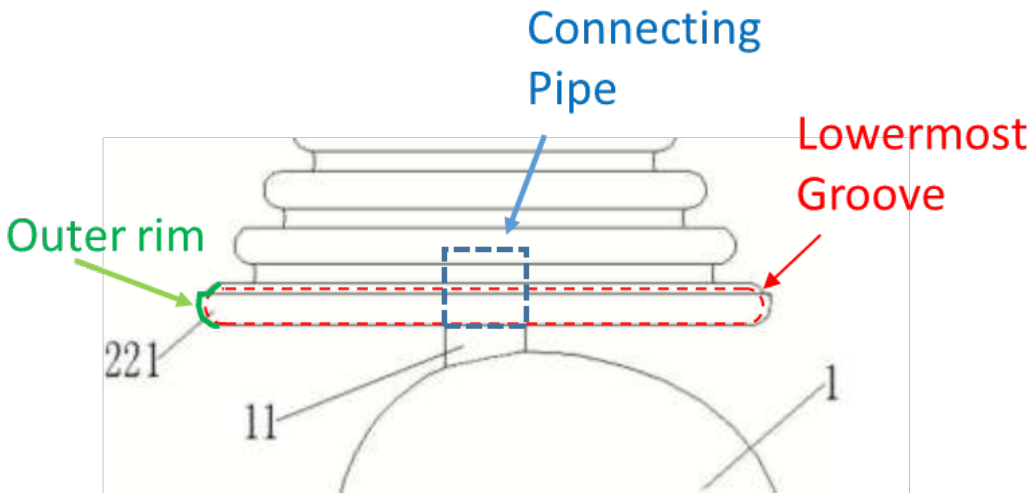
Zhongnan discloses an upper side of the base plate includes a rim structure [*first peripheral side wall*] (**green**) encircling the connecting tube/pipe 222 [*central cylinder*] (**blue**). The rim structure has an upper end that shrinks radially inward to form a stop edge. Zhongnan further discloses the suction device 2 includes a second peripheral side wall, made from an elastic material, and the second peripheral side wall is formed from a plurality of grooves [*layers of outwardly convex folds*]. The rim structure covers the lowermost groove (red) and the stop edge covers the upper side of the lowermost rib.

> On the basis of Embodiment 1, a cylindrical body of the tracheal foreign body suction device comprises: a plurality of grooves 223 arranged sequentially from top to bottom, the groove 223 at the topmost position is connected to the handle 21, and the groove 223 at the bottommost position is connected to the base plate 221.

EX-1005 [0050]; *EX-1003* ¶128.

> Moreover, the cylindrical body is made of a deformable elastic material, such as rubber.

EX-1005 [0043]; *EX-1003* ¶128.



EX-1005 FIG. 1; *EX-1003* ¶128.

Thus, a POSA understood that Zhongnan discloses the additional limitations recited in Claim 5. *EX-1003* ¶129.

Claim 6

> ***The removal device for removing the obstruction in the respiratory tract according to claim 5, wherein a plurality of reinforcement strips are arranged on the upper side of the bottom plate, two opposite ends of each reinforcement strip being separately connected to the inner side of the first peripheral side wall and the outer side of the central cylinder.***

Zhongnan does not disclose reinforcement strips on the upper side of the bottom plate, however the use of reinforcement strips (*e.g.,* corrugations, ribs, gussets, webs, flanges etc.) were well known to a POSA, and thus it would have been obvious to a POSA to include a plurality of reinforcement strips on the upper surface of the base plate in a radial arrangement between the rim structure and the connecting pipe of Zhongnan. *EX-1003* ¶130.

A POSA was motivated to stiffen the bottom plate via reinforcement strips to achieve the dual goals of allow elastic movement of the connector while maintaining an airtight seal during the mechanical operation of the device. A POSA understood that excessive deformation could compromise the air tight connection between the base plate and cylindrical body and/or between the connecting tube and the ventilation pipe, which in turn compromises the operation and durability of the device. Additionally, a POSA understood the excessive deformation of the base plate may reduce the device's effectiveness in drawing a vacuum, as excessive deformation would deform the cylindrical body's circular shape, which resists the pressure differential generated by the suction device in order to dislodge the obstruction. *EX-1003* ¶131.

A POSA also understood that reinforcement strips are a cost effective manner to stiffen elastic structures, they are easily incorporated in a mold, and reduce material cost verses the alternatives of increasing bulk and adding different material. Given the long use of such reinforcement strips, a POSA would be extremely confident of success in the implementation of reinforcement strips onto the bottom plate in a radial orientation. *EX-1003* ¶132.

Claim 8

> ***The removal device for removing the obstruction in the respiratory tract according to claim 3, wherein four first slits are provided, the four first slits being in the shape of a cross.***

This limitation is described for the same reasons as described with respect to Claim 3. *EX-1003* ¶133.

Claim 9

[9.0] A removal device for removing an obstruction in a respiratory tract,

See Claim [1.0].

[9.1] the removal device comprising a collapsible gasbag, a connector and a face mask which are sequentially connected,

See Claim [1.1].

[9.2] wherein the collapsible gasbag is internally provided with a gas storage cavity, the top of the collapsible gasbag is sealed, and the bottom of the collapsible gasbag is provided with an opening in communication with the gas storage cavity;

See Claim [1.2].

[9.3] an upper side of the connector is hermetically connected to the opening, and

See Claim [1.3].

[9.4] the connector is provided with a first check valve and a second check valve; a first gas outlet end of the first check valve is in communication with the gas storage cavity, a second gas inlet end of the second check valve is in communication with the gas storage cavity, and a second gas outlet end of the second check valve is in communication with the outside; and

See Claim [1.4].

[9.5] an upper side of the face mask is hermetically connected to a first gas inlet end of the first check valve, and a lower side of the face mask is provided with a flexible annular pad configured to attach to a face,

See Claim [1.5].

[9.6] wherein the connector is provided with a bottom plate,

See Claim [1.6].

[9.7] the bottom plate being provided with a peripheral cylinder which is vertically through; the second check valve is a duckbill valve, the second check valve comprises a duckbill portion and a second base portion which are connected to each other, the second gas inlet end is a second vent hole provided in the middle of the second base portion, and the second gas outlet end is a second slit provided in the duckbill portion; an outer side of the second base portion is hermetically connected to an inner side of the peripheral cylinder, and the second vent hole of the second base portion is in communication with the gas storage cavity; the duckbill portion extends into the peripheral cylinder, and a lower end of the peripheral cylinder is in communication with the outside; when gas flows into the duckbill portion through the second vent hole, pressure in the duckbill portion gradually increases such that the duckbill portion is deformed by expansion, so that the second slit is opened, thereby allowing gas in the gas storage cavity to be discharged to the outside; and when gas flowing into the duckbill portion through the second vent hole, pressure in the deformation portion is reduced and even reduced to zero, and the duckbill portion shrinks under its own elasticity such that the second slit is closed, thereby preventing outside gas from flowing into the gas storage cavity through the second vent hole.

Zhongnan, while disclosing an one-way exhaust valve [*second check valve*], does not disclose a specific type of check valve. However, as discussed above in the State of the Art section, a duckbill check valve was well-known for ventilation purposes. For example, Yuchang discloses the use of an air exhaust element 131 [*duckbill valve*] (**orange**) in an anti-choking device. Yuchang discloses that the air exhaust element 131 discharges air inside the case [*gas storage cavity*] in response to an increase in pressure inside the case 110, and prevents external air from flowing into the case through the air exhaust element 131:

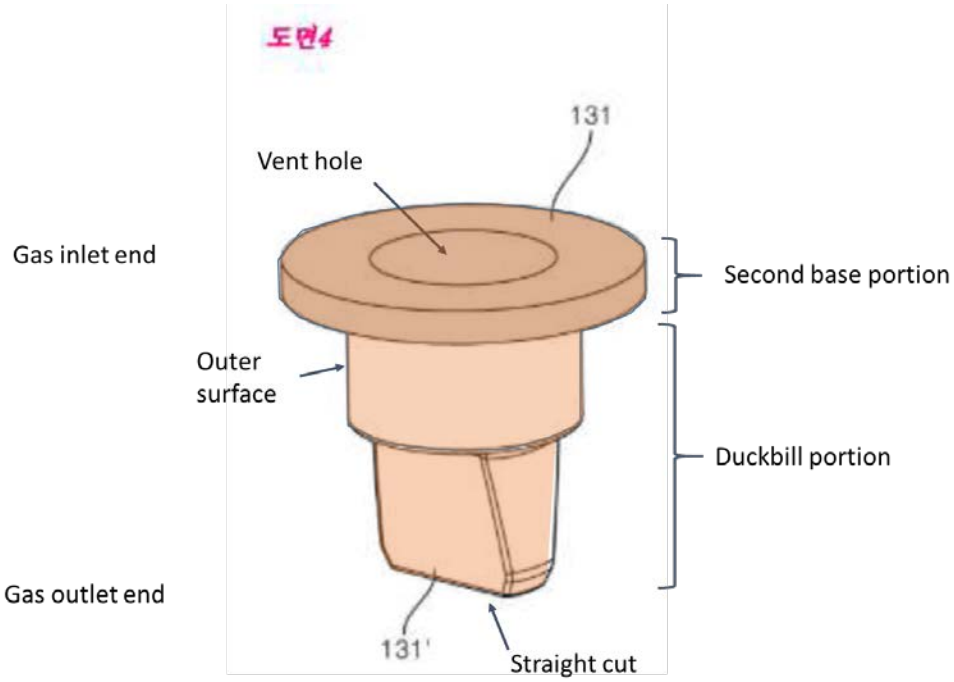
> And the air outlet (130) corresponding to the passage through which air is exhausted inside the case (110) is housed with the air exhaust element (131) as shown in FIG. 4. When the pressurized section (200) is compressed, the air inside the case (110) must be rapidly discharged to the outside with limited movement to the insertion tube (300), for which the air exhaust element (131) is a cylindrical shape on the top part through, and the bottom part is a nip shape with a lower cross-sectional area and an ejection section(131') which is cut straight through and close to each other.
>
> Here, it is preferred that the air exhaust element (131) consists of an elastic material, such as silicon or rubber, because the ejection section (131′) is easily opened when the air of the case (110) is vented, and it is **advantageous to prevent the outside air from entering the ejection section (131′) when the inside of the case (110) is under negative pressure**.

EX-1009 [0036], [0037]; *EX-1003* ¶141.

> The device for removing foreign substances from the esophagus of the present invention is also characterized in that **an air exhaust element (131) capable of discharging air inside the case (110) and blocking the inflow of external air is accommodated in the air outlet (130).**

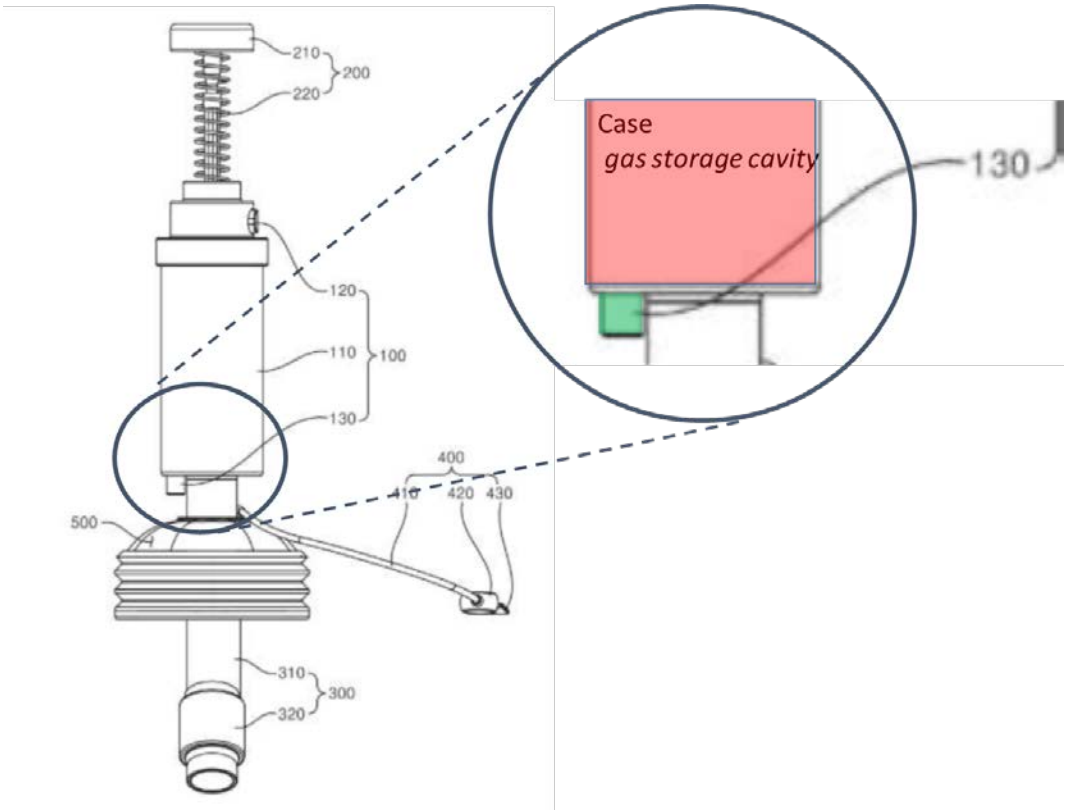
EX-1009 [0018]; *EX-1003* ¶141.

A POSA understood that the air exhaust member 131 of Yuchang to be a duckbill valve. *EX-1003* ¶142. The second base portion (**dark orange**) of the air exhaust element 131 has a vent hole in the middle and the duckbill portion (**orange**) at second gas outlet end has a straight cut [*second slit*].



EX-1009 FIG. 4; *EX-1003* ¶142.

Yuchang discloses the air exhaust member 131 is accommodated in an air outlet 130 [*peripheral cylinder*] in a bottom plate of the case 110. *EX-1009* [0036], Fig. 1; *EX-1003* ¶143.



EX-1009 Fig. 1; *EX-1003* ¶143.

The vent hole of the second base portion (**dark orange**) is in communication with the gas storage cavity (**red**). As understood by a POSA, the duckbill portion extends into the air outlet 130 (green)[*peripheral cylinder*], and the lower end of the air outlet 130 is in communication with the external air. The outer surface of the duckbill portion is in contact with the inner surface of the air outlet port 130 forming an airtight seal. *EX-1009* [0018, Figs. 1, 4; *EX-1003* ¶144.

From the known operation of a duckbill valve and as used in Yuchang, a POSA understood that when gas flows into the duckbill portion through the second vent hole, pressure in the duckbill portion gradually increases such that the duckbill portion is deformed by expansion, so that the straight cut is opened, thereby allowing gas in the case to be discharged externally; and when gas flowing into the duckbill portion through the second vent hole, pressure in the deformation portion is reduced and even reduced to zero, and the duckbill portion shrinks under its own elasticity such that the straight cut is closed, thus preventing outside gas from flowing into the gas storage cavity through the second vent hole. *EX-1009* [0018] [0036], [0037]; *EX-1003* ¶145.

It would have been obvious to a POSA to modify the teachings of Zhongnan's air exhaust one-way valve with Yuchang's teaching of a duckbill valve because the duckbill valve apparatus would share the same location and perform the identical function of the air exhaust one-way valve. A POSA was motivated to use a duckbill valve given the long use and well known properties low cost, ready availability and reliable operation. A POSA would also have been motivated to make the selection as duckbill valves are one of a limited number of check valve types that would meet the cost and function required of the check valves in the device of Zhongnan. *EX-1003* ¶146.

To the extent the PO argues the manner in which the duckbill valve of Yuchang is installed differs from the installation manner claimed, a POSA understood the installation/attachment structure was merely a routine design choice readily within grasp of a POSA, and independent of the function of the check valve. *EX-1003* ¶147.

A POSA would be confident of success in the modification given the ubiquitous and wide-ranging use of duckbill valves and well-known functional characteristics. *EX-1003* ¶148.

Claim 10

The removal device for removing the obstruction in the respiratory tract according to claim 1, wherein the connector is an integrally formed member made from an elastic material.

See Claim 13.

Claim 15

[15.0] The connector according to claim 14, wherein the bottom plate is provided with a central cylinder which is vertically through;

See Claim [3.7].

[15.1] the first check valve is of a hollowed structure and comprises a deformed portion and a first base portion which are connected to each other, and a first gas outlet end and a second vent hole of the first check valve are provided in the deformed portion and the first base portion respectively; the first gas outlet end is composed of at least three first slits provided at a top end of the deformed portion, one ends, extending toward the center, of the at least

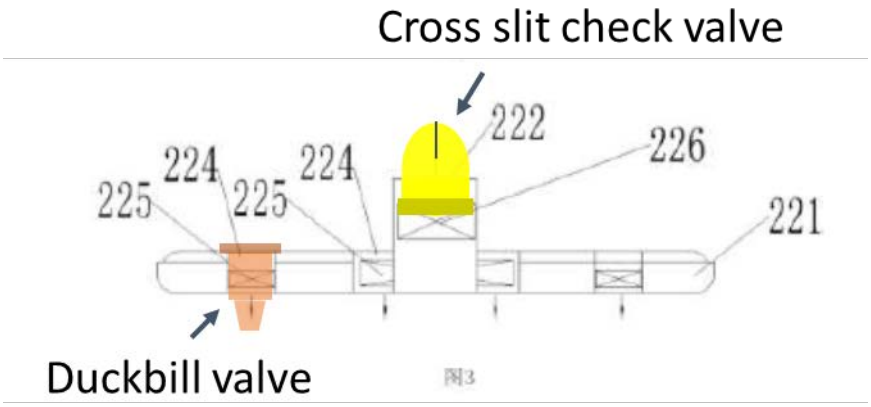
three first slits intersecting at the same point; and the first gas inlet end is a first vent hole provided in the middle of the first base portion.

This limitation is disclosed for the same reasons as discussed with respect to Claim [3.8]. *EX-1003* ¶151.

Claim 16

The connector according to claim 15, wherein the second check valve is a duckbill valve, the second check valve comprises a duckbill portion and a second base portion which are connected to each other, and a second gas outlet end and a second gas inlet end of the second check valve are provided in the duckbill portion and the second base portion respectively; the second gas inlet end is a second vent hole provided in the middle of the second base portion, and the second gas outlet end is a second slit provided in the duckbill portion; and the duckbill portion and the deformed portion separately face two opposite sides of the bottom plate.

As described with respect to Claim [9.7], it would have been obvious to select the duckbill valve apparatus of Yuchang for use in the device of Zhongnan. Furthermore, as discussed with respect to Claim 3.8 and 9.7, the duckbill portion and the deformed portion of Zhongnan separately face two opposite sides of the base plate.



EX-1005 Fig. 3; *EX-1003* ¶152.

Claim 17

[17.1] The connector according to claim 15, wherein the removal device is configured to remove an obstruction in a respiratory tract, the removal device comprising a collapsible gasbag, the connector and a face mask which are sequentially connected,

See Claim [1.1].

[17.2] wherein the collapsible gasbag is internally provided with a gas storage cavity, the top of the collapsible gasbag is sealed, and the bottom of the collapsible gasbag is provided with an opening in communication with the gas storage cavity;

See Claim [1.2].

[17.3] an upper side of the connector is hermetically connected to the opening;

See Claim [1.3].

[17.4] the first gas outlet end of the first check valve is in communication with the gas storage cavity, a second gas inlet

end of the second check valve is in communication with the gas storage cavity, and a second gas outlet end of the second check valve is in communication with the outside; and

See Claim [1.4].

[17.5] an upper side of the face mask is hermetically connected to the first gas inlet end of the first check valve, and a lower side of the face mask is provided with a flexible annular pad configured to attach to a face.

See Claim [1.5].

VIII. The Board Should Not Exercise Its Discretion To Deny Institution

A. The Board Should Not Deny Institution Under 35 U.S.C. § 325(d)

Denial under § 325(d) is not warranted because the challenges presented in this Petition are neither cumulative nor redundant to the prior art considered in the prosecution of the '575 Patent or of the prior art considered by the Board in the prior PGR.

B. The Board Should Not Deny Institution Under 35 U.S.C. § 314(a)

General Plastic Co., Ltd. v. Canon Kabushiki Kaisha, enumerated a number of non-exclusive factors that the Board will consider in exercising discretion on instituting *inter partes* review, especially as to "follow-on" petitions challenging the same patent as challenged previously in an IPR, PGR, or CBM proceeding. IPR2016-01357, pp. 16–18 (PTAB Sept. 6, 2017) (Paper 19) (precedential). Importantly, the Trial Practice guides states that the *General Plastic factors*, alone or in combination, are not dispositive, but part of a balanced assessment of all

relevant circumstances in the case, including the merits. Id. at 15 ("There is no *per se* rule precluding the filing of follow-on petitions"). The *General Plastic* factors are also not exclusive and are not intended to represent all situations where it may be appropriate to deny a petition. Id. at 16. Here, the newly cited reference (previously unknown to the Petitioner, and unearthed as a result of an extraordinary search) so resembles the description and claims of the '575 Patent, as described in Sections II and VII (*above*), that the integrity of the patent system is challenged by allowing the '575 Patent to continue to exist. Nevertheless, a holistic review of the *General Plastic* factors demonstrates that the Board should not deny institution of this Petition.

Factor 1: whether the same petitioner previously filed a petition directed to the same claims of the same patent.

Petitioner previously challenged claims (1-17) of the '575 Patent in PGR2023-00032 which overlap with the claims (1-17) challenged in the current petition.

Factor 2: whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it.

At the time of filing PGR2023-00032, Petitioner was not aware of Zhongnan or Yuchang, and should not have known of them because they would not be found by a skilled searcher conducting a reasonably diligent search.

The board has considered prior art that the Petitioner "should have known" as "whether the prior art references relied on in the follow-on petitions constitute…could have been found with reasonable diligence." *General Plastics* at 20 citing *Apotex Inc. v. Wyeth LLC*, IPR2015-00873, slip op. at 6 (Sept. 16, 2015) (Paper 8)(describing "[w]hat a petitioner 'could have raised,'" as including "prior art which a skilled searcher conducting a diligent search reasonably could have been expected to discover.").

This question is also akin to the IPR estoppel language directed to "any ground that the petitioner raised or reasonably could have raised during that *inter partes* review" (35 U.S.C. § 315 (e)(2)) which has been tangentially touched on by the Federal Circuit and District Courts. With respect to newly found art, the determination rests upon the skilled searcher standard, *i.e.* whether "a skilled searcher conducting a diligent search reasonably could have been expected to discover" the newly found art. *Ironburg Inventions LTD v. Valve Corp*, 64 F.4th 1274 at 1298 (Fed. Cir 2023). The courts have noted this is a factual inquiry. Given the facts below, the Petitioner should not have known of Zhongnan or Yuchang.

Prior to filing the Petition for PGR2023-00032, Petitioner's counsel undertook a search that did not locate Zhongnan or Yuchang. The search resulted

in prior art references Lih, Tarrats and da Costa, which were utilized in the first Petition.

Lih, U.S. patent 10,052,115 was also known by the Petitioner via its relationship with the inventor Arthur Lih. The remaining references, Tarrats and da Costa (U.S. 4,971,053 and 3,939,830 respectively) were identified by the Petitioner's search. From information obtained regarding the first search (discussed below with respect to Factor 4), the Petitioner understands the search was undertaken by a Patent Attorney with membership in the USPTO Bar, who was familiar with and practiced with the search methodologies taught at the USPTO. The search included an initial review of the references from the prosecution, including the IDSs as well as a search of selected terms and classes/subclasses from those references as well as the search terms cited by the examiner with respect to at least the Lih patent and the '575 Patent. The search returned the '575 patent and the Lih patent (the latter of which, the '575 examiner considered the "closest prior art") (Ex. 1002, p 176), as well as the Tarrats and da Costa references. Of the search terms used in first search, at least "bellows" was in addition to the examiner's search terms for the '575 Patent. As evident by the '575 Patent's file history, a classification search alone would return over 32,000 results and thus selective search terms were required to cull the results to a reasonable

number.[2] *EX-1002* p.109. The Petitioner's searcher conducted a reasonable diligent search. The search took between 6 and 8 hours with multiple iterations with a cost of between $2400 and $3200.

Another factor in considering the reasonability of the search effort may be influenced by the surrounding circumstances. As noted by Federal Circuit there is no requirement to undertake a scorched earth search (*i.e.* extraordinary search) in order to for the search to be reasonably diligent.[3] The '575 Patent is unreasonably broad in view of prior art devices but does not impact Petitioner's ability to sell competing devices. Petitioner's portable anti chocking rescue devices are under the umbrella of the Lih Patent U.S. 10,052,115 (*EX-1018*), and both the Petitioner's device (*See EX-1016* and *EX-1017*) and the Lih Patent are prior art to the '575 patent, and importantly the Petitioner's device is not covered by the claims of the '575 Patent as the device does not include the claimed "first check valve" required in each of the challenged claims. Thus, the existence of the '575

[2] The District Court noted that the reference at issue was buried in a return of over 5000 references and would require a scorched earth searching method to find. *EIS, Ins. vs Novolluto GMBH* DDE-1-19-01227, Dkt. 626, at 9 (D.Del.August 30, 2023)

3

Patent does not impact the Petitioner's business, notwithstanding its impermissibly broad scope. Under these circumstances, the Petitioner's search was reasonable.

Subsequent to the DI, Petitioner commissioned another search, this time limited to patents and publications in foreign languages that identified the same features described in the '575 Patent, that could not be found using English only searching This search was conducted by an outside search firm with special experience with breathing devices and foreign language searches. This search involved two teams and cost $6000 and this search turned up, among others, two foreign language patents previously unknown to Petitioner – Zhongnan (written in Mandarin Chinese) and Yuchang (written in Korean).

Zhongnan (Ground 1) and Zhongnan in view of Yuchang (Ground 2) form the basis for the current Petition. Neither, Zhongnan nor Yuchang have a US counterpart patent and were not indexed as a searchable U. S. Patent, thus the use of search terms to winnow the results to a reasonable number, in hindsight likely prevented these references from being found. Additionally, the translation from Chinese of relied upon elements in the references resulted in terms seemingly unrelated to the claimed terms. For example, the equivalent structure to the claimed "Collapsible gas bag" in Zhongnan was translated as a "suction device", "suction cup" or "cylindrical body", the relied upon element for the claimed "connector" was translated as a "Base plate" and in some translations a "Chassis"

and the element meeting the "flexible annular pad" was translated as an "outer edge." *See* Sections II and VII.A.2 above.

Factor 3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition.

At the time of filing the current Petition, the Petitioner had already received the POPR and the denial of institution in PGR2023-00032.

Factor 4: the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition.

As described as with respect to Factor 2, Petitioner requested search quotes on April 4, 2024 and after evaluating the quotes and the relevant competencies of the firms, commissioned a foreign language search on April 10, 2024. The relevant prior art references, Zhongnan and Yuchang, were first brought to Petitioner's attention in an intermediate search report received on April 29, 2024 and the English translations were received on April 30, 2024, with a final search report received on May 1, 2024.

The search results including Zhongnan and Yuchang were reviewed and evaluated between May 9, 2024 to May 22, 2024. Subsequent the review and evaluation, the Petitioner began drafting the current petition which was substantially complete by June 27, 2024. Concurrently, the Petitioner, first sought

information regarding the prior search on June 18, 2024 and after requesting information repeatedly from the prior counsel to ascertain the particularities of the first search, which were complicated by the departure of the attorney responsible for the search to another firm, the Petitioner received an overview of the search of December 3, 2024, the particularities of which are included above with respect to Factor 2. Upon receiving the overview, the Petition's discretion section was drafted and the Petition was finalized on December 17, 2024 with the Petition filed on Jan. 31, 2025, approximately 8 months later, but within a short time of receiving the information related to first search conducted by the prior firm, especially in view of the intervening holiday season.

Factor 5: *whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent.*

The denial of institution on PGR2023-00032 was received on November 29, 2023. After receiving the DI, Petitioner sought legal advice from several law firms regarding an evaluation of the previous petition and institution decision in PGR2023-00032 shortly thereafter on December 13, 2023. After conferring with counsel between December 15, 2024 and February. 26, 2024, the Petitioner engaged present counsel on March 21, 2024 to conduct a new search for foreign language patents and publications. Present counsel consulted with several search

firms experienced in foreign language searches and identified a search firm on April 10, 2024. The search firm returned preliminary results on, April 29, 2024. Present counsel reviewed the preliminary search results, began drafting the Petition and sought information regarding the first search as described above with respect to Factor 4. The present Petition was diligently filed after seeking counsel advice regarding the initial petition, conducting a search, a detailed analysis of the references, drafting of the Petition and obtaining the particulars of the first search.

Factor 6. the finite resources of the Board.

The Petitioner acknowledges the finite resources of the Board and the time already devoted by the Board in PGR 2023-00032. For this reason, the current Petition is limited to one ground for each Challenged Claim, and only two references.

Factor 7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

The current Petition will allow the sufficient time to meet this requirement.

For the reasons identified above, Petitioner respectfully requests that the Board not exercise its discretion and find that the merits of the current petition overwhelmingly demonstrate that the Challenged Claims are fully and plainly disclosed by the foreign language references of Zhongnan and Yuchang.

IX. Mandatory Notices Under 37 C.F.R. §42.8

A. Real Party-in-Interest (37 C.F.R. § 42.8(b)(1))

The real party-in-interest in this Petition is LifeVac, LLC.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

1. Judicial Matters

As of the filing date of this Petition and to the best of Petitioner's knowledge, the '575 Patent is involved in the following litigations:

2. Administrative Matters

As of the filing date of this Petition and to the best of Petitioner's knowledge, the '575 Patent was subject to the following *post grant* review which was not instituted:

PGR2023-00032

3. Related Patents

As of the filing date of this Petition and to the best of Petitioner's knowledge, the '575 Patent does not have any related patents.

C. Lead/Back-up Counsel (37 C.F.R. § 42.8(b)(3)):

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D. Notice of Service Information (37 C.F.R. § 42.8(b)(4)):

Please direct all correspondence to lead and back-up counsel at the above addresses and DC-IPdocketing@duanemorris.com. Petitioner consents to electronic service at the email addresses above.

X. CONCLUSION

For the reasons set forth above, Petitioner has established a reasonable likelihood of prevailing with respect to all Challenged Claims of the ’575 Patent and requests the Board institute *inter partes* review and then cancel all claims as unpatentable.

Respectfully submitted,

DUANE MORRIS LLP

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Dated: January 31, 2025

CERTIFICATION OF SERVICE ON PATENT OWNER

Pursuant to 37 C.F.R. §§ 42.6(e), 42.8(b)(4) and 42.105, the undersigned certifies that on January 31, 2025, a complete and entire copy of this Petition for *Inter Partes* Review of U.S. Patent No. 11,478,575 and all supporting exhibits were served via Federal Express, postage prepaid, to DC Star Inc. by serving the correspondence address of record for the '575 Patent:

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24 *et seq*., the undersigned certifies that this document complies with the type-volume limitations. This document contains 12,388 words as calculated by the "Word Count" feature of Microsoft Word 2010, the word processing program used to create it.

Dated: January 31, 2025

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