

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

**PETITIONER’S OPPOSITION TO PATENT OWNER’S REQUEST
FOR DISCRETIONARY DENIAL OF INSTITUTION**

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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PETITIONERS' EXHIBIT LIST

<i>Exhibit #</i>	<i>Description</i>
1001	U.S. Patent No. 11,478,575 (“the ’575 Patent”)
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 <i>EX-1004</i>
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 <i>EX-1008</i>
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

Patent Owner (“PO”) has requested discretionary denial of institution of the Petition for *inter partes* review of the ’575 Patent on the basis that 1) the Petition is a follow on petition; 2) the same or similar art or arguments were addressed during prosecution and 3) the merits are weak.

First, despite the PO’s assertions, a holistic views of the *General Plastic* factors (*Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357 et al., Paper 19 (September 6, 2017) weigh against the exercise of discretion under §314(a). The newly cited art was in a foreign language and was previously unknown to Petitioner. It was only as a result of an extraordinary search that the reference was found. In addition, no strategic or tactical advantage was gained by the Petitioner, as the prior art used in the Petition is substantially different than the prior art relied upon in the previous PGR petition, and there was no concurrent litigation between the parties. *See* Section III (below).

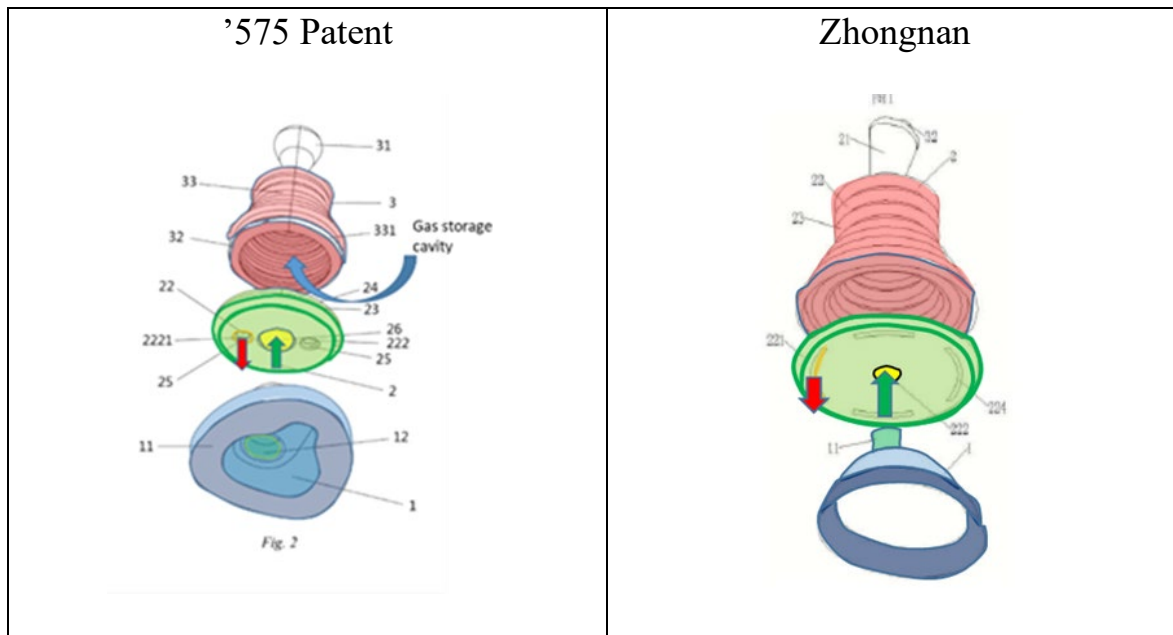
Secondly, PO asserts that the Office has already considered the same or similar art and thus the Petition should be denied under §325(d). The Patent Office has not considered whether the primary reference (Zhongnan) is prior art. Nor does PO assert that Zhongnan is a disclosure by the inventor.

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The Office previously considered whether a prior art reference (IDEAR) applied by the Examiner was a disclosure by the inventor under 102(b)(1)(a). The Examiner withdrew the initial rejection over IDEAR in view of a declaration submitted by the inventor, however, to the extent PO considers the application of Zhongnan as being the same or similar art/arguments, then the Examiner erred in relying upon the inventor's declaration as it was insufficient to establish for the purposes of 102(b)(1)(a) that the disclosure was "made by the inventor or a joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor." As demonstrated below, to the extent they apply, the *Becton* factors (*Becton, Dickinson & Co. v. B. Braun Melsungen AG*, PR2017-01586, Paper 8 (December 15, 2017)) weigh against the exercise of discretion. *See* Section IV (below).

Lastly, with respect to the merits, the application of Zhongnan to the claims leaves no doubt the claims would be rendered unpatentable, given the operational and structural similarities as shown in the comparison of FIGs. 2 of the Patent and of Zhongnan. *See also* Section V.A. (below).

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EX-1001 FIG. 2 and EX-1005 FIG. 2

Zhongnan, is prior art under 102(a)(1):

[a] person shall be entitled to a patent unless—

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention;

35 USC 102(a)(1)

The premise underlying PO's assertion regarding the strength of the merits is that Zhongnan is not prior art, *i.e.* that the Zhongnan reference is subject to exclusion as prior art under §102(b)(1)(B). The burden of establishing the exclusion is borne by the PO and to date that burden has not been met, the

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evidence submitted in the Discretionary Request (EX-2001 and EX-2002), is not only inadequate to establish the applicability of 102(b)(1)(B) but is not admissible as it is merely hearsay. The only issue required to resolve validity is the status the primary reference under 102(b)(1)(B). A determination that properly lies outside the realm of discretionary review.

This Opposition demonstrates that under a proper analysis of the *General Plastic* Factors, the *Becton* Factors, the strength of the grounds set forth in the Petition, and the other considerations, discretionary denial is not warranted, and denial would not further the interest of efficiency, fairness, and patent quality.

Accordingly, Petitioner hereby respectfully requests that the Director deny PO's Request and grant the Petition to institute an *inter partes* review of the '575 Patent.

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:

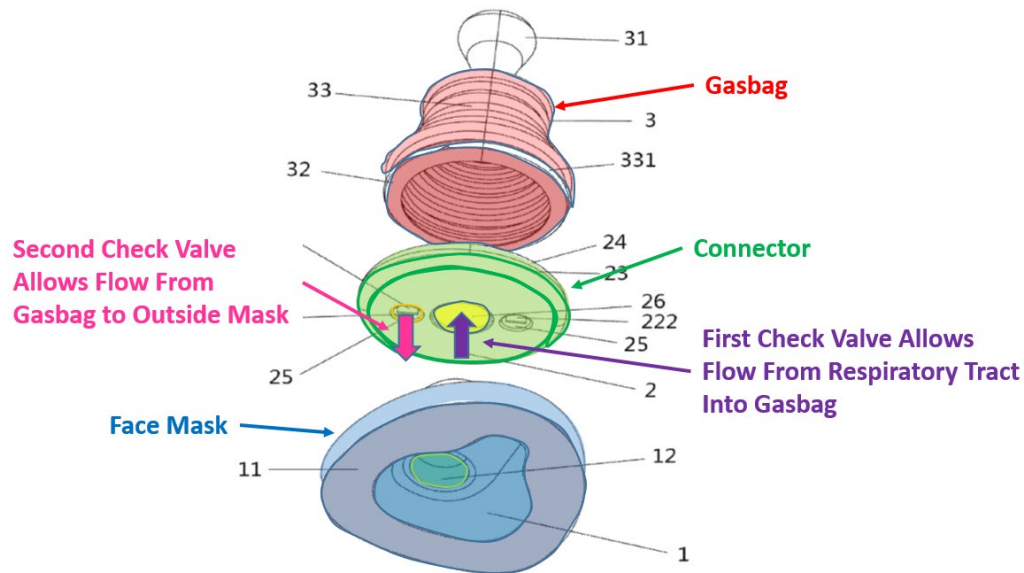


Fig. 2

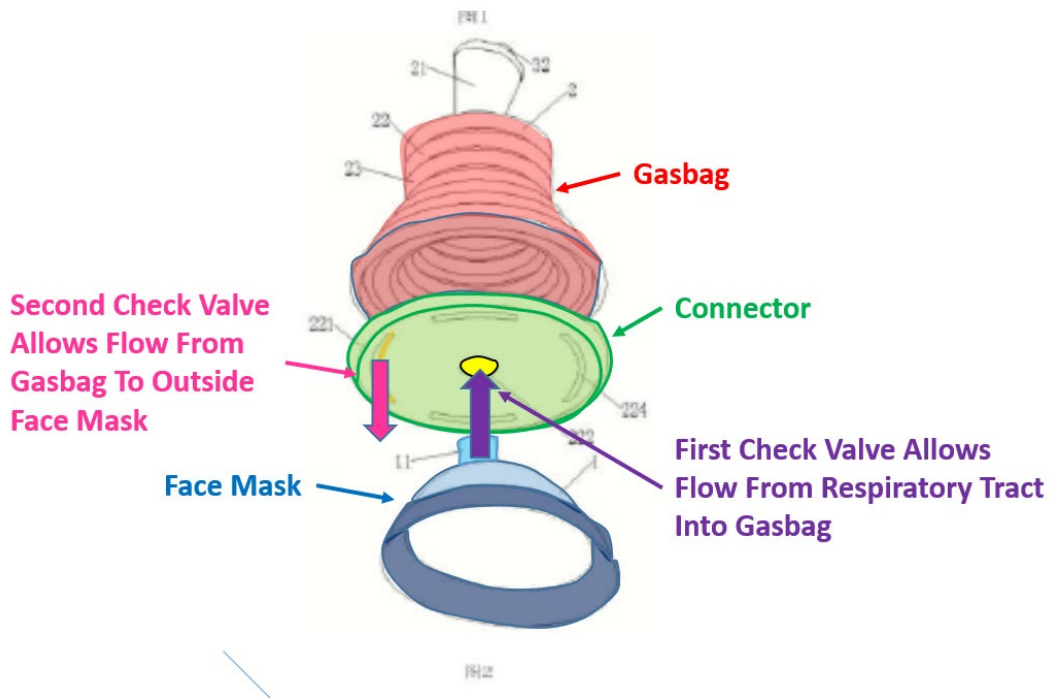
EX-1001 FIG. 2

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.

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

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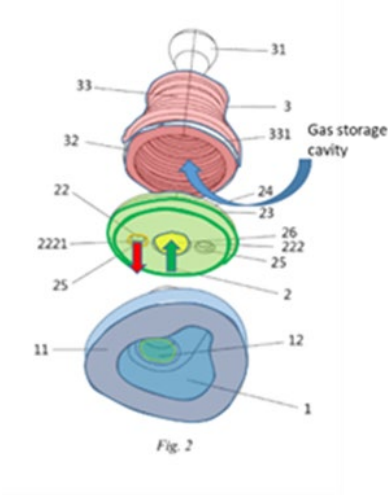
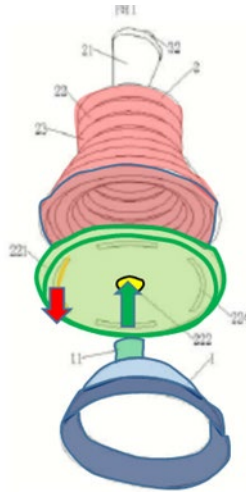
Zhongnan illustrates such a device in FIG. 2:



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:

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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.

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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.

III. THE DIRECTOR SHOULD NOT DENY INSTITUTION PURSUANT TO *GENERAL PLASTICS*.

General Plastic Co., Ltd. v. Canon Kabushiki Kaisha, enumerated a number of non-exclusive factors that the Office 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

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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 Petitioner, and unearthed as a result of an extraordinary search) so resembles the description and claim 1 of the ‘575 Patent, as described in Section II (above) and Section V.A. (below), that the integrity of the patent system is challenged by allowing the ‘575 Patent to remain in force. Moreover as discussed below with respect to the 325(d), the ‘575 Patent was only allowed as a result of an error by the Office, relying on a self serving declaration from the inventor, that was woefully inadequate to support disqualification of anticipating art. (See Section IV (below))

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. Admittedly, factor one weights in favor of exercising discretion.

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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

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1274 at 1298 (Fed. Cir 2023). The courts have noted this is a factual inquiry.

Given the facts below, 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 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 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

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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. 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 reasonableness 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 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 choking rescue devices are under the umbrella of the Lih Patent U.S. 10,052,115 (*EX-1018*), and both Petitioner's device (*See EX-1016* and *EX-1017*) and the Lih Patent are prior art to the '575 patent, and importantly Petitioner's device is not covered by the claims 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)

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

Subsequent to the DI in the prior PGR, Petitioner engaged current counsel (Duane Morris LLP) and commissioned another search, this time limited to patents and publications in foreign languages that identified the same features described in the '575 Patent, which 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

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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 (above) and V.A.2 (below).

With respect to factor two, the PO ignores the skilled searcher/diligent search standard and asserts three characteristics of newly asserted prior art (i) consists of publicly available patent documents; (ii) has similar classifications or are in a related field to the challenged patent; and/or (iii) uses “common terms” as the challenged patent. Request p. 15. Irrespective of whether these characteristics are dispositive, PO’s conclusions are not supported.

PO offers several circa 2025 searches that ostensibly would lead to Zhongnan, notwithstanding the fact each of PO’s searches were undertaken two years subsequent Petitioner’s first search, they each employ hindsight searching (i.e. when you know where something is, it is easier to find). Notably, PO did not include a 2025 Google search of the ’575 Patent.

First a Google search starting with Petitioner’s Patent, would lead to CN112932633 in the “cited by” field, under “Family to Family Citations.” This search was conducted on 4/15/2025, and there is no indication of such a reference existing two years earlier when Petitioner’s first search was conducted.

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PO lists several other 2025 searches it conducted, some resulting in KR102229619 appearing in the “cited by” field when Tarrats (U.S. 4,971,053) is searched, others resulting in Tarrats and Lih appearing in the “cited by” field when Costa (U.S. Patent No.3,939,830) is searched.

PO also suggested that because the “examiner included numerous Chinese and Korean patent publications as semantic search inputs” a reasonable search would have uncovered Zhongnan and Yuchang. Request p.18. However, the examiner did not find Zhongnan and Yuchang which demonstrates the Petitioner’s contention that a reasonable search may not have uncovered these references.

Further PO contends since the references are in the same CPC classification, these references would have been uncovered. Request p. 19. However as noted above, a classification search would have led to over 32000 results, a number far exceeding what would be expected for a diligent search.

And finally, PO suggest the “Petitioner ignores key terms in the challenged patent that are shared with the translations of Zhongnan and Yuchang.” First, it should be noted the “Translations” of Zhongnan and Yuchang were commissioned subsequent to the search and thus are not indicative of the translations in a database that could be utilized in a search. Thus, the very premise of PO’s assertion is faulty.

Factor 2 weighs against exercising discretion.

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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, Petitioner had already received the POPR and the denial of institution in PGR2023-00032. However, the Petitioner did not rely upon the DI or the prior briefing for a road map for the follow on Petition. Specifically, the DI found with respect to Ground 1 the "Petition fails to identify with sufficient particularity how Lih, Tarrats, and da Costa are being combined for satisfying the claim limitations." DI. p. 20. With respect to Ground 2, the DI simply recognized claimed features of the '575 Patent where not found in the asserted prior art, specifically the bottom plate and the second check valve. DI pp. 27-28. None of these references, nor similar references are used in the current Petition. The only road map provided in the DI was that the particular art as applied failed to disclose the claimed limitations, as such the road map does not differ from the claims themselves. No strategic or tactical advantage was obtained from receiving the POPR and DI.

The only change in Petitioner's strategy, alleged by PO as being derived from the POPR and DI, was the refinement of the definition of POSA. However, the difference in scope, if any, is more stylistic than substantive, and as with the prior PGR will not be a dispositive factor.

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Factor 3 weighs against exercising discretion.

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, Petitioner began drafting the current petition which was substantially complete by June 27, 2024. Concurrently, 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, 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

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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 the first search conducted by the prior firm, especially in view of the intervening holiday season.

PO suggests Petitioner filed the petition “after strategically waiting more than eight months after being aware of Zhongnan so it could maximize its use of the full record in the prior proceeding.” Request p. 1. However there was not a record following the DI, nor was any record expected as there was no other petitions or litigations between the parties during this time.

PO's allegation that the delay in filing was an intentional strategy “to stagger its attack and use the prior PGR proceeding as a road map” is entirely without support. As noted earlier, the POPR and DI did not provide a roadmap to applicable to the current grounds and any delay between the DI and the filing of the current Petition did not harm or prejudice the PO.

Factor 4 weights against exercising discretion.

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

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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, as noted previously, Petitioner engaged current 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 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. As described above with respect to Factors 2 and 4, Petitioner was not aware of the new art, and should not have been aware of the new art prior to the second search which was not conducted until after the DI.

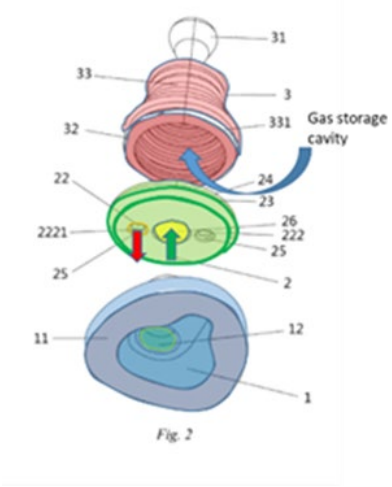
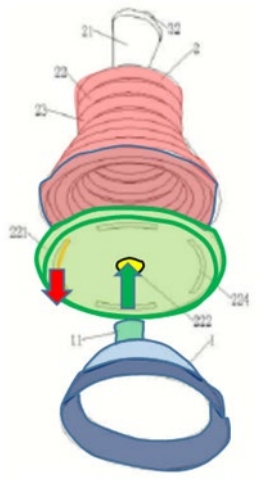
Factor 5 weights against exercising discretion.

Factor 6. the finite resources of the Board.

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

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references. Moreover, the technology is straight forward and the manner in which the prior art meets the claim elements is *prima facie* evident. See Table 1, below and Section V.A.2 (below).

Table 1	
'575 Patent  Fig. 2	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

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The current Petition would not be a significant burden to the Board's resources given its brevity and straight forward application of the art.

Factor 6 weighs against exercising discretion.

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.

Factor 7 weighs against exercising discretion.

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.

IV. THE DIRECTOR SHOULD NOT DENY INSTITUTION PURSUANT TO §325(D)

In evaluating whether to exercise discretion when the same or substantially the same prior art or arguments previously were presented to the Office under section 325(d), the PTAB weighs some common non-exclusive factors (i.e. *Becton* Factors), such as:(a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which

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the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments. These factors however are directed to how the prior art reference was previously applied by the examiner or other body, not to whether the now relied upon art can be excluded under a different section 102(b)(1)(A) vs 102(b)(1)(B).

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, namely because IDEAR was excluded as prior art during prosecution and thus Factors a-c weigh against exercising discretion or are just irrelevant.

PO goes to great length to equate the IDEAR reference with the Zhongnan reference, but there is no connection between the two other than the similarity of the disclosure and the applicability of such disclosure to the claims. Zhongnan was not included in an IDS nor considered during the prosecution. IDEAR was

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determined not to be prior art. It is noted that Zhongnan's filing predates the IDEAR reference.

To the extent, the PO suggests, and the Board adopts that the IDEAR disclosure and Zhongnan are similar and present the same/similar arguments, the only relevant **Becton** factors become (e) and (d).

Becton Factor (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;

The Office rejected Claims 1-3, 5, 7-17 as being anticipated under "35 U.S.C. 102(a)(1) based on public use or sale or other public availability of the invention." EX-1002 135-142. In addition the Office rejected the remaining claims, Claims 4 and 6 as obvious over IDEAR in combination with Lih and Koledin, respectively. EX-1002 142, 143.

In response, PO submitted a declaration and made arguments that the IDEAR disclosure was attributable to the inventor, however PO did not attempt to distinguish the claims over the IDEAR disclosure. EX-1002 126-128. Petitioner asserted Zhongnan and applied Zhongnan to the claims of the '575 Patent (Section V.A.2), thus there is no overlap between the arguments made during prosecution by PO and how Petitioner applied Zhongnan to the claims.

Factor (d) weighs against exercising discretion.

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Becton Factor (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art;

The Office in a subsequent Office Action, withdrew the previous rejections of Claims 1-3, 5, 7-17 based on the IDEAR disclosure. The Office noting the Applicant arguments with respect to those rejections were persuasive. EX-1002 103. The arguments by the Applicant, supported by the He Declaration, were “the subject matter of IDEAR originated from the inventor.” EX-1002 126.

The Office erred in withdrawing the rejection in view of the He Declaration. The Office did not make an error in applying the IDEAR disclosure to the respective claim elements, as IDEAR shows every element of the challenged claims, like Zhongnan, and the examiner's mapping of the claims to IDEAR was un rebutted by the PO. EX-1002 126-128 The He Declaration was insufficient and without corroborating evidence to establish the '575 was entitled to the exclusion under 102(b)(1)(A), a burden borne by the PO. The He declaration includes one relevant paragraph stating:

3. I note that the disclosure of the removal device of IDEAR is based on the subject matter of the present application and is not prior art. That is IDEAR is based on the conception or development of the subject matter disclosed and claimed in the present application which are attributable to me.

EX-1002 131.

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The He Declaration contains nothing more than a conclusion; it lacks any context regarding the IDEAR disclosure. Declarations must be specific and factually supported—conclusory assertions are insufficient. The He declaration does not disclose any context regarding the attribution of the IDEAR disclosure to him. However, an affidavit or declaration under 37 CFR 1.130(a) that is only a naked assertion of inventorship and that fails to provide any context, explanation or evidence to support that assertion is insufficient. See *EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 859 F.3d 1341, 123 USPQ2d 1146 (Fed. Cir. 2017). MPEP 2155. See also Section V.A.3 (below).

The Office withdrew IDEAR as prior art under 102(b)(1)(a), solely in view of the He Declaration, despite the absence of corroborating evidence or context. EX-1002 103. Hence, the error, ultimately resulted in the issuance of the '575 Patent.

In regards to the instant Petition, and irrespective of any error by the Office, the He declaration is merely hearsay and inadmissible. In addition, the declaration has never been subjected to scrutiny by discovery.

Thus Factor (e) weighs against exercising discretion.

Therefore the Board should not exercise discretion under 325(d).

V. OTHER CONSIDERATIONS

A. The Merits of the Petition Are Strong

The merits of the Petition are particularly strong and warrant institution in the interest of the public benefit in strengthening the patent system by allowing the review of patents challenged with sufficiently strong merits showing unpatentability of at least one claim. Here, the Petition sets forth two grounds, each of which presents challenges that plainly demonstrate the unpatentability of the challenged claims.

1. 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.

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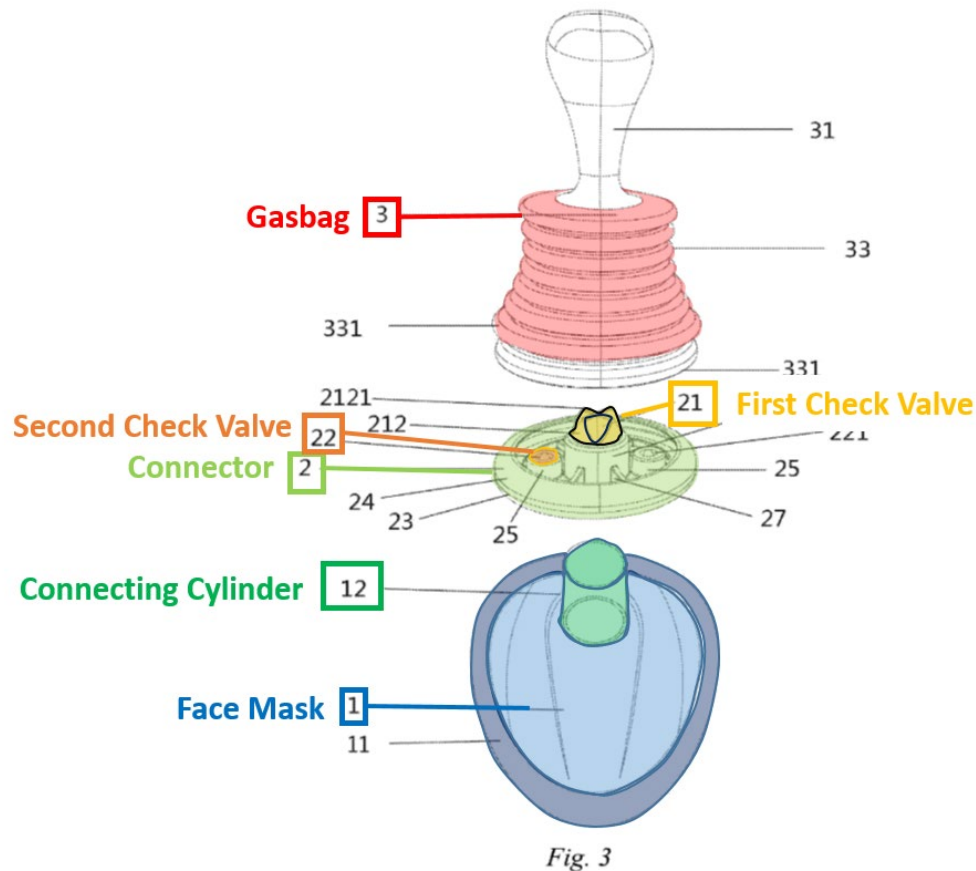
The '575 Patent further explains that connector 2 includes a first check valve 21 (**orange**) allowing the flow of air from the interior of the face mask 1 into the gas storage cavity, and one or more second check valves 22 (**gold**) allowing the flow of air from the gas storage cavity to outside the 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.



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

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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.

**2. Ground 1 Plainly Demonstrates that Claim 1 is
Unpatentable**

Under Ground 1, the Petition challenges Claims 1-2, 7 and 13-14 as unpatentable over Zhongnan alone. The application of Zhongman to Claim 1, the sole independent claim challenged, is shown below and demonstrates the strong merits of the case:

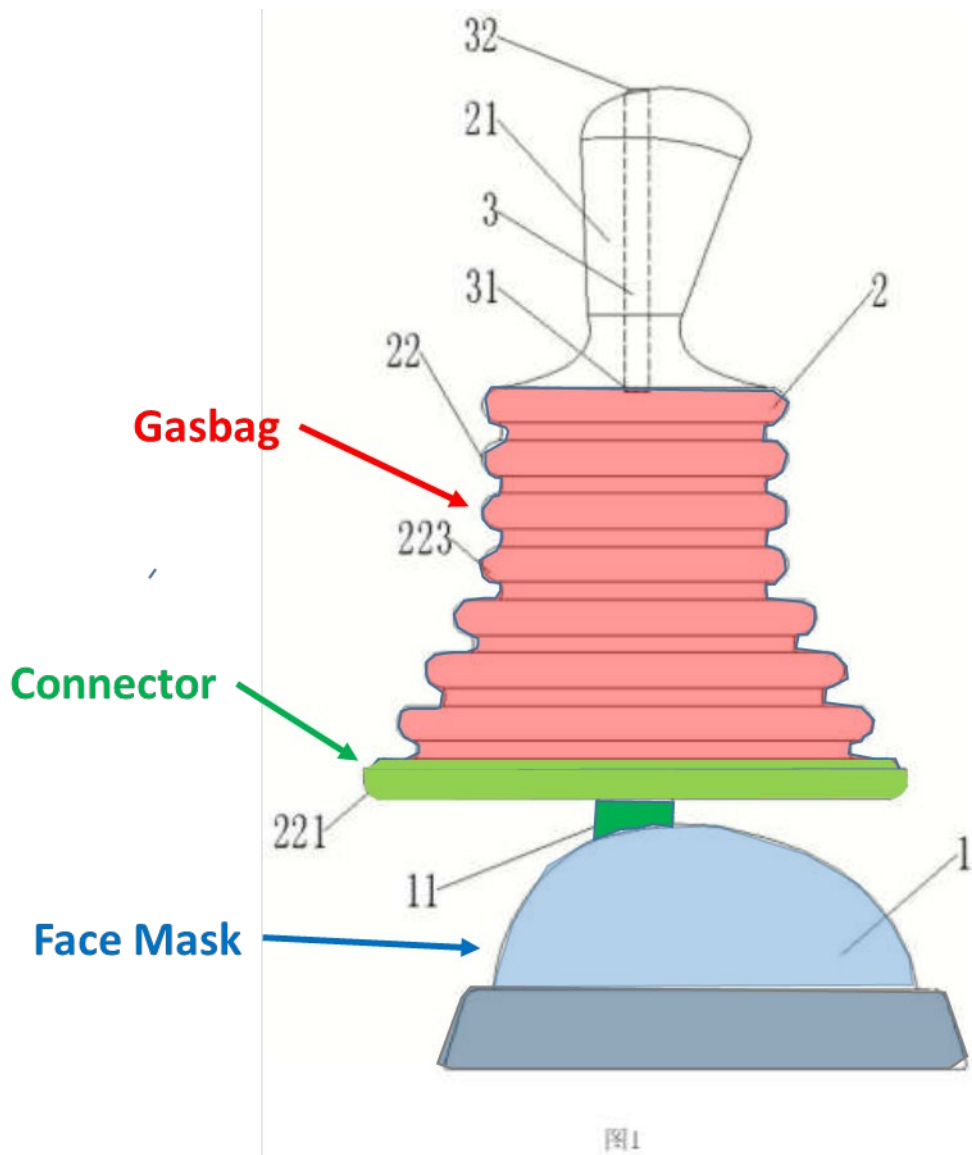
a. Claim 1

[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.

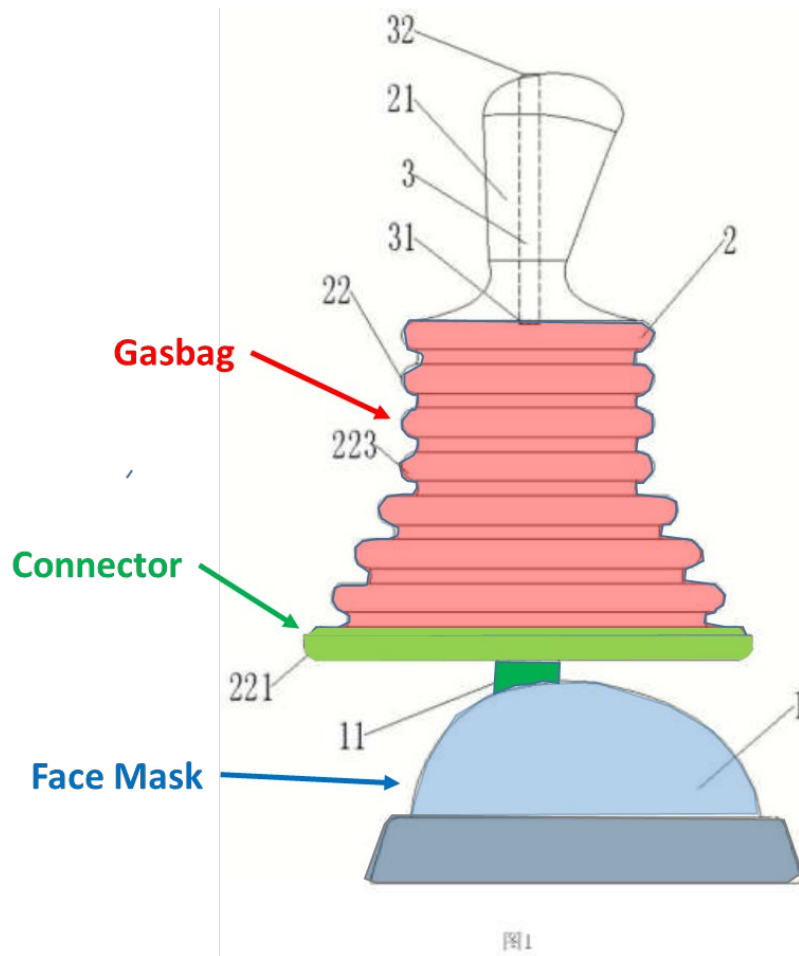


Thus, a POSA understood that Zhongnan discloses element [1.0]. *EX-1003*

¶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.

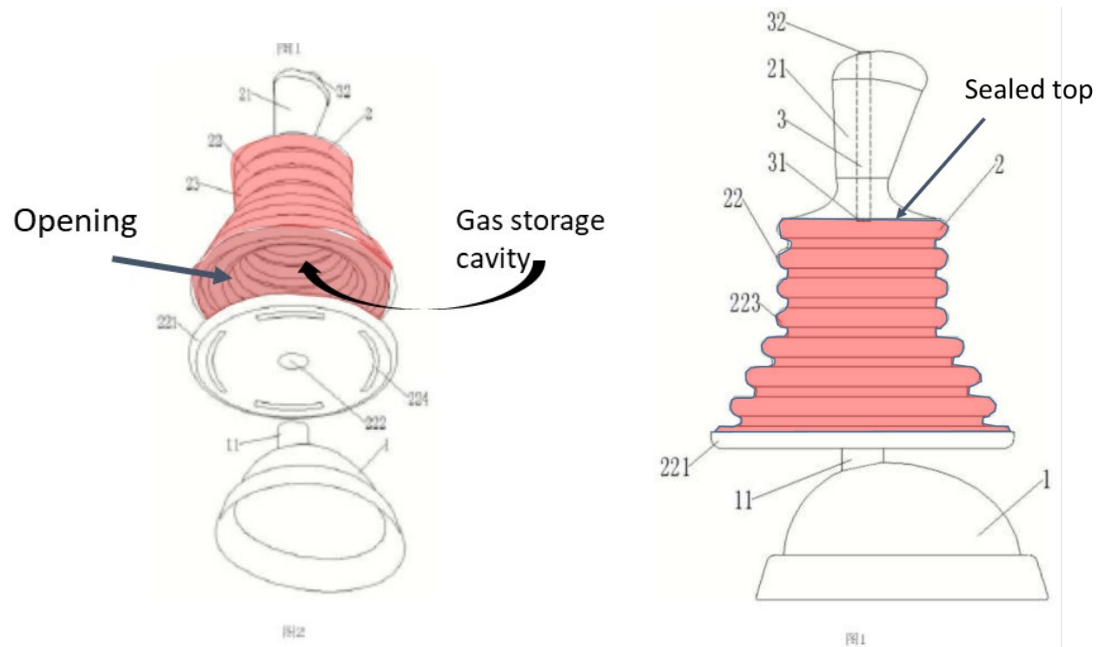
[T]he suction cup is a cylindrical body with an open bottom,

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:

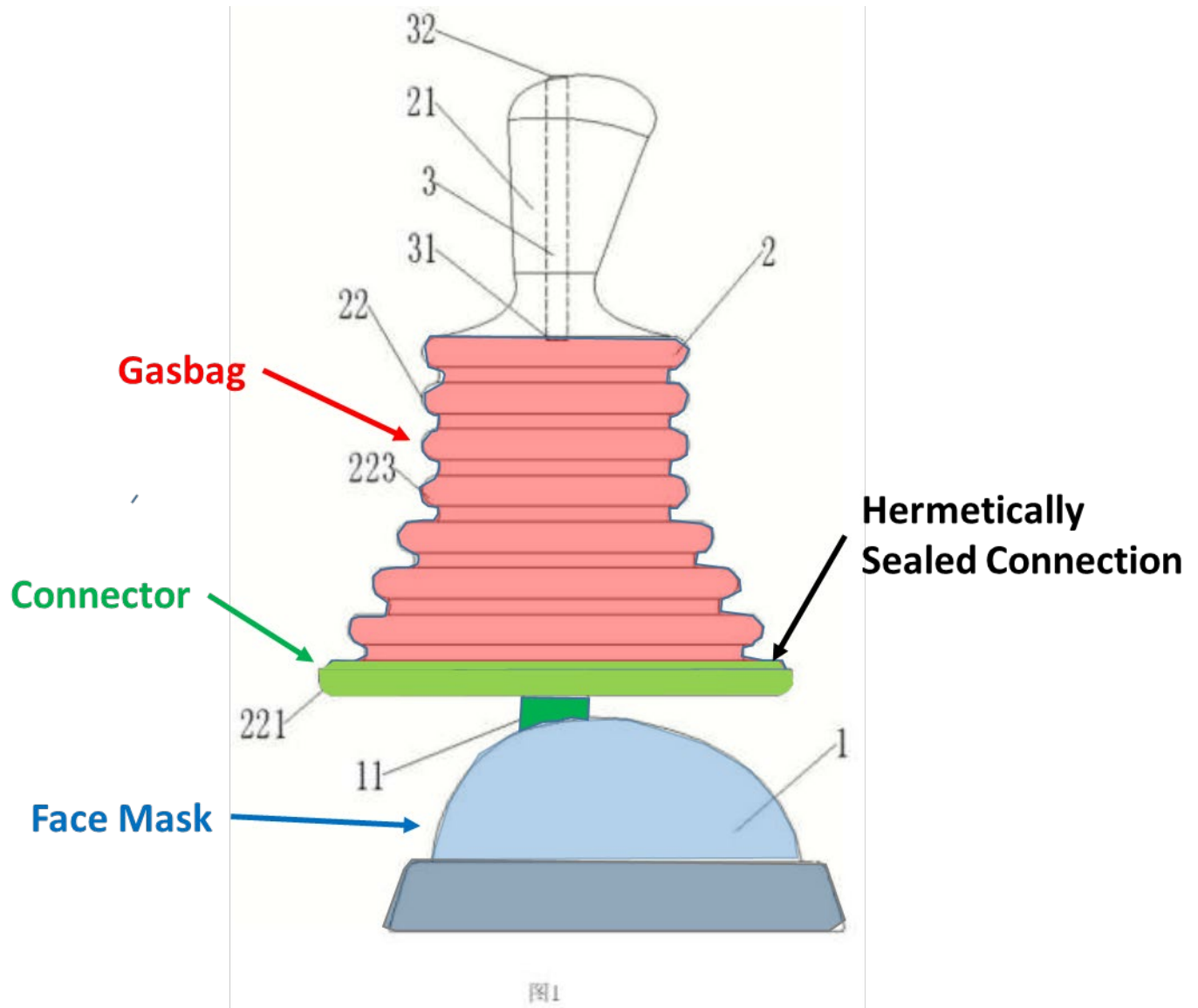
a base plate is disposed at the open bottom of the cylindrical body.

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*

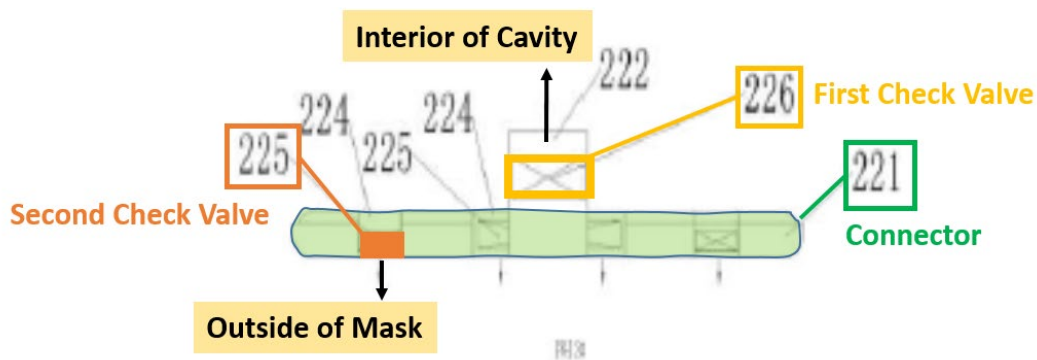
communication with the gas storage cavity, a second gas inlet end of the second check valve is in communication with the gas storage cavity, and a second gas outlet end of the second check valve is in communication with the outside; and

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.

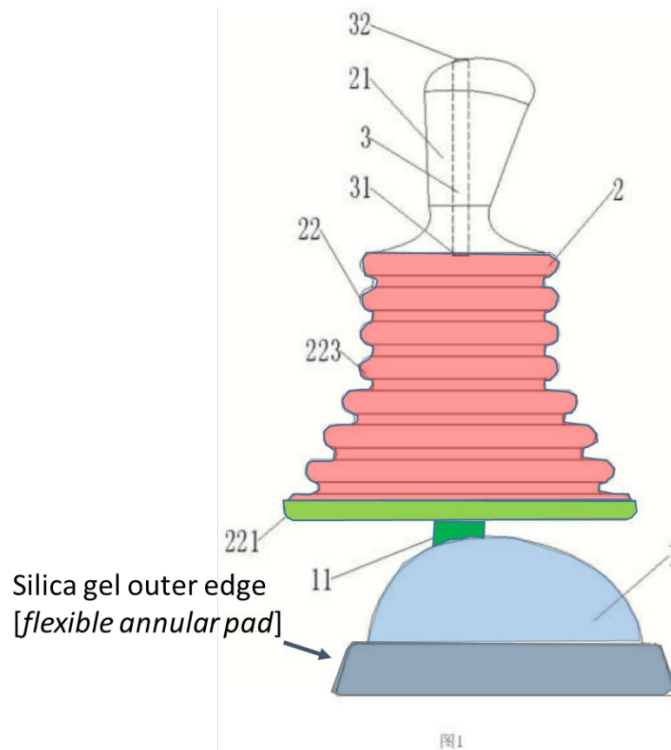
EX-1005 [0034], [0044]; *EX-1003* ¶94.

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.***

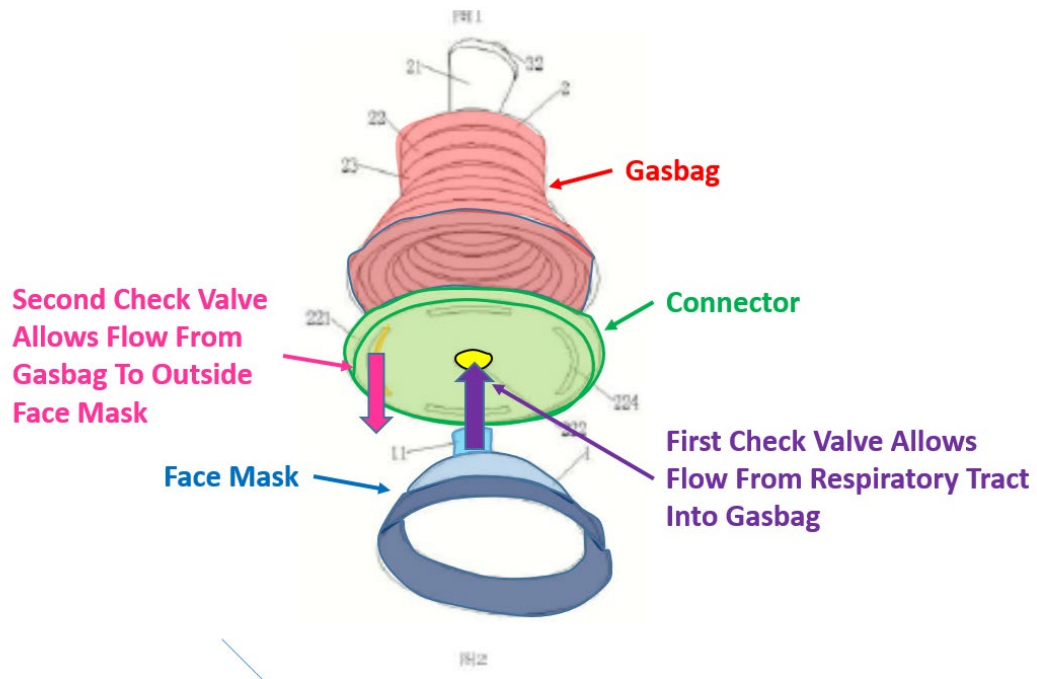
Zhongnan discloses the base plate 221 [connector] (green) includes a
bottom plate and the inlet check valve/one-way inlet valve 226 [first check valve]
(gold) and the outlet one-way valve/one-way exhaust valve 225 [second check
valve] (orange) are arranged on the bottom plate. The inlet check valve 226
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:

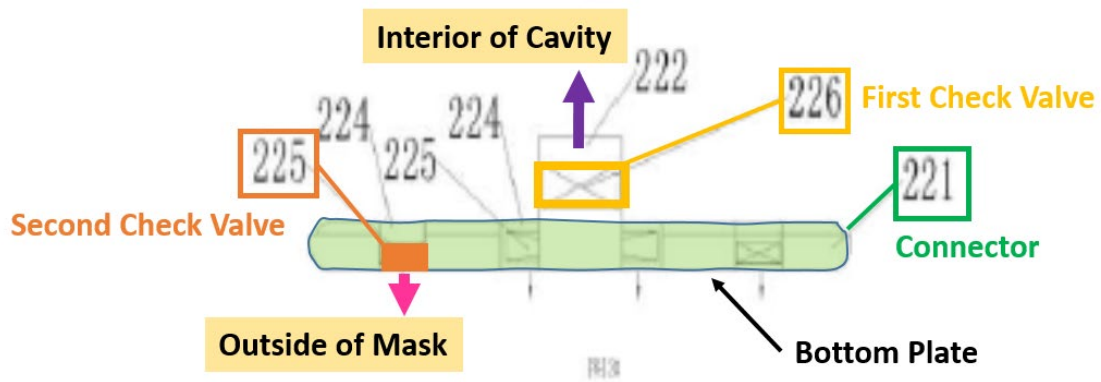
S20. pressing down the handle, driving the cylindrical body to press toward the face; the airflow created inside the cylindrical body flows downward, the one-way exhaust valve opens, the one-way inlet valve closes, and the airflow is discharged through the air outlet, creating a negative pressure inside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

Hence, the Petition plainly demonstrates that Claim 1 is unpatentable under at least Ground 1 based on Zhongnan. The strong merits of Ground 1 highly weigh in support of institution.

**3. The PO has not Demonstrated Zhongnan is Subject to
102(b)(1)(B).**

Zhongnan was filed on March 10th, 2021 and published on June 10, 2021 and thus qualifies as prior art to the '575 Patent subject to the application of 102(b)(1)(B).

In order to disqualify Zhongnan as prior art, PO must demonstrate a prior disclosure by the inventor. PO asserts that as early as April 28, 2021 the IDEAR document (EX-2004) was publicly disclosed. Request p. 6. PO fails to show that the IDEAR document was a public disclosure, that it was disclosed prior to June 10, 2021 and that it was made by the inventor or at his direction.

PO offers EX-2001 and EX-2002, as evidence of public disclosure by the inventor Prior to June 10, 2021, neither of which are admissible.

EX-2001 is a Declaration of RAM.SHAW PTE.LTD signed by the COO, besides being rank hearsay and not admissible, it is not evident whether the COO is attesting to his personal knowledge or that of the company.

EX-2002 is a Declaration of Ligui He executed in 2022 that was submitted to the Examiner as *Declaration of attribution* under 37 CFR 1.130(a). The declaration is hearsay. The He declaration includes one relevant paragraph stating:

3. I note that the disclosure of the removal device of IDEAR is based on the subject matter of the present application and is not prior art. That is IDEAR is based on the conception or development of the subject matter disclosed and claimed in the present application which are attributable to me.

EX-2002 p. 2

The He Declaration contains nothing more than a conclusion and it lacks any context regarding the IDEAR disclosure. Declarations must be specific and factually supported—conclusory assertions are insufficient.

Further, with respect to *Declarations of prior public disclosure* as required here, the MPEP 2155 states:

An affidavit or declaration under this paragraph must identify the subject matter publicly disclosed and provide the date such subject matter was publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

(1) If the subject matter publicly disclosed on that date was in a printed publication, the affidavit or declaration must be accompanied by a copy of the printed publication.

No date was provided in the He declaration, nor was the He declaration accompanied by a printed publication. Thus on its face it is ineffective to exclude Zhongnan.

The evidence offered by PO does not establish the IDEAR disclosure was publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

B. The Settled Expectations of the Parties Favors Institution

The '575 Patent issued on Oct. 25, 2022, and was immediately challenged in a PGR, and presently challenged in this Petition, thus there is no settled expectation other than Petitioner's assertion that the Patent is invalid. In the same manner as a long standing patent that was not challenged for years weights in favor of exercising discretion, a Patent that is challenged almost instantly weights in favor of institution.

C. The Impact to the Health and Safety of the Public

The '575 Patent's claims are directed to a Life-Saving device. Its is incontrovertible that the existent of a patent is an obstacle to entry whether in the manufacturing or sales of a device, or the practicing of a method related to or ostensibly covered by the patent. While, for a valid patent, the public receives value in advancing the technology in exchange for the market encumbrance, for an

invalid patent it receives none. In the health and safety field, the cost may be measured in lost lives, as manufactures are kept out of the market in the shadow of a patent, without the benefit of the bargain. With respect to anti-choking devices, which need to be deployed instantaneously in a choking emergency, the ready availability of the devices to save lives is related to the sheer quantity, distribution and cost of the devices, which in turn are a function of the number of market competitors producing and selling the device. A number deleteriously effected by an invalid patent covering the device.

This factor strongly favors not exercising discretion.

D. Resolution of the Validity of the '575 Patent in the PTAB May Avoid the Future Expenditures of Resources in District Court.

While speculative at best, the nature of the parties as competitors manufacturing and/or selling anti choking devices, increases the likelihood of the '575 Patent's validity being before the District Courts. Petitioner is presently before the U.S. District Court of Northern Texas with respect to the validity of Petitioner's Patent, so it is not unlikely that these parties, or at least PO, could find themselves in court with respect to this patent. The cost of District Court litigation far exceeds the costs compared with an IPR. Therefore, the IPR route would be a more efficient use of the parties and the government resources than resorting to District Court litigation.

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This factor is also against exercising discretion.

VI. CONCLUSION

For the foregoing reasons, the Director should deny PO's request for discretionary denial of institution.

Respectfully submitted,

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/Patrick C. Muldoon/

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USPTO Reg. No. 47, 343

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Dated: May 27, 2025

CERTIFICATION OF SERVICE

I hereby certify that on May 27, 2025, a copy of Petitioner's Response to Discretionary Denial was filed by filing this document through the PTACT's System as well as delivering a copy via electronic mail upon the following:

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nkennedy@kilpatricktownsend.com,

vmoore@kilpatricktownsend.com,

msaia@kilpatricktownsend.com

Respectfully submitted,

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Dated: May 27, 2025

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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 8325 words as calculated by the “Word Count” feature of Word 365, the word processing program used to create it.

Dated: May 27, 2025

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