
BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFE VAC, LLC
Petitioner

v.

DCSTAR INC.,
Patent Owner

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

Case No. PGR2023-00032

PATENT OWNER PRELIMINARY RESPONSE

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Statement of Material Facts in Dispute

Petitioner, LIFE VAC, LLC, did not submit a statement of material facts in its Petition. Accordingly, no response is due pursuant to 37 C.F.R. § 42.23(a), and no facts are admitted.

I. Introduction

DCSTAR (“Patent Owner”) respectfully submits this Preliminary Response in response to the Petition for Post-Grant Review filed by Life Vac, LLC (“Life Vac” or “Petitioner”) challenging Claims 1-17 of U.S. Patent No. 11,478,575 (“the ’575 Patent” or “the challenged patent”). Each of Petitioner’s grounds is legally deficient for the reasons identified below. Institution should be denied.

First, Life Vac’s Petition is an improper serial challenge. Two of the three references relied upon in the Petition were already fully considered by the United States Patent and Trademark Office (the “Office”) and overcome during prosecution and the third reference is cumulative to references of record. Petitioner also has failed to identify a “material error” during examination as required by the precedential *Advanced Bionics* decision. Institution should be denied under 35 U.S.C. § 325(d).

Second, Life Vac’s obviousness positions are legally deficient because: (i) the prior art fails to disclose or suggest a “connector” sequentially connected between a gasbag and a face mask; (ii) no logical motivation exists for combining the piston valves in the second embodiment of da Costa with a face mask/gasbag “connector,” (iii) incorporating the check valves from da Costa into a connector would result in a device unsuitable for removing an obstruction from a choking

patient's airway, and (iv) the prior art fails to disclose or suggest a first check valve having a first gas inlet end hermetically connected to a face mask.

Third, Life Vac's anticipation arguments are factually and legally flawed because numerous features of the claimed invention are completely absent from the cited art. In an attempt to remedy these defects, Life Vac makes cursory citations to a declaration by Carl Stamp ("the Stamp declaration"), which makes numerous factual allegations devoid of supporting evidence. Life Vac also incorrectly applies the inherency doctrine to ostensibly supply features absent from the prior art.

In view of the foregoing, the Petition fails to demonstrate that it is more likely than not that at least 1 of challenged claims 1-17 of the '575 Patent is unpatentable. Institution should be denied.

II. Background

Asphyxiation caused by an obstruction in a respiratory tract will often cause breathing to stop and is fatal if aid is not given within 4 to 6 minutes. (Ex. 1001 at 1:14-16.) It is therefore necessary to race against the clock to remove any respiratory tract obstruction and clear the victim's airway. (*Id.* at 1:18-21.) The claimed invention is a rescue device for choking patients that may be utilized for self-rescue. (*Id.* at 1:36-42.)

The '575 Patent has four independent claims: claims 1, 3, 9, and 13. Claim 1 of the '575 Patent is shown below with reference to annotated FIGS. 1 and 3:

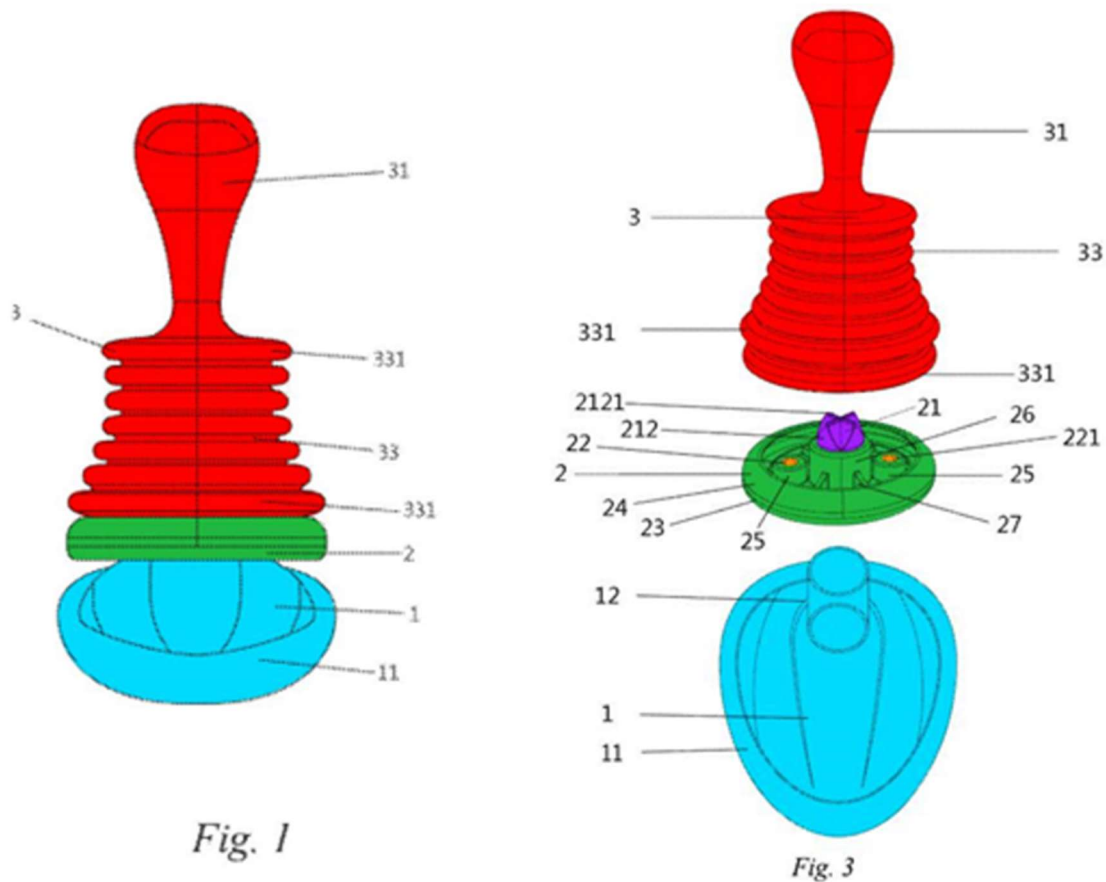
1. A removal device for removing an obstruction in a respiratory tract, the removal device comprising a collapsible gasbag, a connector and a face mask which are sequentially connected,

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;

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

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,

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.



Claims 3 and 9 are substantially similar to claim 1, except for the final wherein clauses, which include additional claim features.

Independent claim 13 is directed to the connector and substantially mirrors the connector language of claim 1. The full text of claim 13 is provided below:

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.

The claimed device includes first and second check valves that allow gas flow to pass in opposite directions. (Ex. 1001 claim 1.) The first check valve, which prevents gas from being pushed into the choking victim's airway, includes a first gas inlet hermetically connected to an upper side of the facemask and a first gas outlet end in communication with the gas storage cavity. (*Id.* at claim 1, 8:6-13.) The second check valve, which directs gas flow from the gasbag to the outside as the gasbag is compressed, has a second gas inlet end in communication with the gas storage cavity and a second gas outlet end that permits gas to exit the gasbag cavity to the outside. (*Id.*).

This structural arrangement is superior to devices having only relief valves and solves a substantial deficiency with existing devices. Specifically, the combined action of the first and second check valves can prevent gas from the gas storage cavity from being pushed into the patient's body, which could cause the airway obstruction to penetrate further into the patient's body resulting in additional harm and making removal of the obstruction even more difficult. Additionally, the first check valve permits the collapsible gasbag to collect debris from the oral cavity and esophagus while beneficially avoiding residual backflow from the collapsible gas bag. (*Id.* at 8:14-28.) In some aspects, the valves employed

are duckbill valves, which advantageously: (i) permit the valves to easily open, (ii) facilitate returning to a closed state upon application of air pressure, and (iii) allow debris to transfer into the gasbag, thereby ensuring effective and safe operation of the device. (*Id.* at 7:26-51, 8:48-63, 8:14-28.)

The many advantages and benefits of the claimed removal device demonstrate that the USPTO's decision to grant the '575 Patent is consistent with the primary goal of the patent system: rewarding innovation for the benefit of society.

III. Person of Ordinary Skill in the Art

A person of ordinary skill in the art (POSA) is a hypothetical person presumed to be aware of all pertinent art, to think along with conventional wisdom in the art, and to have ordinary creativity. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407-09, 420-21 (2007). For the limited purpose of this Preliminary Response, Patent Owner submits that the POSA would be (1) a mechanical or biomedical engineer having at least 2 years of experience in designing devices associated with maintaining or clearing the airway of humans, who would, where necessary or desired, work or consult with a medical clinician such as a respiratory therapist, emergency medical technician (EMT) or physician, to develop such medical devices, or (2) a medical clinician such as a respiratory therapist, EMT or physician with experience maintaining or clearing the airway of humans, who

would, where necessary or desired, work or consult with an engineer, to develop such medical devices.

This POSA standard differs from Petitioner’s POSA standard in that it focuses on the nature of the presently claimed invention—clearing or removing obstructions from the airway of the choking victim. Petitioner’s construction, in contrast, broadly covers POSA’s having experience in any and all medical devices, i.e., “medical devices in general.” (Pet. at 18-19.) Patent Owner submits that Petitioner’s POSA standard is unreasonably broad, defining the POSA as including individuals having experience with in completely unrelated medical fields and devices, e.g., X-Ray and MRI devices, stents, pacemakers, defibrillators, prostheses, etc. Because Patent Owner’s POSA standard more reasonably focuses on the nature of the subject invention, it is a more appropriate POSA standard for this proceeding.

IV. Claim Construction

A. Applicable Law

Claims are ordinarily given their “ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13, 1315 (Fed. Cir. 2005) (citation omitted). To construe a claim term, the PTAB should look to “the words of the claims themselves, the remainder of the

specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.* at 1314 (citation omitted). “A patent’s specification, together with its prosecution history, constitutes intrinsic evidence to which the PTAB gives priority when it construes claims.” *Knowles Elecs. LLC. v. Cirrus Logic, Inc.*, 883 F.3d 1358, 1361-62 (Fed. Cir. 2018) (footnote omitted).

For purposes of this preliminary response, the plain meaning of the terms “bottom plate” and “check valve” should control.¹ Patent Owner submits that the term “connector” requires construction.

B. “bottom plate”

In the Petition, Petitioner turns to a dictionary definition to define “bottom”² and “plate” separately as “the underside of something” and “a smooth flat thin piece of material,” respectively. (Pet. at 20-21.) This definition introduces additional ambiguities to the claim term and is unhelpful. For example, under

¹ Additionally, since these terms do not appear to be in dispute, there is no need to construe them. Patent Owner reserves the right to assert alternative constructions for both claim terms, should trial be instituted.

² In defining the term “bottom,” the Petition curiously cites to Exhibit 1017, which supplies a definition for a different term: “backing.” (Pet. at 21.)

Petitioner's construction, how smooth is smooth? How flat is flat? How thin is thin? Because Petitioner's construction adds ambiguity, it should be rejected.

Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898 (2014). *See Phillips*, 415 F.3d at 1312 (en banc).

Patent Owner contends that no dictionary definition is needed to understand the meaning of the term “bottom plate.” The term is not a term of art, is clear and unambiguous on its face, and would be readily understood by those skilled in the art. As such, the term does not require construction, and its plain and ordinary meaning should control.

C. “check valve”

Citing dictionary definitions, Petitioner proposes that the term “check valve” should be construed as “a valve that permits flow in one direction only.” (Pet. at 21 (citation omitted).) This definition (i) is unhelpful in that it includes the same term “valve” that is included in the term being construed, and (ii) adds ambiguity in that it includes the term “permits” which suggest some unascertainable degree of discretion in what does and does not flow through the valve.

Instead, Patent Owner submits that no express construction of the term “check valve” is required. The term is not a term of art, is clear and unambiguous on its face, and would be readily understood by those skilled in the art. *Phillips*,

415 F.3d at 1312 (en banc). As such, the term does not require construction.

Instead, its plain and ordinary meaning should control.³

D. “connector”

In claim construction, a threshold question is whether the claim term requires construction, i.e., whether the claim term is in dispute. Adopting the examiner’s position, Petitioner asserts that the claimed “connector” reads on the cylindrical “connector 118” of Lih. (Pet. at 25, 49.) Patent Owner disagrees with this interpretation, which is contradicted by the use of the term “connector” in the intrinsic evidence and under the doctrine of claim differentiation. Under this doctrine, a tribunal generally will attach different meanings and scope to different words or phrases used in separate claims. *See Anderson Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1370 (Fed. Cir. 2007); *In re Rembrandt Techs., LP*, 496 F. App’x 36, 42 (Fed. Cir. 2012); *Seachange Int’l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1368-69 (Fed. Cir. 2005). The term “connector” thus requires construction.

The ’575 Patent describes its invention as comprising a collapsible gasbag 3, “a connector 2,” and a face mask 1, which are sequentially connected. (Ex. 1001 at

³ To the extent the Board determines that it is necessary to construe this term, Patent Owner does not object to the dictionary definitions supplied by Patent Owner for this claim term.

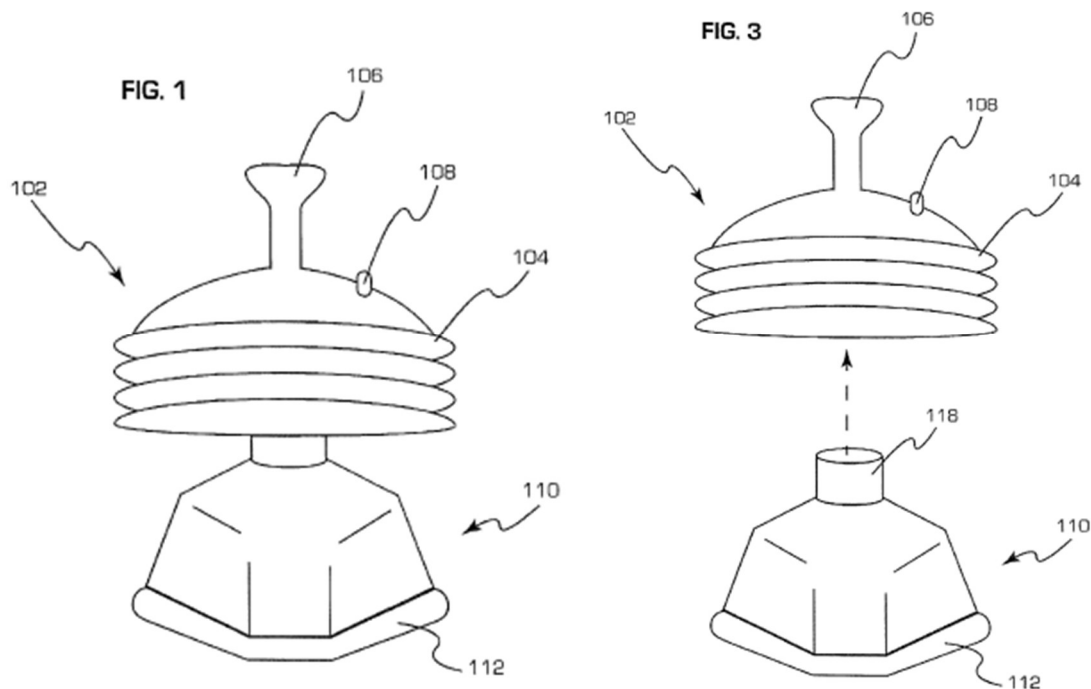
6:4-7, claims 1, 3.) The specification distinguishes “connector 2” from a “connecting cylinder 12,” which is described as being *part of the face mask*, i.e., separate from “connector 2.” (*Id.* at 7:53-61.) Additionally, the ’575 Patent independent claims recite a “connector,” and then recite in dependent claims an *additional* connecting cylinder on the face mask—separate from the connector. Compare claim 3 (reciting a “connector,” separate from the face mask), with claim 4 (reciting that the face mask comprises a “connecting cylinder”). Patent Owner submits that the term “connector” must be construed consistent with its usage in the intrinsic evidence, including the claims, as being a *separate element* from the “connecting cylinder” of the face mask. See *V-Formation, Inc. v. Benetton Grp. SpA*, 401 F.3d 1307, 1310 (Fed. Cir. 2005) (holding intrinsic record “usually provides the technological and temporal context to enable the court to ascertain the meaning of the claim to one of ordinary skill in the art at the time of invention”).

V. The Prior Art

A. Lih (Ex. 1004)

US Patent No. 10,052,115 B2 (Lih, Ex. 1004) describes a choking intervention device comprising a bellows assembly and a removable facemask. (Ex. 1004 at Abstract.) Lih teaches that the “facemask is coupled to the base of the bellows.” (*Id.*). The only disclosure in Lih regarding this coupling shows a direct

connection of the facemask to the bellows as illustrated in FIGS. 1 and 3 of Lih, reproduced below.

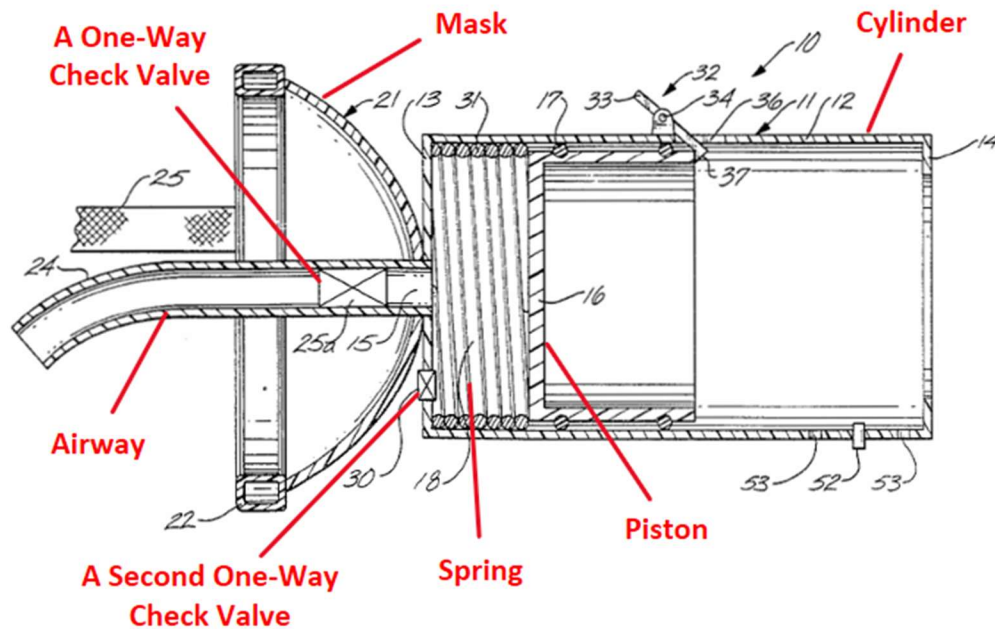


Lih does not disclose the use of a “connector” (as the term is used in the ’575 Patent) to connect the facemask to the bellows—let alone the use of a connector comprising “a bottom plate” as claimed. Notably, although Lih refers to the cylinder 118 of the facemask 110 as a “connector” in its specification (Ex. 1004 at 4:26-45), this cylinder is entirely different from the “connector” that is described and claimed in the challenged patent, as discussed in the claim construction section IV.D, above.

Additionally, although Lih discloses a “relief valve 108” (*id.* at 4:3), nowhere does Lih teach or suggest the use of first and second check valves that “allow gas flow to pass in opposite directions,” as claimed.

B. Tarrats (Ex. 1006)

US Patent No. 4,971,053 (Tarrats, Ex. 1006) discloses an apparatus to remove an obstruction from the trachea of a choking victim that comprises a hollow cylinder (rather than a gasbag), a piston movably disposed within the cylinder, and a mask. The piston is movable by means of a compressed spring within the chamber. In operation, the mask is placed over a choking victim’s mouth and the spring is released causing rearward movement of the piston. This motion reduces the pressure within the cylinder chamber and the person’s mouth, drawing the obstruction out of the trachea. (Ex. 1006 at Abstract.)



Annotated Tarrats FIG. 1

The Tarrats device also includes a tube (“airway 24”), which extends from the facemask into the person’s mouth “preventing the tongue of the victim from blocking the flow of air through the mouth by maintaining the tongue on the floor of the mouth.” (*Id.* at 3:26-35.) The airway may include a “one-way check valve . . . to prevent air from passing through the airway 24 from the chamber 18

and into a victim's mouth.”⁴ (*Id.* at 3:36-42.) The device also includes a second one-way check valve 30 “at the forward end wall 13 of the cylinder 11 to allow air in chamber 18 to escape when the piston 16 is moved forwardly and reset in its forward position.” (*Id.* at 3:43-46.)

In contrast to the challenged claims, Tarrats does not teach or suggest: (i) the claimed gasbag, (ii) a connector having first and second check valves, (iii) a connector comprising a “bottom plate,” or (iv) first and second check valves “arranged on the bottom plate.”

C. da Costa (Ex. 1005)

U.S. Patent No. 3,939,830 (da Costa, Ex. 1005) discloses two different devices for two different purposes. Since the Petition cites to both da Costa embodiments, we separately discuss each of these embodiments below.

In a first embodiment, illustrated in figures 1-4, da Costa discloses a device for removing an obstruction from the throat of a person. In a second embodiment,

⁴ Tarrats discloses an “elastic strap 25” that is attached to the mask and extends around the victim's head. (*Id.* at 3:21-25.) In an apparent typographical error, Tarrats refers to the check valve with the same designation number (25) as the elastic strap. Instead, the check valve illustrated in FIG. 1 has the designation number “25a” rather than “25.” (*Id.* at 3:36-40, fig. 1.)

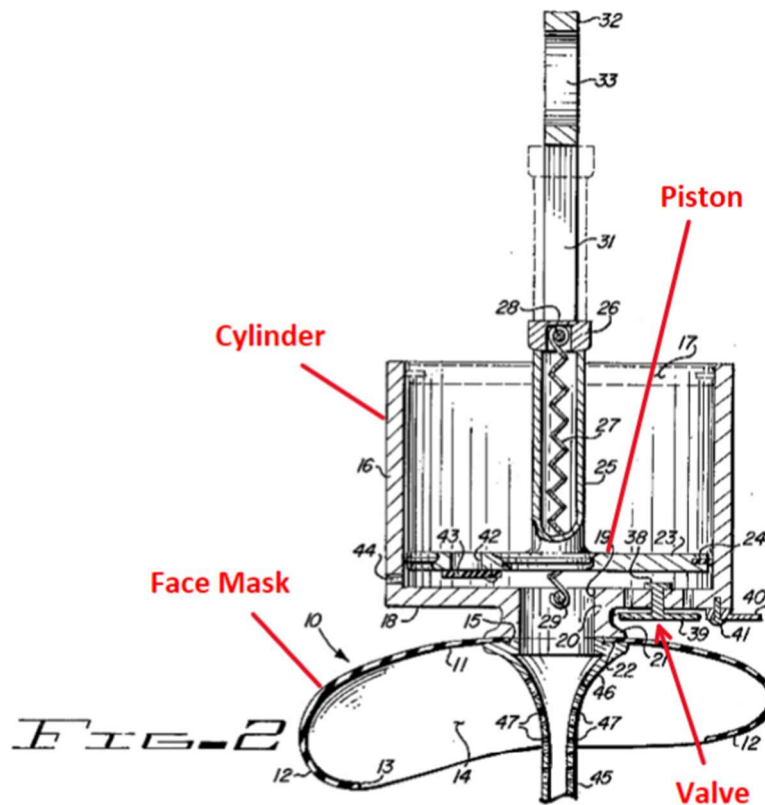
illustrated in figures 5-7, da Costa discloses a device for alleviating heart failure by applying pressure from the lungs to the heart to cause some blood circulation.⁵ (Ex. 1005 at Abstract.)

i. First Embodiment – “De-choker”

Da Costa describes a device for removing an obstruction from the throat referencing figures 1-4. The design of the device is substantially similar to the Tarrats device in that it includes a face mask 10, a cylinder 16, and a piston 23. The da Costa device also includes a valve 36—similar to check valve 30 of Tarrats—secured to the end wall 18 of the cylinder. In use, the valve opens on an instroke and closes on an outstroke. (*Id.* at 4:59-5:8.) That is, outward movement of the piston closes the valve and creates a vacuum, which facilitates removal of the obstruction. If the obstruction is not immediately removed, the plunger is moved inwardly again to reset the device for an additional removal operation. This inward motion does not push the obstruction further down the throat because as the piston is moved inwardly, valve 36 opens to permit air to exit the cylinder without entering the patient’s airway. (*Id.* at 5:45-67.) In this manner, the da Costa de-

⁵ For the reasons discussed below, these embodiments are inconsistent and incompatible with each other and are not combinable.

choking device operates in substantially the same way as—and is cumulative to—the Tarrats device.



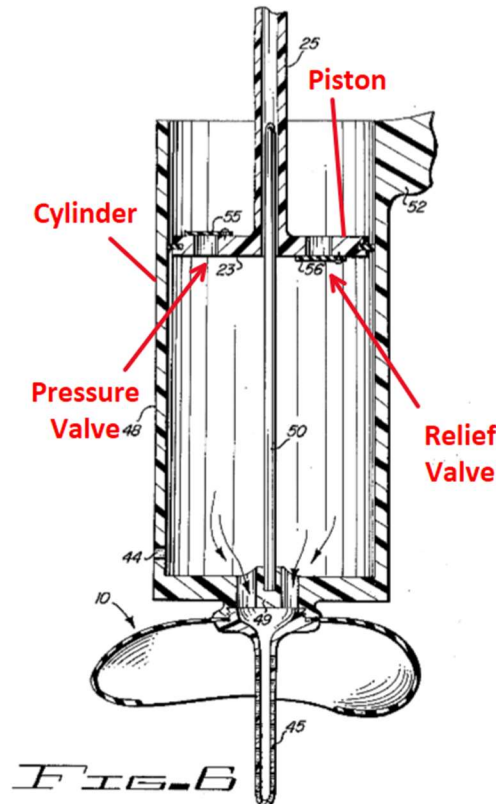
Annotated FIG. 2 of da Costa

ii. Second Embodiment – “Alleviating Heart Failure”

With reference to figures 5-7, da Costa discloses a “modification”⁶ of the de-choking device to form a device suitable for alleviating heart failure. (*Id.* at 6:5-

⁶ Use of the term “modification” in describing the second embodiment supports that these modifications would be inapplicable to the de-choker device of the first embodiment.

59.) In this embodiment, the size of the device is increased to accommodate the capacity of human lungs. (*Id.* at 6:11-15.) Additionally, as illustrated below, the piston “is provided with pressure and relief valves 55 and 56.”⁷ (*Id.* at 6:30-31.)



Annotated FIG. 6 of da Costa

⁷ Petitioner relies on the piston valves of da Costa’s second embodiment for allegedly disclosing the valves in the “connector” of the claimed invention. (Pet. at 29.) As discussed below, however, the piston is situated inside the cylinder and is not “sequentially connected” between the facemask and a gasbag, as claimed. As such, the piston cannot satisfy the “connector” in the challenged claims.

In operation, the mask is placed over the nose and mouth of a patient suffering from heart failure. The piston is then reciprocated in the cylinder, i.e., pumped, in order to fill the lungs “to the limit of their capacity by air under pressure.” (*Id.* at 6:43-44.) In this manner, “the lungs are expanded against heart 54 to compress the latter.” (*Id.* at 6:44-46.) On the outstroke, “the lungs contract to relieve the pressure on the heart and permit it to expand.” (*Id.* at 6:46-48.) The alternating compression and expansion of the heart causes it to perform its pumping function and initiate blood circulation. (*Id.* at 6:48-51.) Thus, this embodiment of da Costa ***expressly requires*** fully inflating the lungs in order to expand the lungs against the heart.⁸

VI. Overview of Arguments

Unlike the lower “reasonable likelihood” standard for granting institution in an *Inter Partes* Review (IPR) proceeding, a Post-Grant Review (PGR) may not be instituted unless the petitioner satisfies a higher burden: that it is “more likely than

⁸ Of course, attempting to fully inflate the lungs of a choking patient would result in adversely pushing the obstruction further into the victim’s airway. (Ex. 1004 at 5:34-39). For this reason, the second embodiment is incompatible with the first embodiment of da Costa.

not” that at least one of the challenged claims is unpatentable. 35 U.S.C. § 324(a) (2018). Petitioner has failed to meet that burden, and institution should be denied.

A summary of Patent Owner’s arguments is provided below.

Ground	Deficiencies of the Ground
1-2	<ul style="list-style-type: none">• Grounds 1 & 2 were fully addressed by the USPTO during prosecution, and Petitioner has failed to identify any material error by the examiner. Institution should be denied under 35 U.S.C. § 325(d).
1: Claims 1-17 as obvious over Lih in view of Tarrats and da Costa	<ul style="list-style-type: none">• None of these references discloses or suggests the claimed “connector” sequentially connected between a gasbag and a face mask.• No logical motivation exists for combining the piston valves in the second embodiment of da Costa with a face mask/gasbag “connector.”• Incorporating the check valves from da Costa into a connector would result in a device unsuitable for removing an obstruction from a choking patient’s airway.• The prior art fails to disclose or suggest a first check valve having a first gas inlet end hermetically connected to a face mask.
2: Claims 1-17 as anticipated by Lih	<ul style="list-style-type: none">• Lih fails to teach several claim elements, including a connector having a bottom plate, a first check valve, and a second check valve arranged on the bottom plate.

VII. Grounds 1 and 2 present the same or cumulative prior art to the prior art that the Office previously considered.

A. Section 325(d) and the *Advanced Bionics* standard

The Office should exercise its discretion under 35 U.S.C. § 325(d) and deny institution because the primary references cited in the Petition, Lih and Tarrats, were fully considered and discussed at length during examination of the ’575

Patent. Moreover, da Costa’s description of a “de-choker” device is cumulative to Tarrats, since both references disclose a removal device comprising a face mask, a cylinder, and a piston within the cylinder.⁹ As such, the Board should exercise its discretion and deny institution.

35 U.S.C. § 325(d) provides:

In determining whether to institute . . . , the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

The purpose of this provision is to protect patent owners from serial challenges and the resulting burden on the patent owner and the Office in managing multiple proceedings involving the same patent. *See* 157 Cong. Rec. S1041-42 (daily ed. Mar. 1, 2011) (statement of Sen. Kyl). The Board uses a two-part framework for evaluating § 325(d): (1) whether the same or substantially the same prior art or

⁹ To the extent da Costa differs from the already considered prior art, its disclosure relates to a *heart resuscitation device*, which is completely unrelated to and incompatible with devices for removing a blockage from a patient’s airway. As discussed below, an examiner’s decision during prosecution not to rely on prior art in wholly unrelated fields cannot reasonably rise to the level of “material” error.

arguments were previously presented to the Office; and (2) if so, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims. *Advanced Bionics, LLC v. Med El Eletromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8-9 (P.T.A.B. Feb. 13, 2020) (precedential).

B. The Petition relies on the same or substantially the same prior art or arguments that were previously presented to the Office.

Addressing the first prong, the subject Petition relies on three prior art patents: Lih, Tarrats, and da Costa. Ground 1 alleges that the challenged claims are obvious over these patents, and Ground 2 alleges that the claims are anticipated by Lih. The prosecution history of the '575 Patent supports that the same or substantially the same prior art was previously presented to the Office.

Both Lih and Tarrats were cited repeatedly throughout the prosecution history of the '575 Patent. The relevant portions of the prosecution history are summarized below:

- On March 2, 2022, the examiner issued an office action, which included a rejection based, in part, on Lih.¹⁰ (Ex. 1002 at P00068.) The examiner also included Lih and Tarrats on the Notice of References Cited. (*Id.* at P000071.)
- On June 8, 2022, the examiner issued a final office action, in which she rejected claims 1, 7 and 10-12 as obvious over Lih and Tarrats. (*Id.* at P000094.)
- On Aug. 25, 2022, the examiner issued a Notice of Allowance in which she indicated that Lih and Tarrats were the “closest prior art,” but that they “fail to disclose a bottom plate and the first check valve and the second check valve are arranged on the bottom plate.” (*Id.* at P000142.) The examiner also stated that “any conclusion of obviousness would be based upon improper hindsight reasoning, using knowledge gleaned only from the applicant’s disclosure.” (*Id.* at P000143.)

¹⁰ Notably, Lih was never relied upon by the Office as an anticipatory reference or as a single reference for obviousness because the examiner repeatedly concluded that Lih fails to disclose certain claim features. (*Id.* at P000094-95 (“Lih . . . lacks a first check valve”), P000142, P000177 (“Lih . . . fail[s] to disclose a bottom plate and the first check valve and the second check valve are arranged on the bottom plate.”).)

By citing Lih and Tarrats during prosecution of the '575 Patent and highlighting them as the “closest prior art,” it is clear that the examiner fully considered and understood both references. (*Id.* at P000142, P000176.) Ultimately, however, Patent Owner overcame the examiner’s rejections, and the examiner allowed the claims currently at issue—fully cognizant of the teachings of these references.

Although not specifically discussed by the examiner, the third reference relied upon in the Petition, da Costa, was cited in the examiner’s search results during prosecution ***at least 22 times***. (Ex. 1002 at P000076, 103, 106, 107, 109, 110, 111, 156, 159, 160, 162, 163, 164 (*see* search results L4, L5, L30, L33-36, L49, L59, L60).) Thus, da Costa was also squarely before the examiner, although the examiner appears to have viewed it as less relevant than Lih and Tarrats (understandably because it is cumulative to Tarrats).

To the extent relevant, da Costa discloses in its first embodiment a de-choking device comprising a face mask, a cylinder, and a piston. All of these features are present in the Tarrats device. Thus, the da Costa de-choking device is substantially similar to the device described in Tarrats. Notably, ***the Petition does not rely on any component in the first embodiment of da Costa that was not also present in Tarrats***. As such, da Costa is cumulative to Tarrats and is “substantially

the same” as prior art that was fully considered by the Office. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8-9.

The second embodiment of da Costa relates to a completely unrelated device—a heart resuscitation device—which is beyond the scope of the present invention.¹¹ Additionally, the second embodiment of da Costa would be contraindicated for choking victims since it expressly requires fully inflating the lungs to repeatedly expand and compress the heart to facilitate blood flow. (Ex. 1005 at 6:43-44.) If air is pumped into the lungs of a choking victim it would be expected to push the obstruction *further into the airway* of the victim rather than removing the obstruction. (Ex. 1004 at 5:34-39.) Thus, the second embodiment is inapplicable to de-choking devices and immaterial for obviousness.

In view of the foregoing analysis, the same or substantially the same prior art relied upon in the Petition was previously presented to the Office—and fully considered. Thus, the first prong of the *Advanced Bionics* analysis has been satisfied.

¹¹ As discussed above in Section III, the relevant level of skill in the art relates to using or designing devices associated with maintaining or clearing the airway of humans. The POSA’s knowledge would *not* extend to unrelated medical fields or devices such as heart resuscitation devices.

C. The Petition fails to demonstrate that the Office erred in a manner material to the patentability of the challenged claims.

Having established that the same or substantially the same prior art was considered by the Office, it is next necessary to determine whether the Petition demonstrates that the Office erred in a manner “material” to the patentability of the challenged claims. *Advanced Bionics*, IPR2019-01469, Paper 6 at 8-9. Here, the Petition provides no explanation concerning how the Office materially erred. Moreover, as explained below, to the extent Petitioner additionally relies on the heart resuscitation device of da Costa, Petitioner’s arguments do not rise to the level of demonstrating a “material” error. As a result, the Board should deny institution under 35 U.S.C. § 325(d).

Concerning Ground 1, by “[a]dopting the Examiner’s arguments,” Petitioner relies primarily on Lih and Tarrats *in the exact same way* that these references were applied by the examiner during prosecution. (Pet. at 28.) The only difference between Petitioner’s position and the examiner’s position appears to be Petitioner’s additional reliance on da Costa. (Pet. at 28-29.) As explained above, however, the first embodiment of da Costa (de-choker) is cumulative to Tarrats, and any reliance in the Petition on the first embodiment fails to rise to the level of demonstrating a “material” error during examination. Petitioner’s additional reliance on the *piston valves* in the *heart resuscitation device* (second embodiment) of da Costa is

similarly unpersuasive. (*Id.*) As discussed below, the removal devices of the challenged claims recite a “gasbag” rather than a cylinder, and piston valves have no applicability to removal devices employing gasbags. Additionally, heart resuscitation devices are in a completely different technical field from removal devices for rescuing choking patients and are beyond the scope of what a POSA would consider.¹² Lastly, no reasonable rationale¹³ has been provided for how a POSA could or would relocate and redesign the piston valves in da Costa into the claimed “connector” having a “bottom plate,” in a manner suitable for the claimed removal devices. For at least these reasons, Petitioner’s reliance on the piston valves in the heart resuscitation device of da Costa in Ground 1 is misguided and fails to demonstrate that the Office erred in a manner “material” to the patentability of the challenged claims.

¹² See *supra* note 11.

¹³ Petitioner’s assertion that da Costa would have been obvious “to initiate blood circulation” (Pet. at 29) is misguided since according to da Costa initiating blood circulation requires filling the lungs “to the limit of their capacity,” which is contraindicated for choking victims. (Ex. 1005 at 6:43-44; Ex. 1004 at 5:34-39 (indicating that pushing air into a choking victim’s airway would “further lodg[e] the foreign object in the respiratory tract . . .”).)

Petitioner's position concerning Ground 2 (anticipation by Lih) also fails to support that the Office erred in a manner material to patentability. In Ground 2, Petitioner relies primarily on a claim chart, which substantially mirrors the examiner's position during prosecution. Critically, other than appearing to simply disagree with the examiner, the Petition fails to address how the examiner committed a material error by taking the position that Lih fails to disclose "a bottom plate and the first check valve and the second check valve are arranged on the bottom plate." (Ex. 1002 at P000142, P000177; *Advanced Bionics*, IPR2019-01469, Paper 6, at 10-11 (indicating that "if the alleged error is a disagreement with a specific finding of record by the Office, then ordinarily the petitioner's required showing of material error must overcome persuasively that specific finding of record").) Here, the Petition's silence concerning the examiner's position fails to overcome persuasively the Office's specific finding of record. As such, the Petition has failed to demonstrate that the Office materially erred in its position that the challenged claims are novel over Lih.

According to Board precedent, when relying on the same or substantially the same prior art that was overcome during prosecution, if a "petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute." *Advanced Bionics*, IPR2019-01469, Paper 6 at 8-9; *see also Prism Pharma Co., Ltd. v. Choongwae Pharma Corp.*, IPR2014-00315, Paper No. 14 at

12-13 (July 8, 2014) (denying institution where “[t]he same prior art . . . and arguments” were “presented previously to the Office” during examination). In this case, Petitioner has relied on the same or substantially the same prior art that was considered during examination and has failed to identify any material error by the examiner. As a result, the Board should follow its *Advanced Bionics* precedent and deny institution under 35 U.S.C. § 325(d).

VIII. Petitioner has not demonstrated that it is more likely than not to prevail on any of the proposed grounds for unpatentability.

A. Ground 1 is unlikely to prevail because it fails to satisfy the legal requirements for obviousness.

In Ground 1, Petitioner asserts that the combination of Lih, Tarrats, and da Costa renders the claims obvious. (Pet. at 28.) To establish that a claim is obvious, Petitioner has the burden of determining: (i) the scope and content of the prior art, (ii) the differences between the claimed invention and the prior art, and (iii) resolve the level of ordinary skill. Against this backdrop, the obviousness or non-obviousness of the subject matter is determined. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). In *KSR Int’l*, 550 U.S. at 418, the Supreme Court reinforced that any rationale for combining references for obviousness must be “made explicit.” According to the Court, “[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal

conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

i. Claims 1, 7, and 10-12

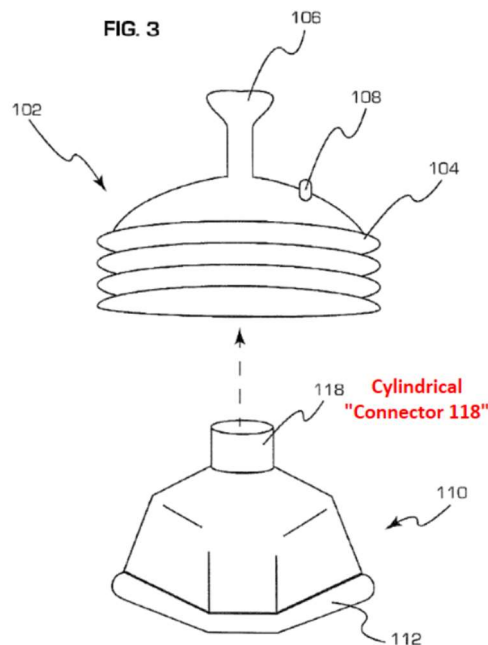
Petitioner has failed to satisfy its burden on obviousness for independent claim 1 and dependent claims 7 and 10-12, which depend from claim 1, because (i) none of these references discloses or suggests the claimed “connector” sequentially connected between a gasbag and a face mask; (ii) no logical motivation exists for combining the piston valves in the second embodiment of da Costa with a face mask/gasbag “connector,” (iii) incorporating the check valves from da Costa into a connector would result in a device unsuitable for removing an obstruction from a choking patient’s airway, and (iv) the prior art fails to disclose or suggest a first check valve having a first gas inlet end hermetically connected to a face mask. In view of these deficiencies, Petitioner has failed to present a legally sound argument that the challenged claims are obvious over Lih in view of Tarrats and da Costa.

a. None of the cited patents disclose or suggest the claimed “connector . . . sequentially connected” between the gasbag and the face mask.

As indicated above, challenged claim 1 includes a “connector” that is “sequentially connected” between a gasbag and a face mask. The connector as claimed “comprises a bottom plate.” First and second check valves “are arranged on the bottom plate” and “allow gas flow to pass in opposite directions.” (Ex. 1001

at 12:37, 39, claim 1.) As discussed below, none of Lih, Tarrats, or da Costa discloses or suggests a “connector” that is “sequentially connected” between a gasbag and a face mask as claimed. For this reason, Petitioner’s obviousness argument is unlikely to prevail.

Petitioner begins Ground 1 by “adopting” the examiner’s position during prosecution and appearing to suggest that it would be obvious to modify the examiner’s position with the piston valves of da Costa. (Pet. at 28-29 (citing Ex. 1002 at P000176).) During prosecution, the examiner initially relied upon the cylindrical connector 118 of Lih as allegedly satisfying the claimed “connector” feature of the claimed invention. (Ex. 1002 at P000176.) By “adopting” this argument, Petitioner incorporated this examiner argument into its Petition.



Annotated FIG. 3 of Lih (Ex. 1004)

As discussed in the Section IV.D, above, the term “connector” must be construed consistent with its usage in the intrinsic evidence as being a *separate element* from the “connecting cylinder” of the face mask. For this reason, the claimed “connector” does not read on the connecting cylinder of the face mask described in Lih. Lih thus fails to disclose this feature of the claimed invention.

Regarding Tarrats, the Petitioner similarly relies on the examiner’s position that Tarrats discloses a connector. (Pet. at 29 (citing Ex. 1002 at P000176-177).) The examiner’s position during prosecution, however, cites to “connector (15, fig 1)” as allegedly satisfying the claim feature. (Ex. 1002 at P000176.) But item 15 in Tarrats is referred to as an “aperture”—not as a connector—and is described as being *a portion of the face mask*. (Ex. 1006 at 2:29-32 (“suction mask 10 comprises . . . end wall 13 having an aperture 15”).) Additionally, tubular airway 24 has a cylindrical shape and is analogous to the connecting cylinder of Lih, which, as discussed above, is not covered by the “connector” feature of the challenged claims. Thus, for similar reasons, the claimed “connector” does not read on the tubular airway of Tarrats.

As for da Costa, the Petition does not appear to rely on that reference for disclosing this claim feature. Instead, the Petition relies primarily on Lih and Tarrats for the “connector” limitation and cites to the piston of da Costa, which “connects to an air chamber” and which contains valves 55 and 56. (Pet. at 29.)

Since it is disposed within the air chamber, however, the piston in da Costa is conclusively not “sequentially connected” between the gasbag and the face mask. Thus, the fact that the piston “connects” to an air chamber is irrelevant to the challenged claims. As such, da Costa also fails to disclose the claimed “connector” of the challenged claims.

Since none of the cited references discloses or suggests a “connector” “sequentially connected” between a gasbag and a face mask as claimed, Petitioner’s obviousness position lacks merit and is unlikely to prevail.¹⁴

b. No logical motivation exists for combining the piston valves in the second embodiment of da Costa with a face mask/gasbag “connector.”

As discussed above, Petitioner adopted the examiner’s position during prosecution and argues that it would be obvious to modify the examiner’s position with the piston valves of da Costa. (Pet. at 28-29 (citing Ex. 1002 at P000176).) During prosecution, the examiner relied on the cylindrical connector 118 of Lih as allegedly satisfying the claimed “connector” feature of the claimed invention. (Ex. 1002 at P000176.) The cylindrical connector 118 of Lih, however, fails to include

¹⁴ Independent claims 3 and 9, and dependent claim 17 also include the “sequentially connected” claim limitation. These claims are thus patentable over the combination of Lih, Tarrats, and da Costa for similar reasons.

a bottom plate as claimed. The Petition acknowledges as much, stating “Lih and Tarrats fail to disclose a bottom plate” (Pet. at 28 (quoting Ex. 1002 at P000177).) The Petition also acknowledges that Lih and Tarrats fail to disclose “a bottom plate and [that] the first check valve and the second check valve are arranged on the bottom plate.” (*Id.* (quoting Ex. 1002 at P000177).) Thus, any obviousness argument starting with Lih or Tarrats must explain *how* and *why* a POSA would modify the Lih cylindrical connector 118 in at least two respects: (1) modifying the shape of the alleged connector from a cylinder to “a bottom plate,” and (2) situating both a first check valve and a second check valve onto the bottom plate. Petitioner’s position fails in both respects, as explained below.

First, concerning the shape of the alleged connector, the Petition provides no articulated reason or rationale as to why (or how) a POSA would modify cylindrical connector 118 from Lih with a flat piston head of the type shown in da Costa. *See KSR Int’l*, 550 U.S. at 418. The totality of Petitioner’s argument appears to be that da Costa is in the “same field of art” and “would have been obvious . . .

(so to avoid pushing the obstruction farther into the user’s airway¹⁵ while in use to initiate blood circulation).” (Pet. at 29.) As an initial matter, “[b]eing in the same field of endeavor and/or addressing similar problems . . . does not provide a reason with a rational underpinning” for modifying the prior art. *See NecksGen, Inc. v. Simpson Performance Prods., Inc.*, IPR2018-00133, Paper 9 at 12-13 (P.T.A.B. May 4, 2018) (denying institution). Additionally, this argument disregards the ***express purpose*** of the piston in da Costa and the purpose of the claimed invention.

The purpose of the piston in the second embodiment of da Costa is to reciprocate in an airtight manner in cylinder 48 to repeatedly fill the lungs with air and cause the heart to pump. (Ex. 1005 at 6:40-52.) This purpose has no application to the claimed invention, which uses a “gasbag” rather than a cylinder to create suction and remove an obstruction from a patient’s airway. Thus, the benefit of the flat shape of the piston in da Costa is absent in the claimed invention, and a POSA would have no reason to adapt a flat piston shape into the face mask

¹⁵ The Petition fails to explain how a POSA could incorporate the valves of the second embodiment of da Costa into the device of Lih/Tarrats in a manner that would “avoid pushing the obstruction farther into the user’s airway.” In fact, as indicated in subsection c, below, incorporating the da Costa valves into Lih/Tarrats would result in a device unsuitable for the treatment of a choking patient.

cylinder of Lih. Because Petitioner has failed to articulate a logical reason for adapting the flat piston head of da Costa into Lih, its obviousness arguments are legally untenable.

Second, Petitioner has provided no clear rationale as to how or why a POSA would somehow incorporate the first and second check valves into a modified (plate-shaped) connector. Here too, the purpose of the check valves in da Costa is different from the purpose of the check valves in the claimed invention. In the second embodiment of da Costa, as a device intended to repeatedly inflate the lungs to their capacity to pump the heart, valves 55 and 56 are provided to control the “pressure” during each instroke and outstroke of the device, presumably for the safety of the patient. (Ex. 1005 at 6:30-31.) The claimed invention, in contrast, is not intended to fill the lungs—which would be contraindicated for treatment of a choking patient. Controlling the pressure in each instroke and outstroke in the manner described in da Costa’s second embodiment is thus unnecessary in the removal devices of the challenged claims. For this reason, a POSA would appreciate that the first and second check valves of da Costa would have no applicability to “connector 118” of Lih.

Petitioner’s reliance on “initiat[ing] blood circulation” as a purported motivation for incorporating valves 55 and 56 into the connector 118 of Lih is also misguided. (Pet. at 29.) As indicated above, the only method described in da Costa

for initiating blood circulation requires inflating of the lungs “to the limit of their capacity,” which is not possible for choking victims without pushing the obstruction further into the patient’s airway. (Ex. 1005 at 6:43-44; Ex. 1004 at 5:34-39.) Because this rationale for incorporating the valves in da Costa into the modified (plate-shaped) connector is inapplicable to choking patients, Petitioner’s obviousness position in Ground 1 lacks merit and is unlikely to prevail. *See, e.g., Comcast Cable Commc’ns v. Rovi Guides, Inc.*, IPR2017-00941, Paper 11 at 37 (P.T.A.B. Sept. 11, 2017) (indicating that a mere “conclusory assertion . . . negates the well-established requirement that an asserted ground of obviousness must demonstrate articulated reasoning with rational underpinning to support the legal conclusion of obviousness”); *Securus Techs., Inc. v. Glob. Tel*Link Corp.*, IPR2016-00313, Paper 7 at 26 (P.T.A.B. June 8, 2016) (denying institution because “similarity” of prior art devices did not rise to the level of an articulated reasoning with rational underpinnings to support obviousness).

c. Incorporating the check valves from da Costa into a connector would result in a device unsuitable for removing an obstruction from a choking patient’s airway.

As discussed above, the check valves 55 and 56 in da Costa are adapted to permit repeated inflation of a patient’s lungs “to the limit of their capacity” to cause the heart to pump and initiate blood circulation. (Ex. 1005 at 6:43-52.) For

the device to function properly, it logically follows that these check valves must be tuned such that air can flow freely into the lungs at a pressure sufficient to apply pressure to the heart.

Petitioner has asserted that it would be obvious to incorporate the valves of da Costa into the device of Lih “to initiate blood circulation.” (Pet. at 29.) Since the valves in da Costa must be tuned to permit full inflation of the lungs in order to initiate blood circulation, it follows that incorporating the da Costa valves into the Lih or Tarrats device would result in a device that would *fully permit air to be pushed into the victim’s airway* during the instroke. Since pumping air into a choking victim’s airway would be contraindicated for a choking patient, it follows that incorporating the da Costa valves into the Lih/Tarrats device for the reasons alleged in the Petition would result in a device unsuitable for removing an obstruction from a choking patient’s airway. (Ex. 1004 at 5:34-39 (indicating that pushing air into a choking victim’s airway would “further lodg[e] the foreign object in the respiratory tract . . .”).) For this reason also, Petitioner’s obviousness position lacks merit and is unlikely to prevail.

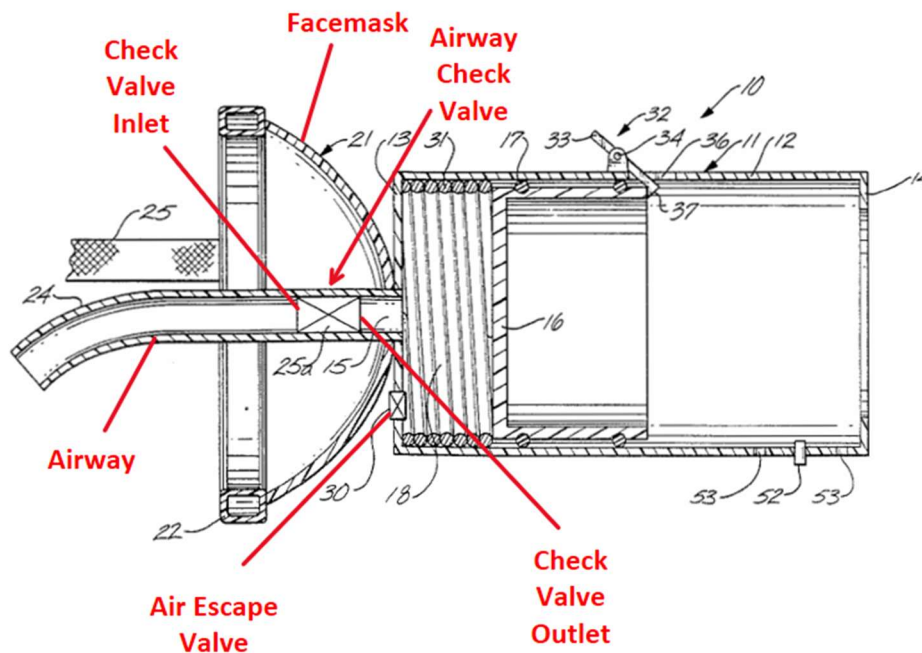
d. The prior art fails to disclose or suggest a first check valve having a first gas inlet end hermetically connected to a face mask.

In addition to requiring that the first check valve is “arranged on the bottom plate,” challenged claim 1 also recites that the “upper side of the face mask is

hermetically connected to a first gas inlet end of the first check valve.” Thus, claim 1 clearly defines the orientation of the first check valve: *it is disposed on the bottom plate and has an inlet hermetically connected to the face mask*. None of the cited references teaches or suggests this orientation of the first check valve. For this reason also, Petitioner’s obviousness position lacks merit.

More specifically, as discussed above, although Lih discloses a relief valve (which is arguably analogous to the claimed second check valve), Lih is completely silent concerning a first check valve. As such, Lih provides no disclosure or suggestion of the first check valve limitation—let alone its inlet/outlet orientation in an obstruction removal device.

Tarrats discloses two check valves, one disposed in tubular airway 24 and one disposed at the forward end wall 13 of the cylinder 11. (Ex. 1006 at 3:36-46.) The airway check valve 25a of Tarrats is described as preventing air from passing through the airway 24 from the chamber 18 and into a victim’s mouth. (*Id.*). As shown in annotated FIG. 1, below, Tarrats indicates that (i) the inlet of valve 25a is disposed within the airway well *upstream* of where the airway contacts the face mask, and (ii) the outlet of valve 25a is disposed adjacent to where the airway contacts the face mask.



Annotated FIG. 1 of Tarrats

Although the outlet of valve 25a in Tarrats is disposed adjacent the face mask, the inlet cannot reasonably be characterized as “hermetically connected to the face mask”—in fact, the *inlet* of valve 25a is not connected to the facemask at all. Thus, this feature of the challenged claims is neither taught nor suggested by Tarrats.

The da Costa disclosure fails to remedy these deficiencies of Lih and Tarrats. As discussed above, da Costa is silent concerning the claimed first check valve in its de-choking device (first embodiment), and the piston valves in the heart resuscitation device (second embodiment) of da Costa are described as a “modification” to the de-choking device, as discussed above. No teaching or suggestion exists in da Costa or elsewhere to move these piston valves to a completely different location, i.e., from the pistons in the cylinder to the claimed

facemask/gasbag “connector”—let alone to completely redesign them to render them suitable for a de-choking device. There also is no teaching or suggestion in da Costa to relocate the first check valve to a specific orientation in which “the inlet” of a first check valve is “hermetically connected to the face mask.”

In view of the foregoing, none of the prior art patents disclose or suggest a first check valve having a first gas inlet end hermetically connected to a face mask, as recited in the challenged claims. For this reason also, Petitioner is unlikely to prevail and institution should be denied.

ii. Claim 2

The Petition asserts that that da Costa FIGS. 3 and 6 disclose “a plurality of check valves” and that it would be obvious to modify the connector of the modified Lih to include multiple check valves in an encircling manner “to evenly remove air from the cavity when the bellow is depressed (and *to stimulate blood circulation*).” (Pet. at 30-31 (emphasis added).)

On the contrary, claim 2 recites “a plurality of *second check valves* . . . encircling the first check valve.” (emphasis added). Figure 3 of da Costa shows a single “valve 36,” and figure 6 shows opposing valves 55 and 56. (Ex. 1005 at 4:61-63, 6:30-31.) Neither figure teaches or suggests “a plurality of *second check valves*”—let alone such valves “encircling the first check valve” as claimed.

Also, the Petition fails to cite any evidentiary support for its alleged motivation. Moreover, as discussed above, “stimulating blood circulation” requires fully inflating the lungs, and the Petition fails to explain how this can be accomplished in a choking patient. The motivation is illogical, lacks merit, and is unlikely to prevail.

iii. Claims 3-6 and 8

The above arguments concerning claim 1 in subsection VIII.A.i. apply equally to claims 3-6 and 8.

Additionally, the Petition lumps its analysis of claims 3-6 and 8 into a single cursory paragraph. (Pet. at 31.) This “analysis” is deficient in that it (i) fails to include **any** pinpoint citations to the prior art for **any** of the features of claim 3, and (ii) does not provide any motivation for modifying the prior art to arrive at the claimed invention. Instead, the Petition wholly ignores features 3.1-3.16 of claim 3 and asserts—***without any evidentiary support***—that features 3.17-3.24 are “obvious features that are inherent to check valves.” (Pet. at 31.) Merely saying that features are obvious does not make them so, and, in addition to the deficiencies discussed above regarding claim 1, none of Lih, Tarrats, or da Costa discloses or suggests the check valve structure recited in features 3.17-3.24 of claim 3. The Petition is devoid of the legal analysis mandated by *Graham* and *KSR* and fails as a matter of law. *See also Johns Manville Corp. v. Knauf Insulation*,

Inc., IPR2018-00827, Paper 9 at 13 (P.T.A.B. Oct. 16, 2018) (denying institution because reasons for modifications were not adequately supported) (informative).
Petitioner’s position regarding claims 3-6 and 8 is unlikely to prevail.

iv. Claims 9 and 16

The above arguments concerning claim 1 in subsection VIII.A.i. apply equally to claims 9 and 16.

Additionally, the Petition breaks down claim 9 into 24 discrete claim elements: 9.1-9.24. (Pet. at 11-12.) In a one sentence obviousness analysis, the Petition states that duckbill valves are “commonly known” and that the ’575 Patent recites “inherent features” to duckbill valves. (Pet. at 32 (citing Ex. 1003 at 14,¹⁶ Ex. 1019,¹⁷ Ex. 1020).) The Petition fails to address *any* of the specific claim features of claims 9 and 16. Additionally, Lih, Tarrats, and da Costa fail to disclose the existence of duckbill valves—let alone any of the specific features listed in valve elements 9.17-9.21 or 16.1-16.2. Petitioner’s argument concerning claims 9 and 16 flies in the face of the *KSR* mandate that obviousness arguments must include an articulated reason with some rational underpinnings and “cannot be

¹⁶ The citation to Exhibit 1003 at 14 does not support this proposition.

¹⁷ Exhibit 1019 is dated August 11, 2021, which is after the August 3, 2021 filing date of the challenged patent. As such, Exhibit 1019 is not prior art.

sustained by mere conclusory statements.” *KSR*, 550 U.S. at 418 (citation omitted).

Petitioner is unlikely to prevail on these claims.

v. Claim 13

The above arguments concerning claim 1 in subsections VIII.A.i.b.-VIII.A.i.d. apply equally to claim 13.

vi. Claim 14

The above arguments concerning claim 2 apply equally to claim 14.

vii. Claim 15

Claim 15 recites a specific valve structure having “at least three first slits,” among other features. Petitioner asserts that da Costa discloses this feature. (Pet. at 33.) In fact, it does not. Although tube 45 appears to have holes in it, tube 45 is *not* a valve and does *not* have slits in it. Nowhere do *any* of the cited references teach or suggest this claim feature. As such, claim 15 is non-obvious over these references.

viii. Claim 17

The above arguments concerning claim 1 in subsection VIII.A.i. apply equally to claim 17.

B. Ground 2: Petitioner has failed to show the challenged claims are anticipated by Lih.

i. Introduction

As discussed above, Lih fails to teach each element of the claims and thus cannot anticipate the claims. Petitioner is thus unlikely to prevail on Ground 2. Institution should be denied.

A claim is anticipated only if a disclosure teaches every element of the claim, either expressly or inherently. The case law is abundantly clear: to establish inherency, evidence must make clear that the missing descriptive matter is “necessarily present” in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. “The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted).

Petitioner has failed to demonstrate that it is more likely than not to prevail on its position that Lih anticipates Claims 1-17 because Lih fails to teach, expressly or inherently, several claim features. As described above, the USPTO explicitly considered Lih and found it to be lacking several claim elements, including the first check valve on the connector, the second check valve on the connector, and the first check valve and the second check valve arranged on the bottom plate. (Ex. 1002 at P00095, P000142, P000177.) Additional claim features are also absent from Lih.

In summary, Lih fails to teach at least the following claim limitations:

- 1) the connector of claims 1-17,
- 2) the first check valve of claims 1-17,
- 3) an upper side of the facemask hermetically sealed to a first gas inlet of the first check valve of claims 1-12 and 17,
- 4) a connector comprising a bottom plate of claims 1-17,
- 5) a first check valve arranged on the bottom plate of the connector of claims 1-17,
- 6) a second check valve arranged on the bottom plate of the connector of claims 1-17,
- 7) a first check valve and second check valve allowing gas flow to pass in opposite directions as required in claims 1, 2, and 10-17; and
- 8) the duckbill valves of claims 9 and 16.

While these elements are addressed above with respect to Ground 1, they are further explained below.

ii. Lih fails to teach the connector as required by claims 1- 17.

Each independent claim requires a connector. The Petition asserts that the connecting cylinder *on the face mask* of Lih satisfies the “connector” feature of the challenged claims. (Pet. at 36.) This position ignores the intrinsic evidence of

the challenged claims as well as the full structural description of the “connector” in the challenged claims. For these reasons, Ground 2 is unlikely to prevail.

As discussed in the claim construction section, above, the term “connector” must be construed consistent with its usage in the intrinsic evidence as being a *separate element* from the “connecting cylinder” of the face mask. For this reason, the claimed “connector” does not read on the connecting cylinder of the face mask in Lih. As such, Lih fails to disclose this feature of the claimed invention.

Additionally, as discussed above, the challenged claims have a very specific structural description of the claimed “connector.” For example, claim 1 states that the connector is “sequentially connected” between a gasbag and a face mask. As discussed above, Lih fails to disclose, expressly or inherently, a “connector” that is “sequentially connected” between a gasbag and a face mask as claimed. For these reasons, Petitioner’s anticipation arguments are unlikely to prevail.

iii. Lih fails to teach the first check valve as required by claims 1-17.

Claims 1-12 and 17 recite a first check valve having a first gas outlet end of the first check valve in communication with the gas storage cavity. Claims 13-16 similarly recite a first check valve. Lih does not teach this claim element. As discussed above, the challenged claims recite a connector having a bottom plate with first and second check valves disposed in the bottom plate. Claims 1, 3, 9, and

17 require that a first gas outlet end of the first check valve is in communication with the gas storage cavity. (Ex. 1001 at 10:4-5, 10:35-37, 11:52-54, 13:14-15.)

The claims also recite that the upper side of the face mask is hermetically connected to a first gas inlet end of the first check valve. Lih does not teach this first check valve, as claimed. Although Lih discloses a “relief valve,” this valve is “configured to allow air to escape from inside the bellows assembly when the bellows is being compressed,” as explained in the Petition. (Pet. at 35 (quoting Ex. 1002 at 53-57).) Thus, the relief valve in Lih is reversed relative to the claimed “first check valve.” In fact, the examiner conceded this point during prosecution, repeatedly stating that “Lih . . . lacks a first check valve on the connector.”¹⁸ (Ex. 1002 at P000094-95, P000142, P000177.) Lih fails to disclose the first check valve as claimed and cannot anticipate the challenged claims.

¹⁸ As indicated above, Petitioner has failed to demonstrate that this conclusion by the examiner was incorrect or constitutes a material error. *Advanced Bionics*, IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) (precedential).

iv. Lih fails to teach that the upper side of the facemask is hermetically sealed to a first gas inlet of the first check valve as required by claims 1-12 and 17.

Claims 1-12 and 17 require that an upper side of the facemask is hermetically sealed to a first gas inlet of the first check valve. Lih does not teach this limitation.

In its Petition, Petitioner cites Lih, stating “wherein the at least one relief valve is disposed on at least one of the bellows assembly, and the facemask.” (Pet. at 38.) This statement misses the point. As indicated above, Lih fails to disclose the first check valve. Lih therefore also fails to disclose a first check valve having the claimed orientation. That is, Lih thus fails to teach *hermetically sealing a first gas inlet* of the first check valve to the face mask as claimed. As such, Lih cannot anticipate the challenged claims.

v. Lih fails to teach a connector comprising a bottom plate as required by claims 1-17.

As explained above, Lih does not teach a connector as claimed. Thus, it cannot have a connector comprising a bottom plate as claimed. Petitioner cites Lih for teaching “a bellows having a base with an opening configured to provide an access to an interior volume of the bellows assembly and dimensioned to be attached to a facemask via a facemask connector.” (Pet. at 38.) As an initial matter, the Petition only cites to the cylindrical feature of the face mask (feature 118 of FIG. 3 of Lih) as an alleged connector. (Pet. at 36.) A cylinder cannot reasonably

be characterized as a “bottom plate.” Additionally, nowhere does Lih suggest that the connector may have a “bottom plate” structure. Because Lih fails to disclose a connector comprising the claimed “bottom plate” structure, Lih cannot anticipate the challenged claims.

vi. Lih fails to teach a first check valve arranged on the bottom plate of the connector as required by claims 1-17.

Claims 1-17 require that the first check valve and second check valve are arranged on the bottom plate of the connector. Petitioner cites to Lih, stating “In various implementations, the relief valve 108 is positioned on [] a base 114 of the bellows 104.” (Pet. at 39 (alteration in original).) As explained above, however, Lih does not teach a connector as claimed, a bottom plate of a connector as claimed, or a first check valve as claimed. In addition, Lih fails to teach a first check valve arranged on the bottom plate of the connector as required by claims 1-17. Thus, Lih also does not anticipate claims 1-17 for at least this reason.

vii. Lih fails to teach a second check valve arranged on the bottom plate of the connector as required by claims 1-17.

As explained above, Lih does not teach a connector as claimed, or a bottom plate of a connector as claimed. Therefore, Lih cannot teach a second check valve arranged on the bottom plate of the connector as required by claims 1-17. For this reason also, Lih does not anticipate claims 1-17.

viii. Lih fails to teach a first check valve and a second check valve allowing gas flow to pass in opposite directions as required in claims 1, 2, and 10-17.

As explained above, Lih does not teach a first check valve as claimed, Furthermore, Lih is completely silent as to orienting check valves to allow gas to pass in opposite directions. Petitioner does not have support for this statement in Lih and instead relies on Lih's "at least one relief valve" language and adds its "explanation" in brackets: "[an inherent function of check valves is to permit gas to flow in one directions]." (Pet. at 39.) First, the bracketed explanation is unsupported by any citation to an expert of actual analysis. A bald statement of inherency does not satisfy the strict evidentiary requirements of the law. Second, this statement, even if true, does not explain how or why Lih would teach a POSA to have a first check valve and second check valve which allow gas to pass in opposite directions. For claim 13, Petitioner adds a slightly different explanation, stating "multiple check valves inherently allow gas flow to pass in opposite directions." (Pet. at 56.) Again, there is no actual analysis, evidentiary support, or citation to Lih for this proposition.

As explained above, Lih describes a "relief valve" as being "configured to allow air to escape from inside the bellows assembly." (Ex. 1004 at 2:52-56, 4:3-4.) Nowhere does Lih suggest an *opposite flow path* for the relief valve, as required

by claims 1, 2, and 10-17. Thus, Lih fails to disclose this claim feature and does not anticipate the challenged claims.

ix. Lih fails to teach the duckbill valve required in claims 9 and 16.

Independent claim 9 recites that “the second check valve is a duckbill valve.” (Ex. 1001 at 11:65-66.) Claim 16 includes a similar limitation. Lih is silent as to the term “duckbill valve.” Petitioner states “with respect to claims 9 and 16, duckbill valves are one type of check valve that are commonly known to one of ordinary skill in the art, and the ‘575 Patent merely recites inherent features that are known to be inherent to duckbill valves.” (Pet. at 32.) This is not the standard for anticipation. Inherency requires that a feature *is necessarily* present in the prior art. Here, Petitioner concedes that a duckbill valve is merely one type of check valve. That argument is insufficient for anticipation. For this reason also, Lih does not anticipate claims 9 and 16.

x. Petitioner’s “functional equivalence” theory is insufficient to show anticipation for claims 2, 3, 6, 8, 9, and 14-17.

Citing *MEHL/Biophile International Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999), and *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1349-50 (Fed. Cir. 2002), Petitioner alleges that various features of the challenged claims are “functionally equivalent” and inherent to features in Lih. (Pet. at 22, 39, 43, 50, 53-54, 57, 59, 61.) Neither of these cases support the “functional

equivalence” theory, and in fact the Federal Circuit has reached the opposite conclusion.

“Anticipation requires that all of the claim elements and their limitations are shown in a single prior art reference.” *In re Skvorecz*, 580 F.3d 1262, 1266 (Fed. Cir. 2009); *see also Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) (explaining that “invalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently”). Courts have stated that a “**functional equivalent** is not enough to be a full anticipation of the specific device claimed.” *Application of Ruskin*, 347 F.2d 843, 846 (C.C.P.A. 1965) (emphasis added). In applying this principle, the Federal Circuit has concluded that it was improper to instruct a jury “that anticipation may be shown by equivalents, a legal theory that is pertinent to obviousness under Section 103, not to anticipation under Section 102.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989); *see also Old Reliable Wholesale, Inc. v. Cornell Corp.*, 635 F.3d 539, 545 (Fed. Cir. 2011) (holding that inventor testimony that “two products were functionally equivalent” did not require a finding of anticipation.).

Each of the above cited cases make clear that Petitioner’s legal theory that an alleged “functional equivalent” is sufficient for anticipation is wrong. Lih’s design is different than that claimed. Lih does not teach, suggest, or even hint at a

first check valve, let alone orienting a first check valve and a second check valve as claimed. Nor does Petitioner provide any analysis or explanation as to *why* numerous features are “functionally equivalent.” A search of the Petition provides 16 instances of “equivalency” arguments, and none are accompanied by analysis or evidentiary support.

Instead, Petitioner provides claim charts, without citations, in which brackets are used to provide attorney argument and conclusory remarks. For example, for claim 2, element 2.1, Petitioner asserts that “a plurality of check valves is functionally equivalent to one or more check valves.” (Pet. at 39.) For element 2.2, Petitioner asserts that “the arrangement of check valves is functionally equivalent to one or more check valves.” (*Id.*) Thus, the entirety of Petitioner’s argument for claim 2 is premised on “functional equivalence.” But Lih does not teach two check valves and does not teach the claimed placement of more than one check valve. With multiple options for numbers and placement of check valves, the “function” cannot necessarily be the same. Each location and valve has a different function. In view of the foregoing, Lih does not anticipate claim 2, which requires a plurality of second check valves encircling the first check valve. The strained bracket “analysis” and legally unsupported “functional equivalence” arguments do not remedy this deficiency. Claim 2 is not anticipated by Lih.

Petitioner makes similar arguments concerning claims 3, 6, 8, 9, and 14-17, as follows:

Claim	Functional Equivalence Arguments (emphasis added)
3	“[T]he intersection of the three slits at the same point is <i>functionally equivalent</i> to the gas outlet of Lih.” (Pet. at 43.)
	“The disclosure of ‘reinforcement strips’ ¹⁹ of Challenged Claim[] 3 . . . is the <i>functional equivalent</i> to the reinforcement inherent to baffles that are connected to bottom plates, as disclosed in Lih” (<i>Id.</i> at 61.)
6	“The disclosure of ‘reinforcement strips’ of Challenged Claim[] . . . 6 is the <i>functional equivalent</i> to the reinforcement inherent to baffles that are connected to bottom plates, as disclosed in Lih” (<i>Id.</i> at 61.)
8	“[T]he . . . ‘four slits’ arranged in a ‘cross’ in Challenged Claim[] 8 . . . [is] <i>functionally equivalent</i> to the gas inlet and outlet that are disclosed in Lih” (<i>Id.</i> at 61.)
9	“[duckbill valves are <i>functionally equivalent</i> to the valve(s) of Lih].” (<i>Id.</i> at 53-54, 61.)
14	“[a plurality of check valves is <i>functionally equivalent</i> to one check valve that inherently allows gas to pass in opposite directions].” (<i>Id.</i> at 57.)
15	Depends from claim 14 and thus incorporates the <i>functionally equivalent</i> argument of claim 14.

¹⁹ This quotation contains an error in that claim 3 does not recite “reinforcement strips.”

	“[T]he ‘three slits’ . . . arranged in a ‘cross’ ²⁰ in Challenged Claim[] . . . 15 [is] functionally equivalent to the gas inlet and outlet that are disclosed in Lih” (<i>Id.</i> at 61.)
16	“[duckbill valves are functionally equivalent to the valves in Lih].” (<i>Id.</i> at 59, 61.)
17	Depends from claims 15 and 14 and thus incorporates the functionally equivalent argument of claim 14.

Even if there was a basis in the law for a “functional equivalent” to be sufficient for anticipation (and there is not), it is noteworthy that none of Petitioner’s “functional equivalency” arguments are supported by evidence. Petitioner makes no attempt to describe *why* the features in Lih must function in the same way as those claimed. The Petition also fails to cite to its accompanying expert declaration to support its functional equivalency theories. And even if it was cited by Petitioner, the testimony of Petitioner’s expert, Mr. Stamp, is unhelpful in this regard since his declaration adds no evidence, explanation, or insight into his conclusions—instead relying on broad, conclusory statements. As an example, Mr. Stamp alleges that Lih inherently anticipates the first check valve of the challenged claims, but without providing any explanation or evidentiary support as to why Lih

²⁰ This quotation contains an error. Claim 15 does not mention a “cross” arrangement.

“necessarily” includes that feature (it does not). (Ex. 1003 ¶ 38.) The lack of support for Mr. Stamp’s testimony renders it unhelpful, and his declaration should be given little weight. *See Verlander v. Garner*, 348 F.3d 1359, 1371 (Fed. Cir. 2003). *See also* 37 C.F.R. § 42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”); *Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997) (nothing in the Federal Rules of Evidence or Federal Circuit jurisprudence requires the fact finder to credit unsupported assertions of an expert witness). In view of the foregoing, Petitioner’s functional equivalence and inherency arguments concerning claims 2, 3, 6, 8, 9, or 14-17 are legally and factually deficient and unlikely to prevail.

IX. Conclusion

For the foregoing reasons, Petitioner is unlikely to prevail on any ground with respect to any of the challenged claims. Patent Owner respectfully requests that the Board exercise its discretion and deny institution under 35 U.S.C. § 324(a) and § 325(d).

Respectfully submitted,

Dated: September 7, 2023

By: /s/ Justin L. Krieger
Justin L. Krieger
Reg. No. 47,719
Lead Attorney for Patent Owner
DCSTAR, Inc.

PGR 2023-00032
US Patent 11,478,575

**KILPATRICK, TOWNSEND &
STOCKTON, LLP**
1400 Wewatta St., Ste. 600
Denver, CO 80202
Telephone: (303) 405-1486
jkrieger@kilpatricktownsend.com

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing Patent Owner's Preliminary Response contains 12,057 words, as measured by the word-processing system used to prepare this paper. This word count does not include the items excluded by 37 C.F.R. § 42.24 as not counting towards the word limit.

Respectfully submitted,

Dated: September 7, 2023

By: /s/ Justin L. Krieger
Justin L. Krieger
Registration No. 47,719

CERTIFICATE OF SERVICE

I hereby certify that on September 7, 2023, I caused a true and correct copy of the foregoing Patent Owner's Preliminary Response to be served electronically on Petitioner at the following email addresses:

emaurer@bsfllp.com

nfundora@bsfllp.com

jvanlobensels@thoits.com

jhanika@thoits.com

By: /s/ Justin L. Krieger
Justin L. Krieger