

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFE VAC, LLC,
Petitioner,

v.

DCSTAR INC.,
Patent Owner.

U.S. Patent No. US 11,478,575
Issued: October 25, 2022

DECLARATION OF CARL STAMP

LIFE VAC v. DCSTAR
U.S. Patent No. 11,478,575
Life Vac Ex. 1003

I. INTRODUCTION

I, Carl M. Stamp, declare as follows:

A. Engagement

1. I have been retained by the external counsel of Life Vac, LLC as a scientific expert to submit this declaration in connection with a petition requesting post-grant review (PGR) of Patent No. US 11,478,575 (“the Petition”) by He, issued on October 25, 2022 and assigned to DCSTAR, Inc. (“the ‘575 Patent”).

2. I have been asked to review relevant materials and render my expert opinion in connection with the state of the art of the technology as it relates to claims 1-17 of the ‘575 Patent, and to render my opinion on certain assertions as framed in the Petition.

3. I am being compensated for my time at my normal consulting rate for my work, plus any actual expenses incurred. I have no financial interest in the outcome of this or any related proceeding, nor do I have any financial interest in Life Vac, LLC or DCSTAR, Inc. My compensation is not dependent upon the opinions that I am providing in this declaration.

B. Background and Qualifications

4. I have personal knowledge of the facts stated in this Declaration. I can, and will, testify competently to them if asked to do so.

5. My resume, attached as Exhibit A, summarizes my education and professional experience.

6. I received a B.S. in Biomedical Engineering with mechanical emphasis from the University of Iowa in 1985. Following graduation, I was employed by Snap-On Tools Corporation as a mechanical testing engineer for one year. I resigned from Snap-On to join Dow Corning Wright in 1986 as a Product

Development engineer. Dow Corning Wright was a medical device manufacturer that designed, manufactured and sold products for orthopedic surgery and plastic surgery. Dow Corning Wright was later renamed Wright Medical Technology, Inc. (“Wright”). I advanced through the engineering ranks over four years and was promoted to Product Manager in 1990.

7. In 1991 I resigned from Wright to take the role of Group Manager of Marketing for Orthomet, Inc. Similar to Wright, Orthomet was a medical device manufacturer that designed, manufactured and sold products for orthopedic surgery. In 1993 Orthomet was acquired by Wright, and I was promoted to Area Director of Sales. In 1996 I was promoted to Vice President of Marketing. In 2001, Wright’s executive leadership team, of which I was a member, took the company public. Shortly after the IPO I was promoted to Vice President of Business Development.

8. While with Wright I was a named inventor on the following four patents: US-5,135,529-A, US-5,002,545-A, US-5,002,581-A and US-4,935,023-A. All of which are associated with medical devices, principally orthopedic implants and the instruments used to insert them.

9. In 2002 I resigned from Wright to take the role of Vice President and General Manager, Cervical Trauma Division with Medtronic’s Spine and Biologics Business Unit. Medtronic is one of the largest medical device manufacturers in the world. In this role I had responsibility for, among other business matters, the development of all cervical spine products, including surgical implants and instruments. In 2005 I was promoted to Vice President of Global Operations, with responsibility for worldwide operations of the Medtronic Spine and Biologics Business Unit. While with the Medtronic Spine and Biologics Business Unit I was a named inventor on the following four patent applications:

US-20080041196-A1, US-20060247773-A1, US-20060247777-A1, US-20060174895-A1, all of which are associated with medical devices, principally spinal implants and the instruments used to insert them.

10. In 2009 I was promoted to Vice President and General Manager of Medtronic's Physiological Research Laboratories, a facility that provides research, development, testing, training and education services to all Medtronic Business Units, included but not limited to the Cardiac Rhythm Management Business, Neuromodulation Business, Diabetes Business, Spine and Biologics Business, Cardiac Surgery Business, and Surgical Navigation Business.

11. In 2015 I joined Smiths Medical as the Senior Vice President of Marketing and Strategy. Smiths Medical designs, manufactures and sells medical devices for respiratory therapy, fluid and medication intravenous infusion, vascular access, and temperature management.

12. In 2019 I retired from Smiths Medical and founded my own consulting company, C M Stamp Consulting, LLC. As a sole proprietorship, C M Stamp Consulting assists and advises companies in the medical device industry. As of this writing, I formally advise seven separate early-stage companies, two of which have products related to patient airway management. I also provide advisory services for several Private Equity companies.

13. I am a member of the Board of Directors for one medical device company, SonoStik, LLC, which designs, develops and manufactures vascular access products, two non-profits, The Bakken Museum and the Saddle Ridge Owners Association, and am a member of the Business Advisory Group for the University of Minnesota. I am also a guest lecturer for the Carlson School of Management (University of Minnesota) and the Kellogg School of Management (Northwestern University).

C. Information Considered

14. I provide opinions in this declaration based on my education, training, background, and work experience, as well as the documents I have reviewed to date, including the '575 Patent. Those documents, and the other materials cited in this declaration, are listed below.

Exhibit 001 - He, Ligui, U.S. Patent No. 11,478,575, "Removal device for removing obstruction in respiratory tract and connector" issued October 25, 2022

Exhibit 002 - Lih, Arthur, U.S. Patent No. 10,052,115, "Choking intervention device and method of use thereof" issued August 21, 2018

Exhibit 003 – da Costa, Harry, U.S. Patent No. 3,939,830, "Manually operable dechoking and resuscitating device" issued February 24, 1976

Exhibit 004 - Tarrats, Edward, U.S. Patent No. 4,971,053, "Suction Mask to Relieve Choking" issued November 20, 1990

Exhibit 005 - Rozinsky, Bernince, U.S. 7,351,245 B2, "Apparatus and method for dislodging object from throat" issued April 1, 2008

Exhibit 006 - PETITION FOR POST-GRANT REVIEW LIFE VAC, LLC (Petitioner) v. DCSTAR INC. (Patent Owner) for U.S. Patent No. US 11,478,575, Issued: October 25, 2022

I have read the materials listed above in their entirety and consider myself to be well informed on their respective positions, inventions, claims and figures. My analysis related to this proceeding, which relies on the Exhibits listed, is ongoing. I will continue to consider any new material as it is provided. I reserve the right to review, supplement, and amend my analyses based on new information and on my continuing review of the materials already provided.

D. Legal Standards

15. I am a biomedical engineer by training and profession. The opinions I am expressing in this declaration involve the application of my education, training, technical knowledge and work experience to the evaluation of certain prior art with respect to the '575 Patent (Exhibit 001) and the Petition (Exhibit 006). Although I am a named inventor on several patents and have been involved in the prosecution of numerous patent applications, I am not a lawyer, nor do I have any legal training. Therefore, I have been advised by Life Vac's counsel of certain principles of patent law applicable in this matter, which I have used in arriving at my determinations and opinions. The paragraphs below express my understanding of how I must apply these principles in forming my opinions, including the legal standard for interpreting claims, as well as those for assessing written description, definiteness, enablement, anticipation and obviousness, as well as claims construction.

Written Description

16. I have been informed by counsel that a claim in a granted patent must be sufficiently supported by the disclosure in the patent's specification, read in the context of what a person of ordinary skill in the art would have known at the time of the claimed invention. I understand that the basic inquiry for written description is whether the specification provides sufficient information for the person of

ordinary skill to recognize that the named inventors possessed the full scope of the claimed invention.

Definiteness

17. I have been informed by counsel that, in addition to written description, a patent specification must also describe the claimed invention so as to inform a person of ordinary skill in the art of the scope of the claimed invention with reasonable certainty. A claim may also be indefinite when it contains words or phrases whose meaning is unclear. Conflicting information between the patent claims and the rest of the patent application, including the figures, may affect that certainty and/or clarity.

Enablement

18. I have been informed by counsel that, in addition to written description, a patent specification must also enable a person of ordinary skill in the art to make and use the full scope of the claimed invention without undue experimentation as of its effective filing date. I understand that multiple factors should be considered when making this determination. These factors include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Anticipation

19. I have been informed by counsel that a claim is “anticipated” if a prior art reference describes, either expressly or inherently, each limitation of the claim. *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). I understand that this description must be recognizable to a person of ordinary skill in the art at the time of the alleged invention. *Id.* Moreover, to anticipate, a prior art reference must

“disclose[] within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008). I understand that an element is “inherent in,” and therefore taught by the prior art, if it necessarily flows from the explicit disclosure of the prior art. *Id.* The fact that a certain result or characteristic may be present in the prior art is not sufficient to establish inherency. However, if the result or characteristic is necessarily present based upon the explicit disclosure in the prior art, it is inherent in the prior art and is therefore disclosed. *Cont’l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). I have been informed that if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999), see also *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349–50 (Fed. Cir. 2002).

Obviousness

20. I have been informed by counsel that a claim is “obvious” if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art at the time of the alleged invention. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) In the case of the ’575 Patent (Exhibit 001), I understand that the Patent Office received the application of the invention on August 3, 2021. I understand that an obviousness analysis takes into account the scope and content of the prior art, the differences between the claimed subject matter and the prior art, and the level of ordinary skill in the art at the time of the invention. In determining the scope and content of the prior art, I understand that a reference is considered analogous (i.e. appropriate) prior art if it falls within the field of the inventor’s endeavor. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995)

(quoting *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986)). In addition, a reference is prior art if it is reasonably pertinent to the particular problem with which the inventor was involved. *Id.* A reference is reasonably pertinent if it logically would have commended itself to an inventor's attention in considering the problem. If a reference relates to the same problem as the claimed invention, that similarity supports use of the reference as prior art in an obviousness analysis. I also understand that a claim may be obvious in light of one or more prior art references. *KSR*, 550 U.S. at 420

21. The references of Lih (Exhibit 002), da Costa (Exhibit 003), Tarrats (Exhibit 004), and Rozinsky (Exhibit 005) discussed in this Declaration are analogous art that is usable in an obviousness opinion. Each reference is from the same field as the '575 Patent, that is, a device to remove the obstruction of a choking person. The references are also pertinent to the problem the inventor was focused on, that is, how to quickly and safely remove a foreign object that is obstructing the airway of a choking person.

22. I understand that the law recognizes several rationales for combining references to show obviousness of a claim. Some of these rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill in the art to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Claim Construction

23. In determining whether a patent claim is patentable in view of the prior art, I have been informed by counsel that the Patent Office construes the claim by giving the claim its ordinary and customary meaning ascribed to it by a person of ordinary skill in the art at the time of the invention, consistent with the specification and prosecution history. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). For the purposes of my analysis and opinions, and to the extent necessary, I have construed each claim term in accordance with its ordinary and customary meaning under the required standard. I have been informed by counsel that claim construction analysis begins and remains centered on the claim language itself. *Id.* I have been informed by counsel that the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). Therefore, claims “must be read in view of the specification, of which they are a part.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995) (en banc), aff’d, 517 U.S. 370 (1996). However, extrinsic evidence is generally considered less reliable than the patent and its prosecution history in determining how to read the claim terms. *Phillips*, 415 F.3d at 1319.

E. Person of Ordinary Skill in the Art

24. It is my understanding that when interpreting the claims of the ’575 Patent, I must do so based on the perspective of a person of ordinary skill in the art at the relevant priority date. I have been instructed to assume for the purposes of my opinions that the relevant priority date of the ’575 Patent is August 3, 2021. I understand that in determining the level of ordinary skill in the art, several factors

are considered. Those factors may include: (i) the type of problems encountered in the art; (ii) prior art solutions to those problems; (iii) the rapidity with which innovations are made; (iv) the sophistication of the technology; and (v) the educational level of active workers in the field. A person of ordinary skill in the art must have the capability of understanding the scientific and engineering principles applicable to the pertinent art.

25. The '575 Patent describes a REMOVAL DEVICE FOR REMOVING OBSTRUCTION IN RESPIRATORY TRACT AND CONNECTOR (Exhibit 001). Based on my review of the specifications and claims of the '575 Patent, it is my opinion that a person of ordinary skill in the art at that time would have been (1) a mechanical or biomedical engineer with at least 5 years of experience in designing or developing medical devices in general, or 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 designing or developing medical devices in the respiratory field, who would, where necessary or desired, work or consult with an engineer, to develop such medical devices.

26. I am able to make this assessment because in 2021, I was familiar with the design of respiratory assistance and airway clearance devices. The engineers and medical clinicians I worked with prior to 2021 had the requisite knowledge to design, make and/or use systems as described in the claims of the '575 Patent. Because I have worked with and managed engineers that design medical devices for over 30 years, I know very well what their capabilities were in 2021.

27. My analyses set forth herein are from the perspective of a person of ordinary skill in the art, as set forth above. At the time of the filing of the '575 Patent, and prior to August 3, 2021, I was an individual having at least ordinary skill in the art according to the above definition.

F. Summary of my Analyses and Opinions

28. I have reviewed the '575 Patent, the Petition for post-grant review filed on behalf of Life Vac, LLC, the art cited therein relevant to claims 1-17 of the '575 Patent, and additional materials as listed herein. Where appropriate, I refer to the Exhibits herein.

29. I understand that the '575 Patent includes 17 claims. I also understand that the Petition seeks to challenge claims 1-17 of the '575 Patent.

Brief overview of airway obstruction removal devices

30. Airway obstruction removal devices, also referred to as airway clearance devices, anti-choking or de-choking devices, respiratory tract obstruction removal devices, choking intervention devices, and other similar names, have been in existence for more than 50 years. This is due to the fact that despite legislation, regulation and education to minimize choking hazards, foreign objects such as food, coins, ice cubes, parts of toys, and other objects, that become lodged in a person's upper airway (or respiratory tract) continue to be a significant cause of Emergency Room visits and, unfortunately, mortality, particularly among children¹.

31. A number of these airway obstruction removal devices use a similar methodology to remove the obstruction. That is, create a rapid, external, negative

¹ Nationwide Children's Hospital. "Choking is a leading cause of injury and death among children." ScienceDaily. ScienceDaily, 28 February 2010.

pressure (vacuum) in the choking person's upper airway, greater than the forces holding the foreign body in the airway, to dislodge the foreign body and suck it out of the airway. In a similar but reverse mechanism the well-known "Heimlich maneuver" is intended to create a rapid, internal, positive pressure in the choking person's lower airway (lungs), greater than the forces holding the foreign body in the airway, to dislodge the foreign body and blow it out of the airway. Exhibits 001, 002, 003, 004 and 005 all ascribe to this suction methodology to address the problem.

32. To create negative pressure (vacuum) in a choking persons upper airway Exhibits 001 (the '575 Patent), 002 (the Lih patent) and 005 (the Rosinsky patent) use a collapsible/expandable bellows (or gasbag). Exhibits 003 (the da Costa patent) and 004 (the Tarrats patent) use a cylinder and piston to create this vacuum.

33. Exhibits 001, 002, 003, 004 and 005 utilize one or more check valves. Check valves, in general, are devices that allow the passage of fluid (air, gases, liquids, etc.) in a single direction only, and prevent fluid from moving in the opposite direction. Check valves have been used throughout the world in countless applications for well over 100 years. The first US patent for a check valve on record was awarded to Frank P. Cotter in 1907 (U.S. patent 865,631). Check valves are also naturally present within the human body, most notably in our circulatory system in the form of our heart valves and venous return valves.

Review of Exhibit 001 (the '575 Patent) with Exhibit 002 (the Lih patent) and the Petition

34. The examiners of the '575 Patent identified the Lih patent as prior art. As previously noted, the '575 Patent and the Lih patent are inventions intended to remove an object from the airway of a choking person, with both patents ascribing

to creating a vacuum as the means of force to do so, and both using a bellows (gasbag) to create the vacuum.

35. Outlined in tabular form of the Petition (Exhibit 006), beginning on page 36, each claim element of the ‘575 Patent has been countered with prior art disclosed from the Lih patent. In my detailed review of the ‘575 Patent and the Lih patent, and subsequent review of each of the tabulated claim elements and prior art disclosures in the Petition, I agree that many, but not all, of the Lih prior art cited in the Petition expressly anticipate the ‘575 Patent claim elements.

36. In reviewing the ‘575 Patent in light of the Lih patent and using the written descriptions of each to fully understand the intended function of each of the design elements of the inventions described, the Lih patent does not expressly teach the use of a check valve between the bellows and the upper airway of the choking person (“the first check valve 21” as described in the ‘575 Patent) that would prevent air within the bellows, when being compressed, to exert pressure in the mask and upper airway.

It should be explained that in the process of compressing the collapsible gasbag 3, gas flows from the inside of the collapsible gasbag 3 to the outside of the collapsible gasbag 3 at the second check valve 22, and the first check valve 21 is tightly closed, that is, gas in the gas storage cavity may be discharged to the outside through the second check valve 22, but may not enter the respiratory tract of the patient through the first check valve 21. (Exhibit 001, Column 8, Lines 6-13):

37. Specifically, those claim elements and opposing prior art disclosures within the table beginning on page 36 of the Petition (Exhibit 006) that are not expressly anticipated in the Lih patent, due to a check valve between the bellows and upper airway of the choking person not being present in the Lih patent, are (by

reference number as noted in the table of the Petition) 1.11, 1.17, 3.9, 3.13, 3.17-3.24, 8.1, 9.9, 9.11, 9.13, 13.1, 14.1, 15.1, 15.2, 17.3.

38. However, without a check valve between the bellows and the upper airway of the choking person (i.e. the Lih patent), the pressure exerted in the mask and airway, when the bellows is being compressed, would only be equal to the opening pressure of the check valve (relief valve 108 as defined in the Lih patent). By definition opening pressure is the minimum pressure differential needed between the inlet and outlet of a check valve to enable flow through the valve. Because check valves are available in many sizes, styles and types, and opening pressure can be designed to be as low as zero, the benefit of having a check valve between the bellows and the facemask is of negligible value, and therefore, the Lih patent inherently anticipates “the first check valve 21” of the ‘575 Patent.

39. It is important to note that the tabular claim elements of 3.17 through 3.24 (Exhibit 006, pages 42-43), referenced in the Petition only serve to provide details regarding the design of a check valve, and for purposes of the invention, have no additional functional value, that is, for the purposes of the invention in the ‘575 Patent the type, style, and size is irrelevant to the intended function of the invention.

Review of Exhibit 001 (the ‘575 Patent) in light of Exhibit 003 (the da Costa patent) and Exhibit 004 (the Tarrats patent)

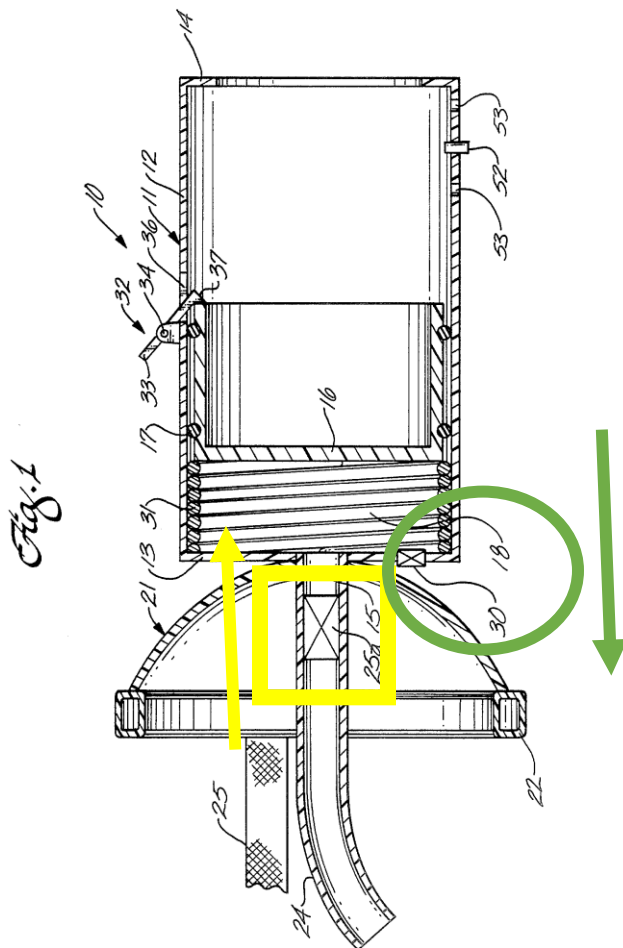
40. The examiners of the ‘575 Patent identified the Tarrats patent as prior art, but it is unfortunate that they did not identify the da Costa patent in the prior art. As previously noted, the ‘575 Patent, the da Costa patent and the Tarrats patent are inventions intended to remove an object from the airway of a choking person. All three patents ascribe to creating a vacuum as the means of force to do

so. The '575 Patent uses a bellows, and the Tarrats and da Costa patents use a piston and cylinder to create the vacuum.

41. The Tarrats patent clearly teaches a check valve between the vacuum device, in this case a piston and cylinder, and the upper airway and facemask, and for the same intended purpose as “the first check valve 21” in the “575 Patent, that is, to prevent air from entering the mask or upper airway when the chamber (gasbag or cylinder) is compressed.

A one-way check valve 25(a) is provided in the airway 24 to prevent air from passing through the airway 24 from the chamber 18 and into a victim's mouth. This might otherwise occur, for example, when the piston 16 is moved forwardly and reset to its forward position after an attempt to dislodge an obstruction which was not completely successful.” (Exhibit 004, Column 3, Lines 36-42)

I have highlighted this check valve in the yellow box overlayed on Exhibit 004, Fig. 1 below. The yellow arrow indicates the direction of flow permitted by check valve 25a.



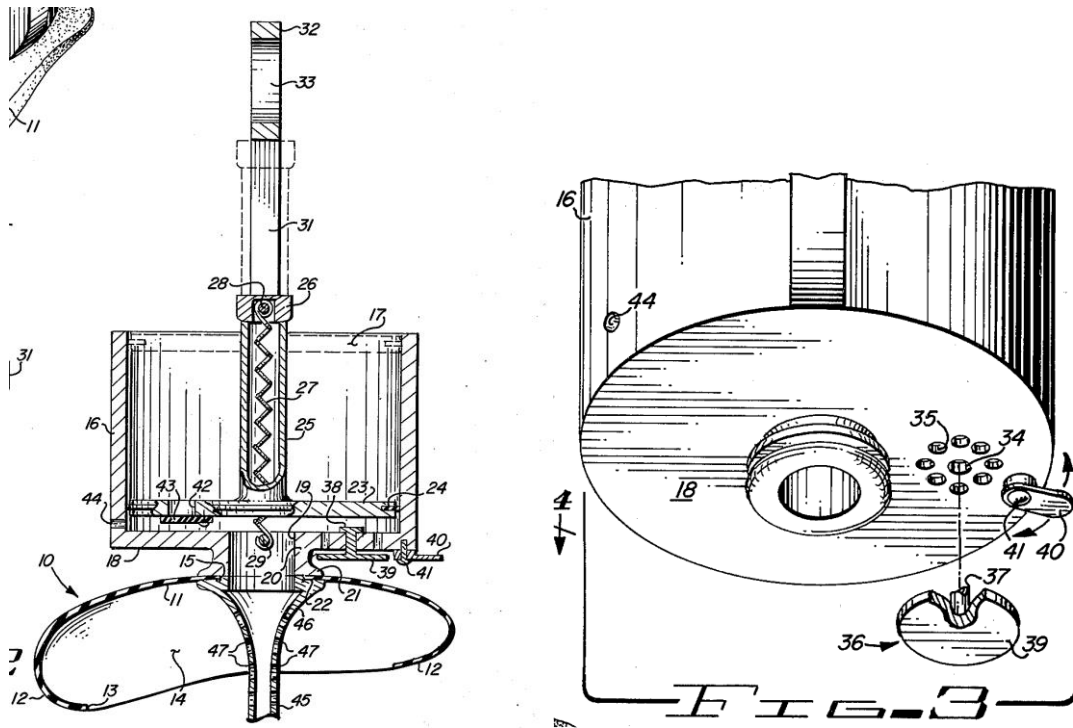
42. The Tarrats patent also teaches the use of two check valves acting in opposing directions.

A second one-way check valve 30 is provided 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. (Exhibit 004, Column 3, Lines 43-46)

I have highlighted the second check valve with a green oval overlayed on Fig. 1 of the Tarrats patent above. The green arrow indicates the direction of flow permitted by check valve 30.

43. Similarly, the da Costa patent also teaches the use of two check valves acting opposing directions.

If a person has an obstruction in his throat that requires immediate removal he is positioned with his head and trunk bent forwardly, preferably at an angle of 45 whereupon an operator first swings detent 40 out of engagement with valve head 39. With one hand he grasps handle member 26 and crossbar 32 and with the other hand places mask 10 over the nose and mouth of the person 16 then tightens his grip on member 26 and crossbar 32 to generate an outstroke of piston 23. This creates a vacuum condition in cylinder 16 which closes passages 35 and the vacuum becomes effective in the throat of the person. This causes air pressure from the lungs and/or partial regurgitation of the stomach contents to eject the obstruction or at least move it partially outwardly in the throat. If the obstruction is not completely removed the operator loosens his grip which permits spring 27 to move piston 23 inwardly. This inward movement is not effective on the obstruction because valve 36 is moved into position opening passage 35. (Exhibit 003, Column 5, Lines 45-64):



G. My Opinions

44. I provide opinions in this declaration based on my education, training, background, and work experience, as well as the documents I have reviewed to date, including the '575 Patent and the documents cited in this declaration. Based on my review of the '575 Patent, the prior art identified by the examiners, the prior art not identified by the examiners, and the information outlined in the Petition, it is my opinion that claims 1-17 of the '575 Patent have been disclosed expressly or inherently in the Lih Patent and would be anticipated by a person with ordinary skill in the art, and therefore are not patentable.

45. Even if the inherency argument of the "the first check valve 21" of the '575 Patent, which I believe is the only slightly questionable inherency position, were to uphold the claim elements associated with "the first check valve 21", the Tarrats patent explicitly discloses a check valve intended for the identical function

as “the first check valve 21” of the ‘575 Patent, thereby making its use obvious to a person with ordinary skill in the art.

46. Finally, the use of at least two check valves “wherein the first check valve and the second check valve allow gas flow to pass in opposite directions” (the ‘575 Patent) is not novel and is disclosed by both Tarrats and da Costa.

Dated: 05/03/2023



Carl Stamp