

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFEVAC, LLC,

Petitioner

v.

DCSTAR INC.,

Patent Owner

U.S. Patent No. 11,478,575

Inter Partes Review No. IPR2025-00454

PATENT OWNER PRELIMINARY RESPONSE

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Statement of Material Facts in Dispute

Petitioner, LifeVac, 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.

Patent Owner's Exhibit List

2001	Declaration of RAM.SHAW PTE.LTD
2002	Declaration of Ligui He
2003	IDEAR Trademark
2004	IDEAR reference
2005	Cultures Inc. Amazon Profile
2006	First cease and desist letter
2007	Second cease and desist letter
2008	IDEAR Amazon listing
2009	U.S. Patent No. 10,052,115 (Lih) (Google Patents)
2010	Zhongnan CNIPA Supplementary Search
2011	U.S. Patent No. 4,971,053 (Tarrats) (Google Patents)
2012	IDEAR reference (Ex. 2004) Annotated
2013	PCT Appl. No. WO2015167709A1 (Lih) (Google Patents)
2014	U.S. Patent No. 3,939,830 (Costa) (Google Patents)
2015	Korean Patent No. 102,229,619 (Yuchang) (Google Patents)
2016	Chinese Patent No. 112,932,633 (Zhongnan) (Google Patents)
2017	Prosecution history index for Zhongnan
2018	Petitioner's prior PGR Petition (PGR2023-00032)
2019	U.S. Patent No. 11,478,575 (Google Patents)

2020	IDEAR Amazon Listing (Marketing Material)
2021	Wayback Machine IDEAR Amazon Listing (ASIN B093NZN5C7)
2022	Declaration of David Luo
2023	Cultures Inc. Amazon Profile “About Seller”
2024	DCSTAR INC. New York Certificate of Incumbency
2025	RAM.SHAW PTE. LTD. Certificate Confirming Incorporation of Company
2026	RAM.SHAW PTE. LTD. Share Certificate
2027	RAM.SHAW PTE. LTD. Business Profile
2028	DCSTAR INC. and RAM.SHAW PTE. LTD. Cooperation Agreement
2029	DCSTAR INC. and Ligui He Product Co-Development Agreement

I. Introduction

DCSTAR Inc. (“Patent Owner”) respectfully submits this Preliminary Response to the Petition for *Inter Partes* Review (“Petition” or “Pet.”) filed by LifeVac, LLC, (“LifeVac” or “Petitioner”) challenging Claims 1-17 of U.S. Patent No. 11,478,575 (“the ’485 Patent”). Institution should be denied for the following reasons.

As explained in Patent Owner’s discretionary denial brief (Paper 6) (“DDB”)¹, Petitioner’s primary reference, Zhongnan, is disqualified as prior art

¹ The Director’s “Interim Processes for PTAB Workload Management” Memorandum states discretionary denial briefing (DDB) may address “the strength of the unpatentability challenge.” Page 2. The issue of whether Zhongnan is disqualified under 35 U.S.C. § 102(b)(1)(B) goes to the strength of the unpatentability challenge and was included in Patent Owner’s DDB, i.e., without Zhongnan, both of Petitioner’s unpatentability arguments fail. It is also relevant to this POPR since the Board panel has been authorized to address merits-based issues under the Director’s Memorandum, 35 U.S.C. § 314(a), and 37 CFR § 42.4(a) (2020). The issue has been included in this POPR in the event the Director determines that it constitutes a merits-based issue better suited for resolution by the Board panel.

under 35 U.S.C. § 102(b)(1)(B). The subject matter disclosed in Zhongnan had, before such disclosure, been publicly disclosed by another who obtained the subject matter directly or indirectly from the inventor. Without Zhongnan, both Grounds 1 and 2 fail, and Petitioner cannot demonstrate a reasonable likelihood of prevailing with respect to at least one challenged claim under 35 U.S.C. § 314(a).

Further, Petitioner relies on art (Zhongnan) that is substantially the same as the IDEAR reference (“IDEAR,” Ex. 2004) which was before the Office during prosecution. Indeed, Petitioner admits as much in its opposition to Patent Owner’s DDB (“DDB Opposition” or “DDB Opp.”). Paper 8 at 24 (“ . . . IDEAR shows every element of the challenged claims, like Zhongnan,”). Relatedly, the central issue in this IPR, whether subject matter disclosed in IDEAR disqualifies Zhongnan, is substantively the same issue that the Examiner considered during prosecution when she concluded that IDEAR was not prior art because it originated from the inventor. The cumulative nature of these issues weighs in favor

of denying institution. Lastly, the Petition makes no mention of any alleged material error by the Office.²

For these reasons, and as explained more fully below, the Board should deny institution.

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 device claimed in the '575 Patent includes first and second check valves that allow gas flow to pass in opposite directions. *Id.* at 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

² As indicated above, the Director's DDB Memorandum states that the DDB may address "the strength of the unpatentability challenge." Page 2. To the extent the Director considers the cumulative nature of Zhongnan to be a merits-based issue appropriate for the Board, this issue is discussed herein for completeness.

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, 420-21 (2007).

In its follow-on Petition, Petitioner has notably changed its POSA definition from what it previously presented and which the Board adopted in PGR2023-00032. Previously, as adopted by the Board, Petitioner proposed that a POSA would include “a mechanical or biomedical engineer with at least 5 years of experience in designing or developing medical devices in general...” Ex. 2018 at 18. But here, Petitioner has broadened its POSA to only requiring 2 years of experience with the same education or 4 years of experience with no formal education. Pet. at 12. Petitioner brushes off this substantive difference as “more stylistic than substantive.” DDB Opp. at 16. On the contrary, there is nothing stylistic about Petitioner’s broadening of the POSA definition. It is a clear attempt to game the PTAB to Petitioner’s advantage.

Although Patent Owner objects to Petitioner’s changing POSA standard, the POSA standard is irrelevant to the disqualification of Zhongnan and the basis for

denying institution that is discussed herein. For the limited purpose of this Preliminary Response, Patent Owner submits that the POSA would be the same as previously adopted by the Board: a mechanical or biomedical engineer having at least 5 years of experience in designing or developing medical devices in general.

IV. Claim Construction

Petitioner proposes that each claim term in the Challenged Claims be given its plain and ordinary meaning, and that no specific construction of any claim term is required. Pet. at 11. At this stage, Patent Owner agrees that the plain and ordinary meaning of the terms in the Challenged Claims should control, and further construction is not necessary.

V. The Cited Art

A. Zhongnan (Ex. 1004)

Chinese Patent Application No. 202110259986.4 (hereinafter “Zhongnan”) titled TRACHEAL FOREIGN BODY SUCTION DEVICE AND METHOD, was filed March 10, 2021, and published June 11, 2021. Zhongnan, relates to the removal of foreign bodies from the trachea. Petitioner alleges Zhongnan qualifies as prior art under 35 U.S.C. § 102(a)(1). Pet. at 20. That statute states that “a person shall be entitled to a patent unless – (1) the claimed invention was . . . described in a **printed publication** . . . before the effective filing date of the

claimed invention.” Zhongnan is alleged to be a printed publication as its June 11, 2021 publication date.

Notably, Petitioner does not allege that Zhongnan is prior art as of its filing date, but as of its June 11, 2021 publication date. Pet. at 20. This is because Zhongnan fails to meet the requirements of 35 U.S.C. § 102(a)(2) to qualify as prior art as of its filing date. Under the statute, an application may only be accorded its filing date for prior art purposes if it is “published or deemed published under section 122(b),” i.e., received in the United States Patent and Trademark Office. *See also* M.P.E.P. § 2151 (indicating that 35 U.S.C. 102(a)(2) may be based only on U.S. patent documents). Zhongnan was neither filed under the Patent Cooperation Treaty (PCT), nor was it later filed in the United States. Therefore, Zhongnan’s filing date of March 10, 2021 is irrelevant to this proceeding, and the earliest possible prior art date of Zhongnan is its publication date of June 11, 2021.³

³ Because this date is less than one year before the effective filing date of the challenged patent, Zhongnan may be disqualified as prior art under 35 U.S.C. § 102(b)(1) as explained in more detail below.

B. Yuchang (Ex. 1008)

Korean Patent Application No. 10-2021-0004323 (hereinafter “Yuchang”) titled REMOVAL APPARATUS FOR ESOPHAGEAL FOREIGN SUBSTANCES, was filed January 13, 2021, and published March 18, 2021. Yuchang relates to a device for removing foreign substances from the esophagus and is alleged to be prior under 35 U.S.C. § 102(a)(1). Yuchang is a Korean Patent Application with no relation to a U.S. or PCT filing. Thus, the earliest possible prior art date for Yuchang under 35 U.S.C. § 102(a)(2) is its March 18, 2021 publication date.

VI. The Board Should Deny Institution Under 35 U.S.C. § 314(a) because Petitioner’s Primary Reference is Not Prior Art Under 35 U.S.C. § 102(b)(1)(B).

Under 35 U.S.C. § 314(a), *inter partes* review may not be instituted “unless the Director determines . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” *See also Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.”). The Director has delegated the authority to institute *inter partes* review under 35 U.S.C. § 314(a) to the Board. 37 CFR § 42.4(a) (2020); *see also United States v. Arthrex, Inc.*, 594 U.S. 1, 9 (2021) (stating “[b]y regulation, the Director has delegated this authority to the PTAB itself.”).

Here, 35 U.S.C. § 314(a) supports denial of institution by the Board. As described below, Zhongnan is not prior art under 35 U.S.C. § 102(b)(1)(B) because an inventor-originated public disclosure occurred before Zhongnan's publication date. Each of Petitioner's challenges to the claims of the Challenged Patent rely primarily on Zhongnan. Pet. at 20. Without Zhongnan, both Grounds 1 and 2 fail, and Petitioner cannot demonstrate a reasonable likelihood of prevailing with respect to at least one challenged claim under 35 U.S.C. § 314(a). For at least this reason, the Board should deny institution.

Petitioner alleges that the Zhongnan publication qualifies as 35 U.S.C. §102(a)(1) prior art as of its June 11, 2021 publication date. Pet. at 20. Although, Zhongnan initially qualifies under 35 U.S.C § 102(a)(1) as of its publication date, that is not the end of the analysis. Under the AIA, section 102(b) expressly provides various exceptions to disclosures like Zhongnan. The statute provides:

A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if . . . the subject matter disclosed had, before such disclosure, been ***publicly disclosed by*** the inventor . . . or ***another who obtained the subject matter disclosed directly or indirectly from the inventor . . .***”

35 U.S.C. §§ 102(b)(1)(B).

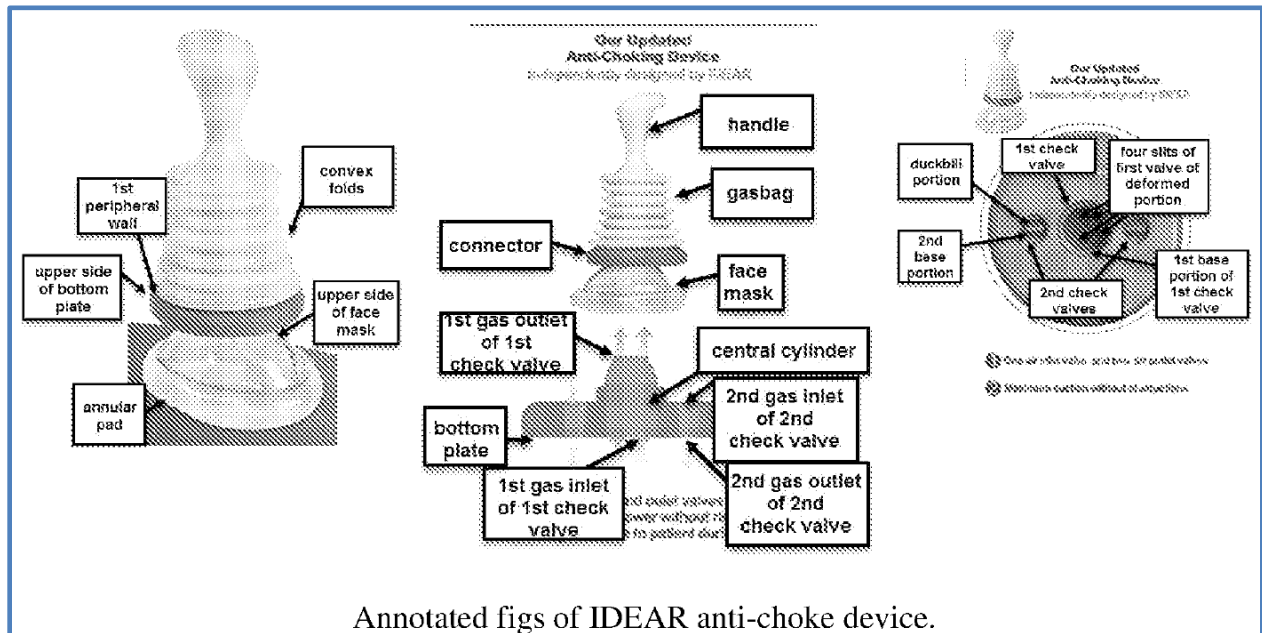
Patent Application 17/393,249, which issued as the challenged patent, was filed on **August 3, 2021**. The alleged publication date of Zhongnan under 35 U.S.C. §102(a)(1) is **June 11, 2021**—less than two months earlier. *Supra*, V. A. Thus, Zhongnan’s publication date falls within the one-year grace period under 35 U.S.C. § 102(b)(1). Therefore, any disclosure by or originating from the inventor after August 3, 2020 and before June 11, 2021 disqualifies Zhongnan as prior art. 35 U.S.C. §§ 102(b)(1)(A)-(b)(1)(B).

A prior public disclosure originating from the inventor, Ligui He, was made as early as **April 28, 2021** in the IDEAR disclosure (Ex. 2004)⁴, which was publicly disclosed on an Amazon storefront doing business as Cultures Inc. Ex. 2001 at ¶¶ 5-6. In fact, this same IDEAR public disclosure was cited by the Examiner during prosecution of the challenged patent in an Office Action dated March 22, 2022.⁵ Ex. 1002 at 132-144. In the Action, the Examiner rejected the

⁴ Clearer versions of IDEAR are provided in Exhibits 2008 (2-pack) and 2021 (3-pack).

⁵ It is notable that Petitioner’s original PGR petition included a detailed discussion of the prosecution history of the challenged patent including how Patent Owner disqualified IDEAR as prior art. Ex. 2018 at 16. In contrast, the current Petition—where that discussion would have been ***much more relevant*** to disqualifying

claims under 35 U.S.C. 102(a)(1) “based upon a public use or sale or other *public availability of the invention*: IDEAR⁶ anti-choke device has been listed on sale *on Amazon since April 28, 2021.*” *Id.* at 134-135. The Examiner also presented a marked-up version of IDEAR, clearly showing that all claim elements of the challenged patent were publicly disclosed in IDEAR:



Id.

Zhongnan—*omitted any mention of IDEAR* or of how Patent Owner overcame IDEAR during prosecution. Pet. at 10-11.

⁶ The IDEAR anti-choking device cited by the Examiner as prior art during prosecution is the same document referenced above as IDEAR and appended hereto as Exhibit 2004.

Patent Owner overcame this rejection by pointing out that the “subject matter of IDEAR is attributable to the inventor” and “originated from the inventor.” *Id.* at 126. Patent Owner’s argument was supported by a Declaration of inventor Ligui He (“He Declaration”) stating that “***IDEAR is based on the subject matter of the present application... IDEAR is based on the conception or development of the subject matter disclosed and claimed in the present application which are attributable to me.***” *Id.* at 131; Ex. 2002. Satisfied that the He Declaration disqualified IDEAR as prior art, the Examiner withdrew her rejection in the following office action. *Id.* at 103 (indicating “Applicant’s arguments . . . with respect to the rejection(s) [based on IDEAR] have been fully considered and are persuasive.”).

The public nature of the IDEAR disclosure was acknowledged by Petitioner in a pair of letters to Cultures Inc. in 2021 and 2022. On September 8, 2021—only 36 days after the challenged patent was filed in the patent office—Petitioner sent a first cease and desist letter (Ex. 2006) to Cultures Inc. In that letter, Petitioner cited the IDEAR anti-choking device on the Amazon storefront listing (Ex. 2004) as purported evidence of infringement of one of Petitioner’s patents. The date of the first cease and desist letter was six months before the Examiner cited IDEAR during prosecution (Ex. 1002 at 132-144), thereby ***showing that the Petitioner and***

the Examiner independently discovered the IDEAR reference and supporting the conclusion that IDEAR was “publicly disclosed” under 35 U.S.C. § 102(b)(1)(B).

Petitioner then sent a second cease and desist letter (Ex. 2007) on July 13, 2022 stating “Cultures Inc. (‘Cultures’) is selling suction products under the IDEAR brand name . . . [and] at least the following IDEAR products shown in table 1 (collectively, the “Accused Products”), may infringe . . .” a LifeVac patent.⁷ Below is a table from Petitioner’s second cease and desist letter that provides a list of the “Accused Products” and includes a “***Date First Available***” listed as April 28, 2021. Ex. 2007.

Table 1 – Cultures Inc. Accused Products on Amazon.com

ASIN	Date First Available	Amazon Storefront
B093NTJ3L5	April 28, 2021	https://www.amazon.com/s?me=A23276YMZUF0ZS&marke_tplaceID=ATVPDKIKX0DER
B093PNYMF8	April 28, 2021	https://www.amazon.com/s?me=A23276YMZUF0ZS&marke_tplaceID=ATVPDKIKX0DER
B093NZN5C7	April 28, 2021	https://www.amazon.com/s?me=A23276YMZUF0ZS&marke_tplaceID=ATVPDKIKX0DER
B09DGBTLN7	August 24, 2021	https://www.amazon.com/s?me=A23276YMZUF0ZS&marke_tplaceID=ATVPDKIKX0DER
B09DGD44G	August 24, 2021	https://www.amazon.com/s?me=A23276YMZUF0ZS&marke_tplaceID=ATVPDKIKX0DER
B09XHYC4TQ	April 8, 2022	https://www.amazon.com/Choking-Rescue-Device-Suction-Portable/dp/B09XHYC4TQ/ref=sr_1_1?crd=727D0UGX0C08&keywords=B09XHYC4TQ&qid=1651512845&sprefix=b09xhyc4tq%2Caps%2C118&sr=8-1
B09XTK23YW	April 13, 2022	https://www.amazon.com/IDEAR-Essential-Apparatus-Obstructed-Material/dp/B09XTK23YW/ref=sr_1_6?keywords=IDEAR&qid=1651511444&sr=8-6

⁷ The Cease and Desist Letters (Exs. 2006, 2007) constitute authorized party admissions and are not hearsay. Fed. R. Evid. 801(d)(2).

Ex. 2007 at 2. As shown above, much like the Examiner during prosecution, Petitioner conceded in its cease and desist letters that the Amazon storefront showing the *IDEAR anti-choking device was publicly available as early as April 28, 2021*.

IDEAR is a federally registered trademark in the United States under U.S. Registration No. 6,693,596, which is registered to RAM.SHAW PTE. LTD., a limited liability company incorporated under the laws of Singapore (hereinafter “RAM.SHAW”). Ex. 2001 at ¶ 2; Ex. 2003; Ex. 2022 at ¶6. RAM.SHAW is under common ownership with DCSTAR, the owner of the challenged patent. Ex. 2022 at ¶¶ 1-2; Exs. 2024-2028 (personal information redacted). DCSTAR granted RAM.SHAW a license to use certain intellectual property owned by DCSTAR INC, including the ‘575 patent. Ex. 2022 at ¶¶ 4, 7; Ex. 2028. RAM.SHAW and David Luo, the CEO and owner of RAM.SHAW and DCSTAR, have each submitted a declaration in support of this POPR. Ex. 2001 at ¶ 3; Ex. 2022 at ¶¶ 1-2. As further evidence the IDEAR disclosure originated from Ligui He, David Luo has testified DCSTAR commissioned Ligui He to invent the subject matter covered by the ‘575 Patent on behalf of DCSTAR. Ex. 2022 at ¶ 3; Ex. 2029.

RAM.SHAW and David Luo testified that the Amazon store doing business as Cultures Inc. is operated by RAM.SHAW to market and sell IDEAR-branded products in the United States, including the anti-choking device shown in Exhibit

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2004. Ex. 2001 at ¶ 3; Ex. 2022 at ¶ 5. Below is an annotated version of the IDEAR reference showing that, although low resolution, it includes the Amazon Standard Identification Number (“ASIN”) number B093NZN5C7. Ex. 2012 at 3.



Id. Exhibit 2021 provides a clearer view of Exhibit 2004, and confirms that the ASIN of the reference considered during prosecution (B093NZN5C7) is the same as the IDEAR reference:

Product details
Package Dimensions : 13.23 x 10.63 x 4.25 inches; 1.08 Pounds
Date First Available : April 28, 2021
Manufacturer : Cultures Inc
ASIN : B093NZN5C7
Best Sellers Rank: #16,792 in Health & Household (See Top 100 in Health & Household)
#32 in First Aid Kits (Health & Household)
Customer Reviews:
★★★★☆ 94 ratings

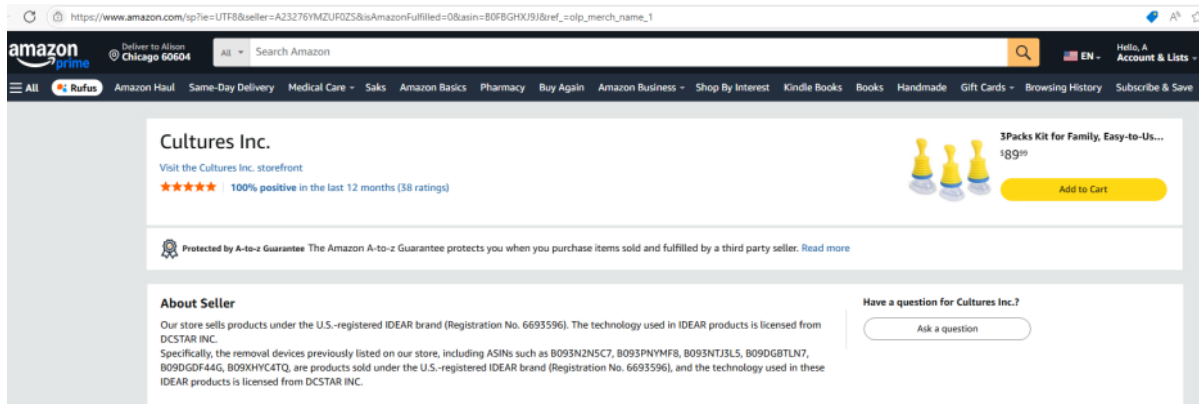
Ex. 2021 at 3 (emphasis added).

RAM.SHAW confirmed that the IDEAR reference cited by the Examiner during prosecution (Ex. 2004) shows Cultures Inc.’s anti-choking device having the ASIN number B093NZN5C7. Ex. 2001 at ¶ 5; Ex. 2004 at 3; Ex. 2021 at 3. The exact same ASIN number is also specifically listed in Petitioner’s cease and desist letter, which shows that Petitioner’s letter cited the same IDEAR document that the Examiner cited during prosecution. Ex. 2007 at 2. As the authorized

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trademark owner of IDEAR, RAM.SHAW also confirmed that the Amazon storefront featured in IDEAR (Ex. 2004) was publicly disclosed at least as early as April 28, 2021. Ex. 2001 at ¶ 5. Like the He Declaration submitted during prosecution of the '575 patent, the RAM.SHAW and David Luo Declarations also support that the subject matter described in IDEAR (Ex. 2004) was obtained directly or indirectly from Ligui He. *Id.* at ¶ 6; Ex. 2022 at ¶¶ 8-9.

Additional support that the public disclosure in IDEAR was obtained directly or indirectly from Ligui He can be found on the Cultures Inc. IDEAR Amazon storefront, which indicates that its products are licensed from the owner of the challenged patent, DCSTAR Inc.:⁸



Ex. 2023 at 1.

⁸ Notably, Petitioner's DDB Opposition fails to address the IDEAR Amazon storefront evidence demonstrating that the IDEAR product in the Cultures Inc. storefront was licensed from Patent Owner under the '575 patent. Ex. 2005 at 1.

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Additionally, the Cultures Inc. Amazon storefront listing shows a “Patent Authorization Certificate” in connection with IDEAR, which states that the technology is “[p]rotected by U.S. Patent No. US11478575B1”:



Ex. 2020 at 1. Similarly, the IDEAR storefront also includes marketing material referencing the device as protected by the '575 patent:



Id. This evidence further supports that the information disclosed on the Cultures Inc. storefront as the IDEAR reference (Ex. 2004) originated from Ligui He, the inventor of the challenged patent.

The Federal Circuit has held that to be “publicly disclosed” under the § 102(b)(1)(B) prior art exception requires that the ***subject matter be made available to the public***. *Sanho Corp. v. Kaijet Tech. Int’l Ltd. Inc.*, 108 F.4th 1376, 1381–83 (Fed. Cir. 2024). Based on the above discussion and evidence, the IDEAR disclosure was available to the public on the Amazon storefront and therefore constitutes a public disclosure under 35 U.S.C. § 102(b)(1)(B) at least as of April 28, 2021, which was before Zhongnan’s June 11, 2021 publication date.

Additionally, an analysis of the prior art exceptions under 35 U.S.C. § 102(b)(1)(B) requires a comparison of the features of the alleged prior art reference to those in the prior public disclosure. The Manual of Patent Examining Procedure explains this analysis as follows:

What is required for subject matter in an intervening grace period disclosure to be excepted under AIA 35 U.S.C. 102(b)(1)(B) is that the same subject matter as in the intervening disclosure must have been previously publicly disclosed by the inventor or a joint inventor (or by another who obtained the subject matter therefrom).

M.P.E.P. § 2153.02. The fact that IDEAR discloses all of the features in Zhongnan does not appear to be in dispute. Indeed, Petitioner argued as much conceding that

“... *IDEAR shows every element of the challenged claims, like Zhongnan.*” DDB Opp. at 24 (emphasis added). Moreover, in its Petition, Petitioner alleges that Zhongnan discloses all of the features of claims 1-2, 7, 13 and 14. Pet. at 21-43. Similarly, the Examiner alleged that IDEAR disclosed all of the features of claims 1-3, 5, and 7-17. Ex. 1002 at 132-142. It follows that all claim features alleged to be present in Zhongnan are also shown in IDEAR. As a result, taking Petitioner’s allegations and admissions as true for purposes of this briefing, it necessarily follows that IDEAR publicly disclosed all relevant features of Zhongnan, thereby disqualifying it as prior art.

Petitioner argues Patent Owner’s evidence showing the IDEAR disclosure originated from the inventor of the ’575 Patent is inadmissible hearsay. DDB Opp. at 4, 25, 45-46. However, *the Board routinely weighs declaratory testimony at the institutions stage and virtually always makes institution decisions without the benefit of cross-examination. LG Electronics Inc. et al v. Wi-LAN Inc. et al*, IPR2018-00704, Paper 14 at 13-14 (PTAB 2018) (citing *Freebit AS v. Bose Corp.*, IPR2017-01308, Paper 8 at 28 (PTAB 2017)); *see also Safe Haven Wildlife Removal and Property Mgmt. Experts LLC v. Meridian Wildlife Svcs. LLC*, IPR2023-01340, Paper 12 at 7-8 (denying institution despite argument that a declaration was hearsay prior to cross-examination); *Dish Network LLC v. Sound View Innovations LLC*, IPR2020-00969, Paper 23 at 12-13 (denying institution

without addressing petitioner’s argument a declaration is inadmissible hearsay prior to cross-examination).

Petitioner does not cite any authority to support its suggestion that the Board must ignore all testimonial evidence when deciding whether to institute the present IPR. In fact, the Board’s rules and the Trial Practice Guide require otherwise. Rule 42.108(c) concerning the standard for deciding whether to institute states:

(c) Inter partes review shall not be instituted unless the Board decides that the information presented in the petition demonstrates that there is a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable. *The Board's decision will take into account a patent owner preliminary response where such a response is filed, including any testimonial evidence. . . .*

37 C.F.R. § 42.108(c)⁹ (emphasis added). The 2019 Consolidated Trial Practice Guide (“TPG”) similarly indicates:

⁹ Notably, this rule was amended in 2020 to *eliminate* any presumption in favor of Petitioner when a Patent Owner submits testimonial evidence concerning an issue of material fact. 85 Fed.Reg. 79120 (Dec. 9, 2020). Instead, “[a]s with all other evidentiary questions at the institution phase, the Board will consider ***all evidence*** to determine whether the petitioner has met the applicable standard for institution of the proceeding.” *Id.* (emphasis added).

The preliminary response may present arguments and supporting evidence (*including testimonial evidence*) to demonstrate that no review should be instituted. . . . Testimonial evidence is permitted to be submitted with a preliminary response.

TPG at 49-50 (emphasis added). Thus, for the same reason the Board considers Petitioner's testimonial evidence when it makes its institution decision, PTAB rules and the Trial Practice Guide *require* that the Board consider Patent Owner's testimonial evidence at the pre-institution stage.

In summary, Zhongnan is not prior art under 35 U.S.C. § 102(b)(1)(B) because: (i) the IDEAR disclosure originated from the inventor of the '575 Patent and was publicly disclosed before Zhongnan's publication date, and (ii) the IDEAR disclosure illustrates all of the relevant features contained in Zhongnan. Because the Petition relies primarily on Zhongnan in each of its Grounds 1 and 2, both Grounds are unlikely to prevail. The vast weight of the evidence submitted in this proceeding supports that IDEAR was a public disclosure originating from Ligui He before the publication date of Zhongnan. *See, e.g.*, Exs. 2001, 2002, 2003, 2004, 2006, 2007, 2012, 2020, 2021, 2022, 2023, 2028, and 2029. Based on this substantial evidence, the Board should exercise its discretion and deny institution.

VII. Institution Should Be Denied Under Because the Office Considered Substantially the Same Prior Art During Prosecution and Petitioner Has Not Demonstrated the Office Erred.

The Petition presents substantially the same art and arguments that the Office previously analyzed during prosecution of the '575 Patent. Accordingly, the Board should exercise its discretion and deny institution.

The Board has established a two-part framework to determine whether it should exercise its § 325(d) discretion:

(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and

(2) if either condition of the first part of the framework is satisfied, whether the Petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB 2020) (precedential).

Under the first part of the framework, the Board first considers “whether the same or substantially the same” art or arguments “previously were presented to the Office.” *Id.* Only if the first part is met will the Board consider “whether the Petitioner has demonstrated that the office erred in a material manner to the patentability of the challenged claims.” *Id.* The Board uses the following six non-

exclusive factors (*Becton Dickinson* factors) to guide their analysis of the

Advanced Bionics framework:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioners rely on the prior art or Patent Owner distinguishes the prior art;
- (e) whether Petitioners have pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Id. at 9-10 (citing *Becton Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (PTAB 2017) (precedential in relevant part) (“*Becton Dickinson*”). *Becton Dickinson* factors (a), (b), and (d) pertain to the first part of the *Advanced Bionics* framework, and factors (c), (e), and (f) to the second part. *Id.* at 10.

Here, both *Advanced Bionics* steps support denial. First, the Petitioner raises substantially the same prior art and arguments as those considered by the examiner during prosecution of the ’575 Patent. Second, Petitioner failed to show that the

Office erred in a manner material to patentability when it allowed the '575 Patent over the already-considered references and arguments.

A. Institution Should Be Denied Because the Office Considered Substantially the Same Art and Arguments

Petitioner primarily relies on Zhongnan in each of its Grounds. Pet. at 20. While Zhongnan was not considered during prosecution of the '575 Patent, Zhongnan is substantially the same as art that was considered during prosecution, including the IDEAR reference. Thus, the first part of the *Advanced Bionics* framework is satisfied.

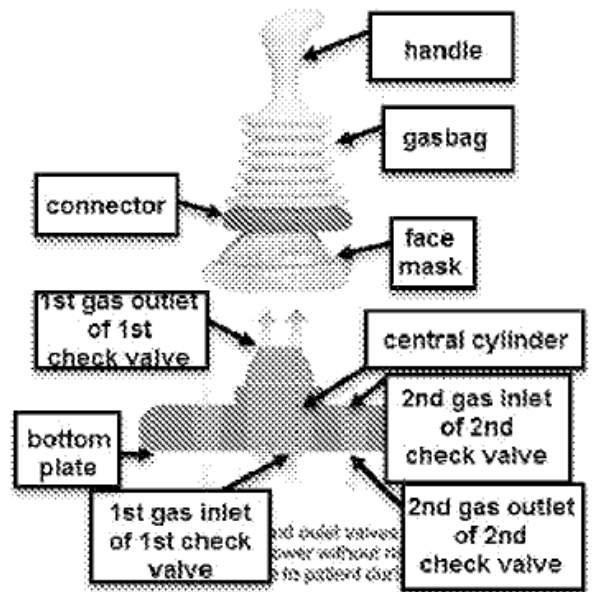
New prior art references are “substantially the same” as prosecution-applied references when there are no material differences between them, i.e., they are substantially similar to each other. *Wolfspeed, Inc. v. Trs. of Purdue Univ.*, IPR2022-00761, Paper 13 at 7-8 (Director Vidal 2023); *see also Evapco Dry Cooling, Inc., v. SPG Dry Cooling USA*, IPR2021-00687, Paper 11 at 24-25 (PTAB 2021) (finding a newly asserted reference not cited during prosecution as being substantially the same as the references that were before the Examiner during prosecution).

Likewise, newly asserted art is “cumulative” when the art’s relevant teachings provide nothing more than what was taught by previously presented prior art. *Gardner Denver v. Utex Industries, Inc.*, IPR2020-00333, Paper 12 at 13-14

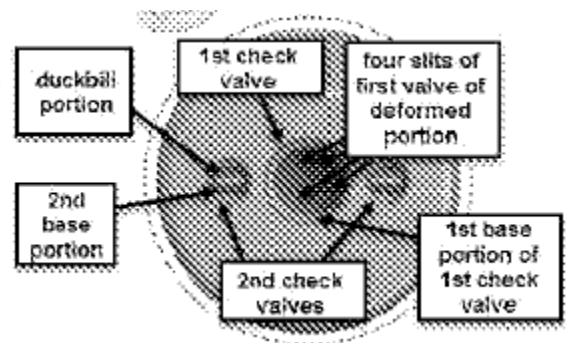
(PTAB 2020) (denying institution upon finding that newly asserted references were no more relevant than references that were presented during prosecution); *Roku, Inc. v. Universal Elecs., Inc.*, IPR2019-01619, Paper 11 at 16-17 (PTAB 2020) (denying institution upon finding that the newly applied reference was cumulative to a reference previously presented, even though the previously-presented reference was not considered for the same limitation in reexamination).

Petitioner plainly admits “... ***IDEAR shows every element of the challenged claims, like Zhongnan.***” DDB Opp. at 24. Additionally, the Petition failed to identify any material difference or teaching in the references now relied upon compared to those previously considered by the Office. Instead, Petitioner states, without explanation, that the references are “neither cumulative nor redundant to the prior art considered in the prosecution of the ’575 Patent.” Pet. at 64. The record indicates otherwise.

The Office laboriously considered IDEAR during prosecution, mapping each claim feature to alleged disclosures. Ex. 1002 at 135-143. There are no material differences between Zhongnan and IDEAR, as acknowledged by Petitioner. Indeed, Petitioner alleges Zhongnan discloses ***the same claim features*** the Office alleged IDEAR disclosed during prosecution. DDB Opp. at 24. Petitioner’s annotated figures from Zhongnan and the Office’s annotated showing of IDEAR



A cross-sectional view of the mask assembly. The interior of the cavity is shown above the bottom plate. The first check valve (226) is located in the interior of the cavity, and the second check valve (225) is located in the bottom plate. The connector (221) is shown at the bottom of the mask assembly. The bottom plate (222) is shown below the mask assembly. The interior of the cavity (224) is shown above the bottom plate. The first check valve (226) is shown in the interior of the cavity. The second check valve (225) is shown in the bottom plate. The connector (221) is shown at the bottom of the mask assembly. The bottom plate (222) is shown below the mask assembly. The interior of the cavity (224) is shown above the bottom plate.



Pet. at 37; Ex. 1005, FIG. 3; Ex. 1002 at 135. As shown above, the relevant features in Zhongnan are also present in IDEAR rendering it cumulative to art fully considered during prosecution.

Additionally, as discussed above, Zhongnan is disqualified as prior art based on the prior public disclosure of IDEAR. The analysis required to determine whether IDEAR disqualifies Zhongnan is effectively the *exact same analysis* that

the Examiner conducted during prosecution in deciding that IDEAR was not prior art. In other words, if the Examiner was correct that IDEAR was a public disclosure of the claimed invention and that it was obtained directly or indirectly from the inventor, then Zhongnan cannot be prior art over the challenged patent. For this reason, the subject Petition asks the Board for a “do-over” of a legal analysis that the Examiner already conducted. Such cumulative analyses are improper in follow-on petitions, and they should be rejected here.

Petitioner argues Zhongnan discloses the same elements as were alleged in IDEAR during prosecution. Pet. at 37; Ex. 1002 at 135-143. Each of *Becton Dickenson* factors (a), (b), and (d) weigh in favor of denying institution because there are no material differences or new teachings in Zhongnan compared to IDEAR. Accordingly, the arguments and art in the Petition are substantially the same as those previously considered by the Office under the first *Advanced Bionics* step. Institution should be discretionarily denied.

B. The Petition Fails to Identify a Material Error in Examination

Petitioner fails to carry its burden to show the Office materially erred in its evaluation of the prior art at least because *the Petition makes no mention of material error at all*. Petitioner’s entire discussion of 35 U.S.C. § 325(d) is one conclusory sentence. Pet. at 64. In it, Petitioner makes no allegation—much less a material showing—of Office error. In its DDB Opposition briefing, Petitioner

attempts to retroactively remedy this deficiency, claiming the Office erred in withdrawing the rejection in view of the He declaration (Ex. 1002 at 131). DDB Opp. at 24-25. The *Advanced Bionics* standard is clear, however: Petitioner must show material error ***in the Petition***. See, e.g., IPR2019-01469, Paper 6, at 7 (noting the institution may be denied where “Petitioner has not pointed to error by the Examiner”).

Even if Petitioner’s attempt to show material error for the first time in the DDB Opposition was appropriate (it is not), Petitioner still has failed to satisfy the threshold set forth in *Advanced Bionics*. Specifically, “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” IPR2019-01469, Paper 6, at 9. Petitioner argues “[t]he Office withdrew IDEAR as prior art under 102(b)(1)(a), solely in view of the He Declaration, despite the absence of corroborating evidence or context.” In so doing, Petitioner misconstrues the standard provided in M.P.E.P. § 2155: declarations must provide “***context, explanation, or evidence*** of inventorship.” The He declaration satisfies that requirement by providing a clear ***explanation*** of inventorship. Ex. 1002 at 131 (“IDEAR is based on the conception or development of the subject matter disclosed and claimed in the present application which are attributable to me.”). Even if Petitioner could retroactively fix its initial failure to assert a material error

by the Office, reasonable minds can disagree regarding the treatment of the He declaration and the IDEAR reference. As a result, Petitioner's alleged "error" is insufficient to satisfy *Advanced Bionics*. For at least these reasons, the second requirement of *Advanced Bionics* (*Benton Dickenson* factors (c), (e), and (f)) weighs in favor of denying institution.

VIII. 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 deny institution.

Respectfully submitted,

Filed: June 10, 2025

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitations of 37 CFR § 42.24(a)(1)(i). This brief contains 5,606 words as measured by the word processing software used to prepare the document, exclusive of table of contents, mandatory notices, certificates of service and compliance and appendix of exhibits.

The undersigned further certifies that this brief complies with the typeface requirements of 37 CFR § 42.6(a)(2)(ii) and typestyle requirements of 37 CFR § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14 point font.

Dated: June 10, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on June 10, 2025, Patent Owner's Preliminary Response (Paper 8), and Exhibits 2020-2029 have been served via email on Counsel for Petitioner at the email address as indicated in their Mandatory Notices Under 37 C.F.R. § 42.8:

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