
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GCE GAS CONTROL EQUIPMENT INC.,

Petitioner,

v.

VBOX, INC.,

Patent Owner.

Inter Partes Review No. IPR2023-00527
Patent No. 10,357,628

PATENT OWNER'S PRELIMINARY RESPONSE

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Exhibit No.	Description
2001	Joint Claim Construction Statement, Dkt. 37, submitted in <i>GCE Gas Control Equip. Inc. v. 3B Medical Mfg., LLC</i> , Case No. 8:22-cv-02550-TDC (D. Maryland).
2002	Screenshot of https://www.inogen.com/ip/ , last viewed on June 12, 2023

I. INTRODUCTION

This case relates to portable oxygen concentrators, which are devices used by patients that require supplemental oxygen. Portable oxygen concentrators are able to convert ambient air, which contains about 78% nitrogen and 21% oxygen, into relatively pure oxygen.

The portable oxygen concentrator of U.S. Patent No. 10,357,628 (Ex. 1001, the “’628 Patent”) includes a separation cartridge containing a specific material, known as adsorbent, which is configured to separate nitrogen from ambient air. With the nitrogen separated out, relatively pure oxygen can be delivered to a patient. Over time, however, the adsorbent loses its ability to adsorb nitrogen and must be replaced. Therefore, the portable oxygen concentrator of the ’628 Patent includes a separation cartridge that is easily replaceable by end users.

Ultimately, providing an easily replaceable cartridge reduces downtime, because a patient can replace the cartridge themselves without needing to send their portable oxygen concentrator in for service every time a cartridge needs replacing.

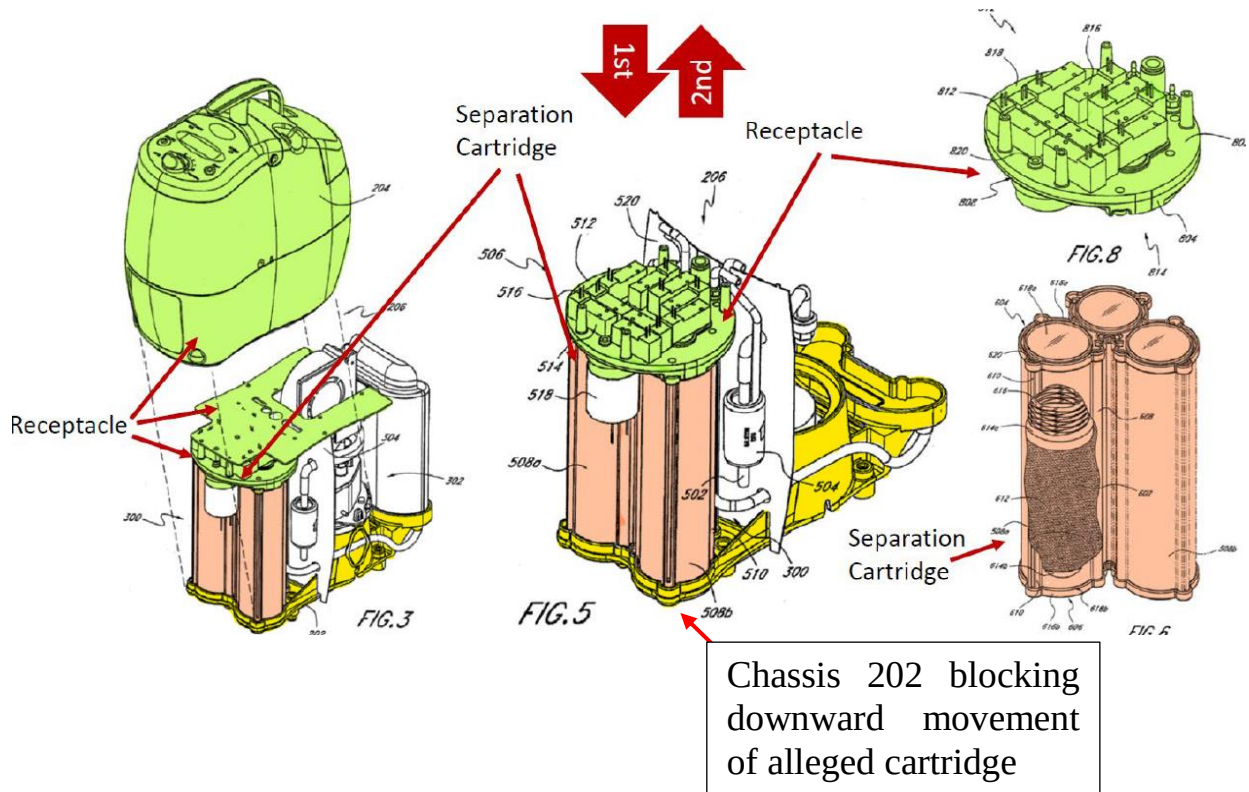
The challenged independent claims both recite “a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction.” Patent Owner will refer to these claim features as the “removal direction limitations.”

In all six proposed grounds, Petitioner alleges that *Deane* (Ex. 1004) teaches the removal direction limitations. However, it does not. Petitioner asserts, without any explanation or evidence in support, that the claims are met by movement of a receptacle relative to a separation cartridge, rather than movement of a separation cartridge relative to a receptacle. The claims explicitly require the latter. This discrepancy is fatal to Petitioner's obviousness analysis.

Petitioner provides the below annotation of *Deane*'s Figures 3, 5, and 6 in an effort to support its position that *Deane* discloses the removal direction limitations. Under Petitioner's interpretation of *Deane*, the components highlighted green allegedly read on the claimed receptacle, and the component in orange allegedly reads on the claimed separation cartridge. The claimed first direction is downward. So, to meet the claims, Petitioner must demonstrate that the orange component moves downward relative to the green components. But it does not. It is actually the green receptacle(s) that are moved upward from the orange separation cartridge, which itself does not move. The orange component of *Deane* cannot be moved down in the first direction because it is supported on a chassis 202 (yellow, below).¹ *Deane* does not teach, and Petitioner has not otherwise established, that the orange

¹ Patent Owner added yellow highlighting and "Chassis 202..." textbox; Petitioner added green and orange highlighting and all other annotations.

component, alone or with the chassis 202, moves downward relative to the green receptacle(s).



The claims expressly require the separation cartridge to be the component that is moved relative to the receptacle for removal, and in *Deane* the required movement is not taught, let alone possible. Institution should be denied for at least this reason.

What's more, *Deane* was cited during prosecution of the '628 Patent and its disclosure was relied on pervasively during prosecution of the family members of the '628 Patent. Petitioner's grounds are therefore duplicative of the art that was already considered by the Office.

II. BACKGROUND

A. The '628 Patent, Generally

Again, the technology at issue in this case relates to portable oxygen concentrators. Ex. 1001 at 1:17-21. Some individuals suffering from certain diseases or lung conditions may require supplemental oxygen. *Id.* at 1:22-35. Receiving oxygen therapy can help these individuals maintain normal and productive lives. *Id.*

Before the priority date of the '628 Patent, supplemental oxygen was primarily provided through high pressure gas cylinders, liquid oxygen in vacuum-insulated containers, and in-home oxygen concentrators. *Id.* at 1:36-49. The high-pressure cylinder and liquid oxygen options both require refilling, which hinders the mobility of the user. *Id.* The in-home oxygen concentrators also hindered mobility, as these concentrators were relatively large and heavy, emitted excessive heat, and were relatively noisy. *Id.*

This case relates to portable oxygen concentrators, which are less bulky, lighter, and permit users to receive oxygen therapy while traveling with significantly more freedom than traditional oxygen tanks. *Id.* at 3:45-52. Instead of a dedicated oxygen tank, portable oxygen concentrators are able to produce their own oxygen from ambient air. *Id.* Specifically, portable oxygen concentrators include pumps that draw in ambient air and feed it to an adsorbent bed that may be located in a separation cartridge. *See, e.g., id.* at 6:47-65. Ambient air is mostly nitrogen (i.e., about 78%),

and contains only about 21% oxygen. Separation cartridges contain a specific material, known as adsorbent, that is able to separate nitrogen from the ambient air, leaving relatively pure oxygen—specifically, up to 95% oxygen. *Id.* at 3:45-52; 6:47-65. With the nitrogen separated out, the portable concentrator is able to deliver the relatively pure oxygen to the patient.

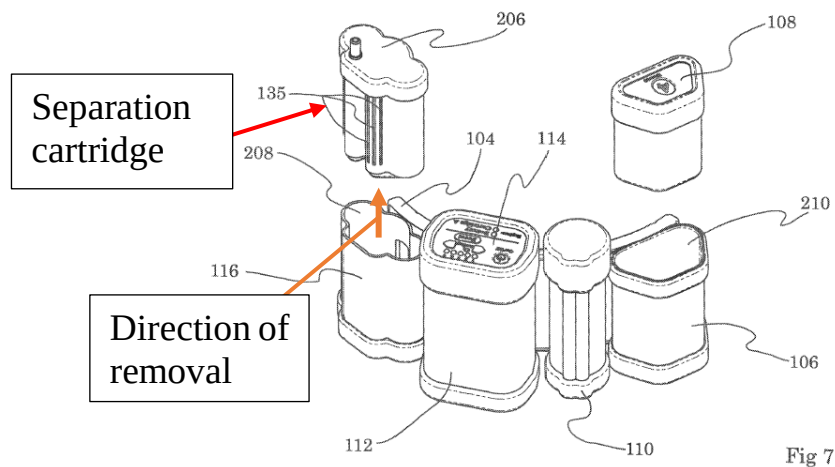
Over time, the adsorbent material becomes less effective at separating nitrogen from ambient air. *Id.* at 12:12-14. When this happens, the adsorbent bed and/or separation cartridge must be replaced. *Id.* at 12:1-14. The '628 Patent describes separation cartridges that are “easily removable to facilitate replacement.” *Id.* The '628 Patent is even titled: “Removable Cartridge for Oxygen Concentrator.” *Id.* at Title.

Increasing the ease with which separation cartridges can be removed and replaced is significant because it reduces patient downtime. It also allows the user to easily remove and replace the cartridges without the assistance of the manufacturer. In other words, when a separation cartridge needs replacing, the entire oxygen concentrator unit does not need to be sent away for service. Rather, the patient or their caregiver can replace the cartridge themselves in a matter of minutes.

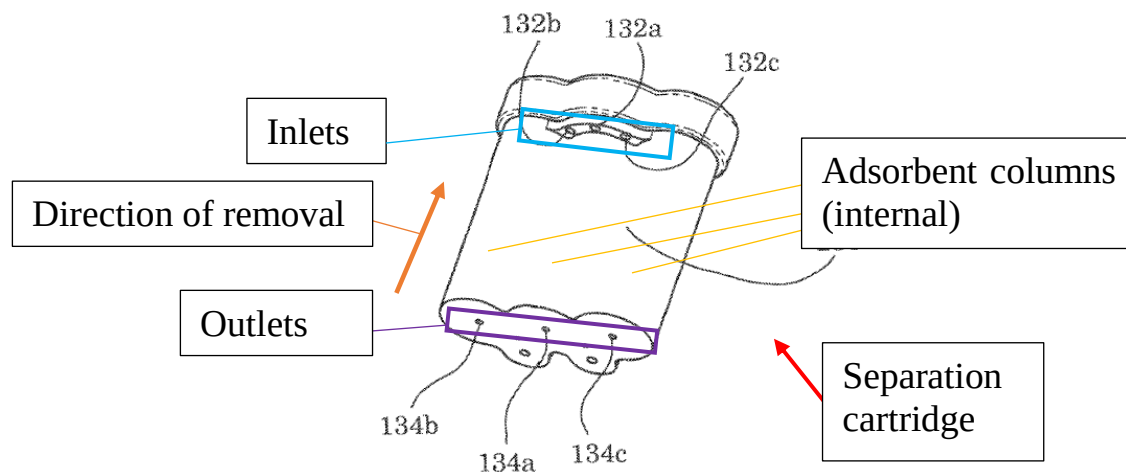
B. The claimed arrangements improve ease of replacement

The oxygen concentrator 100 of the '628 Patent includes, among other things, an adsorbent, or separation, cartridge 206, which is removable from a receptacle 208

of a cartridge module 116. Ex. 1001 at 11:61-12:3. Again, the separation cartridge is “easily removable to facilitate replacement.” *Id.*

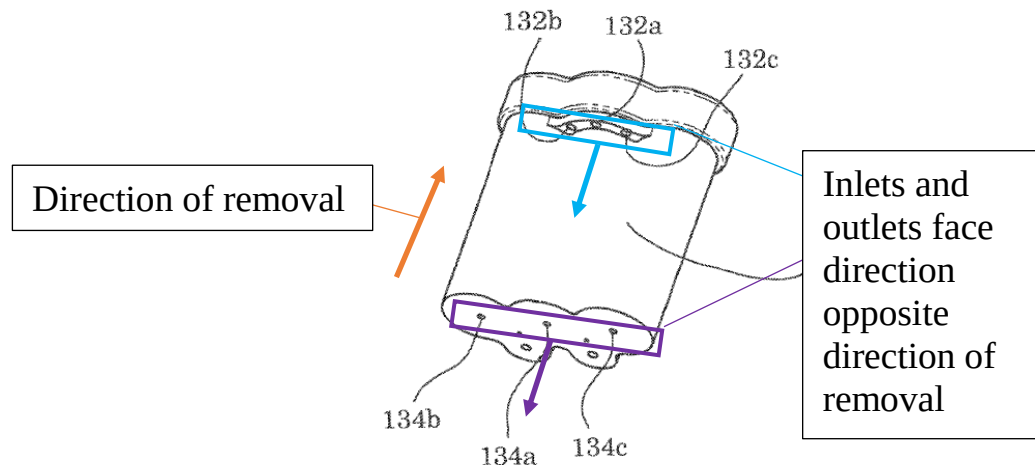


The separation cartridge includes inlet ports 132a-132c and outlet ports 134a-134c configured to direct fluid relative to adsorbent columns 130a-130c. *Id.* at 4:60-66; Figures 15 and 16.

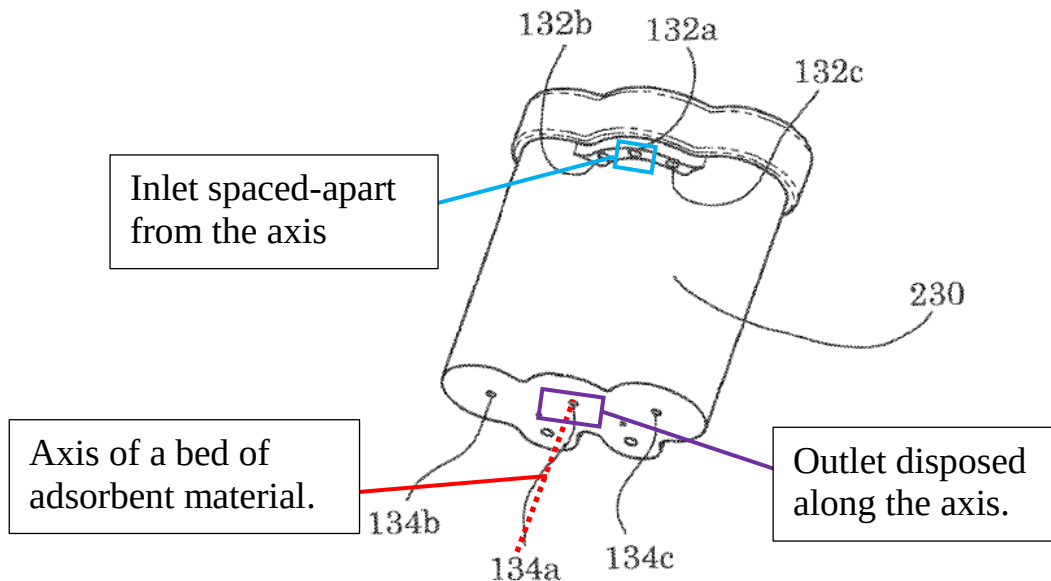


Both independent claims of the '628 patent require a separation cartridge including an inlet and an outlet oriented in a common direction that is opposite to a direction of removal. *See, e.g., id.* at claims 1 and 11. As shown above and below,

the inlet and outlet face toward the receptacle, which is a direction opposite the direction of removal.



In addition to the removal direction limitations, the claims also require the inlets and outlets to be spaced-apart from one another in a particular manner. Specifically, the bed of adsorbent material is disposed along an axis, with the first and second directions being substantially parallel to the axis. One of the inlet and the outlet is disposed along the axis and the other is spaced-apart from the axis. *Id.*

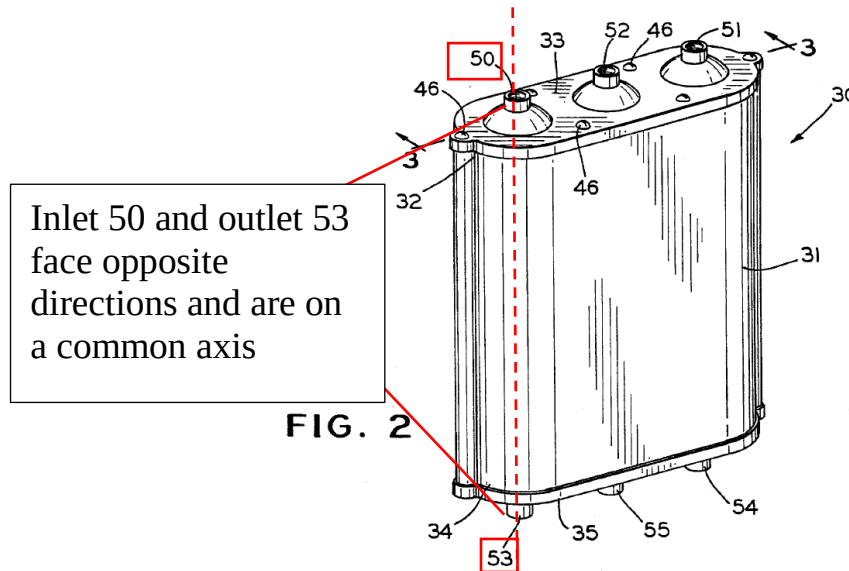


Because the inlets 132a-132c and are spaced-apart from the outlets 134a-134c while also facing a common direction, and because that direction is opposite the direction of removal, the separation cartridge 206 is readily removed simply by moving the separation cartridge 206 vertically relative to the receptacle 208. In turn, after the old cartridge has been removed, a new replacement cartridge is relatively easily placed within the receptacle 208 by a single vertical movement.

Claims 1 and 11 of the '628 Patent are independent claims. These claims each encompass the above-discussed features relating to ease of removability and replacement.

The prior art does not teach or suggest such a configuration. Most of the known art exhibited inlets and outlets that faced opposite directions and were

arranged on a common axis. One example is shown below. See Ex. 1020 at Figure 2.



The above prior art arrangement is not as easily removed and replaced because it cannot couple or decouple the inlet 50 and outlet 53 by movement of the component in a single direction. For instance, if one attempted to remove the above component from a receptacle, moving it vertically downward could potentially detach the inlet 50 from a corresponding inlet interface, but it would not be possible to detach the outlet 53 from its interface in that same downward motion. One or more additional steps or movements would be required to disconnect the component.

C. Relevant Prosecution History

Initially, the *Deane* reference upon which Petitioner relies (Ex. 1004; U.S. 2005/0072306) issued as Patent No. 7,135,059 (the “’059 Patent”), was cited during

prosecution of the '628 Patent and considered by the Examiner. *See* Ex. 1002 at page 332 (Examiner indicating he considered the '059 Patent (item 155)).

Further, the '628 Patent has a relatively large patent family. A number of references that are nearly identical to the *Deane* reference (each of which are also to *Deane*), were cited during prosecution of the '628 Patent and the various family members of the '628 Patent.²

As set forth fully below, the fact that the *Deane* disclosure was considered pervasively throughout prosecution of the '628 Patent's related family weighs in favor of the Board exercising its discretion to deny the Petition under 35 U.S.C. § 325(d). Surprisingly, despite the repeated appearances of the *Deane* disclosure favoring denial of their Petition, Petitioner actually highlights the Office's reliance on *Deane*'s disclosure in an attempt to paint a story that an error occurred when the Office did not reject the claims of the '628 Patent over *Deane*. *See* Petition at pages 7-13. Petitioner's theory is unfounded.

² The *Deane* '059 (Ex. 1038), *Deane* '745 (Ex. 1039), and *Deane* '426 (Ex. 1047) references cited throughout the '628 Patent family have substantially the same relevant disclosure as the *Deane* reference (Ex. 1004) that is relied on in Grounds 1-6. *Cf.* Exs. 1038, 1039, 1047 with Ex. 1004. Patent Owner will refer to these disclosures generally as the "*Deane* disclosures."

The '628 Patent is a continuation of U.S. Application No. 14/193,504 (Ex. 1052, the "'504 Application"), which issued as U.S. Patent No. 10,702,669 (Ex. 1056, the "'669 Patent"). The '628 Patent is also the great grandchild of U.S. Application No. 13/096,362 (Ex. 1050, the "'362 Application"), now abandoned, and a great, great grandchild of U.S. Application No. 11/054,341 (Ex. 1049, the "'341 Application"), which issued as U.S. Patent No. 7,954,490 (Ex. 1055, the "'490 Patent").

1. Prosecution of the grandparents

The '362 Application and '341 Application both included claims that were directed to the function of the disclosed oxygen concentrator, but did not recite specific structural features of the separation cartridge. *See* Exs. 1049, 1050. However, though they differ from the claims of the '628 Patent, the *Deane* disclosure was cited and Patent Owner faced multiple prior art rejections based on the *Deane* disclosure during prosecution of these applications. *See* Ex. 1049 at pages 77-81, 108-112, and 186-191; Ex. 1050 at pages 58-65.

2. Prosecution of the parent

The parent '504 Application issued after the '628 Patent. Regardless, its prosecution history still has relevance here. The '504 Application, like the '628 Patent, included claims directed to a separation cartridge configuration, and specifically included limitations similar to the removal direction limitations. *See* Ex.

1052 at pages 149-154. Examination of the '504 Application was handled by Examiner Vasat, who also handled examination of the '628 Patent. *See, e.g., Id.* at page 2. As with the grandparent applications, the *Deane* disclosure was again cited and discussed during prosecution of the parent '504 Application. *See* Ex. 1052 at page 19 (Examiner Interview Summary explaining that “There was a brief discussion of the prior art to *Deane* (US 20050072426).”). A notice of allowance followed including an Examiner’s amendment and a discussion of the *Deane* disclosure as allegedly being the “closest prior art.” *Id.* at page 13 *et seq.* (under “Reasons for Allowance” the notice states: “The closest prior art to new claims 24-42 is considered to be prior art to *Deane* (US 20050072426) ... The amendment defines over *Deane* because...”). While the Examiner mentioned some limitations that he believed were taught by *Deane*, the Examiner did not allege that *Deane* taught the removal direction limitations. *Id.*

3. Prosecution of the '628 Patent

Again, Examination of the '628 Patent was handled by Examiner Vasat, the same Examiner who noted *Deane* to be the “closest prior art” when allowing the Parent '504 Application. *See* Ex. 1002. During prosecution of the '628 Patent, Patent Owner submitted all of the various *Deane* disclosures, as well as *Dubois* (Petitioner’s secondary teaching reference; Ex. 1005) for consideration in an information disclosure statement (“IDS”). Ex. 1002 at pages 413-434. Examiner

Vasat considered each of the submitted *Deane* disclosures. *Id.* at pages 318-339 (Examiner Vasat placed his initials on that IDS next to “All references considered except where lined through” and *Deane* was not lined through.).

Examiner Vasat subsequently issued a Non-Final rejection which rejected the originally-filed claims under pre-AIA 35 U.S.C. § 103(a) as allegedly being unpatentable over the combination of *Warren* (Ex. 1012) in view of *Dechene* (Ex. 1021) and *McCombs* (Ex. 1009). Ex. 1002 at page 252, *et seq.* Notably, the originally-filed claims did not include the removal direction limitations. *Id.* at pages 399-403.

In response to the Non-Final rejection, Applicant amended the independent claims to recite “a separation cartridge removable from the receptacle by movement relative to the receptacle in a first direction,” “an inlet oriented in a second direction opposite the first direction,” and “an outlet oriented in the second direction,” i.e., the removal direction limitations. *Id.* at page 230, *et seq.* Applicant argued that, while it was not clear, the *Warren* combination appeared to teach removing a bed of adsorbent in a direction perpendicular to the orientations of an inlet and outlet, and therefore failed to teach the removal direction limitations. *Id.* at page 237.

Examiner Vasat subsequently issued a Final rejection that maintained the previous obviousness rejection and also contained a non-statutory double patenting rejection in view of the parent ’504 Application. *Id.* at page 126, *et seq.* However,

the rejection indicated that dependent claims 21 and 23 recited allowable subject matter. *Id.* at page 157.

In the sole interest of advancing prosecution, Applicant amended the independent claims to incorporate the allowable subject matter of dependent claims 21 and 24 and submitted a terminal disclaimer relative to the '504 Application. *Id.* at page 115, *et seq.* A notice of allowance followed. *Id.* at page 32, *et seq.*

4. Summary table: '628 Patent family and the Deane disclosure

The Board may find the below table as a helpful summary of the above discussion.

'628 Patent and Family	<i>Deane</i> disclosure considered by Examiner?	<i>Deane</i> disclosure specifically raised in rejection or discussed by Examiner?
Great, great grandparent: '341 Application	Yes	Yes
Great grandparent: '362 Application	Yes	Yes
Parent: '504 Application	Yes	Yes
'628 Patent	Yes	No

5. Petitioner's Unfounded Theory

Petitioner alleges that claims submitted on January 20, 2022 in the parent '504 Application are “very similar to the Challenged Claims.” Petition at pages 12-13. Petitioner's theory is that Examiner Vasat appears to have required additional

limitations in view of the *Deane* disclosure during prosecution of the parent '504 Application, and therefore Examiner Vasat must have erred by allowing the claims of the '628 Patent over the *Deane* disclosure. Petitioner asserts that, despite Applicant's IDS submission, "there is no evidence Examiner Vasat properly considered *Deane/Deane* '426 vis-à-vis the '628 Patent." Petition at page 21, fn. 4.

It appears that Petitioner is alleging that Examiner Vasat somehow was unaware of the *Deane* disclosure during prosecution of the '628 Patent. This suggestion is completely unfounded. Petitioner fails to address the fact that Examiner Vasat placed his initials on the IDS submission in the '628 Patent to indicate that the various *Deane* disclosures were, in fact, considered. Ex. 1002 at pages 318-339.

What's more, and tellingly, when discussing the applicability of *Deane*'s disclosure in the Notice of Allowance of the parent '504 Application, Examiner Vasat did not allege that *Deane* taught the removal direction limitations, despite similar language being present in the claims of the parent '504 Application. Ex. 1052 at pages 16, 149, 152 (see, e.g., claim 38, reciting "a cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction...").

The prosecution history of the '628 Patent family shows that Examiner Vasat was keenly aware of the *Deane* disclosure. Examiner Vasat just did not believe that

Deane was the closest art for use in a rejection during prosecution of the '628 Patent with its focus on the removal direction limitations.

As discussed further below, the Petition has failed to establish that *Deane* teaches the removal direction limitations. Accordingly, Examiner Vasat did not err in considering and then dismissing the teachings of *Deane*.

III. LEVEL OF ORDINARY SKILL

For purposes of this Preliminary Response only, Patent Owner does not dispute the Petitioner's definition of a person of ordinary skill in the art ("POSITA").

IV. CLAIM CONSTRUCTION

The Board construes claims in an *inter partes* review in accordance with *Phillips*, such that words of a claim are generally given their ordinary and customary meaning in light of the patent's specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005).

In general, the Board does not need to construe any terms raised for construction by Petitioner at this stage because Petitioner's proposed constructions do not bear on the issue of whether *Deane* discloses the removal direction limitations. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[The Board] need only construe terms that are in controversy, and only to the extent necessary to resolve the controversy.")

That said, Patent Owner provides a response to the Petitioner's claim construction arguments below.

A. "Separation Cartridge"

In relevant part, independent claim 1 recites "a separation cartridge ... the separation cartridge comprising a case [], an inlet [], an outlet [], and a bed of adsorbent material configured to preferentially adsorb nitrogen." *See, e.g.*, Ex. 1001 at claim 1. Independent claim 11 also recites similar language, but does not require the separation cartridge to include a case. *Id.* at claim 11.

Petitioner proposes that the term "separation cartridge" should be construed as "a housing that holds multiple adsorbent columns for gas separation and provides separate inlet and outlet ports for each adsorbent column." Petition at page 32. There are two main problems with Petitioner's construction. First, Petitioner seeks to read "multiple adsorbent columns" into the claims. This runs contrary to the explicit language of claims 1 and 11, which plainly recite "a bed of adsorbent," singular. Second, Petitioner seeks to embed the terms "inlet" and "outlet" into the construction by requiring a separate inlet and outlet for each of the multiple adsorbent beds that Petitioner seeks to add into the claims. This is both redundant and contradictory with the rest of the claim language because the claims already specify that the separation cartridge includes an inlet and outlet.

Petitioner states that the embodiments of the '628 Patent support their proposed “multiple column” construction. Petition at pages 30-31. Petitioner further alleges that Patent Owner agreed with an examiner’s position that a separation cartridge must have multiple adsorbent beds. *Id.* Petitioner’s reasoning should be rejected for several reasons.

1. No construction needed at this stage

Petitioner’s proposed construction requiring a separation cartridge to include multiple adsorbent columns and multiple inlets and outlets, while improper and incorrect, does not relate to the applicability of the asserted prior art.

It is not coincidental that Petitioner sells separation cartridges with a single adsorbent bed. Petitioner’s proposed construction is an overt attempt to bait the Board into taking a position that Petitioner will then use in an attempt to establish non-infringement in the corresponding district court litigation between the parties. Whether a “separation cartridge” must include one or more adsorbent beds is not related to any controversy in this IPR proceeding. *See Nidec*, 868 F.3d at 1017.

2. Multiple beds not recited in independent claims

Nevertheless, Petitioner’s substantive reasoning is flawed. First, the fact that some embodiments of the '628 Patent include multiple beds in a separation cartridge does not limit the claims. Petitioner is attempting to read the specification into the claims, in violation of black letter patent law. “[I]t is improper to read limitations

from a preferred embodiment described in the specification – even if it is the only embodiment – into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004); *see also Phillips*, 415 F.3d at 1323 (“[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.”).

Even so, the specification of the ’628 Patent makes it clear that while multiple columns/beds are disclosed in some embodiments, the separation cartridge could have just a single column. Specifically, the specification explains that the adsorption process can “be accomplished with a single column, or with a plurality of columns.” Ex. 1001 at 7:14-19. The text of the ’628 patent could not be clearer: a single column is sufficient.

Second, the alleged failure to rebut the Examiner’s characterization of prior art during prosecution does not serve to limit the claims. A prosecution statement effecting claim scope requires a “clear and unambiguous disavowal of claim scope.” *Saffran v. Johnson & Johnson*, 712 F.3d 549, 559 (Fed. Cir. 2013). The Federal Circuit has declined to find claims limited by prosecution “where the alleged disavowal is ambiguous, or even amenable to multiple reasonable interpretations.” *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016). Silence

regarding an Examiner's characterization of the prior art is not a "clear and unambiguous disavowal of claim scope." *Saffran*, 712 F.3d at 559.

In fact, Petitioner has misrepresented the relevant prosecution history. Specifically, the Petition states "when an Examiner compared a 'separation cartridge' to a single-bed module, applicant argued that the Examiner had not identified a separation cartridge" and, according to Petitioner, "[t]his supports 'separation cartridge' meaning a module with multiple adsorber beds." Petition at 31 (citations omitted). This is a blatant mischaracterization.

During the examination of the parent '504 Application, the Examiner cited a reference, *Warren* (Ex. 1012), and alleged it would be obvious to modify *Warren* to include an outlet port and inlet port directed in a common direction towards the bottom of the gas separation cartridge as required by the pending claims. Ex. 1052 at pages 297-299. In traversing the rejection, Applicant noted that "the Examiner does not even identify a 'separation cartridge' in *Warren*, and instead generally refers to Figures 7 and 8," and therefore "there is no way to tell from *Warren*'s Figures 7 and 8 what is the bottom." Ex. 1052 at pages 255-256. That is, Applicant was arguing that the Examiner had failed to establish a *prima facie* case of obviousness by failing to specify how the Examiner proposed modifying *Warren* to meet the claims. The suggestion that Applicant argued that *Warren* failed to disclose

a separation cartridge because its device happened to only have one bed is completely unfounded.

Further, another claim of the '628 Patent *does* recite a separation cartridge with multiple beds (which Petitioner's proposed construction would call multiple adsorbent columns). Claim 21 of the '628 Patent recites "wherein the bed of adsorbent material is one of a plurality of beds of adsorbent material within the separation cartridge." Ex. 1001 at claim 21. If Patent Owner wished to claim multiple beds in a single separation cartridge, Patent Owner could have used similar language to what is present in claim 21, but Patent Owner did not.

Patent Owner knew how to recite multiple beds of adsorbent in a single separation cartridge, but specifically did not do so in independent claims 1 and 11 of the '628 Patent. Claim differentiation weighs heavily against Petitioner's construction. *Phillips*, 415 F.3d at 1315 ("[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim."); *Beachcombers, Int'l, Inc. v. WildeWood Creative Prods., Inc.*, 31 F.3d 1154, 1162 (Fed. Cir. 1994) (interpretation that renders a dependent claim superfluous is "presumptively unreasonable" under doctrine of claim differentiation).

Construing separation cartridge to require more than one bed is simply unsupported and not the correct construction.

3. Redundant additions of inlet and outlet

Other than the issue with reading multiple beds into the claims, Petitioner also reads in “inlet” and “outlet” into their proposed construction of “separation cartridge.” This is inappropriate because claims 1 and 11 already require the separation cartridge to have an inlet and an outlet. *See TMI Prods. v. Rosen Entm’t Sys., L.P.*, 610 Fed. Appx. 968, 971-972 (Fed. Cir. 2015) (rejecting construction of a term that would render other language in the claim redundant); *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”). Embedding the terms “inlet” and “outlet” into the term “separation cartridge” is at best redundant and more likely would add confusion to the meaning of the claims.

In summary, Patent Owner’s position is that no construction of “separation cartridge” is necessary at this stage. If the Board does wish to construe the term, Patent Owner has taken the position in the parallel district court litigation that the plain and ordinary meaning of a “separation cartridge” is simply “a cartridge configured to separate gas.” *See Ex. 2001* at page 3. At an absolute minimum, the Board should not construe the term “separation cartridge” to require multiple adsorbent beds, each with a separate inlet and outlet, as Petitioner proposes.

B. “Receptacle”

Independent claims 1 and 11 of the ’628 Patent both recite in relevant part “a cartridge module comprising a housing, the housing defining a receptacle” and “a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction...” *See, e.g.*, Ex. 1001 at claim 1.

Petitioner states that “[o]utside the ’628 Patent’s context a POSITA would have generally understood a ‘receptacle’ to be a structure that receives and at least partially contains another component.” Petition at page 32; *see also* Ex. 1062 (“*Webster*”) (defining “receptacle” as “one that receives and contains something”). Petitioner further states that “[c]laim 1 comports with this understanding.” *Id.*

Despite these statements, Petitioner’s construction goes much further. Petitioner ultimately proposes that the term “receptacle” should be construed to mean “a structure that releasably interfaces with the inlet(s) and outlet(s) of the separation cartridge and at least partially contains the separation cartridge.” Petition at page 33. Petitioner’s construction should be rejected for several reasons.

First, Petitioner’s proposed construction should be rejected because whether the alleged receptacle “releasably interfaces” with a separation cartridge does not bear on any issues raised at this stage of the proceeding. *See Nidec*, 868 F.3d at 1017.

Second, the Petition fails to provide any reason for the inclusion of the “releasably interface” language. *Id.* at pages 32-33. There is nothing about the plain

and ordinary meaning of the term “receptacle” that would mean “releasably interfaces.” Petitioner’s construction is an apparent effort by Petitioner to read a particular embodiment into the claims, specifically, the ’628 Patent’s disclosure that the cartridge 206 may connect to the various lines within the receptacle 208 using quick-connect attachments of the cartridge 206. *See* Ex. 1001 at 12:4-14 (“In this embodiment... [c]artridge 206 contains a quick-connect attachment...”). So, whereas the claims do not specify the precise mechanism for connecting the cartridge and the receptacle, Petitioner seeks to limit Patent Owner to “releasably interfac[ing].” This is not proper. *See Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1330 (Fed. Cir. 2012); *see also Phillips*, 415 F.3d at 1323.

If the Board does decide to construe this term, Patent Owner has taken the position in the parallel district court litigation that the plain and ordinary meaning of “receptacle” is “a space configured to receive and contain something.” Ex. 2001 at page 6.

C. “Selectively Removable [From A Receptacle]”

Again, independent claims 1 and 11 recite “a separation cartridge selectively removable from a receptacle by movement relative to the receptacle in a first direction.” Ex. 1001 at Claims 1 and 11. Here, Petitioner seeks a construction of another portion of this phrase. Namely, Petitioner proposes that the phrase “selectively removable [from a receptacle]” should be construed to mean that the

separation cartridge is “withdrawable or separable as a whole from a receptacle.”
Petition at pages 33-34.

Petitioner’s proposed construction should be rejected because, again, it does not bear significantly on the issues raised at this stage of the proceeding. *See Nidec*, 868 F.3d at 1017. What’s more, Petitioner’s proposed construction improperly reads out the word “selectively” from the phrase “selectively removable.” *See Merck*, 395 F.3d at 1372 (“A claim construction that gives meaning to all the terms of the claims is preferred over one that does not do so.”). If for some reason the Board does wish to construe this phrase, Patent Owner has taken the position that the plain and ordinary meaning of “selectively removable” is “can be chosen to be removed.” Ex. 2001 at page 9.

D. “Axis”

Independent claims 1 and 11 recite “wherein the bed of adsorbent material is disposed along an axis, one of the inlet and the outlet is disposed along the axis, and the other of the inlet and outlet is spaced-apart from the axis.” Ex. 1001 at Claims 1 and 11.

Petitioner contends that “axis” should be construed as “the centerline of the bed of adsorbent material.” Petition at page 35. The Board should decline to adopt this narrow construction for several reasons.

First, whether the claimed axis is limited to a centerline of the bed is not relevant to the applicability of the prior art at this stage of the proceeding. *See Nidec*, 868 F.3d at 1017.

Second, an “axis” is not necessarily a central axis. When specifically referring to a central axis, it is common to specifically call out a “centerline,” “central axis,” “axis of symmetry,” or the like. Indeed, the ’628 Patent refers to a “central axis” when describing an aspect of the invention that does not relate to the separation cartridge 206. *See* Ex. 1001 at 11:3-7 (“... a rotary valve that moves 360E (one full revolution about a central axis) for each complete cycle of the VSA process.”). So, while the specification of the ’628 Patent does refer to a “central axis” when describing a rotary valve, a “central axis” or “centerline” was specifically not recited in the claims.

Third, a prior art reference cited by Petitioner and cited during prosecution of the ’628 Patent, *Deane* ’745 (Ex. 1039), refutes Petitioner’s position. *Deane* ’745 describes a battery pack 1900 by referring to various “axes” that are not centerlines of the battery pack 1900. *See* Ex. 1039 at 27:38-62; Figure 19E. When *Deane* ’745 does refer to a central axis it uses the qualifier “central.” *Id.* (referring to axis 1946 as a “central lower axis” while using the term “axis” more generally to refer to non-central axes 1940, 1942, 1944, 1948a, 1948b).

Again, Patent Owner does not believe a construction of “axis” is currently necessary. However, if the Board does choose to construe the term, Patent Owner’s position is that the plain and ordinary meaning of “axis” is “a reference line.” Ex. 2001 at page 12.

V. DEFECTS IN PROPOSED GROUNDS

An *inter partes* review may not be instituted “unless ... the information presented in the petition ... shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). The burden of proof lies with the Petitioner to show that the statutory threshold is satisfied.

The Petition raises six grounds challenging the patentability of claims 1-23 of the ’628 Patent. Each of these grounds relies on *Deane* (Ex. 1004) as a sole or primary reference. The proposed grounds are deficient for at least the below reasons. The below arguments carry additional weight given that the Examiner was well aware of the *Deane* disclosure during prosecution.

A. Ground 1—*Deane*, *Dubois*, and *Berntson* do not support obviousness of claims 1-4, 6-17, and 19-23

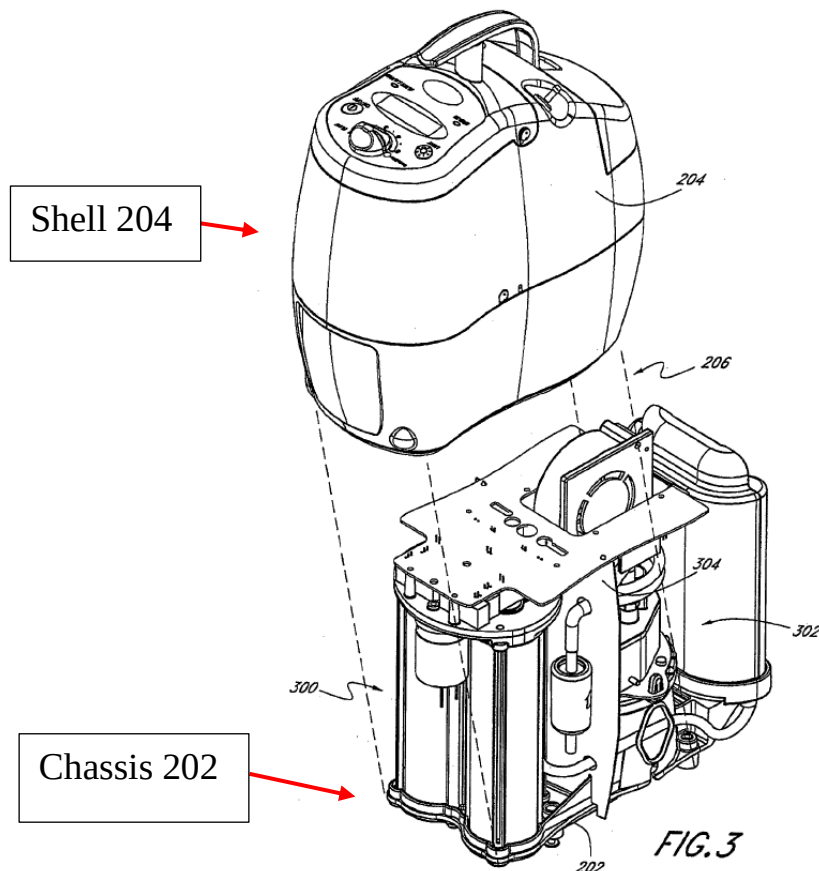
Ground 1 alleges claims 1-4, 6-17, and 19-23 are obvious over *Deane* (Ex. 1004), *Dubois* (Ex. 1005), and *Berntson* (Ex. 1006). Petitioner essentially argues that

Deane teaches all of the claim elements, but includes *Dubois* and *Berntson* as backstops on certain claim elements.

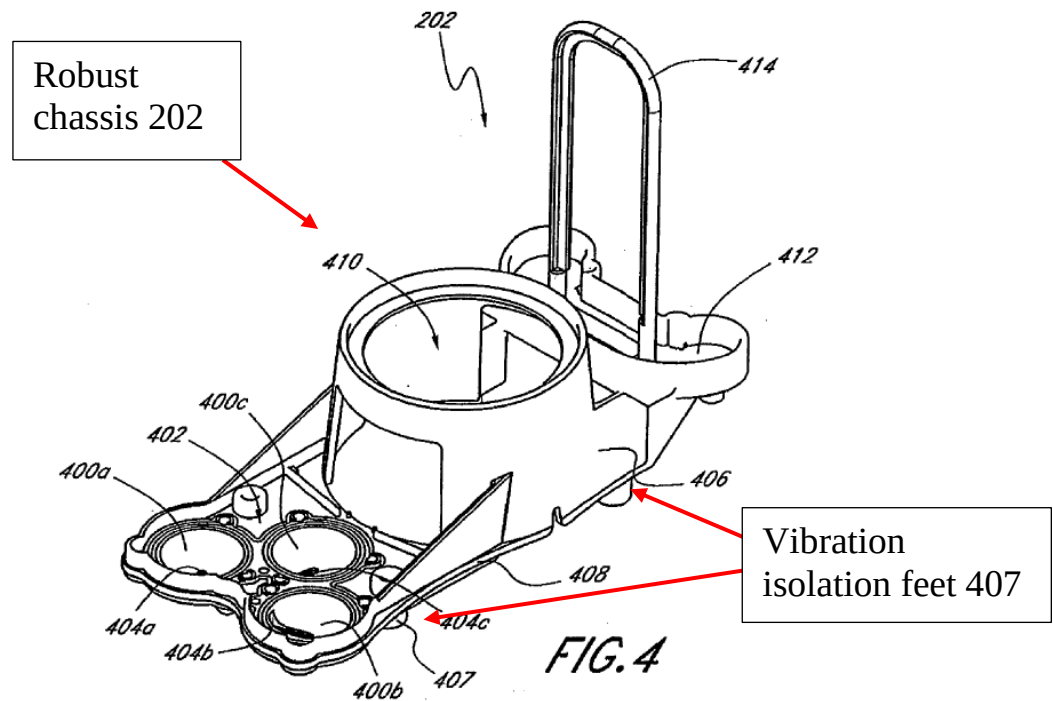
1. *Deane*

Deane discloses a portable gas fractionalization apparatus 200. Ex. 1004 at ¶ [0057]. While referred to as portable, the *Deane* apparatus 200 is rather bulky, and is configured to be carried by a handle or rolled on a wheeled cart 1800. Ex. 1004 at ¶ [0099]; Figure 18B.

Deane's apparatus 200 generally includes a chassis 202 and a shell 204, which together form a housing 206. *Id.* at ¶ [0057]; Figure 3 (below).

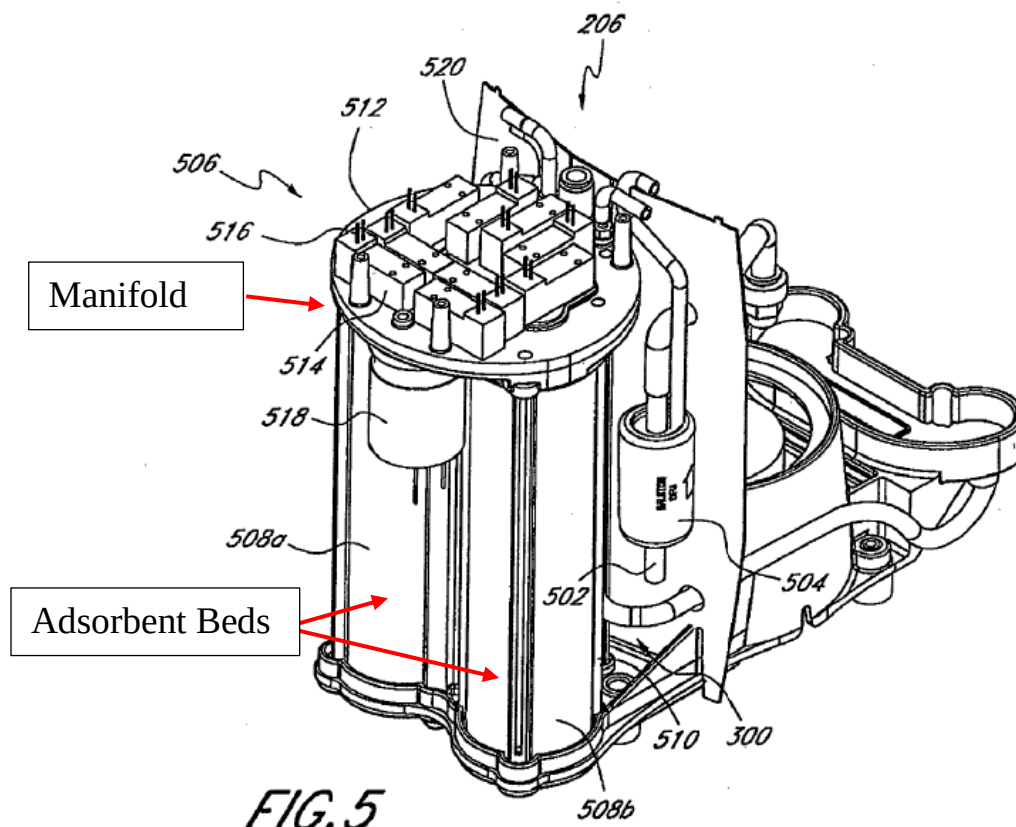


The chassis 202 is a robust frame with vibration isolation feet 407 configured such that the apparatus 200 can rest on a flat surface, such as a floor or table, while supporting the various internal components of the *Deane* device. See *Id.* at ¶ [0060].



Deane's apparatus is not designed to be used in any configuration other than its vertically-upright configuration. On this point, *Deane's* shell 204 exhibits curved, non-planar walls to discourage users from resting the apparatus 200 on its side. See *Id.* at ¶¶ [0057], [0093] (“... the sidewalls 212 a, c of the housing have a curved configuration so as to discourage users from resting the housing against the sidewall, which can block the air inlet or outlet.”).

Inside *Deane's* housing 206, the apparatus 200 includes a first compartment 300 which contains the components that adsorb nitrogen from ambient air, and a second compartment 302 which contains heat generating components. *Id.* at ¶ [0058]. Specifically, the first compartment 300 includes adsorbent bed columns 508a, 508b. *Id.* at ¶ [0061]; Fig. 5. Fluid is directed to the adsorbent bed columns 508a, 508b via manifold 512, which sits near the top of the adsorbent bed columns 508a, 508b. *Id.* at ¶ [0063].

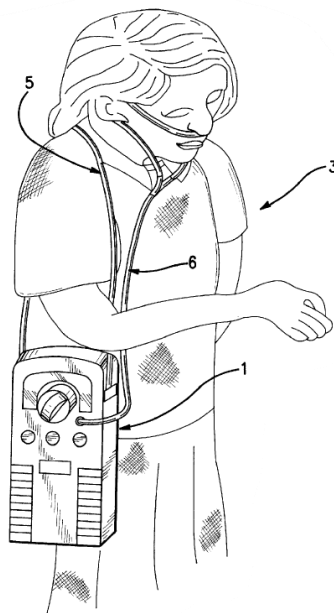


There are a number of differences between *Deane* and the claims.

While the Petition primarily relies on *Deane*, Petitioner does cite to certain secondary teaching references as well, none of which resolve the problems with Petitioner's reliance on *Deane*.

2. *Dubois*

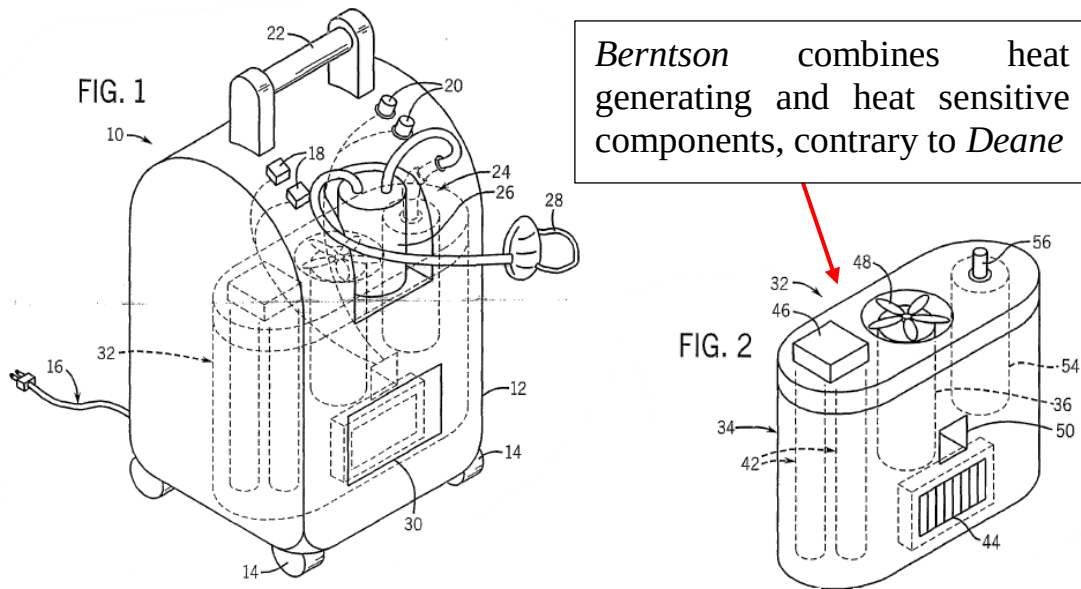
Dubois (Ex. 1005) generally teaches a portable oxygen concentrator. Specifically, *Dubois*' concentrator appears to be more portable than that of *Deane*, namely because it is smaller and can be worn by a patient or user, as shown in Figure 5, which is partially copied below.



Petitioner does not significantly rely on *Dubois*, and *Dubois* does not (and cannot) cure the defects noted in *Deane* below.

3. *Berntson*

Berntson (Ex. 1006) generally teaches an oxygen concentrator with a consolidated oxygen-rich air generator (ORAG) unit including a pump 36, adsorbent containers 42, a valve system 46, a cooling fan 48, an air tank 54, and an air outlet 56 all consolidated in one removable unit. Ex. 1006 at ¶¶ [0012], [0014]. Petitioner relies on *Berntson* purely as a supplement for *Deane* to allegedly teach a “more distinct cartridge” than *Deane* that is “selectively removable from a receptacle.” Petition at pages 36 and 48. However, *Berntson*’s teachings plainly conflict with one of the central teachings of *Deane*. Whereas *Deane* teaches separation of heat generating and heat sensitive components (Ex. 1004 at ¶ [0058]), *Berntson* teaches integrating its heat generating and heat sensitive components. Ex. 1006 at ¶ [0018] (“It may also be desirable to integrate components formerly considered separate. For example, ...the sieve beds may be incorporated into the pump housing...”).



Petitioner has failed to establish a *prima facie* case of obviousness relative to *Deane*, regardless of the teachings of *Dubois* or *Berntson*.

4. Ground 1—*Deane* fails to teach the removal direction limitations

Failure to adequately establish a teaching of each and every limitation of a claim in the prior art is fatal to a determination of obviousness. *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1366-1367 (Fed. Cir. 2016) (reversing Board’s determination of obviousness when a claim limitation was missing from the cited prior art and the Board had improperly relied on “common sense” to fill in the missing limitation); *see also In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970) (“All words in a claim must be considered in judging the patentability of that claim against the prior art.”).

Deane fails to teach “a separation cartridge removable from a receptacle by movement relative to the receptacle in a first direction” (i.e., the removal direction limitations) as required by both of the challenged independent claims. The Petition relies on *Deane* alone as allegedly teaching the removal direction limitations. See Petition at pages 54-55. Yet, there is no evidence that the component which the Petition calls out as *Deane*’s separation cartridge moves in the first direction at all, let alone relative to a receptacle, as recited in independent claims 1 and 11.

In the context of claim 1, the first direction is a direction opposite to an orientation of the inlet and outlet. See Ex. 1001 at claim 1 (“an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction...”). Petitioner specifies the “first direction” as a vertically downward direction of movement in *Deane*’s Figure 3. See Petition at pages 49-55. Petitioner argues that *Deane*’s housing 602 and adsorbent columns 508a, 508b read on the claimed “separation cartridge.” *Id.* at page 49. Finally, Petitioner argues that *Deane*’s manifold 512 alone may meet the claimed receptacle, and then the Petition alternatively advances a combination of manifold 512 and shell 204 together as constituting the claimed receptacle. See Petition at page 42-46.

So, to establish invalidity, the Petitioner must demonstrate that *Deane* teaches movement of the housing 602 and adsorbent columns 508a, 508b in the vertically-downward direction relative to either the manifold 512 or the combination of the

manifold 512 and the shell 204, or otherwise establish that this limitation would be obvious in view of other prior art. Petitioner fails on all accounts.³

a. Movement in the first direction is not taught by Deane

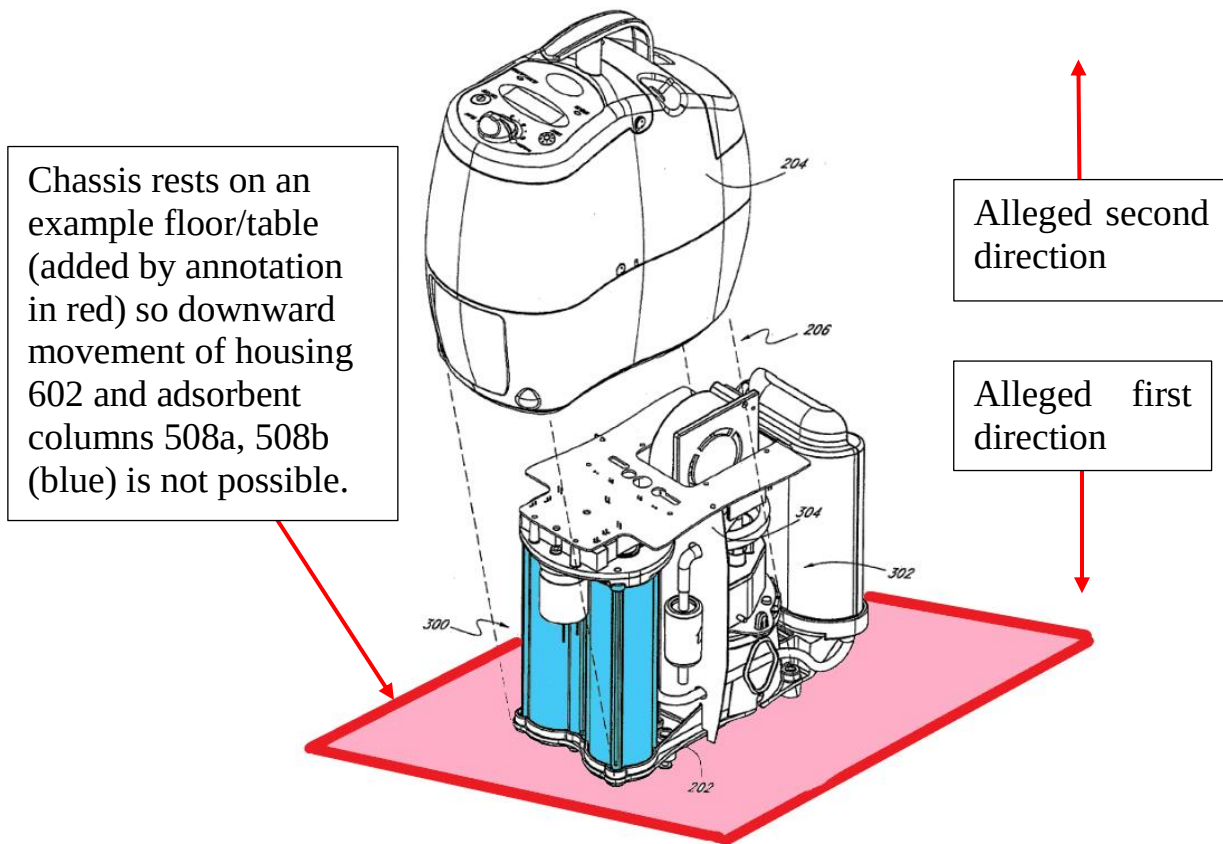
Petitioner improperly equates vertically upward movement of *Deane's* manifold 512/shell 204 with downward movement of the separation cartridge. See Petition at pages 47-55. Petitioner appears to assume, without any explanation or evidence in support, that such relative movement of an alleged receptacle reads on the claims. *Id.* As noted above, Petitioner only proposes a construction for “selectively removable” and fails to provide any analysis for the phrase “by movement relative to the receptacle in a first direction.” The latter phrase modifies how the separation cartridge is “selectively removable,” such that the claimed “movement relative to the receptacle” must be accomplished by the separation cartridge. In other words, the claims require the separation cartridge to be physically movable in the first direction, relative to the receptacle, for removal.

Deane does not teach that the alleged separation cartridge is moveable in the alleged first direction for removal, let alone movable in the first direction relative to

³ These arguments relating to the removal direction limitations and the deficiencies of *Deane* are also applicable to claims 1-11 of U.S. Patent No. 11,389,614 in the related and co-pending *Inter Partes* Review No. IPR2023-00326.

any alleged receptacle. Petitioner's failure to establish that *Deane* meets the actual claim language is a fatal mistake.

Deane's housing 602 and adsorbent columns 508a, 508b cannot be moved downward in the alleged first direction for removal because the bottom of the alleged separation cartridge directly abuts and is supported on the chassis 202. *See* Ex. 1004 at ¶ [0058] and Figs. 4, 5. The chassis 202, in turn, includes vibration isolation feet 407, which are designed to sit on a floor or table surface such that *Deane's* apparatus 200 is held in the vertical upright position. *Id.* at ¶ [0060]; Fig. 3 (annotated by Patent Owner below). In fact, *Deane's* shell 204 is specifically designed to discourage resting the unit on anything other than the feet of the chassis 202. *See Id.* at ¶ [0057], [0093] (non-planar walls “serve to discourage users from setting the housing on its side or placing it in any orientation other than the upright” orientation).



Accordingly, *Deane* does not teach movement of the separation cartridge in the alleged first direction for removal, and, in fact, such movement is seemingly not even possible in *Deane*. There is no *prima facie* case of obviousness for at least this reason.

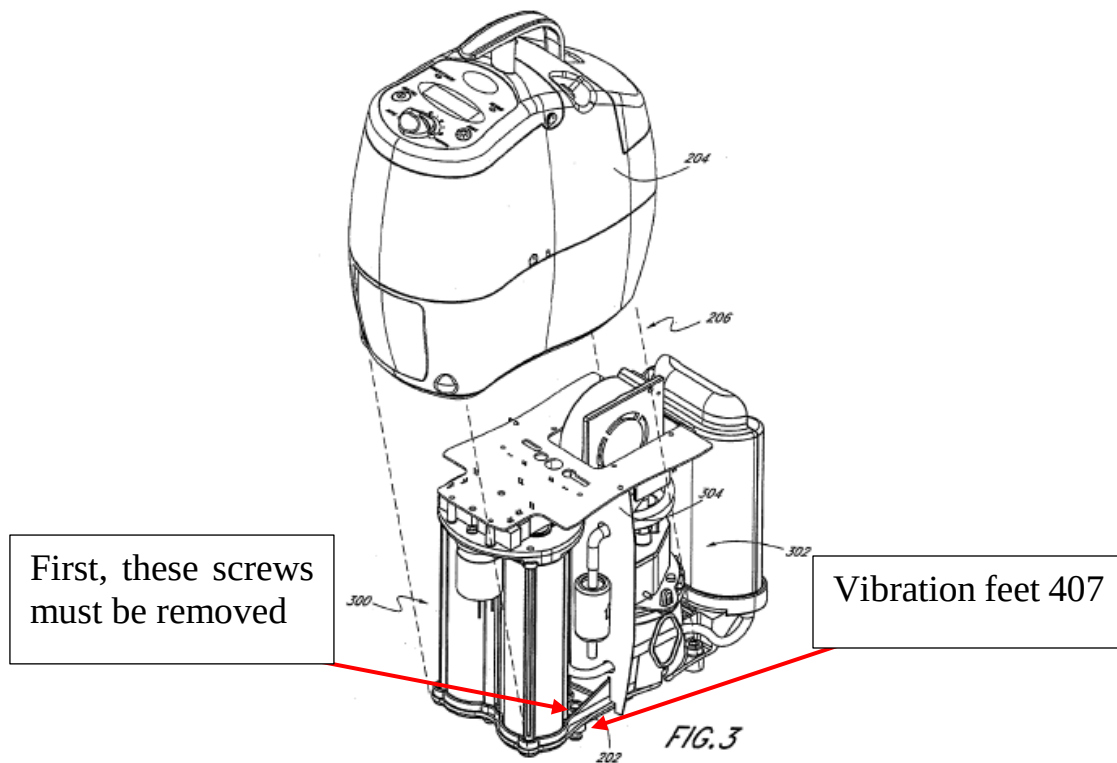
b. Movement relative to a receptacle is not taught by Deane

Not only does *Deane* not teach downward movement of the separation cartridge, but the alleged receptacles must be completely removed before the alleged separation cartridge can be moved at all. Therefore, it is not possible for the housing 602 or adsorbent columns 508a, 508b to be removable from the alleged receptacles

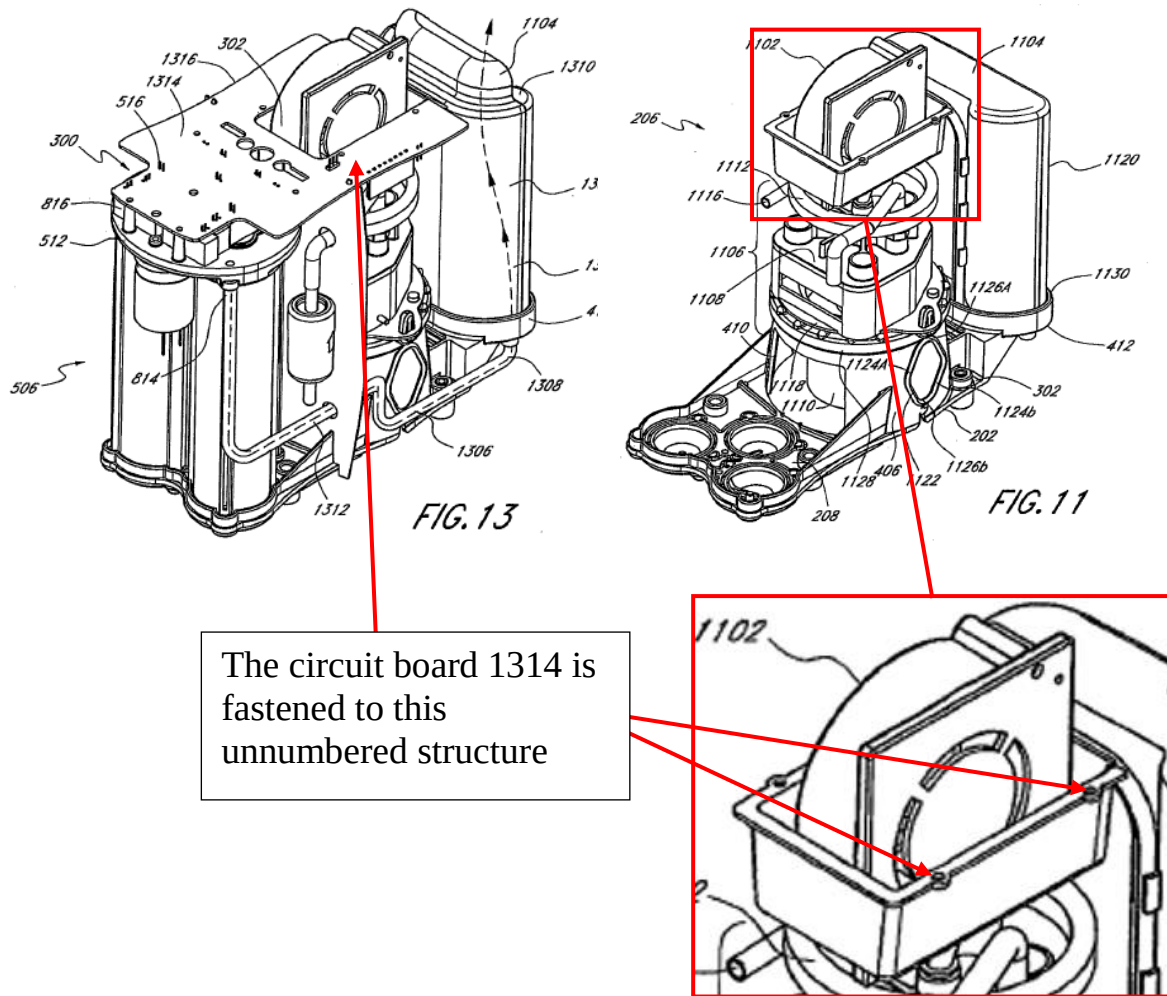
by moving “relative to the receptacle in a first direction” as required by the independent claims.

While *Deane*’s disclosure does not describe a removal process, the teachings of *Deane* suggest that the adsorbent columns 508a, 508b could only be accessed for some sort of removal after a nearly full tear down of *Deane*’s gas fractionalization apparatus 200. And, again, such access would only be achieved after removing Petitioner’s alleged receptacles.

First, to gain any access to the inner workings of *Deane*’s fractionalization device 200, including the adsorbent bed columns 508a, 508b, one must remove the outer shell 204. *See* Ex. 1004 at Figure 3 and ¶ [0058]. *Deane* explains that “the chassis has bottom mounts or vibration isolation feet 407 that are configured to engage with the bottom of the shell. Preferably, screws are inserted through the bottom of the shell and into the bottom of the vibration feet 407.” *Id.* at ¶ [0060]. Accordingly, to remove the shell 204, one must first unscrew the screws extending through bottom of the shell 204 into the vibration feet 407 of the chassis 202.

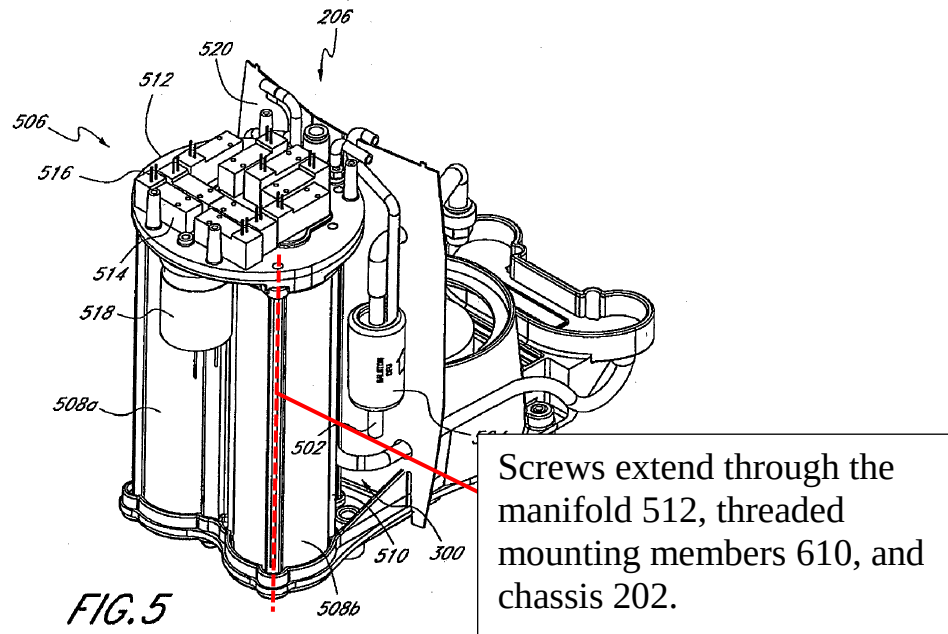


With the shell 202 removed, the adsorbent columns 508a, 508b still remain immovably sandwiched between the chassis 202 and a circuit board 1314. *See, e.g.*, Ex. 1004 at Fig. 3. *Deane* discusses the circuit board 1314 as “mounted directly on top of manifold 512” and “extend[ing] horizontally from the first compartment 300 to the second compartment 302.” *Id.* at ¶¶ [0063], [0087]. Further, *Deane*’s figures indicate that the circuit board 1314 is fastened to the structure surrounding the fan 1102 in the second compartment 302. *See Id.* at Fig. 11, 13. Thus, the next step in the process would be to remove the circuit board 1314 by detaching it from at least the manifold 512 and the structure surrounding fan 1102.



The saga does not end there. With the circuit board 1314 removed, the adsorbent column 508a, 508b component remains fastened to the manifold 512 and chassis 202. *Deane* discloses that the adsorbent bed column 508a includes a plurality of threaded mounting members 610 that are co-extruded with the housing 602. Ex. 1004 at ¶ [0067]. The threaded mounting members 610 “mat[e] with screws that attach the column 508a to the chassis and the manifold.” *Id.* Therefore, these screws

would need to be removed. Only then could the manifold 512 be removed from the housing 602 or the adsorbent columns 508a, 508b.



However, there are additional complications associated with removing the manifold 512. The manifold 512 is not a unitary component but rather is formed of a separable upper plate 802 and lower plate 804. Ex. 1004 at ¶ [0071]; Figure 8. “Bores 820 are [] formed in the upper and lower plates 802, 804 for receiving fasteners used to mount the plates together and onto the PSA column.” *Id.* Thus, removal of the fasteners securing the manifold 512 to the adsorbent columns 508a, 508b component causes the manifold 512 to separate into separate plates 802, 804.

In sum, just to make the alleged separation cartridge accessible, let alone moveable, one would have to (1) remove the screws from the vibration feet 407 and

the bottom of the shell 204, (2) remove the shell 204, (3) remove the circuit board 1314, (4) remove the screws connecting the manifold 512, threaded mounting members 610, and chassis 202, and (5) remove the manifold 512, which has separated into two pieces. Finally, one could then access and remove the housing 602 and adsorbent columns 508a, 508b by lifting them out of the divots 404a-404c of the chassis 202.

Even so, once accessed, the housing 602 and adsorbent columns 508a, 508b would be lifted out of the chassis 202 in what Petitioners call the *second* direction (vertically upward), not the first direction, as claimed. And again, by this point, the shell 204 has already been removed from the apparatus 200 and manifold 512 has already been removed and separated into plates 802, 804. Thus, the housing 602 and adsorbent columns 508a, 508b are not removable in Petitioner’s alleged first direction, let alone relative to any alleged receptacle.

Further, in view of the arduous disassembly process, it is unclear if the housing 602 and adsorbent columns 508a, 508b can even be properly considered “removable” at all. *See Novatek, Inc. v. Sollami Co.*, 559 Fed. Appx. 1011, 1017 (Fed. Cir. 2014) (arduous process needed to separate a component did not meet claim requirement of “removable” because “[t]he process ... to render it removable is not the type of removability the patents contemplate.”). It is also notable that *Deane* uses the term “removable” (or the like) many times—but never relative to the alleged

separation cartridge. *See, e.g.*, Ex. 1004 at ¶ [0058] (chassis “removably attached” to shell), ¶ [0082] (compressor restraint “removably attached” to compressor and chassis), and ¶ [0095] (removable hatch). *Deane* knew how to implement and describe removability, but did not do so with respect to the alleged separation cartridge.

There is no *prima facie* case of obviousness for these additional reasons.

c. Berntson does not cure the defects

Apparently recognizing the deficiencies of *Deane*, Petitioner alleges that *Berntson* also teaches a separation cartridge “selectively removable from a receptacle” “because it teaches its oxygen-rich air generator (ORAG) unit removable as a whole from the receptacle of a concentrator.” *See* Petition at page 53. As noted above, *Berntson* generally teaches a consolidated ORAG unit including a pump 36 (which may be a compressor and motor), adsorbent containers 42, a valve system 46, a cooling fan 48, an air tank 54, and an air outlet 56 all consolidated in one unit. Ex. 1006 at ¶¶ [0012], [0014]. The Petition’s reference to *Berntson* does not cure the above identified issue in *Deane*.

Petitioner’s vague attempt to set forth a combination in view of *Berntson* in the alternative to *Deane* alone is improper. Petitioner does not make clear how the alleged teachings of *Berntson* would be incorporated into *Deane*, or even explain what the alleged “separation cartridge” would be in the resulting combination. *See*

Petition at pages 46, 48, 53-54, 57, and 64. This is insufficient to establish obviousness. *See Apple, Inc. v. ContentGuard Holdings, Inc.*, IPR2015-00355, Paper 9 at 9-11 (PTAB June 26, 2015) (finding no reasonable likelihood of prevailing because “Petitioner leaves it to the Board to ascertain what gaps to fill, and then presents vague statements regarding what the prior art suggests.”).

What’s more, *Berntson* does not teach movement of its ORAG unit 32 in a particular direction relative to a receptacle, let alone anything that could be considered the claimed “first direction.”

Even if it did, one would not have found it obvious to incorporate such a teaching into *Deane* for two reasons. First, if one were to form an ORAG unit similar to *Berntson*’s with the same internal components of *Deane*, that unit could not be moved downward through *Deane*’s chassis 202, which is designed to rest on a table/floor. *See*, e.g., Ex. 1004 at Fig. 3. Second, *Deane* teaches thermal separation of its motor, blower, etc., and the adsorbent columns 508a, 508b (Ex. 1004 at ¶ [0058]), and therefore one would not be motivated to modify *Deane* in view of the ORAG unit of *Berntson* where heat-generating components are combined into a common unit with heat-sensitive adsorbent components. Ex. 1006 at ¶ [0018]. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056 (Fed. Cir. 2016) (a motivation to combine references is not present when a proposed modification “would destroy the basic objective” of a key feature of the base reference). The Petition’s peripheral

citation to *Berntson* does not cure the deficiencies of *Deane* for at least these reasons and institution should be denied.

B. Grounds 2-6 are deficient for the same reasons as Ground 1

Ground 2 relates to dependent claims 2, 3, 14-15, and 22-23. Petitioner applies *Deane*, *Dubois*, *Berntson*, and *Occhialini* (Ex. 1073) to the claims in Ground 2. Ground 3 relates to dependent claims 5 and 18. Petitioner applies *Deane*, *Dubois*, *Berntson*, and *Basset* (Ex. 1007) in Ground 3. Petitioner does not rely on *Occhialini* or *Basset* in an attempt to cure any of the above-noted deficiencies in the proposed grounds of rejection of the independent claims. Therefore, the Petition fails on Grounds 2 and 3 for the same reasons as Ground 1, above.

Grounds 4-6 repeat the allegations of Grounds 1-3, but eliminate the teachings of *Dubois* and *Bernston*. Petition at page 72. Grounds 4-6 fail for the same reasons as Grounds 1-3.

VI. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 325(d)

“In determining whether to institute or order a proceeding..., 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.” 35 U.S.C. § 325(d).

Here, every ground in the Petition relies on *Deane* as the primary reference, the disclosure of which was noted to be the “closest prior art” by Examiner Vasat

during examination of the parent '504 Application (Ex. 1052 at page 16), which Petitioner contends had claims “very similar to the Challenged Claims.” See Petition at page 13. Again, Examiner Vasat also handled the examination of the '628 Patent. See Ex. 1002. Further, *Deane* was cited and considered by Examiner Vasat during prosecution of the '628 Patent. Ex. 1002 at pages 318-339. The Office previously considered *Deane* pervasively during the prosecution of the '628 Patent's family, and Petitioner has failed to provide a compelling reason why the Board should re-adjudicate the same prior art considered and dismissed by Office during prosecution. The Board should thus exercise its discretion under § 325(d) and deny institution.

The Board applies a two-part framework to assess whether to exercise its discretion and deny a petition under § 325(d). First, the Board considers whether the same or substantially the same prior art or arguments previously were presented to the Office. If either condition is satisfied, the Board then assesses 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 Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential). A non-exclusive list of factors, set forth in *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph), guides the Board's application of this framework. *Advanced Bionics*, Paper 6 at 9. Those factors include:

- (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 Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
- (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson, Paper 8 at 17-18.

Importantly, the Board’s analysis should include an evaluation of not only the file history of the subject patent, but also the extent to which the asserted prior art was analyzed by the Office in other applications in the priority chain. *See Becton, Dickinson*, Paper 8 at 23 (finding that the fact that the asserted prior art reference had been “evaluated with respect to obviousness rejections in the parent application

over claims with scope similar to that of the [subject] patent” favored denial under § 325(d)); *Johnson & Johnson Surgical Vision, Inc. v. Alcon, Inc.*, IPR2021-00899, Paper 16 at 2 (PTAB Nov. 9, 2021) (denying institution under § 325(d) where asserted prior art was evaluated in the parent case); *Microsoft Corp. v. IPA Technologies, Inc.*, IPR2019-00839, Paper 9 at 13-18 (PTAB Nov. 8, 2019) (same); *Cultec, Inc. v. Stormtech, LLC*, IPR2017-00777, Paper 7 at 8-11, 13 (PTAB Aug. 22, 2017) (Informative) (denying under § 325(d) based on analysis of the asserted art in a sibling application).

All of the *Becton, Dickenson* factors weigh heavily in favor of denying institution.

A. Previously presented – factors (a), (b), and (d)

Regarding factors (a) and (b), all of the art relied upon in the grounds of the Petition is either identical or cumulative to the prior art presented to the Office during examination of the '628 Patent and its related family. *Deane* is the sole or primary reference applied in all grounds, it was submitted and considered by the Examiner via an IDS submission during examination of the '628 Patent, and it appears on the face of the '628 Patent. Ex. 1002 at pages 329-335; Ex. 1001 at References Cited.

The secondary references of *Dubois*, *Berntson*, *Basset*, and *Occhialini* provide no shield for Petitioner. Notably, the Petition fails to describe any differences or teachings provided by these secondary references compared to the art analyzed

during prosecution. *See Becton, Dickinson*, Paper 8 at 21 (“Petitioner has not ... substantively addressed, any particular differences between the [the prior art of the Petition and the prior art the Examiner considered] as a basis for unpatentability in the Petition. We therefore give little weight to the fact that [Petitioner’s art] is a different secondary reference from [the art in the file history].”).

Moreover, the *Dubois* reference was submitted and considered via an IDS in the ’628 Patent. Ex. 1002 at page 329 (item 122). The *Basset* reference is relied upon only as allegedly teaching a limitation of dependent claims 5 and 18, and thus does not provide any prior art differentiation in relation to the independent claims. The same is true of the *Occhialini* reference, which is relied upon only for allegedly teaching limitations of dependent claims 2-3, 14-15, and 22-23. Lastly, the relied-upon teachings of the remaining *Berntson* reference are cumulative to at least the *Cole* reference (Ex. 1020), which was used in an obviousness rejection in the parent ’504 Application (Ex. 1052 at page 185, *et seq.*) and was submitted and considered during prosecution of the ’628 Patent. Ex. 1002 at page 323. Specifically, the Petition relies on *Berntson* to allegedly teach a distinct and removable cartridge containing adsorbent material. *See* Petition at pages 36, 46, and 48. Petitioner’s Declarant admits that *Cole* “teaches a removable adsorber cartridge.” Ex. 1003 at page 29.

With respect to factor (d), Petitioner relies on *Deane* in a very similar manner to how Examiner Vasat explained the applicability of the *Deane* disclosure in the notice of allowance of the parent '504 Application. Examiner Vasat contended, as does Petitioner, that the *Deane* disclosure teaches an oxygen concentrator cartridge at Figure 6. Ex. 1052 at page 16; Petition at pages 49-50. Both also pointed to the top of the housing 602 at filter portion 618a as a first port/outlet of the alleged cartridge and the upper part of feed tube 608 as a second port/inlet spaced-apart from and faced in the same direction as the first port/outlet. Ex. 1052 at page 16; Petition at pages 55-57.

The notice of allowance of the parent '504 Application and its discussion of *Deane* came after the '628 Patent was allowed. *Cf.* Ex. 1052 at page 9 and Ex. 1002 at page 30. However, both applications were pending before Examiner Vasat at the same time, and Examiner Vasat signed the IDS submissions in both cases indicating that he had considered *Deane* prior to issuing the notice of allowance of the subject '628 Patent. Ex. 1052 at page 608, Ex. 1002 at page 332. The Petition has set forth no basis that would suggest that Examiner Vasat's understanding or consideration of *Deane* changed between the allowances of the '628 Patent and the parent '504 Application.

While the prosecution history of the '628 Patent does not contain relevant "arguments" in view of the *Deane* disclosure, "[s]ection 325(d) is phrased in the

disjunctive (‘or’), not the conjunctive (‘and’), when it refers to ‘whether... the same or substantially the same prior art *or* arguments previously were presented to the Office.’ Thus, Section 325(d) does not require previous presentation of the same art *and* arguments.” *Edge Endo, LLC v. Michael Scianamblo*, IPR2018-01320, Paper 15 at 12 (PTAB Jan. 14, 2019) (emphasis in original) (internal citation omitted). Here, there is significant overlap between how the prior art was applied in the relevant prosecution and the manner in which Petitioner relies on the prior art.

Accordingly, *Becton, Dickenson* factors (a), (b), and (d) all indicate that the first prong of the § 325(d) inquiry is satisfied. *See Advanced Bionics*, Paper 6 at 10.

B. No material error – factors (c), (e), and (f)

With the first prong satisfied, Petitioner must establish material error. Factor (c) clearly favors denial. Again, during prosecution of the ’628 Patent, Examiner Vasat indicated that he had considered *Deane* and the various other *Deane* disclosures via IDS submission. Ex. 1002 at pages 318-339. The same disclosure was cited in three separate obviousness rejections during prosecution of the great grandparent ’362 Application, and was used as a base reference for an obviousness rejection in the great, great grandparent ’341 Application. Ex. 1049 at pages 77-81, 108-112, and 186-191; Ex. 1050 at pages 58-65. Accordingly, the disclosure and applicability of *Deane* was carefully considered by the Office during prosecution.

Petitioner summarily states that factor (c) favors institution because *Deane* was not formally applied in any prior art rejection during prosecution of the '628 Patent. Petition at pages 28. However, the precedential *Becton, Dickenson* decision found that factor (c) favored denial when the asserted prior art reference had been “evaluated with respect to obviousness rejections in *the parent application* over claims with scope similar to that of the [subject] patent.” *Becton, Dickenson*, Paper 8 at 23 (emphasis added). Further, the *Advanced Bionics* decision noted that “although *Becton, Dickinson* factor (c) evaluates ‘the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection,’ *the focus should be on the record.*” *Advanced Bionics*, Paper 6 at 11 (emphasis added).

Accordingly, the fact that the *Deane* disclosure was discussed during prosecution of the '628 Patent's related family, yet was not formally used as a basis for a prior art rejection during prosecution of the '628 Patent, does not carry the weight that Petitioner contends. Indeed, the Board has denied institution when the relevant references were submitted for consideration in an IDS alone and not discussed or applied in any manner during prosecution. *See Biocon Pharma Ltd. v. Novartis Pharmaceuticals Corp.*, IPR2020-01263, Paper 12 (PTAB Feb. 16, 2021); *see also Advanced Bionics*, Paper 6 at 7-8 (“Previously presented art includes art made of record... such as on an Information Disclosure Statement (IDS)”). Here, the

overall prosecution record of the '628 Patent family indicates that Petitioner's interpretation of *Deane* was evaluated by the Office to a significant extent.

Regarding factor (e), “[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.” *Advanced Bionics*, Paper 6 at 9. Here, the only error advanced by the Petition is allegedly that “the Examiner clearly erred by not rejecting the Challenged claims in view of *Deane* '426/*Deane*, alone or in combination with the other Ground references.” Petition at page 28. Accordingly, the alleged “error” appears to be that either Examiner Vasat neglected to consider *Deane* or failed to appreciate Petitioner's flawed interpretation of *Deane*. This is improper for at least the below reasons.

First, Examiner Vasat was required by the MPEP to review the previous analysis of *Deane* in the grandparent applications during prosecution of the '628 Patent. Under MPEP § 609.02(II)(2) an examiner is required to “consider information which has been considered by the Office in a parent application ... when examining: (A) a continuation application...” Similarly, MPEP § 904 instructs that “[i]n all continuing applications, the parent applications must be reviewed by the examiner for pertinent prior art.”

Second, the file history of the '628 Patent clearly shows that Examiner Vasat did, in fact, consider *Deane* in relation to the challenged claims. Examiner Vasat

signed an IDS listing *Deane* with the statement “all references considered except where lined through,” and *Deane* was not lined through. Ex. 1002 at page 332 (item 155). Thus, the suggestion that Examiner Vasat somehow forgot about the *Deane* reference when examining the ’628 Patent is completely unfounded. Indeed, it is presumed that an Examiner handling the examination of a continuation application would substantively review the file history of the family. *See Ultra-Tex Surfaces Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1367 (Fed. Cir. 2000) (noting that the Office and its examiners are “presumed to have properly done [their] job.”).

Third, as shown above, *Deane* does not teach what Petitioner contends. Specifically, *Deane* fails to teach at least the removal direction limitations. Again, during prosecution of the parent ’504 Application, Examiner Vasat noted *Deane*’s disclosure to be “the closest prior art” (Ex. 1052 at page 16) relative to claims that the Petition asserts are “very similar to the challenged claims” (Petition at page 13). Yet, Examiner Vasat did not allege that *Deane* taught the removal direction limitations, despite similar language being present in the claims of the parent ’504 Application. Ex. 1052 at pages 16, 149, 152. Thus, Examiner Vasat’s reasonable interpretation that *Deane* does not meet the Challenged Claims is not a material error by the Office. Again, if reasonable minds can disagree regarding the treatment of the art, no material error is established. *Advanced Bionics*, Paper 6 at 9.

Finally, as to factor (f), the only evidence presented by Petitioner that could arguably be considered new is the declaration of Dr. Knaebel (the “Knaebel Declaration”) (Ex. 1003). However, the Director designated as precedential a decision denying institution of *inter partes* review which held that testimony of a declarant that merely repeats conclusory assertions from a petition, without citing additional supporting evidence or providing technical reasoning to support the testimony, is entitled to little weight. *See Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 at 15 (Aug. 24, 2022) (precedential). Here, the Petition refers generally to the Knaebel Declaration in its brief § 325(d) analysis, but provides no specific citation as to what parts of the Knaebel Declaration provide additional facts and evidence, and no explanation as to how this testimony would change the Office’s previous consideration of the *Deane* reference. *See* Petition at page 28. For example, in discussing how *Deane* allegedly meets the relevant removal direction limitations, the Knaebel Declaration merely parrots language similar to the Petition. *See* Ex. 1003 at 168-169. Thus, the Petition has not provided any meaningful additional evidence, and *Becton, Dickenson* factors (c), (e), and (f) all indicate that the Petition has failed to establish the Office erred in a manner material to the patentability of the Challenged Claims.

C. Petitioner's Cited Decisions are Inapposite

Petitioner advances the decisions of *Asetek Danmark A/S v. Coolit Systems, Inc.*, IPR2019-00705, Paper 19 (PTAB Sept. 6, 2019), *Apple Inc. v. MPH Technologies OY*, IPR2019-00820, Paper 10 (PTAB Oct. 7, 2019), and *Microsoft Corp. v. IPA Technologies, Inc.*, IPR2019-00814, Paper 12 (PTAB Nov. 6, 2019) as examples where the Board granted institution despite the prior art overlapping with references cited during examination. However, the facts presented in these decisions are very different from the present facts.

In *Asetek*, the Examiner only cited the petition's base reference "in a very limited fashion" to teach a limitation of a dependent claim and "did not otherwise analyze or apply" that reference during prosecution. *Asetek*, Paper 19 at 9. This is similar to the *Apple* decision, where the base reference advanced in the IPR was only "considered and applied during examination in a limited, narrow manner" and "only as a secondary reference." *Apple*, Paper 10 at 12. Here, in stark contrast, the *Deane* disclosure was analyzed in the relevant prosecution history as a main reference, and in one instance was expressly deemed by the Examiner to be the "closest prior art." Ex. 1052 at page 16.

In *Microsoft*, the asserted base reference was discussed in prosecution, but a secondary reference necessary to fill a gap in the base reference "was not considered substantively by the examiner" nor was it "cumulative of art considered by the

examiner.” *Microsoft*, Paper 12 at 17-19. There is no such secondary reference here to save Petitioner. The Petition relies on the secondary *Dubois* and *Berntson* references only as fallbacks to allegedly teach a carrying case and a more distinct cartridge. See Petition at page 36. The Petition does not advance any secondary reference to modify *Deane* to be any different than how Examiner Vasat interpreted *Deane*’s disclosure in the parent ’504 Application, for example.

More on point here, the Board has consistently exercised its discretion to deny petitions for *inter partes* review that assert prior art which was at the forefront during examination of the parent application and other related applications. See *Johnson & Johnson Surgical Vision, Inc. v. Alcon, Inc.*, IPR2021-00899, Paper 16 at 2 (PTAB Nov. 9, 2021); *Microsoft Corp. v. IPA Technologies, Inc.*, IPR2019-00839, Paper 9 at 13-18 (PTAB Nov. 8, 2019); *Cultec, Inc. v. Stormtech, LLC*, IPR2017-00777, Paper 7 at 8-11, 13 (PTAB Aug. 22, 2017) (Informative). The Board should follow these decisions and exercise its discretion to reject Petitioner’s attempt to re-adjudicate the *Deane* disclosure.

VII. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(a)

As noted above, there is litigation related to this matter: *GCE Gas Control Equip. Inc. v. 3B Medical Mfg., LLC*, No. 8:22-cv-02550-TDC (“Maryland Case”). In view of this concurrent litigation, the Board would also be justified in exercising

its discretion to deny institution of the Petition under Section 314(a) and *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (PTAB Mar. 20, 2020).⁴

“In exercising discretion under 35 U.S.C. § 314(a) and 37 C.F.R. § 42.108(a), [the Board is] mindful of the goals of the AIA – namely, to ... make the patent system more efficient...” *General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16 (PTAB Sept. 6, 2017).

Institution of the Petition would be extremely inefficient. Thousands of pages of invalidity contentions have already been served by Petitioner in the Maryland Case, and opening claim construction briefs have already been filed. Responsive claim construction briefs are due June 21, 2023. While no trial date is set in the Maryland Case, it appears that trial will occur prior to the projected statutory date for a final written decision in this proceeding. Further, if institution is granted, Petitioner has positioned itself to mount a collateral invalidity attack in the Maryland Case based on system prior art that appears to be materially similar to the prior art of the Grounds. What’s more, the Maryland Case was first filed by Petitioner, seeking a declaratory judgement of non-infringement. The Board should hold Petitioner to their initial choice of forum—the Maryland court.

⁴ Similar arguments to those raised in this section also apply to IPR2023-00326.

A. The Director's Guidance Memo

Petitioner initially alleges the Petition should be instituted because “its merits are compelling” and because Petitioner has allegedly filed a *Sotera*-type stipulation. Petition at page 27. The Petition points to Director Vidal's recent guidance as support that this alone is dispositive on the *Fintiv* issue. See Memorandum from U.S. Patent and Trademark Office Director Katherine K. Vidal, *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation*, June 21, 2022. The Board should reject this reasoning for several reasons.

First, Director Vidal recently explained that “the compelling merits standard is a higher standard than the standard for institution set by statute” and it is met only “if it is highly likely that the petitioner would prevail with respect to at least one challenged claim.” *Commscope Technologies LLC, v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 at 3-4 (PTAB Feb. 27, 2023). The Director further explained that a compelling merits determination is not a substitute for a full *Fintiv* analysis. *Id.* at page 4. As noted above, the Petition has shown no likelihood of success because *Deane* does not teach the removal direction limitations, which are required by all challenged claims. The Petition therefore certainly has not met the higher standard of establishing “compelling merits.”

Second, although Petitioner alleges that it has filed a “*Sotera*-type stipulation,” Petitioner's stipulation makes one key caveat that makes it less

encompassing than a true *Sotera* stipulation. Specifically, the stipulation filed in the parallel district court litigation states “[t]his stipulation is not intended, and should not be construed, to limit GCE’s ability to assert invalidity of any of the claims of the ’628 patent in this case on any other ground that could not have reasonably been raised in the IPR (including but not limited to invalidity ... based on prior art that is not a patent or printed publication or not reasonably presently available to GCE), regardless of whether IPR is instituted.” Ex. 1069 at page 2.

This qualification is significant, particularly with respect to system or product prior art. While the Federal Circuit has not weighed in, some District Courts have held that a full *Sotera* stipulation estops a party from raising prior art systems when those systems are “materially identical” to the disclosures that party advanced in the IPR. *See Hafeman v. LG Elecs., Inc.*, No. 6:21-cv-00696-ADA, Dkt. 203, 2023 U.S. Dist. LEXIS 66459, *44-45 (W.D. Tex. Apr. 17, 2023); *see also Wasica Fin. GmbH v. Schrader Int’l*, 432 F.Supp. 3d 448, 455 (D. Del. 2020) (holding that invalidity contentions based on a prior art system that was “materially identical” to the prior art raised in the IPR were estopped under § 315(e)(1)). So, whereas Petitioner might have been precluded under a full *Sotera* stipulation from pursuing invalidity theories in the Maryland Case based on a prior art system “materially identical” to or embodied by the prior art of the Grounds, Petitioner’s stipulation seeks to establish an exception.

And this possibility of a collateral invalidity attack based on system prior art is not in the abstract. Petitioner’s invalidity contentions in the Maryland Case cite several prior art systems including the “Inogen One.” The assignee of the *Deane* references relied upon by Petitioner here is Inogen. Inogen marks their Inogen One product with the *Deane* reference. See Ex. 2002 (Inogen’s virtual patent marking website, identifying the Inogen One as being covered by the ’059 Patent, which issued from the base *Deane* reference (Ex. 1004), used in each ground raised by Petitioner); see also Reel/Frame 014676/0701 and 014928/0156.

Accordingly, if this Petition is instituted, Patent Owner would likely be placed in the inequitable position of having to repel both a first invalidity attack based on the *Deane* patent disclosures in this proceeding and a second based on Deane’s Inogen One system in the Maryland Case. Accordingly, the Petitioner’s purported “*Sotera*–type stipulation” does not eliminate potential issue overlap and should not be dispositive.⁵

⁵ Notably, the Office is currently seeking comments on a rule it is considering that would make “a *Sotera* stipulation a necessary but not sufficient basis for institution.” See 88 Fed. Reg. 24503 (proposed Apr. 21, 2023).

B. A Full *Fintiv* Analysis Favors Denial

As shown above, a full *Fintiv* analysis is required. Under the full *Fintiv* framework the Board considers six factors:

- (1) Whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
- (2) Proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;
- (3) Investment in the parallel proceeding by the court and the parties;
- (4) Overlap between issues raised in the petition and in the parallel proceeding;
- (5) Whether the petitioner and the defendant in the parallel proceeding are the same party; and
- (6) Other circumstances that impact the Board's exercise of discretion, including the merits.

Fintiv, Paper 11 at 5-6.

Regarding the first *Fintiv* factor, no stay has been granted in the Maryland Case. The Petition cites two orders wherein the District Court of Maryland has granted stays for instituted *Inter Partes* Reviews (Exs. 1064, 1065), however the facts in those cases are quite distinguishable. In the first case, petitions had been instituted on multiple patents and the case dealt with a consolidated multi-district litigation. *See* Ex. 1064. In the second case, only a partial stay was granted for a

period of two months in part due to COVID-19 considerations relating to discovery. *See* Ex. 1065. There is no evidence under the present circumstances that a stay will be granted in the Maryland Case and this factor favors denial.

Regarding the second *Fintiv* factor, the Maryland case does not presently have a trial date set. However, the current scheduling order in place includes quite an accelerated schedule with discovery to be completed by October 3, 2023 and dispositive pretrial motions to be filed by November 2, 2023. The final written decision in this case (if it is instituted) would not be expected until September of 2024 based on the filing date of this Preliminary Response. *See* 35 U.S.C. §§ 314(b)(1) (institution within 3 months of preliminary response), 316(a)(11) (final written decision within 1 year after institution). It is currently unclear whether trial in the Maryland Case will occur before or after the Board's projected statutory deadline for a final written decision, however further guidance in the Maryland Case is expected in relation to an amended scheduling order. This factor is, at best for Petitioner, neutral.

Regarding the third *Fintiv* factor, there has been significant investment in Maryland Case to date. Infringement and invalidity contentions have been exchanged, with Petitioner's invalidity contentions spanning more than seven thousand pages. The claim construction process has begun and the parties have submitted their opening claim construction briefs. Discovery requests have been

served and responses provided. Depositions have begun (specifically, one deposition has recently been taken, with another soon to be scheduled). This factor weighs in favor of denying institution.

Regarding the fourth *Fintiv* factor, there is currently a substantial overlap in issues given that Petitioner's voluminous invalidity contentions in the Maryland Case include invalidity theories based on various *Deane* disclosures, including combinations that are identical to the Grounds raised in the Petition. Further, and as fully discussed above, there appears to be a significant risk of ongoing issue overlap if the Petition is instituted in view of Petitioner's qualified stipulation that attempts to carve out an exception for system prior art covered by the very *Deane* disclosures relied upon in this Petition. This factor therefore also favors denial.

Regarding the fifth *Fintiv* factor, the real parties-in-interest in both proceedings are identical. While the Maryland Case lists 3B Medical Manufacturing ("3B"), 3B is the exclusive licensee of Patent Owner, with all substantial rights in the '628 patent including, but not limited to, the right to enforce the '628 patent against third party infringers. This factor also favors denial.

Regarding the sixth and final *Fintiv* factor, at least three surrounding circumstances also favor denial. First, as set forth above regarding the removal direction limitations, the merits of the Petition are weak. Second, as noted above, the Petition's primary reference *Deane* is assigned to Inogen, Inc. (See Reel/Frame

014676/0701 and 014928/0156) and Inogen has taken a license from 3B for Inogen's portable oxygen concentrator products regarding patent families including U.S. Patent No. 10,357,628, suggesting that *Deane* is not invalidating art. Third, as noted above, the Maryland Case was brought by Petitioner as a declaratory judgment action for non-infringement. Petitioner already chose the District Court of Maryland as a forum, and the Board should hold Petitioner to that selection.

In sum, *Fintiv* factors (1) and (3)-(6) weigh in favor of denial, and factor (2) is, at best for Petitioner, neutral. The Board should therefore exercise its discretion and deny institution.

VIII. CONCLUSION

Patent Owner respectfully requests that institution be denied.

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(b)(1), the undersigned hereby certifies that the foregoing document contains 13,015 words, excluding a table of contents, a table of authorities, mandatory notices under 37 C.F.R. § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing, as measured by the word-processing system used to prepare this paper.

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing document was served electronically via email on June 15, 2023 in its entirety on the following:

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