

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GCE GAS CONTROL EQUIPMENT INC.,

Petitioner,

v.

VBOX, Inc.,

Patent Owner.

Case No. IPR2023-00527

U.S. Patent No. 10,357,628

Declaration of Kent S. Knaebel, Ph.D.

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I, Kent S. Knaebel, Ph.D., declare as follows:

1. My name is Kent S. Knaebel. I am the President of Adsorption Research Inc. and, as described in §IX, am an expert in portable oxygen concentrators and related technologies.

2. I have prepared this declaration as an expert witness retained by GCE Gas Control Equipment Inc. (“GCE”). In this declaration I give my opinions as to whether certain claims of U.S. Patent No. 10,357,628 (“the ’628 patent”) are invalid. I provide technical bases for these opinions as appropriate.

3. This declaration contains statements of my opinions formed to date and the bases and reasons for those opinions. I may offer additional opinions based on further review of materials in this matter, including opinions and/or testimony of other expert witnesses and material from related matters. I make this declaration based upon my own personal knowledge and, if called upon to testify, would testify competently to the matters contained herein.

I. OVERVIEW OF THE TECHNOLOGY

A. Background

4. As discussed below, the ’628 patent generally relates to portable oxygen concentrators, or “POCs.”

5. It has long been known that the provision of supplemental oxygen to patients, such as the elderly or those that are otherwise physically compromised,

including those that suffer from Chronic Obstructive Pulmonary Disease (commonly referred to as “COPD”), is beneficial.

6. Generally speaking, supplemental oxygen may be provided to patients in one of three ways: from high pressure gas cylinders; from vacuum insulated containers (or “dewars”) which store oxygen in liquid form; or from oxygen concentrators.

7. Oxygen concentrators, as their name suggests, are devices that split air (which is a mixture of approximately 78% nitrogen, 21% oxygen, and 1% argon), removing nitrogen from the oxygen via adsorption. Nitrogen is preferentially adsorbed by an adsorbent material (a material that holds gas molecules on its surface). Argon is typically adsorbed equally to oxygen. The separation occurs in a processing chamber called an adsorber, allowing the oxygen-rich (and argon-rich) gas to pass through. The resultant product gas is normally about 85 to 95% oxygen. The balance is about 0 to 10% nitrogen and 5% argon. That is, the amount of nitrogen depends on the design and operating conditions. The basic technology behind oxygen concentrators is pressure swing adsorption (“PSA”) (and/or vacuum swing adsorption (“VSA”)) and has been known for decades.

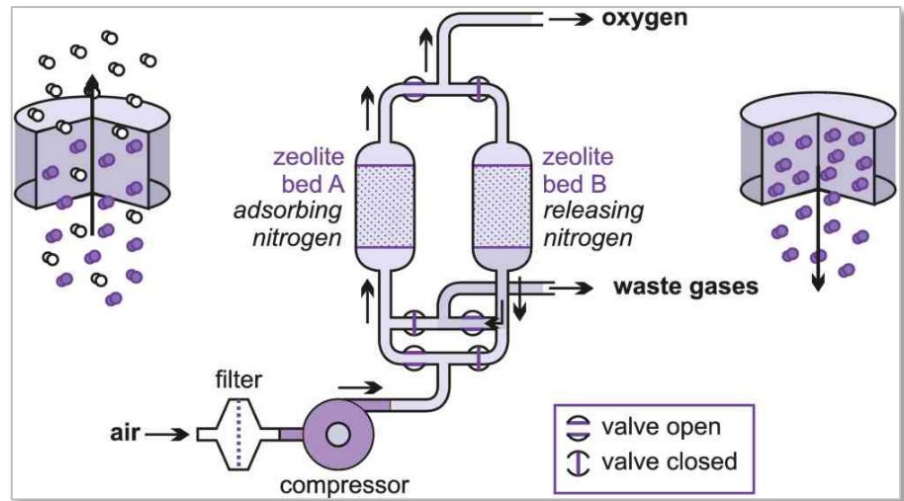
8. The initial versions of oxygen concentrators were often heavy, bulky, machines. Those were intended as replacements for oxygen tanks (or cylinders). Tanks were (and are) delivered to COPD patients’ homes periodically, and were

(and are) large and heavy in order to store enough oxygen for up to two days of continuous service, *e.g.*, at two liters per minute to the patient. Patients needing supplemental oxygen, but who were still mobile and active, used small, portable oxygen tanks. But such small tanks provided only a limited amount of supplemental oxygen before they were emptied (*e.g.*, two to five hours, depending on their size and the oxygen usage rate). The use of both large and small tanks also resulted in a patient having multiple pieces of equipment for supplemental oxygen therapy.

9. POCs, as their name suggests, are portable oxygen concentrators that have been commercialized since the early 2000s. POCs operate on the same principles as traditional oxygen concentrators, but they use smaller and lighter components and are battery-powered. POCs can provide supplemental oxygen in both a home environment (using an AC transformer) and when the patient is mobile.

10. As mentioned above, many POCs use a process called “pressure swing adsorption” (or “PSA”) where air is compressed and fed (as a “feed gas”) alternately into at least two chambers containing adsorbent material (typically a zeolite). See the sketch below. The adsorbent chambers (typically called “zeolite beds,” “sieve beds” (where “sieve” is short for “molecular sieve,” which was a trade name for synthetic zeolites), “adsorbers,” or “adsorbent beds”) remove

nitrogen from the air by adsorption, leaving a concentrated oxygen product (a “product gas”) that continues to flow through the chamber (driven by pressure from the compressor) and is provided to the patient.



11. Because the adsorbent material can only adsorb a certain amount of nitrogen, POCs normally use two or more adsorbers connected in such a way as to perform a PSA cycle, in order to provide a continuous oxygen flow for the patient. The two-bed system shown here, with zeolite beds A and B, is an example. When one zeolite bed (*e.g.*, bed A) reaches the limit of its adsorption capacity, the valves switch to deliver compressed air to the second zeolite bed (*e.g.*, bed B). Simultaneously, the adsorbed nitrogen is removed from the first zeolite bed (*e.g.*, bed A) as the pressure is reduced. The process subsequently switches back to the first zeolite bed (*e.g.*, bed A) when the second zeolite bed (*e.g.*, bed B) reaches the limit of its adsorption capacity. In the illustration above, zeolite bed A adsorbs nitrogen from compressed air to provide concentrated oxygen to the patient, while

zeolite bed B desorbs the nitrogen from its previous adsorption step, which is removed (at about ambient pressure) and is expelled as waste gas.

12. Some POCs use slightly different processes to cause gas movement. For example, a “vacuum swing adsorption” (or VSA) process uses a vacuum to induce the nitrogen to desorb more completely than is possible at ambient air pressure. Other than what causes the fluid flow, the basic functionality of both PSA and VSA POCs is the same, however. It would have been basic knowledge to a POSITA to employ either technique in a POC, or use advantageous features of a PSA system in a VSA system and vice versa. *See* EX1068 (*Ruthven*), 25. *See also, e.g.,* EX1004 (*Deane*), ¶[0055].

B. General POC Configurations Were Known

13. By 2004-2005,¹ the basic configuration of POCs was well known to a person of ordinary skill in the art (“POSITA”), including housings with compressors, manifolds, valves, batteries, and zeolite beds with adsorbent materials, inlets, and outlets, as discussed further in §§I.B-I.J. I discuss several example references here and in the following sections that teach² such basic

¹ I use 2004-2005 herein to represent the timeframe before February 9, 2005, which I understand to be the earliest filing date that could possibly be attributed to the challenged claims. *See* EX1001 (’628 Patent), p. 2 under “Related U.S. Application Data.”

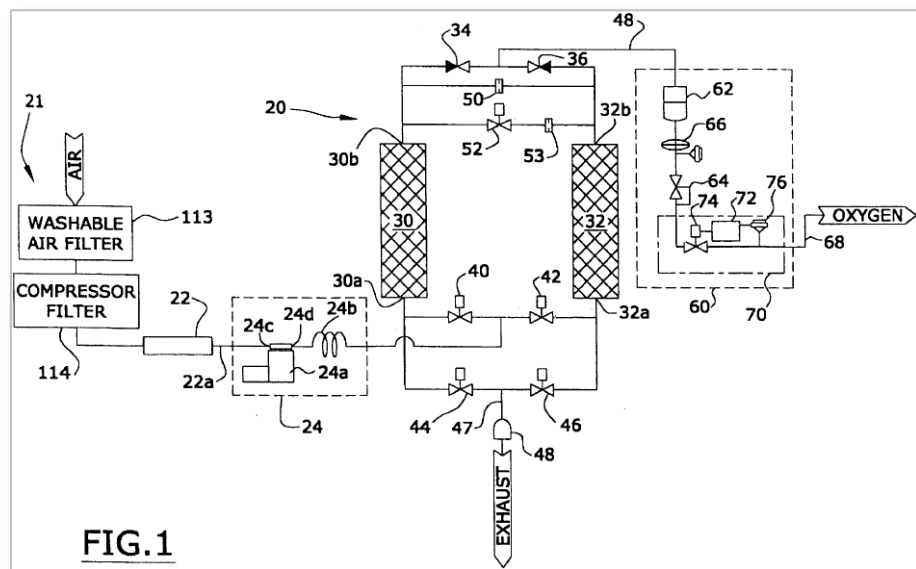
² I use “teach” herein to mean “teach or suggest.”

configurations. Many more examples existed, such as those identified in the Grounds. See §III.

14. **McCombs '924**: U.S. Patent Application Publication No. 2003/0167924 to McCombs et al. (hereinafter “*McCombs '924*”; EX1009) teaches “[a] compact and highly portable combination pressure swing adsorption apparatus” to deliver “a gas with a high concentration of oxygen” to a patient. EX1009 (*McCombs '924*) at Abstract.

15. *McCombs '924*’s FIG. 1 provides a schematic of its PSA apparatus. EX1009 (*McCombs '924*) at ¶[0008]. FIG. 1 teaches similar components to the above diagram.

Specifically, in FIG. 1, ambient air is supplied through intake 21 and is moved by compressor 24a to



first and second adsorbers 30, 32 through feed valves 40, 42. EX1009 (*McCombs '924*) at ¶[0018]. Feed valves 40, 42 alternatively allow air to enter inlets 30a, 32a of adsorbers 30, 32, which contain zeolite or other adsorbent. EX1009 (*McCombs '924*) at ¶[0019]. After sequential adsorption steps in absorbers [sic] 30, 32, the

oxygen enriched product gas is directed through outlets 30b, 32b and check valves 34, 36 to product manifold 48 and delivery control assembly 60 for patient delivery. EX1009 (*McCombs '924*) at ¶[0020].

16. *McCombs '924* further teaches the structure of its POC in FIGS. 2-10, which includes chassis 108 and outer housings 104, 106. EX1009 (*McCombs '924*) at ¶[0025], FIGS. 2-10. As can be seen in FIGS. 4-9 (reproduced here), *McCombs '924* teaches its POC includes individually installable adsorber beds 30, 32 with inlets and outlets on opposite ends, compressor assembly 24 and valve block 26 to provide and control gas flow, and battery pack 90 to provide power. EX1009 (*McCombs '924*) at ¶[0029]-[0033].

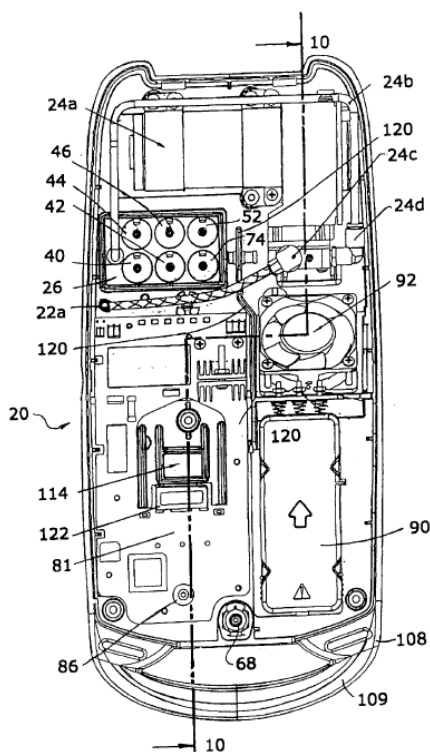


FIG. 5

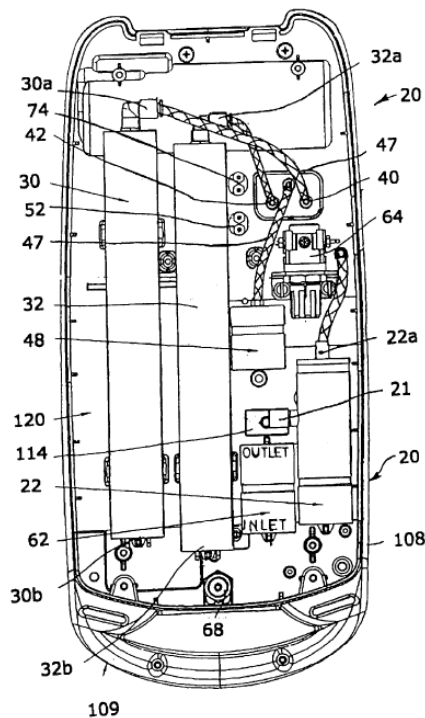
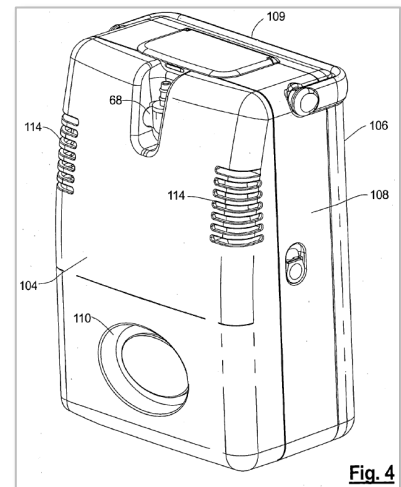


FIG. 6

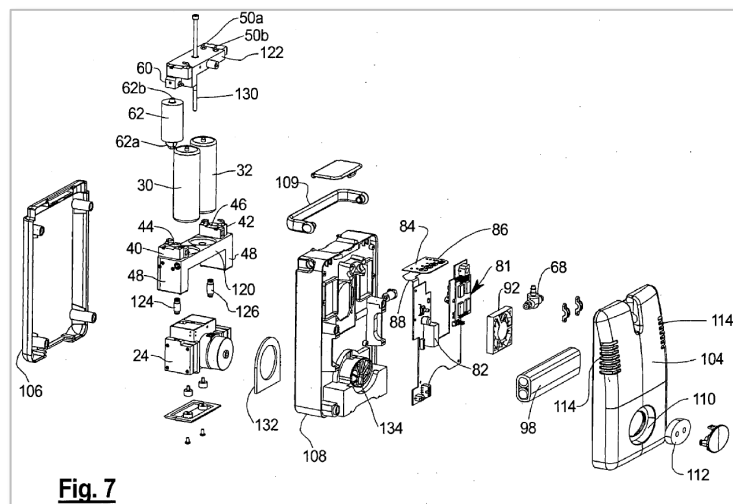
17. **McCombs '957**: U.S. Patent Application Publication No.

2006/0117957 to McCombs et al. (hereinafter “*McCombs '957*”; EX1010)³ builds upon the disclosure of *McCombs '924* and teaches “an even more compact, lighter weight and very highly portable oxygen concentrator for medical uses.” EX1010 (*McCombs '957*) at ¶[0005].

18. *McCombs '957* uses a FIG. 1 similar to *McCombs '924*'s to explain its operation. EX1010 (*McCombs '957*) at ¶¶[0020]-[0023]. *McCombs '957* teaches a different housing, with chassis 108 and enclosures 104, 106, as shown in FIGS. 4-6 (Figure 4 is reproduced here).



19. *McCombs '957* teaches an expanded view of the components of its POC in FIG. 7, including adsorber beds 30, 32 with feed/waste manifold 120 and product manifold 122 mounted on opposite ends, compressor 24, and battery 98. EX1010

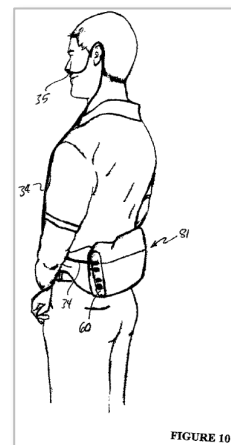


³ *McCombs '957* claims priority to U.S. Provisional Application No. 60/617,834, filed October 12, 2004 and included herewith as EX1011 (*McCombs '834 Prov*).

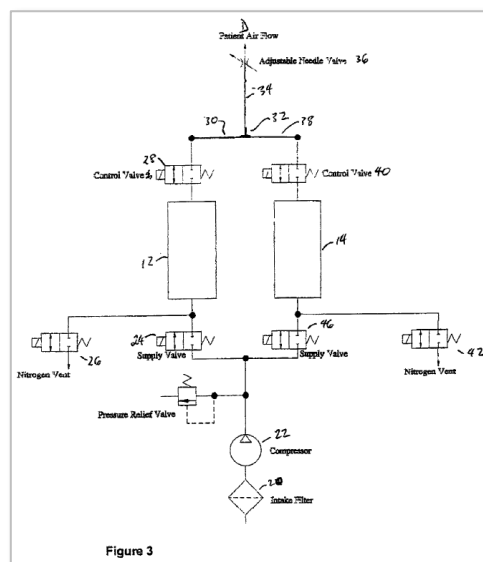
(*McCombs '957*) at ¶¶[0028], [0029], [0044]. Beds 30,32, manifolds 120, 122, and compressor 24 are provided as a unit for easy installation and removal for service. EX1010 (*McCombs '957*) at ¶[0028].

20. In operation, *McCombs '957* teaches that ambient air is provided to manifold 120 via compressor 24 and alternately fed through manifold 120 to beds 30, 32, and product gas is delivered from beds 30, 32 to product manifold 122 and ultimately to the patient. EX1010 (*McCombs '957*) at ¶¶[0028], [0029].

21. ***Warren '095***: U.S. Patent Application Publication No. 2002/0033095 to Warren (hereinafter “*Warren '095*”; EX1012) teaches a miniaturized, wearable, portable oxygen concentrator, such as shown in FIG. 10 (reproduced here). EX1012 (*Warren '095*) at Title, Abstract, ¶[0002], FIG. 10.

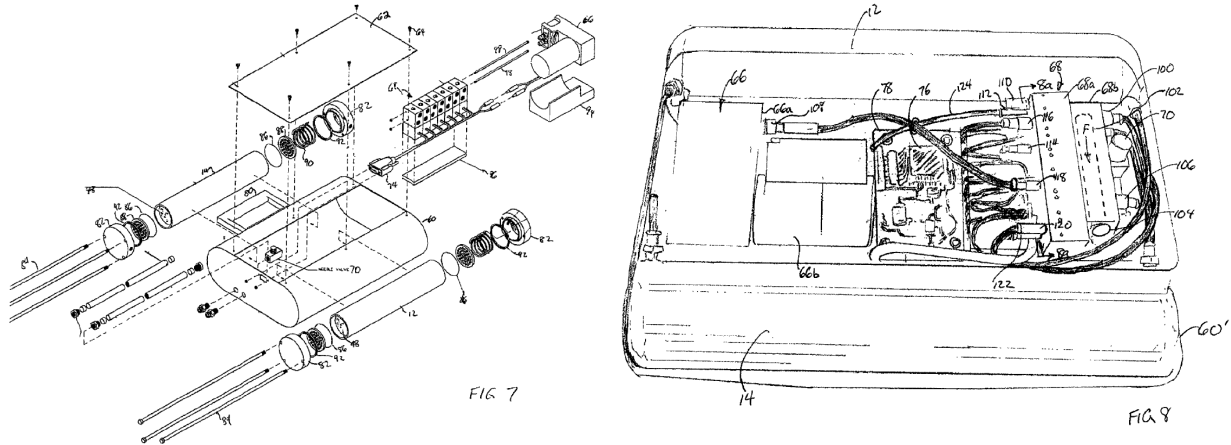


22. More specifically, *Warren '095* teaches, in its FIG. 3, a schematic of its POC that is similar to those of *McCombs '924* and *McCombs '957*. *Warren '095* teaches air is filtered through intake filter 20, pressurized by compressor 22, and directed to one of the zeolite adsorption beds 12, 14 by solenoid valves 24, 46 where adsorption of nitrogen occurs. EX1012 (*Warren '095*) at



¶[0061]. Then, oxygen-rich product gas is released from beds 12, 14 by valves 28, 40 and directed to the patient. EX1012 (*Warren '095*) at ¶[0061].

23. *Warren '095* EX1012 further teaches a particular arrangement of its components in FIGS. 7 and 8 (reproduced below), including housing 60 with individually removable zeolite beds 12, 14 with inlets and outlets on opposite ends, compressor 66, and valve and manifold housing 68 (including an array of valves). EX1012 (*Warren '095*) at ¶[0070]-[0075].



24. **Hill '658**: U.S. Patent No. 6,651,658 to Hill et al. (hereinafter “*Hill '658*”; EX1013) teaches that its invention is directed “to portable oxygen concentration systems for ambulatory respiratory patients that allow them to lead normal and productive lives.” EX1013 (*Hill '658*) at 1:7–10. As shown in the FIG. 2 schematic diagram (reproduced here), *Hill '658* teaches ambient air may be drawn in through inlet muffler 116 by compressor 112 powered by rechargeable battery 104, where the air may be provided to concentrator 114. EX1013 (*Hill*

'658) at 5:30-48. Concentrator

114 separates oxygen from air and provides it to a patient.

EX1013 (*Hill '658*) at 5:58-

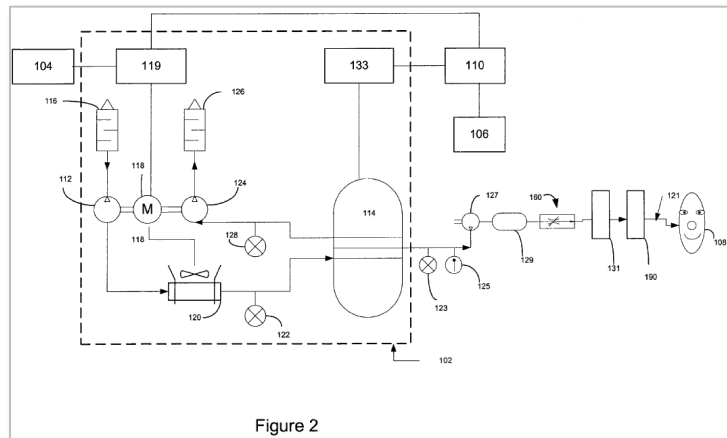
6:5. Similar to *McCombs*

'924, *McCombs '957*, and

Warren '095, *Hill '658* teaches concentrator 114 may utilize zeolite beds with a valve mechanism to control fluid flow. EX1013 (*Hill '658*) at 7:16-43.

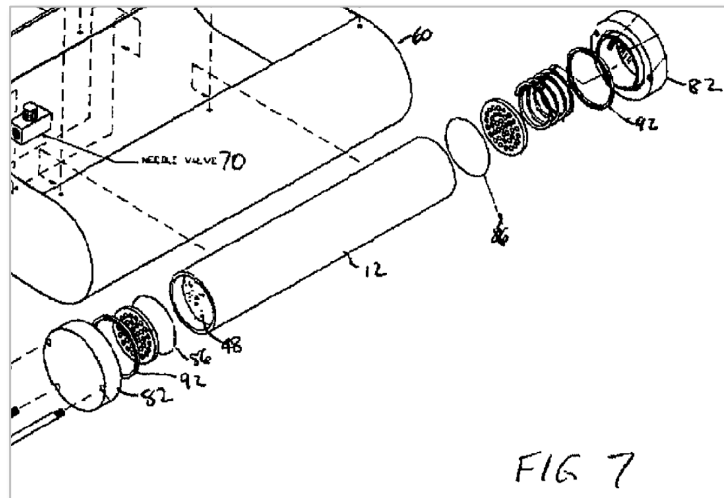
C. POC Adsorber Beds with Zeolite (and LiLSX), Filters, and Springs Were Known

25. By 2004-2005, the use of zeolite adsorber beds (including with LiLSX, which is lithium-exchanged form of low silica type X (LSX) zeolites) with internal filters and springs was well known to a POSITA. A POSITA would have understood that zeolite was a desirable material to use in zeolite beds due to its properties, especially its high adsorption selectivity for nitrogen over oxygen, and that internal filters and springs could be provided within the adsorbent bed at one or both ends to filter incoming air or outgoing enriched oxygen or enriched nitrogen, and to prevent damage to the adsorbent material within the zeolite bed, to improve performance. I identify here where the four example references from §I.B teach such elements, and identify teachings of various other references. Many more examples existed, such as those identified in the Grounds. See §III.



26. Both *McCombs '924* and *McCombs '957* teach: (i) that the adsorbent material “may be a synthetic zeolite or other known adsorbent material having equivalent properties” (EX1009 (*McCombs '924*) at ¶¶[0019], [0021], [0032]; EX1010 (*McCombs '957*) at ¶¶[0021], [0023], [0037]); and (ii) that “beds 30, 32 are spring biased” (EX1009 (*McCombs '924*) at ¶[0032]; EX1010 (*McCombs '957*) at ¶[0037]).

27. *Warren '095* teaches adsorption beds 12, 14 with zeolite (EX1012 (*Warren '095*) at ¶[0061]) and that the zeolite in beds 12, 14 is sandwiched “between a pair of porous membranes 86, themselves sandwiched between a pair of porous backing plates 88. The sandwich of porous backing plates 88, porous membranes 86, and molecular sieve material 48 may be resiliently urged to one end of the bed by a resilient biasing means such as helical spring 90.”

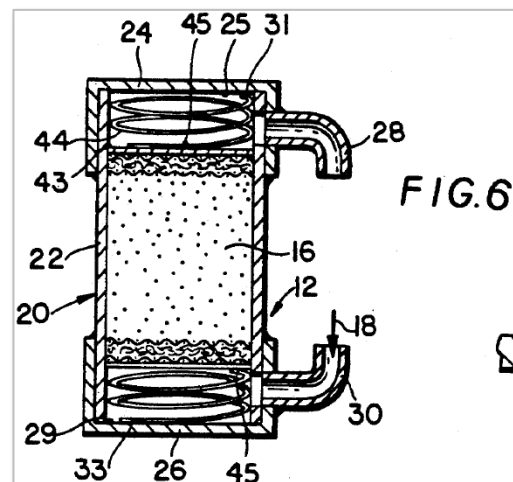


EX1012 (*Warren '095*) at ¶[0073], FIG. 7 (reproduced in relevant part here).

28. Finally, *Hill '658* teaches that its concentrator 114 may include “multiple sieve beds” (EX1013 (*Hill '658*) at 7:15–32) and that “[t]he sieve

material may be a LithiumX [sic] Zeolite that allows for a high exchange of Lithium ions” (EX1013 (*Hill* '658) at 7:54–67).

29. Various other references discussed below also teach these features. For example, U.S. Patent Application Publication No. 2006/0283325 to Sugano (hereinafter “*Sugano*”; EX1014) teaches the use of zeolite in adsorbers. EX1014 (*Sugano*), ¶¶[0057], [0082]. U.S. Patent Application Publication No. 2003/0005928 to Appel et al., (hereinafter “*Appel* '928”; EX1015) teaches the use of Lithium X Zeolite (EX1015 (*Appel* '928), ¶[0063]), highly Lithium exchanged X-type Zeolite (*id.* at ¶[0074]) and spring 810 (*id.* at ¶¶[0105]-[0106]). U.S. Patent No. 4,065,272 to Armond (hereinafter “*Armond*”; EX1018) teaches the use of zeolite. EX1018 (*Armond*), 2:36-39, 4:54-5:2. U.S. Patent No. 7,144,446 to Lessi (hereinafter “*Lessi*”; EX1019), teaches the use of LiLSX zeolite in oxygen concentrators. EX1019 (*Lessi*), 1:55-57, 2:61-3:5. And U.S. Patent No. 5,275,642 to Bassine (hereinafter “*Bassine*”; EX1026) teaches sieve beds with zeolite, retainers 42, filters 38, 38, and springs 44, such as shown in FIG. 6, reproduced here. EX1026 (*Bassine*), 2:26-28, 3:48-52, 6:17-34, FIG. 6.



D. It Was Known That Zeolite in Adsorber Beds Has a Finite Life and Needs to Be Periodically Replaced

30. By 2004-2005, a POSITA would have been well-aware that the zeolite used in adsorber beds has a limited useful life as an adsorbent, and needs to be periodically replaced. A POSITA in 2004-2005 would have understood that this would require adsorbent beds to be periodically removed from the oxygen concentrator and either replaced with new adsorbent beds or emptied of the used zeolite and refilled with new zeolite before being reinstalled. I identify here several example references teaching the above. Many more examples existed, such as those identified in the Grounds. *See* §III.

31. U.S. Patent Application Publication No. 2006/0137522 to Nishimura et. al. (hereinafter “*Nishimura*”; EX1028) teaches that sieve bed degradation decreases concentrator performance. EX1028 (*Nishimura*), ¶[0012]. U.S. Patent No. 4,916,630 to Miller (hereinafter “*Miller ’630*”; EX1027) teaches that sieve bed degradation decreases concentrator performance. EX1027 (*Miller ’630*), 5:19-34.

E. POC Pumps, Valves, and Manifolds Were Known

32. By 2004-2005, a POSITA would have been well-aware that many different configurations of pumps, valves, and manifolds could be used in POCs, including valves and/or manifolds provided on both ends of a POC’s sieve beds to move gas in and out thereof. I identify here where the four example references

from §I.B teach such pump and/or manifold configurations. Many more examples existed, such as those identified in the Grounds. *See* §III.

33. *McCombs '924* teaches that feed valves 40, 42 control the feed such that air alternatively enters inlets 30a, 32a of adsorbers 30, 32 for adsorption. EX1009 (*McCombs '924*) at ¶[0019]. After adsorption, product gas flows out through outlets 30b, 32b and check valves 34, 36 to the patient, and waste valves 44, 46 control waste gas discharge. EX1009 (*McCombs '924*) at ¶[0020].

34. *McCombs '957* teaches its adsorber beds 30, 32 are mounted between feed/waste manifold 120 (with feed valves 40, 42 and waste valves 44, 46) and a product manifold 122. Ambient air is provided to manifold 120 via compressor 24 and alternately fed through manifold 120 to beds 30, 32 via feed valves 40, 42. EX1010 (*McCombs '957*) at ¶[0028]. Product gas is delivered from beds 30, 32 to product manifold 122 and ultimately to the patient. EX1010 (*McCombs '957*) at ¶[0029]. Waste gas is exhausted through manifold 120 via waste valves 44, 46. EX1010 (*McCombs '957*) at ¶[0028].

35. *Warren '095* teaches air is filtered through intake filter 20, pressurized by compressor 22, and directed to one of adsorption beds 12, 14 by solenoid valves 24, 46 where adsorption occurs, and then enriched oxygen is released from beds 12, 14 by valves 28, 40 and directed to the patient, while the nitrogen is vented through valves 26, 42 to the atmosphere. EX1012 (*Warren '095*) at ¶[0061].

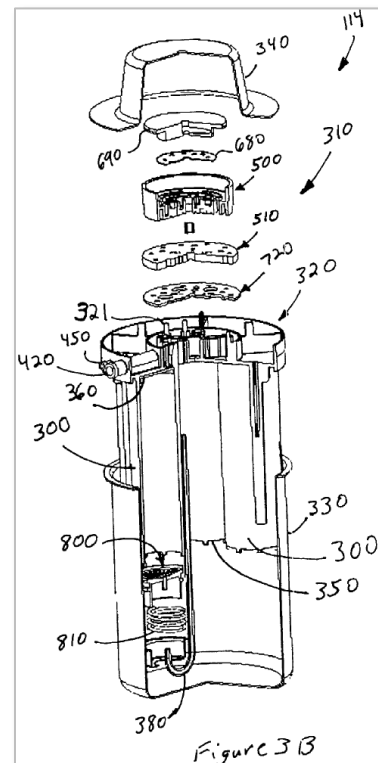
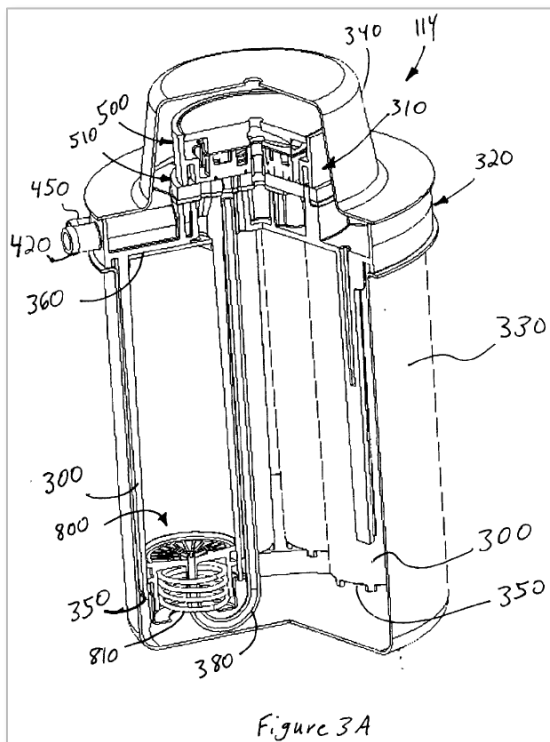
36. *Hill '658* teaches its POC includes a pump such as a compressor 112, “delivers the air under pressure to the concentrator 114.” EX1013 (*Hill '658*) at 5:42-43.

F. Sieve Beds with Inlets and Outlets Facing The Same Direction and On the Same End Were Known

37. By 2004-2005, a POSITA would have been well-aware of various configurations of oxygen concentrators that utilized sieve beds having inlets and outlets facing the same direction and/or on the same end to interface with a single manifold and/or valve assembly (rather than having inlets and outlets facing opposite directions on opposite ends of the sieve beds to interface with manifolds/valves on both ends, as shown in the references discussed above). A POSITA would have understood these to be equivalent design choices or options for inlet/outlet and manifold/valve arrangement, with certain tradeoffs. For example, a POSITA would have understood arranging the system with all inlets, outlets, and valves facing one direction and/or on one end would result in a concentrator with a more compact and simpler construction. I identify here several examples of systems with sieve bed inlets and outlets facing the same direction and/or on the same end to interface with a single manifold and/or valve assembly. Many more examples existed, such as those identified in the Grounds. *See §III.*

38. *Appel '928* teaches a POC with a rotary valve assembly on one end of its adsorption beds. EX1015 (*Appel '928*), Abstract. *Appel '928* is assigned to the

same entity as *Hill* '658, and includes a similar Figure 2 as *Hill* '658, including concentrator 114. EX1015 (*Appel* '928), ¶¶[0045]-[0067], FIG. 2. *Appel* '928 teaches a specific example of concentrator 114 in FIGS. 3A and 3B (reproduced below).



39. *Appel* '928 teaches that its concentrator includes five adsorption beds 300, rotary valve assembly 310 for selectively transferring fluids through adsorption beds 300, manifold 320, product tank cover 330, and valve assembly enclosure 340. EX1015 (*Appel* '928), ¶¶[0070]-[0071]. *Appel* '928 further teaches that feed ends 360 of beds 300 communicate with feed passages of manifold 320, and product ends 350 of beds 300 communicate with product passages 370 (shown

in FIG. 4 of *Appel* '928) of manifold 320 through product lines 380 running along the outer diameter of beds 300 such that the inlets and outlets face the same direction (toward manifold 320) and are at the same end of beds 300. EX1015 (*Appel* '928), ¶¶[0072]-[0073].

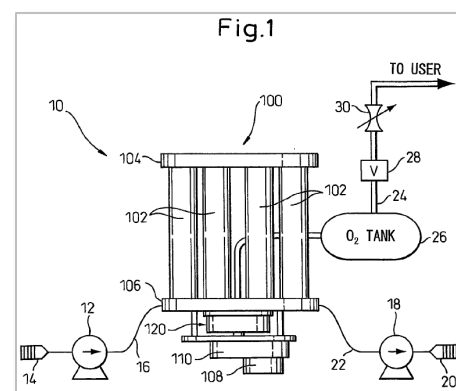
40. In use, *Appel* '928 teaches that air flows from compressor 112 through manifold and through feed passages 390 to feed ends 360 of the adsorption beds 300, which include adsorbent media (here, an adsorbent such as a highly Lithium exchanged X-type Zeolite) that preferentially adsorbs nitrogen relative to oxygen so that oxygen is produced as a product gas. EX1015 (*Appel* '928), ¶[0074].

Then, the oxygen product gas flows from the product ends 350 of adsorption beds 300, through product lines 380, and into product passages 370 of the manifold 320, where it is then routed into the product tank 330 to supply to the patient. EX1015 (*Appel* '928), ¶[0075].

41. Another example of a manifold with valves on one end of a set of adsorption beds can be found in *Sugano*.

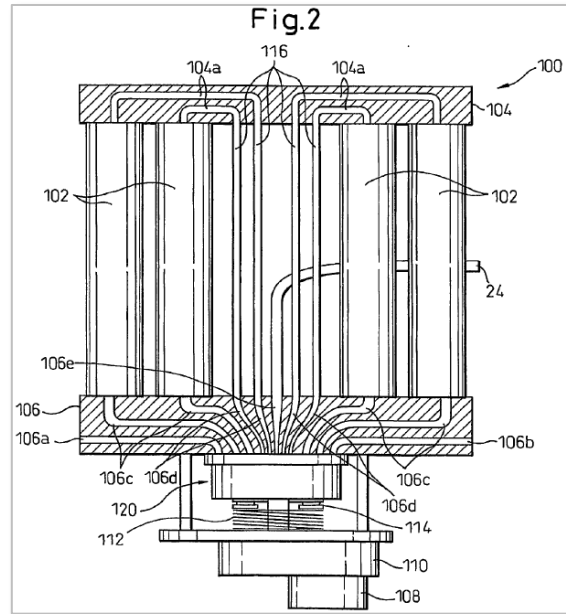
EX1014 (*Sugano*), ¶[0001], FIG. 2. *Sugano* teaches that its rotary valve is an improvement over designs with valves at both ends of adsorber beds. EX1014 (*Sugano*), ¶¶[0004]-[0005].

Sugano 's system includes, as shown in its FIG. 1, oxygen concentrator 100,



compressor 12 for feeding gas, vacuum pump 18 for drawing out nitrogen, and reservoir 26. EX1014 (*Sugano*), ¶[0056].

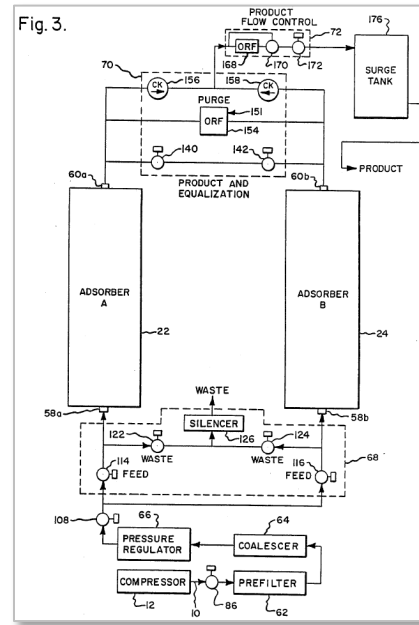
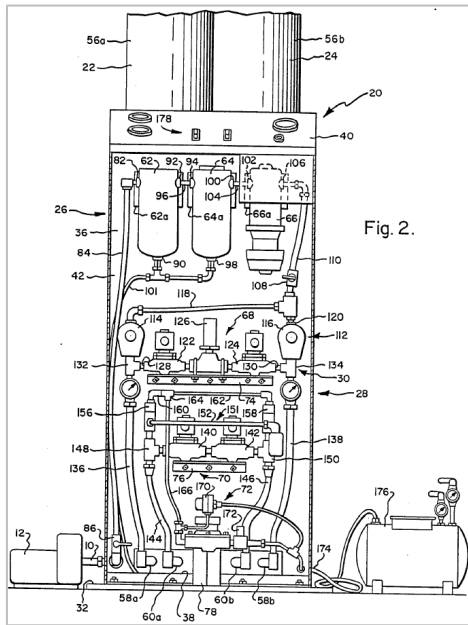
42. *Sugano* further teaches, as shown in its FIG. 2, that oxygen concentrator 100 includes four adsorption cylinders (*i.e.*, beds) 102 (filled with zeolite), upper and lower headers 104, 106 holding adsorption cylinders 102, and a rotary valve 120. EX1014 (*Sugano*), ¶[0057]. Each of the four adsorption cylinders 102 includes top orifices connected to rotary valve 120 via



passages 104a, conduits 116, and passages 106d, and bottom orifices connected to rotary valve via passages 106c. EX1014 (*Sugano*), ¶[0057]-[0058], [0063]-[0078]. Feed gas is introduced into adsorption cylinders 102, and product and waste gases are removed from adsorption cylinders 102, by operation of rotary valve 120 (along with compressor 12 and/or pump 18). EX1014 (*Sugano*), ¶[0063]-[0078]. This arrangement, via the passages and conduits, provides all inlets and outlets for adsorption cylinders 102 facing the same direction (toward rotary valve 120) and on the same end of the cylinders for easy connection with

rotary valve 120, thereby reducing the concentrator's complexity and increasing its efficiency. EX1014 (*Sugano*), ¶¶[0005]-[0006].

43. It was also known to provide inlets and outlets facing the same direction at the same end of sieve beds in oxygen concentrators in non-rotary valve configurations. For example, U.S. Patent No. 4,802,899 to Vrana et al. (hereinafter "*Vrana*"; EX1016) teaches a pressure swing adsorption apparatus with a valving strategy similar to, for example, *McCombs '924*, *McCombs '957*, *Warren '095*, and *Hill '658*, but with components arranged to facilitate service and maintenance. EX1016 (*Vrana*), 1:5-10, 1:63-66, 2:6-8, 2:38-42, FIGS. 1-3 (FIGS. 2 and 3 reproduced below).

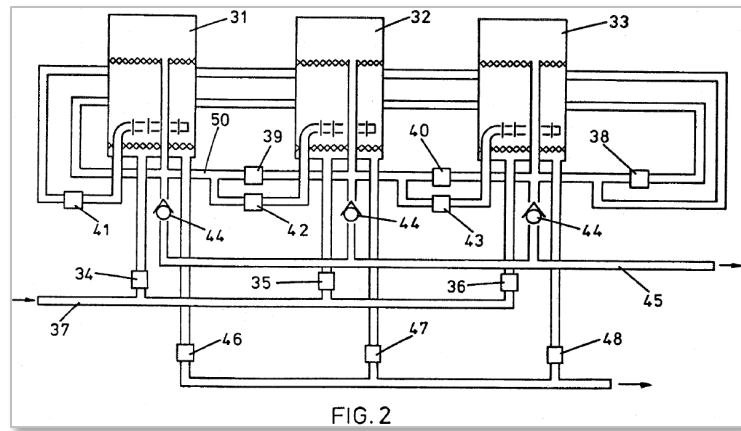
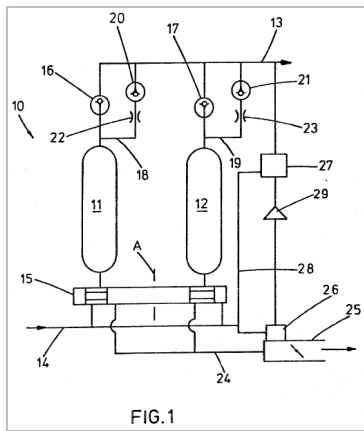


44. More specifically, *Vrana* teaches air separator 20 with base 32, a pair of upstanding adsorber units or towers 22, 24, control box 26, and assembly 28 of

working components for routing the flow of source air through separator 20.

EX1016 (*Vrana*), 3:6-21. Adsorbers 22, 24 includes vessels 56a, 56b supported on base 32, inlets 58a, 58b, outlets 60a, 60b, and beds of adsorption material therein to adsorb nitrogen. EX1016 (*Vrana*), 3:34-4:13. As shown in FIG. 2, the inlets 58a, 58b and outlets 60a, 60b are arranged adjacent each other at the bottom of adsorbers 22, 24. *Vrana* teaches the working components include waste and feed manifold assembly 68 and product manifold assembly 70. EX1016 (*Vrana*), 3:67-4:13. Waste and feed manifold assembly 68 includes feed valves 114, 116 controlling gas feed to adsorber inlets 58a, 58b, and waste valves 122, 124. EX1016 (*Vrana*), 5:15-28. Product manifold assembly 70 is connected to outlets 60a, 60b of adsorbers 22, 24. EX1016 (*Vrana*), 5:55-6:2. A POSITA would have recognized *Vrana* as providing inlets 58a, 58b and outlets 60a, 60b on one end of adsorbers 22, 24 and facing the same direction such that they can be easily accessed for connection/disconnection to allow easy installation/removal of adsorbers 22, 24 for replacement as their life cycles ended.

45. U.S. Patent No. 4,404,005 to Hamlin et al. (hereinafter “*Hamlin*”; EX1017) teaches a “simple and effective molecular sieve type gas separation system.” EX1017 (*Hamlin*), 2:1-8, FIGS. 1-2 (reproduced below).

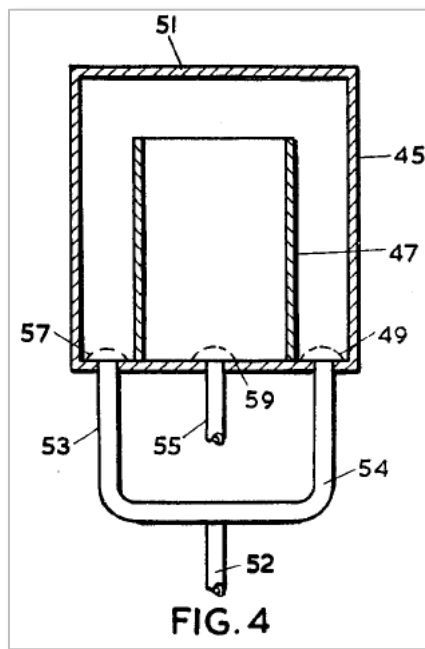
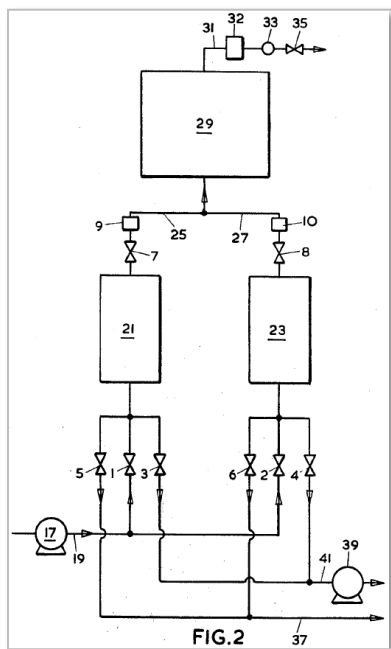


46. *Hamlin* teaches a pressure sieving gas separation system 10 with two sieve beds 11, 12 under the control of valve means 15 and arranged to deliver product gas towards a delivery line 13. EX1017 (*Hamlin*), 3:6-19. *Hamlin* further teaches a three-bed (31, 32, 33) system in FIG. 2, with inlet valves 34, 35, 36, non-return valves 44 leading to product gas delivery line 45, purge valves 38, 39, 40, and vent valves 46, 47, 48. EX1017 (*Hamlin*), 4:60-5:2. As can be seen in FIG. 2, each of the inlets and outlets of beds 31, 32, 33 is arranged to face the same direction at the same end of beds 31, 32, 33.

47. *Armond* teaches, as shown in FIGS. 1 and 2, an oxygen concentrator with compressor 17, feed valves 1, 2, adsorption beds 21, 23 filled with zeolite, product valves 7-10, reservoir 29, and venting/evacuation valves 3-6. EX1018 (*Armond*), 4:54-5:31, FIGS 1, 2 (FIG. 2 reproduced below). *Armond* further teaches that its adsorption beds may be configured as shown in FIGS. 4 (reproduced below) and 5, where an adsorption bed is constructed of outer tube 45

and coaxial inner tube 47 with inlet 52 and outlet 55. EX1018 (*Armond*), 5:32-45.

See also description of FIG. 5. EX1018 (*Armond*), 5:46-59.



48. As can be seen in FIG. 4, inlet 52 and outlet 55 are facing the same direction on the same end of bed 51.

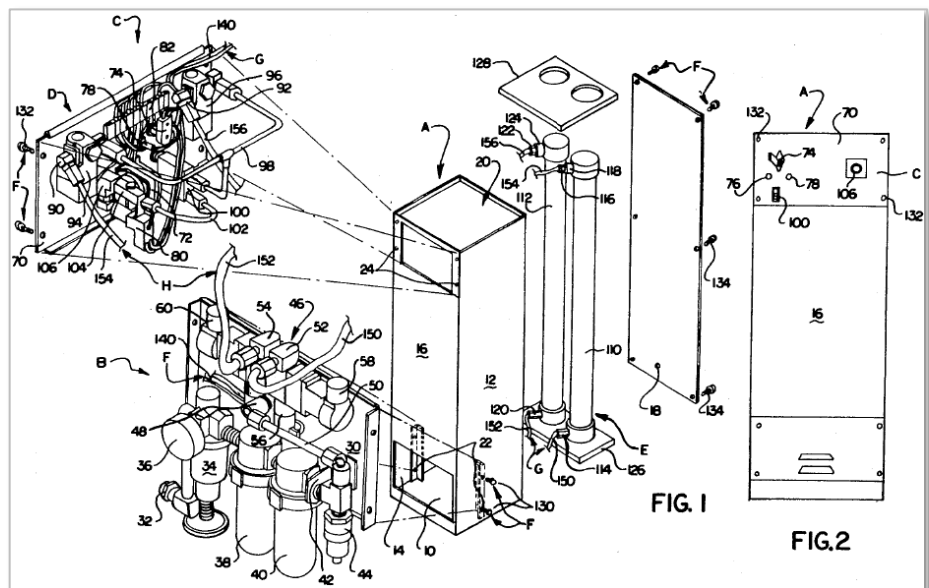
G. Removable Cartridges in POCs Were Known

49. By 2004-2005, a POSITA would have been well-aware of various configurations of POCS that provided one or more of their components in a removable cartridge configuration to improve serviceability and/or manufacturability. I identify here examples of such constructions, along with several examples of cartridges in related art. Many more examples existed, such as those identified in the Grounds. *See* §III.

50. *McCombs '957* teaches, as discussed above, that its beds 30, 32, manifolds 120, 122, and compressor 24 are “held together as a compact unit” that can “be readily assembled in production and readily accessed for servicing.” EX1010 (*McCombs '957*) at ¶[0028]. A POSITA would have recognized that this bed, manifold, and compressor unit was a removable module or cartridge that would be removable from *McCombs '957*’s POC for servicing the compressor or valves and/or replacing the beds 30, 32 as their zeolite reached the end of its life.

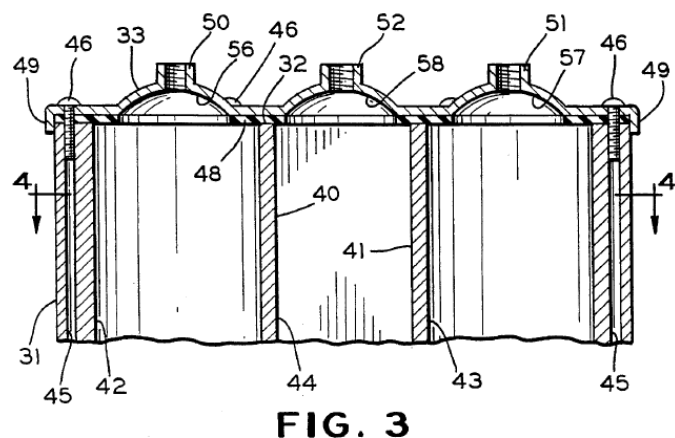
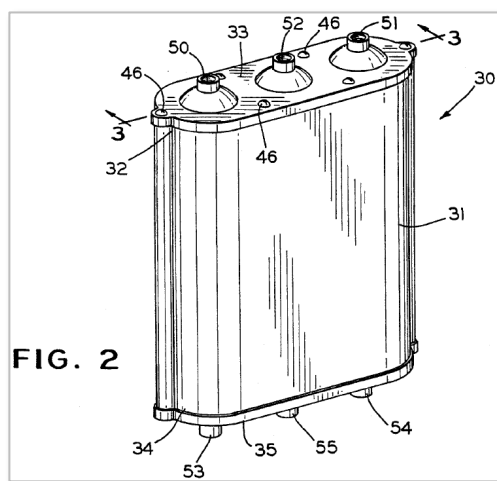
51. U.S. Patent No. 4,584,001 to Dechene (hereinafter “*Dechene*”; EX1021) also teaches a modular oxygen concentrator design. EX1021 (*Dechene*), Abstract, FIGS. 1-3. Specifically, *Dechene* recognizes that previous oxygen concentrator designs were difficult to repair or rebuild, and teaches a modular construction as an improvement. EX1021 (*Dechene*), 1:8-34. As shown in FIGS. 1-2 (reproduced below), *Dechene* teaches housing or cabinet A, gas distribution

module or
assembly B,
control module or
assembly C,
oxygen or
fractioned gas
outlet module or



assembly D, bed module or assembly E, electrical connection assembly G, fluid connection assembly H, and mechanical mounting assembly F. EX1021 (*Dechene*), 2:21-43. *Dechene* further teaches that bed assembly E includes beds 110, 112 filled with zeolite, quick connect fittings 114, 116, 120, 122, and mounting plates 126, 128 with exterior dimensions set to be snugly received in bed receiving region 20 of housing A. EX1021 (*Dechene*), 4:12-31. A POSITA would have recognized that bed assembly E would be removable from housing A for replacing the beds 110, 112 as their zeolite reached the end of its life.

52. U.S. Patent No. 5,578,115 to Cole (hereinafter “*Cole*”; EX1020) also teaches a removable adsorber cartridge. EX1020 (*Cole*), Abstract, FIGS. 2, 3 (reproduced here). As shown in FIGS. 2 and 3, *Cole* teaches sieve unit 30 with



molecular sieve bed containers 56 and 57 having inlet nipples 50, 51 and outlet nipples 53, 54, and a cavity 44 for containing concentrated oxygen, with nipples 52, 55. EX1020 (*Cole*), 3:44:4-22. *Cole* further teaches that passages can be

formed such as to locate all ports on one end of sieve unit 30. EX1020 (*Cole*), 4:15-29. A POSITA would have recognized Cole's construction as being removable, particularly where the ports were all located on one end of sieve unit 30, as the nipples would provide easy and quick connection/disconnection.

53. U.S. Patent Application Publication No. 2005/0045041 to Hechinger et al. (hereinafter "*Hechinger*"; EX1048) also teaches "[a] removable cartridge for the adsorbent bed of a swing-type adsorber system [that] defines a volume for retaining an adsorbent material within an adsorption bed housing during operation of the adsorption system." EX1048 (*Hechinger*), Abstract. Additionally, *Hechinger* teaches that "the cartridge is configured to retain the adsorbent material therein so that the cartridge and the adsorbent material can be removed and installed as a unit." *Id.* *Hechinger* touts the advantages of its removable cartridge and extolls "the realization that a substantial time saving can be achieved by constructing the adsorbent beds of the pressure-swing system with a removable cartridge containing the adsorbent materials." EX1048 (*Hechinger*), ¶[0015].

54. A POSITA would have also recognized that removable and replaceable modules or cartridges were widely used in the medical device field to facilitate the replacement of components (particularly zeolite) that have reached the end of their useful lives. For example, U.S. Patent No. 4,094,755 to Mueller (hereinafter "*Mueller*"; EX1022) teaches replaceable activated carbon [adsorbent]

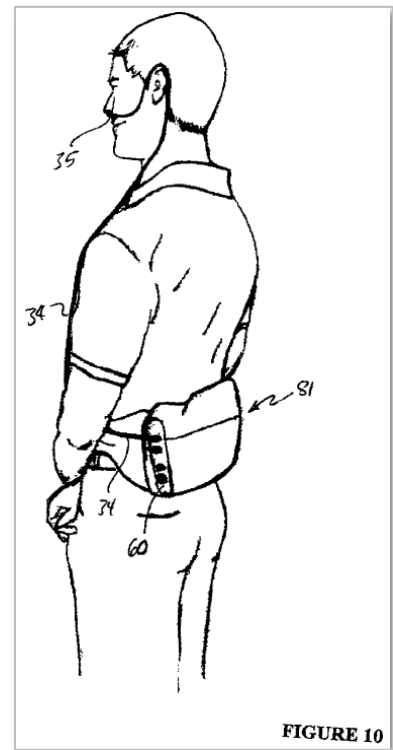
cartridge element 64, urease containing cartridge 60, and blood cartridge 68 in a kidney dialysis machine. EX1022 (*Mueller*), 1:27-30, 5:19-6:4. U.S. Patent No. 4,530,706 to Jones (hereinafter “*Jones*”; EX1023) teaches replaceable adsorbent filter cartridges for respirators, where “cartridges are replaced when their capacity to provide respiratory protection at or below hazardous concentration levels becomes apparent to the user or is otherwise arbitrarily or administratively determined.” EX1023 (*Jones*), 1:11-18, 2:20-26. U.S. Patent Application Publication No. 2006/0000223 to Dickerson (hereinafter “*Dickerson*”; EX1025) teaches a removable desiccant (adsorbent) cartridge, such as for use in POCs, that may use zeolite. EX1025 (*Dickerson*), ¶¶[0001], [0003], [0022], [0053]-[0062], [0064]. A POSITA would have understood that the benefits of providing adsorbent materials in removable and replaceable cartridges taught by these references would be implementable in other adsorbent systems, including the various POC configurations discussed above, such that the adsorbent materials can be easily replaced as they reached the end of their lifespan.

55. In sum, as discussed above, it was well-known to a POSITA that adsorbent materials, such as zeolite, when used in a PSA system, may degrade over time, and that adsorbent materials in many applications would be housed in removable cartridges to facilitate their replaceability.

H. Carrying Devices for POCs Were Known

56. By 2004-2005, a POSITA would have been well-aware that POCs were intended, by their nature, to be highly portable and sized to be carried by patients, such as by harness, belt, backpack, or wheeled carrier. I identify here where the example references from §I.B teach such carrying provisions. Many more examples existed, such as those identified in the Grounds. *See* §III.

57. *McCombs '924* and *McCombs '957* both teach that chassis 108 includes a carry handle 109. EX1009 (*McCombs '924*) at ¶[0025]; EX1010 (*McCombs '957*) at ¶[0025]. *Warren '095* generally teaches a miniaturized, wearable, portable oxygen concentrator. EX1012 (*Warren '095*) at Title, Abstract, ¶[0002]. *Warren '095* further teaches its housing 60 has a handle 80 for carrying, and that its POC is also intended “to be worn by a user, for example in or as a backpack or hip pack or so-called fanny pack 81 such as seen in FIG. 10.” EX1012 (*Warren '095*) at ¶[0072], FIG. 10 (reproduced here).



And *Hill '658* teaches that “[a] number of different types of bags and carrying cases such as, but not by way of limitation, a shoulder bag, a backpack, a fanny pack, a front pack, and a split pack in different colors and

patterns may be used to transport the system 100 or other system accessories ... [and] [t]he system 100 may also be transported with a rolling trolley/cart, a suit case, or a travel case. The travel case may be designed to carry the system 100 and include enough room to carry the cannulae 111, extra batteries, an adapter, etc.” EX1013 (*Hill* '658), at 14:9-37.

I. POC Batteries Were Known

58. By 2004-2005, a POSITA would have been well-aware that POCs were battery powered to enable their portability. I identify here where the four example references from §I.B teach provisions for battery power. Many more examples existed, such as those identified in the Grounds. *See* §III.

59. *McCombs* '924 teaches its POC includes battery pack 90 to provide power. EX1009 (*McCombs* '924) at ¶[0029]. *McCombs* '957 teaches it is powered by internal battery 98. EX1010 (*McCombs* '957) at ¶[0044]. *Warren* '095 teaches that its POC “may be powered by a battery.” EX1012 (*Warren* '095) at ¶[0025]. And *Hill* '658 teaches its POC includes rechargeable battery 104, and that “[t]he battery 104 or battery module including the battery 104 is preferably removable from the system 100.” EX1013 (*Hill* '658) at 8:19-34.

J. It Was Known That Lightweight POCs Were Desirable

60. By 2004-2005, a POSITA would have been well-aware that POCs were intended, by their nature, to be lightweight and small-sized to enable their

portability, and that making POCs lighter and smaller was a widely-recognized design goal. I identify here where the four example references from §I.B teach such features and goals. Many more examples existed, such as those identified in the Grounds. *See* §III.

61. *McCombs '924* teaches “an apparatus with a weight of less than about 10 lb., measuring less overall than 17” in length, 8” in width and 6” in height.” EX1009 (*McCombs '924*) at ¶[0025]. *McCombs '924* further teaches that making a POC “highly portable and easily manipulated and transported even by patients with relatively limited physical capacities” is important. EX1009 (*McCombs '924*) at ¶[0005].

62. *McCombs '957* teaches “an apparatus with a weight of less than about 5 lb., measuring overall less than 4” (or about 3.6”) in depth, less than 7” (or about 6.6”) in width and less than 9” (or about 8.6”) in height.” EX1010 (*McCombs '957*) at ¶[0036]. *McCombs '957* further teaches that making a POC “highly portable and easily manipulated and transported even by patients with relatively limited physical capacities” is important. EX1010 (*McCombs '957*) at ¶[0007].

63. *Warren '095* teaches a miniaturized, wearable, portable oxygen concentrator. EX1012 (*Warren '095*) at Title, Abstract, ¶[0002].

64. *Hill '658* teaches “a portable oxygen concentrator system adapted to be transported by a user” (EX1013 (*Hill '658*) at Abstract) and that its POC is “for

ambulatory respiratory patients that allow them to lead normal and productive lives” (EX1013 (*Hill* ’658), 1:7-10). *Hill* ’658 further teaches that its POC “is small and light (2-15 pounds).” EX1013 (*Hill* ’658) at 9:66.

II. THE ’628 PATENT

A. The Alleged Invention

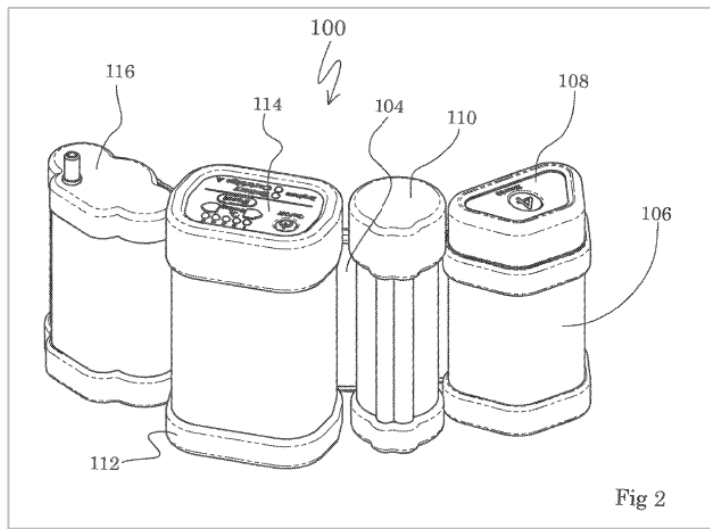
65. The ’628 patent states it relates to oxygen concentrators, and in particular to wearable concentrators using vacuum swing adsorption for creating an oxygen stream for ambulatory respiratory patients. EX1001 (“’628 *Patent*”), 1:16-21.

66. The ’628 patent characterizes prior art oxygen therapy methods as: (i) high pressure gas cylinders; (ii) cryogenic liquid in “dewars”; or (iii) home oxygen concentrators. EX1001 (’628 *Patent*), 1:36-40. The ’628 patent indicates that there was a desire for “an improved portable device for supplying oxygen to a patient,” but that “[o]nly small high pressure gas bottles and small liquid dewars are truly portable enough to be used for ambulatory needs.” EX1001 (’628 *Patent*), 1:50-53. The ’628 patent then goes on to criticize the bottle/dewar implementations as being inconvenient, wasteful, and dangerous. EX1001 (’628 *Patent*), 1:60-2:32.

67. The ’628 patent characterizes its “wearable oxygen concentrator” as being a solution to these problems. EX1001 (’628 *Patent*), 2:48-50. However, as I

explained above in §I and show below in §VI, POCs, including wearable POCs, **were already well-known to a POSITA by 2004-2005**. The '628 patent makes no effort to explain why its alleged invention is in any way different from the these prior art examples—indeed, it **completely ignores** that such devices already existed. The features claimed by the '628 patent are not inventive, for at least the reasons in §VI.

68. FIG. 2 (reproduced here) depicts the oxygen concentrator of the '628 patent, which includes “belt 104, power module 106 containing power pack 108, reservoir module 110, control module 112 containing user interface 114, and separation cartridge module 116.”



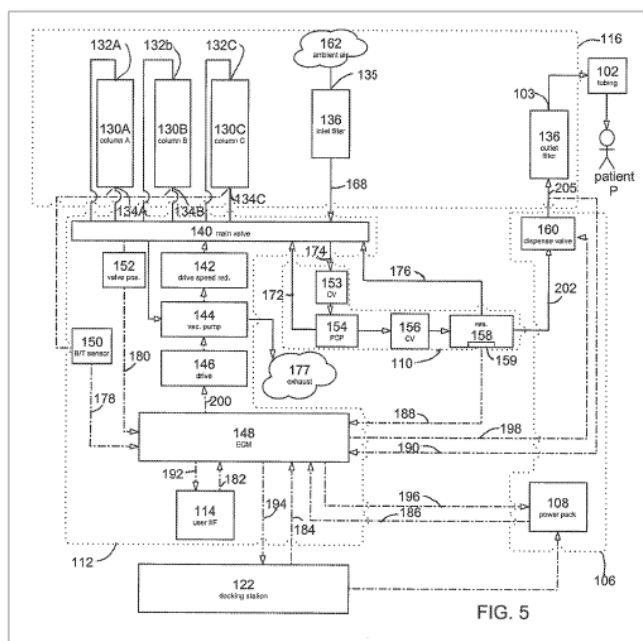
EX1001 ('628 Patent), 3:60-64. “Belt 104 connects and carries the modules 106, 110, 112, and 116 of oxygen concentrator 100.” EX1001 ('628 Patent), 3:66-67. “Power module 106 provides the necessary power to operate the system of oxygen concentrator 100” and “contains replaceable power pack 108.” EX1001 ('628 Patent), 4:7-10. “Reservoir module 110 stores oxygen rich gas that has been separated from ambient air by cartridge module 116. Control module 112 pilots

and regulates the interaction of the power module 106, reservoir module 110, and separation cartridge module 116 of oxygen concentrator 100. User interface 114 on control module 112 is a console which allows patient P to adjust and monitor oxygen concentrator 100.” EX1001 (*'628 Patent*), 4:10-17.

69. With reference to FIG. 5 (reproduced here), separation cartridge module 116 “includes adsorbent columns 130a–130c each containing respective inlet ports 132a–132c and outlet ports 134a–134c, air inlet filter 136, and product gas final filter 138.

Ambient air enters air inlet port 135, passes through air inlet filter 136, and enters valve 140 for distribution to adsorbent columns 130a–130c.

Product gas passes through final



filter 138 and product gas outlet port 103 into tubing 102 for delivery to patient P.”

EX1001 (*'628 Patent*), 4:60-5:1. According to the vacuum swing adsorption

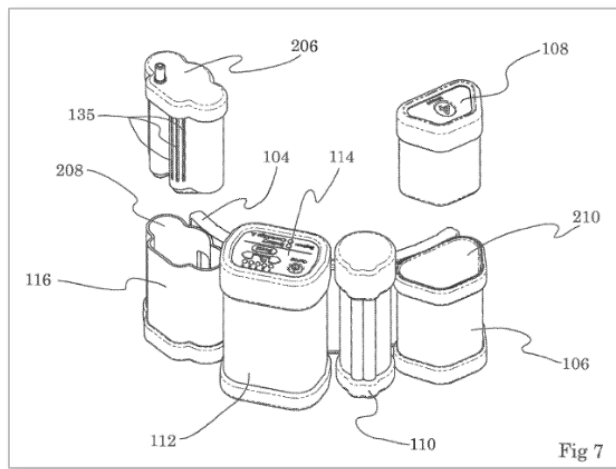
process, ambient air enters the adsorbent column and passes through an adsorbent material (typically zeolite) that retains specific components of air (nitrogen), allowing the desired product (oxygen) to pass through. EX1001 (*'628 Patent*),

6:47-65. The nitrogen is then evacuated from the column through a valve and is discharged by a vacuum pump as waste exhaust. EX1001 ('628 Patent), 7:1-4.

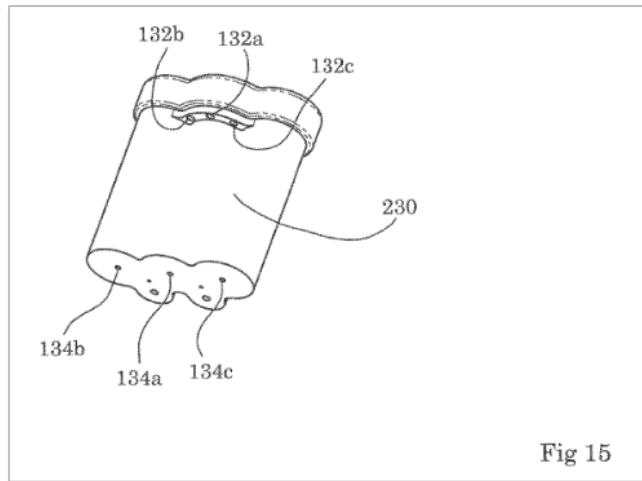
70. While there are some implementation differences, a POSITA would have understood the FIG. 5 schematic as being generally similar in form and function to, for example, the schematics of *McCombs '924*, *McCombs '957*, *Warren '095*, *Hill '658*, *Appel '928*, *Armond*, *Hamlin*, and *Vrana*, discussed in §I.

71. Beyond FIG. 5's features or functions, a POSITA would have understood the '628 patent's claims to specifically read on configurations of the separation cartridge shown in, for example, FIGS. 7, 15, and 16.

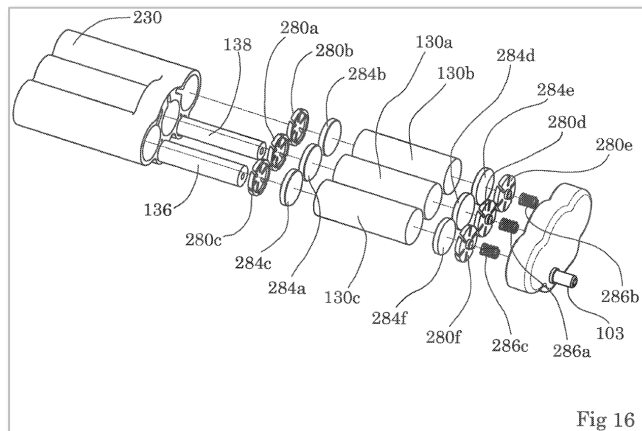
72. More specifically, FIG. 7 (reproduced here) shows an exploded view of oxygen concentrator 100 where separation cartridge 206 has been removed from receptacle 208. EX1001 ('628 Patent), 11:61-12:3. FIGS. 15 and 16 (both reproduced below) show the features of adsorbent cartridge 206 in more detail.



73. FIG. 15 shows separation cartridge 206 having inlet ports 132a–132c, outlet ports 134a–134c, and casing 230. EX1001 ('628 *Patent*), 18:30-34. Three adsorption columns 130a–130c are contained within casing 230, and an inlet port 132a–132c and outlet port 134a–134c are provided for each adsorption column 130a–130c. EX1001 ('628 *Patent*), 18:34-37.



74. FIG. 16 is an exploded view of the components of cartridge 206, including casing 230, adsorption columns 130a-130c (with adsorbent material 282 a-282c, not shown), spin inducers 280a-280f to help evenly distribute gas flow, porous filters 284a-284f to prevent adsorbent particle migration, and springs 286a-286c that hold each adsorbent column 130a-130c in place in casing 230. EX1001 ('628 *Patent*), 18:57-19:14.



75. Inlet ports receive either ambient air (for adsorption) or vacuum, depending on the phase of the process, and the outlet ports expel product gas

(concentrated oxygen for the patient) or receive purge gas, again depending on the phase of the process. EX1001 ('628 *Patent*), 18:47-49. In this embodiment, the respective inlet and outlet ports for a given adsorption column face the same direction (down in FIG. 15) and are spaced both axially and laterally apart from one another.

B. Prosecution History

76. The '628 patent is part of the following family of patent applications:

	App. #	Filing Date	Patent #	Examiner	Notes
A	11/054,341	2/9/2005	7,954,490	Patel	EX1049 ("490 patent FH"); EX1055 ("490 patent")
B	13/069,362	4/28/2011	n/a	Patel	EX1050 ("362 application")
C	13/795,977	3/12/2013	n/a	Jones	EX1051 ("977 application")
D	14/193,504	2/28/2014	10,702,669	Vasat	EX1052 ("669 patent FH"); EX1056 ("669 patent")
E	16/006,915	6/13/2018	10,357,628	Vasat	EX1002 ("628 patent FH"); EX1001 ("628 patent")
F	15/931,716	5/14/2020	11,389,614	Jones	EX1071 ("614 patent FH"), EX1070 ("614 patent"); challenged in IPR2023-00326

77. It is my understanding that the applicant's discussion of: (i) the meaning of claim language; (ii) the differences between claim language and prior art references; or (iii) the teachings of prior art references, during the '628 patent's prosecution can be relevant to an understanding of the scope and validity of the issued claims of the '628 patent. Thus, I have reviewed the prosecution history of the '628 patent (Application E in the chart above, discussed in subsection 5 below).

78. It is also my understanding that the applicant's discussion of: (i) the meaning of claim language similar to that of the '628 patent; (ii) the differences between such claim language and prior art references; or (iii) the teachings of prior art references, during the prosecution of other members of the '628 patent's family can be relevant to an understanding of the scope and validity of the issued claims of the '628 patent. Thus, I have reviewed the prosecution history of the other members of the '628 patent's family (Applications A-D and F in the chart above, discussed in subsections 1-4 and 6 below). It is my opinion that certain portions of these prosecution histories are useful to understand the '628 patent.

1. '490 Patent

79. U.S. Patent No. 7,954,490 ("the '490 patent") was the result of Application No. 11/054,341 ("the '341 application") filed on February 9, 2005. EX1055 (*'490 Patent*), Cover.

80. As an initial matter, I note that the claims of the '490 patent (both during prosecution as reproduced below and as-issued as shown in EX1055 ('490 Patent)) are not directed to the specific structural features of a separation cartridge (such as the arrangement of its ports on the cartridge shown in FIGS. 15-16 discussed immediately above) and thus are not similar to the challenged claims of the '628 patent that I discuss in detail below. Rather, the claims of the '490 patent are directed to methods of operation of a POC. EX1055 ('490 Patent), 26:15-28:31. Thus, the '490 patent's prosecution is of limited relevance to the '628 patent. Nevertheless, I review it here for completeness.

81. As-filed independent application claim 1 is shown below:

1. A method of providing concentrated oxygen product gas to a patient, the method comprising:
producing product gas by:
(a) introducing ambient air into a first end of a column containing an adsorbent material that preferentially adsorbs nitrogen and removes oxygen-rich product gas out a second end of the column;
(b) evacuating the column through the first end to remove adsorbed gas from the column;
(c) repressurizing the column by introducing ambient air into the first end of the column until the vacuum within the column is near 1.0 atmosphere;
(d) repeating steps (a) - (c); and
delivering product gas to the patient.

EX1049 ('490 Patent FH), 383-87. As-filed independent claims 5, 12, and 18 are similar.

82. Examiner Patel was assigned to the '341 application.

83. A May 18, 2006 office action rejected claims 1-10, 12-15, and 17-21. EX1049 ('490 Patent FH), 299-308. Among other rejections, claims: (i) 1-4 and 18-21 were rejected as obvious in view of U.S. Patent No. 6,471,744 to Hill (hereinafter "*Hill '744*"; EX1029) and U.S. Patent No. 6,344,069 to Smolarek et al. (hereinafter "*Smolarek '069*"; EX1030); and (ii) 5-10, 12, 13-15, and 17 were rejected as anticipated by *Hill '744*. EX1049 ('490 Patent FH), 305-07. The office action stated that claims 11 and 16 contained allowable subject matter. EX1049 ('490 Patent FH), 307.

84. Rather than accept the Examiner's indicated allowability, the applicant sought to differentiate claims: (i) 1 and 18 by amending them to recite a "vacuum swing adsorption process" and arguing that *Hill '744* and *Smolarek '069* teach pressure swing adsorption; and (ii) 5 and 12 by arguing that *Hill '744* directs pressurized, not ambient, air into its column. EX1049 ('490 Patent FH), 283-292.

85. A final office action issued on October 31, 2006 rejecting (among other things) claims 1-10, 12-15, and 17-21 as being obvious over *Hill '744*, *Smolarek '069*, and U.S. Patent No. 5,429,666 to Agrawal et al. (hereinafter "*Agrawal '666*"; EX1031).

86. On December 29, 2006, applicant responded, without amending the claims, by again arguing *Hill '744*'s pressure swing adsorption process differed

from the claimed vacuum swing adsorption process, and that a POSITA would not have been motivated to combine *Agrawal* '666 with *Hill* '744 and *Smolarek* '069 because unlike the latter two references *Agrawal* '666 is directed to industrial and not medical separators. EX1049 (*'490 Patent FH*), 258-261. As an aside, it is incorrect to say that there is any substantive difference between industrial and medical separators. These applications differ only in scale, not in underlying technology. A POSITA would have understood that devices and methodologies applicable to one were also applicable to the other.

87. A further April 4, 2007 final office action repeated the prior art rejections of the October 31, 2006 final office action, and rejected applicant's patentability arguments. EX1049 (*'490 Patent FH*), 246-50.

88. On June 4, 2007, applicant responded by amending claims 5 and 12 (as shown below) to accept the level of allowability offered by the Examiner, and canceling claims 1-4, 8, 11, and 16. EX1049 (*'490 Patent FH*), 237-244.

5.(Currently Amended) A method of providing concentrated oxygen product gas to a patient, the method comprising:

producing product gas by:

(a) introducing ambient air into a first end of a column containing an adsorbent material that preferentially adsorbs nitrogen and removes oxygen-rich product gas out a second end of the column;

(b) evacuating the column through the first end to remove adsorbed gas from the column;

(c) repressurizing the column by introducing product gas into the second end of the column and ambient air into the first end of the column;

(d) repeating steps (a) - (c); and

storing product gas produced by the vacuum swing absorption process in a reservoir at a pressure of about 1.0 atm to 2.0 atm; and

delivering product gas to the patient.

89. On July 23, 2007, an office action issued withdrawing the earlier indicated level of allowability in view of newly discovered art, and rejecting claims: (i) 5-7, 9, and 12-15 as obvious over *Agrawal '666* and U.S. Patent No. 5,906,672 to Michaels et al. (hereinafter “*Michaels '672*”; EX1032); (ii) 10 and 17 as obvious over *Agrawal '666*, *Michaels '672*, and U.S. Patent No. 6,547,851 to Warren (hereinafter “*Warren '851*” EX1033)⁴; and (iii) 18-21 as obvious over *Agrawal '666*, U.S. Patent Application Publication No. 20020144596 to Dee et al. (hereinafter “*Dee '596*”; EX1034), *Smolarek '069*, and *Michaels '672*. EX1049 (*'490 Patent FH*), 225-232.

90. On October 23, 2007, applicant responded by trying to distinguish the claims from *Agrawal '666* and *Michaels '672* by arguing that these references

⁴ This is the issued patent version of *Warren '095* (EX1012) discussed in §I.

teach pressure swing adsorption rather than the claimed vacuum swing adsorption.

EX1049 ('490 Patent FH), 222-23.

91. An office action issued on January 10, 2008 rejecting claims: (i) 5-7, 9, 10, 12-15, and 17 as obvious over U.S. Patent No. 5,114,440 to Reiss (hereinafter “*Reiss '440*”; EX1035) and U.S. Patent No. 4,449,990 to Tedford (hereinafter “*Tedford '990*”; EX1036); (ii) claims 18-21 as obvious over *Reiss '440* in view of *Tedford '990* and U.S. Patent No. 6,544,318 to Dee et al. (hereinafter “*Dee '318*”; EX1037). EX1049 ('490 Patent FH), 209-15.

92. On April 8, 2008, applicant responded by amending claim 5 to specify a “vacuum swing adsorption process” and claims 5, 12, and 18 to specify that the separator was “ambulatory,” such as shown in claim 5, below.

5.(Currently Amended) A method of providing concentrated oxygen product gas to a patient, the method comprising:

producing product gas with an ambulatory oxygen separator using a vacuum swing adsorption process that includes by:

- (a) introducing ambient air into a first end of a column containing an adsorbent material that preferentially adsorbs nitrogen and removes oxygen-rich product gas out a second end of the column;
- (b) evacuating the column through the first end to remove adsorbed gas from the column;
- (c) repressurizing the column by introducing product gas into the second end of the column and ambient air into the first end of the column;
- (d) repeating steps (a) - (c);

storing product gas produced by the vacuum swing adsorption process in a reservoir of the ambulatory oxygen separator at a pressure of about 1.0 atm to 2.0 atm; and

delivering a fluid product gas to the patient consisting essentially of the product gas.

EX1049 (*'490 Patent FH*), 201-04. Applicant correspondingly argued, among other things, that *Reiss '440* and *Tedford '990* failed to teach “ambulatory concentrators.” EX1049 (*'490 Patent FH*), 205-07.

93. A final office action issued on July 9, 2008 rejecting claims: (i) 5-7, 9, 10, and 12-15 as obvious over *Reiss '440*, *Tedford '990*, and U.S. Patent No. 7,135,059 to Deane et al. (hereinafter “*Deane '059*”; EX1038); and (ii) 18-21 as being obvious over *Reiss '440*, *Tedford '990*, *Dee '318*, and *Deane '059*. EX1049 (*'490 Patent FH*), 184-91.

94. I understand that the content of *Deane '059* (EX1038) is very similar to that of *Deane* (EX1004), used in the Grounds below (differing only in their claim sets), because both *Deane* and *Deane '059* result from the same application (U.S. Application No. 10/681,456). *Deane '059* is the issued patent from this application while *Deane* (EX1004) is the published version of the application. In the office action, the Examiner cites *Deane '059*'s teaching of an ambulatory oxygen separator (with a reservoir) but does not discuss the specific structural details of *Deane*'s construction or its components. See EX1049 (*'490 Patent FH*), 187, 189.

95. On September 8, 2008, applicant responded by amending claims 5, 12, and 18 to specify that the introduction of product gas occurs during an initial

portion of repressurization of the column and controlling a cycle rate as a function of oxygen delivery, such as shown in claim 5, below:

5.(Currently Amended) A method of providing concentrated oxygen product gas to a patient, the method comprising:

producing product gas with an ambulatory oxygen separator using a vacuum swing adsorption process that includes:

- (a) introducing ambient air into a first end of a column containing an adsorbent material that preferentially adsorbs nitrogen and removes oxygen-rich product gas out a second end of the column;
- (b) evacuating the column through the first end to remove adsorbed gas from the column;
- (c) repressurizing the column by introducing product gas into the second end of the column and ambient air into the first end of the column, wherein introducing product gas occurs during an initial portion of the repressurization;
- (d) repeating steps (a) - (c);

storing product gas produced by the vacuum swing absorption process in a reservoir of the ambulatory oxygen separator at a pressure of about 1.0 atm to 2.0 atm; ~~and~~
delivering a fluid to the patient consisting essentially of the product gas; and controlling a cycle rate at which steps (a) - (c) are performed as a function of oxygen used by the patient.

EX1049 ('490 Patent FH), 174-77. Applicant correspondingly argued that *Reiss '440*, *Tedford '990*, and *Deane '059* failed to teach such functionality. EX1049 ('490 Patent FH), 178-81.

96. Applicant agreed that *Deane '059* “discloses a portable gas fractionalization apparatus that provides oxygen rich air to patients utilizing pressure swing adsorption (PSA).” EX1049 ('490 Patent FH), 178-79.

97. An advisory action issued on October 16, 2008 in which the examiner stood by the previous rejection of the claims. EX1049 ('490 Patent FH), 172.

98. On December 4, 2008, applicant filed a request for continued examination that included amendments to claims 5, 12, and 18 specifying that fluid is delivered to patients through a dispensing valve that regulates the amount of gas delivered, such as is shown in claim 5, below:

5.(Currently Amended) A method of providing concentrated oxygen product gas to a patient, the method comprising:

producing product gas with an ambulatory oxygen separator using a vacuum swing adsorption process that includes:

- (a) introducing ambient air into a first end of a column containing an adsorbent material that preferentially adsorbs nitrogen and removes oxygen-rich product gas out a second end of the column;
- (b) evacuating the column through the first end to remove adsorbed gas from the column;
- (c) repressurizing the column by introducing product gas into the second end of the column and ambient air into the first end of the column, wherein introducing product gas occurs during an initial portion of the repressurization;
- (d) repeating steps (a) - (c);

storing product gas produced by the vacuum swing absorption process in a reservoir of the ambulatory oxygen separator at a pressure of about 1.0 atm to 2.0 atm;

delivering a fluid to the patient consisting essentially of the product gas through a dispensing valve that regulates the amount of product gas delivered from the reservoir to the patient; and

controlling a cycle rate at which steps (a) - (c) are performed as a function of ~~oxygen used by the patient~~ product gas pressure in the reservoir.

EX1049 ('490 Patent FH), 157-60. Applicant correspondingly argued that *Reiss* '440, *Tedford* '990, and *Deane* '059 failed to teach such functionality.⁵ EX1049 ('490 Patent FH), 162-65.

⁵ This is not a feature of the challenged claims herein.

99. On July 8, 2009, a non-final office action issued again rejecting claims: (i) 5, 9, 10, 12, 17, and 22-25 as obvious over *Reiss '440*, *Tedford '990*, and *Deane '059*; and (ii) claims 18, 21, 26, and 27 as obvious over *Reiss '440*, *Tedford '990*, *Dee '318*, and *Deane '059*. The Examiner repeated his analyses from the July 9, 2008 office action, and stated that *Tedford '990* teaches the amended features. EX1049 (*'490 Patent FH*), 105-13.

100. On January 8, 2010, applicant responded by amending claims 5, 12, and 18 to specify the product gas is pumped from the separator to a storage reservoir, such as is shown in claim 5, below:

5. (Currently Amended) A method of providing concentrated oxygen product gas to a patient, the method comprising:

- producing product gas with an ambulatory oxygen separator using a vacuum swing adsorption process that includes:
 - (a) introducing ambient air into a first end of a column containing an adsorbent material that preferentially adsorbs nitrogen and removes oxygen-rich product gas out a second end of the column;
 - (b) evacuating the column through the first end to remove adsorbed gas from the column;
 - (c) repressurizing the column by introducing product gas into the second end of the column and ambient air into the first end of the column, wherein introducing product gas occurs during an initial portion of the repressurization;
 - (d) repeating steps (a) - (c);
- pumping the product gas from the separator to a storage reservoir;

storing product gas produced by the vacuum swing absorption process in a the reservoir of the ambulatory oxygen separator at a pressure of about 1.0 atm to 2.0 atm;
delivering a fluid to the patient consisting essentially of the product gas through a dispensing valve that regulates the amount of product gas delivered from the reservoir to the patient; and
controlling a cycle rate at which steps (a) - (c) are performed as a function of product gas ~~pressure in~~ delivered from the reservoir.

EX1049 ('490 Patent FH), 90-94. Applicant correspondingly argued that *Reiss '440*, *Tedford '990*, and *Deane '059* failed to teach such functionality. EX1049 ('490 Patent FH), 95-97.

101. A final office action then issued on June 9, 2010 repeating the previous rejections. The Examiner stated that *Tedford '990* teaches the amended features. EX1049 ('490 Patent FH), 74-83.

102. In an August 5, 2010 response, the applicant argued, without amending the claims, that the prior art does not teach pumping the product gas from the separator to a reservoir. EX1049 ('490 Patent FH), 68-70.

103. An advisory action issued on August 24, 2010 in which the examiner maintained the rejections. EX1049 ('490 Patent FH), 59-61.

104. The applicant then appealed on September 3, 2010 and filed an appeal brief on November 11, 2010 largely advancing the same arguments from the August 5, 2010 response. EX1049 ('490 Patent FH), 33-48, 53-54.

105. In the appeal brief, applicant explained that *Deane '059* teaches:

a portable gas fractionalization apparatus that provides oxygen rich air to patients. The components are assembled in a housing that is divided into two compartments. ... The apparatus utilizes a PSA unit to produce an oxygen enriched product. The PSA unit incorporates a single ended column design in which all flow paths and valves can be co-located on a single integrated manifold.

EX1049 (*'490 Patent FH*), 40.

106. On February 2, 2011, a notice of allowance issued allowing the pending claims and stating that the prior art does not teach pumping the product gas from the separator to a storage reservoir in combination with controlling a cycle rate at which various claimed steps are performed as a function of product gas delivered from the reservoir. EX1049 (*'490 Patent FH*), 22-27.

107. The '490 patent then issued on June 7, 2011. EX1049 (*'490 Patent FH*), 9.

2. '362 Application

108. A continuation of the '490 patent / '341 application, Application No. 13/096,362 (“the '362 application”), was filed on April 28, 2011. EX1050 (*'362 Application FH*), 457-522.

109. Like the claims of the '490 patent discussed above, the claims pursued in the '362 application (*see below*) are not directed to the specific structural features of a separation cartridge (such as the arrangement of its ports on the cartridge shown in FIGS. 15-16 of the '628 patent) and thus are not similar to the challenged claims of the '628 patent that I discuss in detail below.

110. Rather, the claims of the '362 application are directed to a POC system and its operation more generally. Thus, as a general matter, the Examiner and applicant's discussion of particular claim language in the '362 application's history and/or comparison of such language to those claims is of limited relevance to the '628 patent.

111. However, I note that the Examiner did summarize the teachings of U.S. Patent No. 7,438,745 to Deane et al. (hereinafter "*Deane '745*" (EX1039)) regarding its basic components (*see* below), with which the applicant did not disagree. *Deane '745* (EX1039) has substantially the same disclosure as *Deane* (EX1004), which I use in the Grounds below. Thus, the Examiner's reading of the teachings of *Deane '745* (EX1039) is relevant to my understanding of *Deane* in the Grounds below. Thus, I summarize the prosecution of the '362 application below.

112. The as-filed claims of the '362 application were similar to those advanced in the '341 application. *See, e.g.*, as-filed claims 1 and 5, below.

1. An oxygen concentrator which produces a product gas containing at least about eighty-five percent oxygen by utilizing a vacuum swing adsorption (VSA) process comprising:
 - a gas input system for supplying ambient air;
 - a VSA gas separation system in communication with the gas input system to receive the ambient air, the gas separation system comprising a cartridge containing an adsorbent material for producing oxygen;
 - a delivery system for receiving oxygen produced by the gas separation system;
 - a drive which actuates the delivery system and the gas separation system;
 - a power pack connected to the drive; and
 - wherein the oxygen concentrator has a weight of less than 2.3 kg and a volume of less than 1 liter.

5. A method of providing oxygen separated from ambient air to a patient, the method comprising:
performing vacuum swing adsorption cycles in each of a plurality of adsorbent beds containing an adsorbent selective for nitrogen, each cycle including a feed phase, an evacuation phase, and a repressurization phase; wherein the pressure throughout the vacuum swing adsorption cycles does not rise above that of ambient air; and
delivering product gas containing oxygen separated by the vacuum swing adsorption cycles to the patient.

EX1050 (*'362 Application FH*), 500-02.

113. Examiner Patel (the same Examiner assigned to the parent '341 application) was assigned to the '362 application.

114. An August 5, 2011 office action issued rejecting claims: (i) 1, 3, and 4 as obvious over "*Deane '745*" (EX1039) and "*Hill '658*" (EX1013); (ii) 5-9, 12, 14, 16, and 17 as obvious over *Deane '745* and *Reiss '440* (EX1035); (iii) 2 as obvious over *Deane '745*, *Hill '658*, and U.S. Patent No. 7,250,073 to Keefer et al. (hereinafter "*Keefer '073*"; EX1040); (iv) 18 and 19 as obvious over *Deane '745*, *Reiss '440*, and *Keefer '073*; and (v) 13, 15, and 20 as obvious over *Deane '745*, *Reiss '440*, and *Hill '658*. EX1050 (*'362 Application FH*), 57-66. Claims 10 and 11 were indicated as being allowable if rewritten in independent form. EX1050 (*'362 Application FH*), 65.

115. Regarding *Deane '745*, the Examiner asserted that it teaches: (i) a gas input system 102 for supplying ambient air (see FIG. 1; 9:35-40); (ii) a VSA gas separation system in communication with the gas input system to receive the

ambient air (11:55-60), the gas separation system comprising a cartridge 118a and 118b containing an adsorbent material for producing oxygen (4:4-15); (iii) a delivery system 110 for receiving oxygen produced by the gas separation system (FIG. 1; 11:60-65); (iv) a drive 126 which actuates the delivery system and the gas separation system (see FIG. 1; 11:60-65); (v) a power pack connected to the device (see 14:54-64); (vi) an oxygen concentrator has a weight of less than 2.3 kg (see 6:10-12); and (vii) that the power pack comprises a battery (see 14:54-64). EX1050 ('362 *Application FH*), 58-59.

116. In other words, the Examiner explicitly found that *Deane* '745 teaches the main components of a POC system. This is because he was comparing *Deane* '745 to the claims being sought in the '362 Application, which are directed to a POC system and its operation, as noted above. Because the claims of the '362 Application were not directed to the specific structural features of a separation cartridge (*e.g.*, port location and direction), the Examiner did not take a position or otherwise discuss his views on what *Deane* '745 teaches as to the more specific structural features of a separation cartridge, such as those recited in the challenged claims of the '628 patent discussed in the Grounds below.

117. In response, applicant accepted the indicated level of allowability and canceled claims 1-4, 7, 10, and 16-20, and amended claim 5 to include all the

limitations of claim 10 (*i.e.*, language reciting “partial repressurization”) as well as the intervening limitations of claim 7, as follows

5. (Currently amended) A method of providing oxygen separated from ambient air to a patient, the method comprising:

performing vacuum swing adsorption cycles in each of a plurality of adsorbent beds containing an adsorbent selective for nitrogen, each cycle including a feed phase, an evacuation phase, and a repressurization phase; wherein the pressure throughout the vacuum swing adsorption cycles does not rise above that of ambient air[[:]], and wherein each of the beds has a first end and a second end, and wherein during the repressurization phase, the bed is partially repressurized by product gas introduced through the second end; and delivering product gas containing oxygen separated by the vacuum swing adsorption cycles to the patient.

EX1050 (‘362 *Application FH*), 50-51.

118. On June 4, 2012, an office action issued rejecting claims: (i) 5, 6, 8, and 11-15 as obvious over U.S. Patent No. 6,585,804 to Kleinberg et al. (hereinafter “*Kleinberg ’804*”; EX1041) and *Hill ’658*; and (ii) 9 as obvious over *Kleinberg ’658*, *Hill ’658*, and *Reiss ’440*. EX1050 (‘362 *Application FH*), 35-42.

119. On September 4, 2012, the applicant responded, without amending the claims, arguing that independent claim 5, unlike *Kleinberg ’804*, requires that the pressure during the vacuum swing adsorption cycle does not rise above that of ambient air. EX1050 (‘362 *Application FH*), 28-32.

120. A December 18, 2012 final office action repeated the rejections of the June 4, 2012 office action. EX1050 (‘362 *Application FH*), 16-23.

121. On March 15, 2013, the applicant responded with the same arguments advanced in the September 4, 2012 response. EX1050 (*'362 Application FH*), 7-12.

122. An advisory action issued on August 7, 2013 noting that the specification does not support the requirement that the pressure throughout the vacuum swing adsorption cycle does not rise above that of ambient air. EX1050 (*'362 Application FH*), 4-6.

123. Applicant did not respond, and a notice of abandonment issued on September 9, 2013. EX1050 (*'362 Application FH*), 1-2.

3. '977 Application

124. A continuation of the '362 application, Application No. 13/795,977 ("the '977 application") was filed on March 12, 2013. EX1051 (*'977 Application FH*), 467-515.

125. Like the claims of the '490 patent discussed above and those pursued in the '362 application, the claims pursued in the '977 application (*see below*) are not directed to the specific structural features of a separation cartridge (such as the arrangement of its ports on the cartridge shown in FIGS. 15-16 of the '628 patent) and thus are not similar to the challenged claims of the '628 patent that I discuss in detail below.

126. Rather, the claims of the '977 application are directed to a POC system and its operation more generally. Thus, as a general matter, the Examiner and applicant's discussion of particular claim language in the '977 application's history and/or comparison of such language to those claims is of limited relevance to the '628 patent. Nevertheless, I summarize the prosecution of the '977 application below for completeness.

127. The as-filed claims were similar to those advanced in the '341 and '362 applications. *See, e.g.*, as-filed claims 1 and 5, below.

1. An oxygen concentrator which produces a product gas containing at least about eighty-five percent oxygen by utilizing a vacuum swing adsorption (VSA) process comprising:

- a gas input system for supplying ambient air;
- a VSA gas separation system in communication with the gas input system to receive the ambient air, the gas separation system comprising a cartridge containing an adsorbent material for producing oxygen;
- a delivery system for receiving oxygen produced by the gas separation system;
- a drive which actuates the delivery system and the gas separation system;
- a power pack connected to the drive; and

wherein the oxygen concentrator has a weight of less than 2.3 kg and a volume of less than 1 liter.

5. An oxygen concentrator comprising:

- a portable power pack;
- a vacuum swing adsorption (VSA) oxygen separator powered by the power pack and having a plurality of nitrogen-selective adsorbent beds, each bed operating in VSA cycles including feed, evacuation and repressurization phases, the VSA cycles operating with vacuum levels within a range between about 0.1 atm and about 1.0 atm, wherein the pressure throughout the VSA cycles does not exceed about 1.0 atm; and
- a delivery system for receiving oxygen provide by the gas separation system.

EX1051 ('977 *Application FH*), 512-13.

128. Examiner Jones was assigned to the '977 application, rather than Examiner Patel who had handled the two parent applications—the '362 application and '341 application.

129. A May 13, 2015 office action rejected claims 1-14 as being anticipated by or, in the alternative obvious over, *Hill '658* (EX1013). EX1051 (*'977 Application FH*), 24-30.

130. On August 12, 2015, applicant responded by amending claims 1 and 5 as follows

1. (Currently Amended) An oxygen concentrator which produces a product gas containing at least about eighty-five percent oxygen by utilizing a vacuum swing adsorption (VSA) process comprising:

- a gas input system for supplying ambient air;
- a VSA gas separation system in communication with the gas input system to receive the ambient air, the gas separation system comprising a cartridge containing an adsorbent material for producing oxygen;
- a delivery system for receiving oxygen produced by the gas separation system;
- a drive which actuates the delivery system and the gas separation system;
- a single valve, wherein the single valve connects the gas input system, the delivery system, and gas separation system;
- a power pack connected to the drive; and

wherein the oxygen concentrator has a weight of less than 2.3 kg and a volume of less than 1 liter.

5. (Currently Amended) An oxygen concentrator comprising:
a portable power pack;

a vacuum swing adsorption (VSA) oxygen separator powered by the power pack and having a plurality of nitrogen-selective adsorbent beds, each bed operating in VSA cycles including feed, evacuation and repressurization phases, the VSA ~~eyeles~~ oxygen separator operating with vacuum levels within in a range between about 0.1 atm and about 1.0 atm, wherein the pressure throughout the VSA ~~eyeles~~ oxygen separator does not exceed about 1.0 atm; and

a delivery system for receiving oxygen provide by the VSA oxygen separator ~~gas separation system~~.

EX1051 ('977 *Application FH*), 15-17 (similar amendments as those made to claim 5 were made to claim 10). Applicant correspondingly argued that *Hill '658* does not teach the claimed single valve and was a pressure swing adsorption device rather than a vacuum swing adsorption device as claimed. EX1051 ('977 *Application FH*), 18-20.

131. On November 12, 2015, an office action issued rejecting claims: (i) 1-4 as anticipated by *Hill '658* and/or obvious over *Hill '658* and U.S. Patent No. 6,143,056 to Smolarek et al. (hereinafter "*Smolarek '056*"; EX1042); and (ii) 5-14 as anticipated by or obvious over *Hill '658*. EX1051 ('977 *Application FH*), 3-11.

132. Applicant did not respond, and a notice of abandonment issued on May 19, 2016. EX1051 ('977 *Application FH*), 1-2.

4. '669 Patent

133. The '669 patent issued from a continuation of the '977 application, Application No. 14/193,504 ("the '504 application"), filed on February 28, 2014. EX1056 ('669 *Patent*), Cover.

134. Unlike the claims of the '490 patent, '362 application, and '977 application discussed above, the claims pursued in the '504 application / '669 patent are directed to specific structural features of a POC's separation cartridge, and are therefore somewhat closer to the challenged claims of the '628 patent than those previous applications. Thus, the Examiner's and applicant's comments,

responses, and positions as to particular claim language and prior art teachings is of more relevance. Therefore, I will summarize the prosecution of the '504 application / '669 patent below and highlight its more relevant portions, including how the claims were amended to differentiate them from U.S. Patent Application Publication No. 20050072426 to Deane et al. ("*Deane* '426" (EX1047), which includes the same relevant disclosure as *Deane* (EX1004) used in the Grounds below.

135. The as-filed independent claims (1, 8, and 15) of the '504 application recite general features of the cartridge of FIGS. 7, 15, and 16, as follows:

1. A gas separation cartridge for use in an oxygen concentrator which separates oxygen from ambient air by using an absorption process, the gas separation cartridge comprising:
at least one column in a housing, the at least one column including an inlet side, an outlet side, and a bed of adsorbent material;
an inlet port in the housing configured to connect to a valve; and
an outlet port in the housing configured to connect to the valve.

8. A portable oxygen concentrator comprising:

an outer housing;
a plurality of gas separation columns at least partially covered by the outer housing, each gas separation column having a casing containing an adsorbent material that preferentially adsorbs nitrogen, a first end, and a second end;
a plurality of inlet ports in the outer housing, each inlet port connect to the first end of one of the columns; and
a plurality of outlet ports in the outer housing, each outlet port connected to the second end of one of the columns.

15. A removable gas separation cartridge for use in an oxygen concentrator, the gas separation cartridge comprising:
an adsorbent column having a bed of adsorbent material;
a housing for containing the adsorbent column;

a cap attached to the housing;
wherein the housing and cap are configured to be removable from the oxygen
concentrator;
a first port in the housing; and
a second port in the cap.

EX1052 ('669 *Patent FH*), 1080-82.

136. Examiner Vasat was assigned to the '504 application, rather than Examiner Jones who handled the parent '977 application or Examiner Patel who had handled the two earlier parent applications (the '362 and '341 applications).

137. A July 7, 2017 office action rejected, among other things, claims: (i) 1-5, 7-10, 12-14, and 20 as anticipated by U.S. Patent No. 5,827,358 to Kulish et al (hereinafter "*Kulish*"; EX1043); (ii) 6 and 11 as obvious over *Kulish* and U.S. Patent No. 6,802,889 to Graham et al. (hereinafter "*Graham*"; EX1044); and (iii) 15-19 as obvious over *Kulish* and *Hechinger* (EX1048). EX1052 ('669 *Patent FH*), 583-569.

138. On October 6, 2017, applicant responded by amending claims 1, 8, and 15 such that they each specified that inlet and outlet ports for the cartridge were on opposite ends of the cartridge, but faced in the same direction, as shown:

1. (Currently Amended) A gas separation cartridge for use in an oxygen concentrator which separates oxygen from ambient air by using an absorption process, the gas separation cartridge comprising:

- at least one column in a housing, the at least one column including an inlet side, an outlet side opposite the inlet side, and a bed of adsorbent material;
- an inlet port in the housing configured to connect to a valve; and
- an outlet port in the housing configured to connect to the valve,

wherein the inlet port is adjacent the inlet side of the at least one column, the outlet port is adjacent the outlet side of the at least one column, and the outlet port is directed in a same direction as the inlet port.

8. (Currently Amended) A portable oxygen concentrator comprising:

- an outer housing;
- a plurality of gas separation columns at least partially covered by the outer housing, each gas separation column having a casing containing an adsorbent material that preferentially adsorbs nitrogen, a first end, and a second end;
- a plurality of inlet ports in the outer housing, each inlet port connect to the first end of one of the columns; and
- a plurality of outlet ports in the outer housing, each outlet port connected to the second end of one of the columns,

wherein the plurality of inlet ports are not in axial alignment with the plurality of outlet ports and the inlet ports are directed in a same direction as the outlet ports.

15. (Currently Amended) A removable gas separation cartridge for use in an oxygen concentrator, the gas separation cartridge comprising:

- an adsorbent column having a bed of adsorbent material;
- a housing for containing the adsorbent column;
- a cap attached to the housing;

wherein the housing and cap are configured to be removable from the oxygen concentrator;

- a first port in the housing; and
- a second port in the cap,

wherein the first port is not in axial alignment with the second port and the first port and the second port are directed in a same direction.

EX1052 ('669 *Patent FH*), 541-43. Applicant correspondingly argued that *Kulish's* inlet and outlet ports are directed in opposite directions. EX1052 ('669 *Patent FH*), 545-48.

139. A December 6, 2017 final office action rejected claims: (i) 1-5, 8-10, 12-13, and 20 as obvious over *Kulish* and *Dechene*; EX1021); (ii) 6 and 11 as obvious over *Kulish*, *Dechene*, and *Graham*; (iii) 15, 16, and 19 as obvious over *Kulish*, *Dechene*, and *Hechinger*. EX1052 ('669 Patent FH), 490-509.

140. On February 6, 2018 applicant responded by amending the independent claims 1, 8, and 15 to specify that the inlet and outlet ports both faced towards a bottom of the cartridge, such as shown in claim 1, below:

1. (Currently Amended) A gas separation cartridge for use in an oxygen concentrator which separates oxygen from ambient air by using an absorption process, the gas separation cartridge having a top and a bottom and comprising:

at least one column in a housing, the at least one column including an inlet side, an outlet side opposite the inlet side, and a bed of adsorbent material;

an inlet port in the housing adjacent the bottom of the gas separation cartridge and configured to connect to a valve; and

an outlet port in the housing adjacent the top of the gas separation cartridge and configured to connect to the valve,

wherein the inlet port is adjacent the inlet side of the at least one column, the outlet port is adjacent the outlet side of the at least one column, and the outlet port and the inlet port are directed in a same direction towards the bottom of the gas separation cartridge ~~is directed in a same direction as the inlet port.~~

EX1052 ('669 Patent FH), 468-71. Applicant correspondingly argued that *Kulish*'s inlet and output ports are directed in opposite directions, and that *Dechene*'s ports are directed out the side of the oxygen fractioning apparatus. EX1052 ('669 Patent FH), 472-77.

141. On March 5, 2018, an advisory action issued noting that while the amendments appeared to overcome the rejections based on *Kulish* and *Dechene*,

Bassine (EX1026) teaches arrangements of ports that read on the as-amended claims. EX1052 ('669 Patent FH), 461.

142. After the applicant filed a request for continued examination, a non-final office action issued on October 25, 2018 rejecting claims: (i) 1-5, 8-10, 12, 13, and 20 as obvious over *Kulish* and *Bassine*; (ii) claims 6 and 11 as obvious over *Kulish*, *Bassine*, and *Graham*; and (iii) 15, 16, and 19 as obvious over *Kulish*, *Bassine*, and *Hechinger*. EX1052 ('669 Patent FH), 381-99.

143. On January 28, 2019, applicant responded by amending claims 1, 8, and 15 to specify that there was only one inlet and outlet per adsorbent column. EX1052 ('669 Patent FH), 366-70. The amendments to claims 1 and 15 are shown below (the amendments to claim 8 are similar to those of claim 1):

1. (Currently Amended) A gas separation cartridge for use in an oxygen concentrator which separates oxygen from ambient air by using an ~~absorption~~-adsorption process, the gas separation cartridge having a top and a bottom, and comprising:

at least one column in a ~~housing~~case, the at least one column including an inlet side, an outlet side opposite the inlet side, and a bed of adsorbent material;

an inlet port in the ~~housing~~case adjacent one of the top and the bottom of the gas separation cartridge and configured to connect to a valve; and

an outlet port in the ~~housing~~case adjacent the other of the top and the bottom of the gas separation cartridge and configured to connect to the valve,

wherein the inlet port is adjacent the inlet side of the at least one column, the outlet port is adjacent the outlet side of the at least one column, and the case includes only one inlet port and only one outlet port corresponding to the at least one column, and the outlet port and the inlet port are directed in a ~~same~~-common direction towards the bottom of the gas separation cartridge.

15. (Currently Amended) A removable gas separation cartridge for use in an oxygen concentrator, the gas separation cartridge comprising:

an adsorbent column having a bed of adsorbent material disposed along an axis;

a ~~housing case~~ for containing the adsorbent column, the case including a housing portion and a cap attached to a first end of the housing portion;

~~a top attached to the housing~~;

wherein the ~~housing case and top are~~ configured to be removable from the oxygen concentrator by movement in a first direction relative to the remainder of the oxygen concentrator;

a first port in the ~~housing case~~; and

a second port in the ~~top case~~;

wherein the first and second ports are the only ports in the case corresponding to the adsorbent column,

wherein the first port and the second port are both oriented in a second direction opposite the first direction, and

wherein the first port is concentrically aligned with the axis and is disposed adjacent a second end of the housing portion opposite the first end, and the first-second port is spaced-apart from the axis and is disposed adjacent the first end of the housing portion not in axial alignment with the second port and the first port and the second port are directed in a same direction towards a bottom of the gas separation cartridge.

EX1052 ('669 Patent FH), 366-70. Applicant correspondingly argued that *Kulish* teaches more than one inlet port and outlet port per column, and that there would have been no reason to modify *Kulish* to reach the claims. EX1052 ('669 Patent FH), 371-74.

144. A May 8, 2019 final office action then issued, rejecting (among other things) claims: (i) 1, 4, and 5 as obvious over *Warren '095* (EX1012) and *Bassine*; (ii) 6 as being obvious over *Warren '095* in view of *Bassine* further in view of U.S.

Patent No. 6,691,702 to Appel et al. (hereinafter “*Appel* ’702”; EX1045); (iii) 2, 3, and 21 as obvious over *Warren* ’095, *Bassine*, and *McCombs* ’924, (iv) 8-10 and 12 as obvious over *Cole* in view of *Bassine*, (v) 11 as obvious over *Cole*, *Bassine*, and *Appel* ’702; and (vi) 15 as obvious over *Bassine*; and (vii) 22 and 23 as obvious over *Warren* ’095, *Bassine*, and U.S. Patent No. 4,687,573 to Miller et al. (“Miller ’573”; EX1046). EX1052 (’669 *Patent FH*), 289-314.

145. Applicant then appealed and filed an appeal brief and a corrected appeal brief. EX1052 (’669 *Patent FH*), 251-62, 267-78. In the appeal briefs, applicant argued the prior art either did not teach “portable” oxygen concentrators and/or cartridge outlets and inlets both facing downwards. EX1052 (’669 *Patent FH*), 254-58.

146. Prosecution was re-opened in view of the appeal brief and a December 31, 2019 non-final office action rejected (among other things) claims: (i) 15 as anticipated by *Bassine*; (ii) 1, 4, and 5 as obvious over *Warren* ’095 and *Bassine*; (iii) 6 as obvious over *Warren* ’095, *Bassine*, and *Appel* ’702; (iv) 2, 3, and 21 as obvious over *Warren* ’095, *Bassine*, and *McCombs* ’924; (v) 8–10 and 12 as obvious over *Cole* in view of *Bassine*; (vi) 11 as obvious over *Cole*, *Bassine*, and *Appel* ’702; (vii) 15 as obvious over *Bassine* to the extent it’s not anticipated; and (viii) 22 and 23 as obvious over *Warren* ’095, *Bassine*, and *Miller* ’573.

EX1052 ('669 Patent FH), 162-203. The Examiner also disagreed with applicant's previous arguments. EX1052 ('669 Patent FH), 196-201.

147. On January 20, 2020, applicant responded by canceling claims 1-23 and adding new claims 24-42, including new independent claims 24 and 38, below:

24. (New) A cartridge configured for use with an oxygen concentrator and configured to be removable from the oxygen concentrator by movement in a first direction, the cartridge comprising:

a first bed of adsorbent material disposed along a first axis, wherein the first axis is substantially parallel to the first direction;

a second bed of adsorbent material disposed along a second axis spaced-apart from the first axis, wherein the second axis is substantially parallel to the first direction;

a first port disposed along the first axis, the first port configured to receive fluid flowing to the first bed or to expel fluid flowing away from the first bed;

a second port spaced-apart from the first axis and configured to receive fluid flowing to the first bed or to expel fluid flowing away from the first bed;

a third port disposed along the second axis and configured to receive fluid flowing to the second bed or to expel fluid flowing away from the second bed; and

a fourth port spaced-apart from the second axis and configured to receive fluid flowing to the second bed or to expel fluid flowing away from the second bed;

wherein the first, second, third, and fourth ports are oriented in a second direction opposite the first direction.

38. (New) A portable oxygen concentrator, comprising:

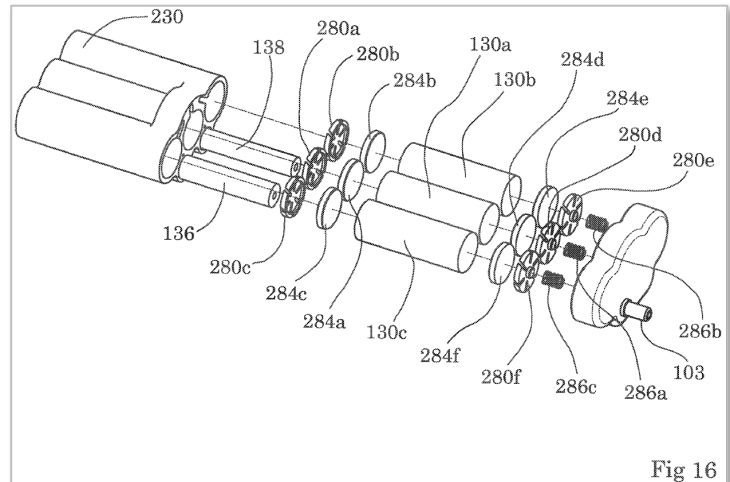
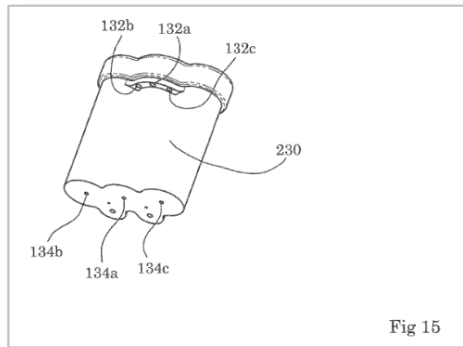
- a receptacle;
- a cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the cartridge comprising:
 - a first bed of adsorbent material disposed along a first axis, wherein the first axis is substantially parallel to the first direction;
 - a second bed of adsorbent material disposed along a second axis spaced-apart from the first axis, wherein the second axis is substantially parallel to the first direction;
 - a first port disposed along the first axis, the first port configured to receive fluid flowing to the first bed or to expel fluid flowing away from the first bed;
 - a second port spaced-apart from the first axis and configured to receive fluid flowing to the first bed or to expel fluid flowing away from the first bed;
 - a third port disposed along the second axis and configured to receive fluid flowing to the second bed or to expel fluid flowing away from the second bed; and
 - a fourth port spaced-apart from the second axis and configured to receive fluid flowing to the second bed or to expel fluid flowing away from the second bed;

wherein the first, second, third, and fourth ports are oriented in a second direction opposite the first direction.

EX1052 ('669 Patent FH), 149-53.

148. In other words, the claims presented in this amendment (*e.g.*, the claim reproduced directly above) required the cartridge to include multiple adsorbent beds (*e.g.*, first and second), each with a port (*e.g.*, first and third) on its axis and another port (*e.g.*, second and fourth) spaced apart from its axis, both facing in the same direction. This reads directly on the embodiment shown in FIGS. 15 and 16 (shown below) of the '669 patent (and '628 patent). The

applicant argued that the art of record does not teach this configuration. EX1052 ('669 Patent FH), 154.

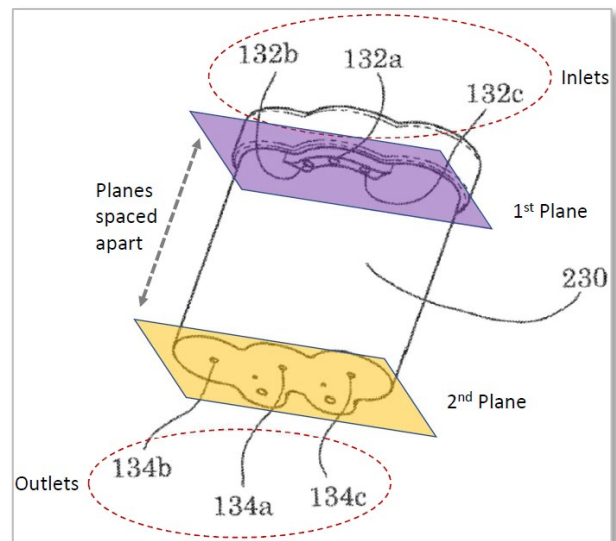


149. But the Examiner did not agree that this claim language was allowable over the prior art. Rather, the Examiner discussed the application with the applicant on April 24, 2020 and, according to an examiner-initiated interview summary, the applicant approved amending claims 24 and 38 to include the language of claim 30 (reciting that a plane including the first and third ports and a plane including the second and fourth ports are spaced apart, *e.g.*, that the ports are on different ends of the cartridge) and also approved an amendment to claim 33. EX1052 ('669 Patent FH), 19. Claim 30 is reproduced below:

30. (New) The cartridge as recited in claim 24, wherein:
a first plane extends through the first and third ports,
the first plane is substantially perpendicular to the first and second axes,
a second plane extends through the second and fourth ports,
the second plane is substantially perpendicular to the first and second axes,
the first and second planes are spaced-apart from one another.

EX1052 ('669 Patent FH), 150.

150. The relationship recited in claim 30 is depicted here in an annotated version of FIG. 15 of the '669 patent, where the purple plane is an example of the first plane and orange plane is an example of the second, where the planes are spaced apart from each other as shown.



151. The summary also indicated that the applicant and Examiner had a “brief discussion” of *Deane* '426; EX1047). EX1052 ('669 Patent FH), 19. *Deane* '426 includes the same relevant disclosure as *Deane* (EX1004) and *Deane* '745 (EX1039). While the substance of the discussion between the Examiner and applicant was not recorded, it seems likely (as confirmed below) that the Examiner found *Deane* '426 relevant to amended claims 24 and 38 but indicated that adding

the language of claim 30 would differentiate the claims from *Deane* '426. For example, it seems likely that the Examiner indicated that *Deane* '426 (and *Deane*) teaches a receptacle and cartridge with multiple adsorbent beds for at least the reasons discussed in the Grounds below (*see, e.g.*, §VI.A.2), but indicated that the two-plane language of claim 30 would differentiate the claims from *Deane* '426 (because *Deane* '426's inlets and outlets are in the same plane at the same end, as discussed in §VI.A.2).

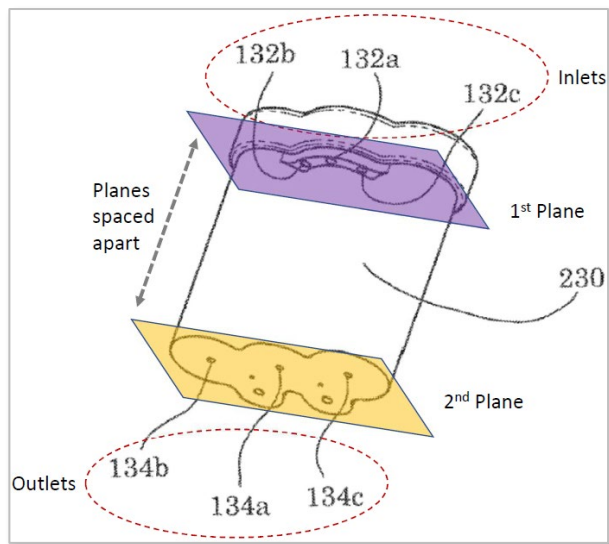
152. A notice of allowance issued on May 5, 2020, including an Examiner's amendment incorporating the language of claim 30 into claims 24 and 38. EX1052 ('669 Patent FH), 9–17.

153. The notice of allowance indicates:

The closest prior art to new claims 24-42 is considered to be prior art to *Deane* (US 20050072426). *Deane* is considered to disclose an oxygen concentrator cartridge, best shown in Figure 6, having a first port corresponding to the filter portion 618a (par. 67) disposed along the first axis defined by the bed of adsorbent material 612 (par. 66) and a second port the upper port of feed tube 608 (par. 68) that lies in the same plane as filter portion 618a and spaced apart from the first port (fig. 6). The amendment defines over *Deane* because *Deane* requires the aforementioned first and second ports to be located in a single plane with the manifold to reduce the number of tubing connections and potential leak points in the unit (par. 64). Modifying *Deane* to read on independent claims 24 and 38, as currently amended, would improperly change *Deane*'s principle of operation. Accordingly, independent claims 24 and 38 and the claims depending therefrom are considered to define over the prior art.

EX1052 ('669 Patent FH), 16.

154. This explanation from the Examiner reinforces my opinion as to why the Examiner allowed the claims of the '669 patent over *Deane* '426 mentioned in ¶151 above. In particular, it is clear that the Examiner found the claimed arrangement of ports in **different** planes (e.g., the purple and orange planes of the '669 patent) to be different from the port arrangement of *Deane* '426 (e.g., a first port at 618a and a second port at the top of 608 are at the same end). These differences are visually shown in the figures below.



'669 patent

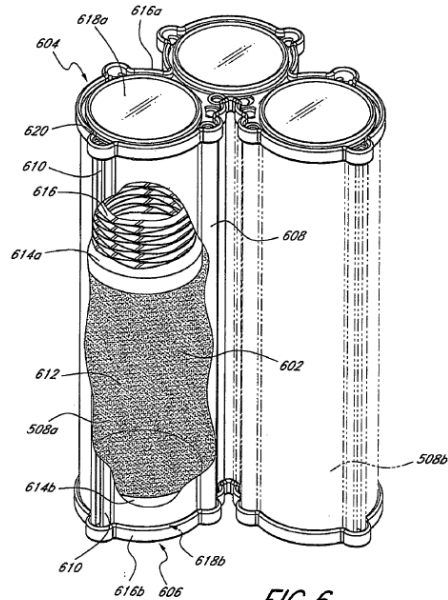


FIG. 6
Deane '426

155. A supplemental notice of allowance issued on May 29, 2020 and the '669 patent issued on July 7, 2020. EX1052 (*'669 Patent FH*), 1-4.

5. '628 Patent

156. The '628 patent issued from a continuation of the '669 patent / '504 application, Application No. 16/006,915 (“the '915 application”), filed on June 13, 2018. EX1001 (*'628 Patent*), Cover.

157. The claims of the '915 application / '628 patent are directed to specific structural features of a POC's separation cartridge. Here, I summarize the prosecution of the '915 application / '628 patent below and highlight its importance, including what I consider to be the failure of the Examiner to properly reject the issued claims of the '628 patent in view of *Deane* (EX1004) (or *Deane '426* (EX1047) or *Deane '745* (EX1039)).

158. Applicant filed an Information Disclosure Statement on June 13, 2018 identifying the patent that ultimately issued from *Deane* (U.S. Patent No. 7,135,059; EX1038 (*Deane '059*)) and *Deane '426* among more than 200 other prior art references. EX1002 (*'628 Patent FH*), 413-34.

159. As-filed independent claims 1 and 8 are shown below:

1. A portable oxygen concentrator, comprising:
a cartridge module comprising a housing;
a separation cartridge selectively removable from the cartridge module, the separation cartridge comprising a case at least partially defining an outer volume of the separation cartridge, an inlet, an outlet oriented in a common direction with the inlet, and a bed of adsorbent material configured to preferentially adsorb nitrogen, the case at least partially surrounding the bed of adsorbent material;
a power pack removable from the portable oxygen concentrator;
a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material;
a user interface configured to allow a patient to adjust and monitor operation of the portable oxygen concentrator;
a carrying device for transporting the portable oxygen concentrator;
wherein the housing of the cartridge module is configured to at least partially surround the case of the separation cartridge.

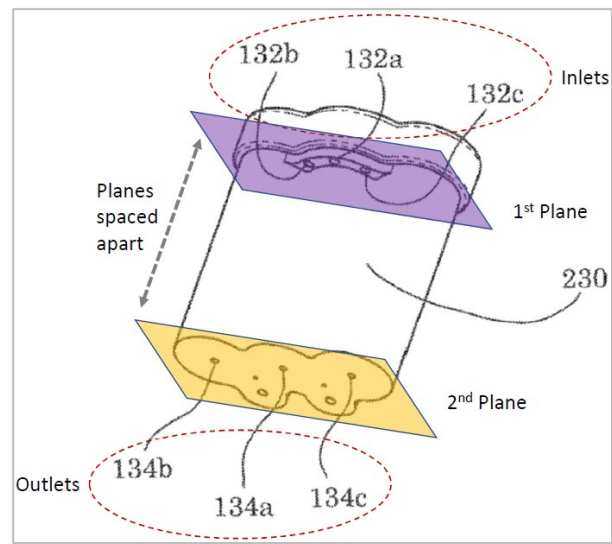
8. A portable oxygen concentrator, comprising:
a cartridge module;
a separation cartridge selectively removable from the cartridge module, the separation cartridge comprising an inlet, an outlet, and a bed of adsorbent material configured to preferentially adsorb nitrogen; and
a power pack removable from the portable oxygen concentrator.

EX1002 ('628 Patent FH), 399, 401.

160. The separation cartridges of the POCs recited in as-filed claims 1 and 8 above include inlet ports, outlet ports, and beds of adsorbent material and, with respect to claim 1, a requirement that the inlet and outlet ports are oriented in a common direction. These separation cartridge features do not appear to be substantively different from those recited in the claims of the '669 patent (the '628

patent's parent) as amended on January 20, 2020, which Examiner Vasat found not to distinguish over *Deane* '426 (EX1047) (and *Deane* (EX1004)) (see ¶¶147-154). To the extent there are other differences between the claims, such as the recitation of a power pack, pump, user interface, and carrying device in claims 1 or 8, these features are clearly obvious over *Deane* '426 (EX1047) (and *Deane* (EX1004)). See §VI.A.2[d]-[g]). Examiner Vasat should have rejected these claims in view of *Deane* '426 (EX1047) (or *Deane* (EX1004)).

161. In particular, claims 1 and 8 do not require their separation cartridge's inlet and outlet ports to be located on different planes spaced apart from each other as recited in the allowed claims of the '669 patent (and as depicted in the annotated drawing here). This is surprising inasmuch as that was the feature the examiner found distinguished the claims of the '669 patent over *Deane* '426. See ¶¶147-154.



162. In other words, with respect to the separation cartridge features, the as-filed claims of the '915 application / '628 patent appear broader than those of

the '669 patent, and to specifically read on *Deane '426* (EX1047) (and *Deane* (EX1004)).

163. Examiner Vasat, who handled the immediate parent '504 application / '669 patent, was assigned to the '915 application.

164. On November 14, 2018, an office action issued rejecting (among other things), claims: (i) 1, 5, 7–11, 16, 18, and 19 as obvious over *Warren '095* (EX1012), *Dechene* (EX1021), and *McCombs '924* (EX1009); (ii) 2 and 12 as obvious over *Warren '095*, *Dechene*, *McCombs '924*, and *Bassine* (EX1026); and (iii) 3, 4, 6, 13, 14, 15, 17, and 20 as obvious over *Warren '095*, *Dechene*, *McCombs '924*, and *Appel '702* (EX1045). EX1002 (*'628 Patent FH*), 253-66.

165. In other words, although the pending claims did not require their cartridge inlet and outlet ports to be located on different planes (which differentiated the allowed claims of the immediate parent '669 patent / '504 application from *Deane '426*) (and/or require any other features not clearly taught by *Deane '426*), Examiner Vasat did not reject the pending claims in view of *Deane '426*.

166. On January 28, 2019 applicant responded to the office action by amending claims 1 and 8 to recite the presence of a receptacle and define the inlets and outlets as facing a direction opposite the direction the cartridge is removable from the receptacle, as shown in claim 1 below:

1. (Currently Amended) A portable oxygen concentrator, comprising:

- a cartridge module comprising a housing, the housing defining a receptacle;
- a separation cartridge selectively removable from the ~~receptacle cartridge module by~~ movement relative to the receptacle in a first direction, the separation cartridge comprising a case at least partially defining an outer volume of the separation cartridge, an inlet oriented in a second direction opposite the first direction, an outlet ~~oriented in a common direction with the inlet~~ oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen, the case at least partially surrounding the bed of adsorbent material;
- a power pack removable from the portable oxygen concentrator;
- a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material;
- a user interface configured to allow a patient to adjust and monitor operation of the portable oxygen concentrator;
- a carrying device for transporting the portable oxygen concentrator;
- wherein the housing of the cartridge module is configured to at least partially surround the case of the separation cartridge.

EX1002 ('628 Patent FH), 231-33 (claim 8 was amended similarly). The applicant correspondingly argued that *Warren '095*'s inlet and outlet ports are arranged along a common axis and *Warren '095*'s device is removable in a direction perpendicular to that axis. EX1002 ('628 Patent FH), 238.

167. These added features (a receptacle and inlets/outlets facing a direction opposite the direction the cartridge is removable from the receptacle) also do not appear to be substantively different from those recited in the claims of the '669 patent (the '628 patent's parent) as amended on January 20, 2020, which Examiner Vasat found not to distinguish over *Deane '426* (EX1047) (and *Deane* (EX1004)) (see ¶¶147-154) and/or otherwise taught by *Deane '426* (EX1047) (and *Deane*

(EX1004)). Examiner Vasat should have rejected these claims in view of *Deane* '426 (EX1047) (or *Deane* (EX1004)).

168. On May 8, 2019, a final office action issued rejecting (among other things), claims: (i) 1, 5, 7-9, 16, 18, and 19 as obvious over *Warren '095*, *Dechene*, and *McCombs '924*; (ii) 2, 12, 22, and 24-27 as obvious over *Warren '095*, *Dechene*, *McCombs '924*, and *Bassine*; (iii) 3, 4, 6, 13-15, 17, and 20 as obvious over *Warren '095*, *Dechene*, *McCombs '924*, and *Appel '702*; and (iv) 28 and 29 as obvious over *Warren '095*, *Dechene*, *McCombs '924* and *Miller '573*. EX1002 (*'628 Patent FH*), 134-57. The Examiner also specifically disagreed with the applicant's arguments, pointing out that *Warren '095*'s inlets and outlets are not on a common axis and that *Dechene* teaches inlets and outlets facing opposite the direction of cartridge removal. EX1002 (*'628 Patent FH*), 157-60.

169. The Examiner indicated that claims 21 and 23 would be allowable if rewritten in independent form (including intervening claims 2 and 12). EX1002 (*'628 Patent FH*), 157.

170. On May 10, 2019, applicant responded by accepting the Examiner's indicated level of allowability by amending claims 1 and 8, such as shown:

1. (Currently Amended) A portable oxygen concentrator, comprising:

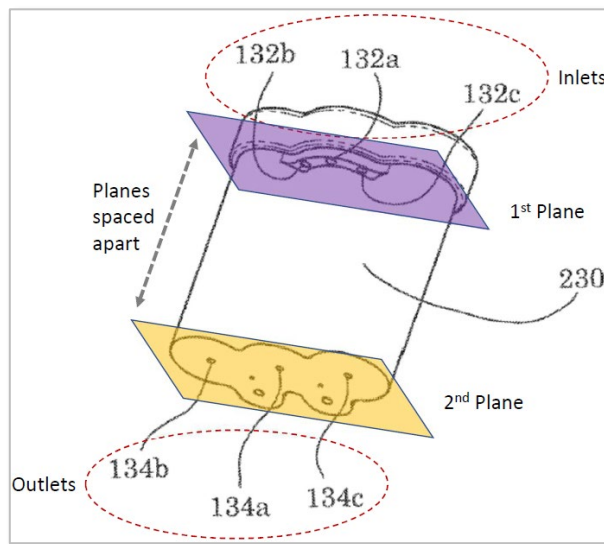
- a cartridge module comprising a housing, the housing defining a receptacle;
- a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the separation cartridge comprising a case at least partially defining an outer volume of the separation cartridge, an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen, the case at least partially surrounding the bed of adsorbent material;
- a power pack removable from the portable oxygen concentrator;
- a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material;
- a user interface configured to allow a patient to adjust and monitor operation of the portable oxygen concentrator;
- a carrying device for transporting the portable oxygen concentrator;
- wherein the housing of the cartridge module is configured to at least partially surround the case of the separation cartridge,
- 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 the outlet is spaced-apart from the axis, and
- wherein the first direction and the second direction are substantially parallel to the axis.

EX1002 ('628 Patent FH), 116-20.

171. The added features were not specifically recited in the independent claims of the '669 patent (the '628 patent's parent) as amended on January 20, 2020, which Examiner Vasat found unpatentable over *Deane* '426 (EX1047) (and *Deane* (EX1004)). See ¶¶147-154. However, these features are clearly taught by *Deane* '426 (EX1047) (and *Deane* (EX1004)), such as in FIGS. 6 and 7A of each. See §VI.A.2[i]-[j], Examiner Vasat should have rejected these claims in view of *Deane* '426 (EX1047) (or *Deane* (EX1004)).

172. Nevertheless, on May 29, 2019, the Examiner issued a notice of allowance allowing the pending claims. EX1002 ('628 Patent FH), 30-38.

173. This allowance is surprising. First, as discussed above, the pending claims of this application did not require their inlet and outlet ports to be located on different planes spaced apart from each other as recited in the allowed claims of the '669 patent (and as depicted in the annotated drawing here). This was the feature that Examiner Vasat found distinguished the claims of the '669 patent over *Deane* '426. See ¶¶147-154.



174. Second, all of the features of the allowed independent claims were either found by Examiner Vasat to be taught by *Deane* '426 (EX1047) (or *Deane* (EX1004)) during the prosecution of the '669 patent (see ¶¶147-154) and/or are otherwise clearly taught by *Deane* '426 (EX1047) (and *Deane* (EX1004)) (e.g., the claimed arrangement of the inlet, outlet, and bed relative to an axis is taught by FIGS. 6 and 7A of each). The features of the POC and removable separation cartridge recited in independent claims 1 and 8 (issued claims 1 and 11) of the '628 patent (e.g., a POC with a cartridge removable from a receptacle and including

inlets/outlets facing a direction opposite the direction the cartridge is removable from the receptacle and axially spaced apart from each other) are similar to those recited in the claims of the '669 patent (the '628 patent's parent) as amended on January 20, 2020, which Examiner Vasat found unpatentable over *Deane '426* (EX1047) (or *Deane* (EX1004)). See ¶¶147-154. And to the extent there are any differences, they are taught by *Deane '426* (EX1047) (or *Deane* (EX1004)). Accordingly, Examiner Vasat should have rejected these pending claims in view of *Deane '426* (EX1047) (or *Deane* (EX1004)).

175. In any event, Examiner Vasat never rejected the pending claims of this application in view of *Deane '426*. Rather, in the notice of allowance, the Examiner indicated, as can be deduced from the office actions, that he believed *Warren '095*, *Dechene*, *McCombs '924*, and *Bassine* to be the “closest prior art.” EX1002 (*'628 Patent FH*), 36.

176. I believe this is incorrect. *Deane '426* (EX1047) (or *Deane* (EX1004)) is the closest prior art.

177. The '628 Patent then issued on July 23, 2019. EX1053 (*'628 Patent FH*), 23.

6. '614 Patent

178. The '614 patent also issued from a continuation of the '669 patent / '504 application, Application No. 15/931,716 (“the '716 application”), filed on May 14, 2020. EX1070 (*'614 Patent*), Cover.

179. The claims of the '716 application / '614 patent are directed to specific structural features of the separation cartridge, and are therefore relevant to the challenged claims of the '628 patent. Thus, the Examiner's and applicant's comments, responses, and positions as to particular claim language and prior art teachings is of relevance. I therefore will summarize the prosecution of the '716 application / '614 patent below and highlight its importance, including what I consider to be the failure of the Examiner to properly reject the issued claims of the '614 patent in view of *Deane* (EX1004) (or *Deane* '426 (EX1047) or *Deane* '745 (EX1039)).

180. Examiner Jones, who handled the abandoned '977 application, was assigned to the '716 application, rather than Examiner Vasat who had handled the immediate parent '504 application and the other continuation therefrom (the '915 application / '614 patent), or Examiner Patel who had handled the two earlier parent applications (the '362 and '341 applications).

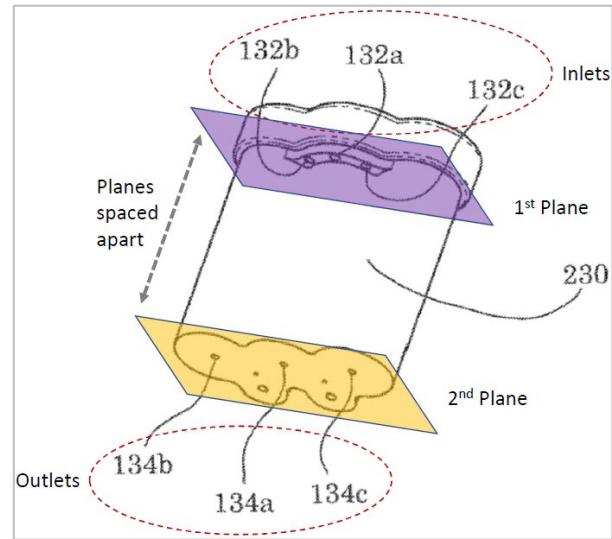
181. On May 14, 2020, the applicant filed an Information Disclosure Statement identifying *Deane* (EX1004) among more than 350 other prior art

references. EX1071 (hereinafter “’614 Patent FH”), 104-518 (*Deane* listed on p. 512).

182. On May 14, 2020, the applicant submitted a preliminary amendment adding new claims 21-36. These claims track issued claims 1-16 of the ’614 patent. EX1071 (*’614 Patent FH*), 88-95.

183. The features of the removable separation cartridge recited in independent claims 21, 32, and 33 (and issued claims 1, 12, and 13) of the ’614 patent (*e.g.*, a cartridge removable from a receptacle and including inlets/outlets facing a direction opposite the direction the cartridge is removable from the receptacle and axially spaced apart from each other) are similar to those recited in the claims of the ’669 patent (the ’614 patent’s parent) as amended on January 20, 2020, which Examiner Vasat found unpatentable over *Deane* ’426 (EX1047) (or *Deane* (EX1004)). See ¶¶147-154. And to the extent there are any differences, they are taught by *Deane* ’426 (EX1047) (or *Deane* (EX1004)). Accordingly, Examiner Jones should have rejected these pending claims in view of *Deane* ’426 (EX1047) (or *Deane* (EX1004)).

184. In particular, the pending claims of this application do not require their inlet and outlet ports to be located on different planes spaced apart from each other as recited in the allowed claims of the '669 patent (and as depicted in the annotated drawing here). This was the feature that Examiner Vasat found distinguished



the claims of the '669 patent over *Deane* '426). See ¶¶147-154. And to the extent Patent Owner (“PO”) argues the flow directions recited in the '614 patent’s claims provide any differentiation from the claims of the '669 patent, these features are clearly taught by *Deane* '426 (EX1047) (and *Deane* (EX1004)), such as in FIGS. 7A of each.

185. An office action issued on May 24, 2022 rejecting claims 21-36 only on the ground of non-statutory double patenting based on claims of the '628 and '669 patents. EX1071 (*'614 Patent FH*), 22.

186. Examiner Jones found the claims of the '614 patent and '669 patent close enough to issue a double patenting rejection (which I understand to mean that he did not view the claims to be separately patentable from each other). In spite of the fact that the pending claims did not include the features that differentiated the

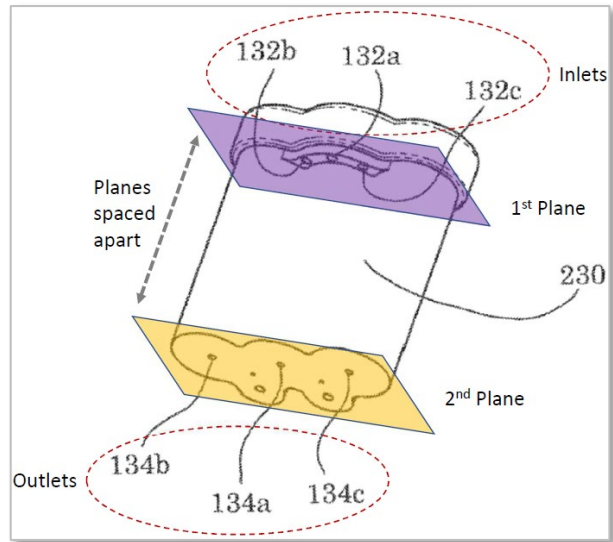
allowed claims of the '669 patent from *Deane '426* in the view of Examiner Vasat (and do not otherwise recite any features not clearly taught by *Deane '426*), Examiner Jones did not reject the pending claims in view of *Deane '426*.

187. Applicant filed a terminal disclaimer and on June 8, 2022 and the Examiner issued a notice of allowance allowing the pending claims. EX1071 (*'614 Patent FH*), 7-18. In the Notice of Allowance itself, the Examiner offered no statement explaining his reasons for allowance of the pending claims, such as over *Deane '426* (*i.e.*, there is no statement similar to that by Examiner Vasat as to the allowed claims of the '669 patent (reproduced in ¶170 above) that indicates what the closest prior art to the claims of the '614 patent was and what makes the claims of the '614 patent patentable in the Examiner's view). The '614 patent then issued on July 19, 2022. EX1071 (*'614 Patent FH*), 1.

C. The Examiner Should Have Rejected the Claims of the '628 Patent In View of *Deane '426* (and/or *Deane*) During Prosecution

188. As I discussed above in connection with the prosecution of the '669 patent, Examiner Vasat found *Deane '426* (EX1047) to be the closest prior art to the issued claims of the '669 patent. EX1052 (*'669 Patent FH*), 16. *Deane* (EX1004), upon which I rely in the Grounds below, includes the same relevant disclosure as *Deane '426* (EX1047).

189. The features that Examiner Vasat required to be added to the claims of the '669 patent to differentiate them from *Deane* '426 (EX1047) (and *Deane* (EX1004)) were that the inlet and outlet ports of the cartridge are disposed on first and second planes spaced apart from each other.⁶ As discussed above, this relationship is depicted in an annotated version of FIG. 15 of the '669 patent, where the purple plane is an example of the first plane and orange plane is an example of the second, where the planes are spaced apart from each other as shown.



190. The Examiner, however, also indicated that the versions of the '669 patent's independent claims as amended on January 20, 2020 (*see, e.g.*, claim 38 below) were **not** patentable over *Deane* '426 (EX1047) (and *Deane* (EX1004)). EX1052 ('669 Patent FH), 16, 19.

⁶ In particular, among other things, the allowed claims of the '669 patent require that the inlet/outlet ports along two axes for two different adsorbent beds be disposed in the same plane and the corresponding respective outlet/inlet ports for the two adsorbent beds be disposed on a separate plane spaced apart from the inlet port plane. *See* ¶149.

38. (New) A portable oxygen concentrator, comprising:

- a receptacle;
- a cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the cartridge comprising:
 - a first bed of adsorbent material disposed along a first axis, wherein the first axis is substantially parallel to the first direction;
 - a second bed of adsorbent material disposed along a second axis spaced-apart from the first axis, wherein the second axis is substantially parallel to the first direction;
 - a first port disposed along the first axis, the first port configured to receive fluid flowing to the first bed or to expel fluid flowing away from the first bed;
 - a second port spaced-apart from the first axis and configured to receive fluid flowing to the first bed or to expel fluid flowing away from the first bed;
 - a third port disposed along the second axis and configured to receive fluid flowing to the second bed or to expel fluid flowing away from the second bed; and
 - a fourth port spaced-apart from the second axis and configured to receive fluid flowing to the second bed or to expel fluid flowing away from the second bed;

wherein the first, second, third, and fourth ports are oriented in a second direction opposite the first direction.

191. In other words, in the Examiner's opinion, the features recited in the January 20, 2020 version of claim 38 of the '669 patent were no different from *Deane '426's* separation cartridge, and claim 38 would not be allowable unless it were amended to include the spaced-apart plane language above. I agree that the features recited in then-pending claim 38 of the '669 patent were no different from *Deane '426's* POC and separation cartridge.

192. The independent claims of the '628 patent are similar in scope to (and broader than) the January 20, 2020 versions of the '669 patent claims in relevant part. To the extent there are added features in the claims of the '628 patent as compared to the '669 patent claims, they relate to well-known features such as removable power packs and user interfaces that are clearly taught by *Deane* '426 (EX1047) (and *Deane* (EX1004)). To the extent there are specific features in the claims of the '669 patent that are not specifically recited in the '628 patent claims (e.g., two beds and four ports), the '628 patent claims recite a broader concept (e.g., one bed and two ports) and are thus not patentably different in my understanding (*see* below). To demonstrate the similarity, I compare below the January 20, 2020 version of claim 38 of the '669 patent (*i.e.*, the version ***before*** the Examiner's amendment resulting in allowance) with issued claim 11 of the '628 patent, with examples of similar claim elements highlighted with the same font color to enable ready comparison.

<u>'628 Patent</u>	<u>'669 patent</u>
[11a] 11. A portable oxygen concentrator, comprising:	38. A portable oxygen concentrator, comprising:
[11b] a cartridge module comprising a housing, the housing defining a receptacle;	a receptacle;
[11c] a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the separation	a cartridge selectively removable from the receptacle by movement relative to

'628 Patent

cartridge comprising an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen; and

[11d] a power pack removable from the portable oxygen concentrator,

[11i] wherein the bed of adsorbent material is disposed along an axis,

[11j] wherein one of the inlet and the outlet is disposed along the axis,

[11k] wherein the other of the inlet and the outlet is spaced-apart from the axis, and

[11l] wherein the first direction and the second direction are substantially parallel to the axis.

'669 patent

the receptacle in a first direction, the cartridge comprising:

a first bed of adsorbent material disposed along a first axis, wherein the first axis is substantially parallel to the first direction;

a second bed of adsorbent material disposed along a second axis spaced-apart from the first axis, wherein the second axis is substantially parallel to the first direction;

a first port disposed along the first axis, the first port configured to receive fluid flowing to the first bed or to expel fluid flowing away from the first bed;

a second port spaced-apart from the first axis and configured to receive fluid flowing to the first bed or to expel fluid flowing away from the first bed;

a third port disposed along the second axis and configured to receive fluid flowing to the second bed or to expel fluid flowing away from the second bed; and

a fourth port spaced-apart from the second axis and configured to receive fluid flowing to the second bed or to expel fluid flowing away from the second bed;

wherein the first, second, third, and fourth ports are oriented in a second direction opposite the first direction.

193. It can be easily seen via this comparison that the scope of these claims is quite similar, as follows (with color coding to ease review):

- Both claims recite a **POC** with a **cartridge selectively removable** from a **receptacle** in **a first direction**;
- Both claims recite that the **cartridge** includes **inlets and outlets (ports) facing a second direction opposite the first**;
- Both claims recite that the cartridge includes **adsorbent arranged on an axis** of the cartridge; and
- Both claims recite one of the cartridge's **inlets and outlets (ports)** **are** disposed on **the first axis** and the other is **spaced apart** from **the axis**.

194. The only apparent differences in these claims is that: (i) the January 20, 2020 versions of the '669 patent's claims (*e.g.*, claim 38 above) expressly recite that its cartridge includes *two* adsorbent beds (in accordance with the exemplary embodiments of the '669 and '628 patents' specification), while claim 11 of the '628 Patent appears to have been drafted in an attempt to more broadly cover a cartridge with at least one adsorbent bed (which is not shown in either the '669 or '628 patents' specifications); (ii) the '628 patent's claim 11 specifies the receptacle is arranged in a cartridge module while claim 38 of the '628 patent does not; and (iii) the '628 patent's claim 11 specifies the presence of a removable power pack in the POC while claim 38 of the '628 patent does not. Difference (i) is not a substantive difference for patentability, in my understanding, because as "at least one" includes two or more. And differences (ii) and (iii) are clearly taught

by *Deane* '426 (EX1047) (and *Deane* (EX1004)). See FIGS. 6 and 7A of each and §VI.A.8[11b]-[11d].

195. Given the above similarity of the above claims (and the teachings of *Deane* '426), Examiner Vasat should have rejected the pending claims of the '628 patent in view of *Deane* '426 (EX1047) (or *Deane* (EX1004)) as he did the claims of the '669 patent. There is no evidence that Examiner Vasat properly considered *Deane* '426 *vis-à-vis* the claims of the '628 patent, as he did not issue any prior art rejections based on *Deane* '426 during prosecution. Had Examiner Vasat properly considered *Deane* '426, along with the remainder of the prior art of record, including the references I discuss herein in §§I and III (or other similar prior art), the claims of the '628 patent would not have issued. In my opinion, the examiner erred by allowing the claims of the '628 patent over *Deane* '426 (EX1047) (or *Deane* (EX1004)).

D. Challenged Claims

196. I understand that Petitioner is challenging the validity of Claims 1-23 of the '628 patent (“the challenged claims”) in the Petition for *Inter Partes* Review to which this declaration will be attached. Those claims are reproduced in Appendix 3.

197. I have considered each of the claims of the '628 patent (Claims 1-23), as well the '628 patent's prosecution history (EX1002), and the other exhibits identified in Appendix 2, in forming my opinions.

III. SUMMARY OF THE PRIOR ART

198. There are a number of patents and publications which constitute prior art to the '628 patent. I have reviewed and considered the prior art discussed in this section, along with the materials listed in Appendix 2.

A. Invalidity Grounds

199. Based on my review and analysis of the materials listed in Appendix 2, my opinions regarding the understanding of a POSITA in the 2004-2005 timeframe, and my training and experience, it is my opinion that the challenged claims of the '628 patent are invalid based on the following grounds:

Grounds	Claims	Statutory Basis	Prior Art
1	1-4, 6-17, 19-23	§103	<i>Deane</i> in view of <i>Dubois</i> and <i>Berntson</i>
2	2, 3, 14, 15, 22, 23	§103	<i>Deane</i> in view of <i>Dubois</i> , <i>Berntson</i> , and <i>Occhialini</i>

3	5, 18	§103	<i>Deane</i> in view of <i>Dubois, Berntson, and Basset</i>
4	1-4, 7-17, 19, 21-23	§103	<i>Deane</i>
5	2, 3, 14, 15, 22, 23	§103	<i>Deane</i> in view of <i>Occhialini</i>
6	5, 18	§103	<i>Deane</i> in view of <i>Basset</i>

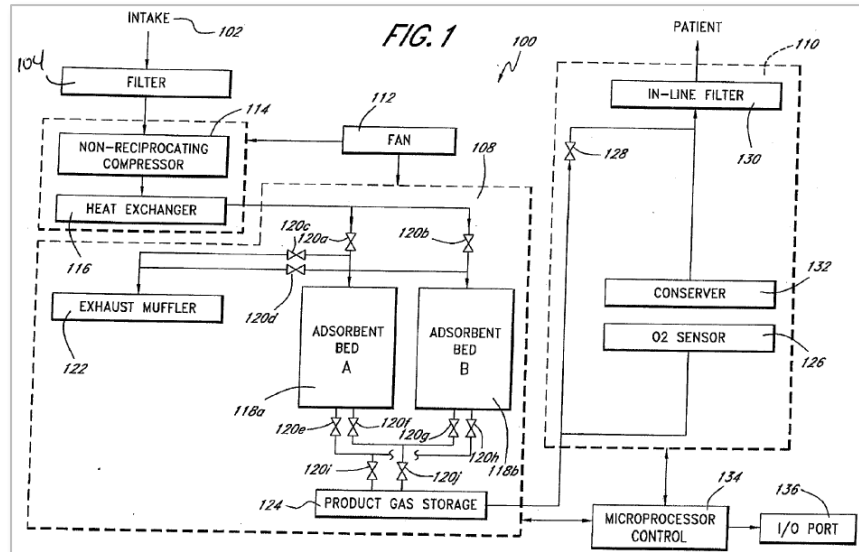
B. *Deane* (EX1004)

200. *Deane* (EX1004) is U.S. Patent Application Publication No. 2005/0072306 to Deane, Taylor, Bare, Sargent, and Scherer, filed on October 7, 2003 and published on April 7, 2005.

201. I understand that *Deane* qualifies as prior art to the '628 patent under at least pre-AIA 35 U.S.C. § 102(e) because it is a publication of an application by another that was filed before the (alleged) invention of the claims of the '628 patent.

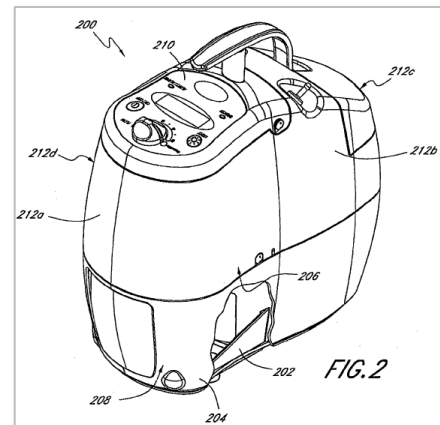
202. As described in much more detail below in relation to the challenged claims, *Deane* teaches a portable, compact, oxygen concentrator suitable for ambulatory use. EX1004 (*Deane*), ¶[0002]. *Deane* teaches its basic component arrangement in its FIG. 1 schematic. Specifically, FIG. 1 shows system 100 with intake 102,

compressor assembly 106 for pressurizing the intake air to provide a feed gas, a pressure swing adsorption (PSA) unit



108 which receives and processes the feed gas to produce a product gas having a higher oxygen content than the ambient air, and a gas delivery system 110 for delivering the product gas to a patient. EX1004 (*Deane*), ¶[0032]. *Deane* teaches that its PSA unit 108 includes two adsorbent beds 118 a, 118 b and a plurality of valves 120 a-j connected thereto for directing gas in and out of the beds 118 a, 118 b. EX1004 (*Deane*), ¶[0036].

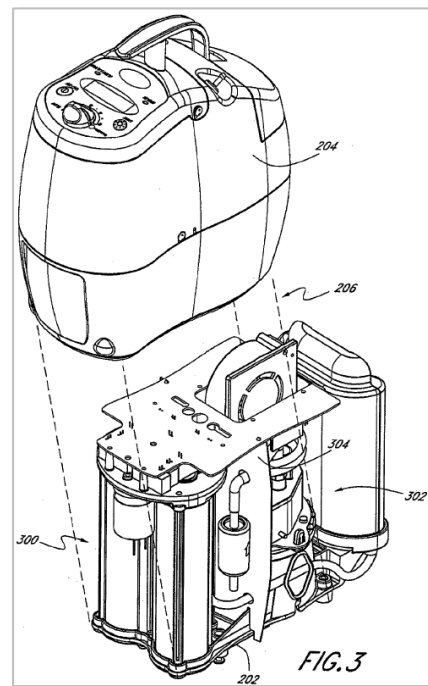
203. *Deane*'s FIG. 2 shows portable oxygen concentrator 200 with chassis 202 and



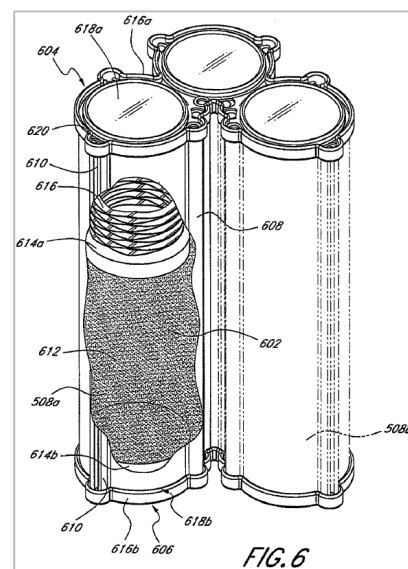
shell 204 forming a housing 206 in which various components are mounted.

EX1004 (*Deane*), ¶[0057].

204. As shown in FIG. 3, the components in the housing 206 are structurally supported by the chassis 202 and the chassis 202 is removably attached to the shell 204 such that the shell can be removed to provide access for testing, repair, or maintenance of the components. EX1004 (*Deane*), ¶[0058].

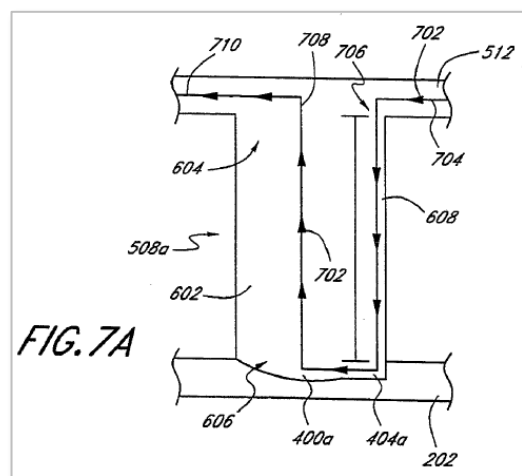


205. FIG. 6 shows adsorbent bed columns 508a, 508b with a “novel single-ended column design” where column 508a includes elongated adsorbent housing 602 with upper end 604 and lower end 606, each defining an opening through which gas can flow in and out of the housing 602, and integrated feed tube 608 extending from upper end 604 to lower end 606, which allows gas to be routed to lower end 606. EX1004 (*Deane*), ¶[0066]. *Deane* teaches that “[t]his design eliminates the need of a second manifold ... and allows all flow passages in the manifold to be co-located in a single plane, which



significantly reduces the number of tubing connections and potential leak points in the unit.” EX1004 (*Deane*), ¶[0066]. Adsorbent bed housing 602 includes adsorbent material 612 (zeolite), upper and lower restraining disks 614a, 614b (filters) for inhibiting movement of the adsorbent material 612, spring 616 that applies pressure across the upper restraining disk 614a to keep disk 614a in position.” EX1004 (*Deane*), ¶[0068].

206. FIG. 7A is a schematic illustration of adsorbent bed column 508a, during feeding. Specifically, feed gas 702 is directed from feed stream 704 into upper opening 706 of feed tube 608, travels downwardly through tube 608 and through recess 400a into lower end 606 of

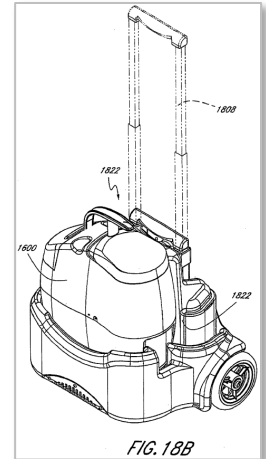


housing 602, then travels upwardly through the adsorbent material in housing 602, which removes nitrogen, and finally flows out of upper end 604 of housing 602 into product stream 710. Similarly, FIG. 7B (not shown here) is a schematic illustration of flow of the purge gas. EX1004 (*Deane*), ¶[0070].

207. *Deane* also teaches that a “mobility cart” 1800 may be provided with its POC, such as shown in FIGS. 18A-18B.

EX1004 (*Deane*), ¶[0099]-[0101].

208. Based on my review of the prosecution history of the '628 patent, while applicant submitted the patent that ultimately issued from *Deane* (U.S. Patent No. 7,135,059; EX1038 (*Deane* '059)) and *Deane* '426 (and some other similar references to *Deane*) among more than 200 prior art references in a June 13, 2018 IDS (EX1002 ('628 Patent FH), 413-34), the Examiner did not apply *Deane* (or any other similar reference to *Deane*) in any rejection or otherwise mention *Deane* during prosecution.



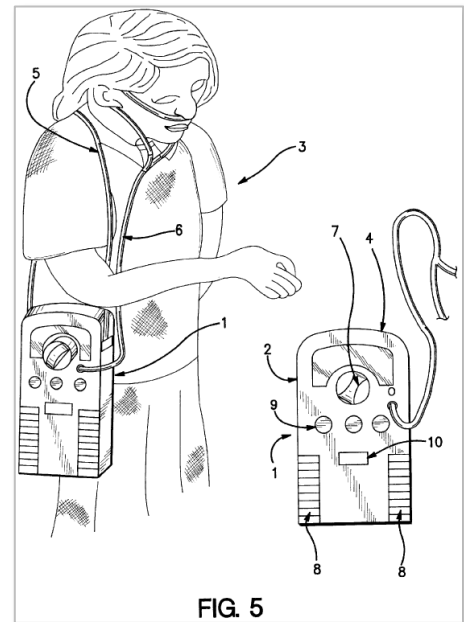
209. As discussed above and below, other references with a similar disclosure to *Deane* were applied by the Examiner(s) in different applications related to the '628 patent, and the Examiner erred by not applying *Deane* (or other similar references to *Deane*) against the claims of the '628 patent.

C. *Dubois* (EX1005)

210. *Dubois* (EX1005) is U.S. Patent No. 6,520,176 to Dubois et al., published on February 18, 2003. *Dubois* was filed on June 30, 2000, and claims priority to French Application 0006697. EX1005 (*Dubois*), Cover.

211. I understand that *Dubois* qualifies as prior art to the '628 patent under at least 35 U.S.C. § 102(b) because it was published more than one year before the earliest filing date attributable to the '628 patent (February 9, 2005).

212. As described in more detail below in relation to the challenged claims, *Dubois* teaches, as shown in FIG. 5 (reproduced here), a portable concentrator 1 with a housing “of a size and weight permitting the patient 3 to carry it while walking.” EX1005 (*Dubois*), 6:16-20, FIG. 5. *Dubois* further teaches that the concentrator may be carried by a handle 4 or shoulder strap 5, as shown in FIG. 5. EX1005 (*Dubois*), 6:21-25, FIG. 5.



213. Based on my review of the prosecution history of the '628 patent, while applicant submitted *Dubois* in a June 13, 2018 IDS (EX1002 ('628 Patent FH), 413-34) along with more than 200 other prior art references, the Examiner did not apply *Dubois* in any rejection or otherwise mention *Dubois* during prosecution. This appears to also be the case with regard to the other patents and applications related to the '628 patent discussed in §II.B.

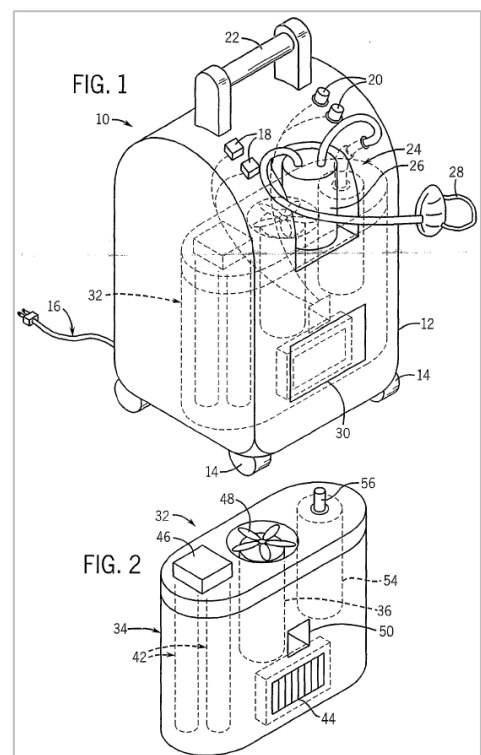
D. *Berntson* (EX1006)

214. *Berntson* (EX1006) is a PCT International Application Publication No. WO 2005/009590 to *Berntson*, published on February 3, 2005. It was filed on July 24, 2004 and claims priority to U.S. Provisional Application No. 60/489,674 (EX1067 (*Berntson Provisional*)), filed July 24, 2003. EX1006 (*Berntson*), Cover; EX1067 (*Berntson Provisional*).

215. I understand that *Berntson* qualifies as prior art to the '628 patent under at least 35 U.S.C. § 102(e) because it is a publication of an application by another that was filed before the (alleged) invention of the claims of the '628 patent.

216. As described in more detail below in relation to the challenged claims, *Berntson* teaches an oxygen concentrator.

EX1006 (*Berntson*), ¶[0003]. *Berntson* teaches that assembling multiple parts of existing oxygen concentrators together is difficult, and reduces serviceability. EX1006 (*Berntson*), ¶¶[0004]-[0006]. *Berntson*'s solution is a separate oxygen-rich air generator (ORAG) unit 32 that is removably provided in the housing 12 of an oxygen concentrator 10, as shown in FIGS. 1 and



2 (reproduced here). EX1006 (*Berntson*), ¶[0011], FIGS. 1-2. Chassis 34 of ORAG may be removably fastened to cabinet 12, and contains pump 36, adsorbent containers 42, inlet filtration 44, valve system 46, cooling fan 48, power connector 50, and an oxygen tank. EX1006 (*Berntson*), ¶¶[0012]-[0013]. *Berntson* specifies that “[s]ome components could be provided either as part of the ORAG 32 or not.” EX1006 (*Berntson*), ¶[0017].

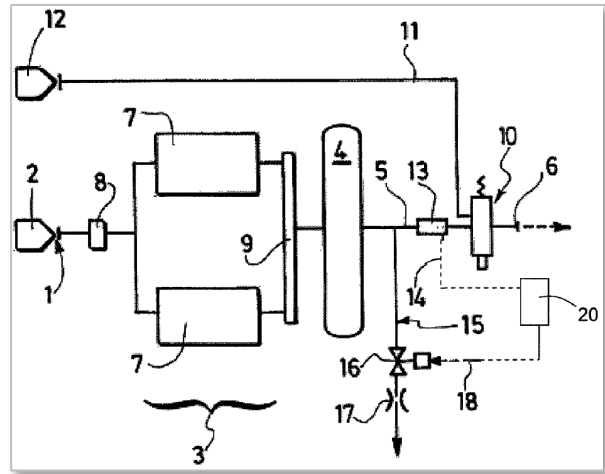
217. Based on my review of the file history of the ’628 patent, it does not appear that *Berntson* was of record and/or considered by the Examiner. I also did not find *Berntson* of record in any of the file histories of the patents related to the ’628 patent discussed in §II.B.

E. *Basset* (EX1007)

218. *Basset* (EX1007) is U.S. Patent Application Publication No. 2005/0028868 to Basset et al., published on February 10, 2005. It was filed on August 2, 2004, and claims priority to French Application No. 0350395 filed August 4, 2003. EX1007 (*Basset*), Cover.

219. I understand that *Basset* qualifies as prior art to the ’628 patent under at least 35 U.S.C. § 102(e) because it is a publication of an application filed by another before the (alleged) invention of the claims of the ’628 patent.

220. As described below in relation to the challenged claims, *Basset* teaches a “self-contained portable oxygen generator”. EX1007 (*Basset*), ¶[0001]. In the embodiment of its FIG., *Basset* teaches an inlet 1, PSA unit 3 with two adsorbers 7, manifold 9, oxygen buffer tank 4, and outlet 5/6.



EX1007 (*Basset*), ¶[0012]. *Basset* also teaches that the adsorbers contain a “Zeolite, advantageously a lithium zeolite of the LiX type, preferably an LiLSX Zeolite.” EX1007 (*Basset*), ¶[0013].

221. Based on my review of the prosecution history of the ’628 patent, it does not appear that *Basset* was of record and/or considered by the Examiner. I also did not find *Basset* of record in any of the file histories of the patents related to the ’628 patent discussed in §II.B.

F. *Occhialini* (EX1073)

222. *Occhialini* (EX1073) is U.S. Patent Application Publication No. 2005/0257686 A1 to Occhialini et al., published on November 24, 2005. It was filed on May 21, 2004. EX1073 (*Occhialini*), Cover.

223. I understand that *Occhialini* qualifies as prior art to the '628 patent at least 35 U.S.C. § 102(e) because it is a publication of an application filed by another before the (alleged) invention of the claims of the '628 patent.

224. *Occhialini* teaches that there is a “need for optimized design of small, easily-carried, adsorption-based oxygen concentrators [that] is met by the various embodiments of the present invention.” EX1073 (*Occhialini*), ¶[0004]. In particular, *Occhialini* teaches:

a minimum weight range can be determined for an adsorption-based system for any operable combination of product flow rate, product purity, product delivery pressure, and run time. This may be achieved by determining the weight of each variable-weight system component as a function of a selected process parameter, adding the weights of these components at various values of the selected parameter, and generating a curve of variable weight vs. the selected parameter. This curve generally exhibits a minimum weight in a preferred range of the selected process parameter. The selected process parameter is the minimum bed pressure during the process cycle.

EX1073 (*Occhialini*), ¶[0004]. In other words, *Occhialini* teaches that many variables, including weight of various components of a POC, may be tuned to achieve particular POC performance metrics.

225. *Occhialini* teaches various examples of relationships between the total system weight, adsorbent, compressor, and battery related to various performance metrics of the POC. EX1073 (*Occhialini*), ¶¶[0098]-[0114], FIGS. 2-17.

226. Based on my review of the prosecution history of the '628 patent, while applicant submitted *Occhialini* in a June 13, 2018 IDS (EX1002 ('628 Patent

FH), 413-34) along with more than 200 other prior art references, the Examiner did not apply *Occhialini* in any rejection or otherwise mention *Occhialini* during prosecution. This appears to also be the case with regard to the other patents and applications related to the '628 patent discussed in §II.B.

IV. LEVEL OF ORDINARY SKILL IN THE ART

227. In determining the characteristics of a hypothetical person of ordinary skill in the art (“POSITA”) of the '628 patent at the time of the claimed invention, I considered several things, including various prior art techniques relating to portable oxygen concentrators and related technologies, the types of problems that such techniques gave rise to, and the rapidity with which innovations were made. I also considered the sophistication of the technologies involved, and the educational background and experience of those actively working in the field at the time. I also considered the level of education that would have been necessary to understand the '628 patent. Finally, I placed myself back in the relevant period of time and considered the engineers that I have worked with and supervised in the field of portable oxygen concentrators and related technologies.

228. I came to the conclusion that a person of ordinary skill in the field of art of the '628 patent would have had at least a bachelor’s degree, or the equivalent degree, in mechanical engineering, chemical engineering, or a related field, and 2-3 years of experience in the research, design, or development of portable oxygen

concentrators and related hardware, software, and firmware, or equivalent experience. A person with less education but more relevant practical experience, or more education and less experience, may also meet this standard.

229. In the 2004-2005 timeframe, and in view of the types of problems encountered in the art and prior art solutions to those problems, a POSITA would have known and had the skills necessary to design, implement, and/or utilize each of the constituent parts of portable oxygen concentrators, including adsorption beds, compressors/pumps, batteries, electronic controls, and various conduits, valves, and related flow control systems and devices. This would include, but is not limited to, how these components operate (alone and together), the adsorption cycles provided by portable oxygen concentrators, and the various techniques and prior art systems discussed above in §I and the Grounds below.

230. I believe that I am at least a POSITA and, furthermore, I have supervised those who were also POSITAs. Moreover, I qualified as a POSITA as of 2004-2005. Accordingly, I believe that I am qualified to opine from the perspective of a POSITA regarding the challenged claims.

V. CLAIM CONSTRUCTION

231. For purposes of this *inter partes* review, I have considered the claim language, specification, and portions of the prosecution history of the '628 patent (and its related patents discussed in §II.B), to determine the meaning of the claim

language as it would have been understood by a POSITA. I understand that the “plain and ordinary meaning” or *Philips* standard has traditionally been applied in district court litigation, where a claim term is given its plain and ordinary meaning in view of the specification from the viewpoint of a POSITA.

232. I have applied the *Philips* standard in my analysis. Unless otherwise stated, I have applied the plain and ordinary meaning to all claim terms.

A. “Separation Cartridge”

233. This term is found in various challenged claims. For example, independent claim 1 recites “separation cartridge” several times (emphasis and element numbers added) as follows:

[1a] 1. A portable oxygen concentrator, comprising:

[1b] a cartridge module comprising a housing, the housing defining a receptacle;

[1c] a ***separation cartridge*** selectively removable from the receptacle by movement relative to the receptacle in a first direction, the ***separation cartridge*** comprising a case at least partially defining an outer volume of the ***separation cartridge***, an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen, the case at least partially surrounding the bed of adsorbent material;

[1d] a power pack removable from the portable oxygen concentrator;

[1e] a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material;

[1f] a user interface configured to allow a patient to adjust and monitor operation of the portable oxygen concentrator;

[1g] a carrying device for transporting the portable oxygen concentrator;

[1h] wherein the housing of the cartridge module is configured to at least partially surround the case of the *separation cartridge*,

[1i] wherein the bed of adsorbent material is disposed along an axis, [1j] one of the inlet and the outlet is disposed along the axis, and [1k] the other of the inlet and the outlet is spaced-apart from the axis, and

[1l] wherein the first direction and the second direction are substantially parallel to the axis.

234. Claim 11 also recites “separation cartridge” several times (emphasis and element numbers added) as follows:

[11a] 11. A portable oxygen concentrator, comprising:

[11b] a cartridge module comprising a housing, the housing defining a receptacle;

[11c] a *separation cartridge* selectively removable from the receptacle by movement relative to the receptacle in a first direction, the *separation cartridge* comprising an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen; and

[11d] a power pack removable from the portable oxygen concentrator,

[11i]⁷ wherein the bed of adsorbent material is disposed along an axis,

[11j] wherein one of the inlet and the outlet is disposed along the axis,

[11k] wherein the other of the inlet and the outlet is spaced-apart from the axis, and

[11l] wherein the first direction and the second direction are substantially parallel to the axis.

⁷ Element numbering intentionally skipped to align like elements.

235. Dependent claims 12 and 21 also recite “separation cartridge.”

236. “Separation cartridge” does not have a specific meaning in the art. Outside of the context of the ’628 patent, a POSITA would have generally understood a “separation cartridge” to be some type of case, housing, or container that is insertable into a POC and that is equipped with at least two ports; one or more to permit fluid to flow inwards, and one or more to permit fluid to flow outwards; that contains at least one medium that separates one or more constituents from a fluid flowing through it. *See, e.g.*, EX1059 (“*American Heritage*”) (defining “cartridge” as, *e.g.*, “[a] small modular unit designed to be inserted into a larger piece of equipment”), EX1060 (“*New Oxford*”) (defining “cartridge” as, *e.g.*, “a container holding a spool of photographic film, a quantity of ink, or other item or substance, designed for insertion into a mechanism” and “separation” as “the division of something into constituent or distinct elements”), (EX1061; (“*Bloomsbury*”) (defining “cartridge” as, *e.g.*, “a container for liquid or powder that is loaded into a device, *e.g.*, a removable ink container for a pen or printer” and “separation” as “the splitting of something into its component parts”), and EX1062 (“*Webster*”) (defining “cartridge” as, *e.g.*, “a usu. Replaceable or refillable case containing loose material and designed to permit ready insertion into a larger mechanism, apparatus, or installation” and separation as “an act of instance of dividing”). I also performed a Google Patents search for “separation cartridge”

appearing in patent documents with priority dates before February 9, 2005.⁸ These documents confirm the above general understanding.

237. Beyond this, the language of the challenged independent claims provides some initial guidance as to the meaning of “separation cartridge.” For example, claim 1 specifies that the “separation cartridge” be “selectively removable from the receptacle” and have a “bed of adsorbent material, a “case at least partially defining an outer volume” and “partially surrounding the bed of adsorbent material,” an “inlet,” and an “outlet.”

238. Beyond the claim language, I have also reviewed the ’628 patent’s specification, which provides more guidance as to the meaning of “separation cartridge.” While the specification does not provide an explicit definition for “separation cartridge,” it repeatedly discusses the features of its “separation cartridge.”

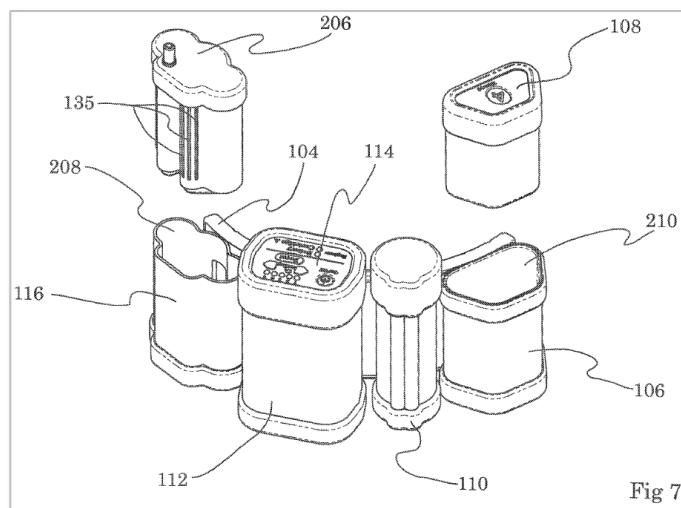
239. First, in the “Brief Summary of the Invention,” the specification states:

A removable gas *separation cartridge* includes a housing having an inlet port, an outlet port, and a bed of adsorbent material. *The cartridge* is removable from an oxygen concentrator which separates oxygen from ambient air by using an adsorption process.

⁸<https://patents.google.com/?q=%22separation+cartridge%22&before=priority:20050205&num=100>

EX1001 ('628 Patent), 2:54-58 (emphasis added). I note that this particular (singular) description, however, was **not** found in original applications of the '628 patent's family. For example, it cannot be found in the '490 Patent (*see, e.g.,* EX1049 ('490 Patent FH) at 341 (showing original application papers)), the abandoned '362 Application (*see, e.g.,* EX1050 at 465), or the abandoned '977 Application (*see, e.g.,* EX1051 at 477). It was only added by applicants to the '669 Patent and its continuations, the '628 and '614 Patents, nine years after the original '490 Patent was filed.

240. As for what was originally described as the alleged invention in the '490 patent's specification and carried through to the '628 patent's specification without change, the '628 patent's specification repeatedly discusses both "adsorbent cartridge 206" and its related "separation cartridge module 116," such as illustrated in FIG. 7, reproduced



here. EX1001 ('628 Patent), 4:7-42. In particular regarding FIG. 7, the '628 patent's specification indicates that "[a]dsorbent cartridge 206 has been removed from receptacle 208 of cartridge module 116" and that "[a]dsorbent cartridge 206

and power pack 108 are easily removable to facilitate replacement.” EX1001

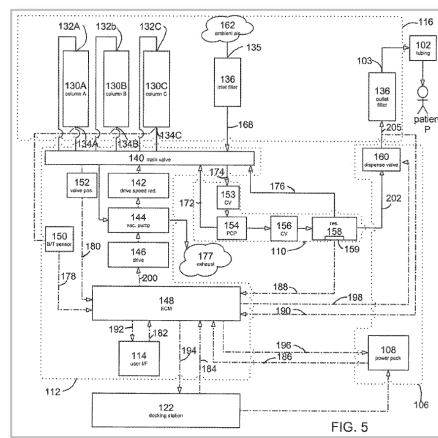
(*'628 Patent*), 11:67-12:3. Further, the *'628 patent's* specification indicates:

Cartridge 206 contains a quick-connect attachment (not illustrated) for inlet lines 164 a-164 c, outlet lines 166 a-166 c, inlet air line 168, and final product gas line 205 (not illustrated) within receptacle 208. Also present on **cartridge 206** are air inlet ports 135 which receive ambient air 162 for separation. **Adsorbent cartridge 206** contains adsorbent material that deteriorates in efficiency as it is used and ages.

EX1001 (*'628 Patent*), 12:6-14 (emphasis added).

241. The *'628 patent's* specification also describes, with reference to FIG. 5, an “adsorbent cartridge module 116” in block figure format, where “adsorbent cartridge module 116” includes

adsorbent columns 130 a-130 c each containing respective inlet ports 132 a-132 c and outlet ports 134 a-134 c, air inlet filter 136, and product gas final filter 138. Ambient air enters air inlet port 135, passes through air inlet filter 136, and enters valve 140 for distribution to adsorbent columns 130 a-130 c. Product gas passes through final filter 138 and product gas outlet port 103 into tubing 102 for delivery to patient P. Inlet ports 132 a-132 c of adsorbent columns 130 a-130 c connect to valve 140 through inlet lines 164 a-164 c. Similarly, outlet ports 134 a-134 c connect to valve 140 through outlet lines 166 a-166 c.



EX1001 ('628 Patent), 4:60-5:4.

242. Separation cartridge 206 is further described by the '628 patent's specification with reference to FIGS. 15 and 16. Regarding FIG. 15 (reproduced here), the '628 patent's specification indicates:

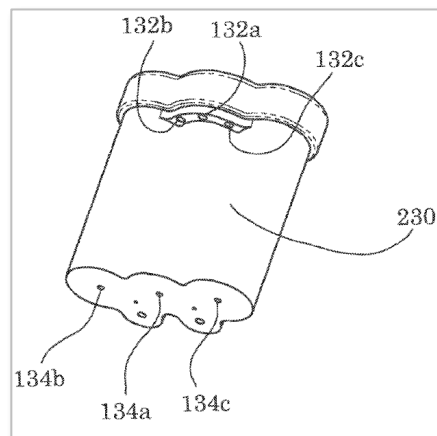


FIG. 15 is a perspective view of separation cartridge 206 contained within separation cartridge module 116. Illustrated are inlet ports 132 a-132 c, outlet ports 134 a-134 c, and casing 230. In the embodiment illustrated, three adsorption columns are contained within casing 230 with one inlet port 132 a-132 c, and one outlet port 134 a-134 c, for each adsorption column 130 a-130 c. Each adsorption column 130 a-130 c is a hermetically sealed container containing a bed of adsorption material, preferably a zeolite capable of adsorbing nitrogen gas, such as lithium low silica 13× zeolite.

EX1001 ('628 Patent), 18:30-40.

243. Finally, regarding FIG. 16 (reproduced here), the '628 patent's specification indicates:

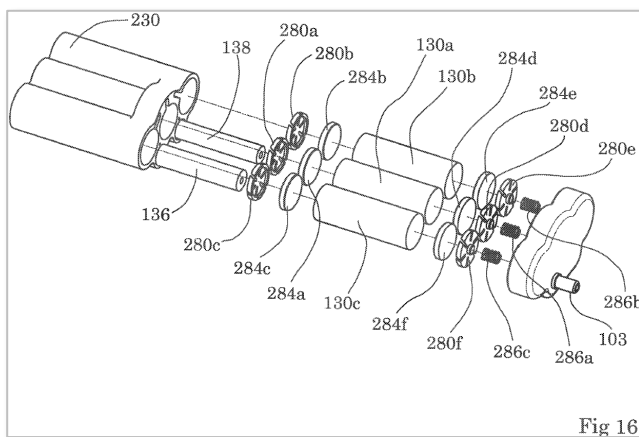


FIG. 16 is a perspective view of the columns 130 a-130 c and the filters 136 and 138 within casing 230 of separation cartridge 206.

Illustrated are final product filter 138 connected to product gas outlet port 103 which connects to tubing 102, inlet air filter 136, and adsorbent columns 130 a-130 c each comprising spin inducers 280 a-280 f, adsorbent material 282 a-282 c, porous filters 284 a-284 f, and springs 286 a-286 c. Springs 286 a-286 c are coil springs that hold

each adsorbent column in compression 130 a-130 c in place within casing 230 of separation cartridge 206 to prevent movement of adsorbent beads. Spin inducers 280 a-280 f help force even distribution of gases through columns 130 a-130 c, which helps to keep the MTZ well defined for more accurate detection.

EX1001 (*'628 Patent*), 18:57-19:3.

244. Thus, each and every preferred embodiment of the '628 patent consistently describes the separation cartridge of the alleged invention as a case having multiple adsorbent columns, each having a dedicated inlet and outlet. In the context of the '628 patent, this makes sense inasmuch as the easy removability of the cartridge (and thus removal of all of its components together) is important according to, for example, the '628 patent's Title, Abstract, Summary of the Invention, *etc.* Moreover, the (allegedly) inventive design of the cartridge also includes, for example, dedicated single inlet and outlet filters (136, 138) for the group of multiple adsorbent columns. Those filters apparently supplement the functions of porous filters (284a-284f), which are at opposite ends of each of the columns. If a single column could be used as a separation cartridge, it would seem that the "dedicated single inlet and outlet filters (136, 138) for the group of multiple adsorbent columns" would be superfluous. Yet, the applicants said nothing about that possible outcome.

245. While it is my understanding that a patent's claim scope should generally not be limited to its exemplary embodiments, I do understand there to be

exceptions where a patent clearly and repeatedly describes its invention in a particular way. Here, each and every preferred embodiment of the '628 Patent utilizes a separation cartridge with multiple adsorbent beds, each having a dedicated inlet and outlet, and that configuration is what provides the usability improvements to which the '628 Patent is directed.

246. The language of claims 1 and 11, read literally, appears to have been drafted in an effort to encompass separation cartridges with only one adsorbent column (or bed). That is, these claims do not explicitly require there to be multiple adsorbent columns, each having a dedicated inlet and outlet. This is contrary to all of the preferred embodiments of the '628 patent, which indicate multiple columns (or beds).

247. There are no single-adsorbent-bed embodiments or alternatives discussed in, or even suggested by, the '628 patent. As discussed above, all of the preferred embodiments have multiple adsorbent columns, each having a dedicated inlet and outlet, which provides the easy removability to which the '628 patent is directed. Moreover, the (allegedly) inventive design of the cartridge also includes, for example, integrated single inlet and outlet filters (136, 138) for the group of multiple adsorbent columns, which militate against the use of multiple separate single columns with individual inlets and outlets.

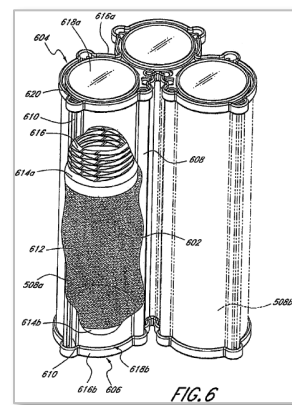
248. Indeed, the only language in the '628 patent that *could* be read as at all supportive of the a single-adsorbent bed arrangement is the language in the Brief Summary of the Invention stating “[a] removable gas separation cartridge includes a housing having an inlet port, an outlet port, and a bed of adsorbent material. The cartridge is removable from an oxygen concentrator which separates oxygen from ambient air by using an adsorption process.” *See. e.g.*, EX1001 ('628 *Patent*), 2:54-58 (emphasis added). But, as I mentioned above, this language did not appear in the original applications of the '628 patent's family (*i.e.*, the '490 patent, the abandoned '362 application, and the abandoned '977 application are silent as to such a concept). Thus, it does not appear to me to be part of what was originally (allegedly) invented here. What was originally (allegedly) invented was the cartridges shown in, for example, FIGS. 5, 7, 15, and 16, which have multiple adsorbent columns, each having a dedicated inlet and outlet, which provides the easy removability to which the '628 patent is directed.

249. Beyond the claims and specification, the '628 patent's prosecution history briefly addresses the meaning of “separation cartridge” as discussed below.

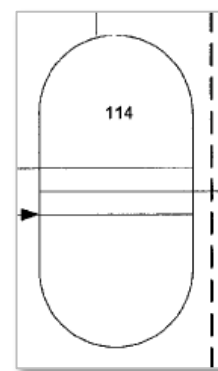
250. Before discussing the '628 patent's prosecution history, however, I will review the prosecution histories of some of the other applications in the '628 patent's family (*see* §II.B above) where the Examiner and/or applicant also addressed the meaning of “cartridge” and/or “separation cartridge.” It is my

understanding that these discussions can inform the meaning of “separation cartridge” in the context of the challenged claims.

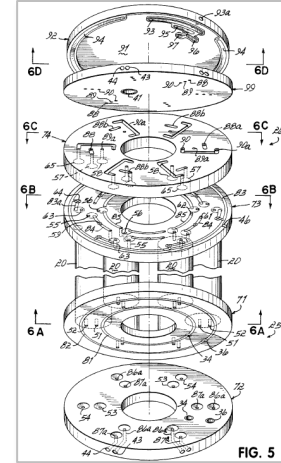
251. For example, in the abandoned '362 application, the Examiner compared “cartridge” to the structure containing two adsorber beds 118a and 118b in *Deane* '745 (EX1039) as part of an obviousness rejection of original claim 1. EX1050 ('362 *Application FH*), 58-59. Like *Deane*, *Deane* '745 teaches the adsorber beds 118a, 118b are arranged in adsorbent housing 602 (see FIG. 6 in each). Applicant did not disagree with the Examiner's position, and instead chose to cancel the rejected claims. EX1050 ('362 *Application FH*), p. 50.



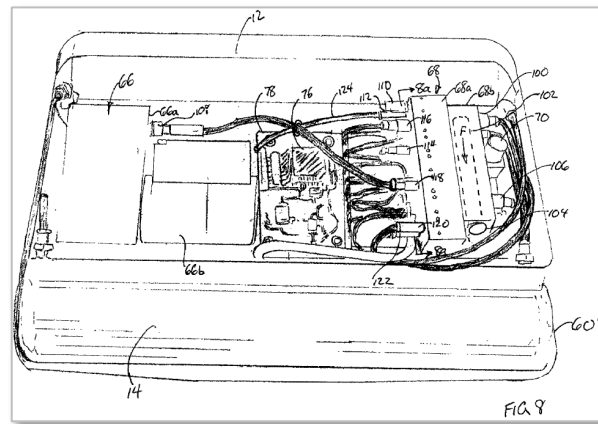
252. In another example, in the abandoned '977 application, the Examiner compared “cartridge” to concentrator 114 in *Hill* '658 (EX1013) as part of an anticipatory rejection of original claim 1. EX1051 ('977 *Application FH*), 27-28. Concentrator 114 includes multiple sieve beds. EX1013 (*Hill* '658), 7:14-32. Applicant did not disagree with the Examiner's position, instead chose to amend the claims to add a specific valve limitation. EX1051 ('977 *Application FH*), 15-20.



253. In another example, during prosecution of the '669 patent, the Examiner compared “separation cartridge” to a housing made up of disks 71a, 37a and cylindrical canisters 21/sieves 20 in *Kulish* (EX1043) as part of an anticipatory rejection of original claim 1. EX1052 ('669 Patent FH), 560-61. Applicant did not disagree with the Examiner’s position, and instead amended the claims to specify the location and opening direction of the inlet and outlet ports. EX1052 ('669 Patent FH), 541-547.



254. In another example, also during prosecution of the '669 patent, the Examiner compared “separation cartridge” to sieve bed 12 of US 2002/0033095 *Warren* '095 (EX1012) as part of an obviousness rejection of amended claim 1 (which recited “at least one column ... and a bed of adsorbent material”). EX1052 ('669 Patent FH),



297-98. This time, applicant **did** argue that the Examiner had not identified a separation cartridge in *Warren* '095. EX1052 ('669 Patent FH), 255-56.

255. Thus, applicant did not disagree with the Examiners’ previous comparisons of prior art multi-adsorber bed cartridges with the claimed “separation cartridge” (e.g., such as *Deane* '745's, *Hill* '658's, and *Kulish* 's). But applicant

did argue that the Examiner had not identified a “separation cartridge” where the Examiner was comparing that element to a cartridge with a single adsorber bed (e.g., *Warren '095's*). This leads me to conclude that applicant viewed “separation cartridge” as reading only on multi-adsorber bed cartridges.

256. Finally, at the end of the prosecution of the '669 patent, the Examiner found that *Deane '426* (EX1047) teaches a cartridge in its FIG. 6. EX1052 ('669 *Patent FH*), 16.

257. Turning back to the '628 patent's prosecution history, the Examiner also compared *Warren '095's* sieve bed 12 to a “separation cartridge.” EX1002 ('628 *Patent FH*), pp. 253-255. Applicant noted the Examiner's position, but did not agree. EX1002 ('628 *Patent FH*), 253-255; *id.* at 237.

258. Based on the above, a POSITA would have understood: (i) the '628 patent's claims require the “separation cartridge” to be removable, have a case, adsorbent beds, inlets, and outlets; (ii) the '628 patent's specification to clearly and repeatedly describe its separation cartridge as a removable housing containing multiple adsorber columns, each having a dedicated inlet and outlet port in the housing; and (iii) the prosecution history of the patents and applications in the '628 patent's family as comporting with the specification's description of multiple adsorber beds.

259. Taking all of the above into account, it is my opinion that a POSITA would have understood “separation cartridge” in the context of the challenged claims of the ’628 patent as “a housing that holds multiple adsorbent columns for gas separation and provides separate inlet and outlet ports for each adsorbent column.”

B. “Receptacle”

260. This term is found in challenged claims 1 and 11 (emphasis and element numbers added) as follows:

[1a] 1. A portable oxygen concentrator, comprising:

[1b] a cartridge module comprising a housing, the housing defining a *receptacle*;

[1c] a separation cartridge selectively removable from the *receptacle* by movement relative to the *receptacle* in a first direction, the separation cartridge comprising a case at least partially defining an outer volume of the separation cartridge, an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen, the case at least partially surrounding the bed of adsorbent material;

[1d] a power pack removable from the portable oxygen concentrator;

[1e] a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material;

[1f] a user interface configured to allow a patient to adjust and monitor operation of the portable oxygen concentrator;

[1g] a carrying device for transporting the portable oxygen concentrator;

[1h] wherein the housing of the cartridge module is configured to at least partially surround the case of the separation cartridge,

[1i] wherein the bed of adsorbent material is disposed along an axis,
[1j] one of the inlet and the outlet is disposed along the axis, and [1k]
the other of the inlet and the outlet is spaced-apart from the axis, and

[1l] wherein the first direction and the second direction are substantially parallel to the axis.

* * *

[11a] 11. A portable oxygen concentrator, comprising:

[11b] a cartridge module comprising a housing, the housing defining a *receptacle*;

[11c] a separation cartridge selectively removable from the *receptacle* by movement relative to the *receptacle* in a first direction, the separation cartridge comprising an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen; and

[11d] a power pack removable from the portable oxygen concentrator,

[11i]⁹ wherein the bed of adsorbent material is disposed along an axis,

[11j] wherein one of the inlet and the outlet is disposed along the axis,

[11k] wherein the other of the inlet and the outlet is spaced-apart from the axis, and

[11l] wherein the first direction and the second direction are substantially parallel to the axis.

261. “Receptacle” does not have a specific meaning in the art. Outside of the context of the ’628 patent, a POSITA would have generally understood a

⁹ Element numbering intentionally skipped to align like elements.

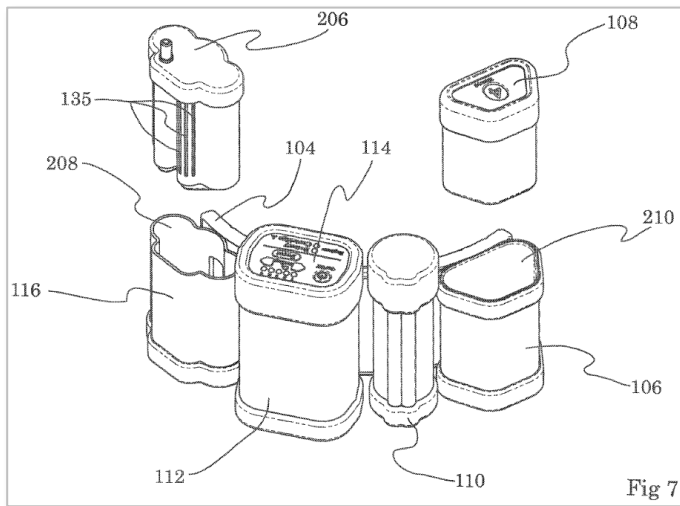
“receptacle” to be a structure that receives and at least partially contains another component, such as an electrical or trash receptacle. See, e.g., EX1059 (“*American Heritage*”) (defining “receptacle” as, e.g., “[a] container that holds items or matter” or “[a] fitting connected to a power supply and equipped to receive a plug”), EX1060 (“*New Oxford*”) (defining “receptacle” as, e.g., “an object or space used to contain something,” for example “an electrical outlet into which the plug of an electrical device may be inserted”), EX1061; (“*Bloomsbury*”) (defining “receptacle” as, e.g., “a container that holds, contains, or receives a liquid or solid”), and EX1062 (“*Webster*”) (defining “receptacle” as, e.g., “one that receives and contains something” or “a permanently mounted female electrical fitting that contains the live parts of the circuit”). I also performed a Google Patents search for “receptacle” appearing in patent documents with priority dates before February 9, 2005.¹⁰ These documents confirm the above general understanding.

262. The language of the challenged independent claims does not provide much further guidance as to the meaning of “receptacle” in the context of the challenged claims, as Claims 1 and 11 simply describe the “receptacle” as being defined by a housing, and the separation cartridge as being removable from the “receptacle” in a first direction.

¹⁰<https://patents.google.com/?q=receptacle&before=priority:20050209&num=100>

263. Beyond the claim, I also reviewed the '628 patent's specification to determine if it provides an explicit definition for "receptacle." It does not. The '628 patent's specification only briefly describes its "receptacles," as follows:

FIG. 7 shows an exploded view of the oxygen concentrator 100, which includes belt 104, power module 106 containing removable power pack 108, reservoir module 110, control module 112, and separation cartridge module 116 containing adsorbent cartridge 206. Power pack 108 has been removed from *receptacle 210* of power module 106. Adsorbent cartridge 206 has been removed from *receptacle 208* of cartridge module 116.



Adsorbent cartridge 206 and power pack 108 are easily removable to facilitate replacement.

In this embodiment, power pack 108 is a rechargeable battery. *Receptacle 210* contains electrical contacts (not illustrated) for connection to power pack 108. Cartridge 206 contains a quick-connect attachment (not illustrated) for inlet lines 164 a-164 c, outlet lines 166 a-166 c, inlet air line 168, and final product gas line 205 (not illustrated) within *receptacle 208*. Also present on cartridge 206 are air inlet ports 135 which receive ambient air 162 for separation. Adsorbent cartridge 206 contains adsorbent material that deteriorates in efficiency as it is used and ages.

EX1001 ('628 Patent), 17:35-38 (emphasis added).

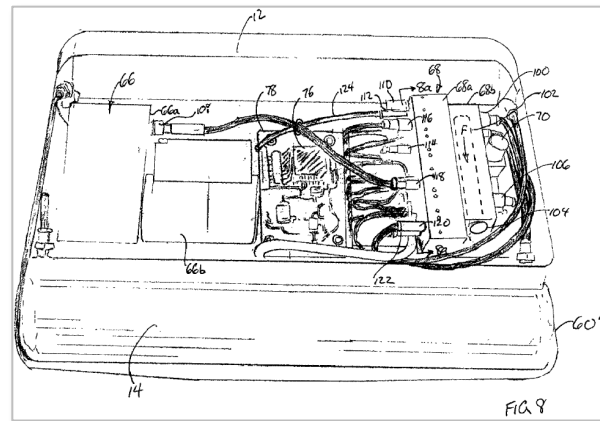
264. The only other mention of "receptacle" in the '628 patent's specification is that an "[i]ndicator light 274 indicates power pack 108 is running

low. Indicator light 276 indicates that there is a problem with separation cartridge 206, such as a bad connection with *receptacle 208*.” EX1001 (‘628 Patent), 17:35-38 (emphasis added).

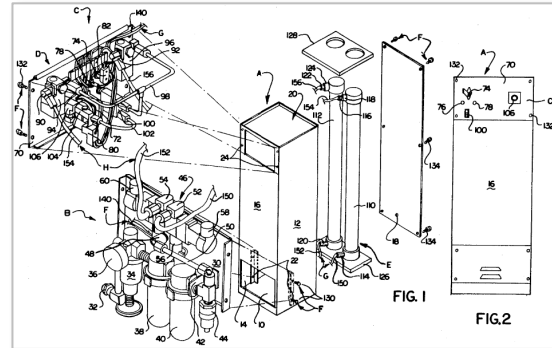
265. Beyond the claims and specification, the ‘628 patent’s prosecution history briefly addresses the meaning of “receptacle” as discussed below.

266. Before discussing the ‘628 patent’s prosecution history, however, I will review the prosecution histories of some of the other applications in the ‘628 patent’s family (*see* §II.B above) where the Examiner did assert (and the applicant did not disagree) that certain prior art features were “receptacles.” It is my understanding that these identifications can inform the meaning of “receptacle” in the context of the challenged claims.

267. For example, during prosecution of the ‘669 patent, the Examiner compared “receptacle” to *Warren* ‘095’s (EX1012) housing 60 in obviousness rejections of claim 2. EX1052 (‘669 Patent FH), 183-84, 301-02. Applicant did not disagree with the Examiner’s position, and instead canceled the claims. EX1052 (‘669 Patent FH), 149.



268. Turning to the '628 patent's prosecution history, the Examiner also compared both *Warren '095*'s housing 60 and *Dechene*'s (EX1021) housing A to a "receptacle" during prosecution of the '628 patent. EX1002 ('628 Patent FH), 135-39. Applicant did not disagree with the Examiner's position, and instead amended the claims to include different subject matter the Examiner found allowable. EX1002 ('628 Patent FH), 115-22.



270. Accordingly, it is my opinion that a POSITA would have understood “receptacle” in the context of the challenged claims of the ’628 patent as “a structure that releasably interfaces with the inlet(s) and outlet(s) of the separation cartridge and at least partially contains the separation cartridge.”

C. “Selectively Removable [From The Receptable]”

271. This term is found in challenged claims 1 and 11, as follows (emphasis and element numbers added):

[1a] 1. A portable oxygen concentrator, comprising:

[1b] a cartridge module comprising a housing, the housing defining a receptacle;

[1c] a separation cartridge *selectively removable* from the receptacle by movement relative to the receptacle in a first direction, the separation cartridge comprising a case at least partially defining an outer volume of the separation cartridge, an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen, the case at least partially surrounding the bed of adsorbent material;

[1d] a power pack removable from the portable oxygen concentrator;

[1e] a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material;

[1f] a user interface configured to allow a patient to adjust and monitor operation of the portable oxygen concentrator;

[1g] a carrying device for transporting the portable oxygen concentrator;

[1h] wherein the housing of the cartridge module is configured to at least partially surround the case of the separation cartridge,

[1i] wherein the bed of adsorbent material is disposed along an axis,
[1j] one of the inlet and the outlet is disposed along the axis, and [1k]
the other of the inlet and the outlet is spaced-apart from the axis, and

[1l] wherein the first direction and the second direction are
substantially parallel to the axis.

* * *

[11a] 11. A portable oxygen concentrator, comprising:

[11b] a cartridge module comprising a housing, the housing defining a
receptacle;

[11c] a separation cartridge *selectively removable* from the receptacle
by movement relative to the receptacle in a first direction, the
separation cartridge comprising an inlet oriented in a second direction
opposite the first direction, an outlet oriented in the second direction,
and a bed of adsorbent material configured to preferentially adsorb
nitrogen; and

[11d] a power pack removable from the portable oxygen concentrator,

[11i]¹¹ wherein the bed of adsorbent material is disposed along an
axis,

[11j] wherein one of the inlet and the outlet is disposed along the axis,

[11k] wherein the other of the inlet and the outlet is spaced-apart from
the axis, and

[11l] wherein the first direction and the second direction are
substantially parallel to the axis.

272. “Selectively removable [from the receptacle]” does not have a specific
meaning in the art. Outside of the context of the ’628 patent, a POSITA would
have generally understood it to be describing a component that is capable of being

¹¹ Element numbering intentionally skipped to align like elements.

chosen for removal. *See, e.g.*, EX1059 (“*American Heritage*”) (defining “select” as, *e.g.*, “adj, 1. [s]ingled out in preference; chosen” and “remove” as, *e.g.*, “to transfer or convey from one place to another”), EX1060 (“*New Oxford*”) (defining “selectively” as, *e.g.*, “adj. (of a group of people or things) carefully chosen from a larger number as being the best or most valuable” and “remove” as, *e.g.*, “take away (something unwanted or unnecessary) from the position it occupies”), EX1061 (“*Bloomsbury*”) (defining “selectively” as, *e.g.*, “chosen from several others and given special treatment or a special privilege” and “remove” as, *e.g.*, “to transfer somebody or something to another place, or change a place of residence”), and EX1062 (“*Webster*”) (defining “selectively” as, *e.g.*, “in a selective manner: by selection,” “select” as, *e.g.*, “to choose from a number of group usu. By fitness, excellence, or other distinguishing feature,” “remove” as “to change or shift the location, position, station, or residence of,” and “removable” as, *e.g.*, “capable of being removed, displaced, transferred, dismissed, or eradicated”). I also performed a Google Patents search for “selectively removable” appearing in patent documents with priority dates before February 9, 2005.¹² These documents confirm the above general understanding.

¹²<https://patents.google.com/?q=%22selectively+removable%22&before=priority:20050205&num=100>

273. The language of the challenged independent claims does not provide much further guidance as to the meaning of “selectively removable [from the receptacle]” other than that the removal is in a first direction.

274. Beyond the claims, I also reviewed the ’628 patent’s specification to determine if it provides an explicit definition for “selectively removable [from the receptacle].” It does not. In fact, the ’628 patent’s specification does not use the phrase “selectively removable” at all.

275. Regarding “selectively,” the ’628 patent’s specification also does not use the word “selectively” at all. It only uses the root word “select” twice, but not in the context of removable separation cartridges. Rather, “select” is used in the context of patients selecting flow settings or modes. EX1001 (*’628 Patent*), 16:56-60, 20:26-30.

276. Regarding “removable,” the ’628 patent’s specification does describe its separation cartridge as “removable” in several instances. *See, e.g.*, EX1001 (*’628 Patent*), 2:54-58 (“The cartridge is removable from an oxygen concentrator which separates oxygen from ambient air by using an absorption [sic] process”), 3:6-8 (“FIG. 7 is an exploded view of the oxygen concentrator in which the power pack and the adsorbent cartridge have been removed”), 11:61-12:3 (In FIG. 7, “[a]dsorbent cartridge 206 has been removed from receptacle 208 of cartridge

module 116. Adsorbent cartridge 206 and power pack 108 are easily removable to facilitate replacement.”).

277. Removal/removed is also used in the '628 patent's specification to explain that “[p]ower pack 108 is easily exchanged with another similar battery pack, and can be removed with a simple pulling or tugging motion” (EX1001 ('628 Patent), 14:48-50) and that the concentrator 100 may be removed from a dock (EX1001 ('628 Patent), 20:9-25).

278. Removal is also used in the '628 patent's specification to explain that

Apertures 216 a-216 d are openings in the case portions 224, 226, 228, and 230, provided for connection of utility tubes 212 to components contained within each module 106, 110, 112, and 116. This allows for removal of a single module 106, 110, 112, or 116 should a specific component require maintenance or replacement. Sockets 218 a-218 d are constructed from the same material as the case portions 224, 226, 228, and 230.

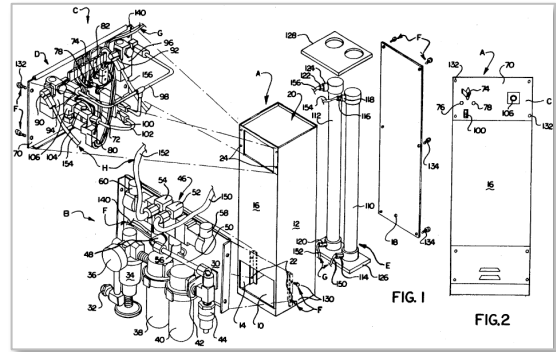
EX1001 ('628 Patent), 13:25-46.

279. Finally, “removed” is also used to describe gas or particulate removal (EX1001 ('628 Patent), 9:20-61, 10:61-11:33, 12:28-32, 17:22-26, 19:5-9) and to describe components omitted from drawings (EX1001 ('628 Patent), 12:15-20, 12:61-64, 14:29-32, 19:32-35).

280. Beyond the claims and specification, the '628 patent's file history does provide some further description of “selectively removable [from the receptacle].”

281. Specifically, the Examiner discussed the meaning of “selectively removable [from the receptacle]” in the context of the challenged claims.

282. For example, during prosecution of the '628 patent, the Examiner took the position that at least one of *Dechene's* (EX1021) columns 110 (in bed assembly E) is a separation cartridge that is “selectively removable” from housing A. EX1002 ('628 *Patent FH*), 135-39. Applicant did not disagree with the Examiner's position, and instead amended the claims to include different subject matter the Examiner found allowable. EX1002 ('628 *Patent FH*), 115-22.



283. Based on the above, a POSITA would have understood: (i) the '628 patent's claims recitation “selectively removable [from the receptacle]” simply to require that the removal or release of the separation cartridge be in a first direction; (ii) the '628 patent's specification to describe “removal” as the disconnection of separation cartridge 206 (or power pack 108) from receptacle 208 (or 210) as a whole component; and (iii) the '628 patent's family prosecution history as showing applicant acquiesced to comparisons of a “selectively removable [from the receptacle]” to the removability of *Dechene's* column 110 from housing A, where

Dechene teaches that columns 110, 112 are part of a single bed assembly E from housing A. EX1021 (*Dechene*), *e.g.*, at 4:12-31.

284. A POSITA would not have understood these explanations or usages of “removable” (or related words) to provide any explanation of “removable” beyond that the adsorbent cartridge 206 is disconnectable from a receptacle. As for the modifier “selectively,” based on the above, a POSITA would have understood it to specify that, for example, the adsorbent cartridge 206 may be selected for removal (*e.g.*, by a user) as a whole from the receptacle as opposed to part-by-part.

285. Based on the above, it is my opinion that a POSITA would have understood “selectively removable [from the receptacle]” in the context of the challenged claims of the ’628 patent means that the separation cartridge is “withdrawable or separable as a whole from the receptacle.”

D. “Axis”

286. This term is found in challenged claims 1 and 11, as follows
(emphasis and element numbers added):

[1a] 1. A portable oxygen concentrator, comprising:

[1b] a cartridge module comprising a housing, the housing defining a receptacle;

[1c] a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the separation cartridge comprising a case at least partially defining an outer volume of the separation cartridge, an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially

adsorb nitrogen, the case at least partially surrounding the bed of adsorbent material;

[1d] a power pack removable from the portable oxygen concentrator;

[1e] a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material;

[1f] a user interface configured to allow a patient to adjust and monitor operation of the portable oxygen concentrator;

[1g] a carrying device for transporting the portable oxygen concentrator;

[1h] wherein the housing of the cartridge module is configured to at least partially surround the case of the separation cartridge,

[1i] wherein the bed of adsorbent material is disposed along an *axis*,

[1j] one of the inlet and the outlet is disposed along the *axis*, and [1k] the other of the inlet and the outlet is spaced-apart from the *axis*, and

[1l] wherein the first direction and the second direction are substantially parallel to the *axis*.

* * *

[11a] 11. A portable oxygen concentrator, comprising:

[11b] a cartridge module comprising a housing, the housing defining a receptacle;

[11c] a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the separation cartridge comprising an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen; and

[11d] a power pack removable from the portable oxygen concentrator,

[11i]¹³ wherein the bed of adsorbent material is disposed along an *axis*,

[11j] wherein one of the inlet and the outlet is disposed along the *axis*,

[11k] wherein the other of the inlet and the outlet is spaced-apart from the *axis*, and

[11l] wherein the first direction and the second direction are substantially parallel to the *axis*.

287. “Axis” does not have a specific meaning in the art. Outside of the context of the ’628 patent, a POSITA would have generally understood an axis to be a straight line with respect to which a body or figure is symmetrical or about which a body rotates. *See, e.g.*, EX1062 (“*Webster’s*”) at p. 153 (defining “axis” as, *e.g.*, “[1]b: a straight line with respect to which a body, figure, or system of points is either radially or bilaterally symmetrical”), EX1061 (“*Bloomsbury*”) at pp. 120-121 (defining “axis” as, *e.g.*, “2. MATHS LINE AROUND WHICH SHAPE IS SYMMETRICAL a straight line around which a geometric figure or three-dimensional object is symmetrical”), EX1060 (“*New Oxford*”) at pp. 112-113 (defining “axis” as, *e.g.*, “an imaginary straight line passing through the center of a symmetrical solid” or “an imaginary line that divides something into equal or roughly equal halves, esp. in the direction of its greatest length”), and EX1059 (*American Heritage*) at p. 126 (defining “axis” as, *e.g.*, “2 *Mathematics* a. An unlimited line, half-line, or line segment serving to orient a space or geometric

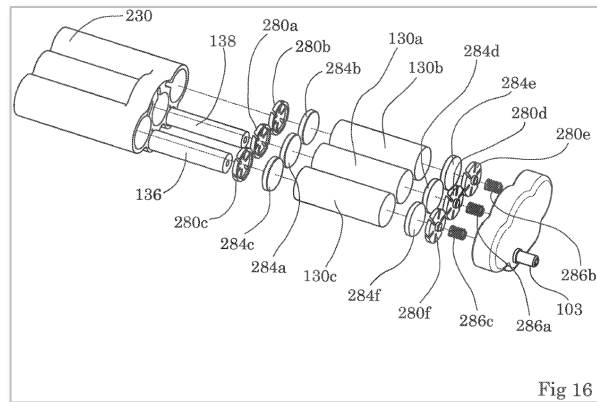
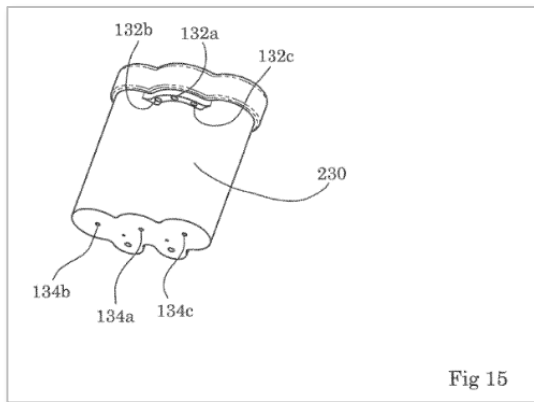
¹³ Element numbering intentionally skipped to align like elements.

object, especially in a line about which the object is symmetric.... 3. A center line to which parts of a structure or body may be referred”). I also performed a Google Patents search for “axis” appearing in patent documents with priority dates before February 9, 2005.¹⁴ These documents confirm the above general understanding.

288. The language of the challenged independent claims does not provide much further guidance as to the meaning of “axis,” although they do specify that “the bed of adsorbent material is disposed along an axis,” which would indicate to a POSITA that the relevant axis is the centerline of the adsorbent material itself, *i.e.*, the line with respect to which the adsorbent material is symmetrical.

289. Beyond the claims, I also reviewed the ’628 patent’s specification to determine if it provides an explicit definition for “axis.” It does not. In fact, the ’628 patent’s specification does not describe any features of the separation cartridge using “axis.” “Axis” appears only once in the specification in a description of the operation of valve 140. EX1001 (*’628 Patent*), 11:3-6. Turning to the figures, FIGS. 15 and 16 are instructive when read in conjunction with the claim language, as they show outlets 134 centered at the ends of the respective ends of adsorbent columns 130. Because the claims also require one of the inlets and outlets to be arranged on the axis, this reinforces the understanding that the axis is the centerline of the adsorbent material beds.

¹⁴<https://patents.google.com/?q=axis&before=priority:20050205&num=100>



290. Based on the above, it is my opinion that a POSITA would have understood “axis” in the context of the challenged claims of the ’628 patent means the centerline of the bed of adsorbent material.

VI. INVALIDITY

291. Based on my review and analysis of the materials cited herein, my opinions regarding the understanding of a POSITA in the 2004-2005 timeframe, and my training and experience, it is my opinion that a POSITA would have found claims 1-23 of the ’628 patent obvious. The reasons for my conclusions are explained more fully below.

A. Ground 1: Claims 1-4, 6-17, and 19-21 Are Rendered Obvious by *Deane* in view of *Dubois* and *Berntson*

292. It is my opinion that a POSITA would have found claims 1-4, 6-17, and 19-21 obvious based on the teachings of *Deane*, *Dubois*, and *Berntson*.

1. Combination of *Deane* with *Dubois* and *Berntson*

293. As discussed in detail herein, *Deane* teaches a portable oxygen concentrator using pressure swing adsorption with a separation cartridge having a

case, beds of adsorbent material, and spaced apart inlets and outlets oriented in the same direction that is opposite the direction in which the cartridge is removable from a receptacle of the concentrator, along with other elements. EX1004 (*Deane*), ¶¶[0032], [0062]-[0070], FIGS. 5-7. *See also* §III.B and elements [1a]-[11]. *Deane* teaches that its portable oxygen concentrator is compact and lightweight so as to be suitable for ambulatory use and stresses the importance of providing patients with “greater ease of mobility.” EX1004 (*Deane*), Abstract, ¶¶[0002], [0005].

294. As discussed above, *Dubois* teaches a portable oxygen concentrator using pressure swing adsorption with a housing “of a size and weight permitting the patient 3 to carry it while walking.” EX1005 (*Dubois*), 6:16-20, FIG. 5. Like *Deane*, the goal of *Dubois* was to “produce a really portable concentrator.” EX1005 (*Dubois*), 3:55-57. In this connection *Dubois* further teaches that its lightweight concentrator may be carried by a handle 4 or shoulder strap 5, as shown in FIG. 5. EX1005 (*Dubois*), 6:21-25, FIG. 5. *Dubois* teaches that this portability is achieved by optimizing the “mass performances” and other aspects of the concentrator’s components, including in particular the air compressor, the adsorbent, and the battery. EX1005 (*Dubois*), 4:12-25.

295. Accordingly, a POSITA would have found it obvious to combine *Deane*’s teachings with *Dubois*’s teachings of optimizing an oxygen concentrator

using pressure swing adsorption for increased portability because such a combination would have provided an improved, more mobile oxygen concentrator system. In combination, these teachings provide an improved oxygen concentrator with lighter weight components and therefore an overall reduced weight and increased portability that is better suited for ambulatory uses, characteristics a POSITA would have recognized as highly desirable by 2004-2005 (as evidenced by *Deane* and *Dubois* themselves, among other references discussed herein).

296. Beyond the specific motivations to combine *Deane* and *Dubois* provided by the references themselves, further support for such motivation can be found in a POSITA's general knowledge at the time, such as described by the references identified in §§I and III. For example, a POSITA would have been well aware of teachings, such as in *Warren '095*, relating to the importance of making oxygen concentrators highly portable. For example, *Warren '095* teaches its housing 60 has a handle 80 for carrying, and that its POC is also intended "to be worn by a user, for example in or as a backpack or hip pack or so-called fanny pack 81 such as seen in FIG. 10." EX1012 (*Warren '095*) at ¶[0072], FIG. 10 (reproduced here). Similarly, *McCombs '924* teaches "an apparatus with a weight of less than about 10 lb., measuring less overall than 17" in length, 8" in width and 6" in height." EX1009 (*McCombs '924*) at ¶[0025]. *McCombs '924* further teaches that making a POC "highly portable and easily manipulated and

transported even by patients with relatively limited physical capacities” is important. EX1009 (*McCombs* ’924) at ¶[0005]. Each of these references and the others discussed above in §I would have informed a POSITA’s general understanding as of 2004-2005 that it was desirable to make oxygen concentrators highly portable.

297. Beyond the specific motivations to combine *Deane* and *Dubois* provided by the references themselves and a POSITA’s general understanding, a POSITA would have found it obvious to combine *Deane* and *Dubois*’s teachings, and would have had a reasonable expectation of success in doing so, at least because both references relate to portable oxygen concentrators using pressure swing adsorption and common components, the optimization of which *Dubois* teaches. EX1005 (*Dubois*), 4:12-25; *see also, e.g.*, element [1a].

298. A POSITA would have also had a reasonable expectation of success in modifying *Deane*’s portable oxygen concentration system with the oxygen concentrator having increased portability taught by *Dubois* because portability was at the time (and is) a basic capability of portable oxygen concentration systems, as was well-known in in the 2004-2005 timeframe. *See* §I.J. In other words, both references teach the portability of portable oxygen concentrators and provide similar features and functionality and have common components. Thus, a POSITA would have been able to utilize the teachings of *Dubois* relating to optimizing the

size and weight of the various components of a pressure swing adsorption portable oxygen concentrator common to *Deane* and *Dubois*'s systems, including the air compressor, adsorbent, and battery, to improve the portability of *Deane*'s portable oxygen concentrator.

299. Therefore, at the time of the alleged invention of the claims of the '628 patent, a POSITA would have been motivated to (and it would have been obvious to a POSITA having the teachings of *Deane* and *Dubois* before him or her, along with the other knowledge explained above) combine the teachings of *Deane* and *Dubois* as described above (and below) to provide improved functionality, with a reasonable expectation that such modifications would have been successful.

300. A POSITA also would have been motivated to combine the teachings of *Berntson* with those of *Deane*, including where *Deane* is modified by *Dubois* as described herein. In particular, as described above and below, *Berntson* teaches an oxygen concentrator with a "separation cartridge"—an oxygen-rich air generator (ORAG) unit—that can be mounted inside a housing or cabinet of an oxygen concentrator and "removably fastened" to the housing within a "receptacle" of the housing/cabinet. *See, e.g.*, elements [1b]-[1c] below.

301. *Berntson* explains that the reason for having the ORAG be removably fastened within the housing is that "for maintenance or service of the oxygen concentrator, the ORAG 32 is replaceable as a unit. This simplifies maintenance

and repair, as the ORAG 32 only needs to be disconnected from the cabinet 12 and from the components 18, 20 and 26 that are mounted to the cabinet 12, and replaced with a new or reconditioned ORAG 32. Service personnel do not have to diagnose the ORAG 32 and repair it, nor inventory replacement parts for the ORAG 32. The ORAG 32 removed from the cabinet 12 is simply taken back or shipped to a central repair facility or to the manufacturer of the ORAG 32 and repaired, replaced or reconditioned there.” EX1006 (*Berntson*), ¶[0019]. *See also* FIGS. 1-2 and ¶¶[0012]-[0013].

302. *Deane* similarly teaches that shell 204 of *Deane*’s oxygen concentrator can be conveniently removed, as shown for example in FIG. 3, “to provide access for testing, repair, or maintenance of the components” of the oxygen concentrator, which components include adsorbent housing 602 / adsorbent columns 508a, 508b with their inlets, outlets, and adsorbent material. EX1004 (*Deane*), ¶[0058], FIG. 3. Accordingly, a POSITA would have found it obvious to combine *Dubois*’s and *Berntson*’s teachings of an easily removable cartridge with *Deane*’s cartridge teachings to improve the ease of maintenance, which both references recognize is important. In combination, these teachings provide an improved oxygen concentrator with an adsorbent-containing cartridge that is more modular and thus more easily and conveniently accessed and removed/replaced for

maintenance, characteristics a POSITA would have recognized as highly desirable by 2004-2005.

303. Beyond the specific motivations to combine *Deane* (and *Dubois*) with *Berntson* provided by the references themselves, further support for such motivation can be found in a POSITA's general knowledge at the time, such as described by the references identified in §I.G, including *McCombs '957's* "compact unit" that is "readily accessed for servicing," *Dechene's* modular oxygen concentrator design with bed assembly E that is removable from housing A such that it is "serviceable and repairable in the field by an untrained operator or technician" (EX1021 (*Dechene*), 1:31-34), *Cole's* removable adsorber cartridge (sieve unit 30) that seeks to reduce assembly errors (EX1020 (*Cole*), 1:48-53), and *Hechinger's* "removable cartridge for the adsorbent bed of a swing-type adsorber system" where "the cartridge and the adsorbent material can be removed and installed as a unit" in order to reduce the required time for replacing the components (EX1048 (*Hechinger*), Abstract). Each of these references and the others discussed above in §I.G would have informed a POSITA's general understanding as of 2004-2005 that it was desirable for adsorbent-containing units in oxygen concentrators to be easily removable/accessible from the concentrators for maintenance purposes and for ease of assembly/disassembly.

304. Beyond the specific motivations to combine *Deane* and *Berntson* (including in combination with *Dubois*) provided by the references themselves and a POSITA's general understanding, a POSITA would have found it obvious to make the combination in the manner described, and would have had a reasonable expectation of success in doing so, at least because the references each relate to portable oxygen concentrators and to adsorbent-containing housings contained in them. Both *Deane* and *Berntson* teach the importance of being able to access and repair/replace the adsorbent-containing unit and *Berntson* and the other references discussed above demonstrate that a modular approach to a removable unit for these purposes was well known and well understood.

305. A POSITA would have also had a reasonable expectation of success in modifying *Deane*'s portable oxygen concentration system, including its adsorbent housing / adsorbent bed columns, with teachings of *Berntson* relating to a separation cartridge having a modular, easily removable/replaceable design because modularity was in the 2004-2005 timeframe (and still is) a basic and well understood capability of many adsorbent-containing units within oxygen concentration systems. *See* §I.G and as explained immediately above. In other words, both references teach easily accessible adsorbent-containing units for repair/maintenance purposes and have similar features and functionality and common components. Thus, a POSITA would have easily and predictably utilized

the teachings of *Berntson* relating to modularity of a “separation cartridge” to improve *Deane*’s system (including when combined with *Dubois*) to further facilitate repair and maintenance of the disclosed portable oxygen concentrators.

306. Therefore, at the time of the alleged invention of the claims of the ’628 patent, a POSITA would have been motivated to (and it would have been obvious to a POSITA having the teachings of *Deane*, *Dubois*, and *Berntson* before him or her, along with the other knowledge explained above to) combine the teachings of *Deane* (and *Dubois*) and *Berntson* as described above (and below) to provide improved functionality, with a reasonable expectation that such modifications would have been successful.

2. Independent Claim 1

307. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* renders the limitations of Claim 1 obvious.

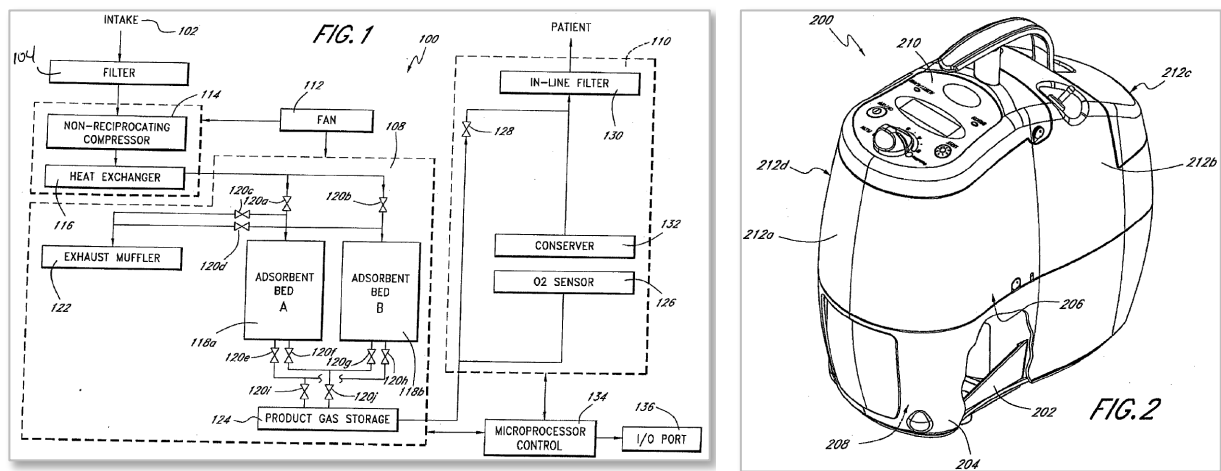
[1a] 1. A portable oxygen concentrator, comprising:
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308. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches element [1a], rendering it obvious.

309. I understand that a preamble generally does not state a claim limitation. However, to the extent it is considered a limitation in this instance, it is my opinion element [1a] is rendered obvious by *Deane* because *Deane* teaches that its “invention relates generally to a portable gas fractionalization system, more

particularly, to a compact oxygen concentrator that is suitable for both in-home and ambulatory use so as to provide users greater ease of mobility.” EX1004 (*Deane*), ¶[0002]. See also ¶¶[0057] (teaching “FIG. 2 illustrates a gas fractionalization apparatus 200 of the preferred embodiment, which is shown in the form of a portable oxygen concentrator”), [0093] (teaching *Deane*’s device is a “portable oxygen concentrator unit 1600”) and elements [1b]-[11] (discussing particular features of *Deane*’s portable oxygen concentrator, which are presented below).

310. *Deane*’s portable oxygen concentrator is further depicted in, for example, FIGS. 1 and 2, reproduced below. EX1004 (*Deane*), FIGS. 1, 2, and ¶¶[0012] (FIG. 1 depicts a “portable gas fractionalization system”) and [0013] (FIG. 2 depicts a “portable gas fractionalization apparatus”).



311. A POSITA would have considered “portable oxygen concentrator” and “portable gas fractionalization apparatus” to be equivalent, and those terms are used interchangeably in *Deane*. Fractionalization in this context means separation,

i.e., dividing into parts. For example, nitrogen is separated from a feed gas, which increases the percentage of oxygen in the resultant product gas (*i.e.*, it concentrates the oxygen), while the nitrogen is exhausted as a byproduct.

312. *Deane* provides many additional teachings of a portable oxygen concentrator. *See, e.g.*, EX1004 (*Deane*), Abstract (“portable gas fractionalization apparatus that provides oxygen rich air to patients”), ¶¶[0005], [0006], [0007] (“portable gas fractionalization apparatus”), [0012], [0013], [0014], [0025], [0026], [0027], [0029], [0030], [0031], [0032] (“portable gas fractionalization system 100” that “produce[s] a product gas having a higher oxygen content than the ambient air”), [0035] (PSA unit 108 “produce[s] an oxygen enriched product gas”), [0036], [0061], [0062] (PSA unit 506 “remove[s] nitrogen from intake air in ... so as to produce an oxygen rich product gas”), [0063], [0065], [0066], [0067], [0068], [0069], [0070], [0086], and [0092] (“Feed gas is directed through the inlet port 812 of the PSA unit 506, into adsorbent columns 508 a-b to produce a product gas in accordance with a PSA cycle, preferably the six step/two bed cycle described above.”), and FIGS. 1, 2, 3 14, 15, 16A, 16C, 17, 18A, 18B.

313. Regarding the “portable” nature of the claimed “portable oxygen concentrator,” *Deane* throughout its disclosure teaches that its portable oxygen concentrator / gas fractionalization apparatus is “portable,” including in the portions cited above and in view of, for example, the handle depicted in FIGS. 2

(reproduced below) and 16A, and/or the wheeled mobility cart 1800 shown in FIGS. 18A, 18B (reproduced below). EX1004 (*Deane*), FIGS. 2, 16A, 18A, 18B, ¶¶[0099]-[0101]. A POSITA would have recognized that devices with handles or devices that are transportable by wheeled carts are “portable.”

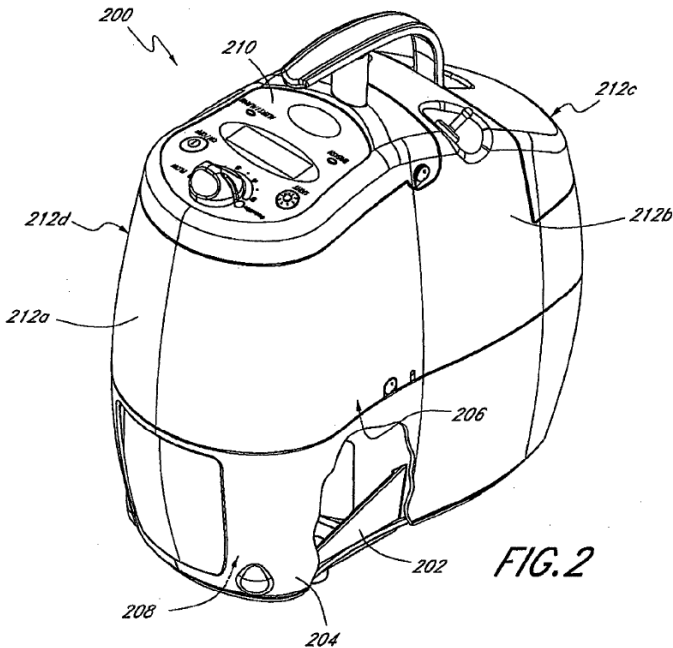


FIG. 2

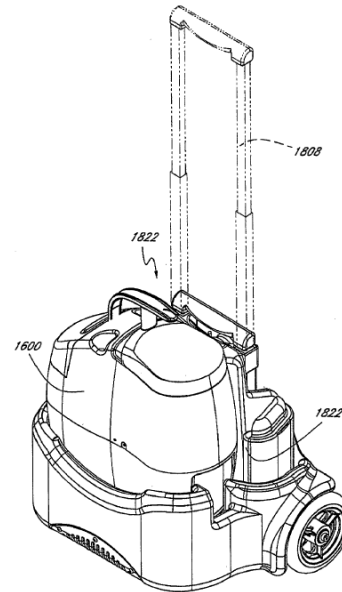


FIG. 18B

314. To the extent PO argues *Deane* does not teach the level of portability required by the claim language, it would also have been obvious to make *Deane*’s portable oxygen concentrator even more portable, including by sizing it such that it would be provided on a patient-wearable belt or strap in the manner depicted in *Dubois*, which teaches a portable gas concentrator

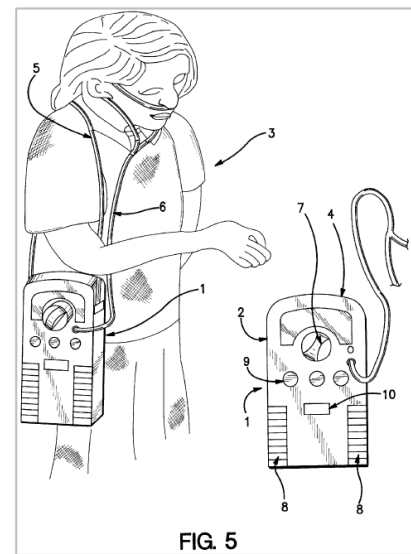


FIG. 5

wearable by a patient on a strap or belt. EX1005 (*Dubois*), 3:25-30, 6:21-25, FIG. 5 (reproduced here).

315. As discussed above in §VI.A.1, a POSITA would have been motivated to modify *Deane* in view of *Dubois* at least because both recognize that the portability of oxygen concentrators is desirable, and *Dubois* teaches how to configure a portable oxygen concentrator like *Deane*'s in a manner such that it can be provided on a patient-wearable belt or strap. *See also* EX1012 (*Warren '095*), FIG. 10.

316. Further, portable oxygen concentrators, including those wearable by patients, were generally known by POSITAs by 2004-2005 (*see, e.g.,* §I.H). Thus, it would have been obvious to a POSITA to configure *Deane*'s portable oxygen concentrator to make it patient-wearable in view of the basic understanding in the art for the same reasons identified above in §VI.A.1 as to *Dubois*.

317. Further, during prosecution of the parent '490 patent, applicant stated that *Deane '059*, which is very similar to *Deane*, “discloses a portable gas fractionalization apparatus that provides oxygen rich air to patients utilizing pressure swing adsorption (PSA).” EX1049 (*'490 Patent FH*), 178-179; *see also* EX1049 (*'490 FH*), 40. As I explained above, “portable oxygen concentrator” and “portable gas fractionalization apparatus” are equivalent. Thus, applicant

effectively conceded *Deane* teaches element [1a]. *See also* EX1049 ('490 Patent *FH*), 40, where applicant makes a similar concession.

318. Finally, my understanding that *Deane* (with or without the teachings of *Dubois*) teaches element [1a] is consistent with the assertion of infringement against Petitioner's product advanced in connection with the litigation. EX1072 (*Infringement Chart*) at 1; EX1074 (*Infringement Contentions*) at 1-4.

319. Therefore, to the extent that element [1a] states a limitation, it is my opinion the limitation is taught by the combination of *Deane*, *Dubois*, and *Berntson*.

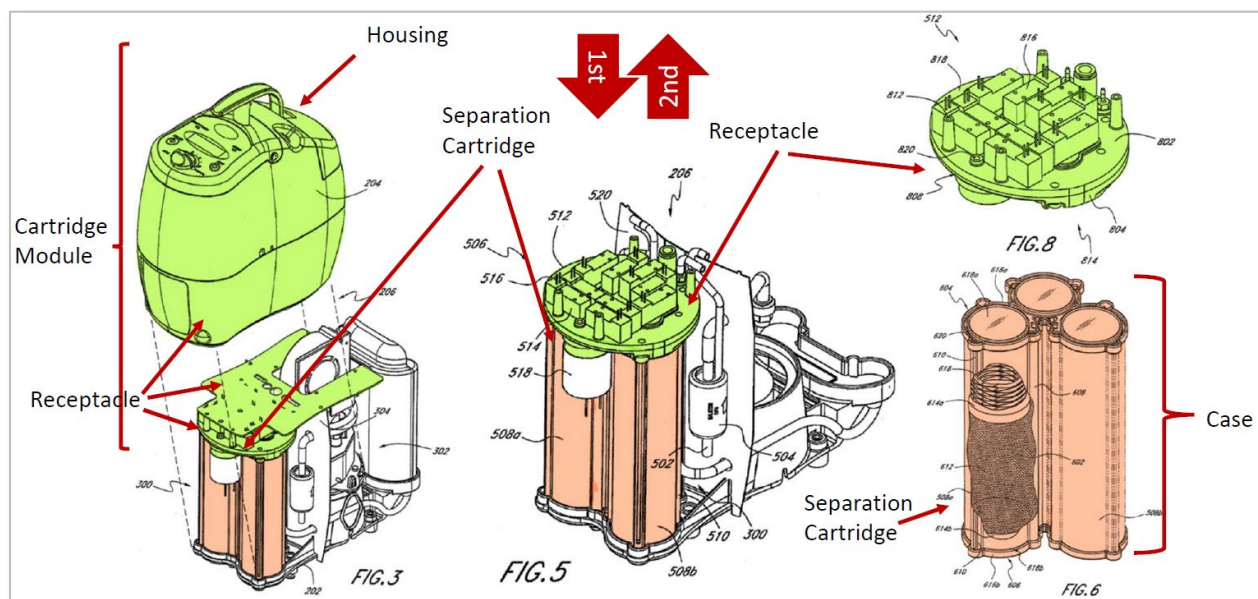
[1b] a cartridge module comprising a housing, the housing defining a receptacle;

320. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches element [1b], rendering it obvious.

321. Specifically, it is my opinion that element [1b] is rendered obvious by *Deane* because *Deane* teaches a cartridge module comprising a housing (*e.g.*, at least shell 204, shaded green in the annotated drawings below), the housing defining a receptacle (*e.g.*, manifold 512 or a combination of manifold 512 and inner surfaces of shell 204, shaded green in the annotated drawings below, along with circuit board 1314 and/or other intervening components). EX1004 (*Deane*) at, *e.g.*, ¶¶[0007], [0008], [0010], [0011], [0013], [0014], [0016]-[0019], [0024]-

[0027], [0035], [0036], [0057]-[0059], [0062]-[0070], [0086], [0092]-[0093], FIGS. 2, 3, 5, 6, 7, 8, 13-16. *Berntson* also teaches a housing or cabinet of an oxygen concentrator defining a “receptacle” into which a “separation cartridge”—an oxygen-rich air generator (ORAG) unit—can be mounted. EX1006 (*Berntson*), ¶¶[0011]-[0012].

322. The annotated versions of *Deane*’s FIGS. 3, 6, and 7A below provide further explanation and examples of how *Deane* teaches each of the features of element [1b] in the manner described above. I also discuss how *Deane* teaches each feature of element [1b] in more detail below.



323. “*a cartridge module comprising a housing ...*”: More specifically (and in addition to the above), *Deane* renders this feature of element [1b] obvious because it teaches a POC with shell 204 (shaded **green** in the annotated drawings),

which a POSITA would have understood to be a cartridge module with a housing. EX1004 (*Deane*) at, e.g., ¶¶[0007], [0008], [0010], [0011], [0013], [0014], [0018], [0024]-[0027], [0035], [0036], [0057]-[0059], [0062]-[0070], [0086], [0092]-[0093], FIGS. 2, 3, 7, 13-16. A POSITA would have considered outer surfaces of shell 204 to be the outer surface of the cartridge module's housing. A POSITA would have further considered one or more of the elements identified below, including the inner surface of shell 204, as forming the inner portion of the "housing" defining the "receptacle," for at least the reasons discussed below.

324. ***"... the housing defining a receptacle"***: More specifically (and in addition to the above), "receptacle" means, as discussed in §V.B, a structure that releasably interfaces with the inlet(s) and outlet(s) of the separation cartridge and at least partially contains the separation cartridge. Thus, *Deane* renders this feature of element [1b] obvious because it teaches that its housing (e.g., shell 204) defines a receptacle formed by: (i) manifold 512; or (ii) a combination of manifold 512 and the inner portion of shell 204 (highlighted in **green** in the annotated figures), as those elements releasably interface with the inlet(s) and outlet(s) of the separation cartridge (adsorbent housing 602¹⁵ / adsorbent bed columns 508a, 508b, shaded **orange** in the annotated drawing, as described in element [1c]) and at least

¹⁵ Adsorbent housing 602 houses adsorbent material and should not be confused with the claimed housing, which corresponds to, e.g., *Deane*'s shell 204.

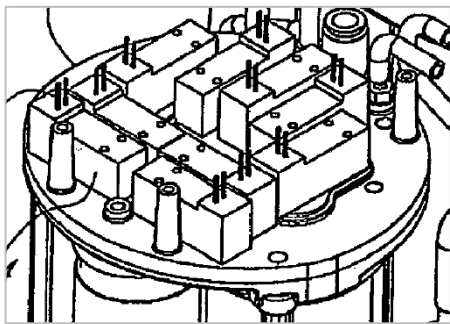
partially contain the separation cartridge. EX1004 (*Deane*) at, e.g., ¶¶[0007], [0008], [0010], [0011], [0014], [0016]-[0019], [0024]-[0026], [0035], [0036], [0057]-[0059], [0062]-[0070], [0086], [0092]-[0093], FIGS. 3, 5, 6, 7, 8, 13-15.

325. For example, a POSITA would have considered manifold 512 to teach a “receptacle” because its structure both: (i) releasably interfaces with the inlet(s) and outlet(s) of the separation cartridge (*via* the gas passage interfaces of manifold 512); and (ii) at least partially contains the separation cartridge (*via* the connective structure of manifold 512 which at least partially contains the end of adsorbent housing 602 / adsorbent bed columns 508a, 508b around its periphery, as shown by comparing FIGS. 5 and 6). Alternatively, a POSITA would have considered the combination of manifold 512 and the inner portion of shell 204 to also provide both requirements, as the inner portion of shell 204 completely laterally surrounds adsorbent housing 602 in addition to the lateral containment offered by manifold. A POSITA would also have considered circuit board 1314 (also highlighted in green in the annotated figures above and also identified in FIGS. 13-14), and/or other intervening structure, part of the receptacle, as necessary.

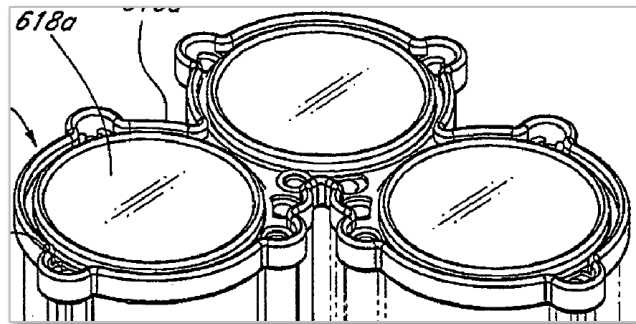
326. More specifically, *Deane* teaches a “receptacle” formed of manifold 512 or the combination of manifold 512 and the inner portion of shell 204, for several reasons.

327. *First*, *Deane* teaches that its separation cartridge (*e.g.*, adsorbent housing 602 / adsorbent bed columns 508a, 508b; *see* element [1c]) may be connected to integrated manifold 512, which releasably interfaces with the inlet(s) and outlet(s) on the upper end of adsorbent housing 602 / adsorbent bed columns 508a, 508b to provide gas flow within the adsorbent housing 602 / adsorbent bed columns 508a, 508b. *See, e.g.*, EX1004 (*Deane*), Abstract, ¶¶[0007] (teaching an “integral fluid flow manifold mounted on one end of the columns”), [0014], [0017], [0018], [0059], [0062] (“PSA unit 506 generally includes a pair of adsorbent bed columns 508 a, 508 b, a product gas storage column 510, and an integrated manifold 512 for controlling fluid flow to and from the columns 508 a-b, 510.”), [0063] (“integrated manifold 512 contains a plurality of integrated flow passages formed in a single plane that permit fluid to flow to and from the columns 508 a-b, 510. ... the integrated manifold 512 is mounted on the upper end of the columns 508 a-b, 510 in a manner such that the integrated flow passages in the manifold are in fluid communication with openings in the upper end of each column.”), [0065], [0066], [0067], [0070] (“FIGS. 7A and 7B provide schematic illustrations of the adsorbent bed column 508 a in combination with the chassis 202 and the manifold 512, showing the manners in which gas flow is directed in and out of the column 508 a in accordance with the single-ended column design.”), [0086], FIGS. 3, 5, 6, 7.

328. *Second*, *Deane* teaches that integrated manifold 512 also at least partially contains adsorbent housing 602 / adsorbent bed columns 508a, 508b via the connective structure of manifold 512 which at least partially contains the end of adsorbent housing 602 / adsorbent bed columns 508a, 508b around its periphery, as shown by comparing FIGS. 5 and 6, as shown by the partial reproductions that follow. *See also, e.g.,* EX1004 (*Deane*), Abstract, ¶¶[0007] (teaching an “integral fluid flow manifold mounted on one end of the columns”), [0014], [0017], [0018], [0059], [0062] (“columns 508 a-b, 510 have substantially the same length so that the integrated manifold 512 can be mounted horizontally on the upper end of the columns 508 a-b, 510.”), [0063], [0065] (“PSA unit 506 is designed to operate with a single, generally planar integrated manifold mounted horizontally on one end of the columns.”), [0066], [0067], [0070], [0086], FIGS. 3, 5, 6, 7. As shown below, when housing 602 / adsorbent bed columns 508a, 508b is mated with manifold 512, manifold 512 couples to and partially surrounds/contains housing 602 / adsorbent bed columns 508a, 508b.



Deane FIG. 5



Deane FIG. 6

329. *Third*, *Deane* teaches the inner portion of its shell 204 also at least partially contains adsorbent housing 602 / adsorbent bed columns 508a, 508b (e.g., a “separation cartridge”). *See, e.g.*, EX1004 (*Deane*), ¶[0057] (shell 204, together with chassis 202, “form[s] a housing 206 in which various components are mounted”), FIGS. 3, 14, 15, 16C.

330. In view of the above, a POSITA would have understood that *Deane*’s manifold 512 alone teaches a “receptacle” as properly construed (*see* §V.B) because it both interfaces with the gas connections on, and at least partially contains the top end of, adsorbent housing 602 / adsorbent bed columns 508a, 508b.

331. Additionally or alternatively, a POSITA would have understood that *Deane*’s manifold 512 and inner portion of shell 204 (and any other intervening components) together teach a “receptacle” as properly construed (*see* §V.B) because manifold 512 interfaces with the gas connections on adsorbent housing 602 / adsorbent bed columns 508a, 508b (as described above) and as manifold 512 and shell 204 jointly contain adsorbent housing 602 / adsorbent bed columns 508a, 508b.

332. Finally, to the extent Patent Owner may argue that *Deane* fails to teach either or both of the above features, *Berntson* does. For example, *Berntson* teaches a housing or cabinet of an oxygen concentrator defining a “receptacle” into

which a “separation cartridge”—an oxygen-rich air generator (ORAG) unit—can be mounted. EX1006 (*Berntson*), ¶¶[0011]-[0012]. FIG. 1 of *Berntson* shows ORAG 32 mounted inside the receptacle, within housing or cabinet 12. As explained in §VI.A.1, a POSITA would have been motivated to incorporate *Berntson*’s teachings into *Deane*’s portable oxygen concentrator to provide a cartridge with an adsorbent bed and other components that is removable as a whole from the receptacle of a concentrator, *e.g.*, for maintenance purposes. EX1006 (*Berntson*), ¶[0019], FIGS. 1-2.

333. Further, my understanding that *Deane* (with or without the teachings of *Berntson*) teaches element [1b] is consistent with the assertion of infringement against Petitioner’s product advanced in connection with the litigation. EX1072 (*Infringement Chart*) at 1-2; EX1074 (*Infringement Contentions*) at 1-4. In particular, for example, PO has asserted the entire outer structure of a POC may be a cartridge module and housing. This comports with my identification of the similar features of *Deane* as teaching the cartridge module and housing.

334. For all of the above reasons, it is my opinion that element [1c] is taught by the combination of *Deane*, *Dubois*, and *Berntson*

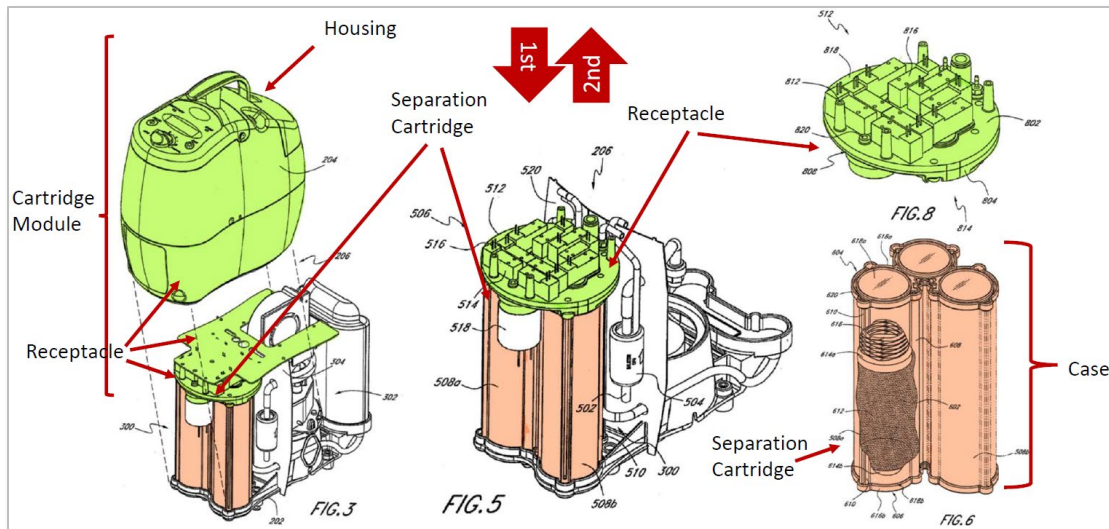
[1c] a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the separation cartridge comprising a case at least partially defining an outer volume of the separation cartridge, an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen, the case at least partially surrounding the bed of adsorbent material;

335. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches element [1c], rendering it obvious.

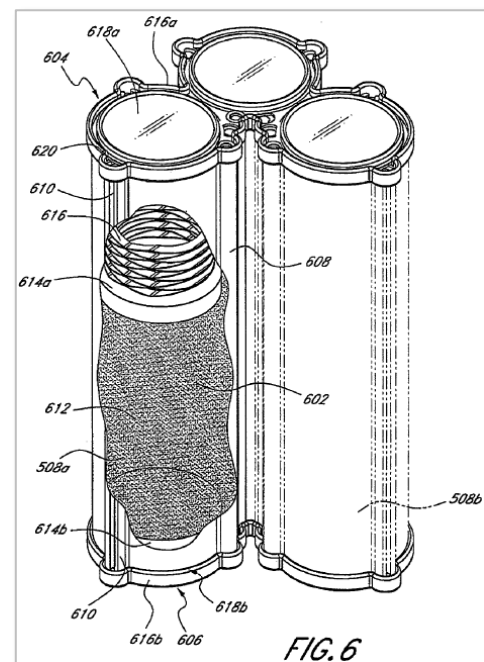
336. Specifically, it is my opinion that limitation [1c] is rendered obvious by *Deane* because *Deane* teaches a separation cartridge (*e.g.*, adsorbent housing 602 / adsorbent bed columns 508a, 508b, shaded in orange in the annotated drawings below) selectively removable from the receptacle (*e.g.*, adsorbent housing 602 / adsorbent bed columns 508a, 508b is removable from manifold 512 or a combination of manifold 512 and shell 204, shaded green in the annotated drawings below, along with circuit board 1314) by movement relative to the receptacle in a first direction (*e.g.*, the direction labeled “1st” in the annotated figures below), the separation cartridge comprising a case at least partially defining an outer volume of the separation cartridge (*e.g.*, adsorbent housing 602 and/or other outer surfaces of adsorbent housing 602 / adsorbent bed columns 508a, 508b, shaded in orange in the annotated drawings below), an inlet oriented in a second direction opposite the first direction (*e.g.*, openings 706 of feed tubes 608 of

adsorber housing 602 / adsorbent bed columns 508a, 508b are oriented in the direction labeled “2nd” in the annotated figures below), an outlet oriented in the second direction (e.g., upper ends 604 of adsorber housing 602 / adsorbent bed columns 508a, 508b are oriented in the direction labeled “2nd” in the annotated figures below), and a bed of adsorbent material configured to preferentially adsorb nitrogen (e.g., adsorbent material 612 in adsorbent bed columns 508a, 508b), the case at least partially surrounding the bed of adsorbent material (e.g., housing 602). EX1004 (*Deane*) at, e.g., ¶¶[0007], [0008], [0010], [0011], [0014], [0017], [0018], [0035], [0036], [0057], [0058], [0059], [0062], [0063], [0065], [0066], [0067], [0068], [0069], [0070], [0086], [0092], FIGS. 3, 6, 7. *Berntson* also teaches a “separation cartridge selectively removable from a receptacle”—an oxygen-rich air generator (ORAG) unit that can be mounted inside a housing or cabinet of an oxygen concentrator and “removably fastened” to the housing within what a POSITA would have understood is a “receptacle” of the housing/cabinet. EX1006 (*Berntson*), ¶¶[0011]-[0012].

337. The annotated versions of *Deane*’s FIGS. 3, 6, and 7A below provide further explanation and examples of how *Deane* teaches each of the features of element [1c] in the manner described above. I also discuss how *Deane* teaches each feature of element [1c] in more detail below.



338. “a separation cartridge ...”: More specifically (and in addition to the above), as discussed in §V.A, a “separation cartridge” is a housing that holds multiple adsorbent columns for gas separation and provides separate inlet and outlet ports for each adsorbent column. *Deane* renders this feature of [1c] obvious because (in addition to the above), it teaches an adsorbent housing 602 / adsorbent bed columns 508a, 508b component (as shown in FIG. 6, reproduced here),¹⁶ where



¹⁶ I use “housing 602 / adsorbent bed columns 508a, 508b” herein to refer to the entire structure taught by *Deane* discussed as to this claim element, such as the entire structure shown in FIG. 6. To the extent I refer to one of these elements singly herein for brevity, I mean the entire structure. As discussed below regarding

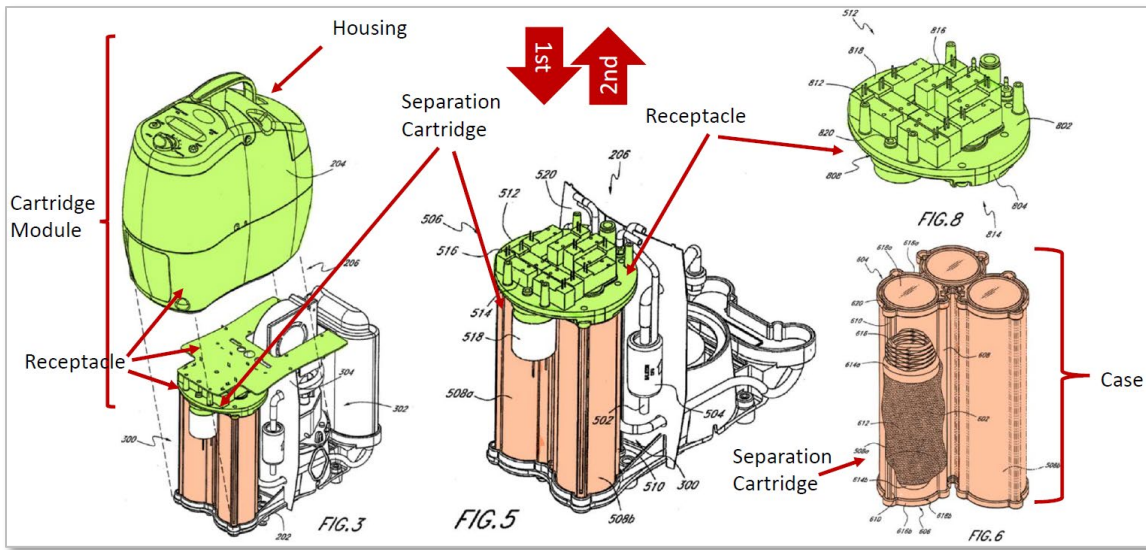
each column 508a, 508b contains an adsorbent material 612 (*e.g.*, zeolite) through which feed gas can flow for separation (*e.g.*, nitrogen is removed from the feed gas to produce an oxygen rich product gas). EX1004 (*Deane*), ¶¶[0007] (“plural adsorbent bed columns mounted side by side”), [0014], [0017], [0018], [0062] (“[e]ach adsorbent bed column 508 a-b comprises an elongated housing containing a nitrogen-selective adsorbent material such as zeolite ... adapted to remove nitrogen from intake air in a known manner in accordance with a PSA cycle so as to produce an oxygen rich product gas ... As shown in FIG. 5, all three columns 508 a-b, 510 are mounted side by side in the housing 206.”), [0066], [0067], [0068] (“adsorbent bed housing 602 contains an adsorbent material 612 ... [that] comprises a granular material such as zeolite.”), [0069], [0070] (teaching gas flow through adsorbent bed housing 602 and that the “adsorbent material selectively removes one or more components in the feed gas 702 in a known manner to form a product gas 708.”), [0092] (teaching feed gas is directed “into adsorbent columns 508 a-b to produce a product gas in accordance with a PSA cycle, preferably the six step/two bed cycle described above.”), FIGS. 3, 6, 7. *Deane’s* columns 508a, 508b each have a separate inlet and outlet as discussed in detail below.

a “case,” a POSITA would have understood *Deane* to teach that its housing 602 extends around each of the adsorbent bed columns (*e.g.*, 508a, 508b) and/or each adsorbent bed columns (*e.g.*, 508a, 508b) to have individual housings 602 that are interconnected, such as along their diameters or by ends 604, 606, as shown in FIG. 6.

339. To the extent “separation cartridge” is defined more broadly as requiring a housing with at least a single adsorber column, inlet, and outlet (which does not seem to be supported by the ’628 patent or its prosecution history), *Deane* also teaches such a configuration, for at least the reasons above, as (for example) a housing with multiple adsorber columns would also be a housing with at least one adsorber column, as “at least one” includes within its meaning multiple columns (*i.e.*, it is not limited to only one).

340. Additionally, as discussed above in §II.B, examiners repeatedly compared the above features of *Deane* to a “separation cartridge” without disagreement by applicant. EX1050 (’362 *Application FH*), 58-59; EX1052 (’669 *Patent FH*), 16.

341. “... ***selectively removable from the receptacle*** ...”: More specifically (and in addition to the above), as discussed in §V.C, “selectively removable [from the receptacle]” means that the separation cartridge is “withdrawable or separable as a whole from the receptacle” and, as discussed in element [1b], *Deane* teaches a “receptacle” as manifold 512, or a combination of manifold 512 and inner portion of shell 204 (highlighted in **green** in the annotated figures).



342. *Deane* renders this feature of element [1c] obvious because it teaches that its adsorbent housing 602 / adsorbent bed columns 508a, 508b (the “separation cartridge” as discussed above and highlighted in orange in the annotated figures) is withdrawable or separable as a whole (e.g., “selectively removable”) from manifold 512, or a combination of manifold 512 and inner portion of shell 204 (e.g., the “receptacle,” highlighted in green in the annotated figures).

343. For example, *Deane* repeatedly illustrates these components as separate pieces or assemblies. *See, e.g.,* EX1004 (*Deane*), FIGS. 3-6, 8, 11, 13. *Deane* also teaches that integrated manifold 512 is “mounted” to adsorbent housing 602 / adsorbent bed columns 508a, 508b. *See, e.g.,* EX1004 (*Deane*), Abstract, ¶¶[0007] (teaching an “integral fluid flow manifold mounted on one end of the columns”), [0014], [0017], [0018], [0059], [0062] (“columns 508 a-b, 510 have substantially the same length so that the integrated manifold 512 can be mounted

horizontally on the upper end of the columns 508 a-b, 510.”), [0063], [0065] (“PSA unit 506 is designed to operate with a single, generally planar integrated manifold mounted horizontally on one end of the columns.”), [0066], [0067], [0070], [0086], FIGS. 3, 5, 6, 7. Based at least on these teachings, a POSITA would have understood that adsorbent housing 602 / adsorbent bed columns 508a, 508b and manifold 512 (or manifold 512 and inner portion of shell 204) would have been connectable to and disconnectable from each other as a matter of basic engineering, and therefore that adsorbent housing 602 / adsorbent bed columns 508a, 508b is “selectively removable” from manifold 512 (or manifold 512 and inner portion of shell 204).

344. Indeed, a POSITA would have recognized that these components are able to be disconnected, or would have considered it obvious to make such disconnection possible, because adsorption beds must periodically be replaced. More specifically, as discussed above in §I.D, it was well known by 2004-2005 that molecular sieve materials degrade over time, and that such degradation impairs the efficiency of the material’s ability to adsorb nitrogen. A POSITA would have understood there to be a limited set of options to address such degradation, including replacing the adsorbent material and/or the component containing the adsorbent material. A POSITA would have understood that the latter option would have been a reasonable way to address the degradation issue,

and would have found it obvious to do so, particularly in view of the teachings of *Deane* discussed above. To replace the adsorption beds in such a manner, a POSITA would have recognized that it would have been advantageous to disconnect the adsorbent housing 602 / adsorbent bed columns 508a, 508b and manifold 512 and/or would have considered it obvious to provide various known connection and disconnection features for the interface between adsorbent housing 602 / adsorbent bed columns 508a, 508b and manifold 512.

345. Still further, *Deane* specifically teaches that its individual components can be connected and disconnected. EX1004 (*Deane*), ¶¶[0057] (teaching *Deane*'s system includes "chassis 202 (see also FIG. 3) and a shell 204 that together form a housing 206 in which various components are mounted"), [0058] (teaching the internal components of *Deane*'s system "can be assembled outside the confines of the shell 204. Also, the shell can be conveniently removed to provide access for testing, repair, or maintenance of the components"). A POSITA would have understood "repair" or "maintenance" of *Deane*'s components to include the replacement of the adsorbent housing 602 / adsorbent bed columns 508a, 508b to address adsorbent degradation discussed above.

346. Thus, *Deane* renders "... selectively removable from the receptacle ..." obvious because it teaches that its adsorbent housing 602 / adsorbent bed columns 508a, 508b (*e.g.*, "separation cartridge") is withdrawable or separable as a

whole (e.g., “selectively removable”) from manifold 512, or a combination of manifold 512 and inner portion of shell 204 (e.g., the “receptacle”), which both: (i) releasably interfaces with the inlet(s) and outlet(s) of adsorbent housing 602 / adsorbent bed columns 508a, 508b; and (ii) at least partially contains the adsorbent housing 602 / adsorbent bed columns 508a, 508b.

347. To the extent Patent Owner argues that “selectively removable from a receptacle” also/alternatively means that adsorbent housing 602 / adsorbent bed columns 508a, 508b must be removable from *Deane*’s system 100 independently from other removable components, such as battery 1104 (such as depicted by independently removable cartridge 206 and battery 108 depicted in FIG. 7 of the ’628 patent), *Deane* also teaches such a configuration. For example, *Deane* teaches that its battery is also removable from battery slot 412. EX1004 (*Deane*), ¶¶[0059], [0080], [0081], [0099], [0100]. Thus, a POSITA would have understood at least *Deane*’s adsorbent housing 602 / adsorbent bed columns 508a, 508b and battery 1104 to be “selectively removable” (independently) from their individual receptacles under this understanding.

348. To the extent Patent Owner argues: (i) that manifold 512 and shell 204 together must be considered in order to satisfy a claimed “receptacle”; and (ii) the manifold 512 and shell 204 cannot satisfy “receptacle” because they are not a *single* component, Patent Owner would be incorrect. For example, it is my

understanding that making individual components separate or integral is simply a matter of preference since no functionality is gained or lost via that choice. It is generally considered to be an obvious change. In this instance, a POSITA would have considered it an obvious variation of *Deane* to connect components such as manifold 512 and circuit board 1314 to shell 204. Indeed, *Deane* teaches that its circuit board 1314 is: (i) in direct contact with shell 204 in at least FIG. 16C; and (ii) directly connected to manifold 512, forming a contiguous structure. EX1004 (*Deane*), Abstract, ¶¶[0007], [0014], [0017], [0018], [0059], [0062], [0063] (“valves 514 of the manifold 512 contain a plurality of contact pins 516 adapted for direct contact with a circuit board in a manner to be shown in greater detail below. A circuit board controlling the valves can be mounted directly on top of the manifold 512 without additional wires, which advantageously simplifies the assembly process and also allows for the construction of a more compact device.”), [0065] (“PSA unit 506 is configured to directly connect to a circuit board without additional wires, which further conserves space and simplifies assembly.”), [0066], [0067], [0070], [0086] (“circuit board 1314 is mounted horizontally on the PSA unit 506, above the valves 816 on the manifold 512. The circuit board 1314 comprises control circuitry which governs the operation of the PSA unit, alarms, power management system, and other features of the apparatus. As described above, contacts on the circuit board 1314 are in direct electrical contact with

ating contacts 516 on the valves 514 of the PSA unit 506, which conserves space and eliminates the need for wiring connections.”), FIGS. 3, 6, 7, FIG. 16C.

Arranging the manifold 512, circuit board 1314, and shell 204 to cooperatively form a “receptacle” would have been an obvious variation of the structure taught by *Deane*.

349. To the extent Patent Owner may argue that *Deane* fails to teach a separation cartridge that is “... selectively removable from a receptacle ...”, *Berntson* teaches such a feature and, as explained above, a POSITA would have been motivated to incorporate *Berntson*’s teachings into *Deane*’s portable oxygen concentrator to provide a cartridge with an adsorbent bed and other components that is removable as a whole from the receptacle of a concentrator, *e.g.*, for maintenance purposes. EX1006 (*Berntson*), ¶[0019], FIGS. 1-2.

350. For example, *Berntson* teaches an oxygen-rich air generator (ORAG) unit that can be mounted inside a housing or cabinet of an oxygen concentrator and “removably fastened” to the housing within what a POSITA would have understood is a “receptacle” of the housing/cabinet. EX1006 (*Berntson*), ¶¶[0011]-[0012]. FIG. 1 of *Berntson* shows ORAG 32 mounted inside the receptacle, within housing or cabinet 12. *Berntson* further teaches that “ORAG 32 is removable [from the housing] as a unit.” EX1006 (*Berntson*), ¶[0019], FIGS. 1-2. FIG. 2 shows ORAG 32 in more detail—*i.e.*, what it would look like when removed from

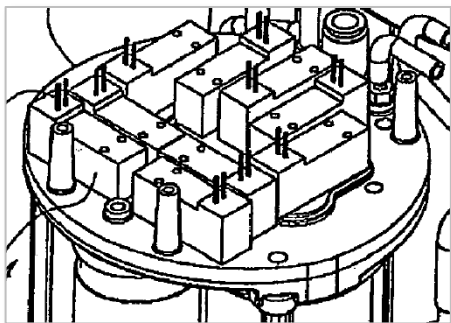
the housing—and further shows the various features and components of ORAG 32. EX1006 (*Berntson*), ¶[0012]. In particular, ORAG 32 contains adsorbent containers 42, among other components, and includes inlet filtration 44 and oxygen-rich air outlet 56. EX1006 (*Berntson*), ¶[0012]. A POSITA would have understood that when ORAG is fastened to the housing within the receptacle of *Berntson*, outlet 56 and inlet filtration interface with the housing. That is, a POSITA would have understood *Berntson* to teach a structure (the inside of the housing/cabinet) that releasably interfaces with the inlet(s) and outlet(s) of *Berntson*'s separation cartridge and at least partially contains the separation cartridge, which is a claimed receptacle. As explained in §VI.A.1, a POSITA would have been motivated to incorporate *Berntson*'s teachings into *Deane*'s portable oxygen concentrator to provide a cartridge with an adsorbent bed and other components that is removable as a whole from the receptacle of a concentrator, *e.g.*, for maintenance purposes.

351. Lastly, selectively removable components, including batteries and separation cartridges, were generally known by POSITAs by 2004-2005 (*see, e.g.*, §I.G). Thus, to the extent Patent Owner argues *Deane* (and/or *Berntson*) is somehow deficient as to teaching this element of [1c], it would have been obvious to a POSITA based on the POSITA's general knowledge to configure *Deane*'s adsorbent housing 602 / adsorbent bed columns 508a, 508b to utilize such

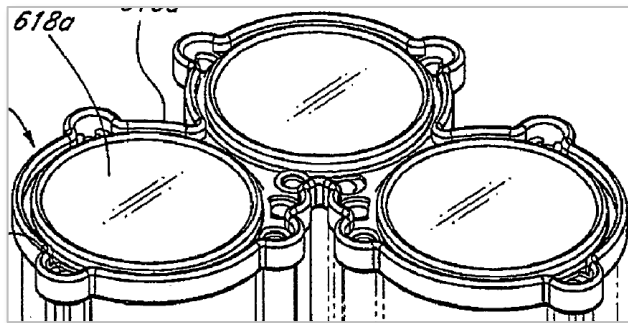
teachings to improve the speed of replacement of the adsorbent material 612 in adsorbent housing 602 / adsorbent bed columns 508a, 508b.

352. “... *by movement relative to the receptacle in a first direction ...*”:

More specifically (and in addition to the above), *Deane* renders this feature of [1c] obvious because, as shown in the annotated figures, a POSITA would have understood that adsorbent housing 602 / adsorbent bed columns 508a, 508b is selectively removable from manifold 512 “by movement relative to the receptacle in a first direction,” which is a direction along the axis of adsorbent housing 602 / adsorbent bed columns 508a, 508b (identified in the annotated drawings herein with a red arrow labeled “1st”), for several reasons. *First*, a POSITA would have recognized this to be the intended removal direction by a simple review of the Figures, which illustrate an assembly direction along the axis of adsorbent housing 602 / adsorbent bed columns 508a, 508b. *See, e.g.*, EX1004 (*Deane*), FIGS. 3, 4, 5, 8, 11, 13, 14, 15. *Second*, the particular mounting configuration described above and as shown in FIGS. 5 and 6 teach a removal direction along the axis of adsorbent housing 602 / adsorbent bed columns 508a, 508b at least because the outer periphery of manifold 512 laterally surrounds the uppermost lateral surfaces of adsorbent housing 602 / adsorbent bed columns 508a, 508b such that disconnection in other directions (such as laterally) would be difficult (see portions of FIGS. 5 and 6 reproduced below).



Deane FIG. 5

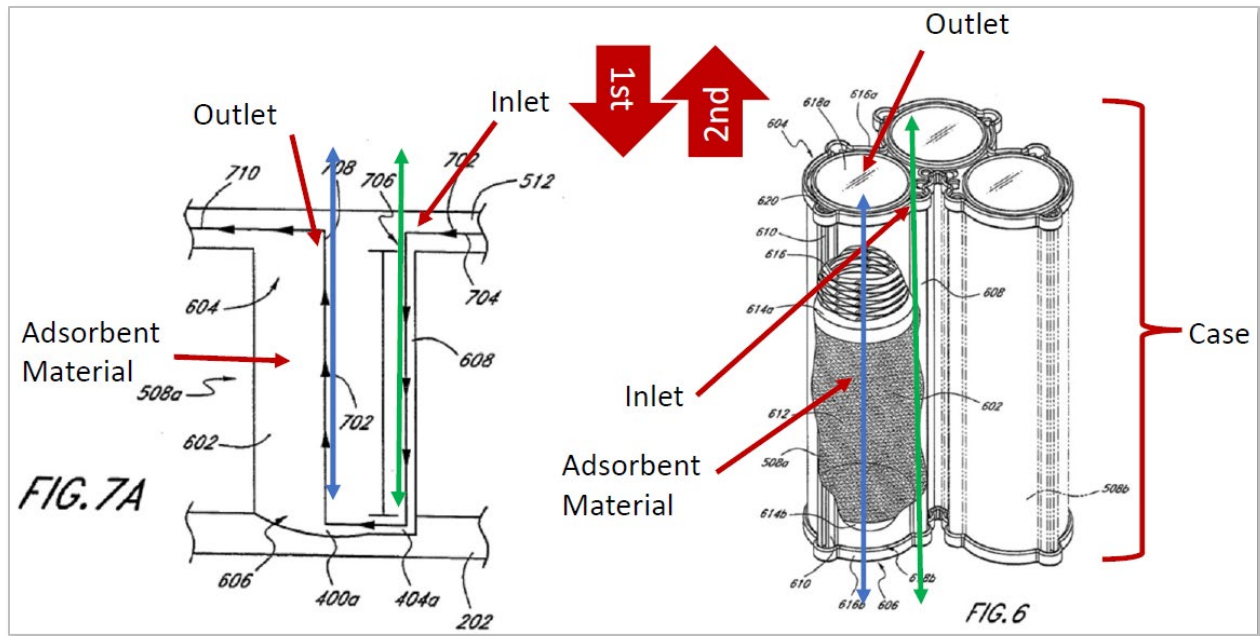


Deane FIG. 6

Third, to the extent removal in a direction other than the 1st direction would even have been possible, a POSITA would have considered it obvious to separate the manifold 512 and adsorbent housing 602 / adsorbent bed columns 508a, 508b in the 1st direction labeled in the annotated figures to maintain the airtightness of the various connections to the adsorbent housing 602's / adsorbent bed columns 508a, 508b inlet(s) and outlet(s), as a POSITA would have considered other directions, such as lateral removal, to result in more wear on the connecting surfaces. For example, if possible, lateral removal would result in the top end of housing 602 / adsorbent bed columns 508a, 508b, including the inlet(s) and outlet(s), scraping against manifold 512.

353. ***“... the separation cartridge comprising a case at least partially defining an outer volume of the separation cartridge, an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction ...”***: More specifically (and in addition to the above), *Deane* renders this feature of [1c] obvious because it teaches that its adsorbent housing 602 /

adsorbent bed columns 508a, 508b (*e.g.*, the “separation cartridge” as discussed above (*see, e.g.*, ¶338) and highlighted in orange in the annotated images) has a case (*e.g.*, the adsorbent housing 602 and/or other outer surfaces of adsorbent housing 602 / adsorbent bed columns 508a, 508b, shaded in orange in the annotated drawings above), inlets (*e.g.*, opening 706 of feed tube 608 connected to lower end 606 of each column 508a, 508b) oriented in a second direction opposite the first direction (*e.g.*, the direction labeled “2nd” in the annotated figures below), and outlets (*e.g.*, upper ends 604 of each column 508a, 508b) oriented in the second direction. EX1004 (*Deane*), [0066] (“FIG. 6 provides a detailed view of the adsorbent bed columns 508 a, 508 b of the PSA unit ... [where] column 508 a generally includes an elongated adsorbent housing 602 having an upper end 604 and a lower end 606, each defining an opening through which gas can flow in and out of the housing 602. The column 508 a further includes an integrated feed tube 608 extending from the upper end

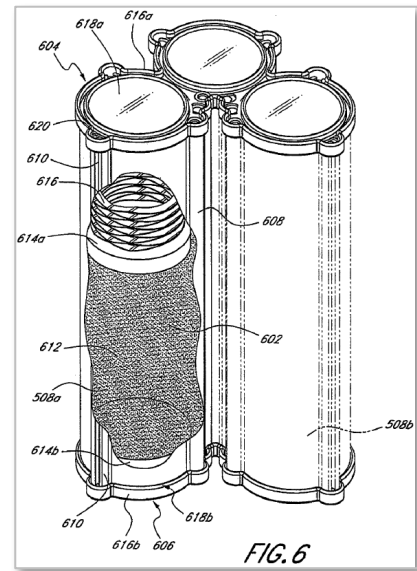


604 of the housing 602 to the lower end 606. The feed tube 608 provides a gas passageway between the manifold and the housing 602 such that gas from the manifold can be routed through the feed tube 608 into the lower end 606 of the housing 602 and vice versa. This design eliminates the need of a second manifold for directing gas into the lower end 606 of the housing 602 and allows all flow passages in the manifold to be co-located in a single plane, which significantly reduces the number of tubing connections and potential leak points in the unit.”), [0070] (“As shown in FIG. 7A, feed gas 702 is directed from a feed stream 704 in the manifold 512 into an upper opening 706 of the feed tube 608. The feed gas 702 travels downwardly through the tube 608 and is diverted by a divot 404 a in the chassis 202 into a recess 400 a underneath the lower end 606 of the adsorbent housing 602. The divot 404 a, which is pre-formed in the chassis 202,

advantageously serves as a lateral gas flow passageway so as to eliminate the need of any flexible tubing on the lower end of the column, which in turn simplifies assembly and reduces potential leak points. The feed gas 702 flows upwardly from the recess 400 a through the lower end 606 of the housing 602 and upwardly through the adsorbent material contained in the housing 602. The adsorbent material selectively removes one or more components in the feed gas 702 in a known manner to form a product gas 708. The product gas 708 flows out of an upper end 604 of the housing 602 into a product stream 710 in the manifold 512.”).

Based at least on the passages cited herein, a POSITA would have understood *Deane* as teaching that both columns 508a, 508b are of the same construction (*i.e.*, each has the same inlet, outlet, filters, springs, *etc.*). See EX1004 (*Deane*), FIG. 6, ¶¶[0062]-[0063], [0066]-[0067], and [0069]-[0070]. This understanding would have been reinforced by a POSITA’s general understanding that POCs generally utilized at least two adsorbent beds of the same construction to provide continuous product gas flow, as taught by the various references in, *e.g.*, §I.B. Thus, to the extent I describe one of the columns 508a, 508b related to an element of any claim herein, it should be understood that I am describing either or both of columns 508a, 508b.

354. More specifically as to the claimed “case,” as shown in FIG. 6, *Deane* teaches elongated adsorbent housing 602 (and/or other outer surfaces of adsorbent housing 602 / adsorbent bed columns 508a, 508b) with upper end 604 and lower end 606, each defining an opening through which gas can flow in and out of the housing 602, and integrated feed tube 608 extending from upper end 604 to lower end 606, which allows gas to be routed to lower end 606. Adsorbent bed housing 602 (and/or other outer surfaces of adsorbent housing 602 / adsorbent bed columns 508a, 508b) includes adsorbent material 612 (zeolite), upper and lower restraining disks 614a, 614b (filters) for inhibiting movement of the adsorbent material 612, spring 616 that applies pressure across the upper restraining disk 614a to keep disk 614a in position.” EX1004 (*Deane*), ¶[0068]. As discussed above, a POSITA would have understood *Deane* to teach that its housing 602 extends around each of the adsorbent bed columns (*e.g.*, 508a, 508b) and/or each adsorbent bed columns (*e.g.*, 508a, 508b) to have individual housings 602 that are interconnected, such as along their diameters or by ends 604, 606, as shown in FIG. 6. In either case, this outer structure of housings 602 (and/or other outer surfaces of adsorbent housing 602 / adsorbent bed columns 508a, 508b) defines a case.



355. *Berntson* also teaches that its ORAG unit (a “separation cartridge” for the reasons above) includes an outer case, as shown in FIGS. 1-2. EX1006 (*Berntson*), ¶¶[0011]-[0012], FIGS. 1-2. As explained in §VI.A.1, a POSITA would have been motivated to incorporate *Berntson*’s teachings into *Deane*’s portable oxygen concentrator to provide a cartridge with an adsorbent bed and other components that is removable as a whole from the receptacle of a concentrator, *e.g.*, for maintenance purposes. EX1006 (*Berntson*), ¶[0019], FIGS. 1-2.

356. More specifically as to the claimed “inlet,” as shown in FIG. 7A, *Deane* teaches that the opening 706 of feed tube 608 at upper end 604 of each column 508a, 508b is an inlet into which feed gas 702 (ambient air) flows. EX1004 (*Deane*), FIG. 7, ¶[0066], [0070] (“[F]eed gas 702 is directed from a feed stream 704 in the manifold 512 into an upper opening 706 of the feed tube 608.”). The opening of feed tube 608 (upper opening 706) is oriented in a second direction opposite the direction in which the housing 602 / adsorbent bed columns 508a, 508b is removed from manifold 512 (as described above). EX1004 (*Deane*), FIGS. 5 and 6.

357. And more specifically as to the claimed “outlet,” FIG. 7A of *Deane* also shows that product gas 708 flows out of upper end 604 of each column 508a, 508b into a product stream. EX1004 (*Deane*), FIG. 7, ¶[0070]. The product gas

flows out of housing 602 / adsorbent bed columns 508a, 508b and into manifold 512 *via* filter portion 618a at upper end 604 of housing 602 / adsorbent bed columns 508a, 508b, as shown in FIGS. 5 and 6 of *Deane*. Thus, *Deane* discloses an outlet (upper end 604) that is oriented in the same direction as *Deane*'s inlet—in the direction opposite from the direction in which the housing 602 / adsorbent bed columns 508a, 508b is removed from manifold 512.

358. *Deane* provides many additional teachings of the claimed configuration. EX1004 (*Deane*), Abstract, ¶[0007] (“[t]he adsorbent columns preferably comprise one or more feed tubes configured to direct fluid to flow from flow passages in the integrated manifold mounted on one end of the columns to an opening in the other end of the columns.”), [0008] (“plural adsorbent beds connected to receive the feed gas from the compressor via a feed gas pathway.”), [0014], [0017], [0018], [0036], [0059], [0062], [0063], (“integrated manifold 512 is mounted on the upper end of the columns 508 a-b, 510 in a manner such that the integrated flow passages in the manifold are in fluid communication with openings in the upper end of each column. While the manifold 512 is positioned on only the upper end of the columns, gas flow from the manifold can enter the column housing through either the upper or lower end due to a novel single-ended column design.”), [0065] (“The PSA unit 506 is also configured with integrated gas flow passages so as to substantially eliminate the use of flexible tubing, which in turn

reduces the number of potential leak points. Moreover, the PSA unit 506 is designed to operate with a single, generally planar integrated manifold mounted horizontally on one end of the columns.”), [0067], [0092], FIG. 3, 6, 7.

359. In addition, providing inlet and outlet ports on the same end of an adsorption cartridge was generally known by POSITAs by 2004-2005 (*see, e.g.*, §I.F). Thus, to the extent Patent Owner argues *Deane* is somehow deficient as to teaching this element of [1c], it would have been obvious to a POSITA based on the POSITA’s general knowledge to configure *Deane*’s adsorbent housing 602 / adsorbent bed columns 508a, 508b to utilize such inlet/outlet teachings to improve the speed of replacement of adsorbent housing 602 / adsorbent bed columns 508a, 508b and/or simplify the manifold arrangement such that it can be arranged on one end of the adsorbent housing 602 / adsorbent bed columns 508a, 508b.

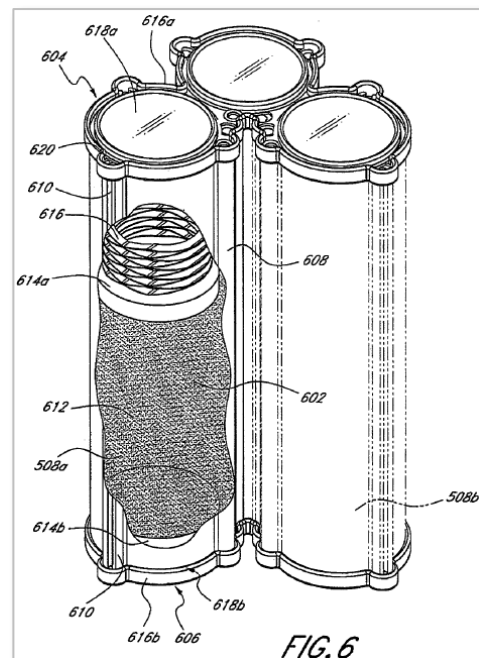
360. Lastly, both the applicant and Examiner in various related applications confirmed that *Deane*’s teachings, as provided in *Deane* ’059 (EX1038) and *Deane* ’426 (EX1047) render this portion of element [1c] obvious. For example, applicant stated in an appeal brief that *Deane* ’059 (EX1038) teaches: “a portable gas fractionalization apparatus that provides oxygen rich air to patients. The components are assembled in a housing that is divided into two compartments. ... The apparatus utilizes a PSA unit to produce an oxygen enriched product. The PSA unit incorporates a single ended column design in which all flow paths and

valves can be co-located on a single integrated manifold.” EX1049 (*'490 Patent FH*), 40. I agree with applicant that *Deane '059* teaches all flow paths and valves co-located on one end of the adsorbent bed columns, namely via a manifold. This is depicted in, for example, FIGS. 5 and 6. A POSITA would have understood from this teaching and other teachings of *Deane '059* that the corresponding flow paths and valves would be co-located on one end of *Deane '059's* separation cartridge (the end that interfaces with the manifold), which similar to *Deane* is adsorbent housing 602 / adsorbent bed columns 508a, 508b.

361. As another example, the Examiner in a related application stated that *Deane '426* (EX1047) teaches “an oxygen concentrator cartridge, best shown in Figure 6, having a first port corresponding to the filter portion 618a (par. 67) disposed along the first axis defined by the bed of adsorbent material 612 (par. 66) and a second port the upper port of feed tube 608 (par. 68) that lies in the same plane as filter portion 618a and spaced apart from the first port (fig. 6).” EX1052 (*'669 Patent FH*), 16. I agree with the examiner: *Deane '426* (EX1047) teaches an inlet (for feed tube 608) spaced apart from an outlet (filter portion 618a), where both the inlet and the outlet are at the upper end of *Deane '426's* (EX1047) “separation cartridge” (adsorbent housing 602 / adsorbent bed columns 508a, 508b) and face the same direction (upward toward the interface with manifold 512). EX1047 (*Deane '426*), FIGS. 5, 6, 7.

362. “... the separation cartridge comprising ... a bed of adsorbent material configured to preferentially adsorb nitrogen, the case at least partially surrounding the bed of adsorbent material”: More specifically (and in addition to the above), *Deane* renders this feature of [1c] obvious because it teaches that its adsorbent housing 602 / adsorbent bed columns 508a, 508b (the “separation cartridge” as discussed above and highlighted in orange in the annotated images above) has beds of adsorbent material 612 configured to preferentially adsorb nitrogen, and that the case (housing 602 and/or other outer surfaces of adsorbent housing 602 / adsorbent bed columns 508a, 508b) at least partially surrounds those beds.

363. First, *Deane* teaches that its separation cartridge includes two adsorbent beds. EX1004 (*Deane*), [0036] (“PSA unit 108 ... includes two adsorbent beds 118 a, 118 b, each containing an adsorbent material that is selective toward nitrogen”), [0062] (“PSA unit 506 generally includes a pair of adsorbent bed columns 508 a, 508 b ... containing a nitrogen-selective adsorbent material such as zeolite ... adapted to remove nitrogen from intake air in a known manner in accordance with a PSA cycle so as



to produce an oxygen rich product gas.”), [0068] (“adsorbent bed housing 602 contains an adsorbent material 612, ... compris[ing] a granular material such as zeolite that can be easily dislodged.”).

364. Second, as discussed above, as shown in FIG. 6, *Deane* teaches its housing 602 (and/or other outer surfaces of adsorbent housing 602 / adsorbent bed columns 508a, 508b) contains (therefore at least partially surrounds) adsorbent material 612 (zeolite), upper and lower restraining disks 614a, 614b (filters) for inhibiting movement of the adsorbent material 612, spring 616 that applies pressure across the upper restraining disk 614a to keep disk 614a in position. EX1004 (*Deane*), ¶[0068] (“the adsorbent bed housing 602 contains an adsorbent material 612”), FIG. 6.

365. *Deane* provides many additional teachings of the claimed configuration. EX1004 (*Deane*), Abstract, ¶¶[0007] (“the preferred embodiments of the present invention provide a portable gas fractionalization apparatus comprising plural adsorbent bed columns mounted side by side.”), [0008] (“the preferred embodiments of the present invention provide a portable gas fractionalization apparatus comprising ... plural adsorbent beds.”), [0010] (“the preferred embodiments of the present invention provide an adsorbent bed column comprising an elongated housing; an adsorbent material positioned inside the housing.”), [0011] (“the preferred embodiments of the present invention provide an

adsorbent bed column comprising an elongated housing; plural adsorbents positioned inside the housing.”), [0014], [0017], [0018], [0035], [0066], [0069], [0070] (“The feed gas 702 flows upwardly from the recess 400 a through the lower end 606 of the housing 602 and upwardly through the adsorbent material contained in the housing 602. The adsorbent material selectively removes one or more components in the feed gas 702 in a known manner to form a product gas 708.”), [0092], FIG. 3, 6, 7.

366. In addition, providing an adsorbent material in an adsorbent cartridge was generally known by POSITAs by 2004-2005. *See, e.g.*, §§I.B, I.C, I.G. Thus, to the extent Patent Owner argues *Deane* is somehow deficient as to teaching this element of [1c], it would have been obvious to a POSITA based on the POSITA’s general knowledge to configure *Deane*’s adsorbent housing 602 / adsorbent bed columns 508a, 508b to include adsorbent material to allow operation of *Deane*’s portable oxygen concentrator.

367. Further, as mentioned above, the Examiner of the related ’669 patent found that *Deane* ’426 (EX1047) discloses a “bed of adsorbent material 612,” and this bed of adsorbent material is contained in adsorbent housing 602 / adsorbent bed columns 508a, 508b, which, similar to in *Deane* discussed above, is a separation cartridge. EX1047 (*Deane* ’426), FIG. 6.

368. Finally, my understanding that *Deane* (with or without the teachings of *Berntson*) teaches element [1c] is consistent with the assertion of infringement against Petitioner's product advanced in connection with the litigation. EX1072 (*Infringement Chart*) at 3-5; EX1074 (*Infringement Contentions*) at 5-8. In particular, for example, PO has asserted that the cartridge of element [1c] includes a adsorbent bed that is removable as a whole from a POC after some disassembly of a POC (*e.g.*, cover removal, *etc.*) and that has inlets/outlets arranged adjacently on one end of the adsorbent bed. This comports with my identification of the similar features of *Deane* as teaching element [1c].

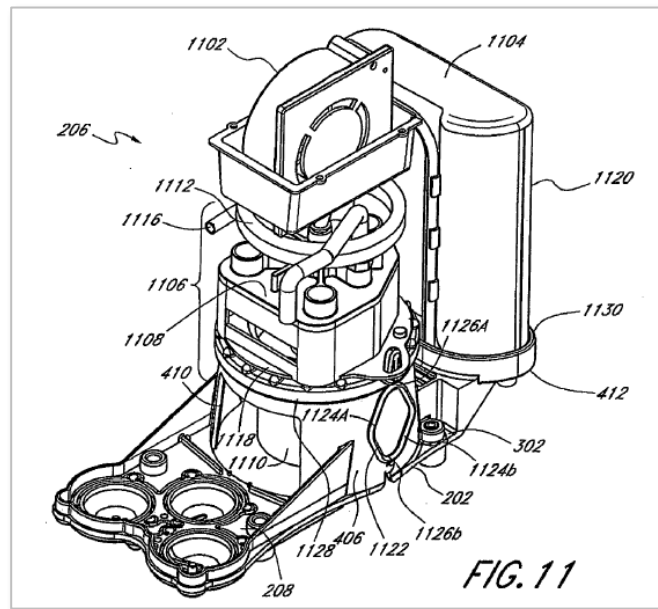
369. For all of the above reasons, it is my opinion that element [1c] is taught by the combination of *Deane*, *Dubois*, and *Berntson*.

- [1d] a power pack removable from the portable oxygen concentrator;**
- [1e] a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material;**
- [1f] a user interface configured to allow a patient to adjust and monitor operation of the portable oxygen concentrator;**
- [1g] a carrying device for transporting the portable oxygen concentrator;**
- [1h] wherein the housing of the cartridge module is configured to at least partially surround the case of the separation cartridge,**

370. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches elements [1d]-[1h], rendering them obvious.

371. Specifically, it is my opinion that limitations [1d]-[1h] are rendered obvious by *Deane* because *Deane* teaches a power pack removable from the portable oxygen concentrator (e.g., battery 1104); a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material (e.g., compressor 1108); a user interface configured to allow a patient to adjust and monitor operation of the portable oxygen concentrator (e.g., user interface panel 1602); a carrying device for transporting the portable oxygen concentrator (e.g., the POC handle and/or mobility cart 1800); wherein the housing of the cartridge module is configured to at least partially surround the case of the separation cartridge (e.g., shell 204 and/or other components identified in [1b] surrounds housing 602 and/or other outer surfaces of adsorbent housing 602 / adsorbent bed columns 508a, 508b). EX1004 (*Deane*) at, e.g., ¶¶[0056], [0068], [0080]-[0081], [0092], [0094], [0098]-[0100], FIGS. 3, 5, 6, 11. *Dubois* also teaches a carrying device. EX1005 (*Dubois*), 3:25-30, 6:21-25, FIG. 5 (e.g., a belt or strap).

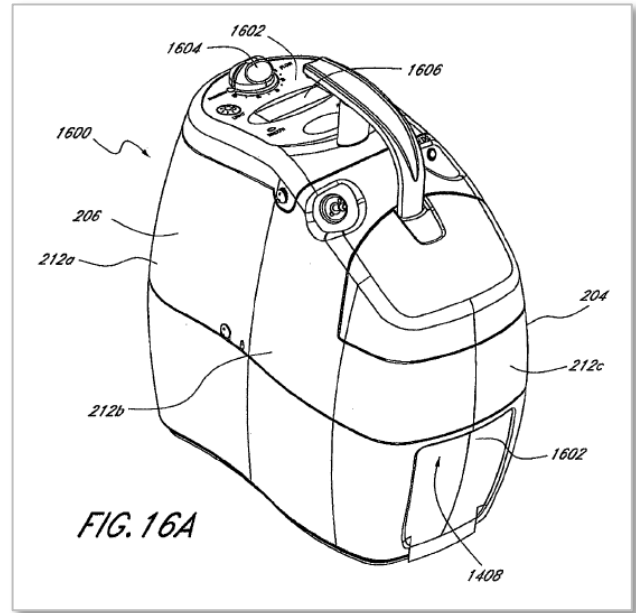
372. “[1d] a power pack removable from the portable oxygen concentrator”: *Deane* teaches element [1d] because *Deane* teaches battery 1104, which is an example given in the ’628 patent of a claimed “power pack,” removably mountable on a portable oxygen concentrator. EX1004 (*Deane*) ¶[0068]. *Deane*’s battery powers its POC, including all its major systems; for example, *Deane* teaches that “[e]ach battery has a rated life of at least 2 hours so that the user is able to enjoy continuous use of the concentrator unit for at least six hours without an external power source.” EX1004 (*Deane*) ¶[0100]. *Deane*’s portable oxygen concentrator is designed with guide rails formed on the battery and adapted to mate with a “battery bail” in order to facilitate “mounting of the battery particularly for those with impaired dexterity.” EX1004 (*Deane*), ¶[0081]. Thus, *Deane*’s battery is “removable from the portable oxygen concentrator,” as claimed. *Deane*’s removable battery 1104 is shown in FIG. 11 reproduced here. See also EX1004 (*Deane*), ¶[0099] (spare batteries secured in slots of mobility cart for carrying and transporting the POC).



373. ***“[1e] a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material”***: *Deane* teaches element [1e] because *Deane* teaches compressor 1108 that pressurizes air and delivers it to heat exchanger so that the air can be cooled and then supplied as feed gas to adsorbent columns to produce a product gas. EX1004 (*Deane*) ¶[0092]. A POSITA would have understood that in order for feed gas (a claimed “flow of fluid”) to become product gas after being supplied to *Deane*’s adsorbent columns, the feed gas would “move relative to the bed of adsorbent material.” That is how POCs such as *Deane*’s work. *Deane* teaches that “the compressor 1108 can...be a vacuum pump or a combination of a vacuum pump and a compressor.” EX1004 (*Deane*) ¶[0080]. *Deane*’s compressor/pump 1108 is electrically coupled to battery 1104. This is shown in FIG. 11 of *Deane* above and is also clear because *Deane*’s battery powers all the systems of *Deane*’s POC.

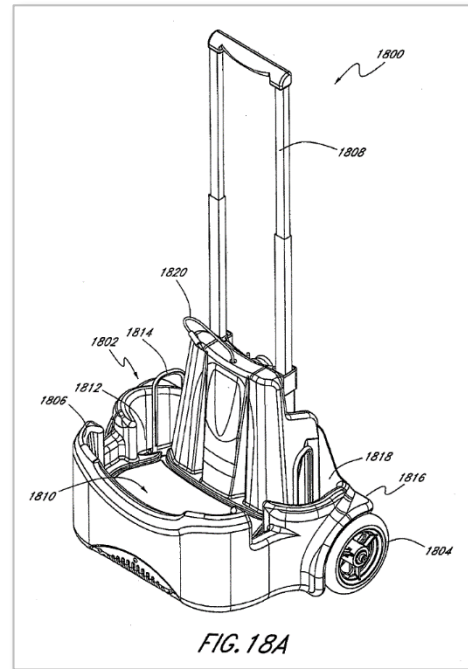
374. ***“[1f] a user interface configured to allow a patient to adjust and monitor operation of the portable oxygen concentrator”***: *Deane* teaches element [1f] because *Deane* teaches “user interface panel 1602 containing a plurality of system controls 1604 such as flow rate and on-off switches[,]” where the user interface is “integrally formed in the shell 204” of *Deane*’s POC. EX1004 (*Deane*), ¶[0094]. *Deane*’s user interface allows a patient to adjust operation of *Deane*’s portable oxygen concentrator, for example by adjusting the flow rate or by

turning the system on/off. EX1004 (*Deane*) ¶[0094]. A POSITA would have understood that *Deane*'s user interface would also be used to monitor the operation of the POC, for example to monitor flow rate, oxygen content, and other functions. EX1004 (*Deane*), ¶[0094]; *see also id.* at ¶[0056] (“oxygen sensor 126 for monitoring oxygen content or product gas”). *Deane*'s user interface panel is shown, among other places, in FIG. 16 reproduced below.

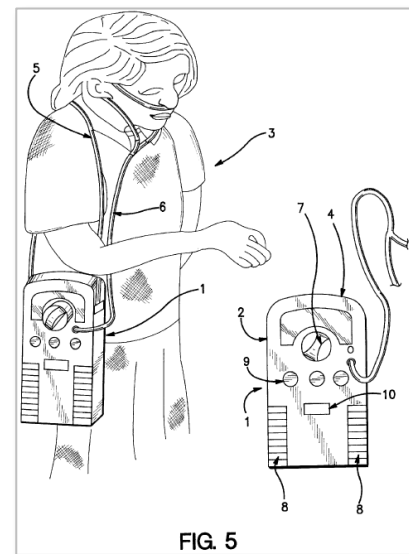


375. “[1g] a carrying device for transporting the portable oxygen concentrator”: *Deane* alone or in combination with *Dubois* teaches element [1g] because *Deane* teaches that its POC has a handle extending from the shell that a user can use to grip and lift the POC for transporting it and placing it in or removing it from compartment 1810 of a mobility cart. EX1004 (*Deane*), ¶[0099]. *Deane*'s handle, shown in for example FIG. 16A above, is a claimed “carrying device for transporting the” POC. Additionally, *Deane* discloses “mobility cart

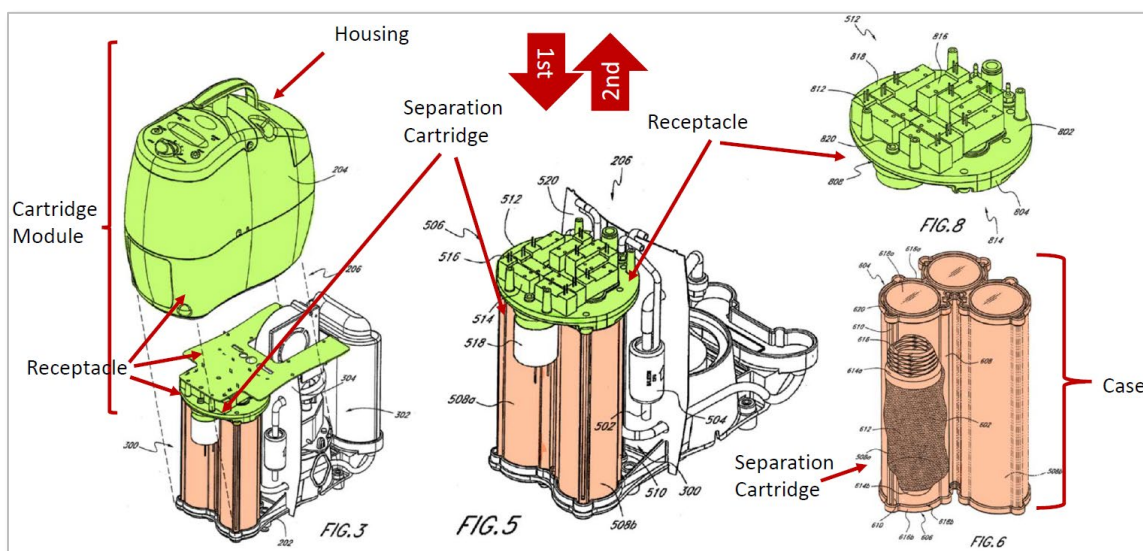
1800 configured to transport an oxygen concentrator unit for users traveling away from home.” EX1004 (*Deane*) ¶[0099]. The mobility cart includes “handle portion 1808 extending upwardly...for users to hold when moving the cart.” EX1004 (*Deane*), ¶[0099]. *Deane*’s mobility cart with handle 1808 and wheels 1804 for transporting the POC is shown, for example, in FIG. 18A reproduced below. The mobility cart is also a claimed “carrying device.”



376. To the extent Patent Owner may argue that *Deane*’s POC’s handle and/or mobility cart with its handle is not a claimed “carrying device,” *Dubois* discloses such a device and, as explained above, a POSITA would have been motivated to combine *Deane* and *Dubois* in the manner described herein such that *Deane*’s POC would be sized for carrying. For example, *Dubois* teaches a portable gas concentrator wearable by a patient on a strap or belt, as shown in FIG. 5. EX1005 (*Dubois*), 3:25-30, 6:21-25, FIG. 5 (reproduced here).



377. “[1h] wherein the housing of the cartridge module is configured to at least partially surround the case of the separation cartridge”: *Deane* alone or in combination with *Berntson* teaches element [1h] because *Deane* teaches that its cartridge module housing (e.g., shell 204 and or other components as discussed in element [1b] and shaded **green** in the annotated figures below) at least partially surrounds its separation cartridge case (e.g., housing 602 and/or other outer surfaces of adsorbent housing 602 / adsorbent bed columns 508a, 508b, as discussed in element [1c] and shaded **orange** in the annotated figures below).



378. To the extent Patent Owner may argue that *Deane* fails to teach this feature, *Berntson* teaches it because, as discussed above, *Berntson* teaches an oxygen-rich air generator (ORAG) unit that can be mounted inside a housing or cabinet of an oxygen concentrator and “removably fastened” to the housing within what a POSITA would have understood is a “receptacle” of the housing/cabinet.

EX1006 (*Berntson*), ¶¶[0011]-[0012]. FIG. 1 of *Berntson* shows ORAG 32 mounted inside the receptacle, within housing or cabinet 12. *Berntson* further teaches that “ORAG 32 is removable [from the housing] as a unit.” EX1006 (*Berntson*), ¶[0019], FIGS. 1-2. In these arrangements, *Berntson*’s housing at least partially surrounds its ORAG 32. As explained above, a POSITA would have been motivated to incorporate *Berntson*’s teachings into *Deane*’s portable oxygen concentrator to provide a cartridge with an adsorbent bed and other components that is removable as a whole from the receptacle of a concentrator, *e.g.*, for maintenance purposes. EX1006 (*Berntson*), ¶[0019], FIGS. 1-2.

379. In addition to the above, the Examiner in a related Application asserted that *Deane* ’745 teaches: (i) a gas input system 102 for supplying ambient air (see fig. 1; col. 9 lines 35-40); (ii) a VSA gas separation system in communication with the gas input system to receive the ambient air (see col. 11 lines 55-60), the gas separation system comprising a cartridge 118a and 118b containing an adsorbent material for producing oxygen (see col. 4 lines 4-15); (iii) a delivery system 110 for receiving oxygen produced by the gas separation system (see fig. 1; col. 11 lines 60-65); (iv) a drive which actuates the delivery system and the gas separation system); (v) a power pack connected to the device (see col. 14 lines 54-64); (vi) an oxygen concentrator has a weight of less than 2.3 kg (see col. 6 lines 10-12); (vii) the power pack comprises a battery (see col. 14 lines 54-64).

EX1050 ('362 *Application FH*), 58-59. Thus, the Examiner confirmed that *Deane* '745 teaches almost all of the elements [1d]-[1h]. *Deane* '745 and *Deane* share common disclosure.

380. Finally, my understanding that *Deane* teaches elements [1d]-[1h] is consistent with the assertion of infringement against Petitioner's product advanced in connection with the litigation. EX1072 (*Infringement Chart*) at 6-8; EX1074 (*Infringement Contentions*) at 8-12. In particular, for example, PO asserts that a battery that is removable from a POC in a separate operation than the alleged separation cartridge falls within the scope of element [1d], that the entire outer structure of a POC may be a cartridge module and housing that surrounds the cartridge module as to element [1h], and that a carrying device may be a carry bag or backpack with a handle as to element [1g]. This comports with my identification of the similar features of *Deane* and/or *Berntson* as teaching these elements.

381. Therefore, it is my opinion that elements [1d]-[1h] are taught by the combination of *Deane*, *Dubois*, and *Berntson*.

- [1i] wherein the bed of adsorbent material is disposed along an axis,**
- [1j] one of the inlet and the outlet is disposed along the axis, and**
- [1k] the other of the inlet and the outlet is spaced-apart from the axis, and**
- [1l] wherein the first direction and the second direction are substantially parallel to the axis.**

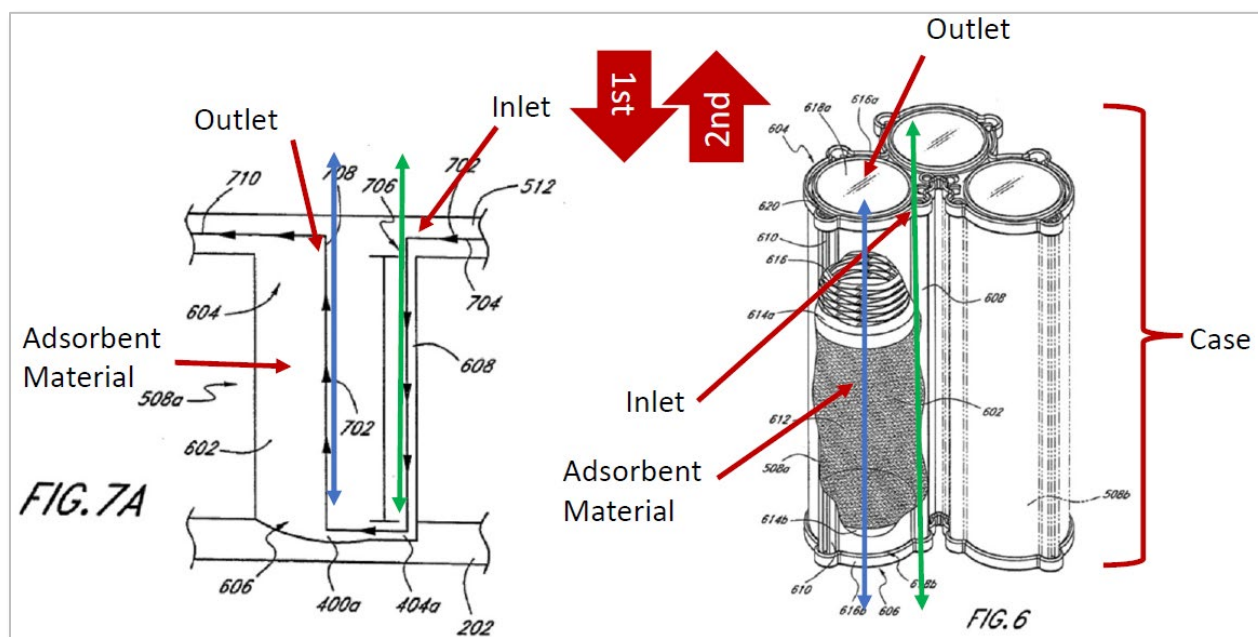
382. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches elements [1i]-[1l], rendering them obvious.

383. Specifically, it is my opinion that limitations [1i]-[1l] are rendered obvious by *Deane* because *Deane* teaches wherein the bed of adsorbent material is disposed along an axis (*e.g.*, adsorbent material 612 in adsorbent bed columns 508a, 508b is arranged along an axis, or centerline (see §V.D), of each column as shown by the blue line in the annotated figures below)¹⁷, one of the inlet and the outlet is disposed along the axis (*e.g.*, the blue line in the annotated figures below passes through outlet 604 of adsorbent housing 602 / adsorbent bed columns 508a, 508b), and the other of the inlet and the outlet is spaced-apart from the axis (*e.g.*, the green line in the annotated figures below passes through inlet 706/608 of adsorbent housing 602 / adsorbent bed columns 508a, 508b and is spaced apart from the axis shown by the blue line), and wherein the first direction and the

¹⁷ As discussed above, a POSITA would have understood *Deane* as teaching that both columns 508a, 508b are of the same construction (*i.e.*, each has a similar inlet, outlet, filters, springs, *etc.*).

second direction are substantially parallel to the axis (e.g., the [blue line](#) is parallel to the first and second directions shown by the red arrows, which are discussed above in element [1c]). EX1004 (*Deane*) at, e.g., ¶¶[0059], [0062], [0066], [0068], [0070], FIGS. 6, 7A.

384. The annotated versions of *Deane*'s FIGS. 6 and 7A reproduced here provide further explanation and examples of how *Deane* teaches each of the features of elements [1i]-[1l] in the manner described above. I also discuss how *Deane* teaches each feature of elements [1i]-[1l] in more detail below.



385. Specifically, *Deane* teaches the arrangement of elements [1i]-[1l] as shown in the annotated version of FIG. 7A above in ¶[0070], which states:

[0070] (“FIGS. 7A and 7B provide schematic illustrations of the adsorbent bed column 508 a in combination with the chassis 202 and the manifold 512, showing the manners in which gas flow is directed

in and out of the column 508 a in accordance with the single-ended column design. As shown in FIG. 7A, feed gas 702 is directed from a feed stream 704 in the manifold 512 into an upper opening 706 of the feed tube 608. The feed gas 702 travels downwardly through the tube 608 and is diverted by a divot 404 a in the chassis 202 into a recess 400 a underneath the lower end 606 of the adsorbent housing 602. The divot 404 a, which is pre-formed in the chassis 202, advantageously serves as a lateral gas flow passageway so as to eliminate the need of any flexible tubing on the lower end of the column, which in turn simplifies assembly and reduces potential leak points. The feed gas 702 flows upwardly from the recess 400 a through the lower end 606 of the housing 602 and upwardly through the adsorbent material contained in the housing 602. The adsorbent material selectively removes one or more components in the feed gas 702 in a known manner to form a product gas 708. The product gas 708 flows out of an upper end 604 of the housing 602 into a product stream 710 in the manifold 512.”).

EX1004 (*Deane*) ¶[0070]. *See also* Abstract, ¶¶[0059], [0062], [0066] (“FIG. 6 provides a detailed view of the adsorbent bed columns 508 a, 508 b of the PSA unit, illustrating the novel single-ended column design briefly described above. As shown in FIG. 6, the column 508 a generally includes an elongated adsorbent housing 602 having an upper end 604 and a lower end 606, each defining an opening through which gas can flow in and out of the housing 602. The column 508 a further includes an integrated feed tube 608 extending from the upper end 604 of the housing 602 to the lower end 606. The feed tube 608 provides a gas passageway between the manifold and the housing 602 such that gas from the manifold can be routed through the feed tube 608 into the lower end 606 of the housing 602 and vice versa. This design eliminates the need of a second manifold

for directing gas into the lower end 606 of the housing 602 and allows all flow passages in the manifold to be co-located in a single plane, which significantly reduces the number of tubing connections and potential leak points in the unit.”), [0068] (“As also shown in FIG. 6, the adsorbent bed housing 602 contains an adsorbent material 612, an upper and a lower restraining disk 614 a, 614 b for inhibiting movement of the adsorbent material 612, a spring 616 that applies pressure across the upper restraining disk 614 a to keep the disk 614 a in position. In one embodiment, the adsorbent material 612 comprises a granular material such as zeolite that can be easily dislodged.”).

386. In addition, various arrangements of inlets and outlets to provide appropriate connectivity were generally known by POSITAs by 2004-2005 (*see, e.g., §I*). Thus, to the extent Patent Owner argues *Deane* is somehow deficient as to teaching these elements, it would have been obvious to a POSITA based on the POSITA’s general knowledge to configure *Deane*’s inlets and outlets as claimed to provide appropriate connectivity.

387. Further, the Examiner in a related application confirmed that *Deane*’s teachings, as provided in *Deane* ’426 (EX1047) render these elements obvious. For example, as I discussed above, the Examiner in a related application stated that *Deane* ’426 (EX1047) teaches “an oxygen concentrator cartridge, best shown in Figure 6, having a first port corresponding to the filter portion 618a (par. 67)

disposed along the first axis defined by the bed of adsorbent material 612 (par. 66) and a second port the upper port of feed tube 608 (par. 68) that lies in the same plane as filter portion 618a and spaced apart from the first port (fig. 6).” EX1052 (*'669 Patent FH*), 16. I agree with the Examiner.

388. Still further, even to the extent PO disagrees that an “axis” is properly construed as the centerline of the adsorbent bed (*see* §V.D), the blue line shown above is still a line passing through both the adsorbent material and outlet as claimed, and therefore satisfies elements [1i]-[1j].

389. Finally, my understanding that *Deane* teaches elements [1i]-[1j] is consistent with the assertion of infringement against Petitioner’s product advanced in connection with the litigation. EX1072 (*Infringement Chart*) at 9-10; EX1074 (*Infringement Contentions*) at 12-14.

390. Therefore, it is my opinion that [1i]-[1j] are taught by the combination of *Deane*, *Dubois*, and *Berntson*.

391. Accordingly, the combination of *Deane*, *Dubois*, and *Berntson* renders claim 1 obvious.

3. Dependent Claims 2-3

- [2] 2. The portable oxygen concentrator as recited in claim 1, wherein the portable oxygen concentrator weighs less than 3 pounds.
- [3] 3. The portable oxygen concentrator as recited in claim 1, wherein the power pack is a battery having a weight of less than 0.7 pounds.

392. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches Claims 2 and 3, rendering them obvious. Specifically, *Deane* teaches “there is a particular need for a portable oxygen concentrator that is lightweight, quiet, and can supply oxygen continuously for an extended period without requiring an external power source. EX1004 (*Deane*), ¶[0006]. *Deane* teaches that its entire apparatus should have “a combined weight of preferably no [more] than about 10 pounds.” EX1004 (*Deane*), ¶[0093]. *Dubois* further teaches that reduction of both overall and battery weight of a POC is important and shows a small and lightweight POC slung around a patient’s shoulder. EX1005 (*Dubois*), 3:64-4:2, FIG. 5.

393. Additionally, as discussed in §I.J, a POSITA would have been well-aware that POCs were intended, by their nature, to be lightweight and small-sized to enable their portability, and that making POCs lighter and smaller was a widely-recognized design goal. *See, e.g.*, EX1009 (*McCombs* ’924) at ¶[0005]; EX1010 (*McCombs* ’957) at ¶[0007]; EX1012 (*Warren* ’095) at Title, Abstract, ¶[0002]; and EX1013 (*Hill* ’658), Abstract, 1:7-10. And many examples of such POCs were known, including POCs: (i) “with a weight of less than about 10 lb.”

(EX1009 (*McCombs* '924) at ¶[0025]); (ii) “with a weight of less than about 5 lb.” (EX1010 (*McCombs* '957) at ¶[0036]); (iii) that are “small and light (2-15 pounds)” (EX1013 (*Hill* '658) at 9:66). It was also known that in such lightweight systems, the battery would also have been lightweight. For example, “to properly function as a lightweight, portable system..., the system...must be energized by a *suitable* rechargeable energy source.” EX1013 (*Hill* '658) at 8:19-23 (emphasis added). A POSITA would have understood that in lightweight portable oxygen concentration systems, the battery represents a portion of the overall weight. *See* EX1013 (*Hill* '658) at 4:66-5:12 (system weighing as little as two pounds includes oxygen concentrator, battery, sensors, and control unit), 9:66. Thus, a POSITA would have understood in the small and light systems known in the art, such as the 2-15 pound system of *Hill* '658, a battery would have weighed less than 0.7 pounds.

394. Based on the above, a POSITA would have understood that weight reduction in a POC was important based on general knowledge in the art and would have considered it obvious to make the POC and battery of the combination of *Deane*, *Dubois*, and *Berntson* as light as possible, including within the claimed weight ranges, to improve the resultant POC's portability.

395. Additionally, it is my understanding that simply changing aspects of a device like the size, shape, weight, dimensions, portability,

integration/separateness, or component arrangement is not patentable and is considered obvious. That is the case here. Still further, it is my understanding that optimizing a known parameter, such as reducing the weight of a POC or its battery here, the reduction of which is a recognized goal in the art, is also considered routine experimentation and obvious. There is no indication in the '628 patent that the claimed weight ranges are the result of some type of unexpected result of experimentation.

4. Dependent Claim 4

[4] 4. The portable oxygen concentrator as recited in claim 1, wherein the bed of adsorbent material comprises a bed of zeolite which provides preferential adsorption of nitrogen.

396. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches Claim 4, rendering it obvious, for at least the reasons discussed in element [1c]. For example, *Deane* teaches that “[e]ach adsorbent bed column 508a-b comprises an elongated housing containing a nitrogen-selective adsorbent material such as zeolite. The adsorbent bed columns 508a-b are adapted to remove nitrogen from intake air in a known manner...so as to produce an oxygen rich product gas.” EX1004 (*Deane*), ¶[0062].

397. Further, my understanding that *Deane* teaches claim 4 is consistent with the assertion of infringement against Petitioner’s product advanced in connection with the litigation. EX1074 (*Infringement Contentions*) at 15.

5. Dependent Claim 6

[6] 6. The portable oxygen concentrator as recited in claim 1, wherein the carrying device is a belt.

398. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches Claim 6, rendering it obvious, for at least the reasons discussed in element [1a]. For example, *Dubois* teaches a portable gas concentrator wearable by a patient on a strap or belt. EX1005 (*Dubois*), 3:25-30, 6:21-25, FIG. 5.

6. Dependent Claim 7

[7] 7. The portable oxygen concentrator as recited in claim 1, wherein the inlet is an inlet port, and the outlet is an outlet port.

399. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches Claim 7, rendering it obvious, for at least the reasons discussed in element [1c].

400. For example, *Deane* teaches that the opening 706 of feed tube 608 at upper end 604 of each column 508a, 508b is an inlet into which feed gas 702 (ambient air) flows. EX1004 (*Deane*), FIG. 7, ¶[0066], [0070] (“[F]eed gas 702 is directed from a feed stream 704 in the manifold 512 into an upper opening 706 of the feed tube 608.”). The opening of feed tube 608 (upper opening 706) is oriented in a second direction opposite the direction in which the housing 602 / adsorbent bed columns 508a, 508b is removed from manifold 512 (as described above). EX1004 (*Deane*), FIGS. 5 and 6.

401. A POSITA would have understood opening 706 of feed tube to be an inlet port because it is an inlet that connects to manifold 512.

402. Further, *Deane* teaches that product gas 708 flows out of upper end 604 of each column 508a, 508b into a product stream. EX1004 (*Deane*), FIG. 7, ¶[0070]. The product gas flows out of housing 602 / adsorbent bed columns 508a, 508b and into manifold 512 *via* filter portion 618a at upper end 604 of housing 602 / adsorbent bed columns 508a, 508b, as shown in FIGS. 5 and 6 of *Deane*. Thus, *Deane* discloses an outlet that is oriented in the same direction as *Deane*'s inlet—in the direction opposite from the direction in which the housing 602 / adsorbent bed columns 508a, 508b is removed from manifold 512.

403. A POSITA would have understood upper end 604 to be an outlet port because it is an outlet that connects to manifold 512.

404. Further, as discussed above, the Examiner in a related application stated that *Deane* '426 (EX1047) teaches “an oxygen concentrator cartridge, best shown in Figure 6, having a **first port** corresponding to the filter portion 618a (par. 67) disposed along the first axis defined by the bed of adsorbent material 612 (par. 66) and a **second port** the upper port of feed tube 608 (par. 68) that lies in the same plane as filter portion 618a and spaced apart from the first port (fig. 6).” EX1052 ('669 *Patent FH*), 16 (emphasis added). I agree with the Examiner that these features are “ports.”

405. Further, my understanding that *Deane* teaches claim 7 is consistent with the assertion of infringement against Petitioner's product advanced in connection with the litigation. EX1074 (*Infringement Contentions*) at 17.

7. Dependent Claim 8-10

- [8] 8. The portable oxygen concentrator as recited in claim 1, wherein the case includes a main housing and a cap coupled to the main housing.
- [9] 9. The portable oxygen concentrator as recited in claim 8, wherein both the inlet and the outlet are formed in the main housing.
- [10] 10. The portable oxygen concentrator as recited in claim 8, wherein the other of the inlet and the outlet is disposed adjacent the cap.

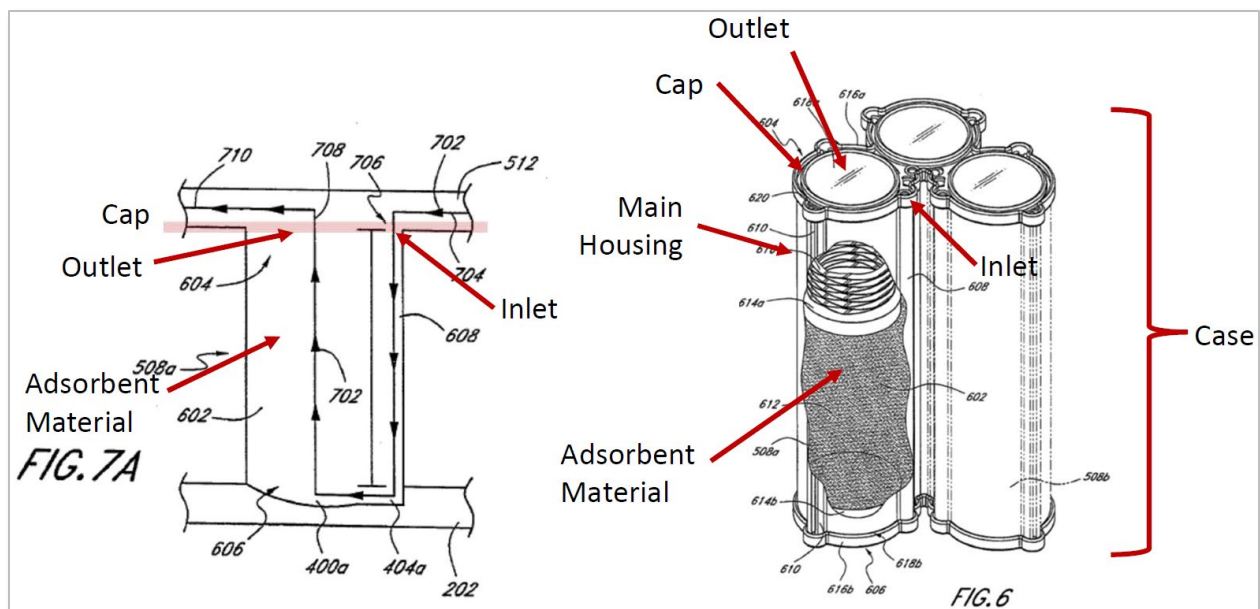
406. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches Claims 8-10, rendering them obvious, for at least the reasons discussed in element [1c] and the following.

407. Specifically, it is my opinion that Claims 8-10 are rendered obvious by *Deane* because *Deane* teaches that the case (*e.g.*, adsorbent housing 602 and/or other outer surfaces of adsorbent housing 602 / adsorbent bed columns 508a, 508b, shaded in orange in the annotated drawings above) includes a main housing (*e.g.*, the vertical walls of housing 602) and a cap (*e.g.*, the structure at the top end of the vertical walls of housing 602) coupled to the main housing, that both the inlet (*e.g.*, openings 706) and the outlet (*e.g.*, upper ends 604) are formed in the main housing (*e.g.*, both openings 706 and upper ends 604 are defined by the top end of the vertical walls of housing 602 and/or other outer surfaces of adsorbent housing 602

/ adsorbent bed columns 508a, 508b), and that the other of the inlet and the outlet is disposed adjacent the cap (e.g., both openings 706 and upper ends 604 are also disposed adjacent the structure at the top end of the vertical walls of housing 602).

EX1004 (*Deane*) at, e.g., ¶¶[0066]-[0070], FIGS. 6, 7.

408. The annotated version of *Deane*'s FIGS. 6 and 7A here provides further explanation and examples of how *Deane* teaches each of the features of claims 8-10.



409. *Deane* also teaches claims 8-10 in ¶[0069], which indicates:

As also shown in FIG. 6, the adsorbent bed column 508 a further includes annular gaskets 616 a, 616 b positioned adjacent to and in sealing engagement with the ends 604, 606 of the column 508 a to contain the pressurized gases therein. In one embodiment, each annular gasket 616 a-b further comprises an integrally formed filter portion 618 a, 618 b for filtering smaller particulate that cannot be captured by the restraining disks 614 a-b. Preferably, the filter portion is capable of filtering particles greater than about 70-120 microns. In

one embodiment, the gasket 616 a-b is made of a silicone material and the filter portion 618 a-b comprises a woven fabric, woven screen, or the like that is cast or molded together with the gasket. In another embodiment, the gasket 616 a-b and filter portion 618 a-b for all three columns of the PSA unit are injection molded as a single piece as shown in FIG. 6. Preferably, the filter portion 618 a-b is embedded in the gasket 616 a-b so as to facilitate placement of the filter portion and ensure a reliable seal between the gasket and the filter portion. Moreover, openings 620 are formed in each gasket 616 a-b to accommodate openings in the feed tubes and the threaded mounting members.

EX1004 (*Deane*), ¶[0069], FIG. 6.

410. Additionally, to the extent PO asserts that any of the features of *Deane*'s separation cartridge identified above do not meet the claim elements, it is my understanding that simply changing aspects of a device like the size, shape, weight, dimensions, portability, integration/separateness, or component arrangement is not patentable and is considered obvious. That is the case here.

411. Further, my understanding that *Deane* teaches claims 8-9 is consistent with the assertion of infringement against Petitioner's product advanced in connection with the litigation. EX1074 (*Infringement Contentions*) at 18-19.

8. Independent Claim 11

412. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* renders the limitations of Claim 11 obvious.

[11a] 11. A portable oxygen concentrator, comprising:

413. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches element [11a], rendering it obvious, for at least the reasons described above in element [1a], as elements [1a] and [11a] are identical.

[11b] a cartridge module comprising a housing, the housing defining a receptacle;

414. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches element [11b], rendering it obvious, for at least the reasons described above in element [1b], as elements [1b] and [11b] are identical.

[11c] a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the separation cartridge comprising an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen; and;

415. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches element [11c], rendering it obvious, for at least the reasons described above in element [1c], as element [1c] includes all the features of [11c].

[11d] a power pack removable from the portable oxygen concentrator,

416. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches element [11d], rendering it obvious, for at least the reasons described above in element [1d], as elements [1d] and [11d] are identical.

[11i] wherein the bed of adsorbent material is disposed along an axis,
[11j] wherein one of the inlet and the outlet is disposed along the axis,
[11k] wherein the other of the inlet and the outlet is spaced-apart from the axis, and
[11l] wherein the first direction and the second direction are substantially parallel to the axis.

417. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches elements [11i]-[11l], rendering them obvious, for at least the reasons described above in elements [1i]-[1l], as elements [1i]-[1l] and [11i]-[11l] are almost identical.

9. Dependent Claim 12

**[12] 12. The portable oxygen concentrator as recited in claim 11, wherein:
the separation cartridge further comprises a case at least partially defining an outer volume of the separation cartridge, and
the case at least partially surrounds the bed of adsorbent material.**

418. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches Claim 12, rendering it obvious, for at least the reasons described above in elements [1c], as element [1c] includes all the features of Claim 12.

10. Dependent Claim 13

[13] 13. The portable oxygen concentrator as recited in claim 12, wherein: the case includes a main housing and a cap coupled to the main housing, the other of the inlet and the outlet is disposed adjacent the cap.

419. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches Claim 13, rendering it obvious, for at least the reasons described above in Claims 8-10, as Claims 8-10 include all the features of Claim 13.

11. Dependent Claims 14-15

[14] 14. The portable oxygen concentrator as recited in claim 11, wherein the portable oxygen concentrator weighs less than 3 pounds.
[15] 15. The portable oxygen concentrator as recited in claim 11, wherein the power pack is a battery having a weight of less than 0.7 pounds.

420. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches Claims 14-15, rendering them obvious, for at least the reasons described above in Claims 2-3, as Claims 2-3 and 14-15 are identical.

12. Dependent Claim 16

[16] 16. The portable oxygen concentrator as recited in claim 15, further comprising a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material.

421. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches Claim 16, rendering it obvious, for at least the reasons described above in element [1e], as Claim 16 and element [1e] are identical.

13. Dependent Claim 17

[17] 17. The portable oxygen concentrator as recited in claim 11, wherein the bed of adsorbent material comprises a bed of zeolite which provides preferential adsorption of nitrogen.

422. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches Claim 17, rendering it obvious, for at least the reasons described above in Claim 4, as Claims 4 and 17 are identical.

14. Dependent Claim 19

[19] 19. The portable oxygen concentrator as recited in claim 11, further comprising a carrying device for transporting the portable oxygen concentrator.

423. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches Claim 19, rendering it obvious, for at least the reasons described above in element [1g], as Claim 19 and element [1g] are identical.

15. Dependent Claim 20

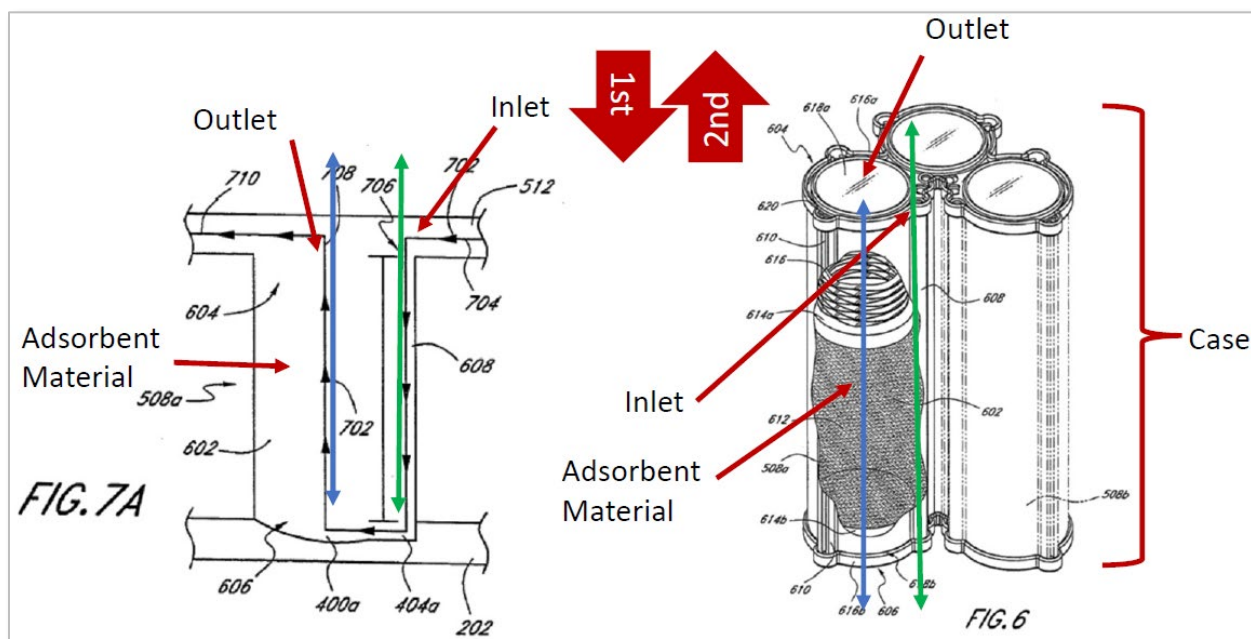
[20] 20. The portable oxygen concentrator as recited in claim 19, wherein the carrying device is a belt.

424. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches Claim 20, rendering it obvious, for at least the reasons described above in Claim 6, as Claims 6 and 20 are identical.

16. Dependent Claim 21

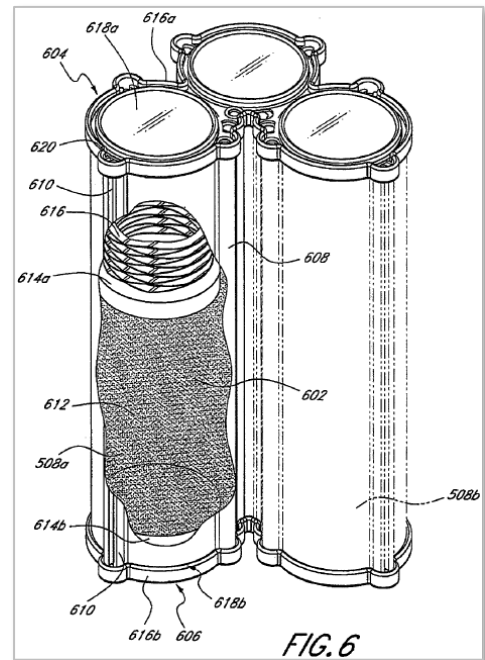
[21] 21. The portable oxygen concentrator as recited in claim 11, wherein the bed of adsorbent material is one of a plurality of beds of adsorbent material within the separation cartridge.

425. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches Claim 20, rendering it obvious, for at least the reasons described above in elements [11c] and [1c], as *Deane* teaches a separation cartridge with two adsorbent columns. For example, as shown in annotated FIGS. 6 and 7A, adsorbent housing 602 has two adsorbent bed columns 508a, 508b.



426. Further, each of adsorbent bed column 508a, 508b has a bed of adsorbent material 612. EX1004 (*Deane*), [0036] (“PSA unit 108 ... includes two adsorbent beds 118 a, 118 b, each containing an adsorbent material that is selective toward nitrogen”), [0062] (“PSA unit 506 generally includes a pair of adsorbent

bed columns 508 a, 508 b ... containing a nitrogen-selective adsorbent material such as zeolite ... adapted to remove nitrogen from intake air in a known manner in accordance with a PSA cycle so as to produce an oxygen rich product gas.”), [0068] (“adsorbent bed housing 602 contains an adsorbent material 612, ... compris[ing] a granular material such as zeolite that can be easily dislodged.”).



17. Dependent Claims 22-23

- [22] 22. The portable oxygen concentrator as recited in claim 11, wherein the bed of adsorbent material contains between five and twenty-five cubic centimeters of adsorbent material.
- [23] 23. The portable oxygen concentrator as recited in claim 22, wherein the bed of adsorbent material contains between fourteen and sixteen cubic centimeters of adsorbent material.

427. It is my opinion that the combination of *Deane*, *Dubois*, and *Berntson* teaches Claims 22 and 23, rendering them obvious. Specifically, *Deane* teaches “there is a particular need for a portable oxygen concentrator that is lightweight, quiet, and can supply oxygen continuously for an extended period without requiring an external power source. EX1004 (*Deane*), ¶[0006]. *Deane* teaches that its entire apparatus should have “a combined weight of preferably no [more] than about 10 pounds.” EX1004 (*Deane*), ¶[0093]. *Dubois* further teaches that

reduction of overall and sieve bed weight of a POC is important. EX1005 (*Dubois*), 3:55-4:30.

428. Additionally, as discussed in §I.J, a POSITA would have been well-aware that POCs were intended, by their nature, to be lightweight and small-sized to enable their portability, and that making POCs lighter and smaller was a widely-recognized design goal. *See, e.g.*, EX1009 (*McCombs* '924) at ¶[0005]; EX1010 (*McCombs* '957) at ¶[0007]; EX1012 (*Warren* '095) at Title, Abstract, ¶[0002]; and EX1013 (*Hill* '658), Abstract, 1:7-10. And many examples of such POCs were known, including POCs: (i) “with a weight of less than about 10 lb.” (EX1009 (*McCombs* '924) at ¶[0025]); (ii) “with a weight of less than about 5 lb.” (EX1010 (*McCombs* '957) at ¶[0036]); (iii) that are “small and light (2-15 pounds)” (EX1013 (*Hill* '658) at 9:66). A POSITA would have understood that in lightweight portable oxygen concentration systems, the beds of adsorbent material represent a portion of the overall weight. *See* EX1013 (*Hill* '658) at 4:66-5:12 (system weighing as little as two pounds includes oxygen concentrator, battery, sensors, and control unit), 9:66. Thus, a POSITA would have understood in the small and light systems known in the art, such as the 2-15 pound system of *Hill* '658, the adsorbent beds would have weighed a fraction of the total weight.

429. Based on the above, a POSITA would have understood that weight reduction in a POC and, in particular, its sieve beds, was important based on

general knowledge in the art and would have considered it obvious to make the POC and sieve beds of the combination of *Deane*, *Dubois*, and *Berntson* as light as possible. This would result in lightweight sieve beds and, because there is a direct relationship between weight and size, would also result in sieve beds in the claimed volume range, all of which would have improved the resultant POC's portability.

430. Additionally, it is my understanding that simply changing aspects of a device like the size, shape, weight, dimensions, portability, integration/separateness, or component arrangement is not patentable and is considered obvious. That is the case here, where the sieve beds are simply being made smaller/lighter. Still further, it is my understanding that optimizing a known parameter, such as reducing the weight of a POC or its sieve beds, the reduction of which is a recognized goal in the art, is also considered routine experimentation and obvious. There is no indication in the '628 patent that the claimed weight/size ranges are the result of some type of unexpected result of experimentation.

B. Ground 2: Claims 2, 3, 14, 15, 22, and 23 Are Rendered Obvious by *Deane* in view of *Dubois*, *Berntson*, and *Occhialini*

431. A POSITA would have found Claims 2, 3, 14, 15, 22, and 23 obvious based on the combination of *Deane*, *Dubois*, *Berntson*, and *Occhialini*.

1. Combination of *Deane*, *Dubois*, *Berntson*, and *Occhialini*

432. As I explained above under Ground 1, *Deane* teaches a portable oxygen concentrator using pressure swing adsorption with a separation cartridge having a case, beds of adsorbent material, and spaced apart inlets and outlets oriented in the same direction that is opposite the direction in which the cartridge is removable from a receptacle of the concentrator, along with other elements. EX1004 (*Deane*), ¶¶[0032], [0062]-[0070], FIGS. 5-7. *See also* §III.B and elements [1a]-[1j]. *Deane* teaches that its portable oxygen concentrator is compact and lightweight so as to be suitable for ambulatory use and stresses the importance of providing patients with “greater ease of mobility.” EX1004 (*Deane*), Abstract, ¶¶[0002], [0005].

433. As discussed above, *Occhialini* teaches that there is a “need for optimized design of small, easily-carried, adsorption-based oxygen concentrators [that] is met by the various embodiments of the present invention.” EX1073 (*Occhialini*), ¶[0004]. In particular, *Occhialini* teaches:

a minimum weight range can be determined for an adsorption-based system for any operable combination of product flow rate, product purity, product delivery pressure, and run time. This may be achieved by determining the weight of each variable-weight system component as a function of a selected process parameter, adding the weights of these components at various values of the selected parameter, and generating a curve of variable weight vs. the selected parameter. This curve generally exhibits a minimum weight in a preferred range of the selected process parameter. The selected process parameter is the minimum bed pressure during the process cycle.

EX1073 (*Occhialini*), ¶[0004]. In other words, *Occhialini* teaches that many variables, including weight of various components of a POC, may be tuned to achieve particular POC performance metrics. *Occhialini* further teaches various examples of the relationship between the total mass of the system (including the variable weights of the adsorbent, compressor, and battery) and various performance metrics of the POC. EX1073 (*Occhialini*), ¶[0098]-[0114], FIGS. 2-17.

434. Accordingly, a POSITA would have found it obvious to combine *Deane*'s teachings with *Occhialini*'s teachings of optimizing an oxygen concentrator using pressure swing adsorption for increased portability because such a combination would have provided an improved, more mobile oxygen concentrator system. In combination, these teachings provide an improved oxygen concentrator with lighter weight components and therefore an overall reduced weight and increased portability that is better suited for ambulatory uses, characteristics a POSITA would have recognized as highly desirable by 2004-2005 (as evidenced by *Deane* and *Occhialini* themselves, among other references discussed herein).

435. Beyond the specific motivations to combine *Deane* and *Occhialini* provided by the references themselves, further support for such motivation can be found in a POSITA's general knowledge at the time, such as described by the

references identified in §§I and III. For example, a POSITA would have been well aware of teachings, such as in *Warren '095*, relating to the importance of making oxygen concentrators highly portable. For example, *Warren '095* teaches its housing 60 has a handle 80 for carrying, and that its POC is also intended “to be worn by a user, for example in or as a backpack or hip pack or so-called fanny pack 81 such as seen in FIG. 10.” EX1012 (*Warren '095*) at ¶[0072], FIG. 10 (reproduced here). Similarly, *McCombs '924* teaches “an apparatus with a weight of less than about 10 lb., measuring less overall than 17” in length, 8” in width and 6” in height.” EX1009 (*McCombs '924*) at ¶[0025]. *McCombs '924* further teaches that making a POC “highly portable and easily manipulated and transported even by patients with relatively limited physical capacities” is important. EX1009 (*McCombs '924*) at ¶[0005]. Each of these references and the others discussed above in §I would have informed a POSITA’s general understanding as of 2004-2005 that it was desirable to make oxygen concentrators highly portable.

436. Beyond the specific motivations to combine *Deane* and *Occhialini* provided by the references themselves and a POSITA’s general understanding, a POSITA would have found it obvious to combine *Deane* and *Occhialini*’s teachings, and would have had a reasonable expectation of success in doing so, at least because both references relate to portable oxygen concentrators using

pressure swing adsorption and common components, the optimization of which *Occhialini* teaches.

437. A POSITA would have also had a reasonable expectation of success in modifying *Deane*'s portable oxygen concentration system with the oxygen concentrator having increased portability taught by *Occhialini* because portability was at the time (and is) a basic capability of portable oxygen concentration systems, as was well-known in the 2004-2005 timeframe. *See* §I.J. In other words, both references teach the portability of portable oxygen concentrators and provide similar features and functionality and have common components. Thus, a POSITA would have been able to utilize the teachings of *Occhialini* relating to optimizing the size and weight of the various components of a pressure swing adsorption portable oxygen concentrator common to *Deane* and *Occhialini*'s systems, including the air compressor, adsorbent, and battery, to improve the portability of *Deane*'s portable oxygen concentrator.

438. Therefore, at the time of the alleged invention of the claims of the '628 patent, a POSITA would have been motivated to (and it would have been obvious to a POSITA having the teachings of *Deane* and *Occhialini* before him or her, along with the other knowledge explained above) combine the teachings of *Deane* and *Occhialini* as described above (and below) to provide improved

functionality, with a reasonable expectation that such modifications would have been successful.

2. Dependent Claim 2, 3, 22, 23

- [2] 2. The portable oxygen concentrator as recited in claim 1, wherein the portable oxygen concentrator weighs less than 3 pounds.
- [3] 3. The portable oxygen concentrator as recited in claim 1, wherein the power pack is a battery having a weight of less than 0.7 pounds.
- [22] 22. The portable oxygen concentrator as recited in claim 11, wherein the bed of adsorbent material contains between five and twenty-five cubic centimeters of adsorbent material.
- [23] 23. The portable oxygen concentrator as recited in claim 22, wherein the bed of adsorbent material contains between fourteen and sixteen cubic centimeters of adsorbent material.

439. It is my opinion that the combination of *Deane, Dubois, and Berntson* teaches Claims 2, 3, 22, and 23, rendering them obvious, for at least the reasons discussed in Ground 1. Additionally, it is my opinion that the combination of *Deane, Dubois, Berntson, and Occhialini* teaches Claims 2, 3, 22, and 23, rendering them obvious, for at least the following reasons.

440. Specifically, in addition to the above, *Occhialini* teaches various examples of the relationship total system mass (including the variable weights of the adsorbent, compressor, and battery) and various performance metrics of the POC. EX1073 (*Occhialini*), ¶¶[0098]-[0114], FIGS. 2-17. These examples include POCs that a POSITA would have understood are less than 3 pounds total, POCs that have batteries that are less than 0.7 pounds, and POCs that have beds of

adsorbent material that are 5-25 cubic centimeters or 14-16 cubic centimeters in volume.

441. More specifically regarding claims 2 and 3, *Occhialini* teaches, in multiple examples, a total system weight less than 3 pounds and a battery weight less than 0.7 pounds. *See, e.g.*, Examples 1-16 in ¶¶[0098]-[0124] and related FIGS. 2-17, along with the desirable weight ranges for the battery shown in FIG. 20 and ¶[0129]. *See also* ¶¶[0098]-[0122] (describing weights of batteries). Moreover, as I explained above, it is my understanding that simply changing the weight of a device and/or its components is not patentable and is considered obvious.

442. More specifically regarding Claims 22 and 23, *Occhialini* teaches, in multiple examples, four- and five-bed systems with a total adsorbent weight between 0.2 and 1.5 pounds. *See, e.g.*, Examples 1-16 in ¶¶[0098]-[0124] and related FIGS. 2-17, along with the desirable weight ranges shown in FIG. 18 and ¶[0127]. Accordingly, a POSITA would have understood that *Occhialini* teaches per-bed weights of 0.04 to 0.375 pounds (18 to 170 grams). A POSITA would also have known in 2004-2005 that the bulk density of 5A Zeolite is in the range of 0.70 to 0.79 kg/l (or 0.70 to 0.79 g/cubic centimeter) depending on the supplier, particle size, and particle shape. *See, e.g.*, EX1075 (*Breck*), Table 9.6 (pp. 747-749, where $1\text{lb}/\text{ft}^3 = 0.016\text{ g}/\text{cm}^3$); EX1076 (*Zeochem*); EX1077 (*Molsiv*); EX1078

(*ARI 2007*); EX1079 (*ARI 2003*). I obtained each of EXS1068 and 1075-1079 from my personal library and/or the internet. Each confirms my understanding that the bulk density of 5A Zeolite known to a POSITA by 2004-2005 was in the range identified above. To the extent any of the data sheets were published after 2004-2005, they still reflect the material properties of 5A Zeolite before 2004-2005 as those material values do not substantively change for the same product over time. Accordingly, a POSITA would have understood *Occhialini's* specific examples to teach bed volumes of 23 to 243 cubic centimeters. This range explicitly teaches at least the features of claim 22.

443. Further, a POSITA would have understood that *Occhialini* teaches even lower bed volume relationships in FIG. 18. For example, a POSITA would have understood *Occhialini's* upper curve in FIG. 18 to extend down and to the left and include an adsorbent weight of 0.12 pounds, which for a five-bed system corresponds to a per-bed adsorbent weight of 0.024 pounds (10.9 grams) and a per-bed volume of 13.8 to 15.6 cubic centimeters. This range explicitly teaches the features of claims 22 and 23.

444. Still further, as discussed above, it is my understanding that simply changing the volume of device and/or its components is not patentable and is considered obvious. Moreover, in this instance, it is my understanding that optimizing a known parameter, such as the weight/size of a POC or its sieve beds,

the reduction of which is a recognized goal in the art, is also considered routine experimentation and obvious. There is no indication in the '628 patent that the claimed size ranges are the result of some type of unexpected result of experimentation.

445. As discussed above, it would have been obvious to modify the configuration of *Deane* alone or in combination with *Dubois* and/or *Berntson* to implement the lighter weight teachings of *Occhialini* to provide a lighter POC.

3. Dependent Claims 14-15

- [14] **14. The portable oxygen concentrator as recited in claim 11, wherein the portable oxygen concentrator weighs less than 3 pounds.**
- [15] **15. The portable oxygen concentrator as recited in claim 11, wherein the power pack is a battery having a weight of less than 0.7 pounds.**

446. It is my opinion that the combination of *Deane*, *Dubois*, *Berntson*, and *Occhialini* teaches Claims 14 and 15, rendering them obvious, for at least the reasons described above in Claims 2 and 3, as Claims 2 and 14 are identical and Claims 3 and 15 are identical.

C. Ground 3: Claims 5 and 18 Are Rendered Obvious by *Deane* in view of *Dubois*, *Berntson*, and *Basset*

447. A POSITA would have found Claims 5 and 18 obvious based on the combination of *Deane*, *Dubois*, *Berntson*, and *Basset*.

1. Combination of *Deane*, *Dubois*, *Berntson*, and *Basset*

448. As I explained above under Ground 1, *Deane* teaches a portable oxygen concentrator using pressure swing adsorption with a separation cartridge that includes adsorbent bed columns, “[e]ach adsorbent bed column 508a-b compris[ing] an elongated housing containing a nitrogen-selective adsorbent material such as zeolite. The adsorbent bed columns 508a-b are adapted to remove nitrogen from intake air in a known manner...so as to produce an oxygen rich product gas.” EX1004 (*Deane*) ¶[0062].

449. *Basset* teaches a “self-contained portable oxygen generator[.]”. EX1007 (*Basset*), 1:10-14. *Basset* teaches its two adsorbers 7 contain a “Zeolite, advantageously a lithium zeolite of the LiX type, preferably an LiLSX Zeolite.” EX1007 (*Basset*), 2:13-29.

450. Accordingly, a POSITA would have found it obvious to combine *Deane*’s teachings of using zeolite as an adsorbent to produce oxygen with *Basset*’s teaching that the zeolite used for producing oxygen is “of the LiLSX type” because such a combination would have provided an improved adsorbent. A POSITA was well aware that LiLSX provided performance improvements as compared to other zeolites. *See, e.g.*, US Patent 4,859,217 to Chao (“*Chao*”; EX1058), teaching: “The highly lithium exchanged forms of zeolite X, particularly the low silica forms of zeolite X [i.e., LiLSX] which contain more than ninety equivalent percent lithium cations, have been found to exhibit extraordinary

capacities and selectivities for nitrogen adsorption. ... Pressure swing adsorption separation process are well suited to take advantage of the exceptional properties of these absorbents [sic].” In combination, these teachings provide a POC with improved performance through improved adsorbent characteristics, which a POSITA would have recognized as highly desirable by 2004-2005.

451. Beyond the specific motivations to combine *Deane* and *Basset* provided by the references themselves, further support for such motivation can be found in a POSITA’s general knowledge at the time, such as described by the references identified in §§I and III. For example, a POSITA would have been well aware of teachings of the uses of both zeolite and LiLSX zeolite, along with other forms, in various prior art POC implementations. For example, *Sugano* teaches the use of zeolite in adsorbers (EX1014 (*Sugano*), ¶¶[0057], [0082]), *Appel* ’928 teaches the use of Lithium X Zeolite (EX1015 (*Appel* ’928), ¶[0063]) and highly Lithium exchanged X-type Zeolite (*id.* at ¶[0074]), *Armond* teaches the use of zeolite (EX1018 (*Armond*), 2:36-39, 4:54-5:2), and *Lessi* teaches the use of LiLSX zeolite (EX1019 (*Lessi*), 1:55-57, 2:61-3:5). Each of these references and the others discussed above in §I would have informed a POSITA’s general understanding as of 2004-2005 that both zeolite and LiLSX zeolite can be used as adsorbent materials in oxygen concentrators.

452. Beyond the specific motivations to combine *Deane* and *Basset* provided by the references themselves and a POSITA's general understanding, a POSITA would have found it obvious to combine *Deane* and *Basset's* teachings, and would have had a reasonable expectation of success in doing so, at least because both references relate to oxygen concentration using types of zeolite as an adsorbent, where *Basset* provides a specific example of a type of zeolite that would be used. No modification to *Deane's* adsorbent or overall system would be necessary to incorporate the teachings of *Basset* relating to LiLSX type zeolite.

453. Therefore, at the time of the alleged invention of the claims of the '628 patent, a POSITA would have been motivated to (and it would have been obvious to a POSITA having the teachings of *Deane* and *Basset* before him or her, along with the other knowledge explained above) combine the teachings of *Deane* and *Basset* as described above (and below) to provide improved functionality and a specific implementation of what *Deane* already teaches, with a reasonable expectation that such modifications, to the extent there even are any, would have been successful.

2. Dependent Claim 5

[5] 5. The portable oxygen concentrator as recited in claim 4, wherein the zeolite is an LiLSX adsorbent.

454. It is my opinion that the combination of *Deane*, *Dubois*, *Berntson*, and *Basset* teaches Claim 5, rendering it obvious.

455. As explained above in connection with Claims 1 and 4 under Ground 1, *Deane* teaches an adsorbent bed of zeolite. *Basset* teaches that its adsorbers 7 contain a “Zeolite, advantageously a lithium zeolite of the LiX type, preferably an LiLSX Zeolite.” EX1007 (*Basset*), 2:21-22.

456. Further, my understanding that *Basset* teaches claim 5 is consistent with the assertion of infringement against Petitioner’s product advanced in connection with the litigation. EX1074 (*Infringement Contentions*) at 16.

3. Dependent Claim 18

[18] 18. The portable oxygen concentrator as recited in claim 17, wherein the zeolite is an LiLSX adsorbent.

457. It is my opinion that the combination of *Deane*, *Dubois*, *Berntson*, and *Basset* teaches Claim 18, rendering it obvious, for at least the reasons discussed in Claim 5.

D. Grounds 4-6

458. To the extent PO does not contest, or the Board finds, *Deane* alone teaches each element of claim 1 in the manner discussed in Ground 1 above, a POSITA would have found: (i) Claims 1-4, 7-17, 19, 21-23 obvious based on the teachings of *Deane* (EX1004) (Ground 4); (ii) Claims 2, 3, 14, 15, 22, 23 obvious based on the combination of *Deane* (EX1004) and *Occhialini* (EX1073) (Ground 5); and (iii) Claims 5 and 18 obvious based on the combination of *Deane* (EX1004) and *Basset* (EX1007) (Ground 6) for at least the reasons in Grounds 1,

2, and 3 above, respectively because *Deane*, the combination of *Deane* (EX1004) and *Occhialini*, and the combination of *Deane* and *Basset* teach all the features of the identified challenged claims (*i.e.*, the teachings of *Dubois* (EX1005) and/or *Berntson* (EX1006) would be unnecessary).

VII. BERNTSON’S TEACHINGS ARE FULLY SUPPORTED BY ITS JULY 24, 2003 PROVISIONAL APPLICATION

459. As discussed above, *Berntson* (EX1006) claims priority to *Berntson Provisional* (EX1067), filed July 24, 2003. *See* §III.D.

460. I have reviewed *Berntson* (EX1006) and *Berntson Provisional* (EX1067). Their contents are almost identical, with only a few insubstantial variations in wording, the formalization of *Berntson Provisional* (EX1067)’s drawings, the deletion of par. [0007] from *Berntson Provisional* (EX1067), and the addition of par. [0019] in *Berntson* (EX1006), which is simply a word description of what a POSITA would have understood to be shown in FIGS. 1-2 as a solution to the problems identified in *Berntson* (EX1006) and *Berntson Provisional* (EX1067).

461. Accordingly, the teachings of *Berntson* (EX1006) I rely on herein (the “relevant teachings”) are also found in *Berntson Provisional* (EX1006). Thus, the relevant teachings of *Berntson* (EX1006) and *Berntson Provisional* (EX1067) are the same, and *Berntson Provisional* (EX1067) provides support for the relevant teachings in *Berntson* (EX1006).

462. Outside of the above, it is my understanding that *Berntson* (EX1006) can rely on the filing date of *Berntson Provisional* (EX1067) if at least one of the claims of *Berntson* (EX1006) is supported by *Berntson Provisional* (EX1067).

463. The following table shows where *Berntson Provisional* (EX1067) provides support for *each* of the claims of *Berntson* (EX1006).

<i>Berntson</i> (EX1006) Claim	Exemplary Written Description in <i>Berntson Provisional</i> (EX1067)
[1.a] A method of making a medical oxygen concentrator for delivering a flow of oxygen enriched air to a patient, comprising the steps of:	¶¶[0003], [0008], [0012]-[0013], [0019], claim 4, FIGS. 1, 2
[1.b] making an oxygen rich air generator unit to produce oxygen enriched air from atmospheric air, including:	¶¶[0003], [0008], [0012]-[0013], [0015], [0019], claims 1, 4, FIGS. 1, 2
[1.b.1] a mounting structure;	¶¶[0013], [0012]-[0013], [0019], claims 1, 4, FIGS. 1, 2
[1.b.2] a compressor connected to the mounting structure;	¶¶[0013], [0012]-[0013], [0016], claims 1, 4, 6, FIGS. 1, 2
[1.b.3] one or more valves in communication with the compressor and connected to the mounting structure; and	¶¶[0012]-[0014], [0016], [0019], claims 1, 4, 6, FIGS. 1, 2
[1.b.4] one or more sieve beds in selective communication with the compressor by way of the one or more valves and connected to the mounting structure; and	¶¶[0012]-[0014], [0016], [0017], [0019], claims 1, 4, 6, FIGS. 1, 2
[1.c] providing a concentrator cabinet, the cabinet mounting one or more components selected from the group consisting of a flow meter, a flow regulator, a patient gas delivery device and a control panel; and	¶¶[0012]-[0013], [0015], [0019], claims 1, 4, 5, 7, FIGS. 1, 2

<i>Berntson (EX1006) Claim</i>	<i>Exemplary Written Description in Berntson Provisional (EX1067)</i>
[1.d] mounting the oxygen rich air generator unit to the concentrator cabinet and connecting the oxygen rich air generator to one or more of said components that are mounted to the concentrator cabinet.	¶¶[0012]-[0015], [0017], [0019], claims 1-5, 7, FIGS. 1, 2
[2] A method of making a medical oxygen concentrator as claimed in claim 1, wherein the oxygen rich air generator includes an oxygen enriched air tank.	¶¶[0015], [0019], FIGS. 1, 2
[3] A method of making a medical oxygen concentrator as claimed in claim 1, wherein the oxygen rich air generator is replaceable as a unit.	¶¶[0006], [0013], [0019], claims 1, 6, FIGS. 1, 2
[4.a] A method of repairing a medical oxygen concentrator, comprising the steps of:	¶¶[0006], [0008], [0012]-[0013], [0019], claims 1, 2, 6, FIGS. 1, 2
[4.b] unfastening from a cabinet of the oxygen concentrator an oxygen rich air generator unit that produces oxygen enriched air from atmospheric air, the oxygen rich air generator having a chassis and at least the following components mounted to the chassis: a pump, one or more valves and one or more sieve beds for producing oxygen enriched air;	¶¶[0006], [0008], [0012]- [0013], [0019], claims 1, 2, 6, FIGS. 1, 2; <i>see also</i> [1.b.2], [1.b.3], [1.b.4], above
[4.c] removing the oxygen rich air generator unit from the cabinet;	¶¶[0006], [0008], [0012]- [0013], [0019], claims 1, 2, 6, FIGS. 1, 2
[4.d] placing a different oxygen rich air generator unit into the cabinet of the oxygen concentrator in place of the oxygen rich air generator unit that was removed from the cabinet; and	¶¶[0006], [0008], [0012]- [0013], [0019], claims 1, 2, 6, FIGS. 1, 2
[4.e] fastening the replacement oxygen rich air generator unit to the cabinet.	¶¶[0006], [0012]-[0015], [0019], claims 1-7, FIGS. 1, 2

<i>Berntson (EX1006) Claim</i>	<i>Exemplary Written Description in Berntson Provisional (EX1067)</i>
[5] A method as claimed in claim 4, further comprising the step of repairing the removed oxygen rich air generator at a central repair facility that is at a location away from the location of the oxygen concentrator.	¶¶[0006]-[0007], [0012]-[0015], [0019], claims 1-7, FIGS. 1, 2
[6.a] A method of doing business in the field of supplying medical oxygen concentrator manufacturers with components for making medical oxygen concentrators, comprising the steps of	Claim 6, FIGS. 1, 2
[6.b] supplying to the manufacturer an oxygen rich air generator unit having two or more oxygen concentrator components selected from the group consisting of a pump, one or more sieve beds, one or more valves, an exhaust cooling system and a pump cooling system assembled into the oxygen rich air generator unit,	¶¶[0012]-[0013], [0017], claim 6, FIGS. 1, 2; <i>see also</i> [1.b.2], [1.b.3], [1.b.4], above
[6.c] the oxygen rich air generator unit to be received by the oxygen concentrator manufacturer and mounted by the oxygen concentrator manufacturer as a unit to a cabinet of the oxygen concentrator.	¶¶[0012]-[0015], [0019], claims 1-7, FIGS. 1, 2
[7] A method of doing business as claimed in claim 6, wherein the oxygen rich air generator unit is connected by the oxygen concentrator manufacturer to one or more other components selected from the group consisting of a flow meter, a flow regulator, a patient gas delivery device and a control panel.	Claim 7, FIGS. 1, 2; <i>see also</i> [1.c], above

464. Accordingly: (i) at least one of *Berntson*'s (EX1006) claims (and in fact, each of *Berntson*'s claims) is fully supported by *Berntson Provisional* (EX1067); and (ii) the relevant teachings of *Berntson* (EX1006) are found in *Berntson Provisional* (EX1067).

465. Therefore, it is my understanding that *Berntson* (EX1006) is entitled to the July 24, 2003 filing date of *Berntson Provisional* (EX1067) and that the relevant teachings *Berntson* are fully supported by *Berntson Provisional*.

VIII. CONCLUSION

466. The '628 patent is an obvious combination of prior art teachings.

IX. BACKGROUND AND QUALIFICATIONS

467. This section contains a summary of my educational background, career history, publications, and other relevant qualifications. My full curriculum vitae is attached as Appendix 1 to this declaration.

A. Background

468. I am currently the president of Adsorption Research, Inc. of Dublin, Ohio.

469. I have been a chemical engineer since 1973. My interest in adsorption began in 1976, while I was a graduate student in chemical engineering at the University of Delaware. Adsorption was the subject of both my master's thesis and Ph.D. dissertation. Starting in 1980, I taught chemical engineering at Ohio State University for twelve years, and taught courses that dealt with adsorption (as

well as other separation processes). My first foray into pressure swing adsorption (PSA) occurred in 1981. While at Ohio State, I also was the thesis advisor for 22 M.S. and 7 Ph.D. students, many of whom studied aspects of PSA. In 1992, I founded Adsorption Research, Inc. For these past 30 years, most of the projects undertaken by my company have been focused on adsorption technologies. For example, we have done contract R&D for companies that make portable and stationary oxygen concentrators, such as Inogen and Respironics. We have also worked for the US Navy and Air Force on their version of portable oxygen concentrators for pilots on fighters and other aircraft, called “on-board oxygen generating systems” or OBOGS for short.

470. A copy of my *curriculum vitae* is included in Appendix A.

B. Compensation

471. For my efforts in connection with the preparation of this declaration I have been compensated at my standard rate for this type of consulting activity. My compensation is in no way contingent on the results of these or any other proceedings relating to the above-captioned patents.

C. Materials and Other Information Considered

472. I have considered information from various sources in forming my opinions. I have reviewed and considered each of the exhibits listed in the attached

Appendix 2 (Materials Considered in the Preparation of This Declaration) in forming my opinions.

X. UNDERSTANDING OF THE LAW

473. I am not an attorney. In forming my opinions in this Declaration, I applied the relevant legal principles provided to me by counsel, which are summarized in Appendix 4.

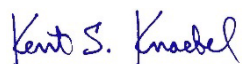
XI. RESERVATION OF RIGHTS

474. My opinions are based upon the information that I have considered to date. I am unaware of any evidence of secondary considerations with respect to the '628 patent that would render any of the challenged claims non-obvious. I reserve the right, however, to supplement my opinions in the future to respond to any arguments raised by the Patent Owner and to take into account new information that becomes available to me.

475. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on February 10, 2023.

By:



Kent S. Knaebel

APPENDIX 1: CURRICULUM VITAE OF KENT S. KNAEBEL

Kent S. Knaebel

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Short Bio:

Dr. Kent S. Knaebel is president of Adsorption Research Inc., Dublin, Ohio. The company performs R&D for companies such as: Air Liquide, Chevron, GE Energy, Inogen, NASA, Statoil, UOP, and Zeochem. In addition, we have designed and commissioned PSA plants for a variety of applications. Most of them produce renewable natural gas, e.g., for Aria Energy (2), EDL (2), Greenlane Biogas – BFI Canada (1), and Waste Management (4). Orders have arrived for 19 other such plants.

Areas of Expertise:

Commercial	Technical
Pressure swing adsorption for: > air separation > upgrading natural gas, landfill gas, and biogas > electronics gases > various industrial gases	adsorption separations mass transfer chemical engineering
Temperature swing adsorption for: > purification of liquid mixtures > purification of gaseous mixtures	

Education:

- Ph.D. Department of Chemical Engineering, University of Delaware, Newark, DE, 1980.
- M.Ch.E. University of Delaware, Newark, DE, 1978.
- B.S.Ch.E. University of Kentucky, Lexington, KY, 1973. With distinction.

Professional Experience:

- Adsorption Research, Inc., Dublin, Ohio. October 1992 to present. Founder and President. Adsorption-based gas and liquid separations, experimental and theoretical research and development.
- Ohio State University, Department of Chemical Engineering. Assistant Professor 6/80 to 10/86; Associate Professor 10/86 to 10/92; Adjunct Associate Professor 10/92 to 10/94; Advisor for 22 M.S. and 7 Ph.D. students.
- Tennessee Eastman Company, Kingsport, Tennessee. June 1973 to April 1976. Chemical Engineer. Advanced Engineering Technology Group. Process design, heat & mass transfer, and extrusion.

Professional Affiliations/Designations:

- Professional Engineer: Ohio No. 45703.
- Editor-in-Chief: *Adsorption*, peer reviewed journal published by Springer; 1995-2010. 16 Volumes.
- Editorial Board: *Separation Science & Technology*, peer reviewed journal publisher: Taylor & Francis.
- AIChE
- American Chemical Society: Separations Subdivision Charter Member.
- International Adsorption Society: Pres. (1989-92); Secretary/Treasurer (1992-2010); Board of Directors (2010-2016).

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APPENDIX 2: MATERIALS CONSIDERED IN THE PREPARATION OF THIS DECLARATION

Exhibit No.	Description
1001	U.S. Patent No. 10,357,628 (“the ’628 patent”)
1002	File History of U.S. Patent No. 10,357,628 (U.S. Application No. 16/006,915) (‘628 <i>patent FH</i>)
1003	<i>Intentionally Omitted</i>
1004	U.S. Patent Application Publication No. 2005/0072306 to Deane, Taylor, Bare, Sargent, and Scherer (<i>Deane</i>)
1005	U.S. Patent No. 6,520,176 to Dubois, Bodelin and Vigor (<i>Dubois</i>)
1006	PCT International Patent Application Publication No. WO 2005/009590 to Berntson (<i>Berntson</i>)
1007	U.S. Patent Application Publication No. 2005/0028868 to Basset, Jean and Schmutz (<i>Basset</i>)
1008	U.S. Patent No. 6,311,719 to Hill, Hill and Hansen (<i>Hill ’719</i>)
1009	U.S. Patent Application Publication No. 2003/0167924 to McCombs, Casey, Chimiak and Klimaszewski (<i>McCombs ’924</i>)
1010	U.S. Patent Application Publication No. 2006/0117957 to McCombs, Bosinski, Casey and Valvo (<i>McCombs ’957</i>)
1011	U.S. Provisional Application No. 60/617,834 to McCombs and Bosinski (<i>McCombs ’835 Prov</i>)
1012	U.S. Patent Application Publication No. 2002/0033095 to Warren (<i>Warren ’095</i>)
1013	U.S. Patent No. 6,651,658 to Hill, Radtke, Schneider and Bixby (<i>Hill ’658</i>)
1014	U.S. Patent Application Publication No. 2006/0283325 to Sugano (<i>Sugano</i>)
1015	U.S. Patent Application Publication No. 2003/0005928 to Appel, Winter, Sward, Sugano, Salter and Bixby (<i>Appel ’928</i>)
1016	U.S. Patent No. 4,802,899 to Vrana and Bansal (<i>Vrana</i>)
1017	U.S. Patent No. 4,404,005 to Hamlin and Taylor (<i>Hamlin</i>)

Exhibit No.	Description
1018	U.S. Patent No. 4,065,272 to Armond (<i>Armond</i>)
1019	U.S. Patent No. 7,144,446 to Lessi (<i>Lessi</i>)
1020	U.S. Patent No. 5,578,115 to Cole (<i>Cole</i>)
1021	U.S. Patent No. 4,584,001 to Dechene (<i>Dechene</i>)
1022	U.S. Patent No. 4,094,755 to Mueller (<i>Mueller</i>)
1023	U.S. Patent No. 4,530,706 to Jones (<i>Jones</i>)
1024	U.S. Patent No. 6,149,138 to Birdsell (<i>Birdsell</i>)
1025	U.S. Patent Application Publication No. 2006/0000223 to Dickerson (<i>Dickerson</i>)
1026	U.S. Patent No. 5,275,642 to Bassine (<i>Bassine</i>)
1027	U.S. Patent No. 4,916,630 to Miller (<i>Miller '630</i>)
1028	U.S. Patent Application Publication No. 2006/0137522 to Nishimura, Makari, Motoki and Kobayashi (<i>Nishimura</i>)
1029	U.S. Patent No. 6,471,744 to Hill (<i>Hill '744</i>)
1030	U.S. Patent No. 6,344,069 to Smolarek, Sinicropi and Schaub (<i>Smolarek '069</i>)
1031	U.S. Patent No. 5,429,666 to Agrawal, Kumar, Naheiri and Watson (<i>Agrawal '666</i>)
1032	U.S. Patent No. 5,906,672 to Michaels, Birangi and Polaseck (<i>Michaels '672</i>)
1033	U.S. Patent No. 6,547,851 to Warren (<i>Warren '851</i>)
1034	U.S. Patent Application Publication No. 2002/0144596 to Dee, Chiang, Miller and Whitley (<i>Dee '596</i>)
1035	U.S. Patent No. 5,114,440 to Reiss (<i>Reiss '440</i>)
1036	U.S. Patent No. 4,449,990 to Tedford (<i>Tedford '990</i>)
1037	U.S. Patent No. 6,544,318 to Dee, Chiang, Miller and Whitley (<i>Dee '318</i>)
1038	U.S. Patent No. 7,135,059 to Deane, Taylor, Bare, Sargent and Scherer (<i>Deane '059</i>)
1039	U.S. Patent No. 7,438,745 to Deane, Taylor and Li (<i>Deane '745</i>)

Exhibit No.	Description
1040	U.S. Patent No. 7,250,073 to Keefer, McLean and Babicki (<i>Keefer '073</i>)
1041	U.S. Patent No. 6,585,804 to Kleinberg, Pillarella and Guro (<i>Kleinberg '804</i>)
1042	U.S. Patent No. 6,143,056 to Smolarek and Kun (<i>Smolarek '056</i>)
1043	U.S. Patent No. 5,827,358 to Kulish and Swank (<i>Kulish</i>)
1044	U.S. Patent No. 6,802,889 to Graham, Occhialini and Puri (<i>Graham</i>)
1045	U.S. Patent No. 6,691,702 to Appel, Winter, Sward, Sugano, Salter and Bixby (<i>Appel '702</i>)
1046	U.S. Patent No. 4,687,573 to Miller and Verrando (<i>Miller '573</i>)
1047	U.S. Patent Application Publication No. 2005/0072426 to Deane, Taylor, Bare, March, Merchant and Smith (<i>Deane '426</i>)
1048	U.S. Patent Application Publication No. 2005/0045041 to Hechinger and Zarate (<i>Hechinger</i>)
1049	File History of U.S. Patent No. 7,954,490 (U.S. Application No. 11/054,341) (<i>'490 patent FH</i>)
1050	File History of U.S. Application No. 13/096,362 (<i>'362 application FH</i>)
1051	File History of U.S. Application No. 13/795,977 (<i>'977 application FH</i>)
1052	File History of U.S. Patent No. 10,702,669 (<i>'669 patent FH</i>)
1053	<i>Intentionally Omitted</i>
1054	<i>Intentionally Omitted</i>
1055	U.S. Patent No. 7,954,490 (<i>'490 patent</i>)
1056	U.S. Patent No. 10,702,669 (<i>'669 patent</i>)
1057	Atmosphere National Geographic Society, https://education.nationalgeographic.org/resource/atmosphere Retrieved December 2, 2022 (<i>National Geographic</i>)
1058	U.S. Patent No. 4,859,217 to Chao (<i>Chao</i>)

Exhibit No.	Description
1059	The American Heritage Dictionary of the English Language, Fourth Edition, Houghton Mifflin Company, 2000, selected pages (<i>American Heritage</i>)
1060	New Oxford American Dictionary, Oxford University Press, 2001, selected pages (<i>New Oxford</i>)
1061	Bloomsbury English Dictionary, Second Edition, Bloomsbury Publishing, 2004, selected pages (<i>Bloomsbury</i>)
1062	Webster's Third New International Dictionary, Merriam-Webster Inc., 2002, selected pages (<i>Webster</i>)
1063	<i>Intentionally Omitted</i>
1064	<i>Intentionally Omitted</i>
1065	<i>Intentionally Omitted</i>
1066	<i>Intentionally Omitted</i>
1067	U.S. Patent Provisional Application No. 60/489,674 to Berntson (<i>Berntson Provisional</i>)
1068	Ruthven et al., Pressure Swing Adsorption (1994) (Ruthven)
1069	<i>Plaintiff/Counter-Defendant GCE Gas Control Equipment Inc.'s Stipulation of Invalidity Contentions</i> , filed in <i>GCE Gas Control Equip., Inc. v. 3B Medical Mfg., LLC</i> , No. 22-cv-02550 (D. Md.) (Dkt. 34) (<i>D. Ct. Sotera Stipulation</i>)
1070	U.S. Patent No. 11,389,614 (<i>'614 patent</i>)
1071	File History of U.S. Patent No. 11,389,614 (U.S. Application No. 15/931,716) (<i>'614 patent FH</i>)
1072	3B's Alleged Infringement Claim Chart (<i>Infringement Chart</i>)
1073	U.S. Patent Application Publication No. 2005/0257686 A1 to Occhialini, Whitley, Wagner, LaBuda, and Steigerwalt (<i>Occhialini</i>)
1074	3B's Infringement Contentions for U.S. Patent No. 10,357,628 against Petitioner's Zen-O Lite product (<i>Infringement Contentions</i>)
1075	Selected pages of Breck, Donald W., Zeolite Molecular Sieves, 1984 (<i>Breck</i>)
1076	Zeochem Type 5A Adsorbent Product Information Sheet (<i>Zeochem</i>)

Exhibit No.	Description
1077	Molsiv Type 5A Adsorbent Product Information Sheet (<i>Molsiv</i>)
1078	ARI Type 5A Property Summary Sheet, 2007 (<i>ARI 2007</i>)
1079	ARI Type 5A Property Summary Sheet, 2003 (<i>ARI 2003</i>)

APPENDIX 3: CHALLENGED CLAIMS

[1a] 1. A portable oxygen concentrator, comprising:

[1b] a cartridge module comprising a housing, the housing defining a receptacle;

[1c] a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the separation cartridge comprising a case at least partially defining an outer volume of the separation cartridge, an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen, the case at least partially surrounding the bed of adsorbent material;

[1d] a power pack removable from the portable oxygen concentrator;

[1e] a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material;

[1f] a user interface configured to allow a patient to adjust and monitor operation of the portable oxygen concentrator;

[1g] a carrying device for transporting the portable oxygen concentrator;

[1h] wherein the housing of the cartridge module is configured to at least partially surround the case of the separation cartridge,

[1i] wherein the bed of adsorbent material is disposed along an axis, *[1j]* one of the inlet and the outlet is disposed along the axis, and *[1k]* the other of the inlet and the outlet is spaced-apart from the axis, and

[1l] wherein the first direction and the second direction are substantially parallel to the axis.

2. The portable oxygen concentrator as recited in claim 1, wherein the portable oxygen concentrator weighs less than 3 pounds.

3. The portable oxygen concentrator as recited in claim 1, wherein the power pack is a battery having a weight of less than 0.7 pounds.

4. The portable oxygen concentrator as recited in claim 1, wherein the bed of adsorbent material comprises a bed of zeolite which provides preferential adsorption of nitrogen.

5. The portable oxygen concentrator as recited in claim 4, wherein the zeolite is an LiLSX adsorbent.

6. The portable oxygen concentrator as recited in claim 1, wherein the carrying device is a belt.

7. The portable oxygen concentrator as recited in claim 1, wherein the inlet is an inlet port, and the outlet is an outlet port.

8. The portable oxygen concentrator as recited in claim 1, wherein the case includes a main housing and a cap coupled to the main housing.

9. The portable oxygen concentrator as recited in claim 8, wherein both the inlet and the outlet are formed in the main housing.

10. The portable oxygen concentrator as recited in claim 8, wherein the other of the inlet and the outlet is disposed adjacent the cap.

[11a] 11. A portable oxygen concentrator, comprising:

[11b] a cartridge module comprising a housing, the housing defining a receptacle;

[11c] a separation cartridge selectively removable from the receptacle by movement relative to the receptacle in a first direction, the separation cartridge comprising an inlet oriented in a second direction opposite the first direction, an outlet oriented in the second direction, and a bed of adsorbent material configured to preferentially adsorb nitrogen; and

[11d] a power pack removable from the portable oxygen concentrator,

[11i] wherein the bed of adsorbent material is disposed along an axis,

[11j] wherein one of the inlet and the outlet is disposed along the axis,
[11k] wherein the other of the inlet and the outlet is spaced-apart from the axis, and
[11l] wherein the first direction and the second direction are substantially parallel to the axis.

12. The portable oxygen concentrator as recited in claim 11, wherein:
the separation cartridge further comprises a case at least partially defining an outer volume of the separation cartridge, and
the case at least partially surrounds the bed of adsorbent material.

13. The portable oxygen concentrator as recited in claim 12, wherein:
the case includes a main housing and a cap coupled to the main housing,
the other of the inlet and the outlet is disposed adjacent the cap.

14. The portable oxygen concentrator as recited in claim 11, wherein the portable oxygen concentrator weighs less than 3 pounds.

15. The portable oxygen concentrator as recited in claim 11, wherein the power pack is a battery having a weight of less than 0.7 pounds.

16. The portable oxygen concentrator as recited in claim 15, further comprising a pump electrically coupled to the power pack, the pump operable to cause a flow of fluid to move relative to the adsorbent material.

17. The portable oxygen concentrator as recited in claim 11, wherein the bed of adsorbent material comprises a bed of zeolite which provides preferential adsorption of nitrogen.

18. The portable oxygen concentrator as recited in claim 17, wherein the zeolite is an LiLSX adsorbent.

19. The portable oxygen concentrator as recited in claim 11, further comprising a carrying device for transporting the portable oxygen concentrator.

20. The portable oxygen concentrator as recited in claim 19, wherein the carrying device is a belt.

21. The portable oxygen concentrator as recited in claim 11, wherein the bed of adsorbent material is one of a plurality of beds of adsorbent material within the separation cartridge.

22. The portable oxygen concentrator as recited in claim 11, wherein the bed of adsorbent material contains between five and twenty-five cubic centimeters of adsorbent material.

23. The portable oxygen concentrator as recited in claim 22, wherein the bed of adsorbent material contains between fourteen and sixteen cubic centimeters of adsorbent material.

APPENDIX 4: UNDERSTANDING OF THE LAW

I have applied the following legal principles provided to me by counsel in arriving at the opinions set forth in this declaration.

Legal Standard for Prior Art

I am not an attorney. I have been informed by attorneys of the relevant legal principles and have applied them to arrive at the opinions set forth in this declaration.

I understand that the petitioner for *inter partes* review may request the cancelation of one or more claims of a patent based on grounds available under 35 U.S.C. § 102 and 35 U.S.C. § 103 using prior art that consists of patents and printed publications.

Anticipation and Prior Art

I understand that § 102 specifies when a challenged claim is invalid for lacking novelty over the prior art, and that this concept is also known as “anticipation.” I understand that a prior art reference anticipates a challenged claim, and thus renders it invalid by anticipation, if all elements of the challenged claim are disclosed in the prior art reference. I understand the disclosure in the prior art reference can be either explicit or inherent, meaning it is necessarily present or implied. I understand that the prior art reference does not have to use the same words as the challenged claim, but all of the requirements of the claim

must be disclosed so that a person of ordinary skill in the art could make and use the claimed subject-matter.

In addition, I understand that § 102 also defines what is available for use as a prior art reference to a challenged claim.

Under § 102(a)(1), a challenged claim is anticipated if it was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the challenged claim(s).

Under § 102(a)(2), a challenged claim is anticipated if it was described in a patent or published application for patent naming another inventor and effectively filed before the effective filing date of the challenged claim(s).

I understand that the effective filing date of a patent or prior art reference is generally the filing date of that application. However, I understand that a patent or prior art reference may be granted an earlier effective filing date if it properly claims priority to an earlier patent application.

I understand that when a challenged claim covers several structures, either generically or as alternatives, the claim is deemed anticipated if any of the structures within the scope of the claim is found in the prior art reference.

I understand that when a challenged claim requires selection of an element from a list of alternatives, the prior art teaches the element if one of the alternatives is taught by the prior art.

Legal Standard for Obviousness

I understand that even if a challenged claim is not anticipated, it is still invalid if the differences between the claimed subject matter and the prior art are such that the claimed subject matter would have been obvious to a person of ordinary skill in the pertinent art at the time the alleged invention.

I understand that obviousness must be determined with respect to the challenged claim as a whole.

I understand that one cannot rely on hindsight in deciding whether a claim is obvious.

I also understand that an obviousness analysis includes the consideration of factors such as (1) the scope and content of the prior art, (2) the differences between the prior art and the challenged claim, (3) the level of ordinary skill in the pertinent art, and (4) “secondary” or “objective” evidence of non-obviousness.

Secondary or objective evidence of non-obviousness includes evidence of: (1) a long felt but unmet need in the prior art that was satisfied by the claimed invention; (2) commercial success or the lack of commercial success of the claimed invention; (3) unexpected results achieved by the claimed invention; (4) praise of the claimed invention by others skilled in the art; (5) taking of licenses under the patent by others; (6) deliberate copying of the claimed invention; and (7) contemporaneous and independent invention by others. However, I understand

that there must be a relationship between any secondary evidence of non-obviousness and the claimed invention.

I understand that a challenged claim can be invalid for obviousness over a combination of prior art references if a reason existed (at the time of the alleged invention) that would have prompted a person of ordinary skill in the art to combine elements of the prior art in the manner required by the challenged claim. I understand that this requirement is also referred to as a “motivation to combine,” “suggestion to combine,” or “reason to combine,” and that there are several rationales that meet this requirement.

I understand that the prior art references themselves may provide a motivation to combine, but other times simple common sense can link two or more prior art references. I further understand that obviousness analysis recognizes that market demand, rather than scientific literature, often drives innovation, and that a motivation to combine references may come from market forces.

I understand obviousness to include, for instance, scenarios where known techniques are simply applied to other devices, systems, or processes to improve them in an expected or known way. I also understand that practical and common-sense considerations should be applied in a proper obviousness analysis. For instance, familiar items may have obvious uses beyond their primary purposes.

I understand that the combination of familiar elements according to known methods is obvious when it yields predictable results. For instance, obviousness bars patentability of a predictable variation of a technique even if the technique originated in another field of endeavor. This is because design incentives and other market forces can prompt variations of it, and predictable variations are not the product of innovation, but rather ordinary skill and common sense.

I understand that a particular combination may be obvious if it was obvious to try the combination. For example, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. This would result in something obvious because the result is the product not of innovation but of ordinary skill and common sense. However, I understand that it may not be obvious to try a combination when it involves unpredictable technologies.

It is further my understanding that a proper obviousness analysis focuses on what was known or obvious to a person of ordinary skill in the art, not just the patentee. Accordingly, I understand that any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

It is my understanding that the Manual of Patent Examining Procedure §2143 sets forth the following as exemplary rationales that support a conclusion of obviousness:

- Combining prior art elements according to known methods to yield predictable results;
- Simple substitution of one known element for another to obtain predictable results;
- Use of known technique to improve similar devices (methods, or products) in the same way;
- Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- Choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to

combine prior art reference teachings to arrive at the claimed invention.

A person of ordinary skill in the art looking to overcome a problem will often use the teachings of multiple publications together like pieces of a puzzle, even though the prior art does not necessarily fit perfectly together. Therefore, I understand that references for obviousness need not fit perfectly together like puzzle pieces. Instead, I understand that obviousness analysis takes into account inferences, creative steps, common sense, and practical logic and applications that a person of ordinary skill in the art would employ under the circumstances.

I understand that a claim can be obvious in light of a single reference, if the elements of the challenged claim that are not explicitly or inherently disclosed in the reference can be supplied by the common sense of one of skill in the art.

I understand that obviousness also bars the patentability of applying known or obvious design choices to the prior art. One cannot patent merely substituting one prior art element for another if the substitution can be made with predictable results. Likewise, combining prior art techniques that are interoperable with respect to one another is generally obvious and not patentable.

In order for a claim to be found invalid based upon a modification or combination of the prior art, there must be reasonable expectation that a person of ordinary skill would have successfully modified or combined the prior art to arrive

at the claimed arrangement. This does not mean that it must be certain that a person of ordinary skill would have been successful – the law only requires that the person of ordinary skill in the art would have perceived a reasonable expectation of success in modifying or combining the prior art to arrive at the claimed invention.

In sum, my understanding is that obviousness invalidates claims that merely recite combinations of, or obvious variations of, prior art teachings using understanding and knowledge of one of ordinary skill in the art at the time and motivated by the general problem facing the inventor at the time. Under this analysis, the prior art references themselves, or any need or problem known in the field of endeavor at the time of the invention, can provide a reason for combining the elements of or attempting obvious variations on prior art references in the claimed manner.

Legal Standard for Claim Construction

I understand that before any invalidity analysis can be properly performed, the scope and meaning of the challenged claims must be determined by claim construction.

I understand that a patent may include two types of claims, independent claims and dependent claims. I understand that an independent claim stands alone and includes only the limitations it recites. I understand that a dependent claim depends from an independent claim or another dependent claim. I understand that

a dependent claim includes all the limitations that it recites in addition to the limitations recited in the claim (or claims) from which it depends.

In comparing the challenged claims to the prior art, I have carefully considered the patent and its file history in light of the understanding of a person of ordinary skill at the time of the alleged invention.

I understand that to determine how a person of ordinary skill would have understood a claim term, one should look to sources available at the time of the alleged invention that show what a person of ordinary skill in the art would have understood the disputed claim language to mean. It is my understanding that this may include what is called “intrinsic” evidence as well as “extrinsic” evidence.

I understand that, in construing a claim term, one should primarily rely on intrinsic patent evidence, which includes the words of the claims themselves, the remainder of the patent specification, and the prosecution history. I understand that extrinsic evidence, which is evidence external to the patent and the prosecution history, may also be useful in interpreting patent claims when the intrinsic evidence itself is insufficient. I understand that extrinsic evidence may include principles, concepts, terms, and other resources available to those of ordinary skill in the art at the time of the invention.

I understand that words or terms should be given their ordinary and accepted meaning unless it appears that the inventors were using them to mean something

else or something more specific. I understand that to determine whether a term has special meaning, the claims, the patent specification, and the prosecution history are particularly important, and may show that the inventor gave a term a particular definition or intentionally disclaimed, disavowed, or surrendered claim scope.

I understand that the claims of a patent define the scope of the rights conferred by the patent. I understand that because the claims point out and distinctly claim the subject matter which the inventors regard as their invention, claim construction analysis must begin with and is focused on the claim language itself. I understand that the context of the term within the claim as well as other claims of the patent can inform the meaning of a claim term. For example, because claim terms are normally used consistently throughout the patent, how a term is used in one claim can often inform the meaning of the same term in other claims. Differences among claims or claim terms can also be a useful guide in understanding the meaning of particular claim terms.

I understand that a claim term should be construed not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the entire specification. I understand that because the specification is a primary basis for construing the claims, a correct construction must align with the specification.

I understand that the prosecution history of the patent as well as art incorporated by reference or otherwise cited during the prosecution history are also highly relevant in construing claim terms. For instance, art cited by or incorporated by reference may indicate how the inventor and others of skill in the art at the time of the invention understood certain terms and concepts. Additionally, the prosecution history may show that the inventors disclaimed or disavowed claim scope, or further explained the meaning of a claim term.

With regard to extrinsic evidence, I understand that all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises, can also be considered. For example, technical dictionaries may indicate how one of skill in the art used or understood the claim terms. However, I understand that extrinsic evidence is considered to be less reliable than intrinsic evidence, and for that reason is generally given less weight than intrinsic evidence.

I understand that in general, a term or phrase found in the introductory words or preamble of the claim, should be construed as a limitation if it recites essential structure or steps, or is necessary to give meaning to the claim. For instance, I understand preamble language may limit claim scope: (i) if dependence on a preamble phrase for antecedent basis indicates a reliance on both the preamble and claim body to define the claimed invention; (ii) if reference to the preamble is

necessary to understand limitations or terms in the claim body; or (iii) if the preamble recites additional structure or steps that the specification identifies as important.

On the other hand, I understand that a preamble term or phrase is not limiting where a challenged claim defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention. I understand that to make this determination, one should review the entire patent to gain an understanding of what the inventors claim they invented and intended to encompass in the claims.

I understand that 35 U.S.C. § 112 ¶ 6 created an exception to the general rule of claim construction called a “means plus function” limitation. These types of terms and limitations should be interpreted to cover only the corresponding structure described in the specification, and equivalents thereof. I also understand that a limitation is presumed to be a means plus function limitation if (a) the claim limitation uses the phrase “means for”; (b) the “means for” is modified by functional language; and (c) the phrase “means for” is not modified by sufficient structure for achieving the specified function.

I understand that a structure is considered structurally equivalent to the corresponding structure identified in the specification only if the differences between them are insubstantial. For instance, if the structure performs the same

function in substantially the same way to achieve substantially the same result. I further understand that a structural equivalent must have been available at the time of the issuance of the claim.