

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PRAXAIR DISTRIBUTION, INC.,  
Petitioner,

v.

INO THERAPEUTICS LLC,  
Patent Owner.

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Case IPR2015-00893  
Patent 8,776,795 B2

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Before KEN B. BARRETT, MICHAEL J. FITZPATRICK,  
and SCOTT A. DANIELS, *Administrative Patent Judges*.

BARRETT, *Administrative Patent Judge*.

FINAL WRITTEN DECISION  
35 U.S.C. § 318(a)

## I. INTRODUCTION

Petitioner Praxair Distribution, Inc. filed a Petition (Paper 1, “Pet.”) for an *inter partes* review of U.S. Patent No. 8,776,795 B2 (“the ’795 patent”). The Petition challenges the patentability of claims 1–20 of the ’795 patent on the grounds of obviousness under 35 U.S.C. § 103. INO Therapeutics, LLC, filed a Preliminary Response to the Petition.<sup>1</sup> Paper 9. The Board instituted a trial for all asserted claims. Paper 14 (“Dec. on Inst.”).

After institution of trial, Patent Owner filed a Patent Owner Response (“PO Resp.”) to the Petition. Paper 29. Petitioner filed a Reply (“Reply”). Paper 39. Petitioner relies on the Declaration testimony of Dr. Robert T. Stone (Ex. 1002). Patent Owner relies on the Declaration testimony of Mr. Warren P. Heim (Ex. 2021).

Patent Owner filed a Motion to Exclude. Paper 43. Petitioner filed an Opposition to that Motion (Paper 47), and Patent Owner filed a Reply (Paper 48).

Oral hearing was conducted on May 16, 2016. The record contains a transcript of the hearing. Paper 52 (“Tr.”).

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a).

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<sup>1</sup> Subsequently, Mallinckrodt Hospital Products IP Ltd. apparently acquired INO Therapeutics and began identifying itself as Patent Owner. See Papers 37, 51; *see also* Paper 52 (Hearing Transcript), 55:6–15.

Petitioner has *not* shown by a preponderance of the evidence that claims 1–20 are unpatentable under the asserted grounds. We dismiss Patent Owner’s Motion to Exclude as moot.

*A. Related Proceedings*

The parties identify as a related proceeding regarding the ’795 patent *INO Therapeutics LLC et al. v. Praxair Distribution, Inc. et al.*, Civil Action No. 1:15-cv-00170 (GMS) (D. Del.). Pet. 7; Paper 6; *see also* Paper 37 (identifying the case as *Mallinckrodt Hospital Products IP Ltd. et al. v. Praxair Distribution, Inc. et al.*). In addition to the subject Petition, Petitioner has filed petitions challenging the patentability of claims 1–7 of U.S. Patent No. 8,573,209 B2, claims 1–16 of U.S. Patent No. 8,291,904, claims 1–20 of U.S. Patent No. 8,776,794, and claims 1–16 of U.S. Patent No. 8,573,210 B2. *See* IPR2015-00889; IPR2015-00884; IPR2015-00888; IPR2015-00891.

*B. The ’795 Patent*

The ’795 patent pertains “to a gas delivery device that may be utilized with a gas delivery system and methods for administering therapy gas to a patient.” Ex. 1001, 1:50–53. In the Background section, the ’795 patent states that “[t]here is a need for a gas delivery device that integrates a computerized system to ensure that patient information contained within the computerized system matches the gas that is to be delivered by the gas delivery device.” *Id.* at 1:40–43.

The ’795 patent describes a gas delivery device comprising a valve assembly 100 having actuator 114, valve 107, and circuit 150 communicating with a control module 200 via a wireless line-of-sight

connection 300 to control administration of the therapy gas to a patient. *Id.* at 5:58–6:10, 6:25–26. Administration of therapy gas to the patient is regulated by a control module that delivers gas via valve 107 from gas source 50 (i.e., a tank to which the valve assembly is mounted) to a medical device for introducing gas to a patient (e.g., a ventilator, nasal cannula, endotracheal tube, face mask, etc.). *Id.*

Figures 2 and 3 are reproduced below.

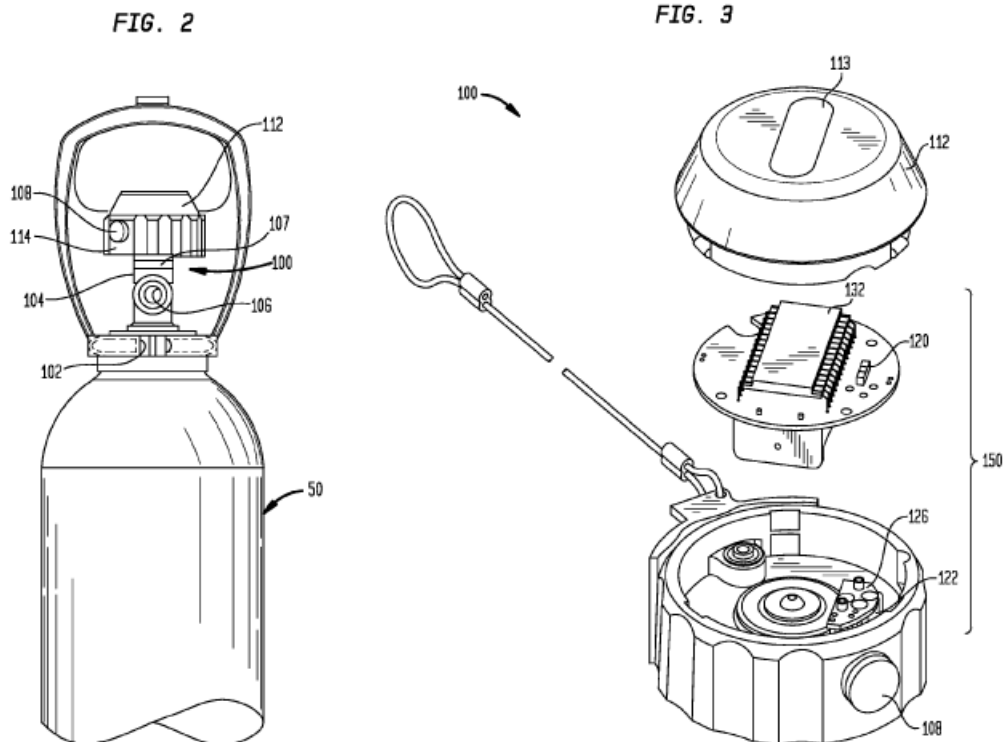


Figure 2 depicts valve assembly 100 and actuator 114 of the gas delivery device in communication via valve 107 with gas source 50, and Figure 3 illustrates an exploded view of actuator 114 and valve assembly 100. *Id.*, 6:11–35. Figure 4 is reproduced below:

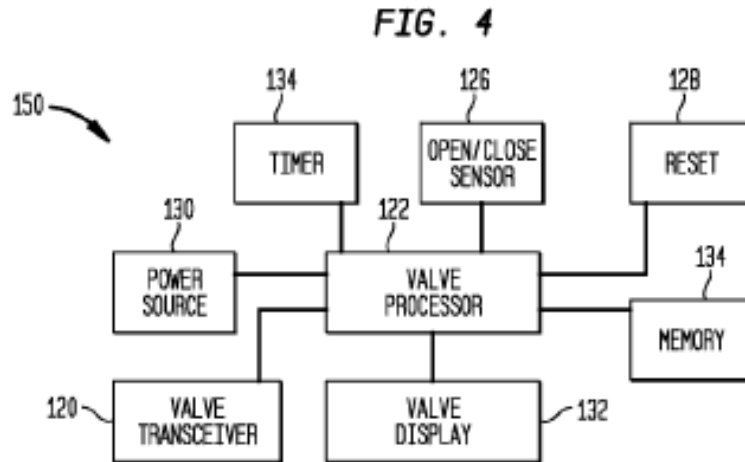


Figure 4 depicts circuit 150 of valve assembly 100, which is disposed in actuator 114. *Id.* at 6:36–49. Circuit 150 includes, *inter alia*, valve processor 122, memory 134, valve transceiver 120, power source 130, timer 124, and valve display 132. *Id.* Memory 134 stores the gas data for the particular gas source to which the valve assembly is attached. Gas data, such as gas composition and concentrations, can be input to memory 134 in various ways such as programmed by the gas supplier or scanned from a bar code on the gas source. *Id.* at 6:63–7:18. Valve display 132 allows a user, via window 113 on actuator 114, to view information regarding valve operation such as open or close, as monitored by open/close sensor 126, and the time duration which the valve was open for an event. *Id.* at 7:26–44. Valve transceiver 120 communicates with the control module that is physically separate from, but in relatively close proximity to, the valve assembly, via an optical wireless line-of-sight signal “during a pre-determined interval in response to a signal from the control module CPU transceiver 220.” *Id.* at 8:4–24, 10:34–46, Figs. 7–9. Control module 200 is ultimately responsible for delivery and regulation of a desired gas to a

ventilator and patient, and requests data from valve transceiver 120 at pre-determined intervals to facilitate the appropriate gas delivery to the patient. *Id.* at 8:38–54, 9:60–10:2.

### *C. The Challenged Claims*

The Petition challenges the patentability of claims 1–20 of the '795 patent. Of the challenged claims, claims 1, 7, and 15 are independent. Claim 1 recites a gas delivery device, claim 7 recites a therapy gas delivery system, and claim 15 recites a method of administering a therapy gas to a patient. Illustrative claim 1 is reproduced below.

1. A gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:
  - a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve; and
  - a circuit including:
    - a memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration; and
    - a processor and a transceiver in communication with the memory to send and receive signals to communicate the gas data to a control module that controls gas delivery to a subject and to verify one or more of the gas identification, the gas concentration and that the gas is not expired.

Ex. 1001, 16:42–57.

### *D. Asserted Grounds of Unpatentability*

We instituted *inter partes* review on the following asserted grounds of unpatentability against the challenged claims (Dec. on Inst. 23):

| Reference[s]                                                                                | Basis | Claim(s)    |
|---------------------------------------------------------------------------------------------|-------|-------------|
| Bathe, <sup>2</sup> Peters, <sup>3</sup> FR '804, <sup>4</sup> the IR Standard <sup>5</sup> | § 103 | 1–12, 14–20 |
| Bathe, Peters, FR '804, the IR Standard, and Lebel <sup>6</sup>                             | § 103 | 4, 5        |
| Bathe, Peters, FR '804, the IR Standard, and Durkan <sup>7</sup>                            | § 103 | 13          |

## II. ANALYSIS

### A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also* *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Neither party has proposed expressly constructions for any term of the challenged claims. Pet. 8–9; PO Resp. 7. We discern no reason to construe expressly any term for purposes of this Decision.

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<sup>2</sup> U.S. Patent No. 5,558,083, iss. Sept. 24, 1996 (Ex. 1005).

<sup>3</sup> U.S. Patent No. 7,114,510 B2, iss. Oct. 3, 2006 (Ex. 1004).

<sup>4</sup> FR 2 917 804 A1, pub. Dec. 26, 2008 (as translated) (Ex. 1006).

<sup>5</sup> ISO/IEEE 11073-30300, “Health informatics – Point-of-care medical device communication – Part 30300: Transport profile – Infrared wireless,” ISO/IEEE, pub. Dec. 15, 2004 (Ex. 1007).

<sup>6</sup> U.S. Patent No. 6,811,533 B2, iss. Nov. 2, 2004 (Ex. 1008).

<sup>7</sup> U.S. Patent No. 4,462,398, iss. July 31, 1984 (Ex. 1010).

*B. Obviousness of Claims 1–12 and 14–20 Over Bathe, Peters, FR '804, and the IR Standard (Ground 1)*

Petitioner argues that claims 1–12 and 14–20 would have been obvious over Bathe, Peters, FR '804, and the IR Standard. Pet. 11–47. Patent Owner argues, *inter alia*, that Petitioner has failed to meet its burden of demonstrating that a person of ordinary skill in the art would have had a reason to combine the cited references. PO Resp. 38. We instituted trial based on Petitioner's arguments and accorded some weight initially to the testimony of Dr. Stone with respect to a motivation to combine based on asserted safety considerations in NO delivery systems. *See* Inst. Dec. 14–18. Now, after considering the evidence and arguments of counsel fully developed on the record before us, for the reasons set forth below, we determine that Petitioner has not met its burden of showing that claims 1–20 are unpatentable by a preponderance of the evidence.

*1. Overview of Bathe*

Bathes discloses a “nitric oxide delivery system that is useable with various means of administering the NO . . . such as a ventilator or with spontaneous ventilation where the NO is introduced by means of a gas proportioning device that provides a continuous flow to the patient.” Ex. 1005, 2:14–19.

Figure 1 of Bathe is reproduced below:

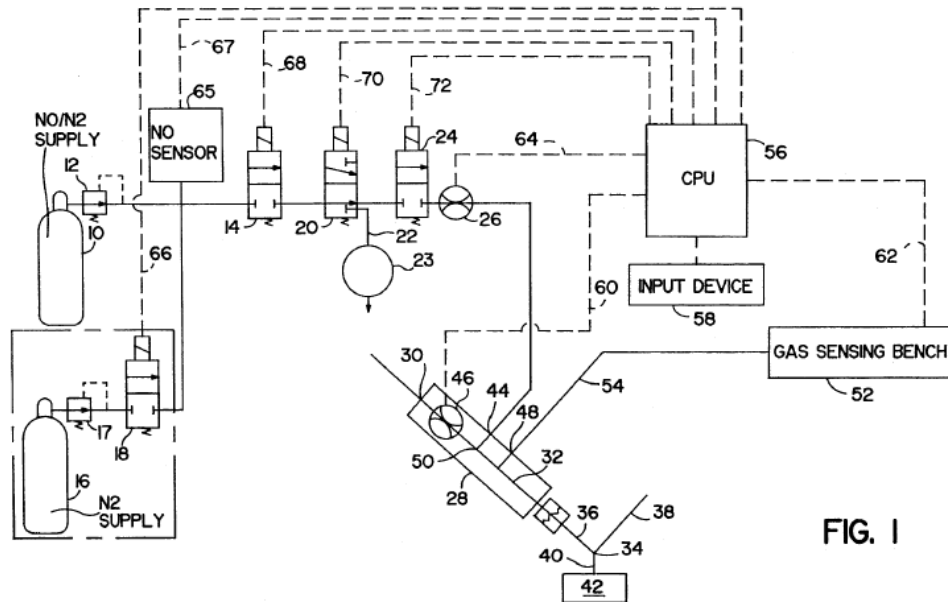


Figure 1 shows a schematic view of the Bathe system having flow sensor 26 and flow transducer 46, which determine the flow of gas in the system, and CPU 56 with input device 58, which provides for an operator to select a desired concentration of NO to the patient. *Id.* at 5:60–6:4. With flow and operator input information, the CPU calculates the desired flow to provide the selected NO concentration and, via feedback loop shown above in Figure 1, adjusts the desired gas concentration and flow via signals sent to valves 14, 18, 20, and 24. *Id.* at 6:5–20. Another input to CPU 56 is the NO concentration in supply cylinder 10. *Id.* at 6:5–6. Bathe states the following about that input:

The NO sensor 65 senses the concentration of NO in the supply cylinder 10 so that the user can verify that the proper supply is being utilized or, alternatively, the CPU 56 may use that input to adjust the system to adapt for any concentrations of NO in the supply within certain limits.

Ex. 1005, 6:6–11. In other words, the CPU knows the gas flow and NO concentration from supply 10, as well as the actual flow of gas administered

to the patient from the delivery device by transducer 46 and gas sensing bench 52, and, knowing the desired NO concentration set by the user via input 58, the CPU can adjust valves 14, 18, 20, and 24 to bring the actual gas flow and NO concentration to the patient into accord with the user's desired input level. *Id.* at 5:60–6:4, 6:43–53.

## 2. Overview of Peters

Peters discloses a valve with a “smart” handle for use with gas cylinders involving the use of gases administered to patients. Ex. 1004, 1:16–17, 1:34–35. The “valve records all the treatment information and makes the information readily accessible for use in tracking and invoicing.” *Id.* at 1:35–37. Figure 1 of Peters is reproduced below:

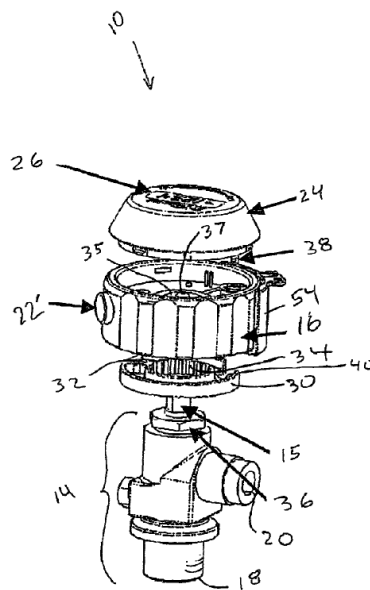


FIG 1

Figure 1 illustrates an exploded view of valve 10 having valve body 14 supporting valve handle 16 and gas inlet port 18 for connecting to and communicating with a gas cylinder (not shown). Within the handle are

several electronic components, namely, processor 23, timer 21, memory 22 and data port 22', sensor 28, battery 25 and display 26. *Id.* at 2:58–64.

Figure 2b is reproduced below:

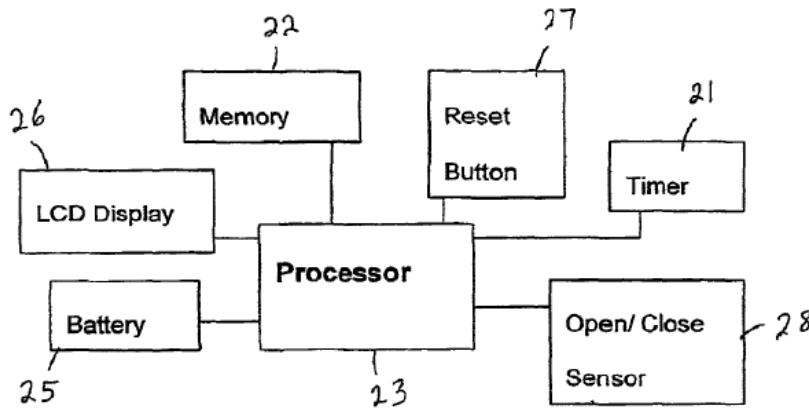


Figure 2b shows a block diagram of the electronic components just mentioned. Peters explains that the memory configuration is established by initial parameters such as the following: born-on date (date when cylinder was filled); cylinder serial number; gas lot number; set the timers (which may include a calendar timer and an event timer); and clear-the-log registers. *Id.* at 5:43–56.

“When the valve handle 16 is turned to open or close the valve, the proximity sensor 28 triggers the processor 23 to instruct the memory device 22 to log the event, including date, time, and whether the event was an opening or a closing of the valve.” *Id.* at 6:21–25. “Thus, as the handle 16 is rotated to open the valve 10 in order to provide gas treatments to patients, the memory device 22 in the handle 16 records the number and duration of the treatments.” *Id.* at 6:29–32. Also, Peters teaches that data recorded in the memory can be downloaded using a wand reader via data port 22', or handle 16 can “include a transmitter to transmit the data to a

remote recording device at intervals or on command, as desired.” *Id.* at 6:47–7:4.

### 3. Overview of FR '804

FR '804 relates to a connection system for a valve to a gas bottle or cylinder. Ex. 1006, 017. The described connection system includes a mechanism whereby valve “opening may take place only if the type of gas contained in the bottle 10 corresponds to the type of gas intended to supply the circuit 1 used through the valve 20, so as to avoid any risk of error in the connection of the bottle to the valve.” *Id.* at 019. Figure 1 of FR '804 is reproduced below.

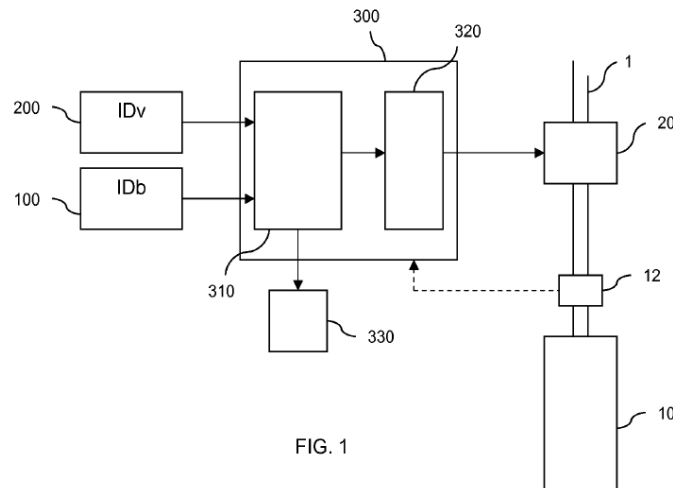


Figure 1 shows a block diagram illustrative of control module 300 for controlling valve 20. The control module receives input signal IDb, which is the identification of gas type being supplied from the bottle, and compares this with input data IDv, which is the desired type of gas for the procedure that is stored in memory 200. *Id.* FR '804 explains that “the control module 300 comprises means 310 for comparing the identification data IDb and IDv and means 320 for transmitting a control signal to the valve 20,

capable of emitting a signal for opening the valve in case of a positive comparison.” *Id.*

In another embodiment, FR ’804 discloses that the type of gas in bottle 10 (IDb) can be acquired from information carrier 120, such as an RFID tag on the bottle, which would be read by sensor 110 when the valve is attached to the bottle. *Id.* at 020.

#### *4. Overview of IR Standard*

IR Standard is a protocol promulgated by the Institute of Electrical and Electronics Engineers (IEEE) as an international standard for short-range infrared (IR) wireless communication for medical devices used at or near a patient. Ex. 1007, Abstract. IR Standard describes wireless communication standards with a goal of “[f]acilitat[ing] the efficient exchange of vital signs and medical device data, acquired at the point-of-care, in all health care environments.” *Id.* at vi. IR Standard further explains that such “standards are especially targeted at acute and continuing care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, etc.” *Id.* IR Standard illustrates an IR communication system including an IR transceiver in order to retrofit a previously hard wired cable-communicating system. *Id.* at 39–40.

#### *5. Petitioner Has Not Shown That Claims 1–12 and 14–20 Would Have Been Obvious Over Bathe, Peters, FR ’804, and the IR Standard*

Petitioner’s challenge relies on multiple references. In particular, the Petition asserts that a “person of ordinary skill in the art would have been motivated to combine the ’083 Patent [Bathe], the ’510 Patent [Peters], the FR ’804 Publication, and the IR Standard to predictably result in an improved nitric oxide delivery system incorporating the advantageous

aspects of each reference.” Pet. 19. We understand Petitioner to argue that the references would have been combined in order to have a safer therapeutic gas delivery system. *See id.* at 21–22, 24. Specifically, Petitioner’s grounds are based on the argument that one of ordinary skill would have combined the valve of Peters with the controller and NO delivery system of Bathe, reasoning that one would have made this combination to improve safety with regard to the delivery of therapeutic gas. *Id.* at 21 (arguing that one would have been motivated to combine the valve and the NO delivery system “to allow the user to better link the gas information with patient treatments”). Patent Owner contends that the system of Bathe and the valve of Peters are directed to disparate purposes, thus undermining Petitioner’s proposed reason to combine the references’ teachings. *See* PO Resp. 42.

After reviewing the record in total, the arguments and evidence presented by both parties and the prior art itself, we find, as Patent Owner argues, that Petitioner has not shown a sufficient reason for a person of ordinary skill in the art to have made the proposed combination of Bathe, Peters, FR ’804, and the IR Standard. PO Resp. 38. Patent Owner points out, correctly, that Petitioner has not shown that a person of ordinary skill in the art would have had a reason to combine Peters’s smart valve, having a memory for compiling data for billing and invoicing functions, with Bathe’s system for delivering a gas to a patient. *See id.* at 41. Moreover, we are not persuaded that Petitioner’s failure to provide sufficient reasoning for combining Peters and Bathe can be remedied by the introduction of FR ’804, particularly given that Bathe already included an in-line sensing unit to sense and verify the gas concentration from the cylinder. *See id.* at 44; *see also*

Reply 11–13 (Petitioner arguing that a safety check of FR '804 would be an additional, not alternative, check to that in Bathe).

Bathe teaches a gas cylinder supplying NO gas to a gas delivery system and has in-line sensor 65 to detect NO concentration in the delivery system prior to delivery to a patient. Ex. 1005, 6:5–11. Peters's smart valve with a memory, teaches delivering data such as on/off times for the valve, to a hand-held or laptop computer for compiling usage and billing reports. Ex. 1004, 6:17–57. Petitioner argues that a reason to combine the references comes from Peters, contending that Peters "explicitly states that the taught valve can control 'the flow of gas from the cylinder 12 to a ventilator or other gas dispensing device,' such as the gas delivery system of [Bathe]." Pet. 20 (citing Ex. 1004, 2:52–55). Making a similar assertion, Petitioner's expert Dr. Stone states that Peters's "teaches a valve assembly for gas delivery that could easily be incorporated into the delivery system described in [Bathe] by installing [Peters's] valve on the cylinder of [Bathe]." Ex. 1002 ¶ 100. This argument and testimony that Peters's valve could work on Bathe's cylinder does not explain why or how a person of skill in the art would combine Bathe and Peters. That Bathe could be modified by simply placing Peters's valve on the cylinder to control gas flow from the cylinder, does not, alone, satisfy the requirements for a reason to combine the prior art. *See InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (characterizing as indicative of a hindsight analysis an expert's "testimony [that] primarily consisted of conclusory references to her belief that one of ordinary skill in the art *could* combine these references, not that they *would* have been motivated to do so.").

The closest Petitioner comes to providing a reason that one of ordinary skill in the art would have been motivated to combine Bathe's NO delivery system and Peters's valve because doing so allegedly would "allow the user to better link the gas information with patient treatments." Pet. 21–22 (citing Ex. 1002 ¶¶ 99–100, 103, 122). This assertion however, leaves several unanswered questions. First, it is unexplained why a direct "link" between the cylinder gas information and patient treatment control module would have been perceived as necessary or better. Second, Petitioner fails to explain why or how a person of ordinary skill in the art would have "linked" Peters's data to patient treatments when Peters, as discussed below, only communicates certain data, such as valve opening and closing times, to a computer for billing and invoicing purposes, and neither Peters's communicated data or computer is used to determine any physiological aspect of patient treatment. *See, e.g.*, Ex. 1004, 6:13–15. ("The hospital or other user, as well as the distributor, may later download the data from the memory device 22 to be used for record keeping and billing."). The testimony of Dr. Stone relied upon in support of this argument also is not persuasive. Dr. Stone again testifies that it would have been feasible to combine the references but not why. *See* Ex. 1002 ¶¶ 99–100. Dr. Stone offers the conclusory opinion that "[a] person of skill in the art would have read [Bathe] and been motivated to apply subsequent improvements to component parts of that system, such as the improved valve of [Peters] and the improved safety regime of the FR '804 Publication." Ex. 1002 at ¶ 103 (citing Ex. 1005, 6:11–15); *see also id.* at ¶ 122 (similarly offering the conclusion that one would have been motivated to combine the references). Dr. Stone does not, however, point to any persuasive evidence or disclosure

in Bathe, or provide sufficient explanation or reasoning to support this statement. *See id.* at ¶ 103. In particular, Dr. Stone does not describe adequately what the “improvements” would have been, or provide sufficient rationale as to why Bathe, which already has a connection between a supply cylinder and a gas delivery device and teaches verification of gas concentration from the cylinder by sensor 65<sup>8</sup> in the delivery system, would be improved by Peters’s manually actuated valve handle and included memory to meet the limitations of the independent claims. *See* Ex. 1005, 6:11–15. We find Dr. Stone’s testimony deficient as to showing any suggestion in Bathe that would have motivated one of skill in the art to add Peters’s valve and memory to Bathe.

Petitioner’s argument also does not persuade us that a person of skill in the art would have “known to combine” Bathe and Peters “to obtain both the benefits of the smart handle of [Peters] and the benefits of the delivery system of [Bathe].” Pet. 20 (citing Ex. 1002 ¶¶ 99, 103). This argument is conclusory because it portrays the motivation in terms of the result, an unstated “benefit” and relies, again, on the insufficient premise that Peters’s valve *could be* incorporated on the cylinder in Bathe. In other words, Petitioner assumes the combination to have occurred structurally and functionally, i.e., Peters’s valve being placed onto Bathe’s cylinder, and

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<sup>8</sup> We acknowledge but do not find persuasive Petitioner’s and Dr. Stone’s citations (*see* Pet. 22; Ex. 1002 ¶ 103) to Bathe’s statement that the NO sensor 65 need not be used if the cylinder is always constant or if another sensor in Bathe’s system is utilized (Ex. 1005, 6:11–15). We do not find that this teaches, as Petitioner implies, the utilization of another data source, such as Peters’s valve, not in the system already.

notes the apparent benefit or improvement to Bathe, but does not provide any rationale to make the combination in the first instance.

It is reasonable to consider, as we did in our Decision to Institute, that the motivation and improvement driving the combination of Peters's valve to Bathe, could have been related to safety issues, e.g. a pre-use safety check of the cylinder in a gas therapy situation. *See* Dec. on Inst. 16–17.

Petitioner reasons that Peters provides such a teaching to combine, arguing:

[S]ince some of the advantages of the '510 Patent involve tracking gas data in the cylinders (*e.g.*, Ex. 1004 at 6:4-8; 7:36-47 (“assign patient ID to cylinders” and “identify and control cylinders for blinded clinical trials”), a person of skill in the art would have understood that the valve memory 22 disclosed in the '510 Patent could be used to store gas data and in turn, that data could be transmitted to a control module, as disclosed in the '083 Patent, to control gas therapy. (Ex. 1002 ¶¶ 100, 107-108.)

Pet. 20. In its Reply, Petitioner expands on this reasoning, quoting the Abstract of Peters as disclosing that data stored in its valve memory can be used ““for inventory control, **and for other record-keeping and control functions.**”” Reply 14 (quoting Ex. 1004, Abstract) (Petitioner's emphasis). Petitioner argues that this reference to “control functions” refers, not to inventory control, but rather to controlling the administration of therapeutic gas to a patient. *Id.* at 14–15 (citing Ex. 2020, 124:16–125:6, 128:23–129:1).

We, after further development of the record, reach a different factual finding. *See* Ex. 2021 ¶ 69 (Patent Owner's expert disagreeing with Dr. Stone's conclusion, testifying that “[n]owhere does Peters '510 suggest that the data stored in the valve memory can be used for controlling delivery of gas to a patient.”). The relevant sentence from the Abstract reads in

entirety as follows: “The log of the events and the corresponding dates and times may be used to prepare invoices for billing gas treatments, for inventory control, and for other record-keeping and control functions.”

Ex. 1004, Abstract. By considering the subject of the sentence—the log of the events and the corresponding dates and times—it becomes clear that Petitioner’s interpretation that “control functions” refers to controlling the administration of therapeutic gas to a patient is unsupportable. Indeed, Peters repeatedly refers to using its smart handle only for post-treatment uses such as billing and inventory control and the like. For example, the “Summary” of Peters provides in full:

The present invention provides a valve with a smart handle for the gas bottle (or cylinder). This valve records all the treatment information and makes the information readily accessible for use in tracking and invoicing. It permits the vendor to invoice the user for total treatment time and to provide users, such as hospitals or clinics, the information to bill individual patients. It also provides both the vendor and the user with data which is useful for trend analysis and inventory control.

The valve handle includes sensors for sensing the opening and closing of the valve, a timer for timing the duration over which the valve is opened, and an electronic memory device which records the pertinent information. The information recorded by the memory device may include the cylinder fill date, the lot batch number, cylinder number, the patient's name, the number of times the valve is opened, and the date, time, and duration of each opening of the valve, as well as additional information, if desired.

The data then can be readily transferred from the memory device to a device that generates reports or invoices.

Ex. 1004, 1:34–54; *see also id.* at 6:56–63 (describing the printing of reports for billing and inventory purposes); 7:9–15 (describing the generation of reports “to track treatments, do billings, and to control inventory”). Peters

does not teach using its smart valve for controlling the administration of therapeutic gas to a patient.

Further, Petitioner never explains adequately why or how Peters's valve, which sends valve opening and closing time for billing purposes, would improve the safety of Bathe's gas delivery system. From a safety perspective, Bathe already teaches connecting a gas supply cylinder to a gas delivery system and that gas concentration is sensed in the delivery system after leaving the supply cylinder and prior to delivery to a patient. Ex. 1005, 6:5–11. Dr. Stone's testimony with respect to the safety issue is that:

A person of skill in the art, with knowledge of [Bathe] and looking to expand [Bathe's] teachings to enable the CPU to perform a safety check using the gas data stored in the valve memory of [Peters], would have looked to art like the FR '804 Publication for one such safety check.

Ex. 1002 ¶ 123. This statement is not persuasive because Dr. Stone—before turning to FR '804 for the teaching of a safety check—presupposes, without adequately explaining why, one of skill in the art would have been “looking to expand [Bathe's] teachings” and would have been motivated to combine Bathe and Peters to perform such a safety check. Petitioner's arguments and Dr. Stone's testimony with respect to modification of Bathe leaves an analytical gap that does not apprise us of how or why one of ordinary skill in the art would have modified Bathe with Peters's capacity to communicate gas use and billing information to a separate computer, only that they could.

Petitioner further argues that “[a] person of skill in the art would have been particularly motivated to incorporate [Peters's] teachings into [Bathe] because both references belong[] to PO, a long-time leader in NO therapy technology.” Pet. 24 (citing Ex. 1002 ¶ 127). We do not find the fact that

two of the four patents in the proposed combination are owned by the same entity to be an adequate explanation as to why the hypothetical person of ordinary skill in the art would have combined the references as proposed. Petitioner's related argument that one "would have been motivated to look to" particular references (*see id.*) similarly fails to explain why one would have combined those references teachings to arrive at the claimed subject matter.

Petitioner has not provided the necessary articulated reasoning with rational underpinning to support its legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). We determine that Petitioner has not satisfied its burden of proving the asserted obviousness of claims 1–12 and 14–20 over Bathe, Peters, FR '804, and the IR Standard by a preponderance of the evidence.

*C. Obviousness of Claims 4 and 5 over Bathe, Peters, FR '804, the IR Standard, and Lebel (Ground 2)*

*and*

*Obviousness of Claim 13 over Bathe, Peters, FR '804, the IR Standard, and Durkan (Ground 3)*

Petitioner asserts that dependent claims 4 and 5 would have been obvious to a person of ordinary skill in the art over the above-discussed combination of Bathe, Peters, FR '804, the IR Standard, and further in view of Lebel. Pet. 47–52. Petitioner also asserts that dependent claim 13 would have been obvious to a person of ordinary skill in the art over that same underlying combination and further in view of Durkan. Pet. 52–60. These two grounds suffer from the same failure as Petitioner's Ground 1. Accordingly, Petitioner has not demonstrated that challenged claims 4, 5, and 13 are unpatentable over the asserted combinations of references.

*D. Patent Owner's Motion to Exclude Evidence*

Patent Owner filed a Motion to Exclude Exhibits 1002 and 2020, i.e., Dr. Stone's declaration and deposition testimony. Paper 43. Because we do not rely on any of Dr. Stone's testimony in a manner adverse to Patent Owner, the motion to exclude is *dismissed* as moot.

III. CONCLUSION

For the reasons given above, Petitioner has *not* shown by a preponderance of the evidence: that claims 1–12 and 14–20 are unpatentable as obvious over Bathe, Peters, FR '804, and the IR Standard; that claims 4 and 5 are unpatentable as obvious over Bathe, Peters, FR '804, the IR Standard, and Lebel; or that claim 13 is unpatentable as obvious over Bathe, Peters, FR '804, the IR Standard, and Durkan.

IV. ORDER

Accordingly, it is

ORDERED that claims 1–20 of the '795 patent have *not* been shown by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that Patent Owner's Motion to Exclude Evidence is *dismissed* as moot.

FURTHER ORDERED that, because this is a Final Written Decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2015-00893  
Patent 8,776,795 B2

FOR PETITIONER:

Sanjay K. Murthy  
sanjay.murthy@morganlewis.com

Margaux Nair  
Margaux.nair@klgates.com

Maria E. Doukas  
maria.doukas@morganlewis.com

Benjamin Weed  
Benjamin.weed.ptab@klgates.com

FOR PATENT OWNER:

Robert Steinberg  
bob.steinberg@lw.com

Daniel G. Brown  
daniel.brown@lw.com

David K. Callahan  
david.callahan@lw.com

Kenneth G. Schuler  
kenneth.schuler@lw.com

Marc N. Zubick  
marc.zubick@lw.com