

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC.,
Petitioner,

v.

INO THERAPEUTICS LLC,
Patent Owner.

Case IPR2015-00888
Patent 8,776,794 B2

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

FITZPATRICK, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner, Praxair Distribution, Inc., filed a Petition to institute an *inter partes* review of claims 1–20 of U.S. Patent No. 8,776,794 B2 (Ex. 1001, “the ’794 patent”) pursuant to 35 U.S.C. § 311(a). Paper 1 (“Pet.”). Patent Owner, INO Therapeutics LLC, filed a Preliminary Response pursuant to 35 U.S.C. § 313. Paper 9 (“Prelim. Resp.”). In a September 22, 2015, Decision, we granted the Petition, instituting trial on all claims on the following grounds:

claims 1–12 and 14–20 as obvious over Bathe (Ex. 1005)¹, Peters (Ex. 1004)², Paoli (Ex. 1006)³, and IR Standard (Ex. 1007)⁴; claims 4 and 5 as obvious over Bathe, Peters, Paoli, INOMAX label (Ex. 1014)⁵, IR Standard, and Lebel (Ex. 1008)⁶; and claim 13 as obvious over Bathe, Peters, Paoli, INOMAX label, IR Standard, and Durkan (Ex. 1010).⁷

Paper 14 (“Inst. Dec.”).

After institution, Patent Owner filed a Patent Owner Response (Paper 30, “PO Resp.”) to which Petitioner filed a Reply (Paper 40, “Pet. Reply”).

¹ U.S. Patent No. 5,558,083, issued Sept. 24, 1996.

² U.S. Patent No. 7,114,510 B2, issued Oct. 3, 2006.

³ French Patent Application Publication No. 2,917,804, published Dec. 26, 2008.

⁴ ISO/IEEE 11073-30300, “Health informatics -- Point-of-care medical device communication -- Part 30300: Transport profile -- Infrared wireless,” ISO, IEEE, (Dec. 15, 2004).

⁵ FINAL PRINTED LABELING, CENTER FOR DRUG EVALUATION AND RESEARCH, Appl’n. No.: NDA 20845 (2000).

⁶ U.S. Patent No. 6,811,533 B2, issued Nov. 2, 2004.

⁷ U.S. Patent No. 4,462,398, issued July 31, 1984.

Also, Patent Owner filed a Motion to Exclude. *See* Paper 44; *see also* Paper 48 (Petitioner’s Opposition); Paper 49 (Patent Owner’s Reply).

A hearing for oral arguments was held on May 16, 2016, and a transcript of the hearing is included in the record. Paper 53.

As discussed below, Petitioner has not shown by a preponderance of the evidence that any of the challenged claims is unpatentable.

A. The ’794 Patent

The ’794 patent relates to the administration of a therapy gas, such as nitric oxide (NO), to a patient. Ex. 1001, 1:50–53. In a background section, it states that there was a need “to ensure that patient information contained within [a] computerized system matches the gas that is to be delivered” to the patient and “also a need for such an integrated device that does not rely on repeated manual set-ups or connections and which can also track individual patient usage accurately and simply.” *Id.* at 1:40–45.

The ’794 patent describes a gas delivery system comprising a valve assembly having a valve and circuit in communication with a control module to control administration of the therapy gas to a patient. *Id.* at 5:62–6:7. Administration of the therapy gas to the patient is controlled by controlling delivery of the gas from the gas source (i.e., a cylinder 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, or face mask). *Id.*

Figures 2 and 3 are reproduced below.

FIG. 2

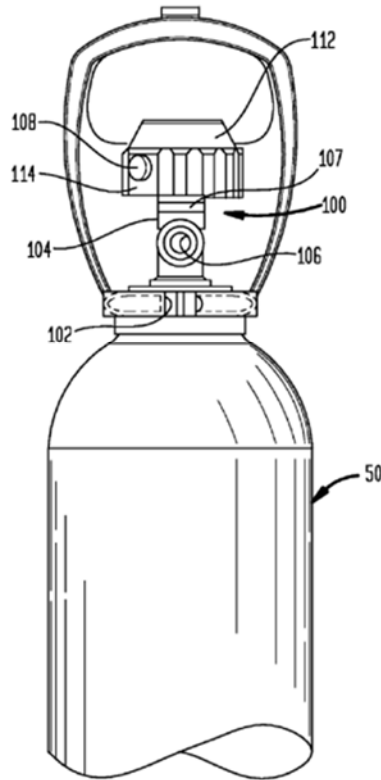


FIG. 3

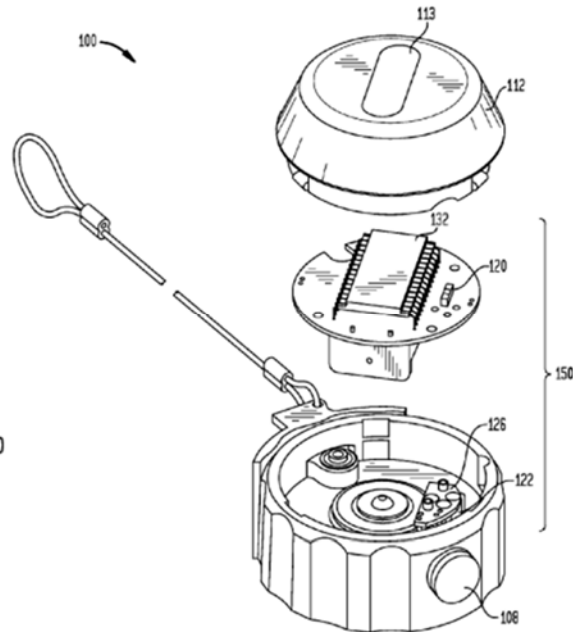


Figure 2 shows valve assembly 100 attached to gas source (cylinder) 50 via attachment portion 102. Ex. 1001, 6:28–31. The valve assembly includes inlet 104, outlet 106, valve 107, data input 108, and actuator 114 with cap 112 mounted thereto, as well as a circuit that is not shown in Figure 2. *Id.* at 6:28–39. Figure 3 shows the assembly valve partially disassembled, thus revealing circuit 150 within the actuator. *Id.* at 6:32–37.

Figure 4 is reproduced below.

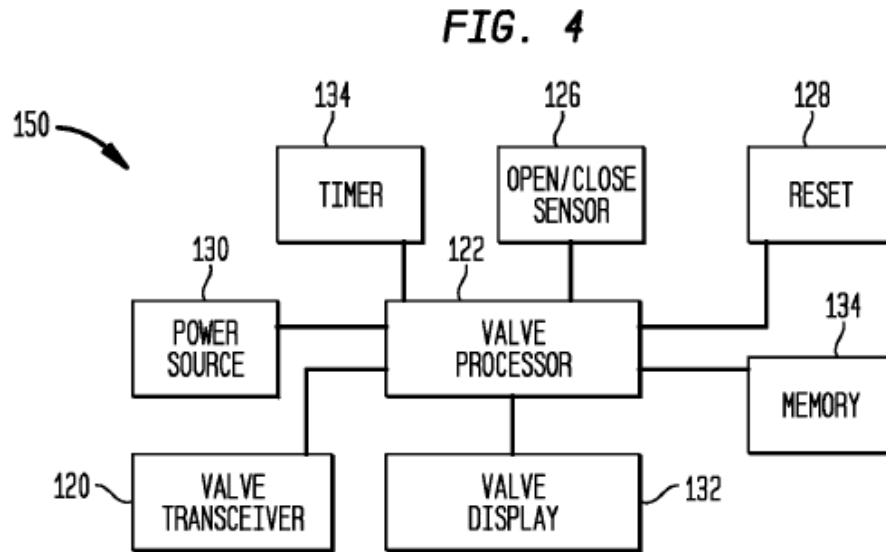


Figure 4 shows a block diagram of circuit 150 having valve processor 122, valve memory 134, valve transceiver 120, valve display 132, reset 128, power source 130, timer 124,⁸ and open/close sensor 126. Ex. 1001, 6:43–56. Gas data, such as gas composition and concentration, can be input to memory 134 in various ways such as programmed by the gas supplier or scanned from a bar code on the gas source. *Id.* at 7:7–23. The valve assembly is configured to communicate with the control module via wireless optical line-of-sight transmission between the valve transceiver and a CPU transceiver of the control module. *Id.* at 8:44–51.

⁸ Figure 4 mislabels the timer as 134. It should be labelled 124. Ex. 1001, 6:45.

Figure 9 is reproduced below.

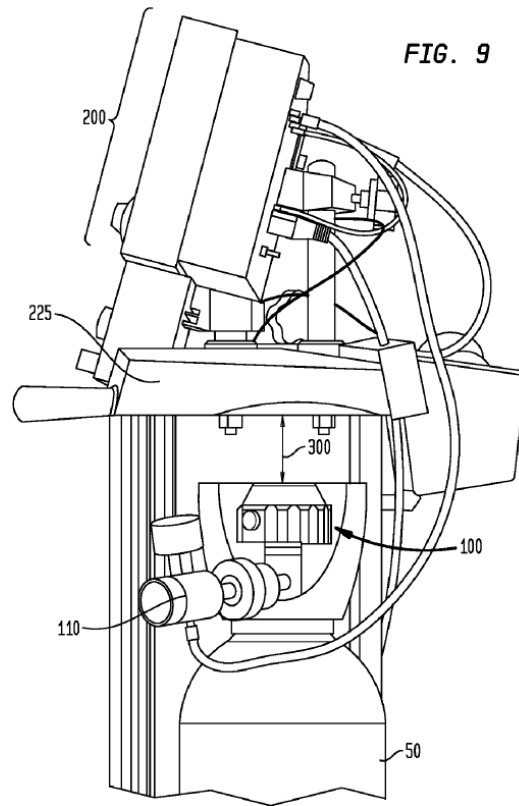


Figure 9 shows control module 200 that is physically separate from, but in close proximity to, the valve assembly 100. *Id.* at 10:38–50. A depiction of the previously mentioned wireless optical line-of-sight transmission between control module 200 and valve assembly 100 is labeled 300. *Id.* at 6:10, 8:27–30. The control module is ultimately responsible for delivery and regulation of a desired gas to a ventilator and patient, and it requests data from circuit 150 within valve assembly 100 at pre-determined intervals to facilitate the appropriate gas delivery to the patient. *Id.* at 8:44–60, 9:65–10:7.

B. The Challenged Claims

Petitioner challenges all claims of the '794 patent, i.e., claims 1–20. Claims 1, 7, and 15 are independent. Claim 1 is illustrative and reproduced below.

1. A gas delivery device comprising:
 - a gas source to provide therapy gas comprising nitric oxide;
 - 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 to a control module that delivers the therapy gas comprising nitric oxide in an amount effective to treat or prevent hypoxic respiratory failure; 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 the 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.

II. ANALYSIS

A. Claim Construction

“A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. § 42.100(b). Pursuant to that standard, the claim language should be read in light of the specification, as it would be interpreted by one of ordinary skill in the art. *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010). Thus, we generally give claim terms their ordinary and customary meaning. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (“The ordinary and customary meaning is the meaning that the term would have to a person of ordinary skill in the art in question.”) (internal quotation marks omitted).

Neither party has proposed expressly construing any term of the challenged claims. Pet. 9–10; PO Resp. 7. We discern no reason to construe expressly any term for purposes of this Decision.

B. Petitioner Ground 1

Petitioner asserts that claims 1–12 and 14–20 are unpatentable because they would have been obvious over Bathe, Peters, Paoli, INOMAX label, and IR Standard. Pet. 10. For the reasons explained below, Petitioner has not met its burden of persuasion in proving that any claim is unpatentable as asserted.

24. Ex. 1005, 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.

Id. at 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 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 in medical treatments. 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.

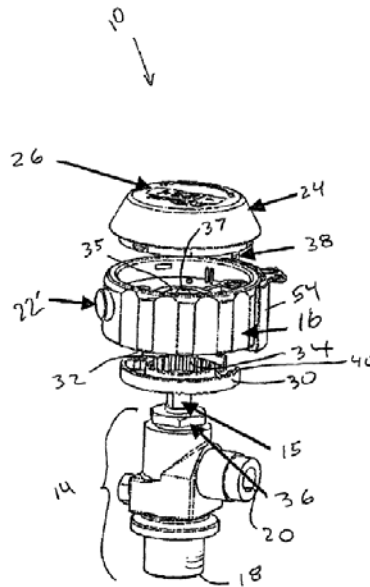


FIG 1

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.

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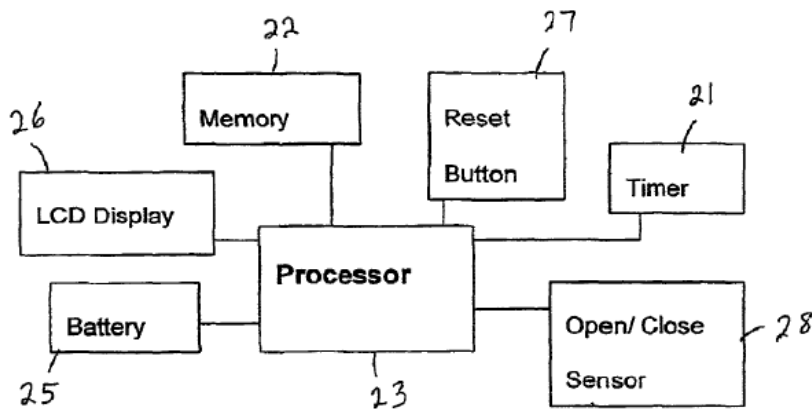


Figure 2b shows a block diagram of the electronic components just mentioned. Peters explains that the memory configuration is established by initial parameters such as the following: born-on date (date when cylinder was filled); cylinder serial number; gas lot number; set the timers (which may include 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 Paoli

Paoli 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 Paoli is reproduced below.

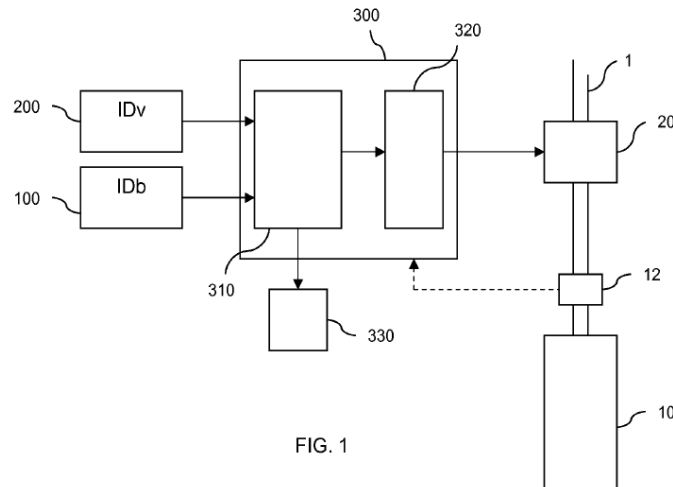


Figure 1 shows a block diagram illustrative of control module 300 for controlling valve 20. The control module receives input signal IDb, which is the identification of gas type being supplied from the bottle, and compares this with input data IDv, which is the desired type of gas for the procedure that is stored in memory 200. *Id.* Paoli 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, Paoli 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 INOMAX Label

The INOMAX label reference is a U.S. Food and Drug Administration (FDA) publication approving labeling for Patent Owner’s INOmax drug generally used in conjunction with NO therapies for newborns

with hypoxic respiratory failure. Ex. 1014, 002. The INOMAX label also indicates that the drug was used with ventilators administering NO to neonatal patients. *Id.* at 006. The INOMAX label states the following:

The nitric oxide delivery systems used in the clinical trials provided operator-determined concentrations of nitric oxide in the breathing gas, and the concentration was constant throughout the respiratory cycle In the ventilated neonate, precise monitoring of inspired nitric oxide and NO₂ should be instituted, using a properly calibrated analysis device with alarms. This system should be calibrated using a precisely defined calibration mixture of nitric oxide and nitrogen dioxide, such as INOcal™. Sample gas for analysis should be drawn before the Y-piece, proximal to the patient. Oxygen levels should also be measured.

Id. The INOMAX label indicates that INOmax is supplied in aluminum cylinders. *Id.*

5. 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.

6. Petitioner Has Not Shown That Claims 1–12 and 14–20 Would Have Been Obvious over Bathe, Peters, Paoli, the INOMAX label, and IR Standard

Although it may not be anticipated, a claimed invention is nonetheless unpatentable “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103(a).⁹ In assessing obviousness, “the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.” *Graham v. John Deere Co.*, 383 U.S. 1, 17 (U.S. 1966). Additionally, secondary considerations such as “commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.” *Id.* at 17–18.

Independent claim 1 is directed to a “gas delivery device” having “a valve attached to [a] gas source.” The recited valve includes a circuit that must have the following components:

⁹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, took effect on March 18, 2013. As the application from which the ’794 patent issued was filed before that date, our citations to 35 U.S.C. § 103 are to its pre-AIA version.

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 the 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.

Independent claim 7 is directed to a “gas delivery system,” that is of similar scope to claim 1. Independent claim 15 is directed to a “method for administering a therapy gas to a patient,” using a “gas deliver device” configured similarly to the gas delivery device of claim 1.

Peters discloses a memory within the handle of its smart valve that stores 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. Ex. 1004, 5:43–56. The memory also stores when and for how long the valve is opened or closed. *Id.* at 6:21–25. Paoli discloses a memory for storing the type of a gas in a supply cylinder (i.e., IDb data), but the Paoli memory is not part of a circuit in a valve that also includes a processor and transceiver in accordance with claim 1. Ex. 1006, 020–021. Bathe teaches obtaining the NO concentration actually being delivered to a ventilator in order to provide feedback for a CPU to adjust as needed administration of NO a patient is receiving but does not store it in a memory in a circuit in a valve. Ex. 1005, 6:5–20. INOmax label teaches the importance of administering precise concentrations of NO gas to neonatal patients. Ex. 1014, 006. IR Standard describes wireless communication standards in medical devices. Ex. 1007, vi.

Each of Petitioner's grounds relies on multiple references. In particular, with respect to Ground 1, 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 [Paoli], the INOMAX label, and the IR Standard to predictably result in an improved nitric oxide delivery system incorporating the advantageous aspects of each reference." Pet. 20.

A claimed invention, however, "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). To prove obviousness, there must have been, at the time of invention, "an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *Id.* Such reason cannot be provided by the very patent being challenged as obvious. *Id.* at 421 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning."); *Cheese Sys. v. Tetra Pak Cheese & Powder Sys.*, 725 F.3d 1341, 1352 (Fed. Cir. 2013) ("Obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.") (quotation marks omitted).

The Petition includes a section titled "Motivation to Combine Prior Art" that runs approximately six pages. Pet. 20–27. It is difficult to discern precisely what Petitioner's proffered reasons are for why a person of ordinary skill in the art would have made a combination that falls within the scope of the challenged claims.

Petitioner offers, in part, the following reasoning:

The '083 Patent [Bathe] teaches a basic NO delivery system including a gas cylinder 10, valves 14, 18, 20, and 24, and a control CPU 56 for controlling the flow and concentration of NO gas. (*See, e.g.*, Ex. 1005 at 6:20–28.) The '510 Patent [Peters] discloses a smart valve and handle attached to a gas cylinder for storing and transmitting information about the gas to a remote module. A person of skill in the art would have known to combine the control module disclosed in the '083 Patent with the smart valve and handle disclosed in the '510 Patent to obtain both the benefits of the smart handle of the '510 Patent and the delivery system of the '083 Patent. (Ex. 1002 ¶ 110.)

Pet. 21. This proffered reasoning, which proposes combining prior art teachings merely for the purposes of obtaining the individual benefits of each, is not persuasive. “Although common sense directs one to look with care at a patent [] that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 550 U.S. at 418. “This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 418–19. It is important—indeed, we determine that it is required in the context of the challenged claims and the relied-upon prior art teachings before us—for Petitioner to identify a reason that would have prompted a person of ordinary skill to combine the prior art in the fashion claimed by Patent Owner.

The above block-quoted Petitioner argument cites to declaration testimony of Dr. Stone. But, the cited testimony is similarly insufficient. It states:

110. The ‘083 Patent [Bathe] teaches a nitric oxide delivery system with various components including a gas cylinder, several valves and a CPU for controlling therapy, and a ventilator for delivering gas to a patient. The ‘510 Patent [Peters] teaches a valve assembly for gas delivery that could easily be incorporated into the delivery system described in the ‘083 Patent by installing the ‘510 Patent’s valve on the cylinder of the ‘083 Patent. When so incorporated, the valve of the ‘510 Patent is placed in fluid communication with the fluid circuit of the ‘083 Patent. The valve from the ‘510 Patent also adds its “smart handle” features to the ‘083 Patent’s system, including a processor, a transceiver, and a memory device disposed in the valve handle. These “smart handle” features provide the same benefits described in the ‘510 Patent to the system of the ‘083 Patent.

Ex. 1002 ¶ 110. Dr. Stone’s reasoning is unpersuasive. First, Dr. Stone testifies that the smart valve of Peters *could* be incorporated into Bathe without saying why a person of ordinary skill in the art *would* do so in the first instance. *Id.* He then describes, albeit vaguely, the benefits of making the combination. *Id.*

In his concluding sentence, Dr. Stone testifies that incorporating the smart valve of Peters into Bathe would provide Bathe with “the same benefits described in” Peters. *Id.* Peters describes the benefits of its smart valve as providing the ability to “record[] the number and duration of the treatments,” to “read or download[]” the recorded information, and to “generate[] reports to keep a record of the treatments on the patients, for record keeping, for billing the patients, and for checking the billing [a healthcare provider] receives from its [therapeutic gas] supplier.” Ex. 1004, 6:21–63.

Petitioner has not provided an adequate reason to combine the teachings in the manner Petitioner asserts renders the claims unpatentable. Even if we were to assume that the described benefits of each reference provided a reason to combine their teachings—as Dr. Stone’s testimony implies—the result would not be the combination Petitioner asserts. Rather, the result would be the Bathe NO delivery system remaining controlled by a CPU that operates based on real time feedback from transducers in which the introduced smart valve separately would record, as Peters teaches, the number and duration of treatments for record-keeping purposes, not for controlling gas delivery.

Relying on the same paragraph 110 of Dr. Stone’s declaration, Petitioner offers the following additional reason to combine the prior art:

Since some of the advantages of the ’510 Patent [Peters] involve tracking gas data in the cylinders (*e.g.*, “assign patient ID to cylinders” and “identify and control cylinders for blinded clinical trials,” (*see* Ex. 1004 at 7:36–47)), 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 gas data could be transmitted to a control module as disclosed in the ’083 Patent [Bathe], to control gas therapy. (Ex. 1002 ¶ 100.)

Pet. 21–22. In its Reply, Petitioner expands on this reasoning, quoting the Abstract of Peters as disclosing:

[R]elevant information, such as cylinder fill date, cylinder I.D. number, batch number, and patient name or account number may also be logged in the memory module. 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 recordkeeping and control functions.**

Reply 14 (quoting Ex. 1004, Abstract) (Petitioner’s emphasis). Petitioner argues that the Peters Abstract’s 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 reach a different factual finding. 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.

Petitioner’s challenge lacks an adequate reason, not only to incorporate the smart valve of Peters into Bathe, but also to: (1) repurpose the incorporated valve by using its memory, processor, and transmitter to store gas data to be communicated to the CPU *and* (2) modify the Bathe system to operate based on the gas data from the incorporated smart valve as opposed to the NO concentration actually being delivered to a ventilator.

Petitioner’s proffered reasons for why a person of ordinary skill in the art would incorporate additional teachings from Paoli, the INOMAX label, and IR Standard into the hypothetical combination do not compensate for the lack of a sufficient reason to combine, in the first instance, the relied-upon teachings of Bathe and Peters. For example, with respect to Paoli, the Petition argues:

The ’083 Patent [Bathe] discloses a general-purpose CPU that can use various stored algorithms to process information it receives about the actual and desired concentrations of gas to control gas delivery. (Ex. 1005 at 2:52–53; Ex. 1002 ¶ 135.) A person of skill in the art would understand that the algorithms used could be modified to allow the control CPU of the ’083 Patent to compare the received data and control gas delivery as described, for example, in the FR ’804 Publication [Paoli]. (Ex. 1002 ¶¶ 73, 111–12, 115–18.) Indeed, the comparison of gas data with patient data by the control module 300 of the FR ’804

Publication can easily be incorporated into the delivery system of the '083 Patent since the CPU of the '083 Patent is taught to compare actual concentration data with desired concentration data to control gas delivery. (Ex. 1002 ¶¶ 111, 131, 135.) As combined, these known prior art elements yield predictable results.

Pet. 22. In this argument, Petitioner again asserts that Bathe *could* be modified to incorporate a feature of another reference and that such modification would yield predictable results. Showing that a combination is possible and yields predictable results does not, at least not in the context of the present challenge (which relies on teachings from five references), demonstrate an adequate reason why a person of ordinary skill would have combined the prior art in the fashion claimed by Patent Owner.

Accordingly, Petitioner has not demonstrated that any of the challenged claims is unpatentable over Bathe, Peters, Paoli, the INOMAX label, and IR Standard.

C. Petitioner Grounds 2 and 3

Petitioner's Grounds 2 and 3, challenging claims 4 and 5 further in view of Lebel and claim 13 further in view of Durkan, respectively, suffer from the same failure as its Ground 1. Accordingly, Petitioner has not demonstrated that any of the challenged claims is unpatentable over the asserted combination of references.

III. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner filed a Motion to Exclude Exhibits 1002 and 2020, i.e., Dr. Stone's declaration and deposition testimony. Paper 44. Because we do

not rely on any of Dr. Stone's testimony in a manner adverse to Patent Owner, we dismiss the Motion as moot.

IV. CONCLUSION

Petitioner has not shown by a preponderance of the evidence that any claim of the '794 patent is unpatentable.

V. ORDER

Accordingly, it is

ORDERED that claims 1–16 of U.S. Patent No. 8,291,904 B2 are not unpatentable on the record presented;

FURTHER ORDERED that Patent Owner's Motion to Exclude is dismissed as moot; and

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

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