

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC.,
Petitioner,

v.

INO THERAPEUTICS, LLC,
Patent Owner.

Case IPR2015-00891
Patent 8,573,210 B2

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

DANIELS, *Administrative Patent Judge*.

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

Praxair Distribution, Inc. (“Praxair”) filed a Petition to institute an *inter partes* review of claims 1–16 of U.S. Patent No. 8,573,210 B2 (Ex. 1001, “the ’210 patent”). Paper 1 (“Pet.”).¹ We instituted trial for claims 1–16 of the ’210 patent on certain grounds of unpatentability asserted in the Petition. Paper 14 (“Decision to Institute” or “Inst. Dec.”). After institution of trial, Patent Owner, INO Therapeutics, LLC, (“Patent Owner” or “INO”), filed a Patent Owner Response. Paper 30 (“PO Resp.”). Praxair timely filed a Reply. Paper 40 (“Reply”).

A consolidated hearing for this proceeding as well as IPR2015-00884, IPR2015-00888, IPR2015-00889, and IPR2015-00893, each involving Praxair and INO but different patents, was held on May 16, 2016. The transcript of the consolidated hearing has been entered into the record. Paper 53. (“Tr.”).

Also before the Board is INO’s Motion to Exclude Evidence (Paper 44), Praxair’s Opposition to the same (Paper 48) and INO’s Reply (Paper 49).

After considering the evidence and arguments of counsel and for the reasons set forth below, we determine that Praxair has not met its burden of showing that claims 1–16 of the ’210 patent are unpatentable.

I. BACKGROUND

A. *The ’210 Patent (Ex. 1001)*

The ’210 patent (Ex. 1001), titled “Nitric Oxide Delivery Device,” relates generally to a gas delivery device used in a gas delivery system, and a method for administering therapy gas, such as nitric oxide (NO), to a

¹ The ’210 Patent is the subject of litigation captioned *INO Therapeutics LLC et al v. Praxair Distribution Inc. et al.*, 1:15-cv-00170-GMS currently pending in the District Court for the District of Delaware.

medical patient. Ex. 1001, 1:14–27, Fig. 1. In the Background section, it 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” 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 1:40–46.

The '210 patent describes specifically gas delivery system 10 including a supply cylinder of gas, i.e. gas source 50, and valve assembly 100 for connecting gas source 50 to a gas delivery circuit including ventilator 400. *Id.* at 6:5–15.

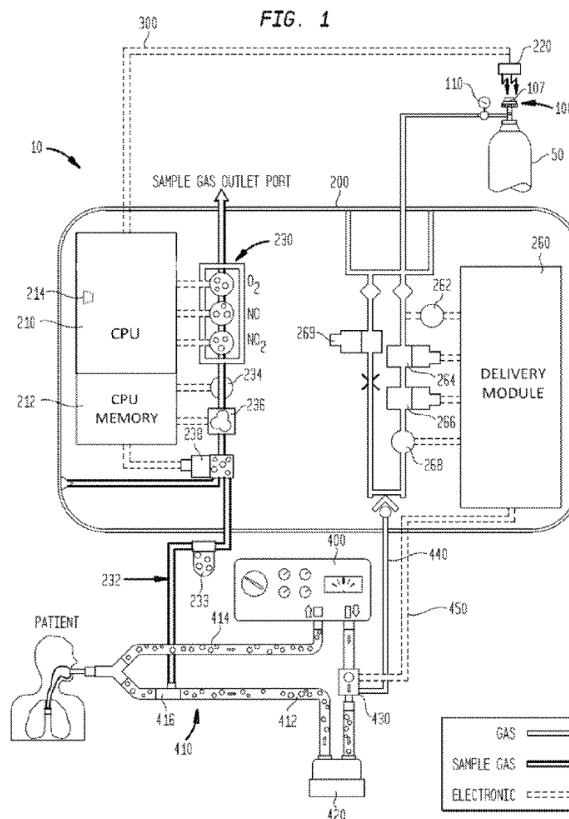


Figure 1 of the '210 patent, above, is a diagrammatic representation of gas delivery system 10 for delivering therapeutic gas to a patient.

The '210 patent is particularly drawn to valve assembly 100 which, by opening and closing, allows gas to flow from gas source 50, generally a cylinder containing NO gas for example, to the gas delivery system. *Id.* at 2:10–20. Figures 2 and 3 are reproduced below depicting valve assembly 100 having manual actuator 114, valve 107 and circuit 150 disposed in the actuator for communicating with a control module to control administration of the therapy gas to a patient. *Id.* at 5:60–6:5.

FIG. 2

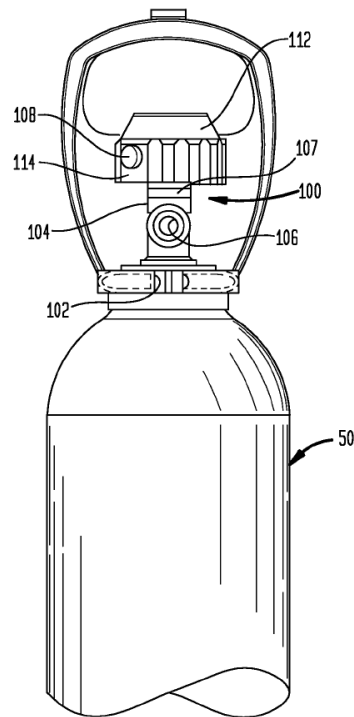


FIG. 3

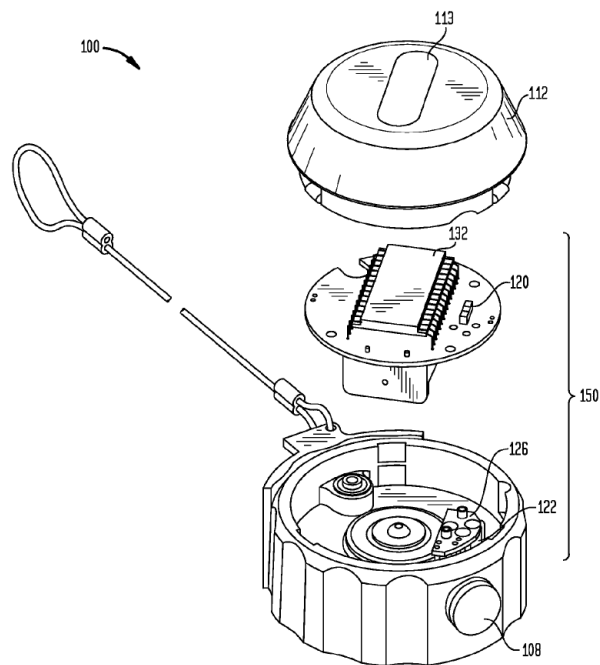


Figure 2, above, depicts valve assembly 100 and actuator 114 of the gas delivery device in communication via valve 107 with gas source 50.

Figure 3, above, illustrates an exploded view of actuator 114 and circuit 150.

Administration of therapy gas to the patient is regulated by a control module that controls delivery from gas source 50 (i.e., cylinder or 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.* Circuit 150 of valve assembly 100, shown diagrammatically below, is disposed in actuator 114 and communicates, for example via a wireless link by valve transceiver 120, with the control module. *Id.* at 6:20–25.

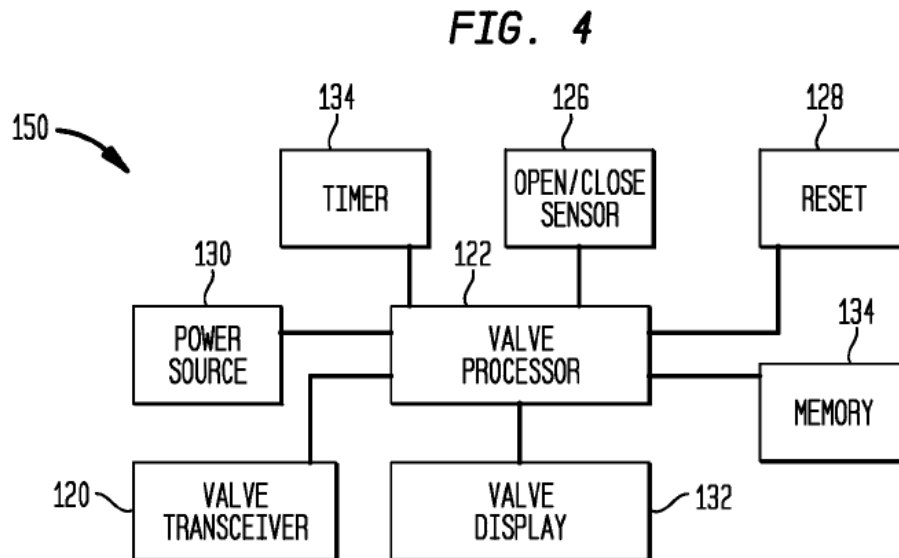


Figure 4 is a block diagram depicting various components of circuit 150.

Figure 4 depicts various components of circuit 150 including, *inter alia*, valve processor 122, memory 134, valve transceiver 120, power source

130, and valve display 132.² 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 itself. *Id.* at 7:5–10. 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 7:30–38. Valve transceiver 120 communicates with the control module that is physically separate, 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 8:24–27, 10:36–48, Figs. 7–9.

Control module 200, shown below in Figure 9, is ultimately responsible for delivery and regulation of a desired gas to a ventilator and patient, and requests data from valve assembly circuit 150 at pre-determined intervals to facilitate the appropriate gas delivery to the patient. *Id.* at 8:41–57, 9:62–10:4.

² Timer component is apparently mislabeled as 134, and recited in the specification as reference number 124.

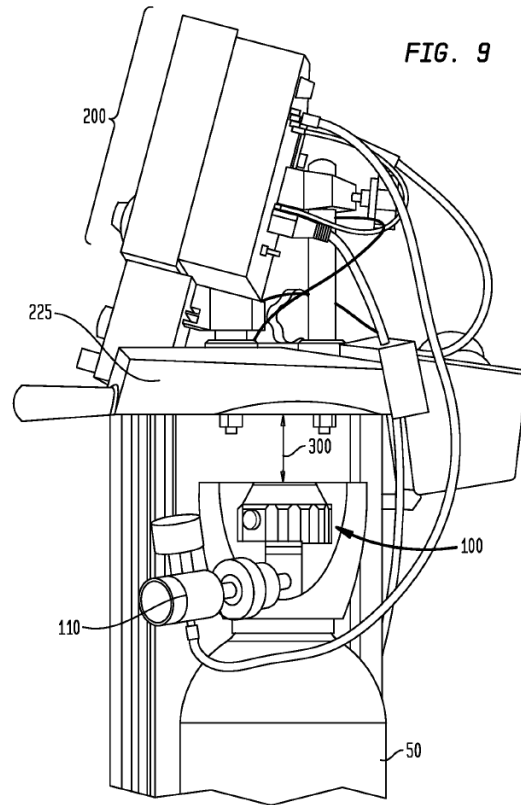


Figure 9 illustrates gas source 50 and valve assembly 100 in communication with control module 200 via a transceiver mounted on cover portion 225.

B. Illustrative Claim

Of the challenged claims, claim 1 is independent. Each of dependent claims 2–11 relate expressly to a nitric oxide delivery device and depend directly or indirectly from claim 1. Claims 12–16 are method claims that depend directly or indirectly from the delivery device recited in claims 1 and 6. Claim 1 illustrates the claimed subject matter and is reproduced below:

1. A nitric oxide delivery device comprising:
a control module to deliver a gas comprising NO to a patient in an amount effective to treat or prevent hypoxic respiratory failure; and

a valve assembly to deliver the gas comprising NO from a gas container containing the gas comprising NO to the control module, the valve assembly comprising:

a valve attachable to the gas container containing the gas comprising NO, 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 comprising NO through the valve to the control module; and

a circuit supported within the valve assembly and disposed between the actuator and a cap, the circuit including:

a valve memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration in the gas container and

a valve processor and a valve transceiver in communication with the valve memory to send and receive wireless optical line-of-sight signals to communicate the gas data to the control module and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired.

C. The Asserted Grounds of Unpatentability

We instituted a trial on Praxair's challenges to claims 1–16 of the '210 patent as obvious under 35 U.S.C. § 103 over the combination of the references listed below and as further supported by the Declaration of Dr. Robert T. Stone (Ex. 1002).

References	Basis	Claims Challenged
Bathe ³ , Peters ⁴ , FR '804 ⁵ , INOMAX label ⁶ , and IR Standard ⁷	§ 103	1–9, and 12–16
Bathe, Peters, FR '804, INOMAX label, IR Standard, and Lebel '533 ⁸	§ 103	4–5
Bathe, Peters, FR '804, INOMAX label, IR Standard, and Durkan '398 ⁹	§ 103	10–11

II. CLAIM CONSTRUCTION

Neither party proposes express constructions for any term. *See* Pet. 8–9; PO Resp. 7. We maintain our earlier determination that no term requires express construction. Inst. Dec. 8.

III. OBVIOUSNESS OVER BATHE, PETERS, FR '804, INOMAX LABEL, THE IR STANDARD, AND LEBEL OR DURKAN

Praxair asserts that claims 1–9 and 12–16 would have been obvious over Bathe, Peters, FR '804, INOMAX Label and the IR Standard and Bathe, Peters, FR '804, INOMAX Label, the IR Standard, and either Lebel or Durkan for claims 4–5 and 10–11 respectively. Pet. 9–10. A patent is invalid for obviousness:

if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was

³ Ex. 1005, U.S. Patent No. 5,558,083 (Sept. 24, 1996)

⁴ Ex. 1004, U.S. Patent No. 7,114,510 B2 (Oct. 3, 2006)

⁵ Ex. 1006, FR Pub. No.: 2 917 804 (Dec. 26, 2008)

⁶ Ex. 1014, FINAL PRINTED LABELING, CENTER FOR DRUG EVALUATION AND RESEARCH, Appl'n. No.: NDA 20845 (2000).

⁷ Ex. 1007, *Health informatics — Point-of-care medical device communication — Part 30300: Transport profile — Infrared wireless*, ISO/IEEE 11073–30300 (2004)

⁸ Ex. 1008, U.S. Patent No. 6,811,533 B2 (Nov. 2, 2004).

⁹ Ex. 1010, U.S. Patent No. 4,462,398 (July 31, 1984).

made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103. Obviousness is a question of law based on underlying factual findings: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966). As the party challenging the patentability of the claims at issue, Praxair bears the burden of proving obviousness by a preponderance of the evidence. *See* 35 U.S.C. § 316(e).

We instituted trial on claims 1–16 based on Praxair’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. 18–20. 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 Praxair has not met its burden of showing that claims 1–16 are unpatentable by a preponderance of the evidence.

A. Scope and Content of the Prior Art

Praxair relies on the combination of Bathe, Peters, FR ’804, the IR Standard, the INOMAX Label, and either Lebel or Durkan as obviousness references. We discuss each reference below.

1. Bathe

Bathe discloses a nitric oxide (NO) delivery system for use with a medical ventilation device. Ex. 1005, 1:1–11. Figure 1 of Bathe is reproduced below.

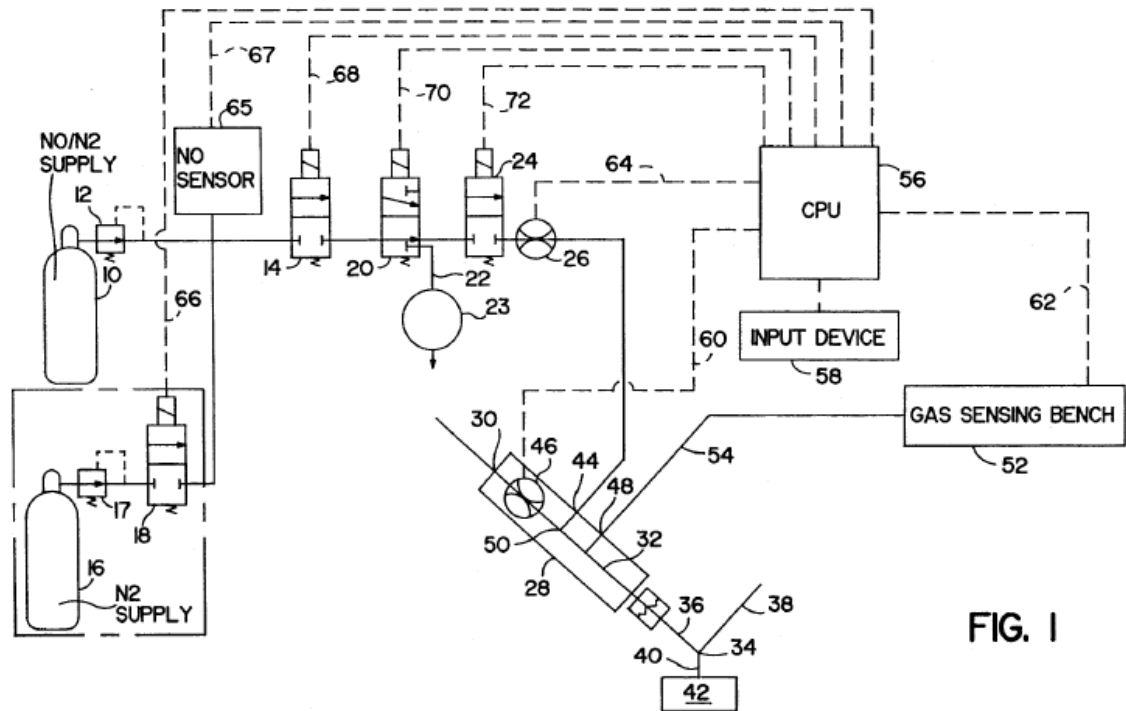


Figure 1 is a depiction of schematic view, partially in block diagram form, of apparatus in accordance with an embodiment of Bathe. *Id.*, 3:33–35.

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, in the 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 explains that

[t]he 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, CPU 56 knows the 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 then knowing the desired NO concentration set by the user via input 58, CPU 56 adjusts valves 14, 18, 20, and 24 to bring the actual gas flow and NO concentration to the patient into accordance with the user's desired input level. *Id.* at 6:43–53.

2. Peters

Peters discloses, as shown in Figure 1 below, valve 10 with “smart” handle 16 having a memory module and circuit to log data such as opening and closing time for the valve. Ex. 1004, Abst., 2:43–51.

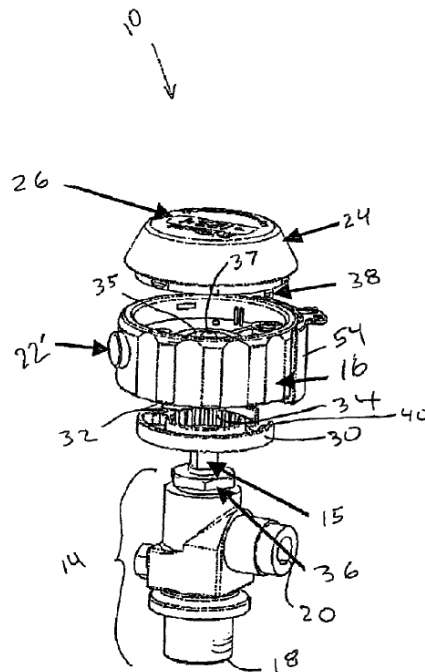


FIG 1

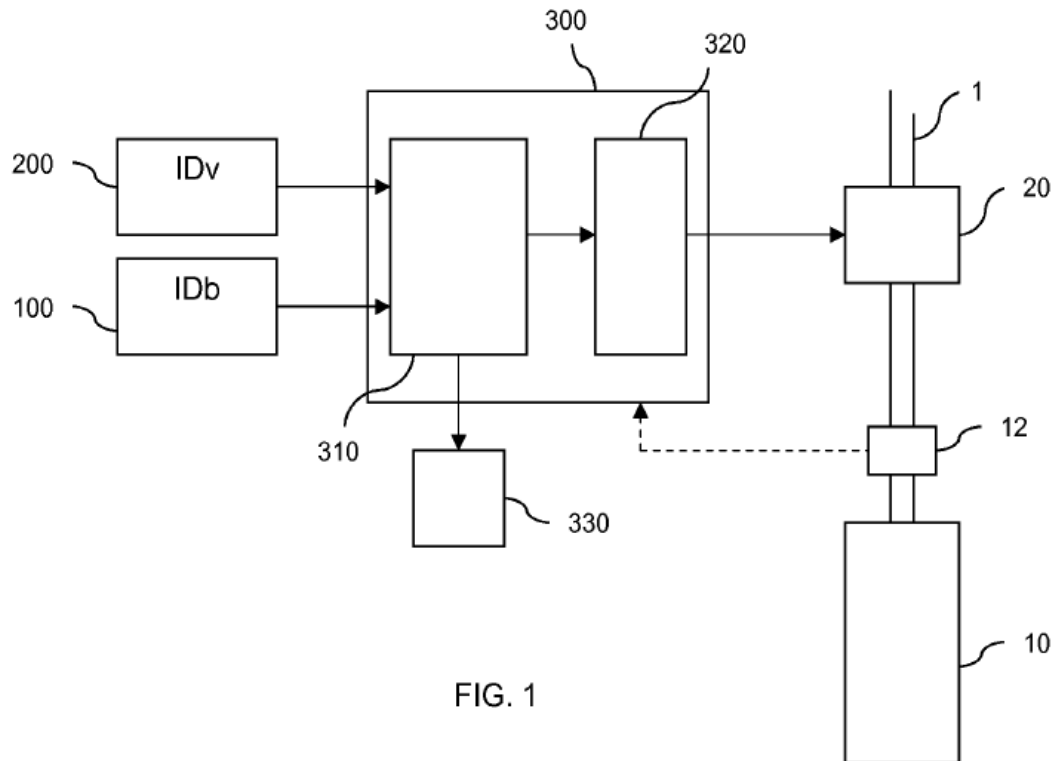
Figure 1 of Peters illustrates an exploded view of valve 10 having valve body 14 supporting valve handle 16 and gas inlet port 18 for connecting to and communicating with a gas cylinder (not shown). *Id.* at 1:58–60; 2:43–51. Inside handle 16 are several electronic devices, namely, processor 23, timer 21, memory 22 and data port 22', sensor 28, battery 25 and display 26. *Id.* at 2:58–64. With respect to the electronics, the '510 patent explains that memory configuration is established by initial parameters such as:

- 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 5:43–53; *see also id.* at 5:54–56 (“Additional area may be available for recording specific notes or information relative to a specific treatment or lot.”). When gas is dispensed through valve 10 during operation, sensor 28 prompts processor 23 to log the event, including parameters such as date, time, and opening or closing of the valve and “[t]hus, 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 6:21–32. 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. FR '804

FR '804 relates to a connection system for a valve to a gas bottle or cylinder. Ex. 1006, 1.¹⁰ 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 3. Observing Figure 1 of FR '804 as reproduced below, control module 300 communicating with valve 20 receives input signal IDb, the identification of gas type being supplied from the bottle 10, and compares this with input data IDv, the desired type of gas for the procedure that is stored in memory 200. *Id.* at 3.



¹⁰ We refer to the top numbered pages of the English translation of FR '804.

Figure 1 of FR '804 is a block diagram illustrative of control module 300 for controlling valve 20. Once IDb and IDv are input to control module 300, 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.* at 3.

In another embodiment, FR '804 also discloses that the type of gas (IDb) in bottle 10 can be input from information carrier 120, such as an RFID tag on bottle 10, that is read by sensor 110 connected to control module 300 when valve 20 and bottle 10 are connected. *Id.* at 4, Fig. 2.

4. *The IR Standard*

The IR Standard is a protocol promulgated by the Institute of Electrical and Electronics Engineers (IEEE) as an international standard for short-range infrared wireless communication for medical devices used at or near a patient. Ex. 1007, Abstract (ii). The IR Standard purports to describe wireless communication standards to “[f]acilitate the efficient exchange of vital signs and medical device data, acquired at the point-of-care, in all health care environments.” *Id.* at vi. This reference 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.* The IR Standard further 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. *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, 2. The INOMAX label also indicates that the drug was used with ventilators administering NO to neonatal patients. *Id.* at 6. The INOMAX label provides guidance and monitoring protocols and states that

[t]he 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 the INOmax™ drug is supplied in aluminum cylinders. *Id.*

6. *Lebel*

Lebel discloses a protocol for an RF telemetry communication system for medical devices. Ex. 1008, Abst. More specifically, Lebel teaches optimizing power consumption in communication devices for instance between a surgically implanted device in a human body, such as an insulin pump, and an external control or monitoring device by sending communications intermittently to conserve battery power. *Id.* at 2:18–35. Lebel states that the time between communications can occur for example “no more than 15 seconds apart, more preferably no more than 10 seconds apart, and even more preferably no more than 5 seconds apart, and most preferably no more than about 2 seconds apart.” *Id.* at 25:5–9. Lebel further explains that power conservation in such medical devices is a balance in which “desire to minimize power drain in the implantable device is balanced

with a desire to have the implantable device respond quickly to commands transmitted by the external communication device.” *Id.* at 25:60–63.

7. *Durkan*

Durkan discloses a gas supply apparatus and method for providing respirating gas to a medical patient. Ex. 1010, 1:6–8. Particularly, Durkan discloses a gas delivery system having a circuit 100 (Figure 5) including a visual signal such as an illuminated LED 92 that provides visual confirmation that a valve is in a position such that a gas pulse is being supplied. *Id.* at 11:43–46. When the valve is in a position that gas is not being supplied, the LED will likewise not be illuminated. *Id.* at 47–51, Fig. 5. Durkan further discloses a dual gas supply for its respiratory system and that the control means disclosed in Figure 5, including alarm circuit 100, can be used with the dual gas supply embodiment to indicate by illuminating LED 92 when both gas supply valves are open and supplying gas to the system. *Id.* at 7:29–54, 13:57–65, 14:8–12.

B. The Level of Ordinary Skill in the Art

Praxair asserts that a person of ordinary skill in the art would have had “a bachelor’s degree in electrical engineering, computer science, computer engineering, or the equivalent, and would have had at least two years’ experience in biomedical engineering designing medical gas delivery or monitoring systems.” Pet. 8 (citing Ex. 1002 ¶¶ 17–18). INO does not expressly dispute the general level of skill in the art proffered by Praxair but adds through its declarant, Mr. Warren P. Heim, that one of skill in the art would “know Food and Drug Administration (FDA) Current Good Manufacturing Practices.” Ex. 2021 ¶ 107.

C. *Claims 1–16 over Bathe, Peters, FR '804, the INOMAX Label, the IR Standard and either Label or Durkin*

1. *Whether One of Ordinary Skill in the Art Would Have Combined and/or Modified the Prior Art to Achieve the Claimed Invention*

INO asserts that Praxair “has failed to meet its burden of proving that a POSA would have been motivated to combine the cited prior art references in the precise manner the claims require.” PO Resp. 38. INO argues that (1) a person of ordinary skill in the art was unaware of the problem solved by the '209 patent; (2) a person of ordinary skill in the art would not have combined Bathe and Peters; (3) a person of ordinary skill in the art would not have combined Bathe and Peters with FR '804; and (4) nothing in the IR Standard, Lebel, Durkan or INOMAX Label cures the improper asserted combination of Bathe, Peters, and FR '804. *Id.* at 39–55.

INO’s first argument is not persuasive because the evidence indicates that a person of ordinary skill in the art *would have been* aware that there was a risk to providing a patient with the incorrect gas or gas concentration. For example, the '210 patent states in the Background section that

[g]as delivery devices are often utilized by hospitals to deliver the necessary gas to patients in need. *It is important when administering gas therapy to these patients to verify the correct type of gas and the correct concentration are being used.* It is also important to verify dosage information and administration.

Ex 1001, 1:22–27 (emphasis added). Bathe also discloses in the Background of the Invention that it was critical to control the concentration of gas to a patient:

There is, of course, a need for that concentration to be precisely metered to the patient since an excess of NO can be harmful to the patient.

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Ex. 1005, 1:37–39. The Federal Drug Administration (“FDA”) also recognized the problem of administering incorrect gas, for example, FDA guidance as of January 24, 2000 promulgated

use of a standard gas-specific fitting (as well as the use of nitric oxide gas analyzer) will control the risk of incorrect drug administration resulting from use of the incorrect compressed gas.

Ex. 1012, 8, § 3.1.1.i. Based on this evidence, we find that the broad problem of verifying gas concentration was known to those of ordinary skill in the art. INO cites to *Novartis Pharm. Corp. v. Watson Labs., Inc.*, 611 Fed. App’x. 988, 995 (Fed. Cir. 2015) in support of its position. PO Resp. 40. *Novartis* is distinguishable because in that case the patent owner solved an entirely unknown problem, not a previously solved problem. *Novartis*, 611 Fed. App’x. 988, 997 (The Federal Circuit upholding the district court’s conclusion of non-obviousness, in part, because of the finding that “rivastigmine was not known to be susceptible to oxidative degradation.”).

INO’s argument is more properly stated as: the problem of verification of supplying the correct gas to a patient had *already* been solved. Therefore, as FDA approval could be obtained based on the current state of the art, there was no incentive or motivation to find a different way. PO Resp. 40–41. We are persuaded that such an argument is directed not to a brand new and novel problem solved by INO, but instead, as discussed below, supports INO’s position that Praxair has failed to present persuasive reasons with rational underpinnings supporting the combination of prior art references.

After reviewing the record in total, the arguments and evidence presented by both parties and the prior art itself, we find that Praxair 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, the INOMAX Label, and the IR Standard. PO Resp. 36–53. INO points out, correctly, that Praxair has not shown that a person of ordinary skill in the art would have been motivated to combine Peters's smart valve having a memory for compiling data for billing and invoicing functions, with Bathe. *Id.* Moreover, we are not persuaded that Praxair's inability to provide sufficient motivation for combining Peters and Bathe is remedied by the introduction of FR '804 and the INOMAX Label, particularly given that Bathe already included an in-line sensing unit to sense and verify the gas concentration from the cylinder as mandated by FDA guidance. *Id.* at 46–47, *see also* Pet. Reply 11–12.

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. Praxair argues that motivation to combine the references springs from the contention that Peters's 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, Praxair's expert Dr. Stone, states that Peters's “valve assembly for gas delivery [] could easily be incorporated into the delivery system described in [Bathe] by installing [Peters] valve on the cylinder of [Bathe].”¹¹ Ex. 1002 ¶ 107. INO correctly points out that this

¹¹ For the purpose of consistency in our Decision we have replaced Petitioner's quoted use of “the '083 patent” with the first named inventor “[Bathe],” and similarly replaced “the '510 patent” with “[Peters].”

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, only that they *could*. PO Resp. 43–44. 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 combining the prior art. *See InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (Experts "testimony 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.").

Petitioner's challenge lacks an adequate motivation, not only to incorporate the smart valve of Peters into Bathe, but also to: (1) repurpose the incorporated valve by using (a) its "memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration" and (b) its processor and transmitter "to send and receive wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject" and (2) modify the Bathe system, such that its CPU would receive the wirelessly transmitted gas concentration data, even though the CPU already receives (and uses) flow and operator input data to provide a desired NO concentration. *See* Ex. 1005, 6:5–20.

2. *Whether the Combination of Prior Art References is Supported by Articulated Reasoning and Evidentiary Underpinning*

The Supreme Court requires an expansive and flexible approach in determining whether a patented invention would have been obvious at the time it was made. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007). The existence of a reason for a person of ordinary skill in the art to modify a prior art reference is a question of fact. *See In re Constr. Equip.*

Co., 665 F.3d 1254, 1255 (Fed. Cir. 2011). In an obviousness analysis, some kind of reason must be shown as to why a person of ordinary skill would have thought of combining or modifying the prior art to achieve the patented invention. See *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 (Fed. Cir. 2008). A reason to combine or modify the prior art may be found explicitly or implicitly in market forces; design incentives; the “‘interrelated teachings of multiple patents’”; “‘any need or problem known in the field of endeavor at the time of invention and addressed by the patent’”; and “the background knowledge, creativity, and common sense of the person of ordinary skill.” *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1328–29 (Fed. Cir. 2009) (quoting *KSR*, 550 U.S. at 418–21).

The closest Praxair comes to providing a reason that one of ordinary skill in the art would have been motivated to combine these references is that doing so allegedly would “allow the user to better link the gas information with patient treatments.” Pet. 22. This assertion however, leaves several unanswered questions in its wake. 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 based on any express or even implicit teachings of either Bathe or Peters or the knowledge of a person of ordinary skill. Second, Praxair fails to explain why or how a person of ordinary skill in the art would have “linked” Peters’s data to patient treatments, as Peters 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 nor computer is used to determine any physiological aspect of patient treatment. See Ex. 1004 5:43–6:15. (“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.”).

Dr. Stone further opines 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].” Ex. 1002 at ¶ 112 (citing Ex. 1005, 6:11–15). 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.* In particular, Dr. Stone does not describe 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 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 or otherwise that would have motivated one of skill in the art to add Peters’s valve and memory to Bathe.

We are also not persuaded that a person of skill in the art would have combined Bathe and Peters “to obtain both the benefits of the smart handle of [Peters] and the benefits of the delivery system of [Bathe].” *See* Pet. 20 (citing Ex. 1002 ¶¶ 93, 96). 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, Praxair assumes the combination to have occurred structurally and functionally, i.e., Peters’s valve being placed onto Bathe’s cylinder, and 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. Praxair, however, never explains adequately why or how Peters's valve, which sends valve opening and closing time for billing purposes, improves 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 ¶ 131. This statement is not persuasive because it presupposes, without explaining why, one of skill in the art would have been motivated by safety concerns to combine Bathe and Peters, and then leaps to FR '804 to show such a safety check.

Praxair'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. Praxair's position appears to be based essentially on the theory that, when combined, the references "predictably result in an improved nitric oxide delivery system incorporating the advantageous

aspects of each reference.” Pet. 19 (citing Ex. 1002 ¶¶ 89–121). In *KSR* the Supreme Court noted the intrinsic problem of establishing a showing of obviousness based on predictable results. *KSR*, 550 U.S. at 417 (“[A] court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions.”). Acknowledging that this was a difficult task in many circumstances, particularly where the combination involved more than a simple substitution of known elements, the Supreme Court stated that “[t]o facilitate review, this analysis should be made explicit.” *Id.* at 418. Clarifying this standard, the Supreme Court quoted with approval *In Re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) as holding:

rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

Id. Praxair’s proposed combination, however, does not fit within the Supreme Court’s framework expressed above. Neither Praxair’s nor Dr. Stone’s assertions that the combination could occur adequately address why one of ordinary skill in the art would combine Bathe’s gas delivery system with Peters’s valve handle that stores opening and closing information for communication of gas billing and use data to a separate computer.

3. *INOMAX Label*

Attempting to bolster its reasons for combining Bathe and Peters Praxair contends that one of ordinary skill in the art would “incorporate the ’510 Patent’s teachings into the ’083 Patent to achieve the INOMAX label’s therapy because each of those references belongs to PO, a long-time leader in NO therapy technology.” Pet 25 (citing Ex. 1002 ¶ 113). As we understand Praxair’s argument, because INO’s inventors were purportedly

knowledgeable about the contents of these three references, they would have been motivated to combine Bathe and Peters as Praxair asserts. This argument is not persuasive because the issue is not INO's inventors' level of skill, but that of a hypothetical person of ordinary skill in the art. *See In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) ("The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art.").

Praxair further asserts that the INOMAX reference teaches verification of therapy NO gas concentration, and thus "a person of skill in the art would have been motivated to look to systems that expressly enable such verification, such as the system of the FR '804 Publication." Pet. 25 (citing Ex. 1002 ¶ 133). That one would have looked to FR '804 based on INOMAX is unpersuasive because INOMAX teaches verification of the gas delivered to a patient "proximal to the patient" in the gas delivery circuit, not from information derived from a memory about contents of the cylinder:

In the ventilated neonate, precise monitoring of inspired nitric oxide and N02 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.*

Ex. 1014, 6 (emphasis added). In INOMAX, sensing and calculating the NO concentration in the gas delivery circuit is a similar teaching to Bathe, not a persuasive reason to look to FR '804. *Compare id.*, with Ex. 1002, 6:29–54. In sum, neither of these arguments with respect to the INOMAX Label reference explains why one of ordinary skill in the art would have combined either Bathe and Peters, or even Bathe, Peters and FR '804.

4. *Lebel and Durkan*

Praxair applies the additional prior art references of Lebel for dependent claims 4 and 5 in ground 2, and Durkan for dependent claims 10 and 11 in ground 3. Neither Lebel or Durkan, however, cure the deficiencies in Praxair's failure to provide sufficient reasons with supporting evidentiary rationale with respect to the underlying Bathe, Peters, and FR '804 references.

5. *Ultimate Conclusion of Non-Obviousness*

Precedent recognizes the pitfalls of judicial hindsight exercised at the time of litigation, *KSR*, (550 U.S. 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.”). “Good ideas may well appear ‘obvious’ after they have been disclosed.” *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 956 (Fed. Cir. 1997).

In the instant case, Praxair's attempt to transform Bathe from having a sensed in-line gas concentration being used to perform verification of gas supply and gas delivery to a subject or patient into a device receiving gas concentration information from Peters's handle and memory on the gas supply cylinder in order to verify and control gas delivery to a patient smacks of hindsight reasoning. After considering the evidence and arguments of both parties, we conclude that Praxair has failed to carry its burden of demonstrating, by a preponderance of the evidence, that independent claim 1 is unpatentable.

Because Praxair's obviousness analysis for dependent apparatus claims 2–11, as well as the dependent method claims 12–16, asserted in each of the grounds in this proceeding relies on the deficient asserted combination including Bathe and Peters, we similarly are not persuaded that Praxair has

sustained its burden of demonstrating, by a preponderance of the evidence that claims 2–16 are unpatentable.

D. INO's Motion to Exclude

Patent Owner seeks to exclude the testimony of Dr. Robert Stone (Exs. 1002, 2020). Because we do not rely on Dr. Stone's testimony in a manner adverse to INO, the motion to exclude is dismissed as moot.

IV. ORDER

For the reasons given, it is

ORDERED that:

1. Claims 1–9 and 12–16 have NOT been shown to be unpatentable as obvious over Bathe, Peters, FR '804, the IR Standard, and the INOMAX Label;
2. Claims 4 and 5 have NOT been shown to be unpatentable as obvious over Bathe, Peters, FR '804, the IR Standard, the INOMAX Label, and Lebel;
3. Claims 10 and 11 have NOT been shown to be unpatentable as obvious over Bathe, Peters, FR '804, the IR Standard, the INOMAX Label, and Durkan; and
4. INO's Motion to Exclude Evidence is dismissed.

This is a Final Written Decision under 35 U.S.C. § 318(a). 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.

For PETITIONER:

IPR2015-00891
Patent 8,573,210 B2

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