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Paper 14
Entered: September 22, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC.,
Petitioner,

v.

INO THERAPEUTICS, LLC.,
Patent Owner.

Case IPR2015-00893
Patent 8,776,795 B2

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

BARRETT, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

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., the owner of the '795 patent, filed a Preliminary Response to the Petition. Paper 9. We have jurisdiction under 35 U.S.C. § 314(a).

Our factual findings and conclusions at this stage of the proceeding are based on the evidentiary record developed thus far. This is not a final decision as to patentability of claims for which *inter partes* review is instituted. Any final decision would be based on the record as fully developed during trial.

After considering the information presented in the Petition, we are persuaded there is a reasonable likelihood Petitioner would prevail with respect to at least one of the claims challenged in the Petition. We institute an *inter partes* review of all of the challenged claims, claims 1–20, of the '795 patent.

II. BACKGROUND

A. 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, it is stated 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.*, 1:40–43.

The '795 patent describes a gas delivery device comprised of 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.

FIG. 2

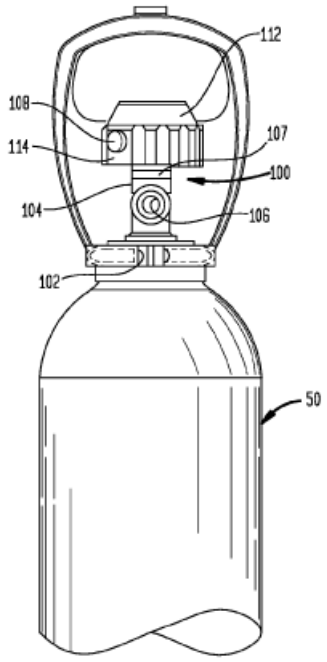

FIG. 3

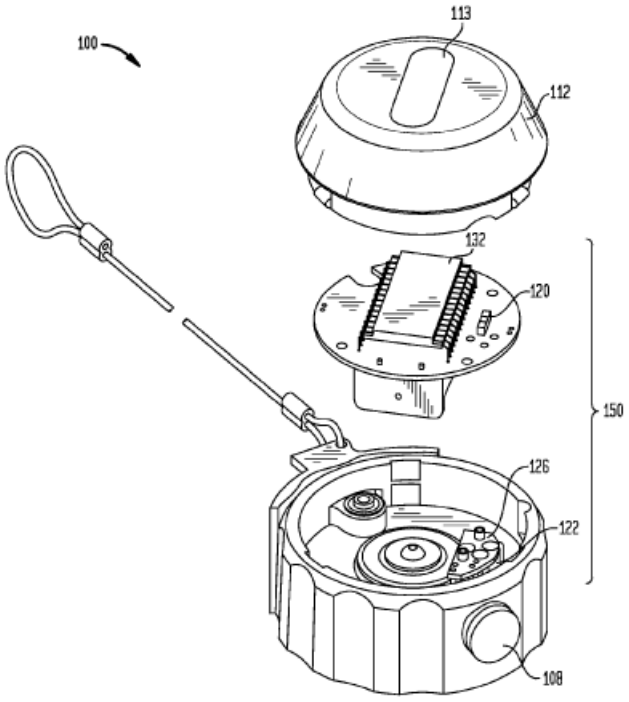

Figure 2 depicts valve assembly 100 and actuator 114 of the gas delivery device in communication via valve 107 with gas source 50, and Figure 3 illustrates an exploded view of actuator 114 and valve assembly 100. *Id.*, 6:11–35. Figure 4 is reproduced below:

FIG. 4

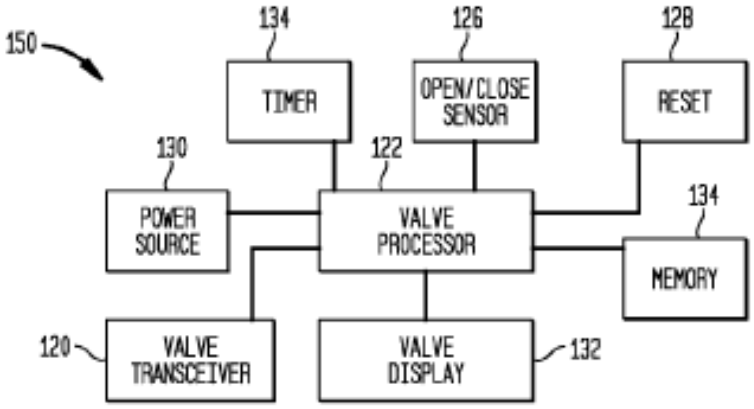

Figure 4 depicts circuit 150 of valve assembly 100, which is disposed in actuator 114. *Id.* at 6:36–49. Circuit 150 includes, *inter alia*, valve processor 122, memory 134, valve transceiver 120, power source 130, timer 124,[1] and valve display 132. *Id.* Memory 134 stores the gas data for the particular 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 itself. *Id.* at 6:63–18. 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

[1] The timer component apparently is mislabeled as 134 in Figure 4, and is recited in the specification as reference number 124. Ex. 1001, 6:40.

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, 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.

B. The Challenged Claims

The Petition challenges the patentability of claims 1–20. Of the challenged claims, claims 1, 7, and 15 are independent. 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.

C. Related Matters

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. 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.

D. The Asserted Grounds

Petitioner asserts the following grounds of unpatentability:

Reference[s]	**Basis**	**Claims**
Bathe,[2] Peters,[3] FR '804,[4] the IR Standard[5]	§ 103	1–12, 14–20
Bathe, Peters, FR '804, the IR Standard, and Lebel[6]	§ 103	4, 5
Bathe, Peters, FR '804, the IR Standard, and Durkan[7]	§ 103	13

[2] U.S. Patent No. 5,558,083, iss. Sept. 24, 1996 (Ex. 1005).
[3] U.S. Patent No. 7,114,510 B2, iss. Oct. 3, 2006 (Ex. 1004).
[4] FR 2 917 804 A1, pub. Dec. 26, 2008 (as translated) (Ex. 1006).
[5] 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).
[6] U.S. Patent No. 6,811,533 B2, iss. Nov. 2, 2004 (Ex. 1008).
[7] U.S. Patent No. 4,462,398, iss. July 31, 1984 (Ex. 1010).

Petitioner relies also on the Declaration of Dr. Robert T. Stone, dated March 13, 2015, (Ex. 1002) in support of Petitioner's arguments.

III. ANALYSIS

A. Claim Construction

The parties agree, for purposes of this Decision, that the claim terms of the '795 patent have their plain and ordinary meaning. Pet. 9; Prelim. Resp. 13. Because currently there is no dispute as to the construction of the claim terms, and our Decision does not turn on any specific claim interpretation different from the plain and ordinary meaning, for purposes of this Decision no claim construction is necessary. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only those terms which are in controversy need to be construed, and only to the extent necessary to resolve the controversy).

Petitioner states: "There is no antecedent for 'drug data' in claims 18 or 19 [and] Petitioner assumes for purposes of this proceeding only that 'drug data' refers to claim 15's 'gas data.'" Pet. 45 n.10. Patent Owner appears to agree with this assumption. *See, e.g.*, Prelim. Resp. 9–10 (referring to gas data recited in claim 18). For purposes of this Decision, we operate under the same assumption.

B. Threshold issue – 325(d)

Patent Owner argues (Prelim. Resp. 16–19) initially that the Petition should be denied because the Bathe and Peters references were specifically cited in an Information Disclosure Statement and considered by the Examiner during prosecution and because Peters was relied upon by the Examiner in rejecting the claims during prosecution. Prelim. Resp. 16–19.

Patent Owner argues that, accordingly, the Petition should be denied because Petitioner "relies on substantially the same prior art and presents substantially the same arguments that Patent Owner already overcame during prosecution." *Id.* at 18. Patent Owner asserts that the Examiner indicated allowance of claims in part because Peters failed to disclose "the specific structure and functional [circuit] limitation as recited in the claims such as claim 1" and "the prior art of record does not disclose the specific method steps [of "establishing communication" and "comparing"] and structural relationships as recited in claim 15." *Id.* at 17–18 (quoting Ex. 1019, 94–95).

The pertinent statute, 35 U.S.C. § 325(d), gives the Director discretion to take into account whether, and reject a petition because, the same or substantially the same prior art or arguments previously were presented to the Office. That Peters and Bathe were considered as prior art in the prosecution record of the '795 patent is a factor which the Board "may take into account" according to 35 U.S.C. § 325(d). However, Patent Owner does not show that the examiner of the application that became the '325 patent considered "substantially the same . . . arguments," as Patent Owner presents here, another factor which the Board "may take into account" according to 35 U.S.C. § 325(d). For example, although Peters and Bathe may have been cited during prosecution and Peters was found to not disclose certain aspects of the claimed inventions, Patent Owner does not identify with specificity where "substantially the same . . . arguments"—substantially the same combinations of references—were before the Examiner.

Absent a showing of substantially the same arguments and considering that Petitioner includes, at least, additional evidence not considered by the examiner in the underlying prosecution, as well as the declaration of Dr. Robert T. Stone, Ph.D. (Ex. 1002), Patent Owner does not show that the *inter partes* review of the '795 patent would be improper under 35 U.S.C. § 325(d).

C. 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 responds. Prelim. Resp. 24–42.

1. Overview of Bathe

Bathe discloses a nitric oxide (NO) delivery system for use with a medical ventilation device. Ex. 1005, 1:1–11. As shown in Figure 1, reproduced below, Bathe's system uses flow transducers 26, 46, to determine the flow of gas in the system, and input 58 provides for an operator to select a desired concentration of NO to the patient.

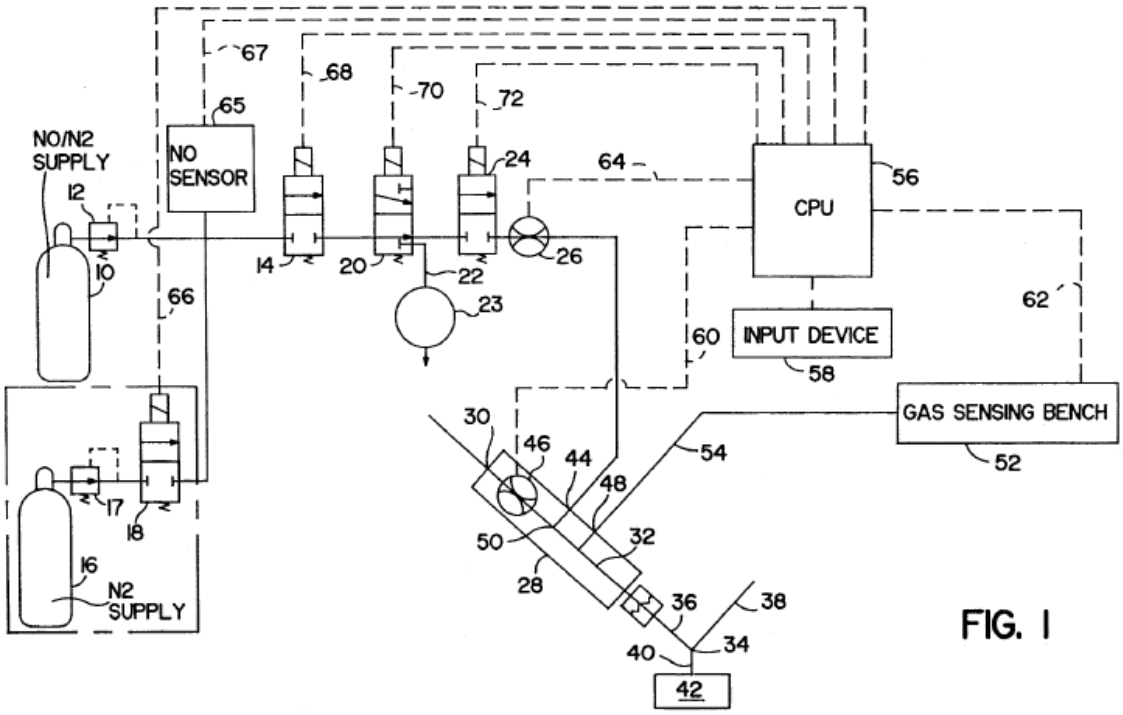

FIG. 1

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.

With flow and operator input information, a system 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 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 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. Overview of 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, Abs., 2:43–51.

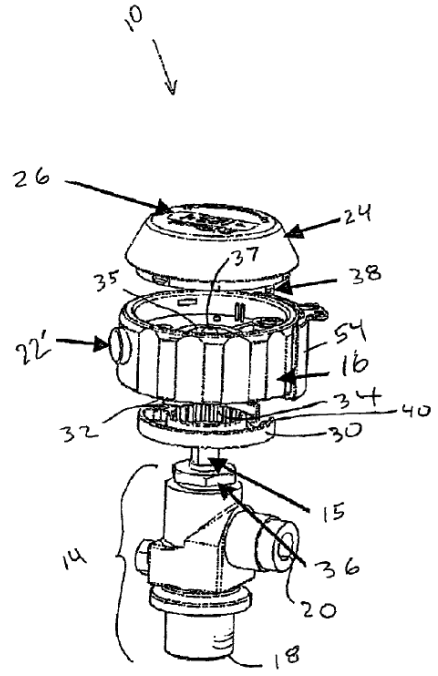

FIG 1

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)
>
> Clear the log registers
>
> Additional area may be available for recording specific notes or information relative to a specific treatment or lot.

Id. at 5:43–56. When gas is dispensed through valve 10 during operation, sensor 28 tells 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. Overview of FR '804

FR '804[8] relates to a connection system for a valve to a gas bottle or cylinder. Ex. 1006, at 1. The described connection system includes a safety 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.

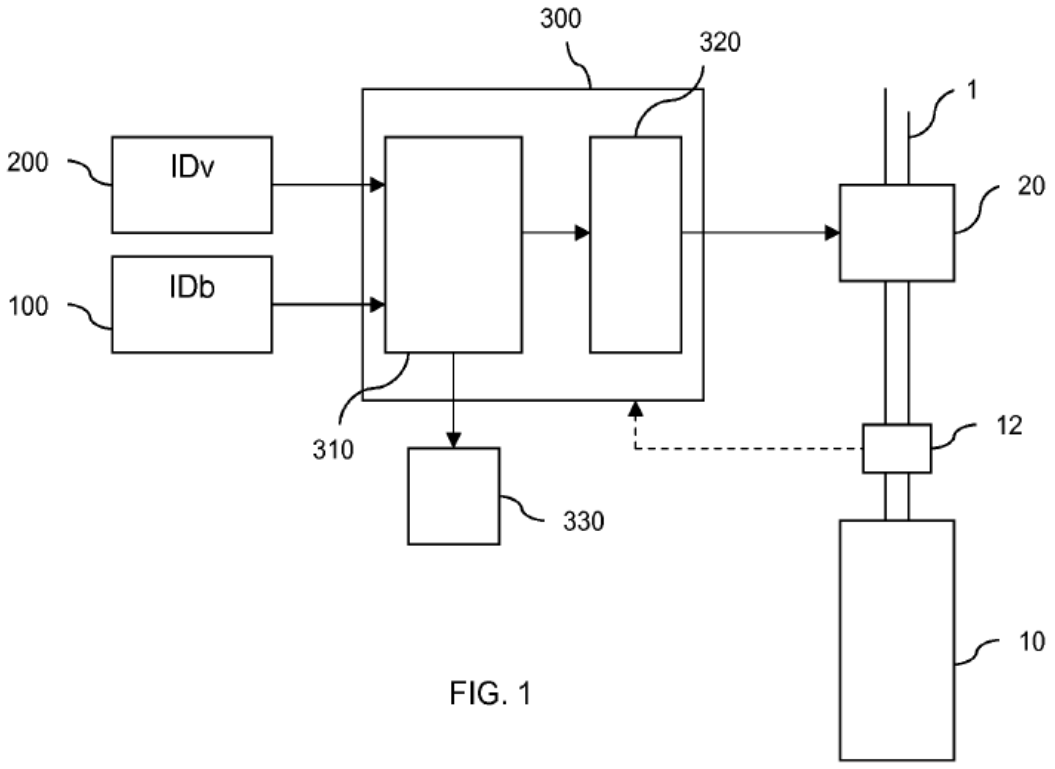

FIG. 1

[8] 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. Overview of IR Standard

The IR Standard is a protocol promulgated by IEEE as an international standard for short-range infrared wireless communication for medical devices used at or near a patient. Ex. 1007, Abst. 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. Discussion

Petitioner asserts that Bathe discloses a gas delivery system having components such as a gas cylinder and valves under the control of a CPU for

controlling gas flow and concentration. Pet. 19. Petitioner relies on Peters for the teaching of a valve having a smart handle, including a memory, processor, and transceiver. *Id.* at 20, 27–28. Petitioner argues that Peters discloses that gas data that can be used to identify the gas and the expiration date could be stored in the memory. *Id.* at 27. Petitioner asserts that one reason why one would have combined the teachings of Bathe and Peters is found in Peters's statement that the valve could be used with a gas dispensing device, which Petitioner maintains is a gas delivery system like that of Bathe. *Id.* (quoting Ex. 1004, 2:52–55).

Petitioner relies on FR '804 for the teaching of a system for verifying that the delivered gas is that expected, and specifically for the disclosure of a control module that compares two pieces of gas data and for the storage of gas identification data. Pet. 15–16, 27–28; *see also id.* at 20–21 ("[T]he FR '804 Publication discloses advantageous safety features that could have been used to enhance gas delivery systems, such as the system described in [Bathe]."). Petitioner asserts that Bathe "discusses the importance of verifying that the gas being delivered is the appropriate gas for that patient," and that this is a motivation to use a gas verification system like that of FR '804 with Bathe's system. *Id.* at 24 (citing Ex. 1005, 8:1–11).

Lastly, Petitioner relies on the IR Standard for the teaching of the use of wireless optical line-of-sight communications in patient related devices. *Id.* at 23–24.

Patent Owner focuses initially on Peters, and argues that certain recitations of claims 1, 7, and 15 of the '795 patent are not found in this reference. PO Resp. 26. Patent Owner distinguishes Peters's circuit

contending that it discloses a memory "useful for 'logging and billing,' and sends such data to 'a device that generates reports or invoices.'" *Id.* at 26 (citing Ex. 1004, 1:9–11, 1:52–53). Patent Owner contends that Peters does not disclose either a "control module" or sending "gas data to a control module" as recited in claim 1. *Id.* at 27.

Patent Owner's arguments here are directed to Peters, whereas the Petitioner relies upon Bathe and FR '804 as disclosing a control module. *See, e.g.,* Pet. 29. Patent Owner's arguments are misplaced because the arguments attack Peters in isolation, whereas Petitioner's proposed combination regarding the disputed feature is predicated on a combination of the teachings of Bathe, Peters, and FR '804. *See In re Merck & Co. Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references"). Similarly, we are not persuaded by Patent Owner's arguments that the data in Peters's valve is not the type of data that would be used to control NO gas to a patient. Prelim. Resp. 27–28. Even were we to accept as true Patent Owner's proposition, the argument fails to address the combined teachings of the references.

Patent Owner further argues that Petitioner has failed to identify a reason why one of skill in the art would store the gas data from FR '804 or Bathe in the valve memory of Peters before sending to a control module such as in Bathe. Prelim. Resp. 31–37. On the record before us, Petitioner persuasively explains that one of ordinary skill in the art would recognize that Peters discloses the memory may be used to store data for advantageous tracking purposes and therefore could be used for gas therapy control

purposes, and explains that one would desire to improve the patient safety aspects of Bathe's NO delivery system with FR '804's gas supply data and delivery data comparison regimen, and that one "would have been motivated to add [a smart] handle and valve, as disclosed in the [Peters] Patent[,] to the NO delivery system disclosed in the [Bathe] Patent in order to allow the user to better link the gas information with patient treatments." Pet. 20, 21–22. That one of skill in the art would look to improve upon the safety and efficacy of a known gas delivery system is not a capricious or implausible statement of motivation.

Patent Owner characterizes the Peters reference as designed solely for administrative purposes such as billing and inventory control. Prelim. Resp. 19, 26. Patent Owner argues that Petitioner and its expert have failed to offer a reason why one would "repurpose" such a valve to interface with a gas delivery module to perform safety checks. *Id.* at 19; *see id.* at 28–29 (similar argument), 39–41 (similar argument). Based on the record before us now, we find persuasive Petitioner's argument that one skilled in the art would recognize that the data could be used for gas therapy purposes. Pet. 20 (citing Ex. 1002 ¶¶ 100, 107–108); *see also* Ex. 1004, 7: 40–47 (Peters teaching that the system could be used to identify and control gas cylinders for clinical trials and other purposes). We decline to find at this time that a person of ordinary skill in the art would conclude, as Patent Owner implies, that the smart valve of Peters could only be used for billing purposes. Further, according to Petitioner, storing gas identification data in the "smart" valve for eventual comparison in a control module with the desired gas, would predictably improve safety of the gas delivery system.

Id. at 22 (citing Ex. 1002 ¶ 99, 101–102). Petitioner has shown sufficiently, at this point in the proceeding, that a person of skill in the art would have the ability and a reason to store gas supply identification data in Peters's memory and have it transmitted to a control module in the manner asserted by Petitioner. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007) ("a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions").

Dependent claim 12 recites that the second processor verifies gas information "prior to delivery of the therapy gas to the patient." Patent Owner argues that Petitioner fails to address the quoted language. Prelim. Resp. 42. This argument is not persuasive as it is reasonably inferred from Petitioner's arguments and the cited evidence that Petitioner's position is that the combination of teachings renders obvious verifying gas information prior to delivery. *See* Pet. 41. For example, Petitioner (Pet. 41) relies upon, *inter alia*, paragraph 108 of its expert's declaration (Ex. 1002), which states: "Likewise, as disclosed by the FR '804 Publication, delivery occurs only if it is verified that the gas in the bottle corresponds to the type of gas intended to supply the circuit 1."

Upon review of Petitioner's analysis and the evidence of record and having considered all of Patent Owner's arguments, we determine that Petitioner has demonstrated that there is a reasonable likelihood that it would prevail in showing that the combination of Bathe, Peters, FR '804, and the IR Standard renders obvious the subject matter of claims 1–12 and 14–20.

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

Petitioner asserts that claims 4 and 5 would have been obvious to a person of ordinary skill in the art over Bathe, Peters, FR '804, the IR Standard, and Lebel. Pet. 47–52. Patent Owner responds. Prelim. Resp. 43–44.

Bathe, Peters, FR '804, and the IR Standard have been described above. 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 where "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.

Patent Owner asserts that Lebel does not overcome the deficiencies with respect to the underlying asserted prior art and claim 1 (Ground 1). Prelim. Resp. 43. Because we discern at this stage no deficiencies to overcome in this regard, this argument is not persuasive.

Patent Owner also asserts that this ground should be rejected as redundant. *Id.* at 44 (citing *Liberty Mutual Ins. Co. v. Progressive Casualty Ins. Co.*, CBM2012-00003 (Paper No. 7), at 2). It is noted that the *Liberty Mutual* case involved four hundred and twenty grounds, the analysis of which "would place a significant burden on the Patent Owner and the Board, and would cause unnecessary delays." *Liberty Mutual* at 2. Petitioner here has articulated a ground relying on Lebel's strength as an additional reference directly related to power conservation in electronic device-to-device communication, also in the medical field, and that expressly discloses intermittent signal propagation as facilitating power conservation. *See* Pet. 47–49. Further, this ground, Ground 2, relates to only two dependent claims.

"When instituting *inter partes* review, the Board may authorize the review to proceed . . . on *all or some* of the grounds of unpatentability asserted for each claim." 37 C.F.R. § 42.108(a) (emphasis added). We exercise that authority and institute on Ground 2 as well as Ground 1.

We are persuaded on this record that there is a reasonable likelihood that Petitioner will prevail as to the obviousness of claims 4–5 over Bathe, Peters, FR '804, the IR Standard, and Lebel.

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

Petitioner asserts that claim 13 would have been obvious to a person of ordinary skill in the art over Bathe, Peters, FR '804, the IR Standard, and Durkan. Pet. 52–60. Patent Owner responds. Prelim. Resp. 44–50.

Bathe, Peters, FR '804, and the IR Standard, have been described above. 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 respirating 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.

Claim 13 depends from claim 7 and adds additional limitations generally directed to having two gas sources each with its own valve and an alarm that is triggered when the valves of both containers are open. Petitioner applies the teachings from Durkan and explains how and why those teachings would be incorporated into its proposed combination (i.e., with teachings from Bathe, Peters, FR '804, and the IR Standard as applied in Ground 1), thereby rendering the subject matter of claim 13 obvious. Pet. 52–60. For the comparison step in claim 13, Petitioner also relies on its Declarant, Dr. Stone. Pet. 59 (citing Ex. 1002 ¶¶ 138, 143). Dr. Stone alleges that one of skill in the art would have understood from a dual-gas source system such as Bathe that a comparison of valve operational signals can be accomplished by the CPU, and "that when warranted (*i.e.*, where both

valves being open creates a detrimental condition for the patient), a signal, such as the [Durkan] Patent's L3 signal could be used t [sic] to drive an appropriate action, such as issuing an alarm." Ex. 1002 ¶ 138.

Patent Owner asserts that Durkan does not overcome the purported deficiencies of Ground 1. Prelim. Resp. 44–45. Because we discern at this stage no deficiencies to overcome in this regard, this argument is not persuasive.

Patent Owner also argues that Durkan does not disclose the limitations of claim 13 because Durkan's signals L3 and L3′ are for actuating valves 26 and 126, not for transmitting information about the valve status. *Id.* at 46. We agree with Patent Owner that signals L3 and L3′ are signals that actuate solenoid valves 26 and 126 when instructed by control means 32. *See* Ex. 1010, 7:48–49, Figs. 5, 6. However, we are not persuaded by Patent Owner's argument overall because LED 92 is actuated based on the same signal tied to L3, and is a visual indication, an alarm, that both valves are open. Petitioner argues persuasively that

> From Fig. 5, it can be seen that when L3 indicates both valves are open, the LED 92 is also illuminated. (*Id.* at Fig. 5; *see also* Ex. 1002 ¶¶ 93-95.) Thus, in the dual gas embodiment of the '398 Patent, when both valves are open, the LED 92 is illuminated. (*Id.*) Otherwise, the LED 92 is not illuminated. (Ex. 1010 at 13:57-65.)

Pet. 54. We are persuaded by Petitioner's position that LED 92, when illuminated, is a visual indication (an alarm) that valves 26 and 126 are in an open position. *See id.* at 55.

We have considered Patent Owners remaining arguments, but do not find them persuasive based on the current record. On this record,

Petitioner's evidence and explanations are persuasive of a reasonable likelihood as to the obviousness of claim 13 over Bathe, Peters, FR '804, the IR Standard, and Durkan.

IV. CONCLUSION

We determine Petitioner has demonstrated there is a reasonable likelihood of establishing the unpatentability of claims 1–20 of the '795 patent. At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claims.

V. ORDER

For the foregoing reasons, it is

ORDERED that pursuant to 35 U.S.C. § 314, *inter partes* review is instituted as to claims 1–20 of the '795 patent on the following grounds:

Claims 1–12 and 14–20 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Bathe, Peters, FR '804, the IR Standard;

Claims 4 and 5 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Bathe, Peters, FR '804, the IR Standard, and Lebel; and

Claim 13 is unpatentable under 35 U.S.C. § 103(a) as being obvious over Bathe, Peters, FR '804, the IR Standard, and Durkan;

FURTHER ORDERED that *inter partes* review is commenced on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that the trial is limited to the grounds of unpatentability listed above, and no other grounds of unpatentability are authorized for *inter partes* review.

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