UNITED STATES PATENT AND TRADEMARK OFFICE

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IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

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PRAXAIR DISTRIBUTION, INC.
Petitioner

v.

INO THERAPEUTICS, LLC. d/b/a IKARIA, INC.
Patent Owner

_____

CASE IPR: UNASSIGNED
U.S. PATENT NO. 8,776,795

_____

PETITION FOR *INTER PARTES* REVIEW

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box. 1450
Alexandria, VA 22313-1450

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I. INTRODUCTION

Praxair Distribution, Inc. ("Petitioner" or "Praxair") hereby petitions for *inter partes* review of claims 1-20 of U.S. Patent No. 8,776,795 ("'795 Patent") (Ex. 1001) under 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.

II. THE '795 PATENT

A. Overview of the '795 Patent

The '795 Patent is listed in the U.S. Food and Drug Administration's ("FDA") list of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book") in connection with the prescription drug product INOMAX®. The patent owner and new drug application holder INO Therapeutics, LLC d/b/a Ikaria, Inc. ("PO") is the exclusive U.S. supplier of inhaled nitric oxide ("iNO"). PO filed the application that issued as the '795 Patent thirteen years after it released INOMAX®[1] in the market. PO's original patents covering iNO expired in 2013, and PO is now trying to use the '795 Patent to impermissibly extend its patent monopoly on INOMAX® to 2031, *35 years* after the original INOMAX patents issued.[2]

[1] INOMAX® is the trade name of PO's iNO drug to treat term and near-term infants with respiratory failure.

[2] The '795 Patent expires on January 6, 2031. Petitioner is concurrently filing petitions for *inter partes* review of four other Orange Book listed patents that

The ’795 Patent describes and claims a compiled gas delivery system with known components operating according to their known functionality, and methods of using the same. More specifically, the ’795 Patent claims a valve assembly including memory, a processor, and a transceiver for communicating with a “control module” that controls gas delivery. (*See*, *e.g.*, Ex. 1001 at 16:42-57.) It also claims methods of using this valve assembly and control module to administer therapy gas to a patient. (*Id.* at 17:6-26.) Such valves and control modules were known by those skilled in the art long before January 6, 2011, the earliest possible priority date for the ’795 Patent. Indeed, the claims of the ’795 Patent are largely directed toward systems PO itself patented years before January 6, 2011. (*See generally* Ex. 1004, Ex. 1005.)

B. Summary of the Prosecution of the ’795 Patent

The application that issued as the ’795 Patent was filed October 29, 2013 as a continuation of International Application No. PCT/US2011/020319, which was filed on January 6, 2011. (Ex. 1019 at 2, 48.)

The ’795 Patent was granted Prioritized Examination on November 21, 2013. (Ex. 1019 at 64.) Applicant conducted an examiner interview on February 19, 2014, during which an examiner’s amendment was discussed. (Ex. 1019 at

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similarly would extend PO’s monopoly: U.S. Patent Nos. 8,291,904; 8,573,209; 8,573,210; and 8,776,794.

97.) Among other minor amendments, the Applicant agreed to add "to verify gas data" to claim 15. (*Id*.) Applicant thereafter filed Terminal Disclaimers over U.S. Patent Nos. 8,291,904, 8,573,209, and 8,573,210. (Ex. 1019 at 79-80.) The only Office Action was a notice of allowance mailed on April 3, 2014. (Ex. 1019 at 87-96). The Notice of Allowance contained "Reasons for allowance" in which the examiner noted that:

> The closest prior art of record Peters [the '510 Patent] discloses a valve with a smart handle including a memory module, a processor, and a transceiver. Peters also discloses that the memory is able to store gas data comprising gas identification. Peters also discloses that the processor and transceiver communicates gas data to a control module. However, Peters fails to disclose, teach, or fairly suggest the specific structure and functional limitation as recited in the claims such as claim 1…"

(Ex. 1019 at 94). The examiner then repeated claim 1 in its entirety. (*Id*.) Applicant did not comment on the reasons for allowance and the '795 Patent issued on July 15, 2014, less than nine months after filing. (Ex. 1019 at 120.)

III. BACKGROUND OF THE TECHNOLOGY

As indicated by PO's prior art patents incorporated by reference in the '795 Patent (which are statutory bars under 35 U.S.C. § 102(b)), the systems claimed in the '795 Patent recite components or sub-systems that were well known before January 6, 2011. (Ex. 1002 ¶¶ 38-39.)

U.S. Patent No. 7,114,510 ("'510 Patent") is owned by PO and is titled

"Valve with a Smart Handle." (Ex. 1004; Ex. 1002 ¶¶ 19-20.) It discloses a valve with a "smart handle" containing electronics to track opening and closing of the valve and to communicate stored data to external devices. (Ex. 1004 at 1:9-15, 6:17-7:15; Ex. 1002 ¶ 21.)) The '510 Patent demonstrates that well before the filing of the '795 Patent, it was known in the art to affix a valve to a gas cylinder, the valve including a processor, memory and a data port or transceiver for transferring data from the valve memory to other devices. (Ex. 1004 at 2:58-67; Ex. 1002 ¶¶ 21-28.) It was also known that electronics mounted in the handle of the valve could include "an open/closed sensor 28, a battery 25, [and] a display 26." (Ex. 1004 at 2:58-61.) Thus, long before January 6, 2011, it was known to include electronics and circuitry, such as processors, memory devices, and LCD displays, in handles of valves used to control delivery of gas to patients. (Ex. 1002 ¶¶ 20-29.)

The '510 Patent's smart handle was capable of storing both data about the gas in the cylinder and data about valve open and close times in the valve memory. (Ex. 1004 at 5:44-56, 6:21-27.) This smart handle also included data ports or transceivers (short for "transmitter/receiver") in communication with the valve processors and memory devices through which data could be communicated from the smart handle to remote devices, such as a computer. (*Id.* at 6:33-55; Ex. 1002 ¶¶ 26-27.) These data ports or transceivers could communicate with the remote

device via wired (*i.e.*, transmission of electrons via conductors) or wireless (*i.e.*, radio signals propagated through the air encoding data) connections. (Ex. 1004 at 6:64-7:4; Ex. 1002 ¶ 26.) The transmitted data could include gas data about the gas in the cylinder. (Ex. 1004 at 5:45-6:12; Ex. 1002 ¶¶ 25, 47.)

Another patent assigned to PO, U.S. Patent No. 5,558,083 ("'083 Patent") titled "Nitric Oxide Delivery System," describes known gas delivery modules for delivering selectable concentrations of NO to a patient. (Ex. 1005; Ex. 1002 ¶ 30.) The '083 Patent issued in 1996 and teaches that gas delivery systems could include a central processing unit ("CPU") that receives and compares signals from two sources. The '083 Patent's CPU receives both a user's desired concentration of NO from an input device, as well as actual gas flow rate from a flow transducer, which it can use to determine gas concentration. (Ex. 1005 at 2:20-23, 2:30-35; Ex. 1002 ¶¶ 31-32.) The CPU uses this information to generate and transmit output signals which control delivery of the gas. (Ex. 1005 at 2:30-35; Ex. 1002 ¶¶ 32-33.) Thus, in gas systems known long before January 6, 2011, CPUs were known to compare user inputted data about the desired gas concentration with the actual concentration being delivered to the patient. (Ex. 1002 ¶¶ 33-34.) Such systems could then generate alarms and/or cease NO delivery as appropriate. (Ex. 1005 at 5:60-65; Ex. 1002 ¶¶ 32-33.)

Known NO delivery systems also enabled two cylinders of gas to be

simultaneously in fluid communication with the delivery system. (Ex. 1005 at 8:38-65, Fig. 2.) Thus, CPUs of known NO delivery systems could simultaneously control gas delivery from two different sources. (*Id.* at 8:46-49, 8:62-65.)

The '795 Patent merely combines PO's own prior delivery system technology and valve technology. A person skilled in the art would have been motivated to combine PO's known technologies, each operating in their intended way, with other well-known teachings, as detailed below, to construct the claimed invention of the '795 Patent. Accordingly, the claims are not patentable and should be cancelled.

IV. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))

Petitioner certifies that (1) the '795 Patent, issued on July 15, 2014 and is available for *inter partes* review; (2) Petitioner is not barred or estopped from requesting *inter partes* review of the '795 Patent on the grounds identified herein; and (3) Petitioner has not filed a complaint relating to the '795 Patent. This Petition is filed in accordance with 37 C.F.R. § 42.106(a).

V. PAYMENT OF FEES (37 C.F.R. §§ 42.15 and 42.103)

Petitioner authorizes the USPTO to charge the required fees for *inter partes* review of 20 claims, and any additional fees, to Deposit Account No. 02–1818.

VI. MANDATORY NOTICES (37 C.F.R. § 42.8)

A. Real Parties-In-Interest

Praxair Distribution, Inc., head office at 28 McCandless Ave., Pittsburgh,

PA 15201, and Praxair, Inc., worldwide headquarters at 39 Old Ridgebury Rd., Danbury, CT 06810 are the real parties-in-interest.

B. Related Matters

Petitioner understands that on February 19, 2015, PO filed a complaint in the District Court for the District of Delaware (Case No. 15-cv-00170) alleging that Petitioner is infringing ten U.S. Patents, including the '795 Patent. Petitioner has not been served with the complaint and has not answered or otherwise pleaded.

Further, U.S. Patent Application Nos. 14/328,150, 14/065,962, 14/6629,742 (unpublished), and 29/471,765 (unpublished) are currently pending and purport to claim the benefit of the ultimate priority document of the '795 Patent.

C. Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3)) and Service Information (37 C.F.R. § 42.8(b)(4))

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Petitioner consents to electronic service by email.

VII. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art is a hypothetical person presumed to know the relevant prior art. *Gnosis S.p.A. v. South Alabama Med. Sci. Found.*, IPR2013-00116, Final Written Decision (Paper 68) at 9. Such a person is of ordinary creativity, not merely an automaton, and is capable of combining teachings of the prior art. *Id*. (citing *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 420-21 (2007)). Petitioner submits that a person of ordinary skill in the art of the '795 Patent as of January 6, 2011 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. (Ex. 1002 ¶¶ 17-18.)

VIII. CLAIM CONSTRUCTION

The claims of the '795 Patent should be given their "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Tech., LLC*, Case No. 14-1301, slip op. at 16, 18-19 (Fed. Cir. Feb. 2, 2015). While the specification cannot be used to impermissibly narrow the meaning of a claim term, terms must be construed broadly enough to encompass all meanings set forth in the specification and the references incorporated therein. *See MSM*

Investments Co. v. Carolwood Corp., 259 F.3d 1335, 1339-40 (Fed. Cir. 2011). Here, a person of ordinary skill in the art would have understood each term of each claim of the ’795 Patent to have its plain and ordinary meaning, and would have understood that no term requires special construction for purposes of this proceeding.[3] Moreover, since the ’510 Patent and the ’083 Patent are owned by PO and the ’795 Patent incorporates both patents by reference (Ex. 1001 at 7:42-44, 9:66-10:2), claim terms of the’795 Patent that are also used in the ’510 Patent or the ’083 Patent should be interpreted at least broadly enough to cover the meaning of the terms in the incorporated patents.

IX. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFORE (37 C.F.R. § 42.22(a) AND 42.104(b))

Petitioner requests review and cancellation of claims 1-20 of the ’795 Patent based on the following grounds:

Ground	35 U.S.C. Section	Relied-On References	Claims
1	§ 103	The ’083 Patent (Ex. 1005) in view of the ’510 Patent (Ex. 1004), the FR ’804 Publication (Ex. 1006), and the IR Standard (Ex. 1007)	1-12, 14-20
2	§ 103	The ’083 Patent (Ex. 1005) in view of the ’510 Patent (Ex. 1004), the FR ’804 Publication (Ex. 1006), the IR	4, 5

[3] Any contention by PO that claim terms should have a special meaning should be disregarded unless PO also moves to amend its claims as permitted to expressly recite that meaning. *See* 77 Fed. Reg. 48764 at II.B.6 (August 14, 2012).

		Standard (Ex. 1007), and the '533 Patent (Ex. 1008)	
3	§ 103	The '083 Patent (Ex. 1005) in view of the '510 Patent (Ex. 1004), the FR '804 Publication (Ex. 1006), the IR Standard (Ex. 1007), and the '398 Patent (Ex. 1010)	13

Per 37 C.F.R. § 42.6(c), copies of the relied-on references are marked as exhibits filed herewith. Petitioner also provides the declaration of Robert T. Stone, Ph.D (Ex. 1002) in support of its proposed grounds of unpatentability.[4]

Claims 1, 7 and 15 are the independent claims of the '795 Patent. Claim 1 is illustrative:

> 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 the 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

[4] D. Robert T. Stone is an expert in the field of the alleged invention and the prior art. (*See, e.g.*, Ex. 1002 ¶¶ 1-16; Ex. 1003.)

identification, the gas concentration and that the gas is not expired. (Ex. 1001 at 16:42-57.)

A. Ground 1: Claims 1-12 and 14-20 Are Unpatentable Under 35 U.S.C. § 103(a) Over the '083 Patent in View of the '510 Patent, the FR '804 Publication, and the IR Standard[5]

1. Overview of the Prior Art

(a) The '083 Patent

The '083 Patent (Ex. 1005) was filed on November 22, 1993 and issued on September 24, 1996. The '083 Patent is assigned to PO (Ex. 1009) and its lead inventor, Duncan Bathe, is the same as the lead inventor of the '795 Patent. The '083 Patent is prior art to the '795 Patent under 35 U.S.C. § 102(b).

The '083 Patent discloses a gas delivery system in which a series of valves

[5] In addition to being incorporated by reference in the '795 Patent, the '510 Patent and the '083 Patent were cited during prosecution. While the '083 Patent was not discussed, the examiner concluded (without objection from PO) that the '510 Patent discloses "a valve with a smart handle including a memory module, a processor, and a transceiver," that "the memory is able to store gas data comprising gas identification," and that "the processor and transceiver communicate[] gas data to a control module." (Ex. 1019 at 94, 98.) The FR '804 Publication and the IR Standard were not cited and the examiner did not consider the combination presented here in Ground 1.

under control of a CPU control the flow and concentration of NO gas given to a patient. (Ex. 1005 at Abstract, 1:20-22.) Commercially available NO usually has a pressure of approximately 2000 psi and a concentration between 800 and 2000 ppm. (*Id.* at 1:20-26.) The '083 Patent teaches a system that can reduce the pressure of the NO gas and can meter the amount of NO that is added to the gas mixture so that "the desired concentration of NO is actually administered to the patient." (*Id.* at 1:26-31.) The '083 Patent's gas delivery system "includes a flow transducer that senses the flow of gas from the gas delivery system and uses that information with a selective algorithm to provide an operator selectable concentration of NO to the patient." (*Id.* at 2:20-24.) This advantageously enables a user to modify the pressure and concentration of gas being delivered to a patient regardless of the concentration of the gas in the cylinder. (*Id.* at 2:13-20.)

The '083 Patent discloses an input device that enables a user to select a desired concentration of gas to be delivered to the patient, and a CPU that can compare the desired concentration with the measured concentration to control delivery of a selected therapy. (*Id.* at 2:30-35, 2:52-67, 6:29-33, 6:40-42.) The CPU triggers alarms if faults occur during gas delivery. (*Id.* at 3:1-4.) A sensor senses the concentration of gas in the supply cylinder and sends a signal indicative of the sensed concentration to the CPU. (*Id.* at 6:5-8, 8:1-12.) The CPU then determines whether the concentration being delivered is appropriate given the user

inputted desired concentration. (*Id.*) Thus, one fault monitored by the CPU of the '083 Patent is a mismatch between the user-entered desired gas concentration and the gas concentration actually being delivered. (*Id.* at 3:1-4; 8:10-12.)

(b) The '510 Patent

The '510 Patent (Ex. 1004), which is also assigned to PO, was filed as a PCT International Application on November 15, 2001 and issued on October 3, 2006. The '510 Patent is prior art to the '795 Patent under 35 U.S.C. § 102(b).

The '510 Patent is directed to a "valve with a smart handle including a memory module to log relevant data." (Ex. 1004 at Abst.) The smart handle includes "several electronic devices…including a processor 23, a timer 21, a reset button 27, an open/close sensor 28, a battery 25, a display 26, and an electronic memory device 22." (*Id.* at 2:58-61.) The processor 23 and the electronic memory device 22 are mounted inside the handle 16 of the valve 10. (*Id.* at 2:58-61, 3:3-7.) The handle also includes a port 22' that "can be used to transfer data from the handle's memory 22 to other devices." (*Id.* at 2:65-66.) Finally, the handle includes a sensor that senses whether the handle is in an open or closed position, and stores a time-stamped indication of a change in position. (*Id.* at 3:34-58.)

The '510 Patent discloses that initial parameters can be loaded into the memory of the handle. (*Id.* at 5:44-56.) These parameters can include gas data such as "[c]ylinder serial number" and "[g]as lot number." (*Id.* at 5:44-56.) The

'510 Patent teaches that this gas data is typically loaded into memory by the distributor providing the cylinder. (*Id.* at 5:57-64.) In certain situations, however, users (such as hospital employees) may add "more data into the memory device 22 of the valve 10." (*Id.* at 6:3-4.) The '510 Patent gives several examples of "more data," including "patient identification number" and "treatment number" usable for "record keeping and for billing …." (*Id.* at 6:3-8.)

After the data is loaded into the valve memory, the cylinder and valve of the '510 Patent are provided to a medical provider, and the medical provider connects the outlet port 20 of the valve 10 to a delivery device, such as a ventilator, which "is used to adjust the concentration and flow rate or to mix gases administered to the patient." (*Id.*at 6:17-21.) The medical provider can rotate the handle, which is an actuator that opens and closes the valve, to "provide gas treatments to patients." (*Id.* at 6:18-22, 6:29-32.) The sensor in the handle senses each time the handle is turned and logs the date, time and event type of each turning event in valve memory 22. (*Id.* at 6:21-25, 6:30-32.) "All of this information may be read or downloaded by the user and/or by the supplier" using appropriate data transfer methods, including transferring data through a port using a wand reader or other appropriate device. (*Id.* at 6:47-55.)

In at least one embodiment, the handle 16 disclosed in the '510 Patent also includes "a transmitter to transmit the data [from the valve memory 22] to a remote

recording device at intervals or on command, as desired." (*Id.* at 7:1-4.) Such remote recording devices necessarily have a transceiver to receive the transmitted data. (Ex. 1002 ¶¶ 72, 109, 112.) The '510 Patent also notes that "many other methods for transmitting the data from the valve 10 to the main computer could be used." (Ex. 1004 at 7:14-15.) After the valve data is transmitted to a remote device, software on the remote device can be used "to generate reports, to track treatments, do billings, and to control inventory." (*Id.* at 7:9-12.)

(c) The FR '804 Publication

The FR '804 Publication (Ex. 1006) was filed on June 20, 2007 and published on December 26, 2008.[6] Accordingly, the FR '804 Publication constitutes prior art under 35 U.S.C. § 102(b).

The FR '804 Publication is assigned to *L'Air Liquide Societe Anonyme Por L'Etude Et L'Exploitation Des Procedes Georges Claude* ("Air Liquide"). (Ex. 1006 at 1.) Air Liquide is a French company that has been involved in manufacturing and selling gasses such as NO and gas delivery systems for more than ten years. (*See* Ex. 1011.) Accordingly, a person of ordinary skill in the art would understand that the FR '804 Publication discloses a system that can be used to deliver gas to a patient. (Ex. 1002 ¶¶ 63-64.)

[6] Ex. 1006 includes the original, French-language version of the FR '804 Publication followed by a certified translation from French to English.

The FR '804 Publication discloses a system for verifying that the gas being delivered is the expected gas. (Ex. 1006 at 17.) It teaches that gas verification can improve safety by ensuring that the desired gas is being delivered to the patient. (*Id.*; Ex. 1002 ¶¶ 64-66.)

To achieve its safety goals, the FR '804 Publication discloses a control module 300 that receives data about (a) the specific type of gas in a cylinder, and (b) the type of gas expected to be supplied to a circuit. (Ex. 1006 at 19.) The control module compares the two pieces of gas data and if the comparison is positive (*i.e.*, the gas in the cylinder is the expected gas), it supplies a control signal to open a valve and deliver gas from the cylinder to the fluid circuit. (*Id.* at 18; Ex. 1002 ¶¶ 65-67.) If a negative comparison occurs (*i.e.*, the gas in the cylinder is not the expected gas), an audible or visible alarm can be emitted. (Ex. 1006 at 19.)

The FR '804 Publication also discloses that the gas identification data (referred to as "IDb data") can be stored on an information carrier 120 affixed to bottle 10. (*Id.* at 20.) This information carrier can be, for example, a bar code or a radio-frequency identification ("RFID") tag. (*Id.* at 20-21.) The data from the carrier is read using sensor 110, which could be a bar code scanner if the gas data is encoded in a bar code or an RFID reader if the gas data is encoded in an RFID tag. (*Id.*) The sensor 110 supplies the gas IDb data read from the carrier 120 to the control module 300 for comparison. (*Id.* at 21.)

With regard to the expected or intended type of gas (referred to as "IDv data"), the FR '804 Publication discloses that this data is stored in a memory 200 associated with the control module 300, and the data is supplied to the control module 300 for comparison with the IDb data read from the carrier on the bottle. (*Id.* at 19.) In the embodiment of Fig. 5, the memory 200 is in a separate physical device from the control module 300. (*Id.* at 21, Fig. 5.) In this embodiment, a transceiver could be used to both read the contents of the memory 200 and transmit a control signal to the valve. (*Id.* at 21, Fig. 5; Ex. 1002 ¶ 68.)

(d) The IR Standard

The IR Standard (Ex. 1007) is a standard that was published by the International Organization for Standardization ("ISO") and the Institute of Electrical and Electronics Engineer ("IEEE") on December 15, 2004. (Ex. 1007; Ex. 1002 ¶¶ 69-70.) It is therefore prior art under 35 U.S.C. § 102(b).

The IR Standard "establishes a connection-oriented transport profile and physical layer suitable for medical device communications that use short-range infrared wireless." (Ex. 1007 at ii.) This infrared wireless communications protocol is appropriate for medical devices that "require intermittent point-and-shoot connectivity" to another device. (*Id.* at 2.) The IR Standard explains that its teachings are appropriate for capturing patient vital signs and device operational data, and that its infrared wireless communication protocol is especially well suited

for use in "acute and continuing care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, etc." (*Id.* at vi.)

The IR Standard discloses that a device's controller communicates in a point-to-point way with a corresponding controller of another device. (*Id.* at 10-11; Ex. 1002 ¶¶70-71.) The IR Standard provides parameters related to the alignment between IR transmitter-receivers ("transceivers") that must be supported by compliant systems. (Ex. 1007 at 33.) The IR Standard teaches both how to build an IR-communicating system from scratch and how to retrofit a previous cable-communicating system with IR transceivers to convert the system into a wireless optical line-of-sight system. (*Id.* at 39-40; Ex. 1002 ¶¶ 78-80, 117.)

The IR Standard also teaches that a compliant system will wait a certain amount of time without receiving valid frames before it disconnects an IR link. (Ex. 1007 at 20.) It explains that while appropriate waiting periods are application-specific, supported waiting periods can be several seconds, typically ranging from 3 to 40 seconds. (*Id.* at 20.) In other words, the IR Standard specifies that signal communications between remote modules can be configured to have periods ranging from 3 to 40 seconds during which no signal is sent. (Ex. 1002 ¶¶ 75-77.)

The IR Standard also discusses supported power options and recommends, for example, systems in which one device communicating by IR is battery-powered. (Ex. 1007 at 15, 33.) It discloses "standard power" and "low power"

modes, stating "[l]ow power uses roughly one-tenth the power of standard power and is appropriate for battery-powered devices." (*Id.* at 15.)

2. Motivation to Combine

A person of ordinary skill in the art would have been motivated to combine the '083 Patent, the '510 Patent, the FR '804 Publication, and the IR Standard to predictably result in an improved nitric oxide delivery system incorporating the advantageous aspects of each reference. (Ex. 1002 ¶¶ 96-128.) The '083 Patent and the '510 Patent are both assigned to PO and disclose systems and methods for monitoring gas flow and providing select concentrations of a therapeutic gas to a patient. (*Id.* ¶¶ 100, 103, 104, 127.) The FR '804 Publication adds certain comparison-based safety features to therapeutic gas delivery systems such as, for example, the system disclosed in the '083 Patent. (*Id.* ¶¶ 101-103.) The IR Standard is a readily-available publication that discloses a well-known communication interface for bedside therapy devices such as therapeutic gas delivery systems. (Ex. 1007 at vi; Ex. 1002 ¶¶ 113-118.) Accordingly, the references are in the same field of endeavor and the problems encountered by designers of the disclosed devices substantially overlap. (Ex. 1002 ¶¶ 122-128.)

More specifically, the '083 Patent teaches a NO delivery system with various component parts such as a gas cylinder 10, valves 14, 18, 20, and 24, and a control CPU 56 for controlling the flow and concentration of NO gas delivery to a

patient (*see* Ex. 1005 at 6:20-28; Ex. 1002 ¶ 100.) The '510 Patent discloses an advanced or smart handle and valve 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 handle and valve disclosed in the '510 Patent to obtain both the benefits of the smart handle of the '510 Patent and the benefits of the delivery system of the '083 Patent. (Ex. 1002 ¶¶ 99, 103.) Indeed, the '510 Patent explicitly states that the taught valve can control "the flow of gas from the cylinder 12 to a ventilator or *other gas dispensing device*" such as the gas delivery system of the '083 Patent. (Ex. 1004 at 2:52-55 (emphasis added).) Thus a person skilled in the art at the time would have understood that the smart handle and valve of the '510 Patent could easily have been incorporated into the gas delivery system of the '083 Patent. (Ex. 1002 ¶¶ 100, 103.) Moreover, since some of the advantages of the '510 Patent involve tracking gas data in the cylinders (***e.g.***, Ex. 1004 at 6:4-8; 7:36-47 ("assign patient ID to cylinders" and "identify and control cylinders for blinded clinical trials"), a person of skill in the art would have understood that the valve memory 22 disclosed in the '510 Patent could be used to store gas data and in turn, that data could be transmitted to a control module, as disclosed in the '083 Patent, to control gas therapy. (Ex. 1002 ¶¶ 100, 107-108.)

Likewise, the FR '804 Publication discloses advantageous safety features

that could have been used to enhance gas delivery systems, such as the system described in the '083 Patent. (*Id.* ¶¶ 105-106, 111, 123-124.) For example, the '083 Patent discloses a general-purpose CPU that can use various 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 ¶ 123.) A person skilled 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. (Ex. 1002 ¶¶ 31, 123.) Indeed, the comparison of gas data with patient data performed 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. (*Id.* ¶¶ 65, 67, 101, 108, 123-124.) As combined, these known prior art elements yield predictable results. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416. The combination is also an example of applying a known technique to a known system to yield predictable results. *Id.* (*See also* Ex. 1002 ¶¶ 99, 137.)

A person of skill in the art reading the '083 Patent would have been motivated to add the handle and valve, as disclosed in the '510 Patent to the NO delivery system disclosed in the '083 Patent to allow the user to better link the gas information with patient treatments. (Ex. 1004 at 1:25-42; Ex. 1002 ¶¶ 99-100,

103, 122.) A person of skill in the art would have also been motivated to add safety features, such as those disclosed in the FR '804 Publication, to the NO delivery system of the '083 Patent. (Ex. 1005 at 6:11-15; Ex. 1002 ¶¶ 99, 101-102, 123.) Since each reference contributes its known benefits, the combination would predictably result in an improved therapeutic gas delivery system. (Ex. 1002 ¶ 99.)

The FR '804 Publication also discloses that gas data can be encoded on a data carrier, such as a bar code, affixed to the cylinder. (Ex. 1006 at 20-21.) A person skilled in the art would have known that the FR '804 Publication's teachings could have been incorporated into the system of the '083 Patent and the smart handle and valve of the '510 Patent. (Ex. 1002 ¶ 101.) As combined, gas data could be encoded in a bar code 120 as disclosed in the FR '804 Publication, and could have been read by the bar code sensor 110. (*Id.*) As disclosed in the '510 Patent, an input port such as port 22' can be used to transfer information, such as the information read by sensor 110 of the FR'804 Publication, to the valve memory 22. (*Id.* ¶¶ 105-106.) Such alternative sources for gas data are disclosed in the '083 Patent and would have been obvious to one of ordinary skill in the art. (Ex. 1005 at 6:11-15; Ex. 1002 ¶¶ 105-107.)

The result of incorporating the '510 Patent and the FR '804 Publication in the '083 Patent's delivery system is that gas data (which can include gas concentration in the cylinder per the '083 Patent) is read from the carrier on the gas

cylinder using an appropriate sensor (such as a bar code reader) and stored in the valve memory. (Ex. 1002 ¶¶ 101, 105.) This data would then be provided to the CPU of the '083 Patent for use in the comparisons discussed above. (*Id.* ¶¶ 101, 108, 123-124.) To provide that data to the CPU of the '083 Patent, a person of skill in the art would have considered at least known medical device communication standards published by the ISO/IEEE. (*Id.* ¶¶ 112-118.) This is particularly true given that the '510 Patent and the FR '804 Publication contain an express teaching to look to wireless communications technologies based on their disclosure of wireless communications technologies for various aspects of their systems. (Ex. 1004 at 7:1-4; Ex. 1006 at 20-21; Ex. 1002 ¶¶ 110-111.)

The IR Standard, which is one such standard, teaches a person of skill in the art how to implement optical line-of-sight communications between two devices in a patient environment. (Ex. 1007 at vi; Ex. 1002 ¶¶ 113-115.) Relying on the IR Standard, a person of skill in the art would have understood to implement infrared transceivers (which use optical line-of-sight to communicate) on the valve and control system to communicate data from the valve memory to the control system for processing by the CPU. (Ex. 1002 ¶¶ 113-115.) A person of skill in the art would have been particularly motivated to rely on the IR Standard given its express statement that it is applicable to systems involving ventilators and other "acute and continuing care" near-patient devices. (Ex. 1007 at vi; Ex. 1002 ¶¶ 114, 116.) A

person of skill would have used the IR Standard's teaching of optical line-of-sight communications to establish communications between the valve of the '510 Patent and the control module of the '083 Patent to provide gas data (as described in the '510 Patent and the FR '804 Publication) to the control module CPU for comparison. (Ex. 1002 ¶¶ 115-118.)

Combining these sub-portions of a gas delivery system (*i.e.*, the control system of the '083 Patent, the valve of the '510 Patent, and the safety check of the FR '804 Publication) into a single system would predictably result in an improved therapeutic gas delivery system, with each reference contributing its known properties and advantages. (*Id.* ¶ 99.) A person of skill in the art would have been particularly motivated to incorporate the '510 Patent's teachings into the '083 Patent because both references belongs to PO, a long-time leader in NO therapy technology. (*Id.* ¶ 127.) Because the '083 Patent discusses the importance of verifying that the gas being delivered is the appropriate gas for that patient (Ex. 1005 at 8:1-11), a person of ordinary 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. (Ex. 1002 ¶ 125.) The motivation is bolstered by the fact that the FR '804 Publication is assigned to Air Liquide, a manufacturer and seller of NO delivery systems. (*See* Ex. 1006; Ex. 1011.) Accordingly, a person of skill in the art would have been motivated to look to its disclosure when designing an

improved NO delivery system. (Ex. 1002 ¶¶ 125, 127.)

After combining the '510 Patent, the '083 Patent, and the FR '804 Publication, a person of skill in the art would have used the IR Standard's standardized techniques to facilitate communication between separate sub-systems (the valve and the control module) with an expectation of success. (*Id.* ¶ 113.) The hardware building blocks of the systems described in the references could be readily combined by a person of skill in the art without substantial architectural modification to any of the sub-systems of any of the references. (*Id.* ¶ 124.) For at least these reasons, the combination of the '083 Patent, the '510 Patent, the FR '804 Publication, and the IR Standard is proper.

3. Specific Identification of Challenge

(a) Independent Claim 1

(i) Gas Source Limitation

Claim 1 of the '795 Patent is an independent claim and recites "[a] gas delivery device to administer a therapy gas from a gas source."[7] Both the '083 Patent and the FR '804 Publication disclose a gas delivery device that can be used to deliver therapeutic gas from a gas container or source. (*See e.g.*, Ex. 1005 at Abstract, 2:14-20, 3:45-48, Fig. 1; Ex. 1006 at 17.) The '510 Patent's valve can be

[7] The preamble should not be interpreted as limiting the claim. Nonetheless, the preamble is disclosed by the prior art as discussed herein.

used to deliver inhaled pharmaceutical gas (Ex. 1004 at 1:16-30), and the FR '804 Publication can be used to provide therapy gas (Ex. 1006 at 19.)

(ii) Valve Limitation

Claim 1 also requires "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." The '083 Patent, the FR '804 Publication, and the '510 Patent all disclose a gas source such as a cylinder or bottle. (Ex. 1004 at 2:40-42; Ex. 1005 at 3:45-47; Ex. 1006 at 19.) The '510 Patent discloses that "the valve body 14 includes a threaded inlet port 18 which screws onto the outlet port of the cylinder12. The valve body 14 also includes an outlet port 20." (Ex. 1004 at 2:46-49, Figs 1, 2.)

The handle 16 of valve 10 of the '510 Patent can be turned to open or close the valve to allow the therapy gas to flow through the valve and into "a ventilator or other gas dispensing device (not shown)," such as the gas delivery system disclosed in the '083 Patent. (Ex. 1004 at 2:52-55; Ex. 1005 at 3:61-63, Figs. 1, 2.) The handle of the '510 Patent is a manual valve actuator that opens or closes the valve. (Ex. 1002 ¶ 21.) Thus, in a combined system, the NO gas exits a valve as disclosed in the '510 Patent and flows into a fluid circuit, such as that disclosed in the '083 Patent. (Ex. 1005 at 3:61-5:59, Figs. 1, 2; Ex. 1002 ¶ 100.) The fluid circuit and the associated control provided by the CPU 56 as disclosed in the '083

Patent, which controls various valves according to stored algorithms, is an example of the claimed control module. (Ex. 1005 at 5:60-6:19, 6:40-54.) Indeed, the '795 Patent refers the '083 Patent's circuit as a "delivery module 260" that forms part of the disclosed "control module 200." (Ex. 1001 at 9:65-10:7.)

(iii) Memory Limitation

The gas delivery device of claim 1 also comprises "a circuit including a memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration." The '510 Patent discloses valve memory, indicated by numeral 22, disposed in the valve. (Ex. 1004 at 2:58-61, 3:3-5.) The '510 Patent discloses that gas data indicative of the gas in the cylinder could be stored in the valve memory. (*See id.* at 5:43-6:12.) This includes data that can be used to identify the gas in the cylinder and the gas expiration date (by virtue of the "born on date"), both of which are included in the claimed *Markush* group. (*Id.* at 5:49-50, 5:54-58, 7:36-51.) This is consistent with the examiner's undisputed finding that at least the '510 Patent discloses a circuit including a memory to store gas identification data. (Ex. 1019 at 94.)

The FR '804 Publication also discloses IDb data or stored data regarding the gas in the cylinder, including at least gas identification data. (Ex. 1006 at 17, 19, 21.) The various disclosed embodiments illustrate different configurations for the circuit and the location of the IDb data, several of which are encompassed by this

limitation in claim 1. In at least one of the disclosed embodiment (Fig. 4), the IDb data is stored in memory at the gas container or valve, similar to the '510 Patent disclosure. (*Id.* at 19, 21, Fig. 4.) Further, the '083 Patent teaches storing gas concentration data and using it to "verify that the proper supply is being utilized." (Ex. 1005 at 5:60-6:8.) Thus, one skilled in the art would have understood at the time based on the combination of references that the circuit of a gas delivery system could include a memory to store gas data. (Ex. 1002 ¶ 67, 107-108.)

(iv) Processor/Transceiver Limitation

The delivery system of claim 1 further requires "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." The valve taught in the '510 Patent includes a valve processor 23 that can access the valve memory 22 and the gas data stored therein. (Ex. 1004 at 2:58-61, 3:40-49, 5:43-6:12, 6:21-25.) The '510 Patent also discloses a transceiver in communication with the memory to send and receive signals to communicate gas data to an external computer. (*Id.* at 6:33-7:15.) This is consistent with the examiner's uncontested conclusion during prosecution that the '510 Patent discloses "that the processor and transceiver communicates gas data to the control module." (Ex. 1019 at 94; Ex. 1002 ¶¶ 25-26.)

The FR '804 Publication discloses communicating gas IDb data to the control module 300 to determine whether the correct gas is delivered to the subject. (Ex. 1006 at 20.) In at least one embodiment, the FR '804 Publication discloses that the IDb data can be read from a carrier (*e.g.*, a bar code) on the cylinder and stored in a memory within the valve housing. (*Id.* at 21, Fig. 4; Ex. 1002 ¶ 101.) A person skilled in the art at the time would have understood from the combined teachings of the '510 Patent, the FR '804 Publication, and the '083 Patent that the gas data stored in memory 22 of the '510 Patent could have been communicated to a remote device (such as the CPU and control module of the '083 Patent) as taught in the FR '804 Publication. (Ex. 1004 at 5:43-6:2; Ex. 1002 ¶¶ 110-111, 118-119.)

To effectively communicate the gas data from the valve to the control module (a physically separate device), a person of skill in the art would have understood to use interfaces disclosed in enabling standards, such as the well-known infrared interface described in the IR Standard. (Ex. 1007 at 10-11, 15, 33; Ex. 1002 ¶¶ 69-71, 74, 113-118, 121-128.) The valve processor 23 of the '510 Patent would work with the transceiver taught in the IR Standard or the '510 Patent to communicate the valve data to the control module. (Ex. 1004 at 3:5-7; Ex. 1007 at 40 (discussing commercially available IR transceivers); Ex. 1002 ¶¶ 110, 118.) The fact that the '510 Patent discloses wireless transceivers for communicating gas data further emphasizes the easy application of the IR Standard to communicate

data to and from the valve memory. (Ex. 1004 at 6:13-15, 6:33-7:15; Ex. 1002 ¶¶ 26, 121-122.) Lastly, since the '083 Patent teaches a control module, and both the '083 Patent and the FR '804 Publication disclose a system in which gas data is provided to a control module (Ex. 1005 at 5:60-6:20, 6:43-53; *see also* Ex. 1001 at 9:65-10:7), the combination described here discloses this limitation. (Ex. 1002 ¶¶ 109-111.)

(v) Verification Limitation

Claim 1 requires that the delivery system "verify one or more of the gas identification, the gas concentration and that the gas is not expired." The gas delivery system disclosed in the '083 Patent specifically includes the ability to verify the gas concentration and that the gas being delivered is the expected gas. (Ex. 1005 at 6:5-15.) In the '083 Patent, the system uses a sensor 65 to detect the concentration of gas coming from the supply cylinder and that information can be used to "verify that the proper supply is being utilized." (*Id.* at 6:5-15.)

Further, the FR '804 Publication discloses a comparison function that verifies that the gas being delivered is the expected gas. (*See e.g.*, Ex. 1006 at 17 (determines "gas bottle whose content does not correspond to the gas intended for use").) The comparison performed by the FR '804 Publication's control module 300 specifically verifies whether the "type of gas contained in the bottle 10 corresponds to the type of gas intended to supply the circuit . . . ." (*Id.* at 19.)

Thus, the FR'804 Publication's disclosure of "positive" or "negative" comparison of gas identification and the verification of gas concentration in the '083 Patent both meet this limitation. (Ex. 1002 ¶¶ 65, 108.) Accordingly, claim 1 is unpatentable in view of the '083 Patent, the '510 Patent, the FR '804 Publication, and the IR Standard.

(b) Dependent Claim 2

Claim 2 depends from claim 1 and further requires that "the valve further comprises a data input in communication with said memory, to permit a user to enter the gas data into the memory." The '510 Patent discloses a port 22' that projects through the valve handle (*i.e.* the claimed actuator) and provides a mechanism to load data into the valve memory. (Ex. 1004 at 2:61-64, 5:61-6:12.) Port 22' is an example of the claimed data input that communicates with the memory and through which a user can enter gas data such as gas identification and expiration data into the valve memory 22. (*Id.* at 5:43-6:12, Ex. 1002 ¶¶ 26-27, 105; *see* Sections III, IX(A)(3)(a)(iii).) Thus, the '510 Patent discloses the additional limitations of claim 2.

(c) Dependent Claim 3

Claim 3 also depends from claim 1 and requires that the signals from the transceiver "comprises wireless optical line-of-sight signals." As combined, the prior art references teach the communication of gas data stored in the memory

(*e.g.*, valve memory 22 of the '510 Patent) to a control module (*e.g.*, the CPU 56 of the '083 Patent). (*See* Sections IX(A)(2), IX(A)(3)(a)(iv); Ex. 1002 ¶¶ 108, 123-124.) To achieve this communication, the IR Standard teaches using a pair of infrared transceivers located at the valve and the control module. (Ex. 1007 at 10-11, 15, 33; Ex. 1002 ¶¶ 71, 121-122.) Indeed, the '510 Patent also teaches a wireless transceivers for communicating data to a remote device. (Ex. 1004 at 6:13-15, 6:33-7:15; Ex. 1002 ¶ 110; Ex. 1019 at 94.) Because infrared communications involves wireless optical line-of-sight (Ex. 1001 at 2:54-58), the relied-on combination discloses each limitation of this dependent claim.

(d) Dependent Claim 4

Claim 4 depends from claim 1 "further comprising a power source, wherein the transceiver periodically sends the signals to the control module and the signals are interrupted by a duration of time at which no signal is sent to conserve the power source." The valve in the '510 Patent has a power source in the form of battery 25. (Ex. 1004 at 2:58-61, 3:7-8.) The '510 Patent also discloses transmission of data from the valve "*at intervals*" using a transceiver. (*Id.* at 7:1-4.) Thus the '510 Patent discloses the required periodicity and "duration of time at which no signal is sent to conserve the power source." (Ex. 1002 ¶ 26.)

Further, the IR Standard discloses its applicability to devices with batteries as a power source, and discloses that a link disconnect time is negotiated, which

time is application-appropriate but typically in the range of 3 s to 40 s. (Ex. 1007 at 15, 20.) This link disconnect time, which is monitored between periodically sent optical line-of-sight signals (*Id.* at 19), discloses the "duration of time at which no signal is sent" between signals (*Id.* at 20) which is important to conserving battery power (*Id.* at 15, Ex. 1002 ¶¶ 32, 76.) The combination of the '510 Patent and the IR Standard thus discloses the additional limitation required by claim 4.

(e) Dependent Claim 5

Claim 5 depends from claim 4 and requires that "the duration of time at which no signal is sent is in the range from about 5 seconds to about 20 seconds." As discussed with regard to claim 4, the combined references disclose a valve transceiver that periodically sends signals to the control module, wherein the signals are interrupted by a duration of time where no signal is sent. (1004 at 7:1-4; Ex. 1007 at 15, 20.) The IR Standard teaches that this period of time can be between 3 seconds and 40 seconds. (Ex. 1007 at 20.) Accordingly, the IR Standard teaches or suggests the claimed duration "in the range from about 5 seconds to about 20 seconds."

(f) Dependent Claim 6

Claim 6 depends from claim 1 and requires that the "memory is disposed between the actuator and a cap." The '510 Patent discloses circuit elements disposed between the actuator ("handle" of the '510 Patent) and a cap ("cover 24"

of the ’510 Patent). (*See generally* Ex. 1004 at Figs. 1, 1A, 2, 2A, 5.) Specifically, the ’510 Patent states that “several electronic devices are mounted in the handle, including…an electronic memory device 22.” (*Id.* at 2:58-61.) Further, “[m]ost of the components of Fig. 2B are housed inside a compartment formed by the handle 16 and the cover 24….” (*Id.* at 3:3-29.) The “compartment” is between the actuator and a cap as required. (Ex. 1002 ¶ 23.) Accordingly, at least the ’510 Patent teaches the additional limitations set forth in claim 6.

(g) Independent Claim 7

(i) Gas Source Limitation

Independent claim 7 is directed to “[a] therapy gas delivery system comprising: a gas delivery device comprising: a gas source.”[8] The ’083 Patent and the FR ’804 Publication both disclose a therapy gas delivery system including a gas delivery device with a gas source. (*See* Section IX(A)(3)(a)(1); *see also* Ex. 1005 at Abstract, 3:43-4:2; Ex. 1006 at 19.)

(ii) Valve Limitation

Claim 7 requires that the gas delivery device includes “a valve attached to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open and close the valve.” As discussed with regard to

[8] The preamble should not be interpreted as limiting the claim. Nonetheless, the preamble is disclosed by the prior art as discussed herein.

claim 1 (*see* Section IX(A)(3)(a)(ii)), the '510 Patent discloses the claimed valve (Ex. 1004 at 2:46-49, 2:52-55, Ex. 1002 ¶¶ 21, 59) attached to the gas source of the '510 Patent, the '083 Patent, and the FR '804 Publication (Ex. 1004 at 2:40-42; Ex. 1005 at 3:45-47; Ex. 1006 at 19.) This confirms what the examiner found (and PO did not dispute) during prosecution. (Ex. 1019 at 94.)

(iii) First Memory/Processor/Transceiver Limitation

Claim 7 requires that the gas delivery device includes a circuit comprising "a first memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration of the gas source." As discussed with regard to claim 1, the '510 Patent discloses a valve memory 22, that stores gas data. (*See* Section IX(A)(3)(a)(iii); Ex. 1004 at 2:58-61, 3:3-5, 5:43-6:12, *see also* 7:36-51; Ex. 1002 ¶¶ 23, 25, 27-28, 107, 119; *see also* Ex. 1019 at 94.) IDb of the FR '804 Publication is also an example of gas data. (Ex. 1006 at 20-21, Fig. 4.) The '083 Patent uses gas concentration in its gas control algorithms to verify the proper supply is being used. (Ex. 1005 at 5:60-6:8.) In the combination, this gas data would be stored in the '510 Patent's valve memory. (Ex. 1002 ¶¶ 107, 119.)

Claim 7 requires that the circuit of the gas delivery device also include "a first processor and a first transceiver in communication with the first memory." As discussed with regard to claim 1, the '510 Patent discloses a valve processor 23 for accessing the valve memory 22 and the gas data stored therein. (Ex. 1004 at 2:58-

61, 3:40-49, 5:43-6:12, 6:21-25.) The '510 Patent discloses a transceiver in communication with the memory to communicate gas data to an external computer. (*Id.* at 6:33-7:15; Ex. 1002 ¶ 26, 122-23; *see also* Ex. 1019 at 94.) The requisite first transceiver is also disclosed by the IR Standard, which contributes an infrared transceiver to communicate data from the first (valve) memory in the relied-on combination. (Ex. 1007 at 10-11, 15, 33; Ex. 1002 ¶¶ 74, 110, 118.)

(iv) Control Module Limitation

Claim 7 requires "a control module that controls delivery of therapy gas to a subject." As discussed with regard to claim 1, the '083 Patent discloses the claimed control module. (Ex. 1005 at 5:60-6:19, 6:40-54; Ex. 1001 at 9:60-10:2 (incorporating the '083 Patent by reference for its disclosure of the "control module"); s*ee* Sections IX(A)(2) and IX(A)(3)(a).)

Claim 7 also requires that the control module comprise "a second memory, a second transceiver and a second processor, wherein the second transceiver and the second processor are in communication with the second memory." As discussed above, the combined references teach a system wherein data from the valve memory 22 of the '510 Patent is transmitted to a control module that has a transceiver, processor, and memory. (*See* Section IX(A)(2).) More specifically, at least the '083 Patent discloses a control module with memory (Ex. 1005 at 2:52-53 "various algorithms maybe stored and used as appropriate") and a processor (*Id.* at

5:60-62 "CPU 56") in communication with the memory. (Ex. 1002 ¶ 123-124.) The IR Standard teaches that a transceiver must be present on both the originating and the receiving devices in order to properly communicate information. (Ex. 1007 at 10-11, 14-16, 40; Ex. 1002 ¶¶ 71, 121-122.) Accordingly, the references as combined disclose this claimed limitation.

(v) Signal Transmission Limitation

Lastly, Claim 7 requires "wherein the first transceiver and the second transceiver send and receive signals to communicate the gas data to the control module and to verify one or more of the gas identification, the gas concentration and that the gas is not expired." When the valve of the '510 Patent and the FR '804 Publication are incorporated into in the '083 Patent, the combination discloses communicating gas data stored in the memory 22 of the '510 Patent to the CPU of the '083 Patent's control module. (Ex. 1004 at 5:43-6:2; Ex. 1002 ¶ 112.) The transceivers taught by the IR Standard, which are present at both the valve of the '510 Patent and the CPU of the '083 Patent, send and receive signals to communicate this data. (Ex. 1004 at 3:5-7; Ex. 1007 at 10-11, 14-16, 40; Ex. 1002 ¶ 115, 118-122.) The '083 Patent enables verification that the gas being delivered is the expected gas. (Ex. 1005 at 6:5-15.) The comparison performed by the control module 300 of the FR '804 Publication also verifies the gas and whether the "type of the gas contained in the bottle 10 corresponds to the type of gas

intended to supply the circuit…" (Ex. 1006 at 19; Ex. 1002 ¶¶ 65-66.) Thus, the references as combined disclose every limitation in claim 7.

(h) Dependent Claim 8

Claim 8 depends from claim 7 and further requires that the control module includes "a display to enter patient information into the second memory." The '083 Patent discloses that its "CPU obtains information from the flow transducer and from an input device that allows the user to select the desired concentration of NO to be delivered…." (Ex. 1005 at 2:30-35, *see also* 6:29-42.) The input device may be a touch screen, which includes the required display. (*Id.* at 6:31-32.) The input concentration desired to be administered to the patient is "patient information." (*Id.* at 2:30-35, 6:29-42.) Finally, since the input information is non-transitory (*i.e.*, it can be used later), it is stored in memory in communication with the CPU for use as an input to the algorithms described in the '083 Patent. (*Id.* at 2:64-67, 5:62-64; Ex. 1002 ¶¶ 31, 123.) Accordingly, the combined references disclose the additional limitation set forth in claim 8.

(i) Dependent Claim 9

Claim 9 depends from claim 8 and requires that the "second processor compares the patient information entered into the second memory via the display and the gas data that the first transceiver communicated to the second transceiver." The '083 Patent discloses this additional limitation because its CPU compares the

actually sensed NO concentration with the NO concentration entered by the user. (Ex. 1005 at 2:52-67, 6:5-15, 8:1-12.) The FR '804 Publication also discloses this limitation, as it determines whether a comparison is "positive" or "negative." (Ex. 1006 at 18.) Since, in the combination, the patient data is entered via the '083 Patent's display and the gas data is received from the valve memory, this limitation is satisfied by the art underlying this Ground. (Ex. 1002 ¶¶ 115-118, 135.)

(j) Dependent Claim 10

Claim 10 depends from claim 9 and requires that "the control module comprises an alarm that is triggered when the patient information entered into the second memory and the gas data from the valve transceiver do not match." The '083 Patent discloses this additional limitation because "[i]n the event the NO detected by the gas sensing bench 52 is a predetermined value away from the set point established by the user, an alarm may be triggered so the user can attend to the problem." (Ex. 1005 at 3:1-4, 3:14-25, 8:4-6, 8:12-20.) The FR '804 Publication also discloses this limitation, as a negative comparison between IDb (which is provided to the control module via the valve transceiver taught by the IR Standard) and IDv results in an alert being issued. (Ex. 1006 at 18, 19 ("audible and/or visual" "to alert the operator" of a "connection error"); Ex. 1002 ¶¶ 32, 65.)

(k) Dependent Claim 11

Claim 11 depends from claim 7 and requires that "the second memory

comprises instructions that cause the second processor to: receive gas data from the gas delivery device; compare the gas data with user-inputted patient information; and control delivery of the therapy gas to the patient." The disclosure in the '083 Patent that "various algorithms may be stored and used as appropriate" (Ex. 1005 at 2:56-58) conveys that instructions are stored in the second memory to cause the CPU to perform certain steps. In the relied-on combination, the gas data is received at the CPU of the '083 Patent from the valve memory 22 of the '510 Patent and stored in the second memory discussed with regard to claim 7. (Ex. 1002 ¶¶ 108, 121.) In the '083 Patent, a user can enter the concentration of gas desired for delivery to the patient. (Ex. 1005 at 5:62-64, 6:29-42.) The '083 Patent processes the user-inputted patient information and the gas data through the disclosed algorithms to compare that data with data about the actual gas being delivered. (*Id.* at 2:52-67, 5:60-6:15, 6:43-7:53, 8:1-12.) In the combination relied on herein, the CPU of the '083 Patent performs the comparison of IDb (the gas data) with IDv (the patient information indicating the expected type of gas). (Ex. 1006 at 18, 19; Ex. 1002 ¶¶ 101, 107-108, 118-119, 123-125.) It discloses controlling delivery of the selected therapy gas to the patient. (Ex. 1005 at 6:16-19 ("[c]ontrol signals are transmitted from CPU 56 to proportional control valve 18, shutoff valve 14, purge valve 20, and proportional valve 24 via signal lines 66, 68, 70, and 72 respectively"), *see also* 7:49-53, 8:16-27.) Accordingly, the combined

references disclose the additional limitations of claim 11.

(l) Dependent Claim 12

Claim 12 depends from claim 11, and requires that "the second processor verifies one or more of the gas identification, the gas concentration and that the gas is not expired prior to delivery of the therapy gas to the patient." As discussed with regard to claims 1 and 7, when the valve of the '510 Patent and the FR '804 Publication are incorporated into in the '083 Patent, the combination discloses verification of the gas identification by the CPU of the '083 Patent (*i.e.*, the second processor) in that it discloses determining that the gas being delivered is the expected gas. (Ex. 1005 at 5:60-6:15, 8:1-12 ; Ex. 1006 at 17 (determines "gas bottle whose content does not correspond to the gas intended for use"), 2, 3, Fig. 4, Ex. 1014 at 6, Ex. 1002 ¶¶ 101-102, 107-108, 118-119, 124.)

(m) Dependent Claim 14

As discussed with regard to claim 3, the relied-on art discloses the claimed wireless optical line-of-sight. (*See* Sections IX(A)(3)(a)(iv) and (c); Ex. 1004 at 5:43-6:2, 6:13-15, 6:33-7:15; Ex. 1007 at 10-11, 15, 33; Ex. 1002 ¶ 118-119, 123-129.)

(n) Independent Claim 15

(i) Therapy Gas Limitation

Independent method claim 15 is directed to "[a] method for administering a

therapy gas to a patient."[9] The '510 Patent and the FR '804 Publication disclose methods for administering a therapy gas. (Ex. 1004 at 1:16-30, Ex. 1006 at 19). The '083 Patent discloses methods of administering a therapy gas. (Ex. 1005 at Abstract, 3:43-4:2; Ex. 1014 at 6.) Accordingly, the combined references teach this limitation. (Ex. 1002 ¶¶ 22, 29, 31, 65.)

(ii) Establishing Communication Limitation

Claim 15 requires "establishing communication between a gas delivery device and a control module for administering therapy gas to a subject via a first transceiver and a second transceiver." When combined, the '510 Patent valve communicates with the CPU 56 of the '083 Patent, which performs the functions of the control module 300 of the FR '804 Publication in addition to the control functionality disclosed in the '083 Patent. (Ex. 1005 at 2:30-42, 5:60-6:4; Ex. 1002 ¶¶ 108, 111, 113, 121-122, 124.) Further, according to the IR Standard, a transceiver must be present on both devices. (Ex. 1007 at 10-11, 14-16, 40; Ex. 1002 ¶¶ 71, 115, 118-122, 124.) Establishing communication as disclosed in the prior art thus satisfies this claim limitation.

Claim 15 also requires that "the gas delivery device comprises a gas source and the first transceiver is in communication with a first memory that stores gas

[9] The preamble should not be interpreted as limiting the claim. Nonetheless, the preamble is disclosed by the prior art as discussed herein.

data comprising one or more of gas identification, gas expiration date and gas concentration of the gas source." As discussed with regard to claim 1, the combination relied on herein discloses the claimed gas source. (*See* Section IX(A)(3)(a)(i); Ex. 1005 at Abstract, 3:43-4:2; Ex. 1014 at 6.) Moreover, as discussed with regard to claim 1, a valve memory (corresponding to the claimed first memory) in communication with the transceiver on the valve stores the requisite gas data. (*See* Section IX(A)(3)(a)(iii); Ex. 1004 at 2:58-61, 3:3-5, 5:43-6:12, 7:36-51; Ex. 1002 ¶¶ 23, 25, 27-28; Ex. 1019 at 94.)

Claim 15 requires that "the control module comprises the second transceiver and a second memory." As discussed with regard to claim 7, the '083 Patent discloses a CPU whose associated memory is the claimed second memory, and the IR Standard's mandated transceiver is an example of the claimed second transceiver. (*See* Section IX(A)(3)(e); Ex. 1005 at 2:30-42, 2:52-53, 5:60-6:4; Ex. 1007 at 10-11, 14-16, 40; Ex. 1002 ¶¶ 108, 111, 113, 121-122, 124.)

(iii) Communicating Data Limitation

Claim 15 additionally requires "communicating the gas data from the first transceiver to the second transceiver via wired or wireless signals." As discussed with regard to claim 1, the combination discloses that the valve processor 23 of the '510 Patent communicates gas data from its transceiver to the transceiver of the '083 Patent's control module (*e.g.* as taught by the IR Standard). (*See* Section

IX(A)(3)(a)(iv); Ex. 1004 at 2:58-61, 3:40-49, 5:43-6:15, 6:21-25, 6:33-7:15 (wired and wireless transceivers and communications); Ex. 1006 at 20, 21, Fig. 4; Ex. 1007 at 10-11, 15, 33, 40; Ex. 1002 ¶ 26, 116-128; Ex. 1019 at 94.)

(iv) Comparing Data Limitation

Claim 15 requires "comparing the gas data with patient information stored in the second memory to verify the gas data." As discussed with regard to claim 1, the '083 Patent and the FR '804 Publication each contribute the required comparison and verification of gas data required by this limitation. (*See* Section IX(A)(3)(a)(v); Ex. 1005 at 6:5-15, 8:1-12; Ex. 1006 at 17, 18, 19; Ex. 1002 ¶ 101, 108, 123.) Thus, the combination discloses this limitation as well.

(v) Controlling Delivery Limitation

Claim 15 further requires "controlling delivery of the therapy gas to the patient." As explained above with respect claim 11, at least the '083 Patent teaches controlling delivery of the gas to the patient. (*See* Section IX(A)(3)(k); Ex. 1005 at 6:16-19, 7:49-53, 8:16-27; Ex. 1002 ¶ 100, 123-125.)

(o) Dependent Claim 16

As discussed with regard to claim 3, the relied-on art discloses the claimed wireless optical line-of-sight. (*See* Section IX(A)(3)(c); Ex. 1004 at 5:43-6:2, 6:13-15, 6:33-7:15; Ex. 1007 at 10-11, 15, 33; Ex. 1002 ¶¶ 108, 121-124.)

(p) Dependent Claim 17

Claim 17 depends from claim 15 and requires "preventing or ceasing

delivery of the therapy gas to the patient based on the comparison of the gas data and the patient information." The '083 Patent discloses this limitation because "[i]n the event that the NO level rises to a dangerous level, CPU 56 will have that information and can take more drastic steps such as to discontinue use of the NO to the patient by shutting off the shutoff valve 14…" (Ex. 1005 at 8:7-10.) The FR '804 Publication also discloses this limitation, as a negative comparison between IDb and IDv prevents the opening of the valve on the disclosed gas source. (Ex. 1006 at 18, 19 (alarm to indicate a "connection error"); Ex. 1002 ¶ 32.)

(q) Dependent Claim 18

Claim 18 depends from claim 15 and requires "emitting an alert based on the comparison of the drug data and the patient information."[10] The '083 Patent discloses this limitation because "[i]n the event the NO detected by the gas sensing bench 52 is a predetermined value away from the set point established by the user, an alarm may be triggered." (Ex. 1005 at 3:1-4, 3:14-25, 8:4-6, 8:12-20.) The FR '804 Publication also discloses this limitation, as a negative comparison between IDb and IDv results in an alert being issued. (Ex. 1006 at 19 ("audible and/or visual" "to alert the operator" of a "connection error"); Ex. 1002 ¶¶ 32, 65.)

[10] There is no antecedent for "drug data" in claims 18 or 19. Petitioner assumes for purposes of this proceeding only that "drug data" refers to claim 15's "gas data."

(r) Dependent Claim 19

Claim 19 depends from claim 15 and requires "entering the drug data into the first memory." The '510 Patent discloses this "entering" based on the loading of initial configuration data by the "distributor who is filling and supplying" the cylinders. (Ex. 1004 at 5:32-6:2, 7:36-39.) The FR '804 Publication also discloses "entering" by virtue of reading carrier 120 by sensor 110 when incorporated in the combination of art. (Ex. 1006 at 20-21, Fig. 4; Ex. 1002 ¶ 108.)

(s) Claim 20

Claim 20 depends from claim 15 and requires "entering the patient information into the second memory." The gas delivery system disclosed in the '083 Patent provides for entering the patient information: "a CPU obtains information from the flow transducer and from an input device that allows the user to select the desired concentration of NO to be delivered to the patient and calculates the flow of NO/nitrogen to obtain that selected concentration." (Ex. 1005 at 2:30-35, *see also* 6:29-42.) The input device may be a touch screen. (*Id.* at 6:31-32.) The input concentration desired to be administered to the patient is "patient information" as claimed. (*Id.* at 2:30-35, 6:29-42.) Finally, since the input information is non-transitory (*i.e.* it can be stored for later use), it is stored in the CPU memory, which communicates with the CPU for use as an input to the algorithms described in the '083 Patent. (*Id.* at 2:64-67, 5:62-64.) This input data

corresponds to the IDv data of the FR '804 Publication (*i.e.*, data indicative of the user-desired type and concentration of gas) and is compared by the CPU with the IDb data (*i.e.* data indicative of the gas in the cylinder). (Ex. 1002 ¶ 68, 119.)

B. Ground 2: Claims 4 and 5 Are Unpatentable Under 35 U.S.C. § 103(a) Over the '083 Patent, the '510 Patent, the FR '804 Publication, the IR Standard, and the '533 Patent[11]

1. Overview of Prior Art

The '083 Patent, the '510 Patent, the FR '804 Publication, and the IR Standard were all previously discussed. (*See* Section IX(A)(1).) The '533 Patent (Ex. 1008) was filed on January 22, 2001 and issued on November 2, 2004. It is therefore prior art under 35 U.S.C. § 102(b).

The '533 Patent discloses a protocol for communicating between a device external to a patient's body and an implanted device, such as an implanted infusion pump. (Ex. 1008 at Abstract; Ex. 1002 ¶¶ 81-87.) It addresses power-management concerns:

> Higher consumption of power from an implantable medical device containing non-rechargeable batteries leads to a shortening of the usable life of the device and an associated increased frequency of surgery, potential pain, recovery, and inconvenience….As such, whether or not an implantable medical device contains rechargeable batteries or non-rechargeable batteries, it is desirable to lower the power consumption of the device. As telemetry reception and transmission are highly energy consumptive, it is desirable to minimize the operation time of telemetry reception and transmission

[11] The '533 Patent was not considered during prosecution.

> modules. As such it is desirable to ensure that message length is kept to a minimum and that repeated transmissions and attempted receptions of previously sent but unsuccessfully received messages be kept to a minimum.

(Ex. 1008 at 2:18-38.) The '533 also discloses that when a device external to the body communicates with an implanted device, "it is preferred that inbound [time] slots be placed relatively close together (e.g. no more than 15 seconds apart, more preferably no more than 10 seconds apart, and even more preferably no more than 5 seconds apart…." (*Id.* at 25:4-8; Ex. 1002 ¶ 84.) The number of outbound time slots (communication from the implanted to the external device) may be less than, equal to, or greater than the number of inbound time slots (communication from the external to the implanted device). (Ex. 1008 at 25:9-17; Ex. 1002 ¶ 84, 85.)

Even though the '533 Patent addresses power management for implanted devices, one skilled in the art would understand from the '533 Patent that it is important to try to conserve battery power, and that one way to conserve battery power is by limiting device-to-device communications to what is necessary for a particular medical application. (Ex. 1002 ¶ 83, 86.) In at least the medical application addressed by the '533 Patent, these power management considerations are satisfied by sending communications separated by 10 second periods of time during which no signal is sent. (Ex. 1008 at 25:4-8; 1002 ¶ 84, 87.)

2. Motivation to Combine

As discussed above in Section IX(A)(2), a person of skill in the art would

have combined the ’083 Patent, the ’510 Patent, the FR ’804 Publication, and the IR Standard to result in a system where data is communicated from a valve memory to a control system to facilitate a safety-based comparison of data by the control system. The ’510 Patent, the FR ’804 Publication, and the IR Standard each disclose using battery power in a system involving one or more portable or remote devices. (Ex. 1004 at 2:58-61; Ex. 1006 at 21; Ex. 1014 at 6, Ex. 1007 at 15.) Thus, a person of skill in the art would have been motivated to incorporate the power management teachings of the ’533 Patent, which apply generally to battery-powered systems, when deciding the specific disconnect time in the 3 to 40 second window suggested by the IR Standard. (Ex. 1002 ¶¶ 126, 130-133.)

The ’533 Patent teaches that the periodicity of signals sent wirelessly in a battery-powered device is application-specific and thus discloses a proposition already familiar to those of skill in the art designing systems that include battery-powered components. (Ex. 1002 ¶ 134-136.) Since the combination of references in Ground 1 discloses a battery-operated component (the valve/smart handle from the ’510 Patent), incorporating the ’533 Patent is merely incorporating the well-known design considerations disclosed in the ’533 Patent. (Ex. 1002 ¶ 129.)

A person of skill designing a wireless communications system using the IR Standard’s teachings would have been motivated to combine the ’533 Patent and the IR Standard. (Ex. 1002 ¶¶ 131, 135.) Such a person would have been

motivated, in part, because both the '533 Patent and the IR Standard teach systems for establishing infrared communication between sub-components of a medical system. (Ex. 1008 at 11:37-55, Fig. 3.) Since the example range of disconnect times in the IR Standard document is from 3 to 40 seconds, a person of skill in the art would have had a reasonable expectation of success when incorporating the 5 second or 15 second time periods specifically articulated by the '533 Patent. (Ex. 1002 ¶¶ 134-135.) The IR Standard also expressly discloses its applicability in point of care applications at or near the patient, including in systems involving communication with ventilators and other drug delivery devices (Ex. 1007 at ii, vi) and that appropriate disconnect times for such applications are between 3 and 40 seconds (*Id.* at 20). This suggests to a person of skill in the art that the design considerations for the implanted device wireless communication system of the '533 Patent are also applicable when designing a wireless communications interface in a NO delivery device. (Ex. 1002 ¶¶ 132-134.) It also suggests that the use of the time periods disclosed in the '533 Patent to separate signals sent between devices in an NO delivery system is nothing by the simple substitution of known timing parameters for similar medical applications with similar battery conservation considerations. (*Id.* ¶¶ 134-137.)

Finally, because the gas data of the FR '804 Publication (IDb data) indicates the type and concentration of gas in the cylinder, and this information cannot

change unless the gas bottle is removed or replaced, a 15 second interval or a 5 second interval between communications, as taught by the '533 Patent, is sufficient to achieve the desired result. (*Id.* ¶¶ 55, 129, 134.) As combined, the '083 Patent, the '510 Patent, the FR '804 Publication, the IR Standard, and the '533 Patent render claims 4 and 5 obvious.

3. Specific Identification of Challenge

(a) Dependent Claim 4

The Ground 1 combination discloses a valve that sends signals to a control module. (*See* Section IX(A)(3)(a).) The '510 Patent valve includes a battery 25 as a power source. (Ex. 1004 at 2:58-61.) The '510 Patent also discloses periodically sending signals from the valve transceiver, wherein the signals are interrupted by a duration of time a which no signal is sent. (*Id.* at 7:1-4.) The IR Standard discloses a "link disconnect time" that compliant devices wait between signals before disconnecting the link. (Ex. 1007 at 20.) It also discloses a "low power" option to conserve the power source when a transceiver is on a battery-powered device. (*Id.* at 15.)

The '533 Patent discloses a battery-powered transceiver, and is concerned with conserving battery power. (*See, e.g.*, 1008 at 2:18-38; Ex. 1002 ¶ 86.) It relies, in part, on infrared wireless optical line-of-sight signaling. (Ex. 1008 at 7:8-14.) It discloses that sent signals are interrupted by a duration of time at which no

signal is sent to conserve the power source. (*Id.* at 25:9-12.) Accordingly, the '533 Patent discloses the additional limitations of claim 3.

(b) Claim 5

The prior art relied on herein discloses the periodicity required by claim 4. (*See* Section IX(A)(3)(d), IX(B)(3)(a).) The IR Standard teaches that the period of time between signals can be between 3 and 40 seconds, and thus discloses the claimed range. (Ex. 1007 at 20.) The '533 Patent also discloses several specific examples within the claimed range. (*See* Ex. 1008 at 25:6-8.) Accordingly, a person of ordinary skill in the art would understand that the '533 Patent discloses the additional limitations of claim 5 because of its general power-management applicability. (Ex. 1002 ¶¶ 131-133).

C. Ground 3: Claim 13 Is Unpatentable Under 35 U.S.C. § 103(a) Over the '083 Patent in View of the '510 Patent, the FR '804 Publication, the IR Standard, and the '398 Patent[12]

1. Overview of Prior Art

The '083 Patent, the '510 Patent, the FR '804 Publication, and the IR Standard were all previously discussed. (See Section IX(A)(1).) The '398 Patent (Ex. 1010) was filed on December 3, 1982 and issued on July 31, 1984. It is prior art to the '795 Patent under 35 U.S.C. § 102(b).

The '398 Patent discloses a respirating gas supply apparatus that uses valves

[12] The '398 Patent was not considered during prosecution.

to supply gas to a patient. (Ex. 1010 at Abstract.) A control circuit operates a valve to supply pulses of gas through a cannula to a patient while the patient is inhaling. (*Id.* at 2:59-64; Ex. 1002 ¶ 90.) In a single gas source and valve embodiment of the '398 Patent, an LED 92 conducts electricity, and thus illuminates, "to provide a visual indication" that gas is being delivered to the patient. (Ex. 1010 at 11:43-46.) Conversely, if the system terminates delivery of the gas, "the signal on line L3 goes false" and the LED is no longer illuminated. (Ex. 1010 at 11:47-63; Ex. 1002 ¶ 94.)

The '398 Patent discloses connecting to and delivering gas simultaneously from two sources of gas. (*See* Ex. 1010 at Abstract; Ex. 1002 ¶¶ 89, 91.) As taught in the '398 Patent, such a system would require coordinating the opening and closing of related valves. The Fig. 6 embodiment "includes means for supplying a second gas to the in vivo respiratory system." (Ex. 1010 at 7:26-30.) To achieve this result, the system includes a second gas source and a second valve. (*Id.* at 7:30-51; Ex. 1002 ¶ 91.) The '398 Patent discloses specific circuitry for its dual-gas source/dual-valve embodiment. (Ex. 1010 at 13:57-65.) In this circuitry, L3 "causes not only the [first] valve 26 to allow the passage of a pulse of a first gas therethrough, but also causes the [second] valve 126 to be actuated to connect the source 120 of the second gas to the cannula 48." (*Id.* at 13:57-65; Ex. 1002 ¶¶ 90-91.) Thus, the L3 signal can indicate when both valves are open. (Ex. 1002 ¶¶ 92-

95, 146.)

FIG. 5 of the ’398 Patent is “a schematic diagram showing a control means.” (Ex. 1010 at 3:64-65.) “The control means 32 of the embodiment of FIG. 5 is suitable for use with the apparatus constructed in accordance with any of the foregoing embodiments,” including the dual-valve embodiment of Fig. 6. (*Id.* at 7:52-54.) 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.)

2. Motivation to Combine

A person of skill in the art would have been motivated to use the dual-valve embodiment of the ’398 Patent with the proposed combination discussed with regard to Ground 1. (Ex. 1002 ¶¶ 138-150.)

The ’083 Patent discloses an NO delivery system in which the “administration [of nitric oxide] must be added in sympathy with the respiration pattern of the patient.” (Ex. 1005 at 1:31-33.) The ’398 Patent achieves this goal. (*See* Ex. 1010 at Abstract.) The ’083 Patent discloses a system that “includes various controls, alarms and safety devices … to shut down the NO system or to reduce the NO concentration to a safer level.” (Ex. 1005 at 3:14-18, 8:1-12.) The

'398 Patent likewise discloses a system where signals (such as L3) can trigger an appropriate alarm and shut down gas delivery. (*See* Ex. 1010 at 11:43-46, 13:57-65.) And like the '083 Patent, the '398 Patent is directed to a system that can connect simultaneously to multiple gas sources. (Ex. 1005 at 8:43-49; Ex. 1010 at 7:27-38.) Accordingly, both are directed to the same field of endeavor, and seek to solve the same problems. (Ex. 1002 ¶¶ 139-142.)

The Ground 1 combination also discloses that multiple gas cylinders can be connected to the '083 Patent's gas circuit simultaneously. (*See, e.g.*, Ex. 1005 at 8:38-49, Fig. 2.) In such embodiments, the CPU of the '083 Patent teaches the capability of the CPU to issue appropriate alarms depending on how the stored algorithms handle delivery of the gas in the cylinders. (Ex. 1002 ¶¶ 143, 147, 149-150.) Because the '398 Patent discloses a particular signal (L3) that can drive an LED to signal users, a person of skill in the art could have readily used the logic from the '398 Patent in conjunction with CPU of the '083 Patent to provide alarms indicative of the valve status of each of the two valves.

A person of skill in the art would have understood that in a multiple gas source embodiment, the LED 92 of the '398 Patent, which is illuminated when valves attached to two cylinders are open, is an example of an alarm to visually indicate a particular condition, similar to the alarms generated by the '083 Patent. (*Id.* ¶¶ 148, 150.) A person of skill in the art would also have understood that the

L3 signal, which indicates that multiple valves are open simultaneously, can be provided as an input to the CPU of the ’083 Patent to trigger action appropriate for such a condition. (*Id.* ¶ 142-144.) Moreover, a person of skill in the art would have understood that the L3 signal could be generated using the valve sensors disclosed in the ’510 Patent. (Ex. 1004 at 3:16-29; Ex. 1002 ¶¶ 143-145.) The generation and use of L3 in this way constitutes the application of a known technique (providing a signal indicative that both valves are open) to a known system (the two gas source system of the ’083 Patent) to yield predictable results (the CPU can take actions appropriate for a situation where two valves are open, such as issuing an alarm or discontinuing gas delivery). Since the ’083 Patent specifically discloses that some of the inputs it can receive are indicative of the flow of gas through a fluid circuit (*see* Ex. 1005 at 5:64-6:4), providing the CPU with a control signal from the valve sensors, indicating that multiple valves are open would be well within the knowledge and capabilities of a person having ordinary skill in the art.

Finally, the FDA’s Guidance document states that “[the device should include provision for attachment of two nitric oxide cylinders, which can be used alternately…” constitutes further motivation to look to the ’398 Patent’s dual-valve alarming logic when implementing the system of the ’083 Patent. (Ex. 1012 at 6; Ex. 1002 ¶¶ 140-142.)

The Ground 1 combination also discloses that multiple gas cylinders can be connected to the '083 Patent's gas circuit simultaneously. (*See, e.g.*, Ex. 1005 at 8:38-49, Fig. 2.) In such embodiments, the CPU of the '083 Patent can send appropriate signals to valves depending on how the stored algorithms handle delivery of the gas in the cylinders. (Ex. 1002 ¶ 145.) Because the '398 Patent discloses a particular signal (L3), which the '510 Patent discloses can be generated by valve sensors, to signal users (by illuminating an LED) and to open or close valves, a person of skill could have used the logic from the '398 Patent in conjunction with CPU of the '083 Patent to provide alarms indicative of the valve status of each of the two valves. (Ex. 1002 ¶¶ 146-148.) When combined, the art teaches using control signals to discontinue delivery of the therapy gas if the algorithms executed by the CPU call for it. (See Ex. 1005 at 8:7-11; Ex. 1002 ¶¶ 147-150.) Neither the circuitry of the '398 Patent nor the circuitry of the '083 Patent would require substantial architectural modification; the L3 signal could be provided to the CPU, and gas delivery algorithms could use that signal as appropriate. Thus, incorporation of the L3 signal into the '083 Patent would constitute the incorporation of known features from the art to address a situation specifically provided by the '083 Patent, with reasonable expectation of success.

Thus, a person of skill in the art would have been motivated to add the '398 Patent to the Ground 1 combination to use L3 from the '398 Patent as a control

signal provided to the ’083 Patent’s CPU for use in its gas delivery control algorithms. When combined, the ’083 Patent, the ’510 Patent, the FR ’804 Publication, the IR Standard, and the ’398 Patent render claim 13 obvious.

A person of skill in the art would have added the ’398 Patent to the Ground 1 combination to use L3 from the ’398 Patent, generated by the open/closed sensor of the valve of the ’510 Patent, as a control signal provided to the ’083 Patent’s CPU for use in its gas delivery control algorithms.

3. Specific Identification of Challenge

(a) Dependent Claim 13

Claim 13 depends from claim 7 and requires that the “second memory comprises instructions that cause the second processor to: receive a first valve status selected from a first open position and a first closed position from a first valve connected to a first gas container; receive a second valve status selected from a second open position and a second closed position from a second valve connected to a second gas container, and compare the first valve status and the second valve status.” The ’398 Patent discloses that signals L3 and L3’ indicate whether valves 26 and 16 are both open. (*See* Ex. 1010 at 13:57-65.) The ’510 Patent teaches that sensors in the valve handles can be the source of L3 and L3’. (Ex. 1004 at 3:16-29.) When the L3 and L3’ signals are incorporated in the Ground 1 combination, the result is a dual-valve, dual-gas system. (Ex. 1002 ¶¶ 138-139,

143.) In this resulting system, the L3 and L3' signals are communicated from the valve to the processing circuitry in the control module via wireless optical line-of-sight signals. (*Id.* ¶ 122.) These inputs are provided to the CPU of the '083 Patent, which compares the signals to determine whether both valves are open. (*Id.* ¶¶ 138, 143.) When the '398 Patent is incorporated in the Ground 1 combination, the CPU of the '083 Patent receives L3 and L3' of the '398 Patent from the valves as disclosed in the '510 Patent and compares the signals to determine a first valve status (open or closed) for a first valve on a first gas container, and a second valve status (open or closed) for a second valve on a second gas container. (*Id.* ¶¶ 143-145.)

Claim 13 further requires that the CPU "emit an alarm if the first valve status comprises the first open position and the second valve status comprises the second open position." The '398 Patent discloses that an LED is illuminated when the signal on line L3 indicates that a valve in the single gas source embodiment is open. (*See* Ex. 1010 at 11:33-46, Fig. 5.) Since Fig. 5's control circuitry applies to all embodiments, including the dual valve/dual gas cylinder embodiment of Fig. 6, the LED 92 of Fig. 5 is likewise illuminated in the dual-valve context when both valves are open. (*Id.* at 13:57-65.) Under the broadest reasonable interpretation of the phrase "emit an alarm," illuminating an LED is an example of emitting an alarm. (*See* Ex. 1001 at 13:62 (alarm resulting from detection that two valves are

open may be "audible and/or visual").) This alarm is an example of the kind of alarm the CPU of the '083 Patent can generate, and would generate in the combined system if based on it comparison, it determined that both valves are open. (*See, e.g.*, Ex. 1005 at 3:1-4.)

For these reasons, adding the '398 Patent to the combination underlying Ground 1 discloses the additional limitations of claim 13.

X. CONCLUSION

Petitioner requests institution of *inter partes* review of claims 1-20 of the '795 Patent based on the grounds presented above.

Respectfully submitted by

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