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. 8,291,904

_____

PETITION FOR *INTER PARTES* REVIEW

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Ex. 1001 U.S. Patent No. 8,291,904 ("'904 Patent")

Ex. 1002 Declaration of Robert T. Stone, Ph.D

Ex. 1003 *Curriculum Vitae* of Robert T. Stone, Ph.D

Ex. 1004 U.S. Patent No. 7,114,510 ("'510 Patent"), filed May 15, 2003, issued October 3, 2006.

Ex. 1005 U.S. Patent No. 5,558,083 ("'083 Patent"), filed November 22, 1993, issued September 24, 1996.

Ex. 1006 French Publication No. 2 917 804 ("FR '804 Publication"), published December 26, 2008.

Ex. 1007 ISO/IEEE 11073-30300, "Health informatics -- Point-of-care medical device communication -- Part 30300: Transport profile -- Infrared wireless," ISO, IEEE, published December 15, 2004 ("IR Standard").

Ex. 1008 U.S. Patent No. 6,811,533 ("'533 Patent"), filed January 22, 2001, issued November 2, 2004.

Ex. 1009 Assignment History of the '083 Patent.

Ex. 1010 U.S. Patent No. 4,462,398 ("'398 Patent"), filed December 3, 1982, issued July 31, 1984.

Ex. 1011 Air Liquide OptiKINOX Brochure, dated 2009.

Ex. 1012 "Guidance Document for Premarket Notification Submissions for

	Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer," ("FDA Guidance") document issued January 24, 2000 by the U.S. Department of Health and Human Services, Food and Drug Administration.
Ex. 1013	U.S. Patent No. 4,308,865 ("'865 Patent"), filed October 19, 1979, issued January 5, 1982.
Ex. 1014	Reserved.
Ex. 1015	Prosecution History of U.S. Patent No. 8,291,904.

I. INTRODUCTION

Praxair Distribution, Inc. ("Petitioner" or "Praxair") hereby petitions for *inter partes* review of claims 1-16 of U.S. Patent No. 8,291,904 ("'904 Patent") (Ex. 1001) under 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.

II. THE '904 PATENT

A. Overview of the '904 Patent

The '904 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®.[1] The patent owner and new drug application holder INO Therapeutics, LLC d/b/a Ikaria, Inc. ("PO") is the exclusive U.S. supplier of iNO. PO filed the application that issued as the '904 Patent twelve years after it released INOMAX® in the market. PO's original patents covering iNO expired in 2013, and PO is now trying to use the '904 Patent to impermissibly extend its patent monopoly on INOMAX® more than *35 years* after the original INOMAX patents issued.[2]

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[1] INOMAX® is the trade name of patent owner's inhaled nitric oxide drug ("iNO") for treating term and near-term infants with respiratory failure.

[2] The ' 904 Patent expires on January 6, 2031. Petitioner is concurrently filing petitions for *inter partes* review of four other Orange Book listed patents that

The ’904 Patent does not claim inventive methods or systems of using iNO. (*See, e.g.*, Ex. 1001 at Abstract.) Instead, it claims a compiled gas delivery system with known components operating according to their known functionality, and methods of using the same. (*See*, *e.g.*, Ex. 1001 at 16:44-63, 18:18-33; Ex. 1002 ¶¶ 35-59, 60.) Indeed, the valves and control systems claimed by the ’904 Patent largely mirror the valves and control systems PO itself patented years before January 6, 2011, the earliest possible priority date for the ’904 Patent. (*See generally* Ex. 1004, Ex. 1005.)

B. Summary of the Prosecution of the ’904 Patent

The application that issued as the ’904 Patent was filed on June 11, 2012, and claimed priority to International Application No. PCT/US2011/020319, which was filed on January 6, 2011. (Ex. 1015 at 2, 33.)[3]

On August 21, 2012, the Examiner issued a pre-interview office action rejecting the claims as obvious over the prior art. (Ex. 1015 at 89.) On August 29, 2012, PO conducted an examiner interview and agreed to amend the claims consistent with the interview. (Ex. 1015 at 156-58.) On August 30, 2012, PO

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similarly would extend PO’s monopoly: U.S. Patent Nos. 8,573,209; 8,573,210; 8,776,794; and 8,776,795.

[3] Petitioner assumes for purposes of this proceeding only that January 6, 2011 is the priority date for the ’904 Patent.

amended claim 1 from its as-filed form as follows:

> 1. (Currently amended) A ~~gas delivery device~~ valve assembly to deliver a ~~administer therapy~~ gas comprising NO from a gas ~~source~~ container containing the gas comprising NO, the ~~gas delivery device~~ valve assembly comprising:
>
> a valve attachable to the gas ~~source~~ container containing the gas comprising NO, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas comprising NO through the valve to a control module; ~~and~~
>
> a circuit supported within the valve assembly and disposed between the actuator and a cap, the circuit including:
>
> a valve memory to store gas data comprising ~~one or more of gas identification, gas expiration date and~~ gas concentration in the gas container and
>
> a valve processor and a valve transceiver in communication with the valve memory to send wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject; and
>
> a data input disposed on the actuator and in communication with said valve memory, to permit a user to enter the gas data into the valve memory.

(Ex. 1015 at 126.) Applicant also filed a terminal disclaimer over a co-pending application that issued as U.S. Patent No. 8,573,209 (for which Petitioner is also requesting *inter partes* review). (Ex. 1015 at 141, 147.) The Examiner issued an examiner's amendment and notice of allowance on September 11, 2012, exactly three months after the application was filed. (Ex. 1015 at 151-60.) The Examiner provided reasons for allowance that essentially paraphrased the language of claim 1. (Ex. 1015 at 159.) The '904 Patent issued on October 23, 2012, just over four months after it was filed. (Ex. 1015 at 188.)

III. BACKGROUND OF THE TECHNOLOGY

As indicated by PO's prior art patents incorporated by reference in the '904 Patent (which are statutory bars under 35 U.S.C. § 102(b)), the assemblies and

systems claimed in the '904 Patent recite components or sub-systems that were well known before January 6, 2011. (Ex. 1002 ¶ 19.)

U.S. Patent No. 7,114,510 ("'510 Patent") is owned by PO and is titled "Valve with Smart Handle." (Ex. 1004; Ex. 1002 ¶ 20.) It discloses a valve including a "smart handle" containing electronics to track opening and closing of the valve and to communicate stored data with external devices. (Ex. 1004 at 1:9-15, 6:17-7:15.) The '510 Patent demonstrates that well before the filing of the '904 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.) 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 ¶¶ 22-25.)

The '510 Patent's smart handle was capable of storing both data about the gas in the cylinder and data about open and close times of the valve in the valve memory. (Ex. 1004, 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. Data could be communicated from the smart

handle via the data port or transceiver to a remote device or computer. (Ex. 1004 at 6:33-55; Ex. 1002 ¶ 26.) Such 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 ¶¶ 27-28.)

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 nitric oxide (also referred to as "NO") to a patient. (Ex. 1005; Ex. 1002 ¶¶ 19, 30.) The '083 Patent, which issued in 1996, teaches that gas delivery systems could include a central processing unit ("CPU") that receives and compares signals from two sources. Specifically, 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. The CPU also generates and transmits output signals which control delivery of the gas. (Ex. 1005 at 2:30-35.) In other words, in known NO delivery systems, the CPU compared user inputted data about the desired concentration of NO with the actual concentration of NO being delivered to the patient. (Ex. 1002 ¶¶ 31-33.) The system would generate an alarm and/or close a valve to stop NO delivery as appropriate. (Ex. 1005 at 5:60-65; Ex. 1002 ¶ 34.)

Known NO delivery systems were also designed to enable two cylinders of gas to be in fluid communication with the delivery system at the same time. (Ex. 1005 at 8:38-65; Fig. 2.) Thus, CPUs of known NO delivery systems could simultaneously control delivery of gas from two different sources. (Ex. 1005 at 8:46-49, 8:62-65.)

The '904 Patent is nothing more than a combination of PO's own prior NO delivery system and valve technology. This tactic is a transparent attempt to extend PO's expiring patent monopoly. However, a person skilled in the art would have combined PO's prior technologies, each operating in their intended way, with other well-known teachings to result in the claims of the '904 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 '904 Patent, issued on October 23, 2012 and is available for *inter partes* review; (2) Petitioner is not barred or estopped from requesting *inter partes* review of the '904 Patent on the grounds identified herein; and (3) Petitioner has not filed a complaint relating to the '904 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 16 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 '904 Patent. Petitioner has not been served with the complaint and has not answered or otherwise pleaded.

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 '904 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 of ordinary skill 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 '904 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 '904 Patent should be given their "broadest reasonable construction in light of the specification" of the '904 Patent. 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 term, a claim term 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 '904 Patent to have its plain and ordinary meaning, and would have understood that no term requires special construction for purposes of this proceeding.[4] Further, as discussed above, the '510 Patent and the '083 Patent are owned by PO. Since the '904 Patent incorporates the '510 Patent and the '083 Patent by reference, claim terms of the '904 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 1-16 of the '904 Patent based on the following grounds:

[4] 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).

Ground	35 U.S.C. Section	Relied-On Reference	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)	1-8, 11-16
2	§ 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 '533 Patent (Ex. 1008)	3-4
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)	9-10

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.[5]

Claim 1 is the only independent claim of the '904 Patent. Claim 1 recites:

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

a valve attachable to the gas container containing the gas comprising NO, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas comprising NO through the valve to a control module;

a circuit supported within the valve assembly and disposed between the

[5] Dr. Robert T. Stone is an expert in the field of the alleged invention and the prior art. (*See, e.g.*, Ex. 1002 ¶¶ 1-18; Ex. 1003.)

actuator and a cap, the circuit including:

a valve memory to store gas data comprising gas concentration in the gas container and

a valve processor and a valve transceiver in communication with the valve memory to send wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject; and

a data input disposed on the actuator and in communication with said valve memory, to permit a user to enter the gas data into the valve memory.

(Ex. 1001 at 14:28-52.)

A. Ground 1: Claims 1-8 and 11-16 Are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over the '083 Patent in View of the '510 Patent, the FR '804 Publication, and the IR Standard[6]

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 '904 Patent. The '083 Patent is prior art under 35 U.S.C. § 102(b).

The '083 Patent discloses a NO delivery system in which a series of valves

[6] The '510 Patent and the '083 Patent are both incorporated by reference in the '904 Patent, but neither was cited in an Information Disclosure Statement or considered as prior art during prosecution. (*See* Ex. 1001 at 7:45-47, 10:1-4.)

under control of a CPU control the flow and concentration of NO and nitrogen 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. (Ex. 1005 at 1:20-26.) The '083 Patent teaches a system that can reduce the pressure of the NO gas and can "precisely meter the amount of the NO and nitrogen mixture so that the desired concentration of NO is actually administered to the patient." (Ex. 1005 at 1:26-31.) Its NO 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." (Ex. 1005 at 2:20-24.) The '083 Patent is advantageous because it can modify the gas in the cylinder to a gas at the desired pressure and concentration for patient delivery. (Ex. 1005 at 2:13-20.)

The '083 Patent discloses an input device that enables a user to select a desired concentration of NO to be delivered to the patient, and a CPU that can compare desired concentration with actual measured concentration to control delivery of a selected therapy. (Ex. 1005 at 2:30-35, 2:52-67, 6:29-33, 6:40-42.) The CPU also triggers alarms if faults occur during NO delivery. (Ex. 1005 at 3:1-4.) A sensor senses the concentration of NO in the supply cylinder and sends a signal indicative of the sensed NO concentration to the CPU. (Ex. 1005 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.*) Accordingly, 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. (Ex. 1005 at 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 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 Abstract.) 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." (Ex. 1004 at 2:58-61.) In the '510 Patent, the processor 23 and the electronic memory device 22 are mounted inside the handle 16 of the valve 10. (Ex. 1004 at 2:58-61, 3:3-7.) The handle also includes a port that "can be used to transfer data from the handle's memory 22 to other devices." (Ex. 1004 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 the valve position. (Ex. 1004 at 3:34-58.)

The '510 Patent discloses that initial parameters can be loaded into the

memory of the handle. (Ex. 1004 at 5:44-56.) These parameters can include gas data such as "[c]ylinder serial number" and "[g]as lot number." (Ex. 1004 at 5:44-56.) The '510 Patent teaches that this gas data is typically loaded into memory by the distributor providing the cylinder. (Ex. 1004 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." (Ex. 1004 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…" (Ex. 1004 at 6:3-8.)

After appropriate data is loaded into valve memory, the cylinder and valve of the '510 Patent are provided to a medical provider for use, 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." (Ex. 1004 at 6:17-21.) The medical provider rotates the handle, which is an actuator that opens and closes the valve, to "provide gas treatments to patients." (Ex. 1004 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. (Ex. 1004 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 of data through a port using a wand reader or other appropriate device. (Ex. 1004 at 6:47-55.)

In at least one embodiment, the handle 16 disclosed in the '510 Patent includes "a transmitter to transmit the data to a remote recording device at intervals or on command, as desired." (Ex. 1004 at 7:1-4.) 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 position 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." (Ex. 1004 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.[7] Accordingly, the FR '804 Publication constitutes prior art under 35 U.S.C. § 102(b).

The FR '804 Publication is assigned on its face to *L'Air Liquide Societe Anonyme Por L'Etude Et L'Exploitation Des Procedes Georges Claude* ("Air Liquide"). Air Liquide is a French company that has been involved in manufacturing and selling NO and iNO delivery systems for more than ten years; indeed, at least by 2009, Air Liquide was manufacturing and selling its own iNO delivery systems. (*See* Ex. 1011.) Accordingly, a person of ordinary skill in the

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

art would understand that the FR '804 Publication covers a system that can be used to deliver iNO. (Ex. 1002 ¶¶ 61-64.)

The FR '804 Publication discloses several embodiments of a system for verifying that the gas being delivered is the expected gas. (Ex. 1006 at 17.) It teaches that gas verification can advantageously improve system safety by ensuring that the desired amount and concentration of gas are being delivered to the patient. (Ex. 1006 at 17; Ex. 1002 ¶¶ 65-66.)

To achieve its safety goals, the FR '804 Publication discloses a control module 300 that receives data about (a) the specific gas in a cylinder and (b) the 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 information matches (*i.e.*, the gas in the cylinder is what it should be), it supplies a control signal to open the valve and deliver gas from the cylinder to the fluid circuit. (Ex. 1006 at 18; Ex. 1002 ¶¶ 68-69.) If a negative comparison occurs (*i.e.*, the gas in the cylinder is not the gas expected to be delivered), an audible or visible alarm can be emitted to indicate the mismatch. (Ex. 1006 at 19.)

The FR '804 Publication also explains that the gas data the control module 300 uses to make its comparison is the gas identification data (referred to as "IDb data"). (Ex. 1006 at 20.) The IDb data can be stored on an information carrier 120 affixed to bottle 10. (*Id.*) This information carrier can be, for example, a bar code

or a radio-frequency identification ("RFID") tag. (Ex. 1006 at 20-21.) The data from the carrier is read using a sensor 110, which could be a bar code scanner (if the gas data is stored on a bar code) or an RFID reader (if the gas data is stored on an RFID tag). (Ex. 1006 at 20-21.) The sensor 110 supplies the gas IDb data read from the carrier 120 to the control module 300 for comparison. (Ex. 1006 at 21.)

With regard to the expected or intended type of gas (referred to as "IDv"), 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. (Ex. 1006 at 19.) In the embodiment of Fig. 5, the memory 200 is in a separate physical device from the control module 300. (Ex. 1006 at 21, Fig. 5; Ex. 1002 ¶ 69.) In this embodiment, a transceiver may read the contents of the memory 200 and to transmit the control signal to the valve. (Ex. 1006 at 21, Fig. 5.)

(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. 1002 ¶¶ 70-80, 109-114.) 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. (Ex. 1007 at 2.) The IR Standard states that it is appropriate for capture of 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." (Ex. 1007 at vi; Ex. 1002 ¶ 72.)

The IR Standard discloses that a device's controller communicates in a point-to-point way with a corresponding controller of another device. (Ex. 1007 at 10-11; Ex. 1002 ¶ 73.) The IR Standard provides parameters related to the alignment between IR transmitter-receivers ("transceivers") to be supported by compliant systems. (Ex. 1007 at 33; Ex. 1002 ¶ 74.) The IR Standard teaches 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. (Ex. 1007 at 39-40; Ex. 1002 ¶¶ 79-80)

The IR Standard teaches that compliant systems 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 seconds to 40 seconds. (Ex. 1007 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 ¶ 76.)

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." (Ex. 1007 at 15.)

2. Motivation to Combine Prior Art

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. (Ex. 1002 ¶¶ 100, 104, 127.) The FR '804 Publication adds certain safety features to therapeutic gas delivery systems such as, for example, the system disclosed in the '083 Patent. (Ex. 1002 ¶¶ 101, 103.) The IR Standard is a readily-available document that discloses a well-known communication interface for bedside therapy devices such as therapeutic gas delivery systems. (Ex. 1002 ¶¶ 111-17.) Accordingly, the references are in the same field of endeavor and the

problems encountered by designers of the disclosed devices substantially overlap. (Ex. 1002 ¶¶ 124-26.)

The ’083 Patent teaches a basic 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). 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 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 ¶ 100.) Indeed, the ’510 Patent itself explains 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 NO delivery system of the ’083 Patent. (Ex. 1002 ¶ 100.) Moreover, since some advantages of the ’510 Patent involve tracking gas data in the cylinders (*e.g.*, “assign patient ID to cylinders” and “identify and control cylinders for blinded clinical trials,” *see* Ex. 1004 at 7:36-47), a person of skill in the art would have

understood that the valve memory 22 disclosed in the ’510 Patent could be used to store gas data, and in turn, that data could be transmitted to a control module, as disclosed in the ’083 Patent, to control gas therapy. (Ex. 1002 ¶ 100.)

Likewise, the FR ’804 Publication discloses advantageous safety features that could have been used to enhance nitric oxide delivery systems, such as the system described in the ’083 Patent. (Ex. 1002 ¶¶ 105-08.) 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 of skill in the art would understand that the algorithms used could be modified to allow the control CPU of the ’083 Patent to compare the received data and control gas delivery as described, for example, in the FR ’804 Publication. (Ex. 1002 ¶¶ 67, 101-06.) 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. (Ex. 1002 ¶¶ 101, 119, 123.) As combined, these known prior art elements yield predictable results. The combination is also an example of applying a known technique to a known system to yield predictable results.

A person of skill in the art reading the ’083 Patent would have added a smart

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. 1002 ¶ 102.) A person skilled in the art would have added 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 ¶¶ 99-103.) Since each reference contributes its known benefits, the combination would predictably result in an improved NO delivery system. (Ex. 1002 ¶ 128.)

The FR ’804 Publication 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 smart handle and valve of the’510 Patent. As combined, gas data could be encoded in a bar code 120 as disclosed in the FR ’804 Publication, and can be read by the bar code sensor 110 and using an input port 22’ as disclosed in the ’510 Patent, the information could be transferred to the valve memory 22. (Ex. 1002 ¶¶ 101, 105-06.) Such alternative gas data sources are disclosed by the ’083 Patent and would have been obvious to one of ordinary skill in the art. (Ex. 1005 at 6:11-15; Ex. 1002 ¶ 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 ¶ 105-06.) This data would then be provided to the CPU of the '083 Patent for use in the comparisons discussed above. (*Id*.) 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. (Ex. 1002 ¶¶ 109-14.) This is particularly true given that the '510 Patent and the FR '804 Publication contain an express teaching or suggestion 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 ¶ 115.)

The IR Standard, which is one such standard, teaches how to implement optical line-of-sight communications between two devices in a patient environment. (Ex. 1007 at vi; Ex. 1002 ¶ 118.) 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. (*Id*.) 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 ¶ 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 the gas data (as described in the ’510 Patent and the FR’804 Publication) to the control module CPU for comparison. (Ex. 1002 ¶¶ 118-19, 122.)

Combining these sub-portions of a NO 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 NO delivery system, with each reference contributing its known properties and advantages. (Ex. 1002 ¶ 128.) A person of skill in the art would have been particularly motivated to incorporate the ’510 Patent’s teachings into the ’083 Patent because each of those references belongs to PO, a long-time leader in NO therapy technology. (Ex. 1002 ¶¶ 104, 127.) Because the ’083 Patent discusses the importance of using gas data to verify that the gas being delivered is the correct gas at the intended concentration (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 ¶ 102.) This motivation to look to the FR ’804 Publication 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 ¶ 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. (Ex. 1002 ¶¶ 113, 126.) 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. (Ex. 1002 ¶ 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. When combined, these references render claims 1-8 and 11-16 of the '904 Patent obvious.

3. Specific Identification of Challenge

(a) Claim 1

Claim 1, the only independent claim of the '904 Patent, is directed to "[a] valve assembly to deliver a gas comprising NO from a gas container containing the gas comprising NO."[8] Both the '510 Patent and the FR '804 Publication disclose such a valve assembly. (*See* Ex. 1004 at Abstract, 2:39-3:30; Ex. 1006 at 19.) The '510 Patent's valve can be used to deliver inhaled pharmaceutical gas, such as NO

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

(Ex. 1004 at 1:16-30)[9], and the FR '804 Publication's teachings can be used in a health facility (Ex. 1006 at 19). The '083 Patent confirms that one such pharmaceutical gas is NO. (Ex. 1009 at 2:13-30, 3:64-4:2.)

Claim 1 further requires that the valve assembly include "a valve attachable to the gas container containing the gas comprising NO, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas comprising NO through the valve to a control module." As discussed above, the proposed combination discloses a system for delivering gas comprising NO. More specifically, the '510 Patent, the '083 Patent, and the FR '804 Publication all disclose a gas container such as a cylinder or bottle. (Ex. 1004 at 2:40-42; Ex. 1005 at 3:45-47; Ex. 1006 at 19.) Figures 1 and 2 of the '510 Patent "show that the valve body 14 includes a threaded inlet port 18 which screws onto the outlet port of the cylinder 12. The valve body 14 also includes an outlet port 20." (Ex. 1004 at 2:46-49.) The handle 16 of the 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

[9] This is apparent since the '510 Patent is assigned to INO Therapeutics, LLC, a biotherapeutics company specializing in NO therapy. (Ex. 1002 ¶ 29.)

actuator that opens or closes the valve as required by claim 1. (Ex. 1002 ¶¶ 21, 58.) Thus, the NO gas exits the valve and flows into a fluid circuit, such as that disclosed in the '083 Patent. (Ex. 1005 at 3:61-5:59, Figs. 1, 2.) The fluid circuit and the control of that circuit by CPU 56 as disclosed in the '083 Patent, is an example of the claimed control module. (Ex. 1005 at 5:60-6:19.) Indeed, the '904 Patent acknowledges the '083 Patent's disclosure of a delivery module that controls the flow of gas in the circuit. (Ex. 1001 at 9:62-10:4.)

Claim 1 also requires that the valve assembly include "a circuit supported within the valve assembly and disposed between the actuator and a cap." The '510 Patent discloses circuit elements disposed between the "handle 16" (or actuator) and the "cover 24" (or cap). (*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 a processor 23, a timer 21, a reset button 27, an open/closed sensor 28, a battery 25, a display 26, and an electronic memory device 22." (Ex. 1004 at 2:58-61.) The '510 Patent also discloses that "[m]ost of the components of Fig. 2B are housed inside a compartment formed by the handle 16 and the cover 24 in this preferred embodiment." (Ex. 1004 at 3:3-29.) The "compartment" of the '510 Patent is between the actuator and the cap as required by claim 1. (Ex. 1002 ¶ 23.) Accordingly, the '510 Patent discloses circuitry (including the valve memory and valve processor discussed below) mounted in the physical arrangement

required by claim 1.

Claim 1 requires the circuit to include a "valve memory to store gas data comprising gas concentration in the gas container." As discussed above, the '510 Patent discloses a valve memory 22, disposed between the actuator and the cap. (Ex. 1004 at 2:58-61, 3:3-5, Ex. 1002 ¶ 23.) The '510 Patent discloses that gas data can be stored in the valve memory to indicate information about the gas in the cylinder. (*See* Ex. 1004 at 5:43-6:12.) This information can be used for gas therapy. (Ex. 1004 at 7:36-47.) The FR '804 Publication also discloses a memory for storing data (*i.e.*, IDb data) about the gas in the cylinder. (Ex. 1006 at 20-21.) Finally, the '083 Patent teaches that one of the gas data characteristics that can be stored and used to trigger alarms is gas concentration. (Ex. 1005 at 5:60-6:4.) The '083 Patent also teaches that the actual concentration of the gas in the cylinder can be used to "verify that the proper supply is being utilized." (Ex. 1005 at 6:5-8.) Accordingly, the combination of references in this Ground discloses that the valve memory can store gas data indicative of the concentration of gas in the container, as required by this limitation. (Ex. 1002 ¶¶ 101, 107.)

Claim 1 further requires the claimed circuit to include "a valve processor and a valve transceiver in communication with the valve memory to send wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject." The valve of the '510 Patent includes a valve

processor 23 that is responsible for, among other things, accessing the valve memory 22. (Ex. 1004 at 2:58-61, 3:40-49, 6:21-25.) The valve memory 22 of the '510 Patent stores gas data when entered by either the cylinder manufacturer or the hospital. (Ex. 1004 at 5:43-6:12.) The '510 Patent also discloses a transceiver in communication with the memory to send and receive signals to communicate the gas data to an external computer. (Ex. 1004 at 6:33-7:15; Ex. 1002 ¶¶ 26, 110-11.) The FR '804 Publication discloses communicating the IDb data to the control module 300 to determine whether the actual gas to be delivered matches the expected gas for the patient. (Ex. 1006 at 19.) In at least one embodiment, the FR '804 Publication further discloses that the IDb data can be read from a carrier (*e.g.*, a bar code) of the cylinder and stored in a memory within the valve housing. (Ex. 1006 at 21, Fig. 4.) This reading technology requires wireless optical line-of-sight. (Ex. 1002 ¶ 115.) When the valve of the '510 Patent and the FR '804 Publication are incorporated into in the '083 Patent, the combination discloses storing gas concentration data in the valve memory for subsequent communication to the CPU of the '083 Patent's control module. (Ex. 1004 at 5:43-6:2; Ex. 1002 ¶ 107.) To communicate data from the valve to the control module (a physically separate device from the valve), a person of skill in the art would have understood to use interfaces disclosed in enabling standards, such as those described in the IR Standard. (Ex. 1002 ¶¶ 108-18.) The valve processor 23 of the '510 Patent and the

transceiver of the IR Standard would work together to communicate this data. (Ex. 1004 at 3:5-7; Ex. 1007 at 40 (discussing commercially available infrared transceivers); Ex. 1002 ¶¶ 114-15.) The fact that the '510 Patent already discloses wireless transceivers for communicating data to and from the valve memory further emphasizes the ease of applying the IR Standard to communicate data from the valve memory to the control system. (Ex. 1004 at 6:13-15, 6:33-7:15; Ex. 1002 ¶ 115.) Since infrared signals are "wireless optical line-of-sight" signals (*see* Ex. 1001 at 2:55-60), the combination discloses this limitation. (Ex. 1002 ¶ 118.)

Claim 1 finally requires "a data input disposed on the actuator and in communication with said valve memory, to permit a user to enter the gas data into the valve memory." The port 22' of the '510 Patent projects through the handle of the '510 Patent (*i.e.*, the claimed actuator) and provides a mechanism to load data into the valve memory. (*See* Ex. 1004 at 2:61-64, Ex. 1002 ¶¶ 26, 105.) Port 22' is an example of the claimed data input disposed on the actuator and in communication with the valve memory. The '510 Patent teaches that gas data can be entered into the valve memory via a data input (Ex. 1004 at 6:3-12), and the '083 Patent teaches that the gas data can include gas concentration data (Ex. 1005 at 5:60-6:8). Thus, the prior art as combined discloses a data input disposed on the actuator (port 22' projecting through handle 16 of the '510 Patent) in communication with the valve memory (valve memory 22 of the '510 Patent) to

permit a user to enter gas data, including gas concentration, into the valve memory. (Ex. 1002 ¶ 105.)

(b) Claim 2

Claim 2 depends from claim 1 and requires that the "gas data is provided in a bar code disposed on the gas container and is entered into the data input by a user-operated scanning device in communication with the data input." The FR '804 Publication discloses using bar codes encoding gas data on gas containers. (Ex. 1006 at 20-21.) Further, the FR '804 Publication discloses using an appropriate sensor 110 (*e.g.*, a bar code scanning device) to read the bar code and provide the read data to a control module 300. (Ex. 1006 at 20-21.) The '510 Patent discloses that gas data is inputted into the valve memory 22 via a user operated transfer device 44. (Ex. 1004 at 5:61-6:2.) Thus the combination discloses that sensor 110 reads the gas data contained in the bar code and inputs that information into the valve memory 22 of the valve 10 of the '510 Patent. (Ex. 1002 ¶ 118.) This arrangement satisfies the additional limitations of claim 2.

(c) Claim 3

Claim 3 depends from claim 1 and requires that "the valve comprises a power source; and the valve transceiver periodically sends the wireless optical line-of-sight signals to the control module, wherein the signals are interrupted by a duration of time at which no signal is sent." The valve in the '510 Patent includes

battery 25 as a power source. (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. (Ex. 1004 at 7:1-4.) The inclusion of the phrase "at interval**s**" in this passage discloses the required periodicity and "duration of time at which no signal is sent." The IR Standard also 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 to 40 seconds. (Ex. 1007 at 15, 20.) Each time data is communicated per the IR Standard, the link disconnect time is monitored. If a pre-determined time is reached before the next frame is sent, the link is disconnected. (Ex. 1007 at 20; Ex. 1002 ¶ 76.) The link disconnect time is monitored between periodically sent optical line-of-sight signals (Ex. 1007 at 19 (periodically sent "data or status information" such as frames)) and provides the "duration of time at which no signal is sent" between signals (Ex. 1007 at 20). The combination thus discloses that signals sent from the '510 Patent valve to the '083 Patent CPU, which implements the comparison of the FR '804 Publication, are timed as required by claim 3.

(d) Claim 4

Claim 4 is directed to the valve assembly of claim 3, "wherein the duration of time at which no signal is sent comprises about 10 seconds." As discussed with regard to claim 3, the combination of references discloses that the valve transceiver

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 the claimed no-signal duration of "about 10 seconds."

(e) Claim 5

Claim 5 is directed to a gas delivery system including the valve of claim 1. As described above, the combination of the '083 Patent, the '510 Patent, the FR '804 Publication, and the IR Standard discloses the valve assembly of claim 1. This combination also discloses the additional limitations of claim 5.

In addition to the requirement that the system of claim 5 include the valve assembly of claim 1, claim 5 also requires that "the control module is in fluid communication with the outlet of the valve." The fluid circuit described in the '083 Patent, in combination with the CPU 56 that implements algorithms to control the fluid circuit, is an example of the claimed control module, and is in fluid communication with the outlet of the valve of the '083 Patent. (*See,* Ex. 1005 at Abstract, Fig. 1 (fluid communication between the outlet of valve 12 and components of the control module), 4:24-6:42; *see also* Ex. 1001 at 9:62-10:4 (describing '083 Patent as disclosing the delivery module of the claimed control module).) When the valve of the '510 Patent is incorporated in the '083 Patent, its

outlet would be in fluid communication with the fluid circuit of the ’083 Patent. (Ex. 1002 ¶ 100.) Therefore, the ’083 Patent discloses the circuit downstream from and in fluid communication with the valve output as required.

Claim 5 also requires that the control module contain “a CPU transceiver to receive line-of-sight signals from the valve transceiver.” When combined, the ’510 Patent valve communicates information in its valve memory 22 to 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, using the teachings of the IR Standard. (Ex. 1002 ¶¶ 101, 119, 121-23.) According to the IR Standard, a transceiver must be present on both devices communicating via infrared: the bedside communications controller (BCC) and the device communication controller (DCC). (Ex. 1007 at 10-11, 40 (referring to “transceivers”), *see also* 14-16 (describing transceivers that form the “physical layer”).) Accordingly, in the combination, the transceiver that must be present at the CPU of the ’083 Patent is an example of the claimed CPU transceiver to receive line-of-sight signals from the valve transceiver. (Ex. 1002 ¶¶ 119, 121-22.)

Claim 5 further requires that the control module contain a “CPU in communication with the CPU transceiver and including a CPU memory.” As discussed above, the ’083 Patent discloses a gas delivery system having components downstream of the valve to control gas delivery; one of these

components is a CPU which forms part of the control module. (*See* Ex. 1005 at 2:30-42, 5:60-6:4.) It also discloses the claimed CPU memory at least by disclosing that "various algorithms maybe stored and used as appropriate." (Ex. 1005 at 2:52-53.) The control module 300 of the FR '804 Publication is also an example of the claimed CPU and includes the required CPU memory. (Ex. 1006 at 20.) The comparison function of the control module 300 of the FR '804 Publication would be performed by the CPU of the '083 Patent when the references are combined. (Ex. 1006 at 19-20, Ex. 1002 ¶ 101.) Since the CPU receives IDb data from the valve memory via the IR Standard's communications link to perform the function of the control module 300 of the FR '804 Publication, the CPU must be in communication with the CPU transceiver to receive IDb data prior to making the required comparison.

Claim 5 also requires "a display to enter patient information into the CPU memory." The gas delivery system disclosed in the '083 Patent includes such a display: "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. (Ex. 1005 at 6:31-32.) The input concentration desired to be administered to the patient is "patient information" as claimed. (Ex. 1005 at

2:30-35, 6:29-42.) Finally, since the inputted information is stored for later use, it must be stored in the CPU memory, which communicates with the CPU for use as an input to the algorithms described in the '083 Patent. (Ex. 1005 at 2:64-67, 5:62-64.) This input data corresponds to the data IDv of the FR '804 Publication (*i.e.*, information regarding the user-desired type and concentration of gas) and is compared by the CPU with the IDb data. (Ex. 1002 ¶ 119.)

Claim 5 further requires that "the valve transceiver communicates the gas data comprising gas concentration to the CPU transceiver for storage in the CPU memory." As described above, in the proposed combination, gas data as taught by the '510 Patent and more specifically gas concentration data as taught by the '083 Patent (Ex. 1005 at 6:5-8) is stored in the valve memory as taught by the '510 Patent, and transmitted to the control module, as taught by the FR '804 Publication and the '083 Patent, wherein the data is stored in the CPU memory. (Ex. 1002 ¶ 122-24.) This occurs via the infrared transceivers taught by the IR Standard. (*Id.*)

A person of skill in the art would have understood based on the teachings of the FR '804 Publication (*i.e.*, IDb data includes data about "the type of gas contained in the bottle") and the '083 Patent (*i.e.*, gas concentration data is obtained via sensor 65), that the gas data transmitted from the valve transceiver to the CPU transceiver could include gas concentration. (Ex. 1005 at 6:5-8, Ex. 1006 at 20; Ex. 1002 ¶ 107.) Accordingly, the combination of references discloses that

the valve transceiver communicates the gas data comprising gas concentration to the CPU transceiver for storage in the CPU memory. (Ex. 1002 ¶ 107.)

Finally, claim 5 requires that "the CPU compares the patient information entered into the CPU memory via the display and the gas concentration from the valve transceiver." As discussed above, the patient information entered using the input (such as the touch screen display) of the '083 Patent is equivalent to the IDv data of the FR '804 Publication that is compared to the IDb data indicating the actual gas data. (Ex. 1002 ¶ 123.) Since IDb data would be gas concentration data received from a valve transceiver, this limitation is disclosed by the combination of the '510 Patent, the FR '804 Publication, the '083 Patent, and the IR Standard.

(f) Claim 6

Claim 6 depends from claim 5 and requires that "the valve comprises a timer including a calendar timer and an event timer, wherein the valve memory stores the date and time of opening and closing of the valve and the duration of time that the valve is open and the valve transceiver communicates the date and time of opening and closing of the valve to the CPU transceiver for storage in the CPU memory." The timers required by this limitation are present in the valve disclosed in the '510 Patent. (Ex. 1004 at 3:8-11, claims 4, 5, 10.) The '510 Patent discloses that the valve memory stores the timer data regarding opening and closing of the valve. (Ex. 1004 at 3:8-11, 3:44-47.) A person of skill in the art would have understood

that the CPU transceiver and CPU memory, which stores gas data in the valve memory and transmits the data via a valve transceiver to a CPU transceiver for purposes of performing comparisons as discussed above, could also store timer data communicated via the same transceiver arrangement. (Ex. 1002 ¶¶ 120-21.) A person of skill in the art would have understood to transmit this timer data along with the gas data based on the '510 Patent's express disclosure of communicating timer data to a CPU transceiver of a remote computer for storage in CPU memory. (Ex. 1004 at 6:33-7:15, 7:1-4; Ex. 1002 ¶¶ 120-21.)

(g) Claim 7

Claim 7 depends from claim 5 and requires that "the CPU comprises an alarm that is triggered when the patient information entered into the CPU memory and the gas data from the valve transceiver do not match." The CPU of the '083 Patent is configured to emit alarms in appropriate situations, including when delivered gas concentration does not match an input, desired concentration. (Ex. 1005 at 3:1-4, 8:1-12.) The FR '804 Publication also discloses that the control module 300 compares IDb data (data regarding the gas being delivered) and IDv data (data regarding the desired gas), and triggers an alarm if a match is not found. (Ex. 1006 at 19.) Accordingly, a person of skill in the art would have understood that in the combined prior art, the CPU of the '083 Patent would perform the comparison required by the FR '804 Publication and would issue an alarm when

the IDb data does not match the IDv data, as required by claim 7.

(h) Claim 8

Claim 8 depends from claim 5 and requires that the CPU memory stores instructions that cause the CPU processor[10] to perform certain steps. The '083 Patent teaches that "various algorithms may be stored and used as appropriate." (Ex. 1005 at 2:56-58.) In other words, the CPU memory stores instructions that allow the CPU to perform certain steps, including those discussed below.

Claim 8 further requires the CPU to "receive gas data comprising gas concentration from the valve via a wireless optical line-of-sight signal with the valve connected to the gas container containing gas comprising NO." As discussed with regard to claim 5, the combination of references underlying this Ground discloses this limitation. (*See* section IX(A)(3)(e).) As discussed with regard to claim 1, the gas in the cylinder is NO. (*See* section IX(A)(3)(a).)

Claim 8 requires the CPU to "compare the gas data with user-inputted patient information." As discussed above with regard to claim 5, the '083 Patent and the FR '804 Publication both disclose comparing gas data with user-inputted information. (*See* section IX(A)(3)(e).)

[10] There is no antecedent basis for "CPU processor." For purposes of this proceeding only, Petitioner presumes this term as used in claims 8-10 relies on the "CPU" of claim 5 for antecedent basis.

Claim 8 requires the CPU to "coordinate delivery of therapy to the patient with a medical device via the wireless optical line-of-sight signal between the CPU transceiver and the valve transceiver." The CPU in the gas delivery system of the '083 Patent executes algorithms to coordinate delivery of therapy. For example, the algorithms can be used to "obtain a steady concentration of NO in a spontaneous or continuous flow situation." (Ex. 1005 at 2:62-66; *see also* 2:56-3:25, 5:60-6:19.) Since at least the gas concentration data resulting from the combination of references is provided from the valve transceiver to the CPU transceiver via a wireless optical line-of-sight signal (Ex. 1002 ¶ 118), and that data is provided as an input to the comparison functionality (comparison of the FR '804 Publication performed by the CPU of the '083 Patent), the combination of references discloses coordinating delivery via the wireless optical line-of-sight signal as recited in this claim.

Claim 8 requires that the CPU "select a therapy for delivery to a patient based on the received patient information; and control delivery of the selected therapy to the patient." The gas delivery system disclosed in the '083 Patent provides this functionality. Specifically, 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.) This data is provided as an input to the CPU; the CPU's processing of this input is an example of the claimed selection of a therapy for delivery to a patient

based on the received patient information. (Ex. 1005 at 2:52-67, 5:60-6:15, 6:43-7:53.) The '083 Patent's disclosure that "[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" discloses controlling delivery of the selected therapy as required by this claim. (Ex. 1005 at 6:16-19, *see also* 7:49-53, 8:16-27.) The decision by the CPU of the '083 Patent to proceed with therapy based on the comparison of IDb data with IDv data (as described in the FR '804 Publication) is a further example of selecting a therapy based on the received patient information. (Ex. 1006 at 19.)

(i) Claim 11

Claim 11 depends from claim 1 and is directed to "[a] method for administering a therapy gas comprising NO to a patient" first comprising "establishing communications via a CPU transceiver with the valve assembly of claim 1 and communicating the gas data from the valve transceiver to the CPU transceiver."[11] At least the '083 Patent clearly discloses a method of administering therapy gas comprising NO to a patient. (*See, e.g.*, Ex. 1005 at claims 15-18.) Moreover, as discussed above with regard to claim 1, the combination relied on for this Ground discloses the valve assembly of claim 1. (*See* section IX(A)(3)(a).)

[11] The preamble should not be interpreted as limiting the claim. Nonetheless, as discussed with regard to claim 1, the preamble is disclosed by the prior art.

The combination further discloses communicating the gas data from the valve transceiver to the CPU transceiver at least to perform the FR '804 Publication function of providing IDb data to the control module 300 for comparison. (Ex. 1006 at 19; *see also* Ex. 1002 ¶ 123.) Since the '083 Patent requires data regarding the concentration of gas as an input to its algorithms, it further requires communicating gas data to the CPU. (Ex. 1005 at 6:5-8.)

Claim 11 requires "comparing the gas data communicated from the valve transceiver with patient information stored within a CPU memory." As discussed above with regard to claim 5, the '083 Patent discloses inputting and storing patient data, such as data indicative of a desired concentration of gas for delivery to a particular patient. (Ex. 1005 at 2:30-35, 2:64-67, 5:62-64, 6:31-32; Ex. 1002 ¶ 108.) As discussed with regard to claim 5, the FR '804 Publication's comparison function discloses this limitation. (Ex. 1006 at 19-20.)

Claim 11 also requires "coordinating delivery of therapy to a patient with the gas delivery device via a wireless optical line-of-sight signal between the CPU transceiver and the valve transceiver, selecting a therapy for delivery to the patient based on the comparison of the gas data and the patient information, and controlling delivery of the selected therapy to the patient." Claim 8 contains nearly the same language, albeit in apparatus claim form, as this limitation of claim 11. Accordingly, for the reasons discussed above with regard to claim 8, the relied-on

combination discloses these limitations of claim 11. (*See* section IX(A)(3)(h); *see also* Ex. 1005 at 2:52-67, 3:1-3:25, 5:60-6:19, 6:29-42, 6:43-7:53, 8:16-27; Ex. 1006 at 19, 20.)

Claim 11 is nothing more than a method claim incorporating the limitations of previously-addressed system claims. Thus, for the reasons previously discussed, the proposed combination discloses each limitation of the method of claim 11.

(j) Claim 12

Claim 12 depends from claim 11 and requires "ceasing delivery of the selected therapy to the patient based on the comparison of the gas data and the patient information." 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 the patient to a safer level." (Ex. 1005 at 3:14-19, *see also* 3:20-26, 8:7-11.) In other words, the '083 Patent teaches monitoring NO delivery to a patient and activating safety features if the information received by the CPU regarding the actual NO concentration does not match the desired NO therapy for the patient. According to the '083 Patent, one remedial action that can be taken if the therapy control algorithms, using the actual gas concentration and/or the desired gas concentration as inputs (*see* Ex. 1005 at 5:62-64, 6:5-8), indicate an unsafe condition is to discontinue treatment. Thus, one skilled in the art would understand from the '083 Patent that implementing such safety features would

allow the system to cease gas delivery if the gas data received from the valve memory did not correspond to the patient therapy information. (Ex. 1002 ¶ 32.)

(k) Claim 13

Claim 13 depends from claim 11 and requires "emitting an alert based on the comparison of the gas data and the patient information." As discussed above with claim 12, the CPU of the '083 Patent is configured to trigger an alarm in appropriate situations, including when delivered gas concentration does not match an input, desired concentration. (Ex. 1005 at 3:1-4, 8:1-12.) Further, the FR '804 Publication discloses that the control module 300 compares IDb data (gas data) and IDv data (patient information) and, if a match is not found, an alarm is triggered. (Ex. 1006 at 19.) A person of skill would have understood that the CPU of the '083 Patent, which would perform the comparison of the FR '804 Publication, would issue an alert based on the comparison of gas data and patient information.

(l) Claim 14

Claim 14 depends from claim 11 and requires "entering the gas data into the valve memory." The '510 Patent discloses that data can be entered into the valve memory by various mechanisms including via a computer, a hand-held device, and other "known data transfer mechanism(s)." (Ex. 1004 at 5:43-6:12.) The '510 Patent also explains that data can be entered into the valve memory initially by the gas distributor and again later by the gas user. Thus, the relied-on combination

discloses entering data into the valve memory.

(m) Claim 15

Claim 15 depends from claim 11 and further requires "entering the patient information into the CPU memory." The FR '804 Publication discloses entering IDv data that is acquired from a remote device into the control module 300. (Ex. 1006 at 21, Fig. 5.) The '083 Patent discloses an input to enable the user to enter data: "the desired NO concentration to be administered to the patient is set by the user by means of an input to CPU 56." (Ex. 1005 at 6:40-42.) The input concentration is specific to each patient and is thus "patient information" as claimed. (Ex. 1005 at 2:30-35.)

Since the inputted information is stored for later use, it must be stored in the CPU memory, which communicates with the CPU for use as an input to the algorithms described in the '083 Patent. (Ex. 1005 at 2:64-67, 5:62-64.) In the context of the combination, this data is the IDv data of the FR '804 Publication, which is compared with the IDb data. (Ex. 1006 at 20; Ex. 1002 ¶ 119.)

(n) Claim 16

Claim 16 is directed to a gas delivery device[12] comprising the valve assembly of claim 1, "and the gas container containing gas comprising NO

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

attached to the valve assembly, wherein a bar code disposed on the gas container provides the gas data." The "valve assembly of claim 1" is disclosed by the relied on combination. (*See* section IX(A)(3)(a).)

The '083 Patent discloses a gas delivery system that includes cylinders 10 for supplying gas to a fluid circuit. (Ex. 1005 at 3:45-51, Fig. 1.) The FR '804 Publication teaches affixing a data carrier 120 (such as a bar code) encoding gas data to the gas container, such as the cylinder 10 of the '083 Patent. (Ex. 1006 at 20-21.) Thus, when combined with the '083 Patent, the gas cylinder could include a bar code encoding gas data about the gas in the cylinder. (Ex. 1002 ¶¶ 101, 115, 118.) The scanner 110 of the FR '804 Publication could be used to obtain the gas data encoded in the data carrier. (*Id*.) The '083 Patent discloses that this gas data could be gas concentration (*see* Ex. 1002 ¶ 118), and thus the relied-on combination discloses this limitation of claim 16.

B. Ground 2: Claims 3 and 4 Are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over the '083 Patent in View of the '510 Patent, the FR '804 Publication, the IR Standard, and the '533 Patent[13]

1. Overview of Prior Art

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). It discloses a protocol for communicating between a device external to a human patient's body

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

and another device, such as an infusion pump, implanted in the patient's body. (Ex. 1008 at Abstract; Ex. 1002 ¶¶ 81-87.) It addresses concerns related to power management in battery-powered devices:

> 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 modules.

(Ex. 1008 at 2:18-38.) The '533 Patent also discloses that in a system that communicates between a device external to the body and a surgically 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…[)]" (Ex. 1008 at 25:4-8; Ex. 1002 ¶ 84.) The number of outbound time slots (*i.e.*, from the implanted device to the external device) may be less than, equal to, or greater than the number of inbound time slots (*i.e.*, from the external device to the implanted device). (Ex. 1008 at 25:9-17; Ex. 1002 ¶ 84, *see also* ¶ 85.)

Though the '533 Patent addresses power management in the context of implanted devices, one skilled in the art would understand from the '533 Patent that it is important to conserve power by requiring communications to only occur

as often as is necessary for a particular medical application. (Ex. 1002 ¶ 86.) In the medical application of 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 ¶ 87.)

2. Motivation to Combine the Prior Art

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 to a control system to facilitate a safety-based comparison of data on 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 devices. (Ex. 1004 at 2:58-61; Ex. 1006 at 21; Ex. 1007 at 15.) Thus, a person of skill in the art would have been motivated to further incorporate the power management teachings of the '533 Patent, which apply generally to battery-powered systems, when deciding on the specific appropriate disconnect time in the 3 to 40 second window suggested by the IR Standard. (Ex. 1002 ¶¶ 96-98, 129-32.)

The '533 Patent teaches that the periodicity of signals sent wirelessly in a battery-powered device is application-specific is thus an articulation of a proposition already familiar to those of skill in the art designing systems that include battery-powered components. (Ex. 1002 ¶ 132.) Since the combination of

references in Ground 1 discloses a battery-operated component (the valve/smart handle from the '510 Patent), combining the '533 Patent with this system involves nothing more than incorporation of well-known design considerations disclosed in the '533 Patent. (*Id.*)

A person of skill designing a wireless communications system using the IR Standard's teachings would have combined its teachings with the '533 Patent. (Ex. 1002 ¶¶ 131-33.) Such a person would have been motivated, in part, because both the '533 Patent and the IR Standard teach a system for establishing infrared communication between sub-components of a medical device. (Ex. 1008 at 11:37-55, Fig. 3; Ex. 1002 ¶¶ 131-33, 135.) Since the example range in the IR Standard document is from 3 to 40 seconds, a person of skill would have had an expectation of success when incorporating the 10 second time period articulated by the '533 Patent. 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 (Ex. 1007 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 ¶ 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. (Ex. 1002 ¶¶ 134, 136-37.)

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 cylinder is replaced, a 10 second interval, as taught by the ’533 Patent, is sufficient to achieve the desired result. (Ex. 1002 ¶¶ 96-98, 134.) When combined, the ’083 Patent, the ’510 Patent, the FR ’804 Publication, the IR Standard, and the ’533 Patent render claims 3-4 obvious.

3. Specific Identification of Challenge

(a) Claim 3

Claim 3 depends from claim 1 and requires that “the valve comprises a power source; and the valve transceiver periodically sends the wireless optical line-of-sight signals to the control module, wherein the signals are interrupted by a duration of time at which no signal is sent.” The Ground 1 combination discloses a valve that sends wireless optical line-of-sight signals to a control module. (*See* section IX(A)(3)(a).) The ’510 Patent valve includes 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 during which no signal is sent. (Ex. 1004 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.)

The '533 Patent discloses a battery-powered transceiver, and thus is concerned with conserving battery power. (*See, e.g.*, 1008 at 2:18-38, 1002 ¶ 86.) The '533 Patent also relies, in part, on infrared wireless optical line-of-sight signals. (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 save battery power. (Ex. 1008 at 25:9-12 "[I]t is generally preferred that the system have relative few outbound slots so that the implantable device doesn't consume excessive power when unsolicited messages from the implantable device are not often used.".) Accordingly, the '533 Patent discloses the additional limitations of claim 3.

(b) Claim 4

Claim 4 is directed to the valve assembly of claim 3, "wherein the duration of time at which no signal is sent comprises about 10 seconds." The prior art relied on herein discloses the periodicity required by claim 3. (*See* section IX(A)(3)(c), IX(B)(3)(a).) The IR Standard teaches that the period of time between signals can be between 3 and 40 seconds. (Ex. 1007 at 20.)

To the extent the IR Standard does not disclose the duration of "about 10 seconds", the '533 Patent discloses this specific duration. (*See* Ex. 1008 at 25:5-6.)

A person of ordinary skill in the art would have looked to the ’533 for its power management teachings and would have understood that at least the ’533 Patent discloses the additional limitations of claim 4. (Ex. 1002 ¶¶ 129, 134-37.)

C. Ground 3: Claims 9 and 10 Are Unpatentable Under 35 U.S.C. § 103(a) as Obvious Over the ’083 Patent in View of the ’510 Patent, the FR ’804 Publication, the IR Standard, and the ’398 Patent[14]

1. Overview of Prior Art

The ’398 Patent (Ex. 1010) was filed on December 3, 1982 and issued on July 31, 1984. (Ex. 1002 ¶¶ 88-95.) It is prior art to the ’904 Patent under 35 U.S.C. § 102(b). The ’398 Patent is directed to a respirating gas supply apparatus that uses valves to supply gas to a patient. (Ex. 1010 at Abstract.) According to the ’398 Patent, a control circuit operates a valve to supply pulses of gas through a cannula to a patient while the patient is inhaling. (Ex. 1010 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, “a false signal from pin 5 stops the transistor T1 from conducting, so that the signal on line L3 goes false” and the LED is no longer illuminated. (Ex. 1010 at 11:47-63; Ex. 1002 ¶ 93.)

The ’398 Patent discloses delivering gas simultaneously from two sources of

[14] The ’398 Patent was not considered during prosecution.

gas. (*See* Ex. 1010 at Abstract; Ex. 1002 ¶ 89.) Such a system would require coordinating the opening and closing of related valves. (*Id.*) 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, the system includes a second gas source and a second valve. (Ex. 1010 at 7:30-51; Ex. 1002 ¶ 91.) The '398 Patent discloses 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." (Ex. 1010 at 13:57-65; Ex. 1002 ¶¶ 91-92.) Thus, the L3 signal in the dual-source embodiment can indicate when both valves are open. (Ex. 1002 ¶ 93-95.)

FIG. 5 is "a schematic diagram showing a control means according to an embodiment of the invention." (Ex. 1010 at 3:64-65.) The '398 Patent explains that "[t]he 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. (Ex. 1010 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. (Ex. 1010 at Fig. 5; *see also* Ex. 1002 ¶¶ 93-95.) In the dual gas embodiment of the '398 Patent, when both valves are open, the LED 92 is illuminated. (*Id.*) Otherwise, it is not illuminated. (Ex. 1010 at 13:57-65.)

2. Motivation to Combine Prior Art

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, as discussed with regard to Ground 1 above. (Ex. 1002 ¶¶ 96-98, 138-50.)

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 shut down delivery of gas from connected sources. (*See* Ex. 1010 at 13:57-65.) Finally, 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, the '398 Patent and the '083 Patent are directed to the same field of endeavor, and seek to solve the same problems. (Ex. 1002 ¶¶ 142-44.)

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.

(Ex. 1002 ¶¶ 146-48.) A person of skill 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*.) 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 ¶ 148.) The generation and use of L3 in this way constitutes the application of a known technique (providing a signal indicative that each of two 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 discontinuing delivery of the gas). 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 multiple valves are open would be well within the knowledge and capabilities of a person having ordinary skill in the art.

The FDA Guidance’s statement that “[t]he device should include provision for attachment of two nitric oxide cylinders, which can be used alternately…” constitutes further suggestion to look to the ’398 Patent’s dual-valve alarm when implementing the system of the ’083 Patent. (Ex. 1012 at 6; Ex. 1002 ¶¶ 140-41.)

The Ground 1 combination 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 ¶ 145.) When combined, the art teaches using control signals to discontinue delivery of the therapy gas if the algorithms executed bythe CPU call for it. (*See* Ex. 1005 at 8:7-11; Ex. 1002 ¶¶ 149-50.) 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.

Accordingly, 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, generated by the valve open/closed sensor of the ’510 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 claims 9 and 10 obvious.

3. Specific Identification of Challenge

(a) Claim 9

Claim 9 depends from claim 8 and requires that the memory “further comprises instructions that cause the CPU processor to: receive a first valve status selected from a first open position and a first closed position from a first valve via a first wireless optical line-of-sight signal with the 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 via a second wireless optical line-of-sight signal with the 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, respectively, are open. (*See* Ex. 1010 at 13:57-65.) The ’510 Patent discloses that sensors in the valve handles can be the source for L3 and L3’. (Ex. 1004 at 3:16-29.) When the L3 signal, generated per the ’510 Patent’s teachings, is incorporated in the combination of references, the result is a dual-valve, dual-gas system. (Ex. 1002 ¶¶ 138-39.) In the resulting system, the signals on L3 and L3’ are communicated from the valve to the processing circuitry via wireless optical line-of-sight signals.

(Ex. 1002 ¶ 145.) Moreover, when the two inputs are provided to the CPU of the '083 Patent, that CPU compares those signals to determine whether both valves are open. (Ex. 1002 ¶ 138.) 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 of the '510 Patent and compares those 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*.)

Claim 9 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. (Ex. 1010 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 13:65 (alarm resulting from detection that two valves are open may be "audible and/or visual").) Accordingly, the '398 Patent discloses comparing the first valve status and the second valve status and emitting an alarm if the first valve status comprises the first open position and the second

valve status comprises the second open position, as required by this claim.

(b) Claim 10

Claim 10 depends from claim 9 and requires instructions that cause the CPU to "terminate delivery of therapy if the first valve status comprises the first open position and the second valve status comprises the second open position."

As discussed with regard to claim 9, the '398 Patent discloses signals that indicate when two valves on two different gas containers are open at the same time. (*See, e.g.*, Ex. 1010 at 13:57-65.) The dual-gas system described in the '398 Patent is presented in the context of two gasses that can be safely delivered together (*i.e.*, oxygen and an anesthetic). (Ex. 1010 at 14:8-12.) A person of skill in the art reading the '398 Patent would understand that the same signal used to drive the LED 92 when both valves are open could be used as an input to a CPU that decides to discontinue treatment, such as by actuating the shutoff valve 14 in the '083 Patent. (Ex. 1005 at 3:14-27, 8:7-11; Ex. 1002 ¶ 149-50.) Using the '083 Patent's teaching that treatment can be ceased when concentration of NO is too high, a person of skill in the art would have understood that if the two valves of the '398 Patent are each connected to cylinders of NO, and are both open, the concentration of NO could become too high and the signal used to drive the LED 92 of the '398 Patent could instead be used to drive the shutoff valve 14 of the '083 Patent. (Ex. 1005 at 6:16-19, 8:8-11; Ex. 1002 ¶¶ 149-50.) Indeed, the '083 Patent

discloses that when the appropriate condition occurs, CPU 56 "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 8:8-10.) Incorporating the '398 Patent's teachings with the teachings of the '083 Patent results in a system where the L3 signal of the '398 Patent, which indicates whether two valves in a dual-valve configuration are open, can drive the shutoff valve 14 of the '083 Patent. (Ex. 1002 ¶¶ 148-50.) In a medical application where two valves being open simultaneously could present a dangerous condition, the '083 Patent teaches that such a condition could be rectified by discontinuing delivery of gas. (*Id*.)

X. CONCLUSION

Petitioner requests institution of *inter partes* review and cancellation of claims 1-16 of the '904 Patent based on the grounds presented above.

Respectfully submitted by

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