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

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CASE IPR: UNASSIGNED
U.S. PATENT NO. 8,573,209

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PETITION FOR *INTER PARTES* REVIEW

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U.S. Patent and Trademark Office
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I. INTRODUCTION

Praxair Distribution, Inc. ("Petitioner" or "Praxair") hereby petitions for *inter partes* review of claims 1-7 of U.S. Patent No. 8,573,209 ("'209 Patent") (Ex. 1001) under 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42.

II. THE '209 PATENT

A. Overview of the '209 Patent

The '209 Patent is listed in the U.S. Food and Drug Administration's ("FDA") list of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book") in connection with the prescription drug product INOMAX®. The patent owner and new drug application holder INO Therapeutics, LLC d/b/a Ikaria, Inc. ("PO") is the exclusive U.S. supplier of iNO. PO filed the application that issued as the '209 Patent twelve years after it released INOMAX®[1] in the market. PO's original patents covering iNO expired in 2013, and PO is now trying to use the '209 Patent to impermissibly extend its patent monopoly on INOMAX® to 2031, *35 years* after the original INOMAX patents issued.[2]

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

[2] The '209 Patent expires on January 6, 2031. Petitioner is concurrently filing petitions for *inter partes* review of four other Orange Book listed patents that

The ’209 Patent does not claim inventive methods and 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 16:22-40; 17:1-34; Ex. 1002 ¶36, 40-60.) Indeed, the valves and control systems claimed by the ’209 Patent largely mirror valves and control systems PO itself patented years before January 6, 2011, the earliest possible priority date for the ’209 Patent. As detailed below, claims of the ’209 Patent largely mirror valves and control systems PO itself patented years before filing the application that issued as the ’209 Patent. (*See generally* Ex. 1004, Ex. 1005.)

B. Summary of the Prosecution of the ’209 Patent

The application that issued as the ’209 Patent was filed on June 11, 2012 after being filed as a national stage entry of International Application No. PCT/US2011/020319, which was filed January 6, 2011. (Ex. 1016 at 164.)[3] On June 12, 2012, PO submitted a preliminary amendment to rewrite certain dependent claims in independent form. (Ex. 1016 at 99-103.)

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similarly would extend PO’s monopoly: U.S. Patent Nos. 8,291,904; 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 of the ’209 Patent.

On March 15, 2013, the Examiner issued a non-final office action rejecting the claims, among other reasons, as invalid over U.S. Patent No. 7,114,510 to Peters (*i.e.*, the '510 Patent (Ex. 1004) herein) and for obvious-type double patenting over the claims of U.S. Patent No. 8,291,904. (Ex. 1016 at 187-200.)

On May 14, 2013, PO conducted an examiner interview. In addition to agreeing to minor amendments to correct antecedent basis, PO agreed to an amendment to the independent claims requiring the following language, which would allegedly overcome the rejections over the '510 Patent:

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

(Ex. 1016 at 210-13.) Finally PO agreed to file a terminal disclaimer to overcome the double patenting rejection. (*Id*.) On June 17, 2013, PO filed a terminal disclaimer and an amendment to the independent claims pursuant to the discussion during the interview. (Ex. 1016 at 217-29, 237.) The amendment to claim 2, reproduced below, is representative:

2. (Currently Amended) A gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:

a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve to a control module; and

a circuit including:

memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration and

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

wherein the valve further comprises a data input in communication with said memory, to permit a user to enter the gas data into the memory.

(Ex. 1016 at 220.)

The Examiner issued a notice of allowance on August 19, 2013. (Ex. 1016 at 248-55.) In the notice of allowance, the Examiner provided the following statement of reasons for allowance:

> The closest prior art of record Peters [the '510 Patent] discloses a valve with a smart handle including a memory module, a processor and a transceiver. Peters also discloses that the memory is able to store gas data comprising gas identification. Peters also discloses that the processor and transceiver for communicating gas data to a control module. However, Peters fails to disclose, teach, or fairly suggest a circuit including a processor and transceiver that is able to communicate with the memory to send and receive wireless signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the correct gas, the

> correct gas concentration and that the gas is not expired. Therefore, claims 2-5, 7, 9, and 10 have been found allowable since any conclusion of obviousness would be based upon improper hindsight reasoning using knowledge gleaned only from the applicant's disclosure.

(Ex. 1016 at 254.) PO did not comment on the reasons for allowance, and the '209 Patent issued on November 5, 2013. (Ex. 1016 at 274.)

III. BACKGROUND OF THE TECHNOLOGY

As indicated by PO's prior art patents incorporated by reference in the '209 Patent (which are statutory bars under 35 U.S.C. § 102(b)), the assemblies and systems claimed in the '209 Patent recite components or sub-systems that were well known before January 6, 2011.

The '510 Patent is owned by PO and is titled "Valve with Smart Handle." (Ex. 1004, Ex. 1001 at 7:26-28.) 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 '209 Patent, it was known in the art to affix a valve to a gas cylinder (Ex. 1002 ¶ 19), 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.) 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, 37-38.) 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.) The transmitted data could include gas data about the gas in the cylinder. (Ex. 1004 at 5:45-6:12, Ex. 1002 ¶¶ 27-28, 39.)

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.) 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. The system would then generate an alarm and/or close a valve to stop NO delivery as appropriate. (Ex. 1005 at 5:60-65.)

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 '209 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 '209 Patent. Accordingly, the claims are not patentable and should be canceled.

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

Petitioner certifies that (1) the '209 Patent, issued on November 5, 2013, is available for *inter partes* review; (2) Petitioner is not barred or estopped from requesting *inter partes* review of the '209 Patent on the grounds identified herein; and (3) Petitioner has not filed a complaint relating to the '209 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)

In accordance with 37 C.F.R. § 42.15 and § 42.103, Petitioner authorizes the USPTO to charge the required fees for *inter partes* review of 7 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 '209 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 '209 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 or 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 '209 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 '209 Patent should be given their "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Tech., LLC*, Case No. 14-1301, slip op. at 16, 18-19 (Fed. Cir. Feb. 2, 2015). While the specification cannot be used to impermissibly narrow the meaning of a 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 the '209 Patent to have its plain and ordinary meaning, and would have understood that no term requires special construction for purposes of this proceeding."[4] In this proceeding, the '510 Patent and the '083 Patent are owned by PO. Since the '209

[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).

Patent incorporates the ’510 Patent and the ’083 Patent by reference, claim terms of the ’209 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 1-7 of the ’209 Patent based on the following grounds:

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)	1-7
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

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]

Claims 1, 3, 5, and 6 are the independent claims of the ’209 Patent. Claim 1 is illustrative, and recites:

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

A gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:

a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve to a control module; and

a circuit including:

memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration and

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

wherein the valve further comprises a data input in communication with said memory, to permit a user to enter the gas data into the memory.

(Ex. 1001 at 16:22-40.)

A. Ground 1: Claims 1-7 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

[6] The '510 Patent and the '083 Patent are both incorporated by reference in the '209 Patent. (*See* Ex. 1001 at 7:26-28, 9:49-52; Ex. 1002 ¶ 35.)

September 24, 1996. (Ex. 1002 ¶ 30.) The '083 Patent is assigned to PO (Ex. 1009), and its lead inventor (Duncan Bathe) is the same as the lead inventor as the '209 Patent. The '083 Patent is prior art under 35 U.S.C. § 102(b).

The '083 Patent discloses a nitric oxide delivery system in which a series of valves 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. 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.) The '083 Patent discloses a NO system that "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; Ex. 1002 ¶ 31.) The system of the '083 Patent is advantageous because it can modify the gas in the cylinder to a gas that is 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; Ex. 1002 ¶ 32.) The CPU also triggers alarms if faults occur during NO delivery. (Ex. 1005 at 3:1-4; Ex. 1002 ¶ 32.) 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; Ex. 1002 ¶¶ 33-34.) 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. (Ex. 1002 ¶ 20.) 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 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 6:4-8.)

After the appropriate data is loaded into the 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; Ex. 1002 ¶

21.) 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 some embodiments, 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 broadly states 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 transfer of the logged position data 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] (Ex. 1002 ¶ 61.) Accordingly, the FR '804 Publication constitutes prior art under 35 U.S.C. § 102(b).

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

The FR '804 Publication is assigned on its face to *L'Air Liquide Societe Anonyme Por L'Etude Et L'Exploitation Des Procedes Georges Claude* ("Air Liquide"). (Ex. 1002 ¶ 63.) 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 art would understand that the FR '804 Publication covers a system that can be used to deliver iNO. (Ex. 1002 ¶¶ 63-64.)

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; Ex. 1002 ¶ 65.) 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, identified as numeral 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 in the event the comparison is positive (*i.e.*, the gas in the cylinder matches the gas expected to be delivered), supplies a control signal to open a valve and deliver gas from the cylinder to the fluid circuit. (Ex. 1006 at 18.) If a negative comparison occurs

(*i.e.*, the gas in the cylinder does not match the gas expected to be delivered), an audible or visible alarm can be emitted to indicate the mismatch. (Ex. 1006 at 19; Ex. 1002 ¶¶ 66-67.)

The FR '804 Publication discusses the source for the data the control module 300 uses to make its comparison. It discloses that the identification data of the gas in the bottle 10 (referred to as "IDb data") can be stored on an information carrier 120 affixed to bottle 10. (Ex. 1006 at 20; Ex. 1002 ¶ 68.) 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 (Ex. 1006 at 14), 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 be used to 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, 105.) 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; Ex. 1002 ¶ 71.) The IR Standard states that its teachings are 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 an architecture in which 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") that must be supported by compliant systems. (Ex. 1007 at 33; Ex. 1002 ¶¶ 74-76.) The IR Standard teaches not only how to build an IR-communicating system from scratch, but also 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 ¶¶ 78-81.)

The IR Standard also 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; Ex. 1002 ¶ 77.) It explains that while appropriate waiting periods are application-specific, supported waiting periods are on the order of several seconds, typically ranging from 3 seconds to 40 seconds. (Ex. 1007 at 20.) In other words, the IR Standard specifies that signal communication between remote modules be configured to have periods ranging from 3 seconds to 40 seconds during which no signal is sent.

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

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 ¶¶ 89-121.) 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 ¶ 97.) 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 ¶ 94.) The IR Standard, a publication by a ubiquitous industry organization, is a readily-available document that discloses a well-known communication interface for bedside therapy devices such as therapeutic gas delivery systems. (Ex. 1002 ¶ 106.) Accordingly, the references are in the same field of endeavor and the problems encountered by designers of the disclosed devices substantially overlap. (Ex. 1002 ¶¶ 118-119.)

The '083 Patent teaches a basic NO delivery system and 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, a CPU 56 for controlling therapy, and a ventilator for delivering gas to a patient (*see* Ex. 1005 at 6:20-28; Ex. 1002 ¶ 93.) The '510 Patent discloses an advanced or smart valve and handle

attached to a gas cylinder for storing and transmitting information about the gas to a remote module. A person of skill in the art would have known to combine the control module disclosed the '083 Patent with the smart valve and handle disclosed in the '510 Patent to obtain both the benefits of the smart handle of the '510 Patent and the benefits of the delivery system of the '083 Patent. (Ex. 1002 ¶¶ 93, 96.) Indeed, the '510 Patent itself explains that the taught valves 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 ¶¶ 93, 96.) Moreover, since some of the 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 ¶¶ 98-101, 104.)

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. 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 ¶ 116.) A person of skill in the art would have understood 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 ¶ 116.) 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 ¶ 116.) 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 been motivated to add a smart handle and valve, as disclosed in the ’510 Patent, to the NO delivery system disclosed in the ’083 Patent in order to allow the user to better link the gas information with patient treatments. (Ex. 1002 ¶ 96.) A person of skill in the art would have also been motivated to add additional 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 ¶ 94.) Since each reference contributes its known benefits, the combination would predictably result in an improved NO delivery system. (Ex. 1002 ¶¶ 98-101.)

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. (Ex. 1002 ¶ 100.) 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 ¶¶ 98-101.) Such alternative gas data sources are expressly contemplated 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 ¶¶ 98-101.)

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. This data would then be provided to the CPU of the '083 Patent for use in the comparisons discussed above. (Ex. 1002 ¶ 94.) 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 ¶¶ 105-111.) 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 ¶ 108.)

The IR Standard, which is one such standard, teaches a person of skill in the art how to implement optical line-of-sight communications between two devices in a patient environment. (Ex. 1007 at vi; Ex. 1002 ¶ 106.) Relying on the IR Standard, a person of skill in the art would have understood to implement infrared transceivers (which use optical line-of-sight to communicate) on the valve and control system to communicate data from the valve memory to the control system for processing by the CPU. (*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 ¶ 109.) 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 ¶¶ 111-112.)

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 ¶ 111-112.) 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 ¶ 97.) 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 ¶ 101.) 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 ¶ 120.) Finally, 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 ¶¶ 108-111, 119.) 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 ¶ 117.)

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 1-7 of the '209 Patent obvious.

3. Specific Identification of Challenge

(a) Claim 1

Claim 1 recites "[a] gas delivery device to administer therapy gas from a gas source."[8] The '083 Patent and the FR '804 Publication both disclose a gas delivery device. (*See* Ex. 1005 at Abstract; Ex. 1006 at 17; Ex. 1002 ¶ 62.) In the '083 Patent the gas delivery device includes a gas source to provide therapy gas. (Ex. 1005 at Abstract, 3:43-4:2.) The '510 Patent's valve can be used to deliver inhaled pharmaceutical gas, (Ex. 1004 at 1:16-30; Ex. 1002 ¶29), and the FR '804 Publication's teachings can be used in a health facility. (Ex. 1006 at 19.)

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

(i) Valve Limitation

Claim 1 further requires "a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve to a control module."

As discussed above, the proposed combination discloses a system for delivering therapy gas. 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 actuator that opens or closes the valve as required by claim 1. (Ex. 1002 ¶¶ 21, 93.) Thus, the therapy 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

'209 Patent acknowledges the '083 Patent's disclosure of a delivery module that controls the flow of gas in the circuit. (Ex. 1001 at 9:43-52.)

(ii) Memory Limitation

Claim 1 also requires "a circuit including: memory to store gas data comprising one or more of gas identification, gas expiration date, and gas concentration."

As discussed above, the '510 Patent discloses a valve memory disposed between the actuator and the cap. (Ex. 1004 at 2:58-61, 3:3-5, Ex. 1002 ¶¶ 23, 98.) 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.) The disclosed data includes at least "gas identification" (Ex. 1004 at 5:49-50, 5:54-55) and "gas expiration date" data (by virtue of the "Born on date", Ex. 1004 at 5:48), both of which are recited as part of the claimed *Markush* group. (*See also* Ex. 1004 at 7:36-51; Ex. 1002 ¶¶ 25, 27.) This confirms the examiner's undisputed finding that at least the '510 Patent discloses a circuit including a memory to store gas identification data. (Ex. 1016 at 254.)

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 stores gas data as required by this limitation. (Ex. 1002 ¶ 100.)

(iii) Processor/Transceiver Limitation

Claim 1 further requires the claimed circuit to include "a processor and a transceiver in communication with the memory to send and receive wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the correct gas, the correct gas concentration, and that the gas is not expired."

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 ¶ 93.)

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 ¶ 103.) 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 memory 22 for subsequent communication to the CPU of the '083 Patent's control module. (Ex. 1004 at 5:43-6:2.)

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 ¶¶ 105-107.) The valve processor 23 of the '510 Patent and the transceiver of '510 Patent/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 ¶ 107.) 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 ¶¶ 105-107.) Since infrared signals are "wireless optical line-of-sight" signals (*see* Ex. 1001 at 9:65-10:7), the relied-on combination discloses this limitation of a processor and a transceiver in communication with the

memory to send and receive signals to communicate the gas data to the control module that controls gas delivery to a subject.

In regards to the limitation of verifying one or more of the correct gas, gas concentration, and that the gas is not expired, the ’083 Patent discloses verification that the gas being delivered is the expected gas. (Ex. 1005 at 6:5-15.) The FR ’804 Publication also discloses a comparison function that verifies that the gas being delivered is the expected gas. (Ex. 1006 at 17 (determines “gas bottle whose content does not correspond to the gas intended for use”).) The comparison performed by the control module 300 of the FR ’804 Publication specifically verifies whether the “type of the gas contained in the bottle 10 corresponds to the type of gas intended to supply the circuit…” (Ex. 1006 at 19.) The FR ’804 Publication’s disclosure of “positive” or “negative” “comparison” thus discloses the verification required by this limitation. (Ex. 1006 at 18, 19.) Accordingly when the FR ’804 Publication’s verification functionality is performed by the CPU of the ’083 Patent, as in the combination relied on herein, the prior art discloses this limitation. (Ex. 1002 ¶¶ 116-117.) Thus, the combination discloses the one limitation the examiner did not find was present in ’510 Patent alone. (Ex. 1016 at 254.)

(iv) Data Input Limitation

Claim 1 finally requires “a data input disposed in communication with said

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.) 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 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 memory. (Ex. 1002 ¶¶ 98-101.)

(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 source 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 ¶¶ 98-99.) This arrangement satisfies the additional limitations of claim 2.

(c) Claim 3

Independent claim 3 recites "[a] gas delivery device to administer therapy gas from a gas source."[9]

The '083 Patent and the FR '804 Publication both disclose a therapy gas delivery system including a gas delivery device. (*See* Ex. 1005 at Abstract; Ex. 1006 at 19.) In the '083 Patent, the gas delivery device includes a gas source to provide therapy gas. (Ex. 1005 at Abstract, 3:43-4:2.) The '510 Patent's valve can be used to deliver inhaled therapy gas, (Ex. 1004 at 1:16-30), and the FR '804 Publication can also be used to provide therapy gas (Ex. 1006 at 19).

(i) Valve Limitation

Claim 3 requires the gas delivery device includes "a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve to a

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

control module." This limitation is the same as the limitation in claim 1 described above in Section IX(A)(3)(a)(i). As discussed above with regard to claim 1, the '510 Patent discloses the claimed valve (Ex. 1004 at 2:46-49, 2:52-55) attached to the gas source of the '510 Patent, the '083 Patent, and the FR '804 Publication. (*See* Section IX(A)(3)(a)(i) for full explanation of how the prior art teaches this limitation; Ex. 1004 at 2:40-42; Ex. 1005 at 3:45-47; Ex. 1006 at 19.) This confirms what the examiner found (and PO did not dispute) during prosecution. (Ex. 1016 at 254.)

(ii) Memory Limitation

Claim 3 further requires "a circuit including: memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration." This limitation is the same as the limitation in claim 1 described above in Section IX(A)(3)(a)(ii). As discussed above with regard to claim 1, the '510 Patent discloses a valve memory, indicated by numeral 22, that stores gas data. (*See* Section IX(A)(3)(a)(ii) for full explanation of how the prior art teaches this limitation; Ex. 1004 at 2:58-61, 3:3-5, 5:43-6:12, *see also* 7:36-51; *see also* Ex. 1016 at 254.) IDb of the FR '804 Publication is also an example of gas data. (Ex. 1006 at 20-21, Fig. 4.) The '083 Patent uses gas concentration in its gas control algorithms to verify the proper supply is being used. (Ex. 1005 at 5:60-6:8.) In the combination, this gas data would be stored in the '510 Patent's valve

memory. (Ex. 1002 ¶ 98.)

(iii) Processor/Transceiver Limitation

Claim 3 further requires "a processor and a transceiver in communication with the memory to send and receive wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired." This limitation is the same as the limitation in claim 1 described above in Section IX(A)(3)(a)(iii).

As discussed above, the valve of the '510 Patent includes a valve processor 23 that is responsible for, among other things, accessing the valve memory 22 and the gas data stored therein. (Ex. 1004 at 2:58-61, 3:40-49, 5:43-6:12, 6:21-25.) The '510 Patent also discloses a transceiver in communication with the memory to send and receive signals to communicate the gas data to an external computer. (*See* Section IX(A)(3)(a)(iii) for full explanation of how the prior art teaches this limitation; Ex. 1004 at 6:33-7:15.) This is consistent with the examiner's uncontested conclusion during prosecution that the '510 Patent discloses "that the processor and transceiver communicates gas data to a control module." (Ex. 1016 at 254.)

(iv) Power Source Limitation

Last, claim 3 requires that "the valve comprises a power source; and the

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.) 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

Independent claim 5 recites a "gas delivery system"[10] that comprises "a gas delivery device to administer therapy gas from a gas source." The '083 Patent and the FR '804 Publication both disclose a gas delivery device. (*See* Ex. 1005 at Abstract; Ex. 1006 at 17.) In the '083 Patent the gas delivery device includes a gas source to provide therapy gas. (Ex. 1005 at Abstract, 3:43-4:2.) The '510 Patent's valve can be used to deliver inhaled pharmaceutical gas, (Ex. 1004 at 1:16-30), and the FR '804 Publication can be used to provide therapy gas. (Ex. 1006 at 19.)

(i) Valve Limitation

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

Claim 5 requires the gas delivery device includes "a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve to a control module that controls gas delivery to a subject." This limitation includes the same elements as the limitation in claim 1 described above in Section IX(A)(3)(a)(i) and further includes the limitation that the control module controls gas delivery to a subject as described in Section IX(A)(3)(a)(iii). As discussed above with regard to claim 1, the '510 Patent discloses the claimed valve (Ex. 1004 at 2:46-49, 2:52-55) attached to the gas source of the '510 Patent, the '083 Patent, and the FR '804 Publication. (*See* Section IX(A)(3)(a)(i) and IX(A)(3)(a)(iii) for full explanation of how the prior art teaches these limitations; Ex. 1004 at 2:40-42; Ex. 1005 at 3:45-47; Ex. 1006 at 19.) This confirms what the examiner found (and PO did not dispute) during prosecution. (Ex. 1016 at 254.)

(ii) Memory Limitation

Claim 5 further requires "a circuit including: memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration." This limitation is the same as the limitation in claim 1 described above in Section IX(A)(3)(a)(ii). As discussed above with regard to claim 1, the '510 Patent discloses a valve memory, indicated by numeral 22, that stores gas data. (*See* Section IX(A)(3)(a)(ii) for full explanation of how the prior art teaches

this limitation; Ex. 1004 at 2:58-61, 3:3-5, 5:43-6:12, *see also* 7:36-51; *see also* Ex. 1016 at 254.) IDb of the FR '804 Publication is also an example of gas data. (Ex. 1006 at 20-21, Fig. 4.) The '083 Patent uses gas concentration in its gas control algorithms to verify the proper supply is being used. (Ex. 1005 at 5:60-6:8.) In the combination, this gas data would be stored in the '510 Patent's valve memory. (Ex. 1002 ¶ 98.)

(iii) Processor/Transceiver Limitation

Claim 5 further requires "a processor and a transceiver in communication with the memory to send and receive wireless optical line-of-sight signals to communicate the gas data to the control module and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired." This limitation is the same as the limitation in claim 1 described above in Section IX(A)(3)(a)(iii).

As discussed above, the valve of the '510 Patent includes a valve processor 23 that is responsible for, among other things, accessing the valve memory 22 and the gas data stored therein. (Ex. 1004 at 2:58-61, 3:40-49, 5:43-6:12, 6:21-25.) The '510 Patent also discloses a transceiver in communication with the memory to send and receive signals to communicate the gas data to an external computer. (*See* Section IX(A)(3)(a)(iii) for full explanation of how the prior art teaches this limitation; Ex. 1004 at 6:33-7:15.) This is consistent with the examiner's

uncontested conclusion during prosecution that the '510 Patent discloses "that the processor and transceiver communicates gas data to a control module." (Ex. 1016 at 254.)

(iv) Control Module Limitation

Additionally, claim 5 requires that "the control module is in fluid communication with the outlet of the valve and a ventilator." 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 and ventilator of the '083 Patent. (Ex. 1002 ¶ 93.) Therefore, the '083 Patent discloses the circuit downstream from and in fluid communication with the valve output and ventilator as required. (Ex. 1002 ¶ 93.)

Claim 5 also requires that the control module contain "a CPU transceiver to receive line-of-sight signals from the 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 ¶¶ 106-107.) 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 ¶¶ 107, 108, 111.)

Claim 5 further requires that the control module contain a “central processing unit (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 20.) 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 further requires that "the transceiver communicates the gas data 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 ¶ 114.) This transmission occurs via the infrared transceivers taught by the IR Standard. (Ex. 1002 ¶¶ 114-115.) 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 ¶

111.) 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 ¶ 114.)

(v) Timer Limitation

Finally, claim 5 requires that "the valve comprises a timer including a calendar timer and an event timer, wherein the 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 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 ¶ 113.) 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 ¶¶ 113-115.)

(f) Claim 6

Independent claim 6 recites a "gas delivery system"[11] that comprises "a gas delivery device to administer therapy gas from a gas source." The '083 Patent and the FR '804 Publication both disclose a gas delivery device. (*See* Ex. 1005 at Abstract; Ex. 1006 at 17.) In the '083 Patent the gas delivery device includes a gas source to provide therapy gas. (Ex. 1005 at Abstract, 3:43-4:2.) The '510 Patent's valve can be used to deliver inhaled pharmaceutical gas, (Ex. 1004 at 1:16-30), and the FR '804 Publication can be used to provide therapy gas. (Ex. 1006 at 19.)

(i) Valve Limitation

Claim 6 requires the gas delivery device includes "a valve attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve to a control module that controls gas delivery to a subject." This limitation includes the same elements as the limitation in claim 1 described above in Section IX(A)(3)(a)(i) and further includes the element of the control module controls gas delivery to a subject as described in Section IX(A)(3)(a)(iii). As discussed above with regard to claim 1, the '510 Patent discloses the claimed valve (Ex. 1004 at

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

2:46-49, 2:52-55) attached to the gas source of the '510 Patent, the '083 Patent, and the FR '804 Publication. (*See* Section IX(A)(3)(a)(i) and Section IX(A)(3)(a)(iii) for full explanation of how the prior art teaches these limitations; Ex. 1004 at 2:40-42; Ex. 1005 at 3:45-47; Ex. 1006 at 19.) This confirms what the examiner found (and PO did not dispute) during prosecution. (Ex. 1016 at 254.)

(ii) Memory Limitation

Claim 6 further requires "a circuit including: memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration." This limitation is the same as the limitation in claim 1 described above in Section IX(A)(3)(a)(ii). As discussed above with regard to claim 1, the '510 Patent discloses a valve memory, indicated by numeral 22, that stores gas data. (*See* Section IX(A)(3)(a)(ii) for full explanation of how the prior art teaches this limitation; Ex. 1004 at 2:58-61, 3:3-5, 5:43-6:12, *see also* 7:36-51; *see also* Ex. 1016 at 254.) IDb of the FR '804 Publication is also an example of gas data. (Ex. 1006 at 20-21, Fig. 4.) The '083 Patent uses gas concentration in its gas control algorithms to verify the proper supply is being used. (Ex. 1005 at 5:60-6:8.) In the combination, this gas data would be stored in the '510 Patent's valve memory. (Ex. 1002 ¶ 116.)

(iii) Processor/Transceiver Limitation

Claim 6 further requires "a processor and a transceiver in communication

with the memory to send and receive wireless optical line-of-sight signals to communicate the gas data to the control module and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired." This limitation is the same as the limitation in claim 1 described above in Section IX(A)(3)(a)(iii).

As discussed above, the valve of the '510 Patent includes a valve processor 23 that is responsible for, among other things, accessing the valve memory 22 and the gas data stored therein. (Ex. 1004 at 2:58-61, 3:40-49, 5:43-6:12, 6:21-25.) The '510 Patent also discloses a transceiver in communication with the memory to send and receive signals to communicate the gas data to an external computer. (*See* Section IX(A)(3)(a)(iii) for full explanation of how the prior art teaches this limitation; Ex. 1004 at 6:33-7:15.) This is consistent with the examiner's uncontested conclusion during prosecution that the '510 Patent discloses "that the processor and transceiver communicates gas data to a control module." (Ex. 1016 at 254.)

(iv) Control Module Limitation

Claim 6 also requires that "the control module is in fluid communication with the outlet of the valve and a ventilator and the control module comprises: a CPU transceiver to receive line-of-sight signals from the transceiver; and a central processing unit (CPU) in communication with the CPU transceiver and including a

CPU memory." This limitation requires the same elements of independent claim 5 in Section IX(A)(3)(e)(iv) above. As described above, 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 and a ventilator (delivery adaptor 28) of the '083 Patent. (*See* Section IX(A)(3)(e)(iv) for full explanation of how the prior art teaches this limitation; Ex. 1005 at Abstract, Fig. 1 (fluid communication between the outlet of valve 12 and components of the control module), 2:13-29 (system can be used to deliver gas via a ventilator), 2:44-46, 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).)

(v) Input Means Limitation

Claim 6 further requires that the control module comprises "an input means to enter patient information into the CPU memory; and a display."

The gas delivery system disclosed in the '083 Patent includes such an input means and 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.) A person of skill in the art would have understood that this passage's use of the verb "select"

discloses that potential concentrations would be displayed to the user, and the user could select accordingly. (Ex. 1002 ¶ 101.) This is confirmed by the disclosure that the input device maybe 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 input information is non-transitory (*i.e.*, it can be used later), it is stored in memory in communication with the CPU for use as an input to the algorithms described in the '083 Patent. (Ex. 1005 at 2:64-67, 5:62-64.) This input data corresponds to the IDv data of the FR '804 Publication (*i.e.*, indication of the gas that is supposed to be used) that is compared with the IDb data indicative of the gas in the cylinder. (Ex. 1002 ¶¶ 110-112 .)

(vi) Comparison Limitation

Finally, claim 6 further requires that "the CPU compares the patient information entered into the CPU memory via the input means and the gas data from the 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 ¶¶ 110-112.) 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.

(g) Claim 7

Claim 7 depends from claim 6 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 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.

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[12]

1. Overview of Prior Art

The '083 Patent, the '510 Patent, the FR '804 Publication, and the IR Standard were all previously discussed. (*See* Section IX(A)(1).) The '533 Patent

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

(Ex. 1008) was filed on January 22, 2001 and issued on November 2, 2004. (Ex. 1002 ¶¶ 82-83.) It is therefore prior art under 35 U.S.C. § 102(b).

The '533 Patent discloses a protocol for communicating between a device external to a human patient's body and another device, such as an infusion pump, that has been implanted in the patient's body. (Ex. 1008 at Abstract.) The '533 Patent addresses concerns around 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.

(Ex. 1008 at 2:18-38; Ex. 1002 ¶ 84.) 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, and even more preferably no more than about 2 seconds apart.[)]" (Ex. 1008 at 25:4-8; Ex. 1002 ¶¶ 85, 88.) 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.)

Even though the '533 Patent addresses power management in the context of

implanted battery-operated devices, one skilled in the art would have understood from the ’533 Patent that it is important to try to conserve battery power by requiring device-to-device communications to only occur as often as is necessary for a particular medical application. (Ex. 1002 ¶¶ 86-87.) 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.)

2. Motivation to Combine

As discussed above in Section IX(A)(2), a person of skill in the art would have combined the ’083 Patent, the ’510 Patent, the FR ’804 Publication, and the IR Standard to result in a system where data is communicated from a valve 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 ¶¶ 122-131.)

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 ¶ 123.) 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. (Ex. 1002 ¶ 122.)

A person of skill in the art designing a wireless communications system using the IR Standard's teachings would have found actual motivation to combine the '533 Patent with the IR Standard. (Ex. 1002 ¶ 128.) 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.) Since the example range in the IR Standard document is from 3 to 40 seconds, a person of skill in the art 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 ¶ 127.) 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.

Finally, because the gas data of the FR ’804 Publication (IDb data) indicates the type and concentration of gas in the cylinder, and this information cannot change unless the gas bottle is replaced by another, a 10 second interval between communications, as taught by the’533 Patent, is sufficient to achieve the desired result. (Ex. 1002 ¶ 127.)

When combined as articulated above, the ’083 Patent, the ’510 Patent, the FR ’804 Publication, the IR Standard, and the ’533 Patent render claim 4 obvious.

3. Specific Identification of Challenge

(a) Claim 3

The combination of the ’083 Patent, the ’510 Patent, the FR ’804 Publication, and the IR Standard discloses each limitation of independent claim 3, as discussed above. (*See* Section IX(A)(3)(c).) To the extent this combination is found not to explicitly disclose the Power Source Limitation (Section

IX(A)(3)(c)(iv)), the ’533 Patent clearly discloses the additional requirements of this limitation.

The ’533 Patent discloses a battery-powered transceiver, and thus is concerned with conserving battery power. (*See, e.g.*, Ex. 1008 at 2:18-38.) The ’533 Patent also relies, in part, on infrared wireless optical line-of-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.” (Ex. 1008 at 25:9-12.) Accordingly, the ’533 Patent discloses the additional limitations of the Power Source Limitation of claim 3.

(b) Claim 4

Claim 4 depends from claim 3 and requires “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 Patent for its power management teachings and would have understood that at least the '533 Patent discloses the additional limitations of claim 4. (Ex. 1002 ¶¶ 127-129.)

X. CONCLUSION

Petitioner requests institution of *inter partes* review of claims 1-7 of the '209 Patent based on the grounds presented above.

Respectfully submitted by

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