

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC.,
Petitioner,

v.

INO THERAPEUTICS LLC,
Patent Owner.

Case IPR2015-00888
Patent 8,776,794 B2

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

FITZPATRICK, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner, Praxair Distribution, Inc., filed a Petition to institute an *inter partes* review of claims 1–20 of U.S. Patent No. 8,776,794 B2 (Ex. 1001, “the ’794 patent”) pursuant to 35 U.S.C. § 311(a). Paper 1 (“Pet.”). Patent Owner, INO Therapeutics LLC, filed a Preliminary Response pursuant to 35 U.S.C. § 313. Paper 9 (“Prelim. Resp.”). In a September 22, 2015, Decision, we granted the Petition, instituting trial on all claims on the following grounds:

claims 1–12 and 14–20 as obvious over Bathe (Ex. 1005)¹, Peters (Ex. 1004)², Paoli (Ex. 1006)³, and IR Standard (Ex. 1007)⁴;
claims 4 and 5 as obvious over Bathe, Peters, Paoli, INOMAX label (Ex. 1014)⁵, IR Standard, and Lebel (Ex. 1008)⁶; and
claim 13 as obvious over Bathe, Peters, Paoli, INOMAX label, IR Standard, and Durkan (Ex. 1010).⁷

Paper 14 (“Inst. Dec.”).

After institution, Patent Owner filed a Patent Owner Response (Paper 30, “PO Resp.”) to which Petitioner filed a Reply (Paper 40, “Pet. Reply”).

¹ U.S. Patent No. 5,558,083, issued Sept. 24, 1996.

² U.S. Patent No. 7,114,510 B2, issued Oct. 3, 2006.

³ French Patent Application Publication No. 2,917,804, published Dec. 26, 2008.

⁴ ISO/IEEE 11073-30300, “Health informatics -- Point-of-care medical device communication -- Part 30300: Transport profile -- Infrared wireless,” ISO, IEEE, (Dec. 15, 2004).

⁵ FINAL PRINTED LABELING, CENTER FOR DRUG EVALUATION AND RESEARCH, Appl’n. No.: NDA 20845 (2000).

⁶ U.S. Patent No. 6,811,533 B2, issued Nov. 2, 2004.

⁷ U.S. Patent No. 4,462,398, issued July 31, 1984.

Also, Patent Owner filed a Motion to Exclude. *See* Paper 44; *see also* Paper 48 (Petitioner’s Opposition); Paper 49 (Patent Owner’s Reply).

A hearing for oral arguments was held on May 16, 2016, and a transcript of the hearing is included in the record. Paper 53.

As discussed below, Petitioner has not shown by a preponderance of the evidence that any of the challenged claims is unpatentable.

A. The ’794 Patent

The ’794 patent relates to the administration of a therapy gas, such as nitric oxide (NO), to a patient. Ex. 1001, 1:50–53. In a background section, it states that there was a need “to ensure that patient information contained within [a] computerized system matches the gas that is to be delivered” to the patient and “also a need for such an integrated device that does not rely on repeated manual set-ups or connections and which can also track individual patient usage accurately and simply.” *Id.* at 1:40–45.

The ’794 patent describes a gas delivery system comprising a valve assembly having a valve and circuit in communication with a control module to control administration of the therapy gas to a patient. *Id.* at 5:62–6:7. Administration of the therapy gas to the patient is controlled by controlling delivery of the gas from the gas source (i.e., a cylinder to which the valve assembly is mounted) to a medical device for introducing gas to a patient (e.g., a ventilator, nasal cannula, endotracheal tube, or face mask). *Id.*

Figures 2 and 3 are reproduced below.

FIG. 2

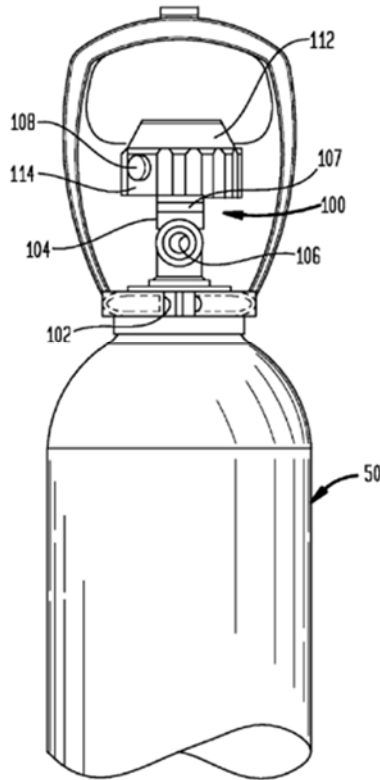


FIG. 3

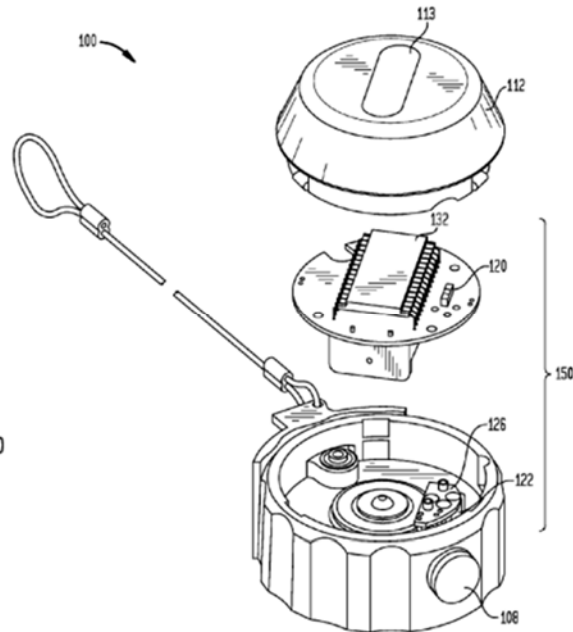


Figure 2 shows valve assembly 100 attached to gas source (cylinder) 50 via attachment portion 102. Ex. 1001, 6:28–31. The valve assembly includes inlet 104, outlet 106, valve 107, data input 108, and actuator 114 with cap 112 mounted thereto, as well as a circuit that is not shown in Figure 2. *Id.* at 6:28–39. Figure 3 shows the assembly valve partially disassembled, thus revealing circuit 150 within the actuator. *Id.* at 6:32–37.

Figure 4 is reproduced below.

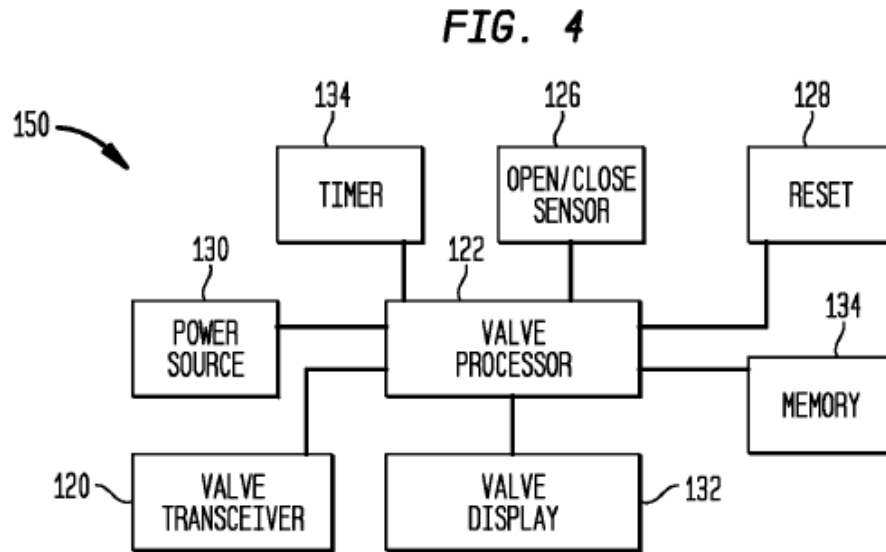


Figure 4 shows a block diagram of circuit 150 having valve processor 122, valve memory 134, valve transceiver 120, valve display 132, reset 128, power source 130, timer 124,⁸ and open/close sensor 126. Ex. 1001, 6:43–56. Gas data, such as gas composition and concentration, can be input to memory 134 in various ways such as programmed by the gas supplier or scanned from a bar code on the gas source. *Id.* at 7:7–23. The valve assembly is configured to communicate with the control module via wireless optical line-of-sight transmission between the valve transceiver and a CPU transceiver of the control module. *Id.* at 8:44–51.

⁸ Figure 4 mislabels the timer as 134. It should be labelled 124. Ex. 1001, 6:45.

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