Filed on behalf of: INO Therapeutics, LLC

Entered: December 9, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC.
Petitioner

v.

INO THERAPEUTICS LLC,
Patent Owner

Case IPR2015-00889
U.S. Patent No. 8,573,209 B2

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

PATENT OWNER'S UPDATED EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner INO Therapeutics LLC ("Ikaria") respectfully submits the following current exhibit list:

EXHIBIT	DESCRIPTION
2001	Drugs@FDA, Application No. NDA 020845, INOMAX – nitric oxide gas, Labeling Revision (Revised: 3/2013), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020845s014lbl.pdf
2002	INOmax DSIR® (Delivery System) Operation Manual (800 ppm INOMAX® (nitric oxide) for inhalation), Part No. 20010 Rev-05, 2012-03, *available at* http://inomax.com/wpcontent/uploads/2015/01/20010_rev_05_INOmax_DSIR_Operation_Manual_with_Links.pdf
2003	Patent Owner's Updated Power of Attorney
2004	Declaration of David K. Callahan in Support of Patent Owner INO Therapeutics LLC's Motion for *Pro Hac Vice* Admission Under 37 C.F.R. § 42.10(c)
2005	Declaration of Kenneth G. Schuler in Support of Patent Owner INO Therapeutics LLC's Motion for *Pro Hac Vice* Admission Under 37 C.F.R. § 42.10(c)
2006	Declaration of Marc N. Zubick in Support of Patent Owner INO Therapeutics LLC's Motion for *Pro Hac Vice* Admission Under 37 C.F.R. § 42.10(c)
2007	RESERVED
2008	RESERVED
2009	RESERVED
2010	RESERVED
2011	RESERVED
2012	RESERVED
2013	RESERVED
2014	RESERVED
2015	RESERVED
2016	U.S. Patent No. 5,913,309 to Sheehan et al.

EXHIBIT	DESCRIPTION
2017	Patent Owner's Certified English Translation of Ex. 1011
2018	Enlarged Image of Air Liquide Santé Opti KINOX Station
2019	Photographs of Praxair NOMIX Delivery System
2020	Deposition Transcript of Robert T. Stone, dated December 2, 2015
2021	Declaration of Warren P. Heim in Support of Patent Owner's Response to Petition for *Inter Partes* Review of U.S. Patent No. 8,291,904
2022	Curriculum Vitae of Warren P. Heim
2023	*Bedfont Scientific Introduces State of the Art Intelligent INO Delivery & Monitoring System*, BIOSPACE (Sept. 10, 2012, 10:56 AM), http://www.biospace.com/News/bedfont-scientific-introduces-state-of-the-art/272542
2024	Bedfont NOxBox & NOxMixer
2025	Letter from Praxair Technology, Inc. to Ikaria, Inc., dated November 25, 2009
2026	Praxair NOmix Brochure [Certified English Translation]
2027	CareFusion PrinterNOx Operating Manual
2028	*General Controls for Medical Devices*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm
2029	*Regulatory Controls*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm
2030	21 C.F.R. § 814.20
2031	21 C.F.R. § 814.82
2032	21 C.F.R. § 807.92
2033	*Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/

EXHIBIT	DESCRIPTION
2034	*Medical Device Classification Product Codes – Guidance for Industry and Food and Drug Administration Staff*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/RegulatoryInformation/Guidances/ucm285317.htm
2035	FDA MAUDE Database Example Results for Product Code MRN (Nitric Oxide Administration Apparatus) between 10/1/2009 and 11/30/2011
2036	Maxim Integrated iButton Products: 1-Wire Adapters, https://www.maximintegrated.com/en/products/ibutton/products/1wire_adapters.cfm
2037	Maxim Integrated Memory Products: iButton 64Kb Memory (DS1996), https://www.maximintegrated.com/en/products/digital/memory-products/DS1996.html
2038	*The New 510(k) Paradigm – Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, Final Guidance*, dated March 20, 1998, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm
2039	*Medical Device Databases*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/medicaldevices/deviceregulationandguidance/databases/default.htm
2040	*The 510(k) Paradigm: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Guidance for Industry and Food and Drug Administration Staff*, issued July 28, 2014, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf

Respectfully submitted,

Dated: December 9, 2015

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