UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC. Petitioner

v.

MALLINCKRODT HOSPITAL PRODUCTS IP LTD., Patent Owner

Case: IPR2015-00884 Patent: 8,291,904 B2

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

Mail Stop PATENT BOARD

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



TABLE OF CONTENTS

I.	Intro	Introduction		
II.		Problem Purportedly Solved by the '904 Patent Was Already I-Known Prior To Its Filing	1	
III.	PO Misinterprets The Instituted Combinations		4	
	A.	PO's Complaints Regarding The Independent Claims	4	
	B.	PO's Complaint Regarding Claim 9	6	
	C.	PO's Complaint Regarding Claim 10	9	
IV.	The Instituted Combinations are Proper Because PO's Arguments About The References Lack Merit		10	
	A.	The '083 Patent	11	
		1. PO's Nitric Oxide-Specific Arguments Are Inaccurate	12	
		2. The '083 Patent Obtains Concentration Data from Different Sources	13	
	B.	The '510 Patent	14	
		1. The '510 Patent Teaches Wireless Transmission	14	
		2. The '510 Patent Suggests Using Stored Data For Control	14	
		3. PO Misrepresented the '510 Patent in Arguing the Open/Close Data is Never Used for Real-Time Tasks	15	
	C.	The FR '804 Publication	16	
V.	Mr.	Heim's Testimony Should Be Accorded No Weight	20	
VI.	PO's FDA Arguments Are Incorrect And Immaterial		22	
	A.	The FDA 510(k) Process is Merely a Path to Marketability	22	
	B.	If Relevant, the FDA Records Support a Finding of Obviousness	24	
VII	Cone	clusion	25	



i

PETITIONER'S UPDATED LIST OF EXHIBITS

- 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 Center for Drug Evaluation and Research, Application Number: NDA 20845, INOMAX®, Final Printed Labeling, ("INOMAX Label") available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/99/20845_inomax_prntlbl.pdf (August 9, 2000)

Ex. 1015 Prosecution History of U.S. Patent No. 8,291,904

Ex. 1016 Reserved

Ex. 1017 Reserved

Ex. 1018 Reserved

Ex. 1019 Reserved

Ex. 1020 Declaration of translator Claudine Joly-King under 28 U.S.C. § 1746 regarding Ex. 1006

Ex. 1021 Resume of Warren P. Heim, P.E. downloaded from http://www.teammedical.us/images/WP%20Heim-

Medical%20Device%20and%20R&D%20Expert.pdf



- Ex. 1022 Transcript of February 2, 2016 Deposition of Warren P. Heim, P.E.
- Ex. 1023 INOvent Delivery System Operation and Maintenance Manual (CGA Variant), Dated 02/08/00
- Ex. 1024 510(k) Summary for INOmax DS (Delivery System), submitted December 18, 2009, published April 15, 2010



DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

