Filed on behalf of: Mallinckrodt Hosp. Prods. IP Ltd.

Entered: June 30, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC. AND NOxBOX LIMITED,
Petitioner

v.

MALLINCKRODT HOSPITAL PRODUCTS IP LTD.,
Patent Owner

Case IPR2016-00777
U.S. Patent No. 8,282,966

Before STEVEN AMITRANI, *Trial Paralegal*.

DECLARATION OF GEOFFREY L. ROSENTHAL, M.D., PH.D. IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE TO PRAXAIR'S PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,282,966

TABLE OF CONTENTS

I, Geoffrey L. Rosenthal, M.D., Ph.D., resident of Millersville, Maryland, hereby declare as follows:

I. QUALIFICATIONS

1. I am a Professor of Pediatrics and Epidemiology at the University of Maryland School of Medicine in Baltimore, Maryland. I have been at the University of Maryland since July 2009. I have had both academic and hospital-based roles at the University of Maryland School of Medicine and the University of Maryland Children's Hospital. The academic roles include Chair of the Division of Pediatric Cardiology (2009-present), and Chair of Pediatric Critical Care Medicine (2009-2014). In these roles I have had responsibility for faculty development, research, and training in several content areas, including training pediatric cardiologists and pediatric critical care physicians and nurses in the management of pulmonary hypertension in neonates, infants, older children, and certain categories of adults (specifically, adults with congenital heart disease).

2. I am also the Co-Director of the Children's Heart Program (2009-present) and the Co-Director of the University of Maryland Heart and Vascular Center (2015-present). I was the Executive Director of Pediatric Critical Care Services (2009-2016). In these hospital-based roles, I oversee quality of care, enhance collaboration across specialties, and assure efficient use of certain

resources within the University of Maryland Medical Center and across the University of Maryland Medical System.

3. I have been a practicing pediatric cardiologist since 1998. Since 1998, I have cared for over 7,000 children. My clinical area of expertise is Pediatric Cardiac Intensive Care, so my experience has been enriched over the arc of my career with neonates and children who are critically ill due to conditions related to their hearts and blood vessels. Neonates and children with critical illness due to the heart and blood vessels often have elevated resistance in the blood vessels which carry blood to the lungs, and they often have pulmonary hypertension. I am very familiar with the use of inhaled Nitric Oxide ("iNO") and other vasodilators in the neonatal and pediatric population.

4. Prior to joining the University of Maryland School of Medicine, I served as the Director of Inpatient Medicine for Pediatric Cardiovascular Services and Director of Pediatric Cardiovascular Research at the Cleveland Clinic. While at the Cleveland Clinic, I developed inpatient services for the Pediatric and Congenital Heart Center and started the Pediatric Cardiology Fellow's Clinic. In these roles I both recommended use of iNO and other vasodilators for neonates, infants, and children in need of these therapies, and I taught both Pediatric Cardiology and Pediatric Critical Care physicians to use these agents properly. Before joining the Cleveland Clinic, I served at Seattle Children's Hospital where I

started the Pediatric Cardiac Intensive Care Program. In this role I prescribed iNO and other vasodilators for neonates, infants, and children in need of these therapies, and I taught Pediatric Critical Care physicians to use these agents properly.

5. I received my undergraduate degree in psychology from Boston University, a master's degree in biostatistics and epidemiology from Georgetown University, a medical degree from the University of Maryland School of Medicine and a doctor of philosophy degree in epidemiology from the University of Maryland Graduate School. I completed my pediatric residency, neonatology chief residency, pediatric cardiology fellowship, and perioperative fellowship in pediatric cardiology at Baylor College of Medicine/Texas Children's Hospital. I am licensed to practice medicine in Maryland, and am certified by the American Board of Pediatrics in General Pediatrics and Pediatric Cardiology. I am board certified through the American Board of Internal Medicine in Adult Congenital Heart Disease.

6. I have been active in various professional committees. For instance, I was the Chair of the Pediatric Advisory Committee to the U.S. Food and Drug Administration (2009-2012) and have been a member or consultant to that committee since 2006. The Pediatric Advisory Committee advises the Food and Drug Administration ("FDA") on matters of drug and other product safety and labeling as they pertain to use in neonates and children. For example, I

DOCKET ALARM

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.