

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

Entered: June 6, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC. AND NO_xBOX LIMITED,
Petitioner

v.

MALLINCKRODT HOSPITAL PRODUCTS IP LTD.,
Patent Owner

Case IPR2016-00781
U.S. Patent No. 8,846,112

Before STEVEN AMITRANI, *Trial Paralegal*.

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	Introduction.....	1
II.	The '112 Patent Claims Novel Methods for Providing Pharmaceutically Acceptable Nitric Oxide to Physicians for the Safe Administration to Neonates	3
A.	The Development of the '112 Patent	3
1.	The Prior Use of iNO in Neonates Suffering From Hypoxic Respiratory Failure Only Excluded Neonates Dependent on Right-to-Left Shunting, Not Those With Preexisting LVD	4
2.	The Original INOT22 Study Protocol Did Not Exclude Neonates with Non-RTL-Dependent LVD.....	8
3.	Unanticipated SAEs Occurred During the INOT22 Study, the Study Was Amended, and the Rate of SAEs Was Significantly Reduced.....	10
B.	The '112 Patent Prosecution History	13
III.	Person of Ordinary Skill in the Art.....	14
IV.	Claim Construction.....	14
V.	Petitioner Is Estopped From Requesting <i>Inter Partes</i> Review Under 35 U.S.C. § 315(e)(1)	15
A.	Petitioner Reasonably Could Have Raised The Proposed Grounds Including <i>Greenough</i> and <i>Jaypee</i> in its First IPR Petition.....	16
B.	The Petitioner and Real Parties-in-Interest From The -00529 IPR Also Filed This Petition, and They Will Soon Be Barred From Requesting or Maintaining This Proceeding.	20
VI.	The Board Should Exercise its Discretion and Deny This Petition Under 35 U.S.C. § 325(d).....	21

A.	The Board Should Deny Institution Because Petitioner Was Aware, or Should Have Been Aware, of the Allegedly New References Cited in the Instant Petition	24
B.	The Board Should Deny Institution Because Petitioner Advances the Same or Substantially the Same Prior Art and Arguments As the First Petition	26
C.	The Board Should Deny Institution Because Petitioner Delayed in Filing the Present Petition and Unfairly Benefited from the Proceedings in the First IPR.....	31
VII.	The Petition Fails to Show a Reasonable Likelihood that the Petitioner Will Prevail with respect to the Challenged Claims.....	37
A.	A POSA Would Not Have Relied Upon the Disclosure of <i>Greenough</i>	38
1.	A POSA Would Have Rejected the Statements in <i>Greenough</i> In Favor of the Instructions in the Label.....	39
2.	A POSA Would Have Rejected the Statements in <i>Greenough</i> As Conclusory and Unsupported	40
3.	A POSA Would Have Rejected the Statements in <i>Greenough</i> As Inherently Contradictory.....	41
4.	A POSA Would Have Disregarded the Statements in <i>Greenough</i> As Inconsistent with the Body of Dr. <i>Greenough</i> 's Work.....	45
B.	A POSA Would Not Have Relied Upon the Disclosure in <i>Jaypee</i>	46
C.	Petitioner Misreads and Misrepresents the Disclosure of the Prior Art to a POSA.....	49
D.	Petitioner Continues to Ignore the Overwhelming Evidence of Non-Obviousness	52
E.	Petitioner's Expert Declaration Should be Afforded Minimal Weight	54

1.	Dr. Lawson Does Not Meet the Level of Ordinary Skill in the Art Proposed by Petitioner.....	55
2.	Dr. Lawson’s Testimony Should Be Given Minimal Weight Because it Does Not Represent Dr. Lawson’s Own Analysis.....	58
VIII.	Conclusion.....	61

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Arista Networks, Inc. v. Cisco Sys., Inc.</i> , No. IPR2015-01710 (P.T.A.B. Feb. 16, 2016), Paper 7	25
<i>Avanir Pharm., Inc. v. Actavis S. Atl. LLC</i> , 36 F. Supp. 3d 475 (D. Del. 2014).....	38
<i>Butamax Advanced Biofuels LLC v. Gevo, Inc.</i> , No. IPR2014-00581 (P.T.A.B. Oct. 14, 2014), Paper 8	23, 32
<i>Conopco, Inc. dba Unilever v. Procter & Gamble Co.</i> , No. IPR2014-00507 (P.T.A.B. July 7, 2014), Paper 17	22
<i>Conopco, Inc. dba Unilever v. Procter & Gamble Co.</i> , No. IPR2014-00628 (P.T.A.B. Oct. 20, 2014), Paper 21	25, 27
<i>CustomPlay, LLC v. ClearPlay, Inc.</i> , No. IPR2014-00783 (P.T.A.B. Nov. 7, 2014), Paper 9	32
<i>Daiichi Sankyo Co. v. Apotex, Inc.</i> , 501 F.3d 1254 (Fed. Cir. 2007)	57
<i>In re Jackson Nat'l Life Ins. Co. Premium Litig.</i> , No. 96-MD-1122, 2000 WL 33654070 (W.D. Mich. Feb. 8, 2000)	58
<i>In re NTP, Inc.</i> , 654 F.3d 1279 (Fed. Cir. 2011)	16
<i>Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.</i> , No. IPR2013-00324 (P.T.A.B. Nov. 21, 2013), Paper 19	passim
<i>Leo Pharm. Prods., Ltd. v. Rea</i> , 726 F.3d 1346 (Fed. Cir. 2013)	54
<i>Medtronic, Inc. v. Nuvasive, Inc.</i> , No. IPR2014-00487 (P.T.A.B. Sept. 11, 2014), Paper 8.....	22, 26
<i>Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.</i> , No. IPR2014-00436 (P.T.A.B. June 19, 2014), Paper 17	26, 37

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.