

Filed on behalf of:

INO Therapeutics LLC

By:

Dominick A. Conde
dconde@fchs.com
(212) 218-2100

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Praxair Distribution, Inc.

Petitioner,

v.

INO Therapeutics LLC

Patent Owner.

Case IPR2015-00522
U.S. Patent No. 8,282,966

**PRELIMINARY RESPONSE BY
PATENT OWNERS PURSUANT TO 37 C.F.R. § 42.107**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND	6
A.	The Development of the '966 Patent	6
1.	The Original INOT22 Protocol Was Carefully Constructed and Reviewed, and Did Not Contain the Claimed Exclusion Criteria.....	6
2.	Unanticipated Serious Adverse Events Initially Occurred During the INOT22 Study	9
3.	Based On the Unexpected Serious Adverse Events Early in the Trial, the INOT22 Protocol Was Amended and the Rate of SAEs Was Significantly Reduced.....	10
B.	The '966 Patent Prosecution History	11
1.	The PTO Considered Many References	11
2.	Praxair Relies on the Same Statements Ikaria Overcame During Prosecution.....	13
a.	References Relating to (1) Adult Studies or (2) Studies in Neonates Dependent on Right- to-Left Shunting Are Not Relevant to the Invention	15
b.	Had It Been Known or Suggested that the Claimed Excluded Group Would Have Had Such SAEs, Including Death, It Would Have Been Negligent To Include Those Patients In The Initial INOT22 Study	17
C.	The '966 Patent Claims	19
III.	PERSON OF ORDINARY SKILL	20
IV.	CLAIM CONSTRUCTION	20

V.	LEGAL STANDARD	23
VI.	A SKILLED ARTISAN WOULD NOT HAVE BEEN MOTIVATED TO EXCLUDE CHILDREN HAVING LVD AND NOT DEPENDENT ON RIGHT-TO-LEFT SHUNTING OR REASONABLY EXPECT THOSE CHILDREN WOULD HAVE EXPERIENCED SAES	27
	A. There was no motivation to implement the claimed exclusion based on studies with adults because left ventricular dysfunction in children is much different than in adults	29
	B. A skilled artisan would not have reasonably expected that the claimed excluded children would have SAEs as initially occurred in the INOT22 Study	32
VII.	GROUND 1: THE BOARD SHOULD NOT INSTITUTE REVIEW BASED ON ALLEGED OBVIOUSNESS OVER BERNASCONI IN COMBINATION WITH INOMAX® LABEL, LOH AND GOYAL	35
	A. Praxiar fails to show that Bernasconi, the INOmax® label, Loh or Goyal include the claimed exclusion criteria	36
	B. Praxair’s Assertions that warnings in the art are applicable to the claimed exclusion criteria are unsupported	45
	C. Praxair fails to raise any new arguments or supplement the record to address issues overcome during prosecution	47
	D. Praxair fails to show that elements in dependent claims 5, 11, 20 and 28 are present in the prior art.....	50
VIII.	GROUND 2: THE BOARD SHOULD NOT INSTITUTE REVIEW BASED ON ALLEGED OBVIOUSNESS OVER BERNASCONI IN COMBINATION WITH INOMAX® LABEL, LOH, GOYAL AND MACRAE	51
IX.	GROUND 3: THE BOARD SHOULD NOT INSTITUTE REVIEW BASED ON ALLEGED OBVIOUSNESS OVER	

ICHINOSE IN COMBINATION WITH NEONATAL
GROUP, MACRAE, LOH, GOYAL AND GERMANN53

X. PRAXAIR FAILS TO DEMONSTRATE A REASONABLE
LIKELIHOOD OF SUCCESS TO COUNTER THE
OBJECTIVE EVIDENCE OF UNEXPECTED RESULTS55

XI. Conclusion57

TABLE OF AUTHORITIES

Cases

<i>Apple, Inc. v. ITC</i> , 725 F.3d 1356 (Fed. Cir. 2013)	56
<i>Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.</i> 776 F.2d 281 (Fed. Cir. 1985)	46
<i>CCS Fitness, Inc. v. Brunswick Corp.</i> , 288 F.3d 1359 (Fed. Cir. 2002)	21
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966).....	23, 56
<i>In re Cuozzo Speed Tech. LLC</i> , No. 14-1301, slip op. (Fed. Cir. Feb. 4, 2015)	20
<i>In re Dembiczak</i> , 175 F.3d 994 (Fed. Cir. 1999)	24
<i>Insite Vision Inc., et al. v. Sandoz, Inc.</i> , 2014-1065 (Fed. Cir. April 19, 2015).....	47
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	23, 24, 56
<i>Leo Pharmaceutical Products, Ltd v. Rea</i> , 726 F.3d 1346 (Fed. Cir. 2013)	24, 34
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005)	20, 21, 22
<i>Rohm and Haas Co. v. Brotech Corp.</i> , 127 F.3d 1089 (Fed. Cir. 1997)	46

Statutes

35 U.S.C. § 103	23, 35, 51, 53
35 U.S.C. § 314(a)	2, 23
35 U.S.C. § 325(d)	47, 50

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.