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 IPR2015-00884
U.S. Patent No. 8,291,904 B2

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

PATENT OWNER INO THERAPEUTICS LLC'S RESPONSE TO PRAXAIR DISTRIBUTION, INC.'S PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,291,904

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND 3

A. Overview of the Board's Institution Decision 3
B. The '904 Patent 4
C. Claim Construction 6
D. Patent Owner's Commercial Embodiments of the Inventions of the '904 Patent 7
E. Other NO Delivery Systems Marketed at or Around the Time of Inventions of the '904 Patent Lacked the Inventions of the '904 Patent 7
1. Petitioner Praxair's NOMIX System 8
2. The Opti Kinox Station from Air Liquide 8
F. The Regulatory Environment Guiding the Work of a POSA Developing Medical Devices Like the Claimed Inventions 9
1. Classes of Regulated Devices 10
2. The 510(k) Process Is Necessary to Market a Class II Device 10
3. The FDA Regulatory Regime Encourages the Use of Known Safety Solutions and Discourages Deviation in the Absence of an Identifiable and Known Problem 11

III. THE CITED REFERENCES 12

A. Bathe (U.S. Patent No. 5,558,083) 12
B. Peters (U.S. Patent No. 7,114,510) 14
C. FR '804 (FR 2,917,804) 16
D. IR Standard (ISO/IEEE 11073-30300) 17

IV. DR. STONE'S "COMBINABILITY" OPINIONS ARE DEFICIENT AS A MATTER OF LAW AND THE BOARD SHOULD DISREGARD THEM 17

A. Dr. Stone Failed to Analyze the Claims 18
B. Dr. Stone Did Not Know or Apply the Correct Legal Standards 22

C. Dr. Stone Failed to Consider Objective Indicia of Non-Obviousness....23
D. Dr. Stone Improperly Used Hindsight Bias....25
E. Given Dr. Stone's Deficient Declaration, the Petition is Insufficient As a Matter of Law....27

V. THE ASSERTED COMBINATION FAILS TO SATISFY ALL LIMITATIONS OF THE CHALLENGED CLAIMS....29

VI. THERE WOULD HAVE BEEN NO MOTIVATION TO COMBINE BATHE '083, PETERS '510, FR '804, and THE IR STANDARD....38

A. Petitioner Has Failed to Show That a POSA Was Aware of the Problem Addressed by the '904 Patent Claims....39
B. A POSA Would Not Be Motivated to Combine Bathe And Peters....42
C. A POSA Would Not Be Motivated to Combine Bathe And Peters with FR '804....46
1. FR '804 Does Not Teach Gas Concentration....47
2. Mechanical Connection Limitations in NO Delivery Systems Eliminate Any Need for FR '804....47
3. Replacing the Peters Manual Valve with the Automatic Valve of FR '804 Would Create Substantial Problems....50
D. The IR Standard, Lebel, and Durkan Do Not Establish Motivation to Combine the Asserted References....54
E. A Generalized Goal of "Improving Safety" Does Not Establish a Motivation to Combine Bathe, Peters, FR '804, and the IR Standard....55
1. FDA Guidelines Did Not Suggest a Safety Check Was Necessary or a "Risk"....56
2. The MAUDE Database Provided No Motivation....57
3. Minimizing Costs and Development Time Would Have Motivated the POSA to Pursue a 510(k) Application....58
4. Real World Evidence Regarding NO Delivery Systems Show That the Claimed Invention Is Not Obvious....59

VII. CONCLUSION....60

I. INTRODUCTION

The Board's initial determination to institute *inter partes* review was erroneous because Petitioner's arguments and evidence fall substantially short of what the law requires to invalidate the claims of the '904 Patent:

- Petitioner's expert declarant, Dr. Stone did not even attempt to examine validity on a ***claim-by-claim*** basis (in fact, Dr. Stone testified he performed no analysis of the claims);
- Petitioner presented no credible evidence whatsoever of any alleged motivation to combine its many asserted prior art references, and ignores entirely the fact that no one in the industry had even ***perceived*** of the problem the '904 Patent ***solves***; and
- Petitioner ignores entirely evidence that those of ordinary skill in the art (including Petitioner, its expert, and the assignee of the FR '804 reference) developed nitric oxide delivery systems without including the patented features Petitioner now claims, in hindsight, would have been "common sense" to add.

First, Petitioner's expert Dr. Stone failed to examine validity on a claim-by-claim basis. He failed to even identify the differences between any of the asserted prior art references and the claims of the '904 Patent, or any the differences between the collection of prior art on which he relies and the claims. As part of what he called a "combinability" analysis, Dr. Stone opined without the benefit of any legal framework, and his opinions are therefore insufficient as a matter of law,

and leave Petitioner without any meaningful evidence. In this complex field, the absence of any appropriate, substantive expert testimony or proof is alone sufficient to prevent Petitioner from being able to invalidate the '904 Patent claims.

Second, Petitioner and its expert declarant failed to prove that a POSA would have been motivated to combine (and further modify) the prior art to create the claimed inventions. Dr. Stone admits that the efforts of those of skill in the field of medical device design are constrained by the FDA regulatory environment, which encourages the use of known safety solutions and discourages deviation in the absence of a known problem. Here, neither party's expert saw any evidence that the problem the '904 Patent addresses was recognized at the time of the invention. Under controlling Federal Circuit law, this failure leaves the Board with no evidentiary basis to conclude that a POSA would have combined the prior art in the manner Petitioner claims.

Third, Petitioner and its expert declarant deliberately ignored ***entirely*** the evidence of what those of ordinary skill in the art actually ***did*** with knowledge of the prior art. Petitioner offered its own NO delivery device shortly before the '904 Patent's priority date (but after all of the prior art Petitioner relies upon was available), and ***was not*** motivated to combine the prior art. Nor was Air Liquide, the assignor of the FR '804 patent publication that Petitioner asserts would have been readily combined with other asserted prior art to arrive at the claimed

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.