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 IPR2015-00889
U.S. Patent No. 8,573,209 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. 8,573,209

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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 '209 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 '209 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 declarant, Dr. Stone, failed to examine validity on a claim-by-claim basis. Indeed, he failed to even identify the differences between any of the asserted prior art references and the claims of the '209 Patent, or any the differences between the collection of prior art on which he relies and the claims of the '209 Patent. As part of what he called a "combinability" analysis, Dr. Stone opined without the benefit of any legal framework. Dr. Stone's opinions are

therefore insufficient as a matter of law, and leave Petitioner without any meaningful expert testimony. In this complicated technological field, the absence of any appropriate, substantive expert testimony or proof is alone sufficient to prevent Petitioner from being able to invalidate the '209 Patent claims.

Second, Petitioner and its expert declarant failed to provide sufficient evidence to establish that a POSA would have been motivated to combine (and in many instances, further modify) the prior art to create the inventions claimed in the '209 Patent. 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 could identify any evidence that the problem the '209 Patent addresses was recognized in the field at the time of the invention. Under controlling Federal Circuit law, this failure alone leaves the Board with no evidentiary basis whatsoever 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 real world evidence of what those of ordinary skill in the art who were actually developing NO delivery systems actually ***did*** with knowledge of the prior art. Petitioner offered its own NO delivery device shortly before the '209 Patent's priority date (but after all of the prior art Petitioner relies upon was available), and

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