

Filed on behalf of: INO Therapeutics, LLC

Entered: November 5, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PRAXAIR DISTRIBUTION, INC.  
*Petitioner*

v.

INO THERAPEUTICS LLC,  
*Patent Owner*

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Case IPR2015-00529  
U.S. Patent No. 8,846,112 B2

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Before LORA M. GREEN, TINA E. HULSE, and  
ROBERT A. POLLOCK, *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. 8,846,112**

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## I. INTRODUCTION

The Board's initial determination to institute *inter partes* review of claims 1-11<sup>1</sup> of the '112 Patent (hereinafter the "subject claims") failed to properly construe and consider the claimed inventions based on the intrinsic evidence, the unanimous opinions of both parties' experts and those of skill in the art, and the controlling case law. The '112 Patent claims methods of providing pharmaceutically acceptable nitric oxide gas to physicians for the safe treatment of hypoxic respiratory failure in neonates. The subject claims disclose a solution to the previously unknown problem that neonates suffering from hypoxic respiratory failure who also suffer from left ventricle dysfunction ("LVD") have a high risk of serious adverse events ("SAEs") such as pulmonary edema if they are administered inhaled nitric oxide ("iNO"). The claimed solution to that previously unknown problem allows for the provision of iNO to physicians for its safe administration to critically ill infants.

The Board recognized the patentability of claims to similar subject matter in its denial of Petitioner's requests to institute IPR of four related patents.<sup>2</sup> The Board's initial determination here is erroneous for several independent reasons.

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<sup>1</sup> This Response does not address claims 12-19 of the '112 Patent.

<sup>2</sup> See Decision Denying Institution of *Inter Partes* Review of Case Nos. IPR2015-00522, -00524, -00525 and -00526 (Paper 12) ("Decision Denying Inst.").

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