# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

MALLINCKRODT HOSPITAL PRODUCT	S IP)	
LTD., INO THERAPEUTICS LLC and IKA	RIA,)	
INC.	)	C. A. No.: 15-170-GMS
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
PRAXAIR DISTRIBUTION, INC. and	)	
PRAXAIR, INC.,	)	
	)	
Defendants	)	

### PRAXAIR'S RESPONSIVE CLAIM CONSTRUCTION BRIEF REGARDING U.S. PATENT NO. 8,846,112

YOUNG CONAWAY STARGATT & TAYLOR, LLP Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
1000 North King Street
Wilmington, DE 19801
(302) 571-6681
msharp@ycst.com
jhiggins@ycst.com

MORGAN, LEWIS & BOCKIUS LLP Michael J. Abernathy Sanjay K. Murthy Maria E. Doukas Jennifer M. Dienes 77 West Wacker Drive, Fifth Floor Chicago, IL 60601 (312) 324-1000

Attorneys for Praxair Distribution, Inc. and Praxair, Inc.

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Mallinckrodt Hosp. Prods. IP Ltd. Exhibit 2035 Praxair Distrib., Inc. et al., v. Mallinckrodt Hosp. Prods. IP Ltd. Case IPR2016-00779

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#### I. INTRODUCTION AND SUMMARY OF THE ARGUMENT

Mallinckrodt Hospital Products IP Ltd.'s, INO Therapeutics LLC's and Ikaria Inc.'s (collectively "Plaintiffs") proposed construction of "pharmaceutically acceptable nitric oxide gas" in U.S. Patent No. 8,846,112 ("the '112 Patent") is flawed for multiple reasons.

First, this term only appears in the preamble of the asserted claims and does not provide an antecedent basis for any limitation appearing in the body of the claims. Plaintiffs try to skirt this fact by arguing that the term is limiting because it was supposedly added "to overcome a prior art rejection during prosecution." (D.I. 70 at 6.) Not so. As Defendants pointed out in their Opening Claim Construction Brief, the patentee added this term to address an issue of priority, not to distinguish the claimed invention from any prior art cited by the Examiner. (D.I. 71 at 7.)

While Plaintiffs cite Federal Circuit authority that relying on the preamble during prosecution to distinguish the claimed invention from the prior art may transform the preamble into a claim limitation, they notably cite no Federal Circuit authority that addressing an issue of priority achieves that same result. (D.I. 70 at 6.)

Second, Plaintiffs' argument that the preamble is the "essence of the invention" ignores the file history. (D.I. 70 at 6.) A limitation cannot qualify as the "essence of the invention" if the patentee did not even deem it necessary to claim it in the first instance. Here the file history confirms that the patentee initially claimed a generic "pharmaceutical product." (Ex. F, '112 Patent File History, Office Action Response dated Dec. 23, 2013 at 11.) It only added the limitation "pharmaceutically acceptable nitric oxide gas" after the Examiner objected that the "priority documents" did not disclose the originally claimed "pharmaceutical product." Rather than suggest that the former term had some special meaning (as Plaintiffs now propose), the

Exhibits A through G were attached to Praxair's Opening Claim Construction Brief



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