Filed on behalf of: Mallinckrodt Hosp. Prods. IP Ltd.

Entered: June 30, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE _____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC. AND NOxBOX LIMITED, Petitioner

v.

MALLINCKRODT HOSPITAL PRODUCTS IP LTD., Patent Owner

Case IPR2016-00780 U.S. Patent No. 8,795,741

Before STEVEN AMITRANI, Trial Paralegal.

PATENT OWNER'S PRELIMINARY RESPONSE



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Harmonic Inc. v. Avid Tech., Inc., 815 F.3d 1356 (Fed. Cir. 2016)1	3
Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., No. IPR2013-00324, Paper No. 19 (P.T.A.B. Nov. 21, 2013)20	0
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