

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

Entered: April 13, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PRAXAIR DISTRIBUTION, INC. AND NO_xBOX LIMITED,
Petitioner

v.

MALLINCKRODT HOSPITAL PRODUCTS IP LTD.
Patent Owner

Case IPR2016-00777
U.S. Patent No. 8,282,966

Before STEVEN AMITRANI, *Trial Paralegal*.

**PATENT OWNER'S MANDATORY NOTICES
UNDER 37 C.F.R. § 42.8**

Pursuant to 37 C.F.R. § 42.8, Patent Owner Mallinckrodt Hospital Products IP Ltd. (“Patent Owner”) submits the following Mandatory Notices in response to the Petition for *Inter Partes* Review of U.S. Patent No. 8,282,966 (hereinafter “the ’966 patent”).

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

The real party-in-interest is Mallinckrodt Hospital Products IP Ltd. INO Therapeutics LLC, Mallinckrodt Hospital Products, Inc., and Mallinckrodt PLC, affiliates of Mallinckrodt Hospital Products IP Ltd., are also real parties-in-interest.

B. Notice of Related Matters (37 C.F.R. § 42.8(b)(2))

Pursuant to 37 C.F.R. § 42.8, Patent Owner hereby provides the following indication of judicial and administrative matters that would affect, or be affected by, a decision in this proceeding:

On February 19, 2015, Patent Owner filed a complaint averring that Petitioner’s Abbreviated New Drug Application (“ANDA”) infringes U.S. Patent No. 8,282,966 under 35 U.S.C. § 271(e)(2). That lawsuit is pending in the United States District Court for the District of Delaware and is captioned: *INO Therapeutics LLC et al. v. Praxair Distribution, Inc. et al.*, Civil Action No. 1:15-cv-00170 (GMS).

In January 2015, Petitioner filed a petition requesting IPR of the ’966 patent in IPR2015-00522 (“the 522 IPR”). On July 29, 2015, the Patent Trial and Appeal

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Board (“Board”) denied that petition. IPR2015-00522, Paper 12. Petitioner also filed four other petitions directed to patents in the same family as the ’966 patent, U.S. Patent Nos. 8,293,284 (“the ’284 patent”); 8,431,163 (“the ’163 patent”); 8,795,741 (“the ’741 patent”); and 8,846,112 (“the ’112 patent”). Three of those petitions were denied on July 29, 2015 in the same decision that denied the 522 IPR. *See* IPR2015-00524, Paper 12; IPR2015-00525, Paper 12; IPR2015-00526, Paper 12. The fourth petition, requesting IPR of the ’112 patent, was granted, and the Board instituted review of that patent on July 29, 2015. IPR2015-00529, Paper No. 12. That proceeding is currently pending, with a final written decision expected in the July/August 2016 timeframe.

Concurrently with this petition, Petitioner has again requested *inter partes* review of the ’163 patent, the ’284 patent, the ’741 patent, and the ’112 patent. *See* IPR2016-00778; IPR2016-00779; IPR2016-00780; IPR2016-00781.

One pending U.S. patent application claims priority to the ultimate parent application of the ’966 patent: U.S. Application No. 13/683,444, filed on November 21, 2012, which is currently on appeal from a final rejection in the US Patent Office.

C. Designation of Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3))

Patent Owner provides the following designation of counsel:

Lead Counsel	Backup Counsel
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D. Service of Information (37 C.F.R. §42.8(b)(4))

Service of any documents via hand-delivery may be made at the postal mailing address of the respective lead and back-up counsel designated above.

Patent Owner consents to electronic service at the email addresses listed above.

Respectfully submitted,

Dated: April 13, 2016

By: /Robert Steinberg/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 13th day of April, 2016, a true and correct copy of the foregoing **Patent Owner's Mandatory Notices Under 37 C.F.R. § 42.8** was served by electronic mail on Petitioner's lead and backup counsel at the following email addresses:

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