

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS LLC

Petitioner,

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD.

Patent Owner

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Case: IPR2015-01980

Patent No. 8,399,413

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**PATENT OWNER'S MANDATORY NOTICES  
PURSUANT TO 37 C.F.R. § 42.8(a)(2)**

**Mail Stop "PATENT BOARD"**  
Patent Trial and Appeal Board  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Pursuant to 37 C.F.R. § 42.8(a)(2), Patent Owner Yeda Research & Development, Co, Ltd., hereby submits the following mandatory notices. This paper is timely filed within 21 days of service of the petition.

**I. REAL PARTY IN INTEREST (37 C.F.R. § 42.8(b)(1))**

Yeda Research & Development Co., Ltd. is the patent owner of the '413 patent. Teva Pharmaceuticals Industries Ltd. is the exclusive licensee of the '413 patent. Teva Pharmaceuticals USA, Inc. is the holder of the New Drug Application for Copaxone®, a drug for which the '413 patent is listed in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as “the Orange Book.” Teva Neuroscience, Inc. markets and sells Copaxone® in the United States. Yeda Research & Development Co., Ltd., Teva Pharmaceuticals Industries Ltd., Teva Pharmaceuticals USA, Inc., and Teva Neuroscience, Inc. are the real parties in interest.

**II. RELATED MATTERS (37 C.F.R. § 42.8(b)(2))**

**a. Judicial Matters**

Patent Owner notes that the following proceedings may affect or be affected by a decision in this proceeding:

Case	Number	Court
<i>Teva Pharmaceuticals USA, Inc., et. al. v. Sandoz Inc., et al.</i>	14-cv-1171	DED
<i>Teva Pharmaceuticals USA, Inc., et. al. v. Doctor Reddy's Laboratories, Ltd., et al.</i>	14-cv-1172	DED
<i>Teva Pharmaceuticals USA, Inc., et. al. v. Mylan Pharmaceuticals Inc., et. al.</i>	14-cv-1278	DED
<i>Teva Pharmaceuticals USA, Inc., et. al. v. Synthon Pharmaceuticals Inc., et. al.</i>	14-cv-1419	DED
<i>Teva Pharmaceuticals USA, Inc., et. al. v. Amneal Pharmaceuticals LLC</i>	15-cv-00124	DED
<i>Teva Pharmaceuticals USA, Inc., et. al. v. Mylan Pharmaceuticals, Inc., et. al.</i>	14-cv-00167	NDWVa
<i>Teva Pharmaceuticals USA, Inc., et. al. v. Synthon Pharmaceuticals Inc., et. al.</i> <i>(dismissed)</i>	14-cv-00975	M.D.N.C.
<i>Teva Pharmaceuticals USA, Inc., et. al. v. Doctor Reddy's Laboratories, Ltd., et. al.</i> <i>(dismissed)</i>	14-cv-5672	D.N.J.

**b. Administrative Matters**

The following pending patent applications are related to the '413 patent:

14/630,326; 14/673,257.

The following proceeding is currently pending in the United States Patent and Trademark Office for the '413 patent: IPR2015-00644.

The following proceedings are currently pending in the United States Patent and Trademark Office for patents related to the '413 patent: IPR2015-01976 (Patent No. 8,232,250); IPR2015-00643 (Patent No. 8,232,250); IPR2015-01981 (Patent No. 8,969,302); and IPR2015-00830 (Patent No. 8,969,302).

**III. LEAD AND BACKUP COUNSEL (37 C.F.R. § 42.8(b)(3))**

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