

Paper No. _____
Filed: August 25, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS-KABI USA LLC

Petitioner

v.

ASTRAZENECA AB

Patent Owner

Case IPR2017-01913

U.S. Patent 8,329,680

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

Pursuant to 37 C.F.R. § 42.8, the undersigned on behalf of and acting in a representative capacity for patent owner AstraZeneca AB, hereby submits the following mandatory notices in connection with the Petition for *Inter Partes* Review of United States Patent No. 8,329,680 (the “’680 patent”), Case No. IPR2017-01913.

REAL PARTY-IN-INTEREST

AstraZeneca AB is Patent Owner. AstraZeneca UK Limited is the beneficial owner of the ’680 patent and holder of approved New Drug Application (“NDA”) No. 21-344 for FASLODEX[®] (fulvestrant) intramuscular injection, in 50 mg/mL dosage forms. AstraZeneca Pharmaceuticals LP is the authorized agent for matters related to NDA No. 21-344 in the United States.

RELATED MATTERS

The ’680 patent has been asserted in the following actions: *AstraZeneca Pharmaceuticals LP et al. v. Sandoz Inc.*, C.A. No. 1:14-cv-03547-RMB-KMW (D.N.J.) (dismissed); *AstraZeneca Pharmaceuticals LP et al. v. Sagent Pharmaceuticals, Inc.*, C.A. No. 1:14-cv-05539-RMB-KMW (D.N.J.) (consolidated as 1:14-cv-03547) (dismissed); *AstraZeneca Pharmaceuticals LP et al. v. Glenmark Pharmaceuticals Inc., USA*, C.A. No. 1:15-cv-00615-RMB-KMW (D.N.J.) (consolidated as 1:14-cv-03547) (dismissed); *AstraZeneca Pharmaceuticals LP et al. v. Agila Specialties, Inc. et al.*, C.A. No. 1:15-cv-06039-RMB-KMW (D.N.J.); *AstraZeneca Pharmaceuticals LP et al. v. Mylan Pharmaceuticals Inc. et al.*, C.A. No. 1:15-cv-7009-RMB-KMW (consolidated as 1:15-cv-06039) (dismissed); *AstraZeneca Pharmaceuticals LP et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 1:15-cv-7889-RMB-KMW (D.N.J.) (consolidated as 1:15-cv-06039) (dismissed); *AstraZeneca Pharmaceuticals LP et al. v. InnoPharma Licensing LLC*, C.A. No. 1:16-cv-1962-RMB-KMW (D.N.J.) (consolidated as 1:15-cv-06039); *AstraZeneca Pharmaceuticals LP et al. v. Teva Parenteral Medicines Inc. et al.*, C.A. No. 1:10-

cv-00018 (D. Del.) (dismissed); *AstraZeneca Pharmaceuticals LP et al. v. Sagent Pharmaceuticals, Inc.*, C.A. No. 1:14-cv-07358 (N.D. Ill.) (dismissed); *AstraZeneca Pharmaceuticals LP et al. v. Mylan Pharmaceuticals Inc. et al.*, C.A. No. 1:15-cv-00183 (N.D. W. Va.) (dismissed); *AstraZeneca Pharmaceuticals LP et al. v. InnoPharma, Inc.*, C.A. No. 1:16-cv-00894-RMB-KMW (D.N.J.) (dismissed); *AstraZeneca Pharmaceuticals LP et al. v. Mylan Institutional LLC*, C.A. No. 1:16-cv-04612 (D.N.J.) (consolidated as 1:15-cv-06039) (dismissed); *AstraZeneca Pharmaceuticals LP et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 1:17-cv-00926 (D.N.J.) (dismissed); *AstraZeneca Pharmaceuticals LP et al. v. HBT Labs, Inc.*, C.A. No. 1:17-cv-2652 (D.N.J.); *AstraZeneca Pharmaceuticals LP et al. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 1:17-cv-02448 (D.N.J.); *AstraZeneca Pharmaceuticals LP et al. v. Amneal Pharmaceuticals LLC*, C.A. No. 1:17-cv-01968 (D.N.J.).

Three related patents have been involved in district court proceedings: U.S. Patent Nos. 6,774,122 (the “’122 patent”); 7,456,160 (the “’160 patent”); and 8,466,139 (the “’139 patent”).

The ’680 patent and three related patents have been involved in *inter partes* review proceedings: IPR2016-01316 on the ’122 patent (terminated before institution); IPR2016-01324 on the ’160 patent (terminated before institution); IPR2016-01325 on the ’680 patent (institution denied); IPR2016-01326 on the ’139 patent (terminated before institution); IPR2017-00904 on the ’122 patent (institution decision pending); IPR2017-00900 on the ’680 patent (institution decision pending); and IPR2017-00905 on the ’139 patent (institution decision pending).

Concurrently with this petition, Petitioner submitted two other petitions for *inter partes* review: IPR2017-01910 on the ’122 patent and IPR2017-01912 on the ’139 patent.

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