

Paper No. \_\_\_\_\_  
Filed: July 20, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.

Petitioner

v.

ASTRAZENECA AB

Patent Owner

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Case IPR2016-01326

U.S. Patent 8,466,139

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**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. 8,466,139 (the “139 patent”), Case No. IPR2016-01326.

### **REAL PARTY-IN-INTEREST**

AstraZeneca AB is Patent Owner. AstraZeneca UK Limited is the beneficial owner of the '139 patent and holder of approved New Drug Application (“NDA”) No. 21-344 for FASLODEX<sup>®</sup> (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 '139 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.); *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); *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); *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); *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); *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.); *AstraZeneca Pharmaceuticals LP et al. v. InnoPharma, Inc.*, C.A. No. 1:16-cv-00894-RMB-KMW (D.N.J.) (dismissed).

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 8,329,680 (the “’680 patent”).

Concurrently with this petition, Petitioner submitted three other petitions for *inter partes* review: IPR2016-01316 on the ’122 patent; IPR2016-01324 on the ’160 patent; and IPR2016-01325 on the ’680 patent.

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Respectfully submitted,

Dated: July 20, 2016

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