

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.,
Petitioner

v.

HORIZON THERAPEUTICS, LLC,
Patent Owner

Case IPR2017-01159
Patent 9,254,278

PATENT OWNER'S INITIAL MANDATORY NOTICES

Pursuant to 37 C.F.R. § 42.8(a), the Patent Owner submits the following initial mandatory notices.

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

U.S. Patent No. 9,254,278 is owned by Horizon Therapeutics, LLC (f/k/a Hyperion Therapeutics, Inc.), a company organized and existing under the laws of the State of Delaware, having its principal place of business at 150 S. Saunders Road, Lake Forest, IL 60045. Pursuant to the requirements of 37 C.F.R. § 42.8(b)(1), the undersigned state that the real parties-in-interest are Horizon Therapeutics, LLC as well its corporate parents (collectively, Horizon):

- Horizon Pharma, Inc., a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 150 S. Saunders Road, Lake Forest, IL 60045, which is wholly owned by;
- Horizon Pharma Finance S.á.r.l., an entity organized and existing under the laws of Luxembourg, having its principal place of business at 19 Rue de Bitbourg, Luxembourg, which is wholly owned by;
- Horizon Pharma Capital Limited, a corporation organized and existing under the laws of Ireland, having its principal place of business at Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, Ireland, which is wholly owned by;

- Horizon Pharma Holdings Limited, a corporation organized and existing under the laws of Ireland, having its principal place of business at Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, Ireland, which is wholly owned by; and
- Horizon Pharma plc, a corporation organized and existing under the laws of Ireland, having its principal place of business at Connaught House, 1st Floor, 1 Burlington Road, Dublin 4, Ireland.

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

The following judicial and administrative matters may affect or be affected by a decision in this proceeding:

- (a) IPR2015-01117, petition filed April 29, 2015, by Par Pharmaceutical, Inc., directed at U.S. Patent No. 8,642,012, which is also owned by Horizon Therapeutics, LLC and has one common inventor with the patent at issue in this case. The Board instituted trial in an institution decision dated November 4, 2015 and issued a final written decision on November 3, 2016.
- (b) IPR2015-01127, petition filed April 29, 2015, by Par Pharmaceutical, Inc., directed at U.S. Patent 8,404,215, which is the grandparent of the patent at issue in this case. The Board instituted trial in an institution

decision dated November 4, 2015 and issued a final written decision on September 29, 2016.

- (c) IPR2016-00283, directed at U.S. Patent No. 8,642,012. The petition was filed December 4, 2015 by the present Petitioners and joined with IPR2015-01117.
- (d) IPR2016-00284, directed at U.S. Patent 8,404,215. The petition was filed December 4, 2015 by the present Petitioners and joined with IPR2015-01127.
- (e) IPR2016-00829, petition filed April 1, 2016, by the present Petitioners, directed at U.S. Patent 9,095,559, which is the parent of the patent at issue in this case. The Board instituted trial in an institution decision dated September 30, 2016.
- (f) IPR2017-01160, petition filed on the same date as this petition, by the present Petitioners, directed at U.S. Patent 9,326,966, which is a child of the patent at issue in this case.
- (g) *Par Pharmaceutical, Inc. v. Horizon Therapeutics, LLC*, Appeal No. 2017-1451 to the Federal Circuit from the Board's Final Written Decision in IPR Nos. IPR2015-01117 and IPR2016-00283 concerning U.S. Patent No. 8,642,012.

- (h) *Hyperion Therapeutics Inc. v. Par Pharmaceutical, Inc.*, Civil Action No. 2:14-cv-00384-JRG-RSP (E.D. Tex. filed April 23, 2014). The Complaint asserts infringement of U.S. Patent Nos. 8,404,215 and 8,642,012. On December 14, 2015, the district court stayed that case pending resolution of IPRs. On March 30, 2017, the district court continued the stay pending the resolution of Par's Appeal No. 2017-1451.
- (i) *Horizon Therapeutics Inc. v. Par Pharmaceutical Inc.*, Civil Action No. 1:16-cv-3910-RBK-JS (D.N.J. filed June 30, 2016). The Complaint asserts infringement of U.S. Patent Nos. 9,095,559, 9,254,278; and 9,326,966.
- (j) *Horizon Therapeutics Inc. v. Lupin Ltd. and Lupin Pharmaceuticals Inc.*, Civil Action No. 1:15-cv-07624-RBK-JS (D.N.J. filed Oct. 19, 2015). The Complaint asserts infringement of U.S. Patent No. 9,095,559.
- (k) *Horizon Therapeutics Inc. v. Lupin Ltd. and Lupin Pharmaceuticals Inc.*, Civil Action No. 1:16-cv-4438-RBK-JS (D.N.J. filed Jul. 21, 2016). The Complaint asserts infringement of U.S. Patent Nos. 9,254,278 and 9,326,966.

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