

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VII LLC,
Petitioner

v.

POZEN INC.,
Patent Owner

Case No. IPR2015-01344
Patent No. 8,858,996

MANDATORY NOTICES

37 C.F.R. § 42.8

Mail Stop “PATENT BOARD”

Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Pursuant to 37 C.F.R. § 42.8, the real parties-in-interest for this proceeding hereby submit the following mandatory notices in response to the Petition for *Inter Partes* Review of U.S. Patent No. 8,858,996 (“the ’996 patent”), case number IPR2015-01344.

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

The real parties-in-interest are:

Pozen Inc.;

Horizon Pharma, Inc., a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois, 60015, 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;

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; and

Horizon Pharma USA, Inc., a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois, 60015, which is wholly owned by Horizon Pharma, Inc.

Pozen Inc. (“Pozen”) is the licensor and patent owner of the ’907 patent.

Horizon Pharma USA, Inc. (“Horizon”) is the exclusive licensee with the right to enforce and defend the ’907 patent in this IPR proceeding.

Horizon obtained rights to the ’907 patent through an exclusive license agreement between patent owner Pozen and Horizon relating to the ’907 patent (“the License Agreement”), a redacted version of which is submitted with these mandatory notices.¹ *See* Ex. 2001 (redacted version of the “License Agreement”). Under the License Agreement, Pozen granted Horizon an exclusive license in the Field of Use for the duration of the ’907 patent’s term, which includes the right to sublicense, enforce, and defend the ’907 patent. *See* Ex. 2001 at §§ 1.43, 1.44, 7.1

¹ The redacted version of the License Agreement was previously submitted as a public document to the Securities and Exchange Commission by Horizon.

9.6.1, 9.6.2, and 9.10.2, and Schedule 1.43. These rights specifically include the right to defend reexamination proceedings. *See* Ex. 2001 § 9.6.2.

Specifically, the License Agreement defines “Licensed Patents” as:

1.43 “Licensed Patents” means: (a) the Patents set forth on Schedule 1.43, and any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, or extensions of such Patents, (b) any Patents in the Territory Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term that claim Inventions (including without limitation POZEN’s interest in Joint Inventions), and (c) all other Patents in the Territory Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term that are necessary or useful for the Development, Manufacture or Commercialization of a Product in the Territory. Notwithstanding anything in this Section 1.43 to the contrary, Licensed Patents shall not include any Patents Controlled by POZEN with Valid Claims that do not cover any Product (e.g., any Patents with Valid Claims solely directed to any product containing acetyl salicylic acid).

Ex. 2001 § 1.43. Schedule 1.43 to the License Agreement identifies U.S. Patent Appl. Nos. 10/158,216 and 11/129,320 as being within the scope of the “Licensed

Patents.” Ex. 2001 Schedule 1.43. The ’996 patent falls within the scope of the “Licensed Patents” as it a Patent explicitly set forth on Schedule 1.43 of the License Agreement.

The License Agreement also provides that Horizon is the exclusive licensee of the “Licensed Technology,” which includes the ’996 patent under the term “Licensed Patents.” Ex. 2001 § 1.44 (“**Licensed Technology**’ means the Licensed Patents and the Licensed Know-How”). The exclusive grant of rights to Horizon for the ’996 patent under the License Agreement is as follows:

7.1 Licensed Technology. Subject to the terms and conditions of this Agreement, POZEN hereby grants to Licensee an exclusive (including with regard to POZEN and its Affiliates), royalty-bearing license, with the right to grant sublicenses as described in Section 7.3 (Sublicenses), under the Licensed Technology to make, use, have made, sell, offer for sale, import and export Products in the Field of Use in the Territory. For the avoidance of doubt, Licensee shall have no license or other right under the Licensed Technology to make, use, have made, sell, offer for sale, import, and export any product containing acetyl salicylic acid (including salts and derivatives thereof).

Ex. 2001 at § 7.1.

The license agreement further gives Horizon the rights to enforce and defend against challenges to the '996 patent. These exclusive rights are set forth in section 9.6 of the License Agreement as follows:

9.6 Enforcement of Licensed Patents.

9.6.1 Infringement by Third Parties. Licensee and POZEN will each, within [redacted]² Business Days of learning of any alleged or threatened infringement of the Licensed Patents or Joint Patents, notify the other Party in writing. Licensee will have the first right, but not the obligation, to prosecute any such infringement. If Licensee does not commence an infringement action against the alleged or threatened infringement (i) within [redacted] days following the detection of the of alleged infringement, or (ii) [redacted] Business Days before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then Licensee will so notify POZEN promptly, and POZEN may commence litigation with respect to the alleged or threatened infringement at its own expense. . . .

² These designations identify redacted material that is not material to demonstrating that Horizon is an exclusive licensee with all substantial rights to the '996 patent.

9.6.2 Challenge by Third Parties. Licensee and POZEN will each notify the other Party in writing within [redacted] Business Days of learning of any alleged or threatened opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability of the Licensed Patents or Joint Patents by a Third Party. Licensee will have the first right, but not the obligation, to defend any such challenge. If Licensee does not commence Diligent Efforts to defend against the alleged or threatened challenge (i) within [redacted] days following the detection of the alleged challenge, or (ii) [redacted] Business Days before the time limit, if any, set forth in appropriate laws and regulations for making a filing in defense of such a challenge, whichever comes first, then Licensee will so notify POZEN promptly, and POZEN may take action with respect to the alleged or threatened challenge at its own expense. . . .

Ex. 2001 §§ 9.6.1, 9.6.2.

As the foregoing terms of the License Agreement demonstrate, Horizon has obtained rights to the '996 patent for purposes of this IPR through the License Agreement with Pozen, and is a real party-in-interest with standing for purposes of this *Inter Partes* Review proceeding.

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

Horizon Pharma, Inc. v. Actavis Labs. FL, Inc., 3:15-cv-03322 (D.N.J.).
Horizon Pharma, Inc. v. Dr. Reddy's Labs., Inc., 3:15-cv-03324 (D.N.J.). *Horizon Pharma, Inc. v. Lupin Ltd.*, 3:15-cv-03326 (D.N.J.). *Horizon Pharma, Inc., v. Mylan Pharmas., Inc.* 3:15-cv-03327 (D.N.J.).

U.S. Patent Nos. 6,926,907, 8,206,741, 8,852,636, 8,557,285, and 8,865,190 and U.S. Patent Appl. Nos. 60/294,588, 10/158,216, 11/129,320, 12/553,804, 13/215,855, 14/045,156, 14/231,971, 14/244,471, 14/515,627 claim, or may claim, the benefit of priority to U.S. Provisional Application No. 60/294,588, filed on June 1, 2001, the same application to which U.S. Patent No. 8,858,996 may claim priority. Additional proceedings involving patents related to 8,858,996 include *Horizon Pharma, Inc. & Pozen Inc. v. Dr. Reddy's Labs. Inc. & Dr. Reddy's Labs. Ltd.*, 3:11-cv-02317-MLC-DEA (D.N.J.); *Horizon Pharma, Inc. & Pozen Inc. v. Dr. Reddy's Labs. Inc. & Dr. Reddy's Labs. Ltd.*, 3:13-cv-00091-MLC-DEA (D.N.J.); *Horizon Pharma, Inc. & Pozen Inc. v. Lupin Ltd. & Lupin Pharms., Inc.*, 3:11-cv-04275-MLC-DEA (D.N.J.); *Horizon Pharma, Inc. et al. v. Actavis Labs. FL, Inc. & Actavis Pharma, Inc.*, 3:13-cv-03038-MLC-DEA (D.N.J.); *Horizon Pharma, Inc. & Pozen Inc. v. Mylan Pharms., Inc. et al.*, 3:13-cv-04022-MLC-DEA (D.N.J.); *Dr. Reddy's Labs., Inc. v. Pozen Inc.*, IPR2015-00802 (P.T.A.B.); and *Coalition for Affordable Drugs v. Pozen Inc.*, IPR2015-01241 (P.T.A.B.).

Patent Owner does not concede that any of these applications or patents would affect, or be affected by, a decision in the present *inter partes* review of U.S. Patent No. 6,926,996.

LEAD AND BACK-UP COUNSEL (37 C.F.R. § 42.8(b)(3))

Counsel for Horizon Pharma, Inc.:

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SERVICE INFORMATION (37 C.F.R. § 42.8(b)(4))

Horizon and Pozen hereby consent to electronic service. Please direct all correspondence to: IPR2015-01344@cooley.com, shash@velaw.com, and msampson@velaw.com.

Date: June 29, 2015

Respectfully submitted,

BY: /s/ Ricardo Rodriguez
Ricardo Rodriguez
Reg. No. 40,789
Counsel for Patent Owner

CERTIFICATION OF SERVICE UNDER 37 C.F.R. §§ 42.6(e), 42.105(a))

I, Ricardo Rodriguez, hereby certify that on this 29th day of June, 2015, the foregoing Patent Owner's Mandatory Notices pursuant to 37 C.F.R. § 42.8 and Pozen Exhibit 2001 were served electronically via email on the following:

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Date: June 29, 2015

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