

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**COALITION FOR AFFORDABLE DRUGS VII LLC,
Petitioner**

v.

**HORIZON PHARMA USA, INC.,
Patent Owner**

**Case No. IPR2015-01718
Patent No. 8,945,621**

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. 8,945,621 (“the ’621 patent”), case number IPR2015-01718.

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 ’621 patent.

Horizon Pharma USA, Inc. (“Horizon”) is the exclusive licensee with the right to enforce and defend the ’621 patent in this IPR proceeding.

Horizon obtained rights to the ’621 patent through an exclusive license agreement between patent owner Pozen and Horizon relating to the ’621 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 ’621 patent’s term, which includes the right to sublicense, enforce, and defend the ’621 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.

The '621 patent contains claims directed to, *inter alia*, methods of treatment employing compositions including those claimed in U.S. Patent Appl. Nos. 10/158,216 (U.S. Pat. No. 6,926,907) and 11/129,320 (now U.S. Pat. No. 8,206,741), which are explicitly listed as “Licensed Patents” in Schedule 1.43 of the License Agreement. In addition, the '621 patent is a “Patent[] 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). Ex. 2001 § 1.43. “Inventions” as defined by the License Agreement “means any invention, discovery or Know-How that is conceived during the Term in the performance of activities undertaken pursuant to this Agreement by employees, agents, or independent contractors of either Party, its Affiliates or Sublicensees and is Controlled by such Party, Affiliates or Sublicensees.” Ex. 2001 § 1.37. Accordingly, the '621 patent falls within the scope of the “Licensed Patents.”

The License Agreement also provides that Horizon is the exclusive licensee of the “Licensed Technology,” which includes the '621 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 '621 patent under the License Agreement is as follows:

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.