

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

PATENT OWNER'S MOTION TO FILE UNDER SEAL
37 C.F.R. § 42.14

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. § 42.12, Horizon Pharmaceuticals, Inc. and Pozen Inc. (hereinafter, “Patent Owner”) hereby submits this Motion to Seal Exhibit 2012 to Patent Owner’s Preliminary Response filed concurrently herewith.

I. Good Cause Exists for Sealing Certain Confidential Information

The Office Patent Trial Practice Guide provides that “the rules aim to strike a balance between the public’s interest in maintaining a complete and understandable file history and the parties’ interest in protecting truly sensitive information.” 77 FED. REG. 48756, 48760 (Aug. 14, 2012). These rules “identify confidential information in a manner consistent with Federal Rule of Civil Procedure 26(c)(1)(G), which provides for protective orders for trade secret or other confidential research, development, or commercial information.” *Id.* (citing 37 C.F.R. § 42.54).

Patent Owner requests to file two documents under seal. Exhibit 2012 is a confidential communication from the FDA to Patent Owner regarding the development of Patent Owner’s proprietary Vimovo product. Exhibit 2012 is cited in Patent Owner’s Preliminary Response. A non-redacted version of Patent Owner’s Preliminary Response has been filed under seal and a redacted version of Patent Owner’s Preliminary Response has been publicly filed. To preserve its confidentiality, Patent Owner moves to maintain Exhibit 2012 and the non-redacted version of Patent Owner’s Preliminary Response as filed under seal.

II. Certification of Non-Publication

On behalf of Patent Owner, undersigned counsel certifies that, to the best of their knowledge, the information sought to be sealed by this Motion to Seal has not been published or otherwise made public. Efforts to maintain the confidentiality of this information have been undertaken by Patent Owner in a related district court proceeding. Exhibit 2012 has been produced in co-pending patent infringement litigation in the United States District Court for the District of New Jersey¹ directed to, inter alia, related U.S. Patent No. 6,926,907 (“the ’907 patent”) under the parties’ agreed upon protective order, and designated confidential in those cases.

III. Certification of Conference with Opposing Party Pursuant to 37 C.F.R. § 42.54

¹ *Horizon Pharma, Inc. and Pozen Inc. v. Dr. Reddy’s Laboratories, Inc. & Dr. Reddy’s Laboratories, Ltd.*, 3:11-cv-02317-MLC-DEA (D.N.J.); *Horizon Pharma, Inc. and Pozen Inc. v. Dr. Reddy’s Laboratories, Inc. & Dr. Reddy’s Laboratories, Ltd.*, 3:13-cv-00091-MLC-DEA (D.N.J.); *Horizon Pharma, Inc. and Pozen Inc. v. Lupin Ltd. & Lupin Pharmaceuticals, Inc.*, 3:11-cv-04275-MLC-DEA (D.N.J.); *Horizon Pharma, Inc. and Pozen Inc. v. Mylan Pharmaceuticals, Inc.*, 3:13-cv-04022 (D.N.J.); and *Horizon Pharma, Inc., AstraZeneca AB, AstraZeneca LP and Pozen Inc. v. Actavis Labs., FL, et. al.*, 3:13-cv-03038-MLC-DEA (D.N.J.) (collectively, “the ’907 litigation”).

Patent Owner has conferred with Petitioner, and both parties consent to the stipulated protective order attached as Appendix A.

IV. Proposed Protective Order

Patent Owner submits a copy of the stipulated protective order attached as Appendix A, to which both parties have agreed. It is a revised version of the Default Protective Order in the Office Patent Trial Practice Guide, 77 FED. REG. 48756, 48771 (Aug. 14, 2012), and a red-line reflecting the revisions is also attached as Appendix B. Almost all of the provisions remain unchanged (including access by the PTO staff). The single revision made to Paragraph 2(A) allows both parties and real parties-in-interest to access confidential information.

V. Conclusion

For the reasons stated above, Patent Owner respectfully requests that Exhibit 2012, as well as the non-redacted version of Patent Owner's Preliminary Response, remain under seal.

Date: September 18, 2015

Respectfully submitted,

/s/ Ricardo Rodriguez

Ricardo Rodriguez

Reg. No. 40,789

Counsel for Patent Owner

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

I, Ricardo Rodriguez, hereby certify that on this 18th day of September 2015, the foregoing Patent Owner's Motion to File Under Seal Under 37 C.F.R. § 42.14 was served electronically via email on the following:

Amy E. LaValle
amy.lavalle@wickphillips.com

Jerry C. Harris, Jr.
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Wick Phillips Gould & Martin, LLP
3131 McKinney Avenue, Suite 100
Dallas, TX 75204

Date: September 18, 2015

BY: /s/ Ricardo Rodriguez

Ricardo Rodriguez

Reg. No. 40,789

Counsel for Patent Owner

EXHIBIT A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VII LLC
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PROPOSED PROTECTIVE ORDER

Mail Stop “PATENT BOARD”
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P.O. Box 1450
Alexandria, VA 22313-1450

PROTECTIVE ORDER

1. Confidential information shall be clearly marked “PROTECTIVE ORDER MATERIAL.”

2. Access to confidential information is limited to the following individuals who have executed the acknowledgment appended to this order:

(A) Parties and Real Parties-in-Interest. Persons who are owners of a patent involved in the proceeding and other persons who are named parties and real parties-in-interest to the proceeding.

(B) Party Representatives. Representatives of record for a party in the proceeding.

(C) Experts. Retained experts of a party in the proceeding who further certify in the Acknowledgement that they are not a competitor to any party, or a consultant for or employed by, such a competitor with respect to the subject matter of the proceeding.

(D) In-house counsel. In-house counsel of a party.

(E) Other Employees of a Party. Employees, consultants or other persons performing work for a party, other than in-house counsel and in-house counsel’s support staff, who sign the Acknowledgement shall be extended access to confidential information only upon agreement of the parties or by order of the

Board upon a motion brought by the party seeking to disclose confidential information to that person. The party opposing disclosure to that person shall have the burden of proving that such person should be restricted from access to confidential information.

(F) The Office. Employees and representatives of the Office who have a need for access to the confidential information shall have such access without the requirement to sign an Acknowledgement. Such employees and representatives shall include the Director, members of the Board and their clerical staff, other support personnel, court reporters, and other persons acting on behalf of the Office.

(G) Support Personnel. Administrative assistants, clerical staff, court reporters and other support personnel of the foregoing persons who are reasonably necessary to assist those persons in the proceeding shall not be required to sign an Acknowledgement, but shall be informed of the terms and requirements of the Protective Order by the person they are supporting who receives confidential information.

3. Persons receiving confidential information shall use reasonable efforts to maintain the confidentiality of the information, including:

(A) Maintaining such information in a secure location to which persons not authorized to receive the information shall not have access;

(B) Otherwise using reasonable efforts to maintain the confidentiality of the information, which efforts shall be no less rigorous than those the recipient uses to maintain the confidentiality of information not received from the disclosing party;

(C) Ensuring that support personnel of the recipient who have access to the confidential information understand and abide by the obligation to maintain the confidentiality of information received that is designated as confidential; and

(D) Limiting the copying of confidential information to a reasonable number of copies needed for conduct of the proceeding and maintaining a record of the locations of such copies.

4. Persons receiving confidential information shall use the following procedures to maintain the confidentiality of the information:

(A) Documents and Information Filed With the Board.

(i) A party may file documents or information with the Board under seal, together with a non-confidential description of the nature of the confidential information that is under seal and the reasons why the information is confidential and should not be made available to the public. The submission shall be treated as confidential and remain under seal, unless, upon motion of a party and after a hearing on the issue, or sua sponte, the Board determines that the documents or information do not to qualify for confidential treatment.

(ii) Where confidentiality is alleged as to some but not all of the information submitted to the Board, the submitting party shall file confidential and non-confidential versions of its submission, together with a Motion to Seal the confidential version setting forth the reasons why the information redacted from the non-confidential version is confidential and should not be made available to the public. The nonconfidential version of the submission shall clearly indicate the locations of information that has been redacted. The confidential version of the submission shall be filed under seal. The redacted information shall remain under seal unless, upon motion of a party and after a hearing on the issue, or sua sponte, the Board determines that some or all of the redacted information does not qualify for confidential treatment.

(B) Documents and Information Exchanged Among the Parties. Information designated as confidential that is disclosed to another party during discovery or other proceedings before the Board shall be clearly marked as “PROTECTIVE ORDER MATERIAL” and shall be produced in a manner that maintains its confidentiality.

**ACKNOWLEDGEMENT FOR ACCESS TO PROTECTIVE ORDER
MATERIAL**

I _____, affirm that I have read the Protective Order; that I will abide by its terms; that I will use the confidential information only in connection with this proceeding and for no other purpose; that I will only allow access to support staff who are reasonably necessary to assist me in this proceeding; that prior to any disclosure to such support staff I informed or will inform them of the requirements of the Protective Order; that I am personally responsible for the requirements of the terms of the Protective Order and I agree to submit to the jurisdiction of the Office and the United States District Court for the Eastern District of Virginia for purposes of enforcing the terms of the Protective Order and providing remedies for its breach.

Signature

Date

EXHIBIT B

REDLINED PROTECTIVE ORDER

1. Confidential information shall be clearly marked “PROTECTIVE ORDER MATERIAL.”

2. Access to confidential information is limited to the following individuals who have executed the acknowledgment appended to this order:

(A) Parties and Real Parties-in-Interest. Persons who are owners of a patent involved in the proceeding and other persons who are named parties and real parties-in-interest to the proceeding.

(B) Party Representatives. Representatives of record for a party in the proceeding.

(C) Experts. Retained experts of a party in the proceeding who further certify in the Acknowledgement that they are not a competitor to any party, or a consultant for or employed by, such a competitor with respect to the subject matter of the proceeding.

(D) In-house counsel. In-house counsel of a party.

(E) Other Employees of a Party. Employees, consultants or other persons performing work for a party, other than in-house counsel and in-house counsel's support staff, who sign the Acknowledgement shall be extended access to confidential information only upon agreement of the parties or by order of the Board upon a motion brought by the party seeking to disclose confidential

information to that person. The party opposing disclosure to that person shall have the burden of proving that such person should be restricted from access to confidential information.

(F) The Office. Employees and representatives of the Office who have a need for access to the confidential information shall have such access without the requirement to sign an Acknowledgement. Such employees and representatives shall include the Director, members of the Board and their clerical staff, other support personnel, court reporters, and other persons acting on behalf of the Office.

(G) Support Personnel. Administrative assistants, clerical staff, court reporters and other support personnel of the foregoing persons who are reasonably necessary to assist those persons in the proceeding shall not be required to sign an Acknowledgement, but shall be informed of the terms and requirements of the Protective Order by the person they are supporting who receives confidential information.

3. Persons receiving confidential information shall use reasonable efforts to maintain the confidentiality of the information, including:

(A) Maintaining such information in a secure location to which persons not authorized to receive the information shall not have access;

(B) Otherwise using reasonable efforts to maintain the confidentiality of the information, which efforts shall be no less rigorous than those the recipient

uses to maintain the confidentiality of information not received from the disclosing party;

(C) Ensuring that support personnel of the recipient who have access to the confidential information understand and abide by the obligation to maintain the confidentiality of information received that is designated as confidential; and

(D) Limiting the copying of confidential information to a reasonable number of copies needed for conduct of the proceeding and maintaining a record of the locations of such copies.

4. Persons receiving confidential information shall use the following procedures to maintain the confidentiality of the information:

(A) Documents and Information Filed With the Board.

(i) A party may file documents or information with the Board under seal, together with a non-confidential description of the nature of the confidential information that is under seal and the reasons why the information is confidential and should not be made available to the public. The submission shall be treated as confidential and remain under seal, unless, upon motion of a party and after a hearing on the issue, or sua sponte, the Board determines that the documents or information do not to qualify for confidential treatment.

(ii) Where confidentiality is alleged as to some but not all of the information submitted to the Board, the submitting party shall file confidential and

non-confidential versions of its submission, together with a Motion to Seal the confidential version setting forth the reasons why the information redacted from the non-confidential version is confidential and should not be made available to the public. The nonconfidential version of the submission shall clearly indicate the locations of information that has been redacted. The confidential version of the submission shall be filed under seal. The redacted information shall remain under seal unless, upon motion of a party and after a hearing on the issue, or sua sponte, the Board determines that some or all of the redacted information does not qualify for confidential treatment.

(B) Documents and Information Exchanged Among the Parties. Information designated as confidential that is disclosed to another party during discovery or other proceedings before the Board shall be clearly marked as “PROTECTIVE ORDER MATERIAL” and shall be produced in a manner that maintains its confidentiality.

**ACKNOWLEDGEMENT FOR ACCESS TO PROTECTIVE ORDER
MATERIAL**

I _____, affirm that I have read the Protective Order; that I will abide by its terms; that I will use the confidential information only in connection with this proceeding and for no other purpose; that I will only allow access to support staff who are reasonably necessary to assist me in this proceeding; that prior to any disclosure to such support staff I informed or will inform them of the requirements of the Protective Order; that I am personally responsible for the requirements of the terms of the Protective Order and I agree to submit to the jurisdiction of the Office and the United States District Court for the Eastern District of Virginia for purposes of enforcing the terms of the Protective Order and providing remedies for its breach.

Signature

Date