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THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. AUROBINDO PHARMA LIMITED, and AUROBINDO PHARMA USA, INC., Defendants.	Case No. 07-CV-06020 (MLC)(JJH) **NOTICE OF MOTION TO SEAL** **Motion Date: April 7, 2008** ***DOCUMENT ELECTRONICALLY FILED***

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PLEASE TAKE NOTICE that on April 7, 2008 at 10:00 a.m., or as soon thereafter as counsel may be heard, Defendants Aurobindo Pharma Limited ("Aurobindo India") and Aurobindo Pharma USA, Inc. ("Aurobindo USA"), shall appear before the Hon. John J. Hughes, U.S.M.J., United States District Court, Room 5W, Trenton, New Jersey 08608 and will move this Court pursuant to Local Civil Rule 5.3(c), for an Order to Seal EXHIBIT A OF THE MARCH 14, 2008 DECLARATION OF EDWARD J. PARDON IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION.

PLEASE TAKE FURTHER NOTICE THAT Defendants shall rely upon the accompanying Brief and Proposed Findings of Fact and Conclusions of Law that are submitted herewith. A proposed form of Order is also submitted for the Court's consideration.

Dated: March 14, 2008.

Respectfully submitted,

/s/ Arnold B. Calmann

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FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. AUROBINDO PHARMA LIMITED, and AUROBINDO PHARMA USA, INC., Defendants.	Case No. 07-CV-06020 (MLC)(JJH) **Motion Date: April 7, 2008** ***DOCUMENT ELECTRONICALLY FILE***

BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO SEAL EXHIBIT A OF THE MARCH 14, 2008 DECLARATION OF EDWARD J. PARDON IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

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PRELIMINARY STATEMENT

Defendants Aurobindo Pharma Limited ("Aurobindo India") and Aurobindo Pharma USA, Inc. ("Aurobindo USA") (collectively "Defendants") submit this brief in support of their motion pursuant to Local Civil Rule 5.3(c) to Seal Exhibit A of the March 14, 2008 Declaration of Edward J. Pardon in Support of Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction ("Dismissal Declaration Exhibit").

As confirmed by the Declaration of Edward J. Pardon in Support of Motion to Seal, submitted concurrently herewith, the Dismissal Declaration Exhibit contains information relating to Aurobindo India's Abbreviated New Drug Application ("ANDA"). The facts in the Dismissal Declaration Exhibit could be used to ascertain whether Aurobindo India maintains "First to File" status[1] as well as the current progress towards FDA approval. Disclosure of this information could seriously injure and impair one or more Defendants' competitive posture in the marketplace.

Accordingly, Defendants respectfully ask this Court to grant their motion to seal these documents for the reasons set forth herein.

STATEMENT OF FACTS

Defendants respectfully incorporate herein the factual details set forth in the Proposed Findings of Fact and Conclusions of Law submitted herewith regarding the Dismissal Declaration Exhibit sought to be sealed herein. Those facts demonstrate the highly confidential and proprietary nature of the information that is the subject of this motion.

[1] 21 U.S.C. § 355(j)(5)(B)(iv) grants 180 days of exclusivity to all those applicants who file on the first day that any party files an ANDA. This 180 day period is extraordinarily valuable to those who qualify and whether an applicant is "first to file" is not general knowledge.

LEGAL ARGUMENT

I. Legal Standards

There exists in civil cases a common law public right of access to judicial proceedings and records. Goldstein v. Forbes (In re Cendant Corp.), 260 F.3d 183, 192 (3d Cir. 2001) (citing 851 F.2d 673, 677-78 (3d Cir. 1988). The party seeking to seal any part of a judicial record bears the burden of demonstrating that "the material is the kind of information that courts will protect." Miller v. Indiana Hosy., 16 F.3d 549, 551 (3d Cir. 1994) (quoting Publicker Indus. Inc. v. Cohen, 733 F.2d 1059, 1071 (3d Cir. 1984)). This Court has the power to seal where confidential information may be disclosed to the public. In particular, Fed. R. Civ. P. 26(c)(7) provides for the protection by courts of materials containing "trade secret[s] or other confidential research, development, or commercial information[,]" upon motion by a party, to prevent harm to a litigant's competitive standing in the marketplace. Zenith Radio Corp. v. Matsushita Fleet Indus. Co. Ltd., 529 F. Supp. 866, 889-91 (E.D. Pa. 1981).

Local Civil Rule 5.3(c) identifies the standards for sealing or otherwise restricting public access to filed materials. Specifically, Local Rule 5.3(c)(2) requires a showing of:

(a) the nature of the materials or proceedings at issue;

(b) the legitimate private or public interest which warrants the relief sought;

(c) the clearly defined and serious injury that would result if the relief sought is not granted; and

(d) why a less restrictive alternative to the relief sought is not available.

Generally, the information contained in the Dismissal Declaration Exhibit that is the subject of this motion relates to commercially sensitive and/or proprietary non-public business and financial information of Aurobindo India. Specifically, the Dismissal Declaration Exhibit contains details of Aurobindo India's ANDA for rosuvastatin, including the date of application

and information useful in determining Aurobindo India's progress towards FDA approval. This information is held in confidence by the FDA and is generally unavailable to the public. Disclosure to the public would result in substantial competitive harm to one or more Defendants.

II. Aurobindo India Meets the Requirement of Rule 5.3(c)(2)(b) By Showing That There Are Legitimate Interests that Warrant Sealing

Courts have recognized that the public right of access to judicial proceedings and records is not absolute and may be rebutted. Republic of Philippines v. Westinghouse Elec. Corp., 949 F.2d 653, 662 (3d Cir. 1991). "Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes." Littlejohn v. BIC Corp., 851 F.2d 673, 678 (3d Cir, 1988)(quoting Nixon v. Warner Communications Inc., 435 U.S. 589, 598 (1978)). Courts may deny access to and seal a document when it encompasses business information that might harm a litigant's competitive standing. See id. (citation omitted).

The District Court of New Jersey has held that the inclusion of trade secrets and other confidential information in documents warrant the sealing of such documents. "A well-settled exception to the right of access is the protection of a party's interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm." In re Gabapentin Patent Litig., 312 F. Supp. 2d 653, 664 (D.N.J. 2004) (citation omitted) "The presence of trade secrets or other confidential information weighs against public access and, accordingly, documents containing such information may be protected from disclosure." Id. (citations omitted). Moreover, commercially sensitive information from which a litigant's market competitiveness may be harmed is often sealed from public access. See Faulman v. Security Mutual Financial, 2006 WL 1541059 at *1 (D.N.J. May 31, 2006); Miles v. Boeing Co., 154 F.R.D. 112, 114 (E.D. Pa. 1994).

The private interests at stake in this action warrant the relief sought. Here, plaintiffs and defendants—private parties—are in a dispute relating to patents and a generic drug product. The sealing of the identified document requested herein serves to protect the private proprietary business interests of defendant Aurobindo India. Publicly disclosing the subject confidential information may pose a substantial harm risk of harm to Aurobindo India's legitimate business interests and competitive position.

III. Aurobindo India Meets The Requirement of Rule 5.3(c)(2)(c) By Showing That Serious Injury That Would Result If The Confidential Documents Are Not Placed Under Seal

This Court has discretion to balance the factors for and against access to court documents. See Pansy v. Borough of Stroudsburg, 23 F.3d 772, 781 (3d Cir. 1994). Protection of a party's interest in confidential commercial information, such as a trade secret, is a sufficient threat of irreparable harm, and is clearly defined as a serious injury. See Publicker, 733 F.2d at 1071.

If relief is not granted, Aurobindo India's highly sensitive and confidential business information will be compromised, exposing them to substantial financial risks. Unless the Dismissal Declaration Exhibit is filed under seal, competitors and others will have access to important confidential and/or proprietary business information Aurobindo India that ordinarily would not be available to the public, let alone to its competitors in this highly competitive industry. Competitors and others in the marketplace might exploit such information to their advantage and benefit, and to Aurobindo India's unfair detriment.

IV. Aurobindo India Meets The Requirement of Rule 5.3(c)(2)(d) By Showing That No Less Restrictive Alternative Is Available

Once confidential information is disclosed to the public, it can never again be sealed or maintained as private. No less restrictive alternative is available because the request is tailored

to only the specific confidential Dismissal Declaration Exhibit, the release of which would pose a financial and competitive risk to one or more Defendants. Accordingly, the only way to protect Aurobindo India's confidential interests is to seal the Dismissal Declaration Exhibit.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion in its entirety.

Respectfully submitted,

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THE UNITED STATES DISTRICT COURT
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ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. AUROBINDO PHARMA LIMITED, and AUROBINDO PHARMA USA, INC., Defendants.	Case No. 07-CV-06020 (MLC)(JJH) **Motion Date: April 7, 2008** ***DOCUMENT ELECTRONICALLY FILED***

PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO SEAL EXHIBIT A OF THE MARCH 14, 2008 DECLARATION OF EDWARD J. PARDON IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

INTRODUCTION

Pursuant to Local Civil Rule 5.3(c), Defendants Aurobindo Pharma Limited ("Aurobindo India") and Aurobindo Pharma USA, Inc. ("Aurobindo USA") hereby submit Proposed Findings of Fact and Conclusions of Law in support of their Motion to Seal filed with the Court on March 14, 2008. Local Civil Rule 5.3(c) places the burden of proof on the moving party as to why a motion to seal or otherwise restrict public access should be granted. Specifically, it requires a showing of:

(1) the nature of the materials or proceedings at issue;
(2) the legitimate private or public interest which warrants the relief sought;
(3) the clearly defined and serious injury that would result if the relief sought is not granted; and
(4) why a less restrictive alternative to the relief sought is not available

Defendants seek to seal Exhibit A of the March 14, 2008 Declaration of Edward J. Pardon in Support of Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction ("Dismissal Declaration Exhibit").

Set forth below are the findings of fact and conclusions of law addressing each of the elements of Local Civil Rule 5.3(c). These findings of fact and conclusions of law support the granting of Defendants' Motion to Seal the Dismissal Declaration Exhibit identified herein:

I. The Nature of the Materials or Proceedings at Issue

A. Findings of Fact

1.) The Dismissal Declaration Exhibit refers extensively to Aurobindo India's Abbreviated New Drug Application ("ANDA") and contains highly confidential and/or proprietary information including information related to whether Aurobindo India enjoys first-to-file status, details regarding the status of completion of Aurobindo India's

ANDA, and details that could allow a competitor to ascertain its likelihood of approval.

B. Conclusions of Law

2.) There exists in civil cases a common law public right of access to judicial proceedings and records. Goldstein v. Forbes (In re Cendant Corp.), 260 F.3d 183, 192 (3d Cir. 2001) (citing Littlejohn v. BIC Corporation, 851 F.2d 673, 677-78 (3d Cir. 1988). The party seeking to seal any part of a judicial record bears the burden of demonstrating that "the material is the kind of information that courts will protect." Miller v. Indiana Hosp., 16 F.3d 549, 551 (3d Cir. 1994) (quoting Publicker Indus., Inc. v. Cohen, 733 F.2d 1059, 1071 (3d Cir. 1984)).

3.) This Court has the power to seal where confidential information may be disclosed to the public. Fed. R. Civ. P. 26(c)(7) allows the protection by courts of materials containing "trade secret[s] or other confidential research, development, or commercial information[,]" upon motion by a party, to prevent harm to a litigant's competitive standing in the marketplace. Zenith Radio Corp. v. Matsushita Elec. Indus. Co., Ltd., 529 F. Supp. 866, 889-91 (E.D. Pa. 1981).

II. The Legitimate Private or Public Interest which Warrants the Relief Sought

A. Findings of Fact

4.) The Dismissal Declaration Exhibit sought to be sealed contains ANDA related information that Aurobindo India asserts is confidential and proprietary.

5.) Defendants have an interest in not publicly disclosing this information and rely on such information to gain a competitive advantage in the generics pharmaceutical industry.

B. Conclusions of Law

6.) Courts have recognized that the public right of access to judicial proceedings and

records is not absolute. Id. (citations omitted).

7.) The presumption of public access is not absolute and may be rebutted. Id. (citing Republic of Philippines v. Westinghouse Elec. Corp., 949 F.2d 653, 662 (3d Cir. 1991). "Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes." Littlejohn, 851 F.2d at 678 (quoting Nixon v. Warner Communications, Inc., 435 U.S. 589, 598 (1978)).

8.) Courts may deny access to and seal a document when it encompasses business information that might harm a litigant's competitive standing. See id. (citation omitted).

9.) The District Court of New Jersey has held that the inclusion of trade secrets and other confidential information in documents warrant the sealing of such documents. "A well-settled exception to the right of access is the 'protection of a party's interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm.'" In re Gabapentin Patent Litig., 312 F. Supp. 2d 653, 664 (D.N.J. 2004) (citation omitted). "The presence of trade secrets or other confidential information weighs against public access and, accordingly, documents containing such information may be protected from disclosure." Id. (citations omitted).

10.) Commercially sensitive information, such as information from which profit margins can be deduced, and from which a litigant's market competitiveness may be harmed is often sealed from public access. Faulman v. Security Mutual Financial, 2006 WL 1541059 at *1 (D.N.J. May 31, 2006).

11.) Information that reflects a corporation's price competitiveness in the marketplace constitutes confidential commercial information. Miles v. Boeing Co., 154 F.R.D. 112,

114 (E.D. Pa. 1994).

III. The Clearly Defined and Serious Injury that would Result if the Relief Sought is Not Granted

A. Findings of Fact

12.) Given its reference to, and disclosure of, non-public business information that is otherwise unavailable to third parties, including ANDA information, the public disclosure of the Dismissal Declaration Exhibit without redactions poses a substantial risk of harm to Defendants' legitimate proprietary interests and competitive position.

B. Conclusions of Law

13.) The district court has discretion to balance the factors for and against access to court documents. See Pansy v. Borough of Stroudsburg, 23 F.3d 772, 781 (3d Cir. 1994). Protection of a party's interest in confidential commercial information, such as trade secrets or profit margin, is a sufficient threat of irreparable harm, and is clearly defined as a serious injury. See Publicker, 733 F.2d at 1071; Faulman, 2006 WL 1541059 at *1.

IV. Why a Less Restrictive Alternative to the Relief Sought is not Available

A. Findings of Fact

14.) Once confidential information is disclosed to the public, it can never again be sealed or maintained as private.

15.) The disclosure of this confidential and/or proprietary information would pose a financial and competitive risk to one or more Defendants. Accordingly, the only way to protect Aurobindo India's confidential interests is to seal the identified documents.

B. Conclusions of Law

16.) Under Local Civil Rule 5.3(c)(2), a party seeking to seal documents must meet

the fourth prong that a no less restrictive alternative to the relief sought is available. See Securimetrics, Inc. v. Iridian Techs., Inc., No. 03-cv-04394, 2006 WL 827889, at *2 (D.N.J. Mar 30, 2006).

17.) The sealing of confidential documents and information is an accepted practice in the District of New Jersey. In re Gabapentin Patent Litig., 312 F. Supp. 2d 653, passim.

Dated: March 14, 2008.

Respectfully submitted,

/s/ Arnold B. Calmann

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON DIVISION

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED,
IPR PHARMACEUTICALS, INC., and
SHIONOGI SEIYAKU KABUSHIKI KAISHA,

Plaintiffs,

v.

AUROBINDO PHARMA LIMITED, and
AUROBINDO PHARMA USA, INC.,

Defendants.

Case No. 07-CV-06020 (MLC)(JJH)

Document Filed Electronically

DECLARATION OF EDWARD J. PARDON
IN SUPPORT OF MOTION TO SEAL

I, Edward J. Pardon, do declare and state as follows:

1. I am an attorney at Michael Best & Friedrich LLP.

2. I submit this declaration in support of Defendants Aurobindo Pharma Limited ("Aurobindo India") and Aurobindo Pharma USA, Inc.'s ("Aurobindo USA"), Motion to Seal Exhibit A of the March 14, 2008 Declaration of Edward J. Pardon in Support of Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction.

3. I have personal knowledge of the facts set forth in this Declaration.

4. This case concerns the alleged infringement of U.S. Patent No. Re 37,314 arising out of the filing of an abbreviated new drug application by Aurobindo India.

5. Exhibit A of the March 14, 2008 Declaration of Edward J. Pardon in Support of Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction contains significant details regarding the contents of Aurobindo India's Abbreviated New Drug Application ("ANDA").

6. Aurobindo India has spent substantial amounts of time and money preparing the ANDA application.

7. The facts and circumstances surrounding the preparation and filing of the ANDA application are presently confidential and not available to the public.

8. The information in Aurobindo India's ANDA is highly confidential. Examples of such confidential and proprietary information include information related to the date upon which the application was filed, which can have an impact on whether Aurobindo India is entitled to 180 days of market exclusivity should it be successful in this litigation. Another example of confidential and proprietary information is that descriptions of the content of the ANDA may permit a competitor to ascertain the degree to which the ANDA is complete and/or the likelihood

of it being approved in its present form.

9. Such information is critical to Aurobindo India's ability to effectively compete in the marketplace and especially in connection with its ability to effectively compete against other generic competitors.

10. If Aurobindo India's highly confidential and/or proprietary internal corporate information were to become available to the public, Aurobindo India's competitors could use that information to its detriment.

11. Accordingly, it is respectfully requested that the Court protect Aurobindo India's highly confidential corporate information and ANDA related information, and grant Defendants' Motion to Seal.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: March 14, 2008.

Edward J. Pardon

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THIS MATTER having been opened to the Court by Defendants Aurobindo Pharma

Limited ("Aurobindo India") and Aurobindo Pharma USA, Inc. ("Aurobindo USA"), by and through their attorneys, SAIBER LLC and MICHAEL BEST & FRIEDRICH LLP, in connection with their Motion to Seal pursuant to Local Civil Rule 5.3(c) Exhibit A of the March 14, 2008 Declaration of Edward J. Pardon in Support of Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction, and the Court having considered the papers submitted by Defendants in support of the within Motion, and any papers submitted by Plaintiffs herein in opposition thereto; and the Court having considered oral argument of the parties, if any; and having found that the standards of Local Civil Rule 5.3(c) have been met and support the sealing of the foregoing documents, testimony and information, and for the reasons set forth in the record of the proceedings, and for other and good cause having been shown,

IT IS on this ___ day of _____ 2008;

ORDERED that Defendants' Motion pursuant to Local Civil Rule 5.3(c) to Seal the subject documents, information and testimony be and the same is hereby granted; and it is further

ORDERED, that said documents, information and testimony shall be sealed and shall be filed **UNDER SEAL** with this Court.

HONORABLE JOHN J. HUGHES
UNITED STATES MAGISTRATE JUDGE

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THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA, Plaintiffs, v. AUROBINDO PHARMA LIMITED, and AUROBINDO PHARMA USA, INC., Defendants.	Case No. 07-CV-06020 (MLC)(JJH) **CERTIFICATE OF SERVICE**

ARNOLD B. CALMANN, hereby certifies as follows:

1. I am an attorney-at-law of the State of New Jersey and admitted to practice before the Courts of the State of New Jersey and the United States District Court for the District of New Jersey.

2. I hereby certify that on this 14th day of March, 2008, I caused the following documents to be served upon all counsel of record via ECF:

- Notice of Motion Pursuant to Local Civil Rule 5.3(c) to Seal Exhibit A to Declaration of Edward J. Pardon;
- Proposed Findings of Facts and Conclusions of Law in Support of Defendants' Motion Pursuant to Local Civil Rule 5.3(c) to Seal;
- Brief in Support of Defendants' Motion Pursuant to Local Civil Rule 5.3(c) to Seal;
- Declaration of Edward J. Pardon in Support of Motion to Seal;
- Proposed Form of Order; and
- Certificate of Service

3. I also hereby certify that on this 14th day of March, 2008, I caused the aforementioned documents to be served via electronic mail and first class mail upon the following:

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Dated: March 14, 2008

/s/ Arnold B. Calmann
Arnold B. Calmann