THE SUPREME COURT FOR THE STATE OF ALASKA

ELI LILLY AND COMPANY, Appellant, v. BLOOMBERG, LLC d/b/a BLOOMBERG NEWS, Intervenor, Appellee.	Supreme Court Case No. S-13152 Superior Court Case No. 3AN-06-05630 CI

REPLY TO BLOOMBERG NEWS' OPPOSITION TO ELI LILLY'S EMERGENCY MOTION FOR STAY AND FOR ORDER PROHIBITING PUBLICATION OR DISSEMINATION OF DOCUMENTS PENDING APPEAL

I. INTRODUCTION

Bloomberg LLC d/b/a Bloomberg News ("Bloomberg") has failed to show that this Court erred in granting Eli Lilly and Company's Motion for Emergency Stay and that Eli Lilly should be denied additional time to brief the merits of Judge Rindner's June 13, 2008, Order Granting Bloomberg's Motion ("June 13 Order") to unseal docket entries in the case of State of Alaska v. Eli Lilly and Company. Eli Lilly's Motion for Emergency Stay should be upheld and Eli Lilly should be given additional time for briefing the merits of the June 13 Order for the following reasons:

First, the trial court denied Eli Lilly its right to file a Motion for Reconsideration of the court's final order within ten days of issuance of the order. The trial court unsealed the documents five days after it issued its Order Granting Bloomberg's Motion; thus, at a

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minimum, Eli Lilly is entitled to an additional five days to brief the issue of whether these documents should have been unsealed by the trial court.

Second, this Court properly granted Eli Lilly's Motion for a Stay based on the motion's articulation of the severe and irreparable harm to Eli Lilly, especially given the sensitive and proprietary nature of communications between Eli Lilly and the FDA, some of which are at issue in this case. Furthermore, maintaining the stay to allow Eli Lilly an opportunity to brief the merits of the June 13 Order causes little harm to Bloomberg or the public interest due to the volume of information already in the public domain.

Third, prior restraints on speech are permissible where, as here, the restraint is necessary to prevent significant harm and the restraint is the least restrictive measure available to prevent the harm. Premature release of the unsealed documents will harm the FDA regulatory drug approval process, Eli Lilly, and patients currently taking Zyprexa; thus, preventing release of the contents until adequate briefing has been completed is the only way to prevent this harm.

II. FACTS

In March 2006, the Attorney General of the State of Alaska filed suit against Eli Lilly in the Superior Court of Alaska regarding Eli Lilly's antipsychotic medication Zyprexa.[1] On July 30, 2007, pursuant to Alaska Rule of Civil Procedure 26(c)(7), the

[1] Zyprexa is an antipsychotic medication approved for the treatment of schizophrenia, bipolar I disorder, bipolar mania, and bipolar maintenance treatment.

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Superior Court entered a protective order to govern discovery.[2] By its terms, the protective order extended to all "information that the producing party in good faith believes is properly protected under Alaska Rule of Civil Procedure 26(c)(7); under any state or federal statutes, regulations or court rules; or under Federal or state constitutions."[3] Relying upon this Protective Order and the Court Administrative Rules 37.5 through 37.6,[4] the parties filed under seal numerous motions and exhibits containing confidential information, including internal Lilly documents and confidential communications with the FDA. The parties also filed several iterations of confidential deposition designations discussing trade secrets and other confidential business information.

At the outset of trial, on March 7, 2008, Bloomberg filed a Motion to Intervene and Unseal Records; the motion requested the unsealing of pleadings and attachments related to 25 separate docket entries.[5] On March 20, 2008, Eli Lilly filed a Motion in Opposition which explained the legal standards for unsealing the documents at issue, provided information about the trade secret protections that should be afforded to Lilly's documents, and requested

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[2] Exhibit C, Protective Order, p. 1.

[3] *Id.* at 2.

[4] Administrative Rule 37.6 permits this Court, as under Alaska Rule of Civil Procedure 26(c), to keep documents filed with the court confidential. Administrative Rule 37.5(e)(1)(C) provides that any document deemed "sealed or confidential pursuant to . . . court order" is "not accessible to the public." These are, therefore, "non-public records" under the definition of Administrative Rule 37.5, and Bloomberg's argument to the contrary is without basis. *Cf.* Bloomberg's Mem. in Supp. of Mot. to Intervene and to Unseal Records at 12.

[5] Exhibit E, Bloomberg, LLC d/b/a/ Bloomberg News' Motion to Intervene and Unseal Records (hereinafter "Bloomberg's Motion to Unseal Records").

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the court not release any documents until after the conclusion of trial.[6] On March 26, 2008, the State of Alaska and Eli Lilly reached a settlement.

On April 25, 2008, Eli Lilly filed a Supplemental Response to Bloomberg's Motion. The Supplemental Response undertook a thorough document analysis, designating the confidentiality of documents which did not contain trade secrets and asserting the confidentiality of those documents which would present harm to Lilly if competitors were provided an opportunity to review them. In support of its motion, Lilly filed affidavits of Lilly employees Timothy Franson and Gerald Hoffman, experts in the Regulatory Process and Competitive Intelligence, respectively. Both documents explained to the Court in detail the value of Lilly's trade secret information. On May 2, 2008, Bloomberg filed a reply to Lilly's motion.

On June 13, 2008, the trial court entered its Order Granting Bloomberg's Motion to Unseal Records. Despite Lilly's strong showing of the significance of the confidentiality of documents containing trade secrets and internal business information, the trial court's order unsealed virtually every document Bloomberg sought to have designated as not confidential.[7] Although the Order was executed on June 13, 2008, Eli Lilly's counsel was

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[6] Exhibit F, Eli Lilly's Opposition to Bloomberg, LLC d/b/a/ Bloomberg News' Motion to Intervene and Unseal Records (hereinafter "Eli Lilly's Opposition to Bloomberg's Motion to Unseal Records").

[7] Exhibit A, Order Granting Bloomberg's Motion to Unseal Records.

not able to review the Order and consult with its client until Monday, June 16, 2008.[8] On June 16, 2008, Lilly sent Judge Rindner a letter notifying him that Eli Lilly intended to seek a stay of the court's order and file a motion for reconsideration. Lilly also attempted to contact counsel for Bloomberg in hopes of agreeing to stipulation which would allow Lilly time to brief the merits of the June 13 Order. Later that same day, Lilly filed a Motion to Stay in which it explained to the court that it had just become aware of the June 13 Order and that Lilly intended to file a Motion for Reconsideration which would be filed no later than June 23, 2008 – ten days after the June 13 Order was issued.[9] On June 17, 2008, Bloomberg filed an opposition to Lilly's Motion to Stay, alleging that Lilly could not properly file a motion for reconsideration.[10]

On June 18, 2008, only five days after its final order, the Superior Court issued an order denying Lilly's motion to stay; this order stated in part: "This Court will not stay unsealing the records. The records now are available for public access."[11] Due to the Superior Court's failure to notify Eli Lilly prior to releasing the documents, Bloomberg's counsel was able to obtain the documents before the close of business on June 18, 2008. Eli

[8] *See* Affidavit of Brewster H. Jamieson (originally filed with Eli Lilly's Motion to Stay Unsealing of Records) at ¶ 2.

[9] *See* Eli Lilly's Motion to Stay Unsealing of Records Pending Filing of Motion for Consideration.

[10] *See* Exhibit 6 to Bloomberg's Opposition [Eli Lilly's Motion to Stay Unsealing of Records Pending Filing of Motion for Reconsideration].

[11] Exhibit B, Order Denying Eli Lilly and Company's Motion to Stay Unsealing of Records Pending Filing of Motion for Reconsideration, at p. 1.

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Lilly then sought relief from this Court by filing its Emergency Motion for Stay and For Order Prohibiting Publication or Dissemination of Documents Pending Appeal.

III. ARGUMENT

Bloomberg's demand that this Court lift the Temporary Stay and allow it to publish the contents of the unsealed documents fails to acknowledge Eli Lilly's rights to exhaust its judicial remedies to protect its valuable trade secrets. Additionally, Bloomberg ignores the importance of trade secret protection and the value of confidentiality of communications between regulatory authorities and pharmaceutical companies.

A. The Trial Court Violated The Alaska Rules of Civil Procedure When It Denied Eli Lilly's Motion To Stay The Court's June 13, 2008 Order.

Under Alaska Rule of Civil Procedure 77(k), Eli Lilly was entitled to ten days from the date of the trial court's final ruling to file its motion for reconsideration of the court's decision. Judge Rindner's Order Granting Bloomberg's Motion to Unseal Documents was entered on June 13, 2008; therefore, by rule, Eli Lilly had until Monday, June 23, 2008 to file its motion for reconsideration. On Monday, June 16, 2008, Eli Lilly notified the Court that it intended to file a motion for reconsideration and it was seeking to stay the implementation of the Court's Order to unseal the documents – that is, Eli Lilly requested the trial court delay unsealing the documents until Eli Lilly exhausted its remedies for review of the court's decision.[12]

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[12] Exhibit H, Eli Lilly's Motion to Stay, at p. 2.

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On June 18, 2008, merely five days after its final order, the trial court denied Eli Lilly's motion for stay and ordered immediate release of the unsealed documents.[13] Prior to its June 18 Order, the trial court provided no notice to Eli Lilly that its reconsideration motion would be due in less than 10 days nor did it allow Eli Lilly time to seek a judicial remedy before allowing access to the documents. Due to the trial court's failure to notify Eli Lilly prior to releasing the documents, Bloomberg was able to obtain the documents before the close of business on June 18, 2008. It was only through this Court's Temporary Stay Order that Eli Lilly's rights were protected against having its confidential information made available to its competitors and the public. Because the trial court failed to allow Eli Lilly the time it is allotted by law, this Court acted properly when it granted Eli Lilly's Motion for an Emergency Stay Pending Appeal and it should extend the stay so that Eli Lilly can appeal Judge Rindner's ruling.

B. Eli Lilly Made An Adequate Showing For This Court To Grant Its Emergency Motion For Stay Pending Appeal And Provide Eli Lilly With Additional Opportunity To Challenge The June 13 Order.

Bloomberg improperly asserts that Eli Lilly has not established the requisite showing to warrant the grant of its Motion to Stay. The four factors Eli Lilly must satisfy to obtain a stay pending appeal are: (1) likelihood of success on the merits; (2) harm to petitioner (Eli Lilly); (3) harm to other interested persons (Bloomberg); and (4) and no harm

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[13] Exhibit B, Order Denying Lilly's Motion to Stay Unsealing of Records

to the public interest.[14] Eli Lilly has satisfied all factors; thus, the temporary stay should remain in place until the merits of the June 13 Order are fully briefed and decided.

1. Eli Lilly's Appeal of the June 13 Order Is Likely to Succeed Because the Unsealed Documents Contain Non-public Materials Reflecting Internal Eli Lilly Processes.

Bloomberg falsely asserts that Eli Lilly should not succeed in its appeal because Eli Lilly is trying to "delay for delay's sake" and was attempting to use the Motion for Reconsideration as a tool to "seek an extension of time for the presentation of additional evidence on the merits of the claim."[15] On the contrary, Eli Lilly was entitled to seek reconsideration of the trial court's June 13 Order on the basis that "[a] party may move the court to reconsider a ruling previously decided if, in reaching its decision, [t]he court has overlooked or misconceived some material fact or proposition of law."[16]

The trial court failed to appreciate the importance of trade secret protection for information regarding Eli Lilly's marketing, promotional, regulatory practices, and scientific strategies and developments. This is particularly evident, for example, in the trial court's treatment of Plaintiff's Exhibit No. 10106, which is a portion of Eli Lilly's submission to the

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[14] *Powell v. City of Anchorage*, 536 P.2d 1228, 1229 n.2 (Alaska 1975).

[15] *See* Bloomberg's Opposition to Eli Lilly's Emergency Motion for Stay and For Order Prohibiting Publication or Dissemination of Documents Pending Appeal, at p. 9, 11.

[16] Alaska R. Civ. R. 77(k)(1)(ii).

FDA in response to allegations from articles published in *The New York Times* in 2006.[17] In denying Lilly's request that this document remain under seal, Judge Rindner gave only passing reference to an affidavit from Timothy Franson, Eli Lilly's Vice President of Global Regulatory Affairs, noting only that:

> Lilly relies on a declaration by…Timothy Franson ("the Franson declaration") to support its argument that the submissions and communications contained in Plaintiff's Ex. No. 10106 "are so current that companies with products in competition with Zyprexa and Symbyax could use this information to gain unfair insight to their benefit as well as to exploit this information to harm Lilly in the marketplace."[18]

The court's order went on to state that the document did not contain trade secrets because "Lilly's possible knowledge of Zyprexa side effects, specifically hyperglycemia and diabetes, were the subject of extensive testimony at trial."[19] These statements reflect that the trial court failed to consider the Franson affidavit's discussion of the particular documents at issue and the seriousness of the protections that must be afforded to regulatory submissions. As Franson's affidavit explains,

> Pharmaceutical companies and regulatory bodies regularly exchange confidential information to facilitate the drug approval and compliance process in an efficient and fair manner. These protections encourage full and frank communications, and both parties maintain these communications in confidence.

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[17] The portion of Plaintiff's Ex. 10106 at issue contains discussions of Lilly market research and Lilly's analysis of *The New York Times's* allegations against the company, including actual questions used to conduct the research and Lilly's analysis of the research.

[18] Exhibit A, June 13 Order Granting Motion to Unseal Records, at p. 16.

[19] *Id.* at 17.

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> Regulatory submissions and communications between Lilly and the FDA are private and confidential, not subject to public disclosure. They contain confidential proprietary information, confidential commercial information, confidential trade secret information, and other confidential information. These submissions and communications are exchanged between Lilly and the FDA with an expectation and understanding that they will not be disclosed or disseminated.[20]

Information that is submitted to the FDA and which contains Lilly's internal analysis and information that will give competitors insight to its market research and scientific development must be protected from disclosure as trade secrets.

The Alaska Uniform Trade Secrets Act, which gives statutory protection to trade secrets, defines "trade secrets" as information that

> (A) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and
>
> (B) is the subject of efforts that are reasonable under the circumstances to maintain secrecy.[21]

In addition to Plaintiff's Ex. 10106, many of the other documents at issue contain non-public information Eli Lilly uses to create business plans, including documents that discuss Eli Lilly's strategies for market research, training and motivating of its sales force, and creation of marketing and promotional campaigns. If this information became publicly available, competitors would be able to benefit from Eli Lilly's significant investment of time, money,

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[20] Exhibit L, Franson Aff. at ¶¶ 8-9.

[21] AS 45.50.940(3).

and energy in developing its business.[22] For example, information about the strategies Eli Lilly used when creating market research questionnaires would be of great interest and value to a competitor because it would then be able to take research done by Eli Lilly to undermine the company's marketing efforts or create its own marketing campaigns targeting Eli Lilly's customers. Thus, the July 13 Order does not properly weigh the significance of the information contained in Eli Lilly's documents, and portions of this order should be overturned.

Additionally, Bloomberg's assertion that Eli Lilly relies on conclusory statements and stories of "theoretical" harm fails to acknowledge the extensive treatment Eli Lilly gave each document in its Supplemental Motion Opposing Unsealing of Bloomberg Documents. In support of its motion, Eli Lilly submitted a declaration by Gerald Hoffman (Eli Lilly's Manager of Global Competitive Intelligence Strategy) and an affidavit by Timothy Franson (Eli Lilly's Vice President of Global Regulatory Affairs). While it is true that the Hoffman declaration was originally prepared for another case, this document outlines the issues that are of concern when documents containing private company information are released into the public domain. (*e.g.*, "Public dissemination [of documents containing internal strategies and processes for implementation] would reveal the manner in which the company considered or developed research information, strategic plans, marketing plans, strategies, competitive analyses, market research, clinical trials and non-clinical trials, and interactions with

[22] *See, generally,* Exhibit M, Hoffman Declaration.

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regulators or publishers.") [23] The affidavit of Timothy Franson speaks directly to the importance of maintaining the confidentiality of regulatory submissions sought by Bloomberg in its discussion of the documents submitted to the FDA in response to articles published in *The New York Times*.[24] The trial court failed to adequately consider the applicability and significance of statements in these documents.

2. Eli Lilly's Motion for a Stay was Properly Granted Because Premature Release of the Content of the Unsealed Documents Would Cause Irreparable Harm to Eli Lilly.

Eli Lilly's motion adequately illustrated that severe and irreversible harm would occur to Eli Lilly if the contents of the documents were prematurely released. As Eli Lilly states in its motion, once the documents have been distributed to the public, Eli Lilly will have no recourse to keep its confidential information from the hands of competitors. Without an opportunity to fully brief the merits of the June 13 Order, Eli Lilly would be unfairly forced to endure the consequences of its private strategizing and internal business processes being displayed for competitors to emulate and undermine.

3. Bloomberg Would Not Suffer Substantial Harm as a Result of the Stay.

Despite Bloomberg's arguments that it will experience substantial harm, a temporary stay would result in very little, if any, harm to Bloomberg and the public interest. The documents Eli Lilly seeks to protect contain confidential business information regarding, for example, Eli Lilly's marketing and promotional strategies, Eli Lilly's training programs

[23] Exhibit M, Hoffman Decl., ¶ 18.

[24] Exhibit L, Franson Affidavit, ¶ 4, 8-13.

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for sales associates, and Eli Lilly's communications with the FDA.[25] There is no harm caused by prohibiting Bloomberg from publishing the contents of documents to which they should have never had access; therefore, Bloomberg cannot claim it will suffer harm if the Court prohibits it from committing an act which it has no right to commit.

4. The Public Interest is Not Harmed by Preventing the Public Access to Confidential Documents which Contain Trade Secrets and Protected Information.

The public interest in this information is minimal due to the information already publicly available and the type of information Bloomberg would receive as part of the trial court's order. A good deal of information regarding Eli Lilly and Zyprexa was discussed openly at trial and Eli Lilly has voluntarily removed the confidential designation from several documents sought by Bloomberg.[26] The public interest is satisfied by information contained in these documents and open discussions in court; therefore, there is no additional public interest that outweighs Eli Lilly's ability to seek protection of its private information. Any information to which the public had access to by virtue of the documents being discussed at trial or admitted at trial are sufficient to protect the public's interest in information regarding Eli Lilly and Zyprexa. Additionally, as discussed III.C.3 below, publication of partial information obtained by Bloomberg through the Court's Order would harm patient care by

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[25] Examples of documents which fit into these categories include Plaintiff's Exhibits No. 10106 which is a submission to the FDA containing (among other things) market research and information reveal research strategies. Additionally, some deposition excerpts attached to filed deposition designations contain discussions of Lilly's inner processes.

[26] *See* Exhibit 3 to Bloomberg's Opposition [Lilly's Supplemental Response to Bloomberg, LLC d/b/a Bloomberg New's Motion to Intervene and to Unseal Records].

providing excerpts of a small number of documents which will not present an accurate picture of Lilly or its behaviors with regard to Zyprexa or the drug regulatory process.

C. The Temporary Stay Was Properly Entered Due To The Irreparable Harm That Would Be Caused By Publication Of The Documents Contents And The Lack of A Less Intrusive Means Of Prohibiting Publication.

Bloomberg's reliance on the prior restraint doctrine to establish that the temporary stay was improperly entered fails to take into account the significant harm that would be done to the FDA drug approval process, Eli Lilly, and Zyprexa patients were Bloomberg to prematurely publish the contents of the documents. A temporary stay is an appropriate remedy to prohibit distribution of information or documents when (1) the damage caused by the speech would be "great and certain"; and (2) there is no less intrusive measure to avoid the harm that would be caused by the publication.

1. Harm to the Regulatory Process

As Eli Lilly has stated in its prior briefing, it is imperative that information exchanged between the FDA and pharmaceutical companies remain confidential in order to facilitate the drug review and approval process. Submission of trade secret information to the FDA has long been protected by statute and case law.[27] This right is protected to foster candor between the FDA and drug companies. Without this protection, the FDA approval process would be hampered because companies might limit the information they provide to

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[27] Under 5 U.S.C. § 552(b)(4), FOIA's disclosure requirements "[do] not apply to matters that are . . . trade secrets and commercial or financial information obtained from a person and privileged or confidential." *And see Jerome Stevens Pharmaceuticals, Inc. v. FDA*, 402 F.3d 1249 (D.C. Cir. 2005).

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the FDA (and other regulatory agencies) for fear of their business practices and confidential communications becoming known to their competitors.[28] Accordingly, the temporary stay was necessary to allow Eli Lilly an opportunity to seek relief from the trial court's June 13 Order, so that it can protect its communications with the FDA from being improperly displayed for public consumption.

2. Harm to Eli Lilly

Bloomberg minimizes the irreparable damage that would be done to Eli Lilly by classifying Eli Lilly's justified attempts to protect its trade secrets as attempts to protect its vanity and avoid public relations problems. Eli Lilly would be substantially harmed by release of these documents, because they would provide competitors with insight into Eli Lilly's business structure, marketing and promotional strategies, and other internal processes that have been developed through the investment of significant time, money, and energies of Eli Lilly. Eli Lilly has taken significant efforts to protect this information from the public because of its value to Eli Lilly's functioning and continued competitive success;[29] therefore, it would be inappropriate for the Court to release unseal these documents until it has fully considered the true harm Eli Lilly if this information is disclosed.

Further, the documents sought by Bloomberg represent only a very small fraction of documents discussing Zyprexa. Bloomberg's discussion of the documents would

[28] Exhibit L, Franson Aff.

[29] Lilly has exempted many of these documents from FOIA and has instituted policies within the company to protect the dissemination of information. *See*, Exhibit M, Hoffman Decl. at ¶¶ 10-22. *See also*, Exhibit L, Franson Aff. at ¶¶ 8-14.

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necessarily be skewed because of its limited knowledge of all of the facts. This would cause even greater harm to Eli Lilly. As Judge Weinstein wrote when discussing the irreparable harm that could be caused to Eli Lilly by publication of selected portions of Eli Lilly's confidential documents,

> The harm faced by Lilly is amplified by the fact that the protected documents which respondents seek to disseminate are segments of a large body of information, whose selective and out-of-context disclosure may lead to confusion in the patient community and undeserved reputational harm – 'what appears damning may, in context, after difficult proof, be shown to be neutral or even favorable to the defendant.'[30]

Consequently, publication of Lilly's internal business strategies and processes will result in harm to Lilly from its competitors, and implementation of the temporary stay is the only remedy which will allow Lilly to brief this issue on the merits before it suffers irreparable and unjustified harm.

3. Harm to Patients

The disclosure of selected portions of deposition transcripts and communications between the FDA and Eli Lilly endangers a vulnerable patient population medicated with Zyprexa. Patients treated with Zyprexa suffer from life-threatening mental illnesses, including schizophrenia and bipolar mania. Publication of out-of-context information about the inner workings of the company and its strategies for marketing and scientific development will cause confusion and alarm in patients who may then discontinue their

[30] *In re Zyprexa Litigation*, 474 F.Supp.2d 385, 425 (E.D.N.Y. 2007), quoting Note, *Secrecy in Civil Trials: Some Tentative Views,* 9 J.L. & Pol'y 53, 58 (2000).

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medication without seeking the guidance of a medical professional. When left untreated, schizophrenia and bipolar mania can lead to serious impairments in judgment and dangerous behaviors.

In sum, this Court properly limited Bloomberg's ability to publish or otherwise produce the contents of the unsealed documents because failure to allow Eli Lilly to protect its trade secret information would cause harm to Eli Lilly, the FDA drug approval process, and the Zyprexa patient population. This Court should continue to prohibit Bloomberg's use of the documents until such time as Eli Lilly has an opportunity to challenge the trial court's June 13 Order unsealing the documents at issue. Any action short of a stay would allow Bloomberg and others to disseminate information that rightfully belongs to Eli Lilly and should be protected by the trial court and this Court.

IV. CONCLUSION

For the foregoing reasons, Eli Lilly requests that this Court keep in place the stay which it granted Eli Lilly and allow Lilly to brief the merits of the Superior Court's June 13 Order.

RESPECTFULLY SUBMITTED this 25th day of June, 2008.

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