

IN THE
UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
Orlando Division

MDL Docket No. 06-MD-1769

IN RE: Seroquel Products Liability Litigation.)
_____)

This Document Relates to All Cases

Motion of Bloomberg L.P. to
Intervene to Seek Access to Judicial Records
and Memorandum of Law

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TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

MOTION.....1

MEMORANDUM OF LAW2

FACTS GIVING RISE TO THIS MOTION4

 Bloomberg News4

 Bloomberg News Reporting About this Case.....5

 Sealing of Summary Judgment and *Daubert* Motions & Responses.....6

 Partial Disclosure of Sealed Records.....6

 Defendants’ Two Motions to Seal (Doc. Nos. 1222 & 1237)7

 Plaintiffs’ Three Motions to Seal (Doc. Nos. 15, 1230 & 42).....10

 The Notice of Hearing11

 Public Interest in This Litigation12

ARGUMENT15

 I. Bloomberg L.P. Has Standing to Intervene15

 II. There is No Basis to Maintain the
 Confidentiality or to Seal the Records at Issue.....16

CONCLUSION.....23

CERTIFICATE OF CONFERENCE.....24

CERTIFICATE OF SERVICE25

TABLE OF AUTHORITIESCases

<i>Alaska v. Eli Lilly Co.</i> , No. 3AN-06-5630 CI (June 12, 2008)	3
<i>Brown v. Advantage Engineering, Inc.</i> , 960 F.2d 1013 (11th Cir. 1992)	15
<i>Chicago Tribune Co. v. Bridgestone/Firestone, Inc.</i> , 263 F.3d 1304 (11th Cir. 2001)	<i>passim</i>
<i>Citizens First National Bank of Princeton v. Cincinnati Insurance Co.</i> , 178 F.3d 943 (7th Cir. 1999)	4, 19
<i>Estate of Dr. Martin Luther King v. CBS, Inc.</i> , 184 F. Supp. 2d 1353 (N.D. Ga. 2002)	9, 10, 20, 23
<i>Horwitch v. Diamond Aircraft Industrial, Inc.</i> , No. 6:06-cv-1703-Orl-19KRS, 2007 WL 1753006 (M.D. Fla. June 16, 2007).....	9
<i>KnowledgeAZ, Inc. v. DeFosset</i> , No. 1:05-cv-1019-DFH-TAB, 2006 WL 3201932 (S.D. Ind. June 28, 2006).....	4
<i>McCarthy v. Barnett Bank of Polk County</i> , 876 F.2d 89 (11th Cir. 1989)	16
<i>Newman v. Graddick</i> , 696 F.2d 796 (11th Cir. 1983)	15
<i>Nixon v. Warner Commission, Inc.</i> , , 435 U.S. 589 (1978).....	16, 17
<i>In re Subpoena to Testify Before Grand Jury</i> , 864 F.2d 1559 (11th Cir. 1989)	15
<i>Union Oil Co. of California v. Leavell</i> , 220 F.3d 562 (7th Cir. 2000)	19, 23
<i>United States v. Camacho</i> , 22 Media L. Rep. (BNA) 1845 (S.D. Fla. 1994)	21

<i>United States v. Ellis</i> , 90 F.3d 447 (11th Cir. 1996)	15
<i>United States v. Rosenthal</i> , 763 F.2d 1291 (11th Cir. 1985)	21
<i>Wilson v. American Motors Corp.</i> , 759 F.2d 1568 (11th Cir. 1985)	15
<i>In re Zyprexa Injunction</i> , 474 F. Supp. 2d 386 (E.D.N.Y. 2007)	13
<i>In re Zyprexa Products Liability Litigation</i> , 253 F.R.D. 69 (E.D.N.Y. Sept. 5, 2008).....	3, 13, 14
 <u>Rules</u>	
Fed. R. Civ. P. 26.....	16, 17
Fed. R. Civ. P. 26(c)	16
Middle District of Florida General Rule 1.09	9, 21

MOTION

Bloomberg L.P. d/b/a Bloomberg News (“Bloomberg”), seeking to vindicate the public’s right of access to judicial documents, moves to intervene in this action to:

1. Oppose four pending motions to seal judicial records (MDL All Cases Doc. Nos. 1222, 1230, 1237 & MDL Case Nos. 6:07-cv-10291 & 15733 Doc. No. 42).

2. Unseal defendants’ motions for summary judgment and motions to exclude evidence and plaintiffs’ responses and supporting documents, including:

- a. Plaintiffs’ Omnibus Legal Memorandum In Opposition to AstraZeneca’s Summary Judgment Motions In Florida Trial Pool “Group One” Cases and Exhibits.
- b. AstraZeneca’s Summary Judgment Motion and Memorandum and Exhibits and Plaintiff Whittington’s Response In Opposition in Case No. 6:07-cv-10475.
- c. AstraZeneca’s Summary Judgment Motion and Memorandum and Exhibits and Plaintiff Curley’s Response In Opposition in Case No. 6:07-cv-15701.
- d. AstraZeneca’s Summary Judgment Motion and Memorandum and Exhibits and Plaintiff Haller’s Response In Opposition in Case No. 6:07-cv-15733.
- e. AstraZeneca’s Summary Judgment Motion and Memorandum and Exhibits and Plaintiff McAlexander’s Response In Opposition in Case No. 6:07-cv-10360.
- f. AstraZeneca’s Summary Judgment Motion and Memorandum and Exhibits and Plaintiff Guinn’s Response In Opposition in Case No. 6:07-cv-10291.
- g. AstraZeneca’s Summary Judgment Motion Plaintiff Unger’s Response In Opposition and Memorandum and Exhibits in Case No. 6:07-cv-15812.
- h. AstraZeneca’s Summary Judgment Motion Plaintiff Burns’ Response In Opposition and Memorandum and Exhibits in Case No. 6:07-cv-15959.

- i. Plaintiffs' Response In Opposition to AstraZeneca's Motion to Exclude General Causation Testimony of Plaintiffs' Generic and Case Specific Causation Witness and Supporting Memorandum and Exhibits.
- j. AstraZeneca's Motion to Exclude Specific Causation Testimony of Plaintiffs' Case Specific Causation Witness and Supporting Memorandum and Exhibits and Plaintiffs' Response In Opposition.
- k. AstraZeneca's Motion to Exclude Non-Causation Expert Testimony Under Federal Rules of Evidence 702, 401 and 403 and Supporting Memorandum and Exhibits and Plaintiffs' Response In Opposition.
- l. AstraZeneca's Motion under *Daubert* and Federal Rules of Evidence 702, 401 and 403 to Exclude or Limit Testimony of Paul Deutsch and Frederick Raffa and Supporting Memorandum and Exhibits and Plaintiffs' Response in Opposition.

Bloomberg also requests an opportunity to appear at the hearing scheduled in this case before Magistrate Judge David Baker at 9:00 a.m. on Thursday, February 26, 2009, to address the issues raised by the four pending motions to maintain the confidentiality of or to seal documents that have been filed in this action.¹

Bloomberg respectfully requests that the Court also consider at the February 26, 2009, hearing, this motion to intervene and to unseal judicial records, including the records sealed upon plaintiffs' motion to allow their responses to AstraZeneca's motions for summary judgment and to exclude testimony. (Case No. 6:07-cv-10291 Doc. No. 15 & 17).

¹ The motions were originally noticed for hearing on February 13, 2009. The parties filed a joint motion to postpone the hearing until February 26, 2009, and the Court granted that motion. Unless the parties agree that all of the judicial records that are the subject of Bloomberg's motion should be made publicly available, any agreement among the parties will not moot the issues raised by this motion, for reasons addressed herein.

MEMORANDUM OF LAW

It is now well established that “access to judicial proceedings, an essential component of our system of justice, is instrumental in securing the integrity of the process.” *Chicago Tribune Co. v. Bridgestone/Firestone, Inc.*, 263 F.3d 1304, 1309 (11th Cir. 2001). Access to the records of this proceeding is particularly instrumental in allowing the public to ensure the integrity of this Court’s process in light of the serious public health implications of the MDL plaintiffs’ allegations that AstraZeneca’s antipsychotic drug Seroquel causes diabetes and increases the risk of death in certain patient groups and that AstraZeneca knew about these risks, concealed them for several years, and marketed Seroquel for unapproved uses. Similarly, the public must be afforded an opportunity to gauge AstraZeneca’s response to these allegations. Thousands of similar claims are pending not only before this Court but in state courts across the country. While this litigation is pending, Seroquel remains on the market. Public health is very much here at stake, and more information rather than less will help all to assess the magnitude of those risks.

Courts in Alaska and New York have recognized the need for public access in litigation of this type. In addition to Judge Weinstein’s decision unsealing previously confidential Eli Lilly documents in very similar litigation, *In re Zyprexa Products Liability Litigation*, 253 F.R.D. 69 (E.D.N.Y. Sept. 5, 2008), which the parties have cited in their papers, an Alaskan court granted Bloomberg’s motion to unseal several documents in a related Zyprexa lawsuit, *Alaska v. Eli Lilly Co.*, No. 3AN-06-5630 CI (June 12, 2008) (attached as Exhibit A), in a decision the parties have not cited.

“The parties to a lawsuit are not the only people who have a legitimate interest in the

record compiled in a legal proceeding.” *Citizens First Nat’l Bank of Princeton v. Cincinnati Ins. Co.*, 178 F.3d 943, 944 (7th Cir. 1999) (Posner, J.). The public at large “has an interest in what goes on at all stages of a judicial proceeding.” *Id.* at 945. The Court “is the primary representative of the public interest in the judicial process and is duty-bound therefore to review any request to seal the record (or part of it),” even if the parties agree to the sealing of certain documents. *Id.* Accordingly, “Any request to seal any portion of the record will be closely scrutinized and must be rigorously justified.” *KnowledgeAZ, Inc. v. DeFosset*, No. 1:05-cv-1019-DFH-TAB, 2006 WL 3201932, at *1 (S.D. Ind. June 28, 2006) (Baker, M.J.).

FACTS GIVING RISE TO THIS MOTION

The following facts are pertinent to the disposition of this motion.

Bloomberg News

Bloomberg News is a 24-hour global news service with more than 2000 journalists in 120 bureaus around the world. Bloomberg News supplies real-time business, financial and legal news to more than 300,000 desktop subscribers world-wide. As a wire service, Bloomberg provides news to more than 400 newspapers in 73 countries with a combined circulation of 76.2 million readers.

Bloomberg subscriber papers in this jurisdiction include *The Orlando Sentinel*, *The Tampa Tribune* and the *Tampa Bay Review*. Bloomberg also provides daily radio and television programming throughout the world through its 750 radio affiliates. Bloomberg News also operates eleven 24-hour cable news television outlets globally and publishes four monthly magazines. Its Bloomberg Press division publishes more than 50 book titles each year, and its internet website www.bloomberg.com receives 3.5 million individual user visits

each month.

Bloomberg News Reporting About this Case

Bloomberg News has been reporting regularly to the public about this case and is attempting to continue to inform the public regarding the allegations of the plaintiffs, the defenses of AstraZeneca, and the methods that the Court will use to adjudicate the controversy.² Bloomberg News reported on December 5, 2008, that records filed in this case, including a report prepared in 2000 by AstraZeneca safety director Wayne Geller, revealed that AstraZeneca was aware of Seroquel risks in 2000.³ Reporters Joe Schneider and Margaret Cronin Fisk explained to the public that in this case AstraZeneca is facing more than 15,000 consumer claims alleging the antipsychotic drug Seroquel causes diabetes and that the company knew about the risks at the heart of the case as early as 2000, according to

² See, e.g., Margaret Cronin Fisk, *AstraZeneca Faces 10,000 Lawsuits Over Seroquel Drug*, Bloomberg.com (Feb. 13, 2007) (<http://www.bloomberg.com/apps/news?pid=20601102&sid=a.ZTdmV67chI&refer=uk>);

Joe Schneider & Margaret Cronin Fisk, *AstraZeneca Was Aware of Seroquel Risks in 2000, Records Show* (Dec. 5, 2008) (<http://www.bloomberg.com/apps/news?pid=20601202&sid=arcAPvYRDKn4&refer=healthcare>) (hereinafter “Schneider & Cronin Fisk”);

Margaret Cronin Fisk & Jef Feeley, *AstraZeneca is Asked to Expand Warning, Lawyer Says*, Bloomberg.com (Jan. 27, 2009) (<http://www.bloomberg.com/apps/news?pid=20601087&sid=a8uwQ1qo0GLc&refer=home>);

Jef Feeley & Margaret Cronin Fisk, *AstraZeneca Wins Dismissal of First Seroquel Cases*, Bloomberg.com (Jan. 28, 2009) (<http://www.bloomberg.com/apps/news?pid=20601087&sid=alsVfUp65MT4&refer=home>);

Sophia Pearson & Doris Bloodworth, *AstraZeneca Drug Raises Diabetes Risk, Doctor Says*, Bloomberg.com (Jan. 16, 2009) (http://www.bloomberg.com/apps/news?pid=20601202&sid=av_Gg66oOeWA&refer=healthcare).

³ See Schneider & Cronin Fisk, note 2 *supra*.

its own documents shown in court.⁴ Bloomberg News explained to readers that although the internal documents were shown publicly during a hearing over the qualifications of expert witnesses the plaintiffs plan to use at trial, the documents themselves remain sealed.⁵

Sealing of Summary Judgment and *Daubert* Motions & Responses

In response to defendants' request (Doc. No. 1105), Magistrate Judge Baker entered an order on October 29, 2008, directing the parties to file in the public record summary judgment and *Daubert* motions that redacted "medical information deemed confidential under prior Orders." (Doc. No. 1107 at 1). The order further provided:

The redacted version shall be as complete as reasonably possible while protecting individually identifiable medical information. It is the Court's intention that the redacted public version of anything filed pursuant to this Order be sufficiently complete and informative so as to allow anyone reading them to be able to discern the nature and basis for the arguments presented. To that end, it may be necessary to include general statements regarding the nature of the redacted material, without revealing specific individually identifiable medical information. By way of example: facts and argument predicated on a particular plaintiff's treatment history or use of other medicines could be redacted with an accompanying notation that the redacted portion of the document includes a discussion of the plaintiff's medical history as it bears on the particular argument being advanced.

(Doc. No. 1107 at 1-2). Notwithstanding this order, defendants filed *entire* summary judgment and *Daubert* motions and supporting documentation under seal. Plaintiffs similarly filed *entire* responses to summary judgment and *Daubert* motions under seal.

Partial Disclosure of Sealed Records

Counsel for the plaintiffs, Paul Pennock, disclosed in open Court on December 4,

⁴ See Schneider & Cronin Fisk, note 2 *supra*.

⁵ See Schneider & Cronin Fisk, note 2 *supra*.

2008, that in a January 8, 2008, letter, the U.S. Food and Drug Administration, had asked AstraZeneca to provide an analysis of all its clinical trials relating to Seroquel. In addition, Laura Massey Plunkett, a human risk assessment specialist, testified at the hearing that AstraZeneca responded to the FDA letter on June 26, 2008, with an analysis that showed 2.4 percent of people who began treatment with normal levels of sugar in the blood became technically diabetic after 52 weeks and that people taking Seroquel were 70 percent more likely to develop diabetes than people who were not taking the drug. Bloomberg anticipates that AstraZeneca has filed the June 26, 2008, letter and is seeking to maintain its confidentiality (*see* Doc. No. 1222 Ex. A #1).

In addition, a 2000 report by AstraZeneca safety director Wayne Geller, indicating that the company knew about the risk that Seroquel can cause diabetes and related conditions, was presented at the December 4, 2008 hearing. Despite the public disclosure of the contents of this report, the report and related internal AstraZeneca documents remain under seal. (*See* Doc. No. 1222 Ex. A #8: 08/18/00 email from Geller including attached Safety Position Paper).

Defendants' Two Motions to Seal (Doc. Nos. 1222 & 1237)

On January 21, 2009, prompted by plaintiffs' objections to confidentiality designations, AstraZeneca filed a motion to maintain confidentiality status of certain documents referenced and filed under seal in connection with plaintiffs' oppositions to AstraZeneca's *Daubert* and summary judgment motions. (Doc. No. 1222). The motion divided the documents into two categories: (1) those that should remain confidential only

until trial,⁶ and (2) those that should remain confidential even at trial.⁷ The motion is supported by two declarations, one from Charles Peipher, the Seroquel brand director for managed market and healthcare professionals, and another from Dr. Arthur Lazarus, AstraZeneca's senior director, clinical development.

AstraZeneca claimed the former should remain sealed because plaintiffs had no legitimate need for declassification shortly before a then-impending trial date; publication of the documents could mislead and harm the public and generate negative publicity for AstraZeneca; and public disclosure could taint the jury pool. AstraZeneca asserted that they contain trade secret or proprietary commercial information and dissemination of the documents would cause competitive harm. (Doc. No. 1222).

AstraZeneca's motion ignored the Eleventh Circuit's controlling precedent in *Chicago Tribune Co. v. Bridgestone/Firestone, Inc.*, 263 F.3d 1304 (11th Cir. 2001), failed to cite decisions of this Court, and did not cite or discuss the state or federal decisions unsealing

⁶ Exhibit A to the motion lists 46 specific documents or categories of documents that should remain confidential until offered at trial. Eleven of the documents are identified as exhibits to the plaintiffs' opposition to AstraZeneca's motion to exclude the general causation testimony of plaintiffs' generic and case specific witnesses that were filed on Nov. 21, 2008 (Doc. No. 1158). Twenty-eight of the documents are identified as exhibits filed in opposition to the omnibus summary judgment motion. Five relate to specific plaintiffs' summary judgment motions. One document relates to a supplemental memorandum regarding a general causation witness. Document 46 on the Exhibit A list is described as "Various Expert Declarations, Expert Reports, and Expert Dep Excerpts, as well as Prescriber Dep Excerpts, which discuss confidential documents that were attached as exhibits to plaintiffs' responses." This catchall category appears to include numerous documents.

⁷ Exhibit A to the motion lists 13 specific documents or categories of documents to remain confidential even at trial. Six documents are identified as filed in opposition to AstraZeneca's motion to exclude the general causation testimony of plaintiffs' generic and case specific witnesses that were filed on Nov. 21, 2008 (Doc. No. 1158). Seven documents are identified filed in opposition to summary judgment motions.

documents in the Zyprexa litigation which will be discussed below. Further, it did not address the standards set forth in this Court's own local rule governing the sealing of documents. Magistrate Karla Spaulding recently observed that Local Rule 1.09 "requires, among other things, that the movant show 'the reason that a means other than sealing is unavailable or unsatisfactory to preserve the interests advanced by the movant in support of the seal.'" *Horwitch v. Diamond Aircraft Indus., Inc.* No. 6:06-cv-1703-Orl-19KRS, 2007 WL 1753006, at *2 (M.D. Fla. June 16, 2007). AstraZeneca's motion did not address why the exhibit could not be presented in a redacted or summarized form.

Plaintiffs responded on February 2, 2009, noting that both Judge Conway and Magistrate Judge Baker had cautioned the parties that they would not allow broad categories of documents to be sealed. (Doc. No. 1258). Plaintiffs also appropriately cited to precedents such as *Chicago Tribune Co.*, 263 F.3d 1304, and *Estate of Dr. Martin Luther King v. CBS, Inc.*, 184 F. Supp. 2d 1353 (N.D. Ga. 2002), as establishing the ground rules for determining whether documents filed with the Court should remain under seal. (Doc. No. 1258 at 3-8). The plaintiffs contend that AstraZeneca has not in the first instance established that any of the documents at issue are trade secrets that warrant protection, and that the public interest in the documents outweighs AstraZeneca's interest in secrecy, emphasizing that a large number of the documents are 6-10 years old or older and therefore would have very limited value and disclosure would do very limited harm. (Doc. No. 1258 at 8-10).

On January 26, 2009, AstraZeneca filed a second motion to seal exhibits in opposition to the plaintiffs' notice of intent to file an emergency motion for sanctions for discovery abuse. (Doc. No. 1237). This motion asked the Court to allow it to submit under

seal “correspondence with the FDA deemed confidential by the Protective Order governing this MDL.” (*Id.* at 1).

Plaintiffs’ Three Motions to Seal (Doc. Nos. 15, 1230 & 42)

On November 24, 2008, plaintiffs in Case Nos. 6:07-cv-10291, 15959, 15812, 15701, 10475, 10360, and 15733 moved to seal their response to AstraZeneca’s summary judgment motions and motions to exclude testimony. (MDL No. 6:07-cv-10291 Doc. No. 15). They asserted that the sealing of the documents was necessitated solely by AstraZeneca’s designation of certain documents and materials as “confidential” under an earlier entered protective order and that the documents were filed under seal pursuant to an instruction the Court gave at the November 5, 2008, telephone conference. The Court granted the motion on December 17, 2008, without opinion. (MDL No. 6:07-cv-10291 Doc. No. 17).

On January 22, 2009, plaintiffs filed a motion to seal certain exhibits referenced in their responses in opposition to AstraZeneca’s motions in limine to exclude evidence and argument about Dr. Macfadden’s personal relationships, ghostwriting, and clinical investigators’ misconduct. (Doc. No. 1230). Plaintiffs asserted that submission of these documents under seal was necessary solely because the items had been designated as confidential by AstraZeneca. Neither plaintiffs nor AstraZeneca have attempted to show what interests would be served by allowing these documents to be filed under seal.

On January 26, plaintiffs Linda Guinn and David Haller filed a motion for sanctions claiming that AstraZeneca had withheld letters from the FDA until shortly before trial (Doc. No. 41) and a motion to seal exhibits referenced in their sanctions motion (Doc. No. 42). The exhibits filed under seal are said to consist of December 18 and 22, 2008 correspondence

and attachments from the FDA to AstraZeneca regarding “significant, FDA-directed changes to Seroquel’s warning labels.” (Doc. No. 41, MDL Doc. No. 1253). The plaintiffs claimed that the letters contained “critical information directly supporting Plaintiffs’ liability case.” (Doc. No. 41 at 3). On January 30, 2009, Judge Conway granted summary judgment for AstraZeneca on these plaintiffs’ claims and ruled that the motion for sanctions became moot by entry of summary judgment. (Doc. No. 48). Judge Conway did not find the motion to seal the documents filed with the motion for sanctions moot, and it is not moot because Bloomberg seeks access to those documents.⁸

On February 2, 2009, plaintiffs filed a notice of filing additional exhibits to their motions in limine. (Doc. No. 1254).

The Notice of Hearing

On January 28, 2009, this Court noticed a hearing for February 13, 2009, on (1) defendants’ motion to maintain the confidentiality of certain challenged documents filed under seal as exhibits to plaintiffs’ motion responses (Doc. No. 1222), (2) plaintiffs’ unopposed motion to seal exhibits to their responses in opposition to motions in limine (Doc. No. 1230), (2) defendants’ emergency unopposed motion to seal its submissions (with exhibits) in opposition to plaintiffs’ notice of intent to file emergency motion for sanctions for discovery abuse (Doc. No. 1237), and (4) plaintiffs unopposed motion to seal exhibits referenced in emergency motion for sanctions (MDL Case Nos. 6:07-cv-10291 & 15733

⁸ The documents at issue in *Chicago Tribune Co. v. Bridgestone/Firestone, Inc.*, 263 F.3d 1304, 1309 (11th Cir. 2001), were sought by the press only after final disposition of the claims in the case, but both the district court and the Eleventh Circuit held that the request for access to documents filed in the case presented a live controversy.

Doc. No. 42). At the request of the parties, the Court postponed the hearing until February 26, 2009.

Public Interest in This Litigation

Bloomberg News seeks to intervene on behalf of the public to provide the Court with a perspective on the pending motions that cannot be fully explicated by the parties. This litigation comes in the wake of similar litigation against Eli Lilly arising from its marketing of Zyprexa, an atypical antipsychotic used, like Seroquel, for the treatment of schizophrenia, bipolar disorder, and certain other afflictions. In 2005, Eli Lilly settled approximately 8,000 cases for \$700 million.⁹ In April 2006, Bloomberg reported that Eli Lilly had a lingering problem and that plaintiffs had filed another five to ten thousand lawsuits; several states also were claiming the company had downplayed the risk of Zyprexa and marketed the drug for off-label uses.¹⁰ On December 17, 2006, *The New York Times* reported that internal Eli Lilly documents and e-mail messages showed that the company had engaged in a 10-year effort to downplay certain evidence that Zyprexa increased risk for diabetes while it sold \$4.2 billion of that drug. Bloomberg News reported that in January 2007, Lilly settled with an additional 18,000 patients and several states' attorney generals for \$500 million.¹¹ Enormous public controversy ensued concerning the release of the Lilly documents and resulted in the issuance of various injunctions requiring return of the documents. Judge Weinstein initially

⁹ See Joe Schneider & Margaret Cronin Fisk, *Eli Lilly Settles Zyprexa Suit with 18,000 Patients*, Bloomberg.com (Jan. 4, 2007) (<http://www.bloomberg.com/apps/news?pid=20601087&sid=aaePGELtBkx4&refer=home>).

¹⁰ See Karen Gullo & Margaret Cronin Fisk, *Lilly Faces New Lawsuits Claiming Excess Marketing of Zyprexa*, Bloomberg.com (April 20, 2006).

imposed a far-reaching injunction on February 13, 2007. *See In re Zyprexa Injunction*, 474 F. Supp. 2d 386 (E.D.N.Y. 2007).

On July 7, 2007, the plaintiffs in that action, like the plaintiffs here, challenged the confidentiality designations of all the documents produced by Eli Lilly that were cited in plaintiffs' summary judgment and *Daubert* pleadings. *In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 93. Bloomberg and other media appeared in the action on Aug. 18, 2008, to request the unsealing of the documents in the public interest. *Id.* at 94.

While that matter remained pending before Judge Weinstein, Alaska Superior Court Judge Mark Rindner ruled on June 13, 2008, at Bloomberg's request, that Eli Lilly documents that had been filed in a Zyprexa action pending before him would be unsealed in light of the public interest in those documents. Bloomberg argued there, as it does here, that pleadings and documents had been sealed or designated as confidential without sufficient findings. That Court looked to both state and federal precedents to guide its decision and concluded that it was required to undertake a document-by-document analysis. It then ordered disclosure of numerous documents submitted in support of non-dispositive motions because good cause did not support sealing them and the disclosure of all documents in support of dispositive motions due to the public interest in such documents. The Court found that Lilly had failed to present evidence that release of "call notes" or communications between Lilly and the FDA would cause harm to Lilly. After attempts to stay the order in the Alaska Supreme Court failed, the Lilly documents were ordered released.

Just three months later, on September 5, 2008, Judge Weinstein also ordered the

¹¹ *See Schneider & Cronin Fisk*, note 9, *supra*.

release of the Eli Lilly documents filed in the MDL Zyprexa litigation pending before him. *In re Zyprexa Prods. Liab. Litigat.*, 253 F.R.D. at 93-94. In doing so, he commented: “Based on this country's long-standing tradition of open access to the courts and court records, the enormous number of people who have taken or will take Zyprexa, the involvement of government regulatory bodies, absent class members' interest in the proceeding, and the age of the documents, the motions to unseal are granted.” *Id.* at 94. His order extended to “All documents, reports, depositions, arguments, and transcripts referred to in the First Amended Complaint, the motions to dismiss, motions for summary judgment (including plaintiffs' Fact Proffer), and certification motions.” *Id.* at 208. “Public access” Judge Weinstein wrote, “is now advisable because this litigation involves issues of great public interest, the health of hundreds of thousands of people, fundamental questions about our system of approval and monitoring of pharmaceutical products, and the funding for many health and insurance benefit plans. Public and private agencies and organizations have a right to be informed. At this stage public disclosure, congruent with our long tradition of open courts, is desirable.” *Id.* at 209.

In January 2009, Bloomberg News reported that Lilly agreed to plead guilty to a misdemeanor charge of illegally marketing Zyprexa for off-label use and to pay \$1.4 billion in addition to the \$1.2 billion it had already paid to settle more than 31,000 civil lawsuits.¹² The fine was the largest ever against an individual company in a federal prosecution.¹³

¹² See Margaret Cronin Fisk & Cary O'Reilly, *Lilly to Pay Biggest Fine Ever to End Zyprexa Probe*, Bloomberg News.com (Jan. 15, 2009) (<http://www.bloomberg.com/apps/news?pid=20601087&sid=aGDaxYMRGIw0&refer=home>).

¹³ See Cronin Fisk & O'Reilly, *supra*, note 11.

The plaintiffs' allegations against AstraZeneca in this case are similar to the allegations made by the plaintiffs in the Zyprexa litigation. The world therefore is watching this litigation closely and with great concern that yet another pharmaceutical product may have been widely marketed without adequate warning of its health risks. Investors in AstraZeneca also are watching closely for fear that AstraZeneca will suffer a similar fate to that suffered by Eli Lilly. Many observers also are watching this litigation to assess how the Courts deal with claims that may have enormous impact on public health and welfare.

ARGUMENT

I.

Bloomberg L.P. Has Standing to Intervene

As a member of the news media, Bloomberg, L.P. has standing as the eyes and ears of the public to intervene to seek access to judicial proceedings and records. *See, e.g., Chicago Tribune Co.*, 263 F.3d 1304, 1309 (11th Cir. 2001) (allowing press standing to seek to unseal settlement in civil case); *United States v. Ellis*, 90 F.3d 447, 449 (11th Cir. 1996) (media has standing to oppose sealing of records or to seek unsealing of records); *In re Subpoena to Testify Before Grand Jury*, 864 F.2d 1559, 1561 (11th Cir. 1989) (intervening members of news media had standing to appeal scope of closure order); *Newman v. Graddick*, 696 F.2d 796, 800 (11th Cir. 1983) (allowing standing to seek access in civil case); *Brown v. Advantage Eng'g, Inc.*, 960 F.2d 1013, 1015-16 (11th Cir. 1992) (plaintiff in unrelated case allowed intervention to unseal records); *Wilson v. American Motors Corp.*, 759 F.2d 1568, 1570 (11th Cir. 1985) (same).

The precedent in this circuit is consistent with precedents in other circuits and in state

courts. In both the federal Zyprexa litigation in New York and the state Zyprexa litigation in Alaska, Bloomberg was allowed to intervene as a matter of right to oppose the continued sealing of judicial records and ultimately prevailed in its arguments that the public interest in disclosure of the records outweighed interests in keeping the records secret. Accordingly, Bloomberg should be permitted to intervene in this case as well.

II.

There is No Basis to Maintain the Confidentiality or to Seal the Records at Issue

In *Chicago Tribune Co. v. Bridgestone/Firestone, Inc.*, 263 F.3d 1304, 1309 (11th Cir. 2001) (per curiam), the Eleventh Circuit established standards to be applied both to the sealing of documents filed in court and to the maintenance of a sealing order when challenged. Those standards are rooted both in First Amendment and common law principles.

In order to seal documents in the first instance, a party must meet the good cause standard of Federal Rule of Civil Procedure 26(c). “Where discovery materials are concerned, the constitutional right of access standard is identical to that of Rule 26(c) of the Federal Rules of Civil Procedure. *McCarthy v. Barnett Bank of Polk County*, 876 F.2d 89, 91 (11th Cir. 1989) (citations omitted). Accordingly, where a third party seeks access to material disclosed during discovery and covered by a protective order, the constitutional right of access, like Rule 26, requires a showing of good cause by the party seeking protection. *Id.*” *Chicago Tribune Co.*, 263 F.3d at 1310.

The common-law right of access to judicial proceedings “includes the right to inspect and copy public records and documents.” *Id.* at 1311 (citing *Nixon v. Warner Comm’n, Inc.*,

435 U.S. 589, 597 (1978)). “[W]hen applying the common-law right of access federal courts traditionally distinguish between those items which may properly be considered public or judicial records and those that may not; the media and public presumptively have access to the former, but not to the latter.” *Id.* Mere discovery material is not presumptively open, but documents filed with the court are presumptively open. *Id.*

“[M]aterial filed with discovery motions is not subject to the common-law right of access, whereas discovery material filed in connection with pretrial motions that require judicial resolution of the merits is subject to the common-law right.” *Id.* at 1312. Where a party has sought the protection of Rule 26, filed material in support of a substantive motion under seal, and the sealing of the material is challenged, a court must “conduct the common-law right of access balancing test,” *id.* at 1313, utilizing the Rule 26 good cause balancing test. “This standard requires the district court to balance the party's interest in obtaining access against the other party's interest in keeping the information confidential.” *Id.*

None of the documents at issue were filed with the Court merely to help with the resolution of discovery disputes. The records were filed (1) in opposition to the defendants’ summary judgment motions, (2) in connection with *Daubert* motions, and (3) in support of a motion for sanctions: all dispositive and substantive motions. The Eleventh Circuit’s decision in *Chicago Tribune Co.* expressly requires application of the balancing test to the first of these three categories of documents. *Daubert* motions are so closely akin to summary judgment motions that the balancing standard should be applied to them as well.

Plaintiffs’ sanctions motion also is the equivalent of a dispositive motion. The motion contends that shortly before trial, AstraZeneca produced 43,800 pages of materials

and that plaintiffs found “[n]estled among the tens of thousands of pages were, among other critical documents, two letters from the FDA to AstraZeneca regarding significant, FDA-directed changes to Seroquel’s warning label dated December 18, 2008, and December 22, 2008.” (Doc. No. 41 at 2). The plaintiffs claimed that the letters contained “critical information directly supporting Plaintiffs’ liability case.” (Doc. No. 41 at 3). Plaintiffs sought to use these documents to oppose summary judgment, arguing that one of the letters “wholly contradicts AstraZeneca’s arguments in their summary judgment briefing and at oral argument 1st week” and that the Court should allow the plaintiffs to “supplement their summary judgment and *Daubert* responses to include the FDA letters and related documents as exhibits.” (Doc. No. 40 at 2 & 5; Doc. No. 41 at 1 & 7).

When the balancing test is applied to any of the documents at issue, it easily comes out in favor of granting public access.¹⁴ The first aspect of balancing requires an assessment of whether in fact there is any legitimate interest in keeping them confidential.

When documents are claimed to contain trade secrets, the “first question that must be addressed . . . is whether [the] documents do in fact contain trade secrets.” 263 F.3d at 1313. The party must show that the documents have been “consistently treated . . . as closely guarded secrets, that the information represents substantial value . . . , that it would be valuable to . . . competitors, and that it derives its value by virtue of the effort of its creation and lack of dissemination.” *Id.* In addition, “information that is public knowledge or

¹⁴ Bloomberg’s judgment in this regard is based upon its review of publicly available information. Court inspection of the records together with additional evidentiary materials now being developed by the parties through depositions and presented at trial would allow a more particularized balancing of interests than is possible here.

generally known cannot be a trade secret.” *Id.* at 1315. Documents may not be considered trade secrets merely because they are embarrassing or the litigant prefers secrecy. *Union Oil Co. of California v. Leavell*, 220 F.3d 562, 567 (7th Cir. 2000). “The determination of good cause cannot be elided by allowing the parties to seal whatever they want, for then the interest in publicity will go unprotected. . . .” *Citizens First Nat’l Bank of Princeton*, 178 F.3d at 945. In making its determination, the court must “explain its conclusion.” *Chicago Tribune Co.*, 263 F.3d at 1314. The findings must be “sufficiently detailed to permit meaningful appellate review,” and be based on examining the sealed documents, the arguments of counsel, any privilege log, and evidence submitted. *Id.*

If the Court determines “that these documents do in fact contain trade secrets, the district court must balance [the] interest in keeping the information confidential against the Press's contention that disclosure serves the public's legitimate interest in health and safety.” *Id.* at 1314-15. If the Court finds that the interest in access outweighs the interest in secrecy it should make specific findings in this regard. *Id.*

Bloomberg urges the Court to consider the context in which this case arises. It comes before the Court in the wake of substantially similar litigation involving the widespread marketing of a similar pharmaceutical product. In that case, two courts closely examined the arguments that doctors’ call notes, internal company documents, and FDA correspondence with the defendant all were documents in which the public has great interest, overriding any proprietary interest of the defendant. These cases are strong precedent that the same result should be reached here. Even, however, without these precedents, the Court could find from the evidence before it that the public’s interest in access easily overrides the interests in

secrecy advanced by AstraZeneca.

AstraZeneca's motion presents arguments in favor of secrecy in blunderbuss fashion. As plaintiffs' point out, 254 exhibits are now before the Court under seal notwithstanding the Court's frequently stated view that the proceedings should be conducted as openly as possible and without blanket protection of documents. Bloomberg agrees with plaintiffs that AstraZeneca did not meet its initial burden of showing good cause for the sealing of any documents in this case. Simply "calling a document confidential does not make it so in the eyes of the court." *Estate of Martin Luther King, Jr., Inc.*, 184 F. Supp. 2d at 1362.

Bloomberg further agrees with the plaintiffs that AstraZeneca cannot now establish that many of the documents at issue are properly treated as trade secrets. Although Bloomberg does not have access to the documents and therefore cannot fully address the matter, it notes plaintiffs' observation that many of the exhibits "have been used as exhibits in depositions where lawyers for AstraZeneca's competitors . . . were present" (Doc. No. 1258 at 6) and that "a large number of documents are 6-10 years old or older." (Doc. No. 1258 at 7). Both the disclosure of the documents to competitors and the age of the documents weigh heavily against finding that the documents actually contain trade secrets.

AstraZeneca certainly cannot argue that documents that have been partially disclosed in open court should remain under seal. Bloomberg reporters attended the open court proceedings and reported on the testimony that revealed contents of a 2000 report by AstraZeneca safety director Wayne Geller, January 2008 FDA correspondence to AstraZeneca, and AstraZeneca's June 2008 response to that correspondence. The gist of those communications is now publicly known. Release of the entire documents simply

would ensure that the press and public have the full context of the documents and not simply those portions that the parties chose to disclose in court. In such circumstance, the continued withholding of records from public view serves little or no purpose.¹⁵

The Court's Local Rule 1.09 obviously was intended to impose a high burden on any party seeking to seal documents. It prohibits the making of generalized arguments and the mass sealing of documents through its clear and specific requirements that a party seeking to seal judicial records must provide "(i) an identification and description of *each* item proposed for sealing; (ii) the reason that filing each *item* is necessary; (iii) the reason that sealing *each* item is necessary; (iv) the reason that a means other than sealing is unavailable or unsatisfactory to preserve the interest advanced by the movant in support of the seal; (v) a statement of the proposed duration of the seal; and (vi) a memorandum of legal authority supporting the seal." (Emphasis added). Defendant's motion makes no attempt to meet these specificity requirements.

The weakness of AstraZeneca's arguments in favor of secrecy contrasts with the strength of the public interest in this litigation. As the Court is aware through the parties' filings and the history of this litigation, annual sales of Seroquel have reached approximately \$4.7 billion. The patent on the drug expires in 2011, and therefore pressure to market the drug is at a zenith. The drug has been marketed through such broad media as PARADE

¹⁵ See *United States v. Rosenthal*, 763 F.2d 1291, 1294 (11th Cir. 1985) (factor to consider in determining whether the presumption in favor of public access has been overcome is "whether the press has already been permitted substantial access to the contents of the records"); *United States v. Camacho*, 22 Media L. Rep. (BNA) 1845, 1849 (S.D. Fla. 1994) (Marcus, J.) (ordering release of records that previously had been available to some media).

magazine and TV Guide, encouraging consumers to demand prescription of the drug for children notwithstanding that the National Institutes of Health recommends against use of the product by children or those under 18.¹⁶ The implications for public health cannot be understated, and the public is entitled to public disclosure of information that will assist it in assessing the magnitude of those risks. As well, millions wonder whether this litigation is a replay of the Zyprexa claims and will cripple another pharmaceutical giant or the plaintiffs are perhaps advancing claims that they cannot sustain. The ability of the courts to adjudicate claims of this magnitude also is under scrutiny. It is the judicial interest in preserving its own integrity that has tipped the balance in favor of openness in cases of this type.

Regarding any claims that the documents at issue contain medical information that would invade the privacy interests of the plaintiffs, Magistrate Judge Baker attempted to create a reasonable solution to the problem by directing the parties to redact individually identifiable “medical information deemed confidential” and to include in the redacted documents “*general* statements regarding the nature of the redacted material.” (Doc. No. 1107 at 1). Had this procedure been followed by the parties, the public would have been allowed to better assess the merits of the plaintiffs’ claims and defenses while claimed privacy interests remained protected. Disclosure of the redacted documents also would have helped the public and press better assess whether claimed privacy interests are in fact legitimate. At a minimum, the Court should direct the parties to comply with that order in a timely fashion.

¹⁶ See Medline Plus, a Service of the U.S. National Library of Medicine & the National Institutes of Health (<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a698019.html>).

The Court's order granting summary judgment in Case No. 6:07-cv-10291, involving plaintiff Linda Guinn, disclosed that Ms. Guinn "has been treated for numerous medical ailments including schizophrenia, bipolar disorder, depression, epilepsy, hypertension, high cholesterol, back and knee pain, gastroesophageal reflux disease, arthritis, degenerative disc disease and, most recently, diabetes." (Doc. No. 47 at 3-4). It further revealed the specific dosage she was prescribed for Seroquel and other medical information. The order concluded that Ms. Guinn could not establish specific medical causation. Ms. Guinn placed her medical condition in controversy when she filed suit and the Court appropriately treated those claims as a fair subject for judicial and public scrutiny. The order seriously calls into question the legitimacy of any claim that summary judgment and *Daubert* filings in these cases must be sealed to protect privacy interests.

Senior District Judge O'Kelley of the Northern District of Georgia well explained that "[w]hat happens in the halls of government is presumptively public business. Judges deliberate in private but issue public decisions after public arguments based on public records." *Estate of Martin Luther King, Jr.*, 184 F. Supp. 2d at 1362. (quoting *Union Oil Co. of California v. Leavell*, 220 F.3d 562, 568 (7th Cir.2000)). This Court should follow that principle here, lift the confidentiality that AstraZeneca has affixed to the documents at issue, and deny the pending motions to file additional documents under seal.

CONCLUSION

The Court should (1) grant Bloomberg L.P.'s motion to intervene to oppose the maintenance of confidentiality and the sealing of judicial records, (2) deny the defendants' motions to maintain confidentiality of or seal documents (Doc. No. 1222 & 1237) and plaintiffs' motions to deal documents (Doc. No. 1230 and Case Nos. 6:07-cv-10291 & 15733 Doc. No. 42), and (3) unseal plaintiffs' responses and supporting documents opposing AstraZeneca's motions for summary judgment and to exclude testimony (MDL Case No. 6:07-cv-10291 Doc. No. 15, listing the responses at issue).

Respectfully submitted.

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CERTIFICATE OF CONFERENCE

I hereby certify that prior to the filing of this motion, Bloomberg's counsel conferred with Robert Cowan of Bailey Perrin Bailey LLP, plaintiffs' lead counsel, Larry Roth, plaintiffs' liaison counsel, Richard Laminack, lead trial counsel for plaintiff Linda Guinn, and Steven B. Weisburd, defendants' lead trial counsel, regarding the issues raised and relief requested in this motion. Mr. Cowan consented to this motion on behalf of his partner Camp Bailey. Mr. Roth deferred to Mr. Bailey's judgment. Mr. Laminack had not returned counsel's call by the time this motion was filed. Mr. Weisburd returned counsel's call, but was continuing to consult with AstraZeneca about the position it would take regarding this motion when the motion was filed. Mr. Weisburd also advised that he is working with plaintiffs' counsel to attempt to resolve differences that the plaintiffs and defendants have regarding access to judicial records.

s/ Thomas R. Julin

Thomas R. Julin

CERTIFICATE OF SERVICE

I hereby certify that, on February 13, 2009, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system through which all participating parties are deemed served. I further certify that, by using the CM/ECF, the foregoing has been served on plaintiffs' liaison counsel, who is charged with serving any non-CM/ECF participants on the attached Service List.

s/ Thomas R. Julin

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