

UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF FLORIDA

ORLANDO DIVISION

IN RE: Seroquel Products Liability Litigation

MDL DOCKET NO. 1769

This Document Relates to All Cases

ASTRAZENECA'S MOTION TO MAINTAIN THE CONFIDENTIALITY

OF CERTAIN CHALLENGED DOCUMENTS FILED UNDER

SEAL AS EXHIBITS TO PLAINTIFFS' MOTION RESPONSES

Defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP (AstraZeneca) file this motion to maintain the confidential status of certain documents referenced and filed under seal in connection with Plaintiffs' oppositions to AstraZeneca's Daubert and Summary Judgment Motions.

INTRODUCTION

The first MDL trial is less than two weeks away. Although Plaintiffs have no legitimate litigation need for lifting the confidentiality status of AstraZeneca's documents before trial, on December 12, 2008, they challenged the designation of over 60 AstraZeneca documents, most of which are internal company documents and all of which contain proprietary, commercial or

sensitive information. During extensive meet and confers on this issue, AstraZeneca (1) agreed to de-designate several documents; (2) acknowledged that with the exception of a few trade secret, highly sensitive and commercially valuable documents, the remaining documents will become public if they are introduced at trial; and (3) asked Plaintiffs to table their confidentiality

challenge because the issue will be mooted either at trial or through pretrial motions. Plaintiffs refused AstraZeneca's request to defer their challenge. Pursuant to the Protective Order in this matter, AstraZeneca was accordingly left with no choice but to file this motion to prevent Plaintiffs from publicly disclosing the challenged documents. See Protective Order at ¶ 12 (C).

(Doc. 478).1

Plaintiffs are unable to articulate any litigation-driven reason for their current challenge. Indeed, premature release of these documents would present several problems, including presentation of an inaccurate or incomplete picture of Seroquel that could be harmful to the health of patients that use or need the drug, potential of negative publicity, and pretrial embarrassment to AstraZeneca that could taint the jury pool right before the first trial. The

documents should retain their confidential status until trial for the reasons stated below.2

First, Plaintiffs' confidentiality challenge is premature. AstraZeneca's motions for summary judgment in each of the seven trial cases are pending before the Court, and the Court has heard argument on AstraZeneca's Daubert motions and summary judgment motions in the first two trial cases. If summary disposition is granted, there will be no trials, and thus no real

litigation need for the de-designation of the challenged documents. Moreover, many of the challenged documents are subject to AstraZeneca's pending motions in limine and may be ruled

1 Under the Protective Order, AstraZeneca must file a motion within 30 days of a challenge by Plaintiffs to its designation of a document as "confidential" or waive that designation and allow the Plaintiffs to publicly disclose the document. See Protective Order at ¶ 12(C). Because Plaintiffs' challenge occurred on December 12, 2008, AstraZeneca's motion was due on January

12, 2009, but the parties agreed to an extension until January 21, 2009, as permitted by the Protective Order, so that the meet and confer process could continue. However, despite the extension the parties were unable to reach an agreement.

2 A list of the challenged documents which AstraZeneca seeks to keep confidential is attached as Exhibit A. In addition to the documents, Plaintiffs have also challenged the confidentiality designation of portions of various deposition transcripts discussing AstraZeneca documents.

AstraZeneca also seeks to maintain the confidentiality of all deposition transcripts or expert reports discussing those documents until trial.

inadmissible by the Court; other challenged documents may not be presented at trial. It is unnecessary to waste the Court's time to entertain document-by-document confidentiality disputes now when many of the issues will soon be narrowed by the Court's other rulings.

Second, AstraZeneca has already agreed with Plaintiffs in the meet and confer process that with the exception of a small subset of documents (discussed below), the bulk of the challenged documents could become public at trial, subject to AstraZeneca's motions in limine.

Selective publication of these documents by Plaintiffs before trial, however, would present incomplete and out of context information relating to Seroquel's safety and efficacy to the public. This could mislead the public and healthcare providers and create a potential public health risk. To the extent this information is offered at trial, the documents will be placed in context and the whole story will be presented at once.

Third, allowing plaintiffs to publicly disseminate a handful of cherry-picked documents containing out of context and incomplete information will present a misleading and unfairly negative image of AstraZeneca right before trial and taint the potential jury pool.

Fourth, as explained below and in the accompanying Affidavits of Charles Peipher, and Arthur Lazarus (attached as Exhibits B and C), some of the challenged documents in the Seroquel Investigational New Drug application (IND), certain call notes, and the unpublished Clinical Study Reports subject to the peer-review process contain competitively sensitive and proprietary research, product development, marketing and other trade secret or commercial

information. AstraZeneca has always kept this information confidential. Public disclosure of this information would harm AstraZeneca's pecuniary interests by creating a commercial and competitive disadvantage. These documents are entitled to continued confidentiality protection.

AstraZeneca has offered to further meet and confer with Plaintiffs to discuss a plan for redacting these documents in a way that would protect AstraZeneca's proprietary interests and still allow Plaintiffs to use select portions at trial. Plaintiffs have not accepted this offer.

Under the governing balancing of interests analysis, *Farnsworth v. Proctor & Gamble Co.*, 758 F.2d 1545, 1547 (11th Cir. 1985), AstraZeneca's interest in having these internal documents continue to receive the confidentiality protections afforded by the Protective Order substantially outweighs any interest of Plaintiffs to avoid the Protective Order.

ARGUMENT

I.

1 ALL OF THE CHALLENGED DOCUMENTS SHOULD RETAIN THEIR
CONFIDENTIAL STATUS UNTIL TRIAL.

A.

4 Plaintiffs Have No Legitimate Need For Declassification Of Documents Two
Weeks Before Trial.

No legitimate reason exists to declassify highly sensitive AstraZeneca documents now, only weeks before trial. Maintaining the confidentiality of these documents until trial will not hinder Plaintiffs in the preparation of their cases in any way. Plaintiffs have already used many of these confidential documents to depose corporate and third-party witnesses; provided the

documents to their testifying experts; served expert reports offering opinions based on these documents; filed their oppositions to AstraZeneca's dispositive and Daubert motions citing to these documents; and otherwise used the documents to prepare their

cases for trial. The only thing Plaintiffs cannot do with these confidential documents is release them to the media. That is not a legitimate litigation need.

Trial in the first Group One case will commence on February 2, 2009. AstraZeneca's Daubert and summary judgment motions are still pending. AstraZeneca has filed a number of

3 The challenged documents include non-public correspondence between AstraZeneca, the FDA and foreign regulatory agencies, as well as non-public internal communications relating to marketing strategy, clinical trial data, research, safety, labeling, and other regulatory issues.

motions in limine directed at some of the challenged documents. The universe of documents at issue may be narrowed through the Court's rulings on these various motions. Importantly, AstraZeneca has advised Plaintiffs that it recognizes that most of the challenged documents will become public if they are introduced at trial. At trial, however, such documents will be presented in context and both sides will be permitted to examine the witnesses on the documents.

The Court should not indulge Plaintiffs' premature and wasteful challenge at this time.

B.

5 Publication of Out-of-Context Documents May Mislead and Harm the Public
and Generate Negative Publicity.

Most of the documents challenged by Plaintiffs reflect snippets of discussions, deliberations and analysis of Seroquel-related safety and regulatory issues.³ Publication of such documents now (which are cherry-picked by Plaintiffs from over thirty million pages of documents produced by AstraZeneca) would present incomplete, inaccurate, and/or out of context information about Seroquel to the public. This could jeopardize public safety by causing confusion and alarm in patients, who may then discontinue their medication without seeking the guidance of a medical professional. See Peipher Decl. at ¶ 5; Lazarus Decl. at ¶ 8. It is for this very reason that the FDA heavily regulates what information about prescription products is

disseminated to the public. See Peipher Decl. at ¶ 4; Lazarus Decl. at ¶ 8. Absent unique circumstances not present here, AstraZeneca is not permitted to publicly disseminate safety information that is inconsistent with its FDA-mandated product labeling. See Requirement on Content and Format of Labeling for Human Prescription Drug and Biological Products Final

Rule, 71 Fed. Reg. 3922, 3935 (January 24, 2006) (FDA interprets its regulations to establish both a "floor" and a "ceiling" for disclosure of risk information); see also Lazarus Decl. at ¶ 8.

FDA policy for many years has been to use its approved labeling as the cornerstone for conveying information about drug safety that has been carefully reviewed by agency scientists and has been found sufficiently substantiated by clinical and other data. 71 Fed. Reg. at 3934 (the centerpiece of risk management of prescription drugs generally is the labeling which reflects thorough FDA review of pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively.) Public dissemination of incomplete, misleading or out of context safety information as a consequence of the litigation process — without being vetted and substantiated through the FDA — would accordingly run afoul of the principles and purposes behind the FDA regulatory scheme, and could lead to misleading inferences about a drug critical to the well-being of millions of seriously mentally ill patients. Id. at 3935

(describing potential for "overwarning" to "erode and disrupt the careful and truthful representation of benefits and risks" because "[o]verwarning, just like underwarning can similarly have a negative effect on patient safety and public health.')

Given the FDA's concern about both over and under-warning, and about presenting both drug risks and benefits in context, preventing disclosure of these documents before trial serves the critical purpose of protecting a vulnerable patient population. See *In re Zyprexa Injunction*, 474 F. Supp.2d 385, 398 (E.D.N.Y. 2007) (material that might be misunderstood by the lay reader . . . might do some harm'). At trial, these documents will be presented in context with the entire body of scientific and regulatory evidence.

Additionally, out of context disclosure of select and incomplete information could also generate unfair negative publicity about AstraZeneca and ultimately be commercially detrimental to the company. See *Gelb v. American Tel. & Tel. Co.*, 813 F.Supp. 1022, 1035 (S.D.N.Y. 1993) (sealing internal documents which "constitute potential negative publicity about [defendants'] marketing tactics" because of "their potential to do commercial harm"). As another Court noted:

"The harm faced by [defendant] 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 defendant."

In *re Zyprexa Injunction*, 474 F. Supp.2d at 425 (quoting Note, *Secrecy in Civil Trials: Some Tentative Views*, 9 J.L. & Pol'y 53, 58 (2000)) (internal quotations omitted). Plaintiffs should not be allowed to selectively, publicly disseminate AstraZeneca's internal documents absent a true litigation need for this additional reason.

C.

Public Disclosure Of These Documents Now Has The Potential To Taint the Jury Pool.

Given that trial is scheduled to commence in two weeks, the release of these documents could generate substantial media interest and publicity in the days immediately preceding trial.

Pre-trial publicity surrounding individual documents, taken out of context, could prejudice the pool of potential jurors against AstraZeneca.

Courts have recognized this danger. *Murphy v. Florida*, 421 U.S. 794 (1974) (analyzing situations in which pre-trial publicity may threaten a criminal defendant's Constitutional right to a fair trial); *Gannett Co. v. DePasquale*, 443 U.S. 368, 387-88 (1979) (holding that there is no Constitutional right of public access to pretrial proceedings, and noting that this limitation on

public access was founded on "concern for a fair trial."); *In re Reporters Committee for Freedom of the Press*, 773 F.2d 1325, 1334 (D.C. Cir. 1985) (holding the district court's order delaying public access to materials used in connection with a summary judgment motion and trial proceedings until the entry of judgment did not violate the First Amendment, noting that "access

is not a matter of right before judgment except to the extent that material is disclosed at trial") (emphasis in original).

In short, publication of internal, out of context, sensitive documents would make trial and resolution of these cases more difficult "by creating probable prejudice largely irrelevant to the issues posed by the pending case and by making impartial juror selection more difficult."

In *re Zyprexa Injunction*, 474 F.Supp.2d at 429. Plaintiffs should not be permitted to try their cases in the media through the premature release of AstraZeneca's confidential documents.

II.

2SOME OF THE CHALLENGED DOCUMENTS CONTAIN TRADE SECRET OR OTHER COMMERCIAL INFORMATION AND ARE ENTITLED TO CONTINUED CONFIDENTIALITY PROTECTION EVEN AT TRIAL.

AstraZeneca acknowledges that most of the challenged documents will become public if they survive pretrial motions and are introduced at trial. AstraZeneca will, however, stand on its confidentiality designation of a small subset of the challenged documents that contain commercially valuable and trade secret information. AstraZeneca recognizes that portions of this subset of confidential documents might be deemed admissible at trial. Plaintiffs have not yet identified which select portions of these lengthy documents they wish to admit at trial.

4 As mentioned above, AstraZeneca has already offered to further meet and confer with Plaintiffs to discuss a plan for redacting these documents in any way that would protect AstraZeneca's proprietary interests and still allow Plaintiffs to use select portions in trial, but Plaintiffs refused this offer. Notably, many of these documents are hundreds of pages in length, so there is no reason to believe that further negotiations could not yield a mutually agreeable redaction plan.

AstraZeneca expects and indeed has offered -- that the parties will meet and confer with respect to these documents to determine if any redactions at trial will be necessary.⁴

The subset of protectable documents fall into three categories: (1) the Seroquel IND submitted to the FDA; (2) call notes; and (3) unpublished Clinical Study Reports (iCSRs) which are currently in the peer-review process. All of these documents are entitled to continued protection even at trial.

The Protective Order (Doc. 478) and Federal Rule of Civil Procedure 26(c)(1)(G) provide broad protection for discovery materials such as the materials at issue here that involve confidential commercial information. Courts recognize the important policy considerations underlying Rule 26(c) to permit litigants and the courts to examine a party's internal records, which may include . . . valuable business secrets and commercial data, without unnecessarily

exposing them to the public's and competitors' view. In re Zyprexa Injunction, 474 F. Supp.2d at 394. Rule 26(c)(1)(G) itself explicitly extends protection to a broad range of commercial information. Fed. R. Civ. P. 26(c)(1)(G). Commercial information includes trade secrets or other confidential research, development, or commercial information. Fed. R. Civ. P.

26(c)(1)(G); 8 Wright, Miller & Marcus, FEDERAL PRACTICE & PROCEDURE: CIVIL 2D B 2043, at p. 556 (1994) (describing Rule 26(c)(1)(G) as containing an open-ended series of terms entitled to protection); 6 MOORE'S FEDERAL PRACTICE: CIVIL B 26.105[1][b], 26.105[8][a]

(2007).

5 Although plaintiffs only referred the Court to two pages of the IND in all of their briefing in opposition to AstraZeneca's Daubert and summary judgment motions, they have challenged the confidentiality of the entire IND.

The key factors in determining what materials are protected under Federal Rule

26(c)(1)(G) as confidential commercial information, are (1) whether the party has improperly safeguarded the proprietary information at issue by limiting access to only corporate personnel, and (2) whether public disclosure of the information would threaten to place that party at a commercial disadvantage or competitive disadvantage. Nestle Foods Corp. v. Aetna Cas. & Surety Co., 129 F.R.D. 483, 484 (D.N.J. 1990); accord Duracell Inc. v. SW Consultants, Inc., 126 F.R.D. 576, 577 (N.D. Ga. 1989); Zenith Radio Corp. v. Matsushita Elec. Indus. Co., 529 F. Supp. 866, 890 (E.D. Pa. 1981); see also 6 MOORE'S FEDERAL PRACTICE: CIVIL § 26.105[8][a].

An analysis of these factors weighs in favor of maintaining the confidentiality of the challenged documents.

A.

7 The IND, The Call Notes And The Clinical Study Reports Contain Trade Secret Information Or Proprietary Commercial Information.

1.

9 The IND

The Seroquel IND, which was submitted to the FDA, contains over 5,000 pages of comprehensive information relating to Seroquel's physical, chemical and pharmacological makeup, as well as development and manufacturing process, much of which is facially irrelevant to Plaintiffs' claims.⁵ AstraZeneca has always safeguarded this information. See Lazarus Decl. at ¶ 9. The trade secret and proprietary nature of an IND has been recognized. See *Judicial Watch, Inc. v. Food & Drug Admin.*, 449 F.3d 141, 148-149 (D.C. Cir. 2006). Applicants spend

a great deal of resources to obtain data for an IND or NDA, and the FDA could not expect full and frank disclosure if it later released such proprietary information into the public domain. Id. at 149. AstraZeneca expended tremendous resources to compile the Seroquel IND, and the IND contains highly valuable non-public information regarding nearly every facet of Seroquel.

2.

10 Call Notes

The call notes are certain documents or log entries prepared internally by sales employees reflecting mental impressions of the company's sales employees about their periodic in-person discussion with physicians and other healthcare professionals. See Peipher Decl. at ¶ 6.

The call notes reflect AstraZeneca's proprietary business information that it acquired or compiled in the course of its business. In particular, the call notes reflect years of competitive intelligence about how AstraZeneca approaches sales calls and reveal internal insight about the effectiveness of AstraZeneca's strategies for marketing Seroquel to physicians. See Peipher Decl. at ¶¶ 6-8. The call notes include descriptions by company sales personnel reflecting the personal preferences, views and opinions of each physician or healthcare provider about Seroquel as compared to competitor medications. Id. Call notes also reflect key messages that AstraZeneca determined to be most effective at given points in time and, thus, reflect key corporate strategies

for Seroquel. Id. at ¶ 8. Call notes are maintained on a strictly confidential basis at AstraZeneca. Id. at ¶ 11.

The call note information is analogous to the sort of proprietary information related to customer lists, and individual customer preferences and interactions, that courts have routinely held to constitute the sort of commercial information entitled to protection. See, e.g., *Jazz Photo*

Corp. v. United States, 439 F.3d 1344, 1358 (Fed. Cir. 2006); *Duracell*, 126 F.R.D. at 578-79.

3.

1 1 Unpublished Case Study Reports

The unpublished CSRs (for trials 125, 127, 144 and 165), which are each several hundred page summaries of the results of AstraZeneca clinical studies, contain non-public proprietary research, methodologies and analyses. See Lazarus Decl. at ¶ 10. This information is entitled to continued protection. See e.g., *Cumberland Packing Corp. v. Monsanto Co.*, 184 F.R.D. 504, 506 (E.D.N.Y. 1999) (documents falling into commonly protected/sealed are those containing confidential research and development information); *In re Zyprexa Injunction*, 474 F. Supp.2d at 404 (confidential preliminary research is protectable). Additionally, these unpublished CSRs are currently in the peer-review publication process and slated for publication in medical journals

in 2009. Disclosure of these confidential documents now could jeopardize the publication. See Lazarus Decl. at ¶ 10.

B.

8 Dissemination Of These Confidential Documents Will Cause Competitive and Commercial Harm to AstraZeneca.

Public dissemination of these documents containing otherwise unavailable insight into AstraZeneca's manufacturing process, research and sales and marketing strategy would be detrimental to AstraZeneca by effectively handing competitors and potential new entrants to the market a roadmap to success. That is, competitors could use this information to develop, improve and promote their own products and counter-detail against Seroquel, thereby capturing a

larger percentage of the market. See Peipher Decl. at ¶¶ 8-11. Indeed, if the trade secret information contained in the IND were publicly disclosed, other companies could make use of the information in the IND[] in order to eliminate much of the time and effort that would otherwise be required to bring to market a product competitive with [Seroquel] for which [AstraZeneca] filed the IND. *Judicial Watch*, 449 F.3d at 148-49 (citations omitted). Similarly, disclosure of the call notes would provide AstraZeneca's competitors with a "free ride" to

AstraZeneca's years of efforts, and allow competitors to capitalize on AstraZeneca's internal marketing insights and strategies. See Peipher Decl at ¶ 11.

In short, competitors' use of this material has the potential to inflict severe commercial harm on AstraZeneca. See *In re Zyprexa Injunction*, 474 F.Supp.2d at 424-25; see also *Duracell*, 126 F.R.D. at 578 ("The discovery rules are not intended to forfeit a party's ability to compete effectively in the market by opening up tangentially relevant financial and marketing information to competitors"). Accordingly, the IND, the call notes, and the unpublished CSRs

should continue to receive confidentiality protection under the Protective Order.

3 CONCLUSION

For the foregoing reasons, AstraZeneca's Motion should be granted, and the challenged documents should continue to be afforded confidential treatment.

DATED: January 21, 2009

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CERTIFICATE OF CONFERENCE

As per Local Rule 3.01(g), AstraZeneca attempted to meet and confer on these issues but the parties have been unable to resolve their disputes.

/s/ Elizabeth A. Balakhani

CERTIFICATE OF SERVICE

I hereby certify that, on January 21, 2009, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system through with 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/ Elizabeth A. Balakhani