

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS
EAST ST. LOUIS DIVISION**

IN RE PRADAXA)	MDL No. 2385
(DABIGATRAN ETEXILATE))	3:12-md-02385-DRH-SCW
PRODUCTS LIABILITY)	Judge David R. Herndon
LITIGATION)	

This Document Relates to:

ALL CASES

CASE MANAGEMENT ORDER NUMBER 56
Regarding the PSC Motion Challenging Confidentiality (Doc. 343)

HERNDON, Chief Judge:

I. INTRODUCTION

This matter is before the Court on the plaintiffs' motion, pursuant to Amended Case Management Order Number 2 ("Amended CMO 2") (Doc. 208), challenging the confidentiality designations that the defendants, Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively, "BI") placed on certain documents produced in discovery (Doc. 343). The plaintiffs are challenging the confidentiality designations placed on 85 documents (filed under seal at Docs. 345-1 through 355-7) (and identified by ECF No. in Exhibit A attached hereto) (the "Challenged Documents"). The plaintiffs assert that more than 93% of the documents produced to date have been designated either "confidential" or "highly confidential." They further contend that

such conduct violates Amended CMO 2 and violates the public's right to an open court system. BI is opposed to the motion (Doc. 374). BI contends that the subject documents were appropriately designated as confidential, the plaintiffs' case is not prejudiced by maintaining that designation, and therefore, the Court should deny the motion (Doc. 374). The plaintiffs have filed a reply in support of their motion (Doc. 383).

The Court has considered the parties' briefing and has reviewed each of the Challenged Documents. For the reasons discussed herein, the Court **GRANTS** the plaintiffs' motion in its entirety.

II. AMENDED CMO 2

Amended CMO 2 employs a two tiered designation system for "Confidential information" and "Highly Confidential Information." The relevant definitions for each category of information are as follows:

Confidential Information

[M]eans information, documents, things or data of any type, kind or character that the Producing Party believes in good faith constitutes, reflects, discloses, or contains information subject to protection under Fed. R. Civ. P. 26(c) or other applicable law, whether it is a document, information contained in a document, information revealed during a deposition or other testimony, information revealed in an interrogatory response, or information otherwise revealed. Any transcript of an in camera hearing shall be treated as confidential pursuant to this Order.

(Doc. 208 ¶ 6)

Highly Confidential Information

[M]eans highly sensitive Confidential Information which, if disclosed

to a competitor or the general public, could result in substantial business harm by revealing trade secrets, manufacturing processes, proprietary design, drug formulation, drug development, sequencing, chemical stability and characteristics, analytical methods used in manufacturing, quality control processes, CMC information exchanged with the FDA and not the subject of a patent, source and specifications for drug components and raw materials, manufacturing plans, unpublished patent applications, strategic intellectual property plans, notices of invention, including but not limited to confidential intellectual property and patentable data, information, products or processes.

(Doc. 208 ¶ 7).

CMO 2 also provides a mechanism for challenging a party's confidentiality designation for lack of good cause:

A Receiving Party may challenge a Producing Party's confidentiality designation by notifying the Producing Party, in writing, of its good faith belief that the confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within fourteen (14) business days of receiving such a challenge, the basis of the designation. If that does not resolve the dispute over the designation, then either party may apply to the Court for a determination as to whether the designation is appropriate. The burden of proof as to a designation of Confidential Information or Highly Confidential Information rests on the Producing Party to demonstrate that such designation is proper.

(Doc. 208 ¶ 16) (emphasis added).

Additionally, CMO 2 does not permit global designations:

In designating materials as "Confidential Information" or "Highly Confidential Information," the Producing Party shall do so in good faith, consistent with the provisions of this Order. Nothing contained herein shall be construed to allow global designations of all materials or documents as "Confidential Information" or "Highly Confidential Information."

(Doc. 208 ¶ 8).

Finally, with respect to German law, CMO 2 provides as follows:

Any entity subject to the jurisdiction of German law producing documents in this litigation may designate as CONFIDENTIAL those documents (including electronic or paper form) containing “personal data” within the meaning of the German Federal Data Protection Act (the “Act”) if such documents would otherwise fall within the jurisdiction and scope of the Act. “Personal data” consists of any and all information concerning the personal or material circumstances of an identified or identifiable natural person. In particular, this provision applies to the following documents:

- (i) any correspondence (electronic or paper form) that identifies or through recourse to other sources of information available to the data processor allows identification of its author(s)/sender(s) and/or its addressees/recipients (e.g., all email correspondence, letters and faxes, including transmission reports);
- (ii) any document, such as memoranda, notes, and presentations, if it identifies or allows identification of its author/sender and/or its addressee/recipient through recourse to other information available to the data processor;
- (iii) minutes of internal or external meetings as far as they include information about which individual(s) did or did not attend the meeting; and
- (iv) personnel records and information.

(Doc. 208 ¶ 21)

III. BACKGROUND

On October 28, 2013, the Plaintiffs’ Steering Committee (“PSC”) sent a letter to BI challenging the confidentiality designations of 86 documents. BI responded on November 13, 2013 with a four-paragraph cover letter and a table listing the documents, along with brief boilerplate bullet points as to the basis for

each designation (Doc. 355-9). For the most part, BI asserted that the challenged documents were “internal,” “non-public,” and/or contained proprietary information. BI agreed that one document had been improperly designated but asserted that the remaining 85 documents had been properly designated (BI did downgrade one document from Highly Confidential to Confidential and upgraded two documents from Confidential to Highly Confidential). The remaining 85 documents are the subject of the plaintiffs’ current motion.

IV. GOOD CAUSE

The Federal Rules of Civil Procedure provide that “for good cause shown, the court ... may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including ... that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way....” Fed.R.Civ.P. 26(c). A party seeking a protective order under Rule 26(c) bears the burden of demonstrating good cause. Fed.R.Civ.P. 26(c)(7).

In the instant case, the Court entered a protective order that allowed BI to designate materials, in good faith, as Confidential or Highly Confidential without a preliminary showing of good cause for the purpose of facilitating discovery. CMO 2 further provides that if and when the plaintiffs challenge any such designation, BI carries the burden of demonstrating that its confidentiality designations are appropriate. Accordingly, BI’s duty to establish good cause for its confidentiality

designations was triggered when the plaintiffs' raised an issue with respect to the Challenged Documents.

To successfully carry the burden of establishing good cause, BI must demonstrate a particular need for protection. There must be evidence that a clearly defined and serious injury will result otherwise. See 8 C. Wright & A. Miller, *Federal Practice And Procedure* § 2035 (3d ed.). In this regard, “[t]he courts have insisted on a particular and specific demonstration of fact, as distinguished from stereotyped and conclusory statements.” *Id.*; *Gulf Oil Co. v. Bernard*, 452 U.S. 89, 102, 101 S. Ct. 2193, 2201, 68 L. Ed. 2d 693 (1981) (citing Wright & Miller). See also *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (“Good cause is established on a showing that disclosure will work a clearly defined and serious injury to the party seeking closure. The injury must be shown with specificity.”). Further, the Seventh Circuit has explained that “[t]he 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 unless the media are interested in the case and move to unseal.” *Citizens First Nat. Bank of Princeton v. Cincinnati Ins. Co.* 178 F.3d 943, 945 (7th Cir. 1999).

V. DISCUSSION

The pertinent issue before the Court is whether BI has established good cause for the Court to protect the Challenged Documents as provided for by CMO

2. In opposing the plaintiffs' motion, BI contends that the Challenged Documents'

designations are appropriate, but devotes very little attention to the actual content of the documents at issue. Instead, BI spends a great deal of time trying to discern the “real motive” behind the plaintiffs’ decision to contest the subject designations. BI insists that the plaintiffs are challenging the subject confidentiality designations because “they would like to use selective and out-of-context document leaks to try this case in the press” (Doc. 374 p. 1). The Court fails to see the significance of this position. The plaintiffs are not under a duty to establish an appropriate motive. The plaintiffs have challenged the subject confidentiality designations and it is now incumbent upon BI to establish that those designations are appropriate.

The little time BI devotes to establishing good cause is wasted on generic, boilerplate, conclusory assertions. BI’s briefing says little more than what they asserted in their November 13, 2013 letter to the PSC – which is that the documents are non-public internal communications consisting of sensitive proprietary business information. BI also generically contends that enforcement of the confidentiality designations are necessary to prevent a trial by media and/or to protect the public (*See e.g.*, Doc. 374 p. 1) (granting the plaintiffs’ motion could “bias the jury pool,” threaten “the integrity of the adversarial process,” and “harm the public health through the dissemination of misleading and incomplete snippets of internal documents that might unjustifiably scare patients and lead them to stop taking their medicine.”).

BI’s non-specific arguments do not sufficiently establish that the confidentiality designations are proper. The fact that a document or

communication was internal or non-public does not establish good cause for maintaining its confidentiality under the protective order. The same is true with regard to BI's generic assertions of proprietary information. Further, vague claims about harm that might result do not suffice to demonstrate that any particularized or serious harm will result from disclosure or that good cause exists.

The undersigned Judge has painstakingly reviewed each of the Challenged Documents and finds that they lack confidentiality of any kind. The Challenged Documents do not contain information subject to protection under Fed. R. Civ. P. 26(c) or other applicable law. Other than using generalized conclusory terms, BI fails to explain why any particular document is appropriately designated as confidential. As to some of the specific confidentiality concerns raised by BI the Court notes the following:

(1) Patient Information: Any sensitive patient information has been sufficiently redacted and is not grounds for a blanket confidentiality designation.

(2) German Law: CMO 2 provides for the protection of personal data in accord with German law. BI states that fourteen of the challenged documents are housed by and produced by custodians in Germany (Doc. 374 p. 11 n.8) (the "German Custodial Documents").¹ BI proposes that it be allowed to provide redacted copies of the German Custodial Documents in the event that the Court

¹ The German Custodial Documents are identified in Exhibit A to BI's opposition (Doc. 374-1). The German Custodial Documents are also identified in Exhibit A attached hereto.

orders de-designation. The Court notes that the German custodians identified in these documents are already well known to this litigation. Accordingly, the Court feels that a confidentiality designation with respect to these employees is unnecessary. Nonetheless, out of an abundance of caution and comity, the Court will accept the proposal suggested by BI in footnote 8 of their briefing.

(3) Earnings and Marketing Information: The subject documents contain some earnings and Marketing Information from 2012. The information does not reflect a trade secret or other confidential research, development, or commercial information that would subject it to protection. Further, BI has failed to demonstrate that any particularized serious harm would result from the disclosure of this information. Accordingly, BI has failed to meet its burden with respect to this information.

VI. CONCLUSION

For the reasons discussed herein, the plaintiffs' motion is GRANTED. The Court ORDERS de-designation of the 85 Challenged Documents. However, the Court is GRANTING BI's request with regard to the German Custodial Documents. The German Custodial Documents shall only be released in redacted form.

FURTHER, EXCEPT FOR THE 14 GERMAN CUSTODIAL DOCUMENTS (identified in Exhibit A attached hereto), the Challenged Documents (identified in Exhibit A attached hereto) shall be unsealed. The Court DIRECTS the Clerk of the

Court to take the necessary steps to unseal the appropriate documents as identified in Exhibit A attached hereto.

FURTHER, within 7 days of the entry of this Order, BI is DIRECTED to FILE redacted copies of the German Custodial Documents.

SO ORDERED:

 Digitally signed by
David R. Herndon
Date: 2014.01.29
15:00:25 -06'00'

**Chief Judge
United States District Court**

Date: January 29, 2014