UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

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 50
Regarding the PSC's Second Motion for Sanctions (Doc. 302)

HERNDON, Chief Judge:

I. INTRODUCTION

Presently before the Court is the PSC's motion seeking sanctions against Boehringer Ingelheim International GMBH ("BII") and Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") (collectively, "the defendants") for various alleged discovery abuses (Doc. 302). The defendants filed a responsive brief on November 26, 2013 (Doc. 311). The Court heard oral argument on the motion on December 2, 2013. During oral argument, the defendants requested leave to file a supplemental response to address any new information alleged by the PSC during

the hearing. The request for leave was granted and the defendants filed their supplemental brief on December 4, 2013 (Doc. 317).

The PSC's motion for sanctions addresses alleged discovery violations that fall into one of four categories: (1) the defendants' failure to preserve the custodial file of Professor Thorstein Lehr (a high-level scientist formerly employed by BII intricately involved in Pradaxa), as well as the failure to identify Prof. Lehr as a custodian with potentially relevant evidence; (2) the defendants' failure to preserve evidence relating to and/or untimely disclosure and production of material in the possession of the defendants' Sales Representatives, Clinical Science Consultants and Medical Science Liaisons; (3) the production issues related to the G Drive (one of the defendants' shared networks); and (4) the failure to preserve and/or untimely production of business related text messages on certain employees' cell phones.

A number of the alleged discovery violations are tied to the defendants' duty to preserve evidence relevant to this litigation and the gross inadequacy of the litigation hold that has been adopted by the defendants' to date. In the instant case, the defendants' preservation obligation was triggered in February of 2012 (as to BIPI) and, at the latest, April 2012 (as to BII). Further, there is no question that, as of June 2012, both defendants knew that nationwide Pradaxa product liability litigation, involving hundreds of cases, was imminent. Thus, while the defendants may have been able to justify adopting a narrow litigation hold as to

some employees prior to June 2012,[1] they cannot justify failing to adopt a company-wide litigation hold as of June 2012 – when they knew nationwide Pradaxa product liability litigation was imminent.

II. BACKGROUND DISCOVERY ABUSES

A. Cumulative Effect of Ongoing Discovery Abuses

Unfortunately, this is not the defendants' first instance of discovery issues or having to answer serious allegations of discovery abuse and defend requests for court sanctions. Almost since its inception, this litigation has been plagued with discovery problems primarily associated with misconduct on the part of the defendants. The Court is continuously being called upon to address issues relating to untimely, lost, accidentally destroyed, missing, and/or "just recently discovered" evidence. The defendants' justifications for these discovery violations include but are not limited to the following: (1) placing the blame on others such as third-party vendors (production is delayed due to "vendor issues"), their own IT departments (we told IT to give the vendors full access to the database but for some reason IT provided the vendors with limited access), their own employees

[1] For instance, when only one or two cases had been filed (assuming the defendants did not know or did not have reason to know that nationwide litigation was imminent), it may have been appropriate to limit the litigation hold as to sales representatives (for example) to those sales representatives detailing Pradaxa in the same region where the subject plaintiff received his or her prescription for Pradaxa. However, even with just a few cases on file, the defendants' would have owed a duty to preserve the custodial files of top Pradaxa scientists (for example) as such information could be potentially relevant to any individual plaintiff's Pradaxa product liability action.

(the defendants' deponent did not understand that work related day planners should have been produced or the employees did not understand that work related text messages should have been retained and produced); (2) the defendants' and/or counsel's lack of experience in addressing litigation of this size; (3) the defendants' did not know, until recently, that this would turn into a large nationwide MDL; (4) unusual technical issues (despite our best efforts, that employee's hard drive was accidentally erased during a routine windows 7 update); (5) minimizing the alleged abuses (yes, we failed to produce this database but it was only 500,000 pages of documents compared to the 3 million we already produced or yes that material was accidentally destroyed but the PSC doesn't really need it); (6) blaming the PSC for submitting too many discovery requests that are broad in scope (only as an excuse after discovery violations are alleged but never as a proactive motion to limit discovery); and (7) the defendants' did not know about the "gaps" in their production until they began a comprehensive re-check or audit of the discovery process in September 2013.

The Court has been exceedingly patient and, initially, was willing to give the defendants the benefit of the doubt as to these issues. However, as the Court has warned the defendants in the past, when such conduct continues, there is a cumulative effect that the Court not only can but should take into account. Accordingly, the Court initially reviews the issues that have arisen to date.

B. Discovery Issues Preceding the PSC's First Motion for Sanctions

1. History of Discovery Abuses Outlined in the PSC's First Motion for Sanctions

The PSC's first motion for sanctions provides an overview of the discovery issues that had arisen as of the date of its filing (September 11, 2013) (Doc. 266). The Court will not recount all of the discovery issues detailed in that motion and instead incorporates them by reference. The Court also incorporates by reference the defendants' response to that motion (Doc. 271). The Court notes, however, that, for the most part, it agrees with and adopts the list of discovery abuses as detailed by the PSC. Further, with regard to the discovery issues that had arisen as of September 2013, the Court specifically notes the matters outlined below.

2. Cancellation of Depositions to Allow Defendants to Get Their House in Order

At the status conference on June 10, 2013 the Court cancelled approximately two months of depositions. In a subsequent Case Management Order, the Court reflected on the cancellations as follows:

> At the status conference on June 10, 2013, the Court approved the parties' request to cancel approximately two months of depositions. The cancellation was necessitated by a number of document production deficiencies in relation to the custodial files of former and present BIPI and BII employees identified by the PSC as deponents. The parties indicated that, in light of the document production deficiencies, the custodial depositions should be delayed to allow the defendants to get their house in order and to ensure that the PSC had complete custodial files prior to taking the subject depositions. The parties further represented that the depositions could be cancelled and rescheduled without delaying the bellwether trial dates already in place. The Court concluded the requested cancellation was in the best interest of the litigation and directed the parties to confer and

> negotiate a revised document production and pretrial schedule that maintained the bellwether trial dates already in place.

(CMO 38, Doc. 231 p. 1)

3. CMO 38 and the Court's Findings Regarding Certain Discovery Abuses

The PSC alerted the Court to problematic supplemental custodial file productions that included thousands of pages of "old" documents (documents that should have already been produced) and the production of otherwise incomplete custodial files. The Court found, in relevant part, as follows:

> Although some of the supplemental productions may have been made for legitimate reasons (vendor issues, technical problems, supplemental privilege review), the Court takes issue with the lack of transparency in alerting the Court or the PSC to matters that delayed the production of complete custodial files on the dates ordered by this Court. In general, the Court finds that BIPI failed to timely produce or timely respond to discovery as outlined by the plaintiffs letter-brief.
>
> In addition, the Court is particularly concerned with what appears to be a unilateral decision by BIPI to withhold "highly confidential" documents from the custodial files of non-German custodians – without informing the Court or the PSC that such documents were being withheld….BIPI's unilateral decision to do so violated this Court's orders. Considering the above, the Court finds that BIPI inappropriately withheld "highly confidential" documents contrary to its agreement with the PSC and with this Court's orders.

(CMO 38, Doc. 231 pp. 5-8). As a result of the Court's findings, the Court adopted a revised production schedule (CMO 37, Doc. 230). Further, the Court imposed a certification requirement on BIPI and BII (CMO 38, Doc. 231 p. 8). The certification required both defendants "to provide a certification attesting to the completeness of productions."

C. The Court's Ruling Regarding the PSC's First Motion for Sanctions

On September 18, 2013, after hearing oral argument on the PSC's first motion for sanctions, the Court ruled from the bench. The following are relevant excerpts from that ruling:

> The Court finds here today that the defendant has violated or failed to meet either the letter or spirit of the Court's orders relative to discovery in a number of respects. It's hard for the Court, in this context and on this record to determine exactly where the fault lies in relation to the questions that I gave to Mr. Schmidt. I am not provided with the information. As I asked Mr. Schmidt, there could be outright deliberate violation of the order for the purpose of delaying production. It could be that there is gross negligence on the part of employees. There could be a failure of leadership at BIPI or BII in failing to make the employees understand their responsibilities.
>
> The upshot is, however, that the defendants have simply failed to follow the Court's orders. I agree with the list that was – I asked the plaintiffs to provide a list of what they thought were failures on the part of the defendants. I agree with that list, adopt it for the purpose of this order. I find for the remedy that I will fashion that I need not rule upon the motive that the plaintiffs suggest, but I also agree and find that there have been the additional violations since September 11, the five that Mr. Katz set out. I have in my notes the entire list, but for purposes of this order I'll simply adopt the list by reference. They're so numerous, which is one of the things that's so distressing to me.

(Doc. 277 p. 92 l. 23 – p. 93 l. 22)

> I've never seen a litigation where the problems are just ongoing and continual, and every month or every week there's an issue of this failure and that failure and the other failure. It just is astounding. The reason, that it's because of the volume or because of the scope or because of the breadth or because of the this or that, the vendor or this other or that other, that's fine in the early going perhaps but as the litigation matures the reasons just don't make sense and just simply can't be tolerated by the Court.

So it finally got to the point where we last met on September the 4th where I simply drew a line and said, The next time I hear of a failure we're going to talk about this in court with employees from the defendants, and it just took a matter of a few hours before I heard about the next failure. So there simply has to be a way to make this stop and to resolve once and for all this issue of failure after failure, and, in my eyes, violation after violation after violation of this Court's orders. It gets to the point where, from the Court's viewpoint, it's not simply working through rough patches and how to handle litigation, but a simple disregard of the Court's orders regardless of the motivation.

So throughout these countless discussions over these issues and defendants' counsel doing everything they could to try to minimize the overall impact of these violations, the Court has just become frustrated beyond comprehension with these violations, some causing delays, some causing extraordinary delays, others just simply being glitches in the process of trying to get these cases in a posture to either be tried or resolved. And the ultimate goal, of course, giving the medical community an answer to this issue, giving the defendant an answer to this issue, giving the plaintiffs an answer to the issues, and performing the duties that we're all here to perform.

My conclusion, therefore – and I agree with the plaintiffs. I'm not sure if Mr. Katz kept count of the number of times they used "totality" or not, as he did with the defendant's use of words, but I agree that the totality of the circumstance here is and the totality of the violations is what counts. If you violate a Court order and remedy it, you don't get to start from scratch as far as I'm concerned. Your conduct is what it is, and if the conduct continues it's – there is a cumulative effect that the Court not only can but should take into account as time goes on.

And so my finding and conclusion is that there has been a clear pattern of numerous and substantial violations of the Court's many orders that have occurred in the past. I believe these have prejudiced the Court prejudiced the plaintiffs, I'm sorry, and have held this Court and demonstrated a holding of this Court in low regard, and they have amounted to a contumacious disregard for its authority. Under Rule 37 and the Court's inherent authority, I have available to me a number of options, one of which, of course, is the option which the plaintiffs seek, which is to strike the defendant's pleadings in whole or in part. It's my finding that that is an option which is too draconian. I will not exercise my discretion in that regard. If this were a single plaintiff and a single defendant, perhaps that would be

an appropriate response, but I choose not to exercise my option in that regard. However, I find that an appropriate response would be a couple of things: One, to impose a fine on the defendant, and two, to impose certain mandatory injunctions on the defendant. And my order is as follows:

In accordance with my inherent authority, in accordance with Rule 37, I hereby sanction the defendants by ordering them to pay a fine in the registry of this court in the amount of $29,540. For anybody that's done the math quickly, that amounts to $20 per case, not a very drastic amount, I don't believe. However, the defendant should understand I also believe in progressive discipline should this Court have to visit this issue again.

I further order the defense counsel, together with the five officers who appeared here today, to oversee a communication to all known witnesses – and this is the mandatory injunction part – and custodians of every known or potential source of discoverable material to do an immediate search for any yet undisclosed materials that are relevant in the broadest possible definition of that word to this litigation and to advise counsel of its existence by Monday of next week.

I understand you said you've been conducting an audit, but I absolutely do not know what that consists of, but I want some sort of communication from you folks that are involved in overseeing of this litigation something in writing that makes it quite clear to everybody that has some sort of control over discoverable material, so they have no way to mistake their duties and obligations, to make sure they search their records high and low for anything that's discoverable, and to report their results by Monday. If any – a witness or custodian is not present at the place where they maintain such records or discoverable material, they're to do so within two days of returning to said location, if they're on vacation, they're out of the office, whatever that circumstance may be.

The communication which conveys this instruction shall describe in detail what is required of the witness or custodian and shall provide the name and contact information of a person with specific legal knowledge whom the witness or custodian may communicate with for information in the event he or she has any questions about what must be disclosed. The communication must also suggest that any individual questions of inclusion – in other words, if they wonder whether a matter of material is discoverable or not, should be resolved on the side of assuming that disclosure to counsel is the best course, and counsel can thereafter examine the material for

exclusion, if appropriate. This may have already been done. Mr. Schmidt referred to it in his argument, but for depositions in the past that were cancelled as a result – this continues with a mandatory injunction part. For depositions in the past that were cancelled as a result of the defendants' failure to timely produce documents and for which defendants have not already agreed to reimburse, the plaintiffs may petition the Court to have their expenses reimbursed by defendants for appearing if no part of the deposition took place. In such event, expenses of Judge Stack will be borne solely by the defendant. For future depositions, should a deposition be cancelled due to the failure of defendants to timely produce material which it was required to produce, and no part of the deposition was taken, plaintiffs may petition the Court to have their expenses reimbursed by defendants. In such event expenses of Judge Stack shall be borne solely by the defendants. Once again, if defendants agree to the reimbursement, plaintiffs need not petition the Court.

In the event of a petition by plaintiffs for reimbursement, plaintiffs shall provide the Court with detail regarding the reason for the reimbursement, an itemization for the expenses they seek reimbursement, and shall include – for the expenses they seek for reimbursement. Plaintiffs shall forward a copy to defendants, who shall have 14 days to respond. If they intend to contest the request, that is, if the Court grants the request, the action by the Court automatically means Judge Stack's expenses for the cancelled deposition shall be borne solely by the defendant.

As a further mandatory injunction, should a scheduled deposition be cancelled due to an alleged failure of defendants to abide by discovery order of this Court and is the only deposition scheduled for that location, whether that venue is outside or within the United States, the parties are hereby directed to submit the facts of the occurrence to the Court within seven days of its occurrence. In addition to the facts, the parties will submit to the Court the available dates they suggest the deposition should be reset, given the need to examine the late-filed material and the upcoming deposition schedules, together with the names of the likely lead interrogators for the deposition. Court will then select a date for the scheduled – for rescheduling the deposition and will select a venue for the deposition, most likely the city of the main office of the lead interrogator, or St. Louis, as the Court determines is the reasonable location.

Should the defendants continue to violate discovery orders this Court has entered, the Court will consider, on motion by the plaintiffs or its own motion, further sanctions, including all sanctions authorized by

> Federal Rule of Civil Procedure 37, or its inherent authority. Furthermore, if the Court is forced to hold such a hearing the defendant can expect to produce at that hearing certain employees as designated by the Court, pursuant to its inherent authority, for testimony so that the Court can determine the nature of defendants' good faith in complying with the Court's order announced today, as well as their good faith in complying with the discovery orders generally in this litigation.

(Doc. 277 p. 95 l. 10 – p. 102 l.1)

D. The Court's Expectations with Respect to the Audit

As part of the Court's oral ruling addressing the PSC's first motion for sanctions, the Court ordered the defendants to take the necessary steps to locate any yet undiscovered material and to report back to the Court ("the audit"). The Court did not expect the "audit" it was ordering to uncover voluminous or broad based materials. Given an expected limited scoped and the already very untimely nature of the disclosures, the Court required completion within mere days. The audit has revealed some gaps in discovery that the Court expected to find. For example, emails such as those of Dr. Clemons' which were not stored in his custodial file and a few BIPI and BII custodians who reported finding some additional documents not previously disclosed. The Court does not now take umbrage with these matters because given the issues that had long plagued this litigation which were discussed at the first sanction hearing, it was anticipated that such matters, hopefully minimal in number, would be uncovered by the court-ordered audit.

There are, however, a growing number of "gaps" in production to which the Court takes considerable exception. The Court has asked repeatedly throughout the many discussions about discovery problems, and at the first sanction hearing, how these problems could be occurring and for such a duration of time. The answer is now clear to the Court. The defendants have taken a too narrow and an incremental approach to its "company-wide" litigation hold.

The Court has been relying on the common meaning of the words that that the defendants have a company-wide litigation hold on all persons who have custody of any documentation relevant to Pradaxa. The production requests of the plaintiffs are so broad as to cover any possible derivation of means to document someone's thoughts, words and deeds short of attaching electrodes to their scalps and electronically downloading what is contained in their minds. This extreme statement is meant to convey that all of the materials that are discussed in this order were clearly covered by production requests and further anticipated by the Court as subject to the "company-wide" litigation hold.

The Court has examined the defendants' "holds," submitted *in camera,* and does not take umbrage with the language or scope thereof. As it turns out, the problem was in the implementation. For example, the Court learned at the second sanction hearing that the defendants chose to incrementally place holds on certain classes of employees, and have unilaterally chosen not to hold regarding an employee because the company decided he didn't fit the description of "important enough" and wasn't specified by the PSC. Further, while their vendor was given

access to one part of a computer drive, it did not have password access to a subpart with relevant material. All of the materials discussed heretofore, should have been produced long, long before now. Some may never be able to be produced.

The defendants have had many conversations with the Court regarding discovery problems. During these conversations, the defendants did not hesitate to voice concerns regarding issues associated with the timing of producing certain documents, data or files. The defendants, however, never sought leave of Court to delay the implementation of the litigation hold on the premise that it was too burdensome – financially or logistically. Therefore, the Court relied on the presumption that the defendants were preserving all relevant documents of every description. It only came to light recently that such was not the case. The Court did not expect that nor was that the subject of specific discussion in the last sanction debate.

III. CASE-SPECIFIC BACKGROUND AND LEGAL AUTHORITY WITH RESPECT TO THE DEFENDANTS' DUTY TO PRESERVE

A. When the Duty to Preserve Arose

1. Relevant Legal Authority

The duty to preserve documents and material that may be relevant to litigation generally arises with the filing of the complaint. *See Norman–Nunnery*, 625 F.3d at 428–429. However, The Seventh Circuit has held that the obligation

to preserve evidence arises when a party "knew, or should have known, that litigation was imminent." *Trask–Morton v. Motel 6 Operating L.P.*, 534 F.3d 672, 681 (7th Cir. 2008).

2. When the Duty to Preserve was Triggered in This Case

In the instant case, as the Court has previously concluded, BIPI's duty to preserve material relevant to this litigation arose in February 2012 when it received a lean letter regarding the first post-launch Pradaxa product liability suit. BII has indicated that it issued a litigation hold shortly thereafter – in April 2012. For purposes of this order, the Court concludes that BII's duty to preserve evidence relevant to this litigation arose – at the latest – in April 2012.

The Court further notes that at least as of June 2012, the defendants were acutely aware that nationwide litigation involving hundreds of cases (if not more) was imminent. On May 31, 2012, Plaintiff Vera Sellers filed a Motion for Transfer of Actions Pursuant to 28 U.S.C. § 1407. *See* MDL No. 2385 (Doc. 1), *In re Pradaxa Prod. Liab. Litig*. ("MDL Motion"). At that time, approximately 30 product liability actions involving the prescription drug Pradaxa were pending in 14 different federal district courts. The MDL Motion stated that at least "500 additional complaints" were expected to be filed in the near future (MDL Motion p. 2). In June 2012, the defendants filed their responsive brief and included the following argument regarding where the growing number of Pradaxa cases should be consolidated:

> Beyond the pending actions, Plaintiff states that "more than 500 additional Complaints will be filed in the near future." Given the nationwide soliciting, the distribution of forthcoming cases would be expected to be spread across the United States. This is, in fact, what has happened. Even after the "wave" of cases were filed in the Southern District of Illinois, followed by the instant MDL request, various plaintiffs filed cases in the Eastern District of Louisiana (including a purported class action), Middle District of Tennessee, Eastern District of Kentucky, Southern District of Florida, Northern District of Ohio, Eastern District of New York, and the District of South Carolina (removed). This distribution reinforces the national scope of the Pradaxxa litigation – both in terms of where the cases stand today and where they are likely to be filed.

MDL No. 2385, *In re Pradaxa Prod. Liab. Litig* (Doc. 54 p. 9). Considering the above, there is absolutely no question that the defendants knew nationwide Pradaxa product liability litigation involving hundreds (if not more) cases was imminent. Therefore, the defendants cannot contend, in good faith, as they attempted to do at the sanctions hearing, that they did not understand the size and scope of this litigation until recently. Nor can they contend that their decision to adopt an extremely limited litigation hold was based on an appropriate good faith belief that this litigation would be limited in size.

B. Scope of Duty to Preserve

The general scope of discovery is defined by Fed. Rule Civ. Proc. 26(b)(1) as follows:

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense--including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be

> admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.

"The key phrase in this definition—'relevant to the subject matter involved in the pending action'—has been construed broadly to encompass any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case." *Oppenheimer Fund, Inc. v. Sanders* 437 U.S. 340, 351, 98 S.Ct. 2380, 2389 (1978).

The broad scope of discovery outlined in Rule 26 is vital to our system of justice. *See Hickman v. Taylor*, 329 U.S. 495, 507, 67 S.Ct. 385, 392 (U.S. 1947) ("Mutual knowledge of all the relevant facts gathered by both parties is essential to proper litigation. To that end, either party may compel the other to disgorge whatever facts he has in his possession."). It was adopted, in part, to restore a sense of fair play and to combat a growing sense of frustration with the often contentious nature of litigation. *See e.g.*, Roscoe Pound, *The Causes of Popular Dissatisfaction with the Administration of Justice, Address Delivered Before the Convention of the American Bar Association* (Aug. 26, 1906), in 35 F.R.D. 241, 273 (1964).

As other district courts in this Circuit have recognized, this vital element of our discovery process "would be a dead letter if a party could avoid [its duty to disclose] by the simple expedient of failing to preserve documents that it does not wish to produce." *Danis v. USN Communications, Inc.*, 2000 WL 1694325, *1 (N.D. Ill. Oct. 20 2000) (Schenkier, M.J.). "Therefore, fundamental to the duty of

production of information is the threshold duty to preserve documents and other information that may be relevant in a case." *Id*.

Commiserate with Rule 26(b)(1), the scope of the duty to preserve evidence is broad, encompassing any relevant evidence that the non-preserving party knew or reasonably could foresee would be relevant to imminent or pending litigation. *See, e. g*., *Langley*, 107 F.3d at 514; *Melendez v. Illinois Bell Tel. Co*., 79 F.3d 661, 671 (7th Cir. 1996); *Marrocco v. General Motors Corp*., 966 F.2d 220, 223–225 (7th Cir. 1992). Thus, once the duty to preserve is triggered, the party owes a duty to preserve evidence that may be sought during discovery and should implement a plan to find and preserve relevant evidence. Finally, a party's duty to preserve information is not a passive obligation; it must be discharged actively. See *Marrocco*, 966 F.2d at 224-25.

C. Timeline of Issues Relevant to Duty to Preserve

The Court notes the following with respect to the defendants' preservation obligation in the instant case:

- February 2012 – BIPI's duty to preserve is triggered
- April 2012 (at the latest) – BII's duty to preserve is triggered
- June 2012 – the defendants know that nationwide litigation involving hundreds (if not more) Pradaxa product liability cases is imminent
- July 13, 2012 – The Court and Counsel for BIPI Discuss the Duty to Preserve. Counsel indicates that BIPI has established a litigation hold and represents that, with respect to custodians, the company issues a physical document preservation notice to custodians of relevant evidence

Transcript of July 13, 2012 Status Conference

Page 22 of 33

THE COURT: So one of the things that I was
concerned about – and it turns out it wasn't included in
your production order – and that is preservation. Do you
have a preservation direction issue corporate-wi[d]e?[2]
MR. HUDSON: Yes, Your Honor.
THE COURT: People understand, obviously, this is
not your first – presume this is not your first piece of
litigation in this corporation.
MR. HUDSON*:* It's not, and the cases filed here

Page 23 of 33

were not the first filed cased, so there were preservation
orders in effect before these cases were even filed.
THE COURT: So explain to me essentially how
that – without revealing any attorney-client privilege, how
does that work and how is it maintained and how is it
policed in effect? Briefly. I don't need –
MR. HUDSON: Let me think about how to best explain
this. I know the process but I want to be careful about
discussing in open court the process the corporation uses
for this, because there are attorneys involved, but there is
a physical document preservation notice that is issued to
potential custodians of relevant evidence. There's a
process by which the custodians confirm acknowledgment of
the obligation to comply with the litigation hold, and that
is monitored and followed up on.
And I think – Your Honor, does that adequately
answer your question or would you like me to go into more
detail there?
THE COURT: No, that's fine. And in general, there
are officers, coordinators, employees who are charged with
overseeing the preservation?
MR. HUDSON: Individuals within the legal
department, and there are contact points identified on the
preservation notice as well, as far as who the people are

[2] The Court, based on independent recollection, agrees with plaintiffs' assertion that the transcript contains a transcription error. The transcript reads "wise" but should read "wide." Further, as the Court noted during oral argument, it finds no difference in the terms.

25 involved in that process. So the people charged with the

Page 24 of 33
1 preservation obligation receive the document preservation
2 notice, actually know who – in addition to the person who's
3 issued the letter from the legal department, but the person
4 they can go to with questions, yes.

(Doc. 57 p. 22 l.17 – p. 24 l.3)

- **November 5, 2012** -- Counsel for BII confirms that BII is aware of the Court's preservation order (Doc. 69 p. 11 l.14-17) ("As I told the Court in chambers, BII is aware of the preservation obligations, and document preservation notices went out prior to the cases being transferred to this MDL.").

IV. POTENTIALLY SANCTIONABLE CONDUCT PRESENTLY IN ISSUE

A. Thorsten Lehr

1. Background

Professor Thorsten Lehr is a pharmacometrician formerly employed by BII (Doc. 311 p. 9). While working for BII, Prof. Lehr was a high-level scientist that worked on Pradaxa and published articles on Pradaxa as a lead author (Doc. 302 p. 5). Prof. Lehr was responsible for quantitative analysis relating to the interaction between Dabigatran and specific patient populations (Doc. 302-5 p. 5). Prof. Lehr left employ at BI at the end of September 2012 – well after the

defendants were under a duty to preserve evidence relevant to this litigation (Doc. 302-4 p. 6; Doc 302-5 p. 5). Dr. Lehr is currently employed by Saarland University (Doc. 302-5 p. 5). There is a cooperation agreement between BII and Saarland University under which Prof. Lehr continues to have access to certain Pradaxa clinical trial data (Doc. 302-5 p. 5).

According to the PSC, BII never disclosed Prof. Lehr in any answers to the PSC's interrogatories. Further, Prof. Lehr was not on the list of custodians with relevant knowledge provided by BII. *Id.*

The PSC did not learn of Prof. Lehr's relevance to this litigation until September 25, 2013 when Lehr was identified during the deposition of one of the defendants' employees, Martina Brueckman (Doc. 317-1 p.6). That same day, the PSC requested Prof. Lehr's custodial file be produced by October 7, 2013 (Doc. 317-1). BII did not respond to the request for production of Prof. Lehr's custodial file for two weeks and at that time indicated that it would need 45 days to produce his custodial file (invoking a case management order previously adopted by the Court) (Doc. 317-1).

On October 25, 2013, in a letter to the Court, BII stated that Prof. Lehr "was not subject to a litigation hold when he left BII because he had not been identified as a custodian" (Doc. 302-5 p. 5). On November 4, 2013, BII again informed the Court that Prof. Lehr was not subject to a litigation hold when he left the company because he had not been identified as a custodian (Doc. 302-4 p. 6),

On November 7, 2013, counsel for BII (Beth S. Rose) provided an affidavit with additional information pertaining to Prof. Lehr (Doc. 302-6). The affidavit provides, in relevant part, as follows:

> Contemporaneous with this Affidavit BII is making the production of responsive e-mails from Thorsten Lehr. Thorsten Lehr is a former BII employee who formally left the company at the end of September 2012. At the time he left, Prof. Lehr was not identified as a custodian and, therefore, was not subject to the document preservation notice. We have confirmed with Prof. Lehr that when he left the company, he did not take his workstation or any other documents with him. Prof. Lehr's workstation, user share, and paper documents are not available to be collected. The only part of Prof. Lehr's custodial file available for collection is his e-mails.

(Doc. 302-6 ¶ 2). In other words, with the exception of Prof. Lehr's emails, BII failed to preserve Prof. Lehr's custodial file at a time when it was under a duty to do so.

BII has stated that they chose not to preserve Dr. Lehr's custodial file because, at the time of his departure in September 2012, he had not been identified as a custodian. This statement lends itself to one of two interpretations. Either BII is asserting that it did not realize that Prof. Lehr was a custodian with potentially relevant information and therefore failed to preserve his custodial file when he left the company; or BII is asserting that because the PSC had not yet requested Dr. Lehr's custodial file, it had no duty to preserve Dr. Lehr's custodial file (even if it contained information relevant to this litigation). Both interpretations are problematic for BII.

2. BII Cannot Believably Contend it Did Not Recognize Prof. Lehr as a Custodian with Potentially Relevant Information

BII cannot believably contend it did not know Prof. Lehr's custodial file contained information relevant to this litigation. Prof. Lehr was unquestionably a high-level scientist actively involved in working on Pradaxa. For instance, in an email dated May 31, 2012, Dr. Yasser Khder (employed by BII) introduces "Dr. Thorsten Lehr" to his "colleagues" as "our company expert for dabigatran" (Doc. 317-1 p. 16). He goes on to state that Prof. Lehr "did all the M&S for the [REDACTED BY THE COURT] program (Doc. 317-1 p. 16). Dr. Lehr will get in contact with you to further discuss the different aspects to this request" (Doc. 317-1 p. 16).

The PSC has also learned that Prof. Lehr co-authored at least 10 Dabigatran (Pradaxa) articles published between September 2011 and September 2013 (Doc. 317-1 pp. 9-14). Further, although Prof. Lehr is no longer employed by BII, he continues to work with BII scientists on future Pradaxa publications (Doc. 317-1 p. 14).

Even more telling, is a group of company emails exchanged in 2011 and 2012 reflecting an internal debate over whether a scientific paper being drafted by Prof. Lehr (the "exposure paper") should include Prof. Lehr's conclusions regarding Pradaxa's therapeutic range.[3] In the exposure paper, Prof. Lehr (and his co-authors) concluded, in the early versions of the paper, that both safety and efficacy of dabigatran are related to plasma concentrations and conclude that

[3] Notably, in an email dated October 31, 2012, addressed to Dr. Jeffrey Friedman, Dr. Andreas Clemens (BIPI employee) refers to Dr. Lehr as the "father" of the exposure paper (Doc. 317-1 p. 17).

there is a therapeutic range for Pradaxa and further specify what that range is. (Doc. 317-1 p. 20).

These emails reveal Dr. Lehr's desire to publish a paper that included a therapeutic range for Pradaxa was highly controversial. An email from Dr. Andreas Clemens, dated December 19, 2011, demonstrates the discussion and disagreement flowing through the company regarding Dr. Lehr's conclusions (Doc. 317-1 p. 23). As does a July 30, 2012 email from Stuart Connolly (Doc. 317-1 p. 29). Ultimately, an email from Dr. Jeffrey Friedman, dated October 23, 2012, seems to require a revised version of the exposure paper without inclusion of the therapeutic levels suggested by Prof. Lehr (Doc. 317-1 p. 31). An email from Dr. Clemens to Prof. Lehr, dated October 24, 2012, confirms that (Doc. 317-1 p. 33).

The following email describes Prof. Lehr's position on the matter at the end of October, 2012.

October 31, 2012 email from Dr. Andreas Clemens

> Thorsten wants to tailor the message according our ideas. I see value in this manuscript especially with regard to a manuscript which will in the next step focus on lab levels (aPTT) to give the physicians an understanding what they have to expect in specific situations regarding aPTT. The world is crying for this information – but the tricky part is that we have to tailor the messages smart. Thorsten wants to do that.

(Doc. 317-1 p. 17).

Eventually, another scientist, Paul Reilly, was tasked with revising the exposure paper. The following email from Paul Reilly further demonstrates the

internal debate over inclusion of an optimal therapeutic range in the exposure paper:

> I have been facing heavy resistance internally on this paper about the concept of a therapeutic range, at least stating it outright. Perhaps you can help me with solving this dilemma. I am working on a revision to deal with this and I will come back to you with it. I think they just don't want the message that one range fits all, it's patient specific.

(Doc. 317-1 p. 28).

The emails also reveal the importance of keeping the debated issue confidential. Dr. Clemens October 24, 2012 email to Prof. Lehr (above) closes with a statement written in German, roughly translated as follows:

> I think – "the banana is still shuttered". Please treat this confidential because Jeff currently interacts with Paul Reilly directly – and I do not know if they know this is actually on file.

(Doc. 317-1 p. 33). Prof. Lehr subsequently responded to Dr. Clemens' request for confidentiality as follows:

> I will keep it absolutely confidential! I'm personally very disappointed about the exposure-response manuscript. I have put a LOT of effort and time into the analysis. But I don't like the way how the manuscript is written and the message conveyed. I'm working again on a revision of the document and I hope that Paul will consider them. It is the last time, that I agree to put people as first author who were not involved in data analysis. Let's try to get this manuscript in a shape that everybody is happy. Maybe we need a TC (Jeff, Paul, Andreas, Thorsten) to discuss open issues.

(Doc. 317-1 p. 34).

In addition, the emails exchanged during this time period demonstrate that the exposure paper and Dr. Lehr's controversial

conclusions regarding an optimal dosing range for Pradaxa were being considered and discussed in the highest levels of the company and with the defendants' legal team. For example, consider the following emails:

December 19, 2011 email from Dr. Janet Schnee to Dr. Andreas Clemens

> I noticed this email only this evening, but have now forwarded [Dr. Lehr's draft exposure paper] to the US product lawyer for an opinion.

(Doc. 317-1 p. 24)

June 4, 2012 email from Dr. Paul Reilly

> Exposure response is definitely on the OC radar and I have been heavily pressed to revise and submit the manuscript. It has been "on hold" for almost 6 months. I had to wait several weeks for some analyses from Thorsten, at his request.

(Doc. 317-1 p. 25)

July 16, 2012 email from Dr. Lehr to Paul Reilly

> I met Jeff last Thursday. We discussed the ER [exposure paper] analysis together with management. As management liked it (and also Jeff seemed to like it), I believe we have some tailwind. Maybe you can meet with Jeff and see how to move forward.

(Doc. 317-1 p. 26)

Considering the material pertaining to Prof. Lehr, including the email excerpts noted above and those not excerpted for confidentiality purposes but which the Court was able to read in the motions filed under seal, it is evident that Dr. Lehr was a prominent scientist at BII that played a vital role in researching Pradaxa. The defendants' management, legal team, and other top-scientists were familiar with Prof. Lehr's work and communicated with him regarding the same. The Court is stunned that Prof. Lehr was not identified by the defendants as a

custodian with potentially relevant knowledge about Pradaxa. Further, given the above, it is evident that the defendants knew that Prof. Lehr's custodial file contained information relevant to this litigation in September 2012 when Prof. Lehr left his employ with BII. The emails also may lead a reasonable person to infer a motive for the defendant to abstain from placing a litigation hold on his materials, including the early versions of the exposure paper. The entire debate is relevant, or at least conceivably relevant, to this litigation and without question any documents, no matter who generated them, should have been the object of the litigation hold.

3. The Duty to Preserve is not Defined by What has or has not Been Requested by Opposing Counsel

The second possible interpretation of BII's statement regarding why it chose not to preserve Dr. Lehr's custodial file is that BII is blaming the PSC for failing to identify Dr. Lehr as a custodian. In other words, a party only has a duty to preserve relevant evidence that has actually been requested by the opposing party. This position is nonsense. The very purpose of the duty to preserve, is to protect potentially relevant material so it is available for production when and if the opposing party requests that material. Furthermore, the defendant, not the plaintiff, is in the best position to identify persons such as Dr. Lehr.

4. Final Points Regarding the Defendants' Supplemental Response

During oral argument, the PSC showed the Court draft version number 5 of the exposure paper. The PSC raised questions regarding whether draft versions 1-

4 had been destroyed. In their supplemental response, the defendants contend that their productions have included seven earlier distinct drafts of the exposure paper (presumably from sources other than Prof. Lehr's custodial file), dating back to January 2011 (Doc. 317 p. 2). This argument misses the point. The defendants do not get to pick and choose which evidence they want to produce from which sources. At issue here are the missing documents and material contained in Dr. Lehr's custodial file. The question is, of the draft versions stored on Dr. Lehr's work stations, what was lost when the defendants failed to preserve Dr. Lehr's custodial file.

The defendants also argue that because their preservation obligation only attached in February of 2012, they were under no duty to produce documents created prior to February of 2012 (Doc. 317 p. 2). This contention distorts the nature of the duty to preserve. The fact that the defendants preservation obligation did not attach until February of 2012 (or, at the latest, April of 2012 for BII), does not mean that the defendants are entitled to destroy documents created prior to that date. It means that as of February 2012, the defendants have a duty to preserve any documents in the defendants' control – even those created before February 2012 – that are potentially relevant to this litigation and destruction occurring after February 2012 is a violation of that duty.

Finally, the defendants contend that because they have produced discovery from other sources that reveals the internal dispute over the exposure paper and over issues relating to therapeutic range, the failure to preserve Prof. Lehr's

custodial file must be innocent (Doc. 317 pp. 3-4).[4] In light of all the other discovery abuses that have been discussed herein, this argument does not win the day. One does not know what annotations are or were contained on the personal versions of Dr. Lehr or what statements he made in his "share room" space about the controversy that was brewing. Plaintiffs are entitled to discovery on such matters for interrogation or cross examination purposes.

B. Inadequate Litigation Hold for Pradaxa Sales Representatives, MSLs and CSCs

1. Background

The Court will now address issues related to the litigation hold as it was applied (or not applied) to the defendants' Sales Representatives, Clinical Science Consultants (CSCs) and Medical Science Liaisons (MSLs). First, however, the Court will provide some background with regard to CSCs and MSLs.

CSCs are specialized sales representatives.[5] In November 2011, CSCs began delivering unbranded disease state messages to health care providers

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[4] This position was also asserted during oral argument when counsel for BIPI argued, in essence, that if this was a cover-up it was the worst cover-up in the world.

[5] In the PSC's initial motion for sanctions, they describe CSCs as follows:

> [A CSC] is a part of the promotional arm of BIPI and specifically Pradaxa. CSCs are individuals with some level of advanced education or certification such as PharmD. They serve a nuanced purpose of delivering an "unbranded" message to physicians, allowing them to say things that a sales representative could not say, such as discussing a-fib rather than non-valvular a-fib, and discussing Warfarin in general terms and not just in relation to comparison studies. The documented purpose of the CSC was to 'disrupt'

concerning atrial fibrillation ("A-fib") (Pradaxa is used to reduce the risk of stroke and blood clots in people with A-fib not caused by a heart valve problem) (Doc. 271 p. 8). Purportedly, CSCs met with physicians to discuss A-fib without reference to Pradaxa (Doc. 271 p. 8). According to the defendants, the CSCs received Pradaxa-specific training in September 2012 to address physician questions they were receiving from physicians related to Pradaxa. Notably, the existence of the CSC sales force was never disclosed by the defendants even though this information was specifically requested by the PSC in prior discovery and in the Defendant Fact Sheet ("DFS") (Doc. 266 p. 18-19; Doc. 302-8 § II.C). Instead, the PSC discovered the existence of CSCs only when they noticed the word "CSC" in other documents the defendants had produced (Doc. 266 p. 19). The PSC began asking about the CSCs by title in July 2013 (Doc. 266 p. 19). The defendants repeatedly told the PSC that all of the CSC physician call information was contained in the VISTA database and had already been produced (Doc. 266 p. 19). The PSC was suspicious of this answer and continued to press the issue. Only after another five conversations with the defendants was it learned that there

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> physicians' confidence in Warfarin. The CSCs originally did not discuss a particular product to treat the disease, but in theory were trying to raise disease awareness – however they never raised awareness of a disease Defendants did not have a product to treat. In fact, originally BIPI had 'guardrails' to prevent a doctor from being detailed about a product within 24 hours of a call by a CSC because they wanted to avoid the appearance of 'off-label' promotion. In 2012, however, CSCs began to educate the doctors on the branded product – here Pradaxa – at the same visit they raised awareness to a disease.

(Doc. 266 p. 19).

was in fact a separate field within VISTA that contained the CSC data and that this field had not been disclosed to the PSC and had not been produced (Doc. 266 p. 20). Defendants insisted that this was an unintentional oversight and on September 10, 2013 provided the PSC with the missing information (Doc. 271 p. 8).[6]

MSLs are another separate specialized group within BIPI. The defendants describe MSLs as "individuals with medical and scientific backgrounds whose role is to interact with health care providers who are deemed to be scientific experts and key opinion leaders" (Doc. 271 p. 9). According to the PSC, MSLs were "responsible for making direct contact with a physician under the auspices of having a scientific conversation about a-fib, Warfarin and other subjects that could not be discussed as part of the direct promotion of Pradaxa" (Doc. 266 p. 20). Information about MSL visits with physicians is contained in what is known as the BOLD database. The existence of BOLD was not disclosed to the PSC in discovery or as part of the 30(b)(6) deposition process. Instead, the existence of MSLs and BOLD was disclosed to the PSC only in relation to the PSC uncovering the CSC issue and only when the PSC asked the defendants if there were any other forces that called on physicians (Doc. 266 p. 21). The defendants "[did] not dispute that the BOLD database and relevant MSLs should have been identified

[6] In addition, the defendants noted that they could not possibly have intended to hide the CSC data considering they produced documents from other sources which referenced CSCs. They also noted that the omitted data was only a small percent of the total data produced in the VISTA data base. Similar arguments have been raised in response to the PSCs current motion for sanctions.

and produced to Plaintiffs earlier in this litigation (Doc. 271 p. 10). They insisted, however, that this failing was another innocent inadvertent mistake.

2. Inadequate Litigation Hold

In recent weeks, it has come to light that the defendants' litigation hold, as it relates to Pradaxa sales representatives, MSLs, and CSCs, has been grossly inadequate for a litigation of this scope and size. On November 4, 2013, the defendants informed the Court and the PSC that they had been "addressing questions recently raised at sales representative depositions that the volume of email produced for certain witnesses was smaller than expected," (Doc. 302-4 p. 2). The PSC had also raised concerns that individual sales representatives custodial files did not seem to go back sufficiently far in time (Doc. 311 p. 12). In reviewing these questions, the defendants decided to "examine the dates that the sales reps/CSCs/MSLs requested for the deposition became subject to the litigation hold" (Doc. 302-4 p. 2). This examination revealed following:

- When the defendants first instigated a litigation hold in February 2012, they only intended to apply the hold to the specific sales representatives who detailed specific plaintiff's physicians. It takes time, however, to identify each plaintiff's prescribing physician and the corresponding sales representative(s). Rather than taking steps (such as placing all Pradaxa sales representatives on a litigation hold) to preserve the relevant material while these specific sales representatives were identified, the defendants did nothing.

- It was not until September 26, 2012, at which point 127 cases were on file, that the defendants decided to "expand" the then non-existent litigation hold for Pradaxa sales representatives (Doc. 311-15 p. 2; Doc. 311 p. 13). Even then, however, the litigation hold was only applied to those Pradaxa sales representatives *currently* detailing Pradaxa (Doc. 311 p. 13).
- In March 2013, with 262 cases filed, the defendants finally decided to extend the litigation hold to all sales representatives who had ever detailed Pradaxa (Doc. 311 p. 13).
- The Clinical Science Consultants (CSCs) and Medical Science Liaisons (MSLs) who detailed Pradaxa were not included in the litigation hold until August 2013 (Doc. 311 p. 13). However, the only CSCs and MSLs included in *this* hold were the CSCs and MSLs who detailed the treating physicians in the bellwether cases.
- All CSCs and MSLs who detailed Pradaxa were not placed on litigation hold until sometime after August 2013 (the defendants responsive brief simply states that they "subsequently" added "the remaining CSCs and MSLs" – the Court suspects that "subsequently" means just before the defendants filed their responsive brief) (Doc. 311 p. 13).

The litigation hold described by the defendants is wholly inadequate in light of the size and scope of this litigation. The defendants were under a duty to preserve information that they knew or reasonably could foresee would be relevant to imminent or pending litigation. In the instant case, the duty to

preserve arose in February 2012 for BIPI and in April 2012 (at the latest) for BII. Once the duty to preserve was triggered, the defendants owed a duty to preserve evidence that may be sought during discovery and should have implemented an adequate plan to find and preserve relevant evidence.

The defendants argue that the proportionality requirement of Rule 26 allowed them to implement an extremely narrow litigation hold.[7] They contend it would have been unreasonable to require them to place, for example, all Pradaxa sales representatives on a litigation hold. That might be true if this was a regional case involving only a few plaintiffs with no indication of the litigation expanding into nationwide litigation. That, however, is not the scenario we are faced with. As discussed above, as of June 2012, the defendants were aware that nationwide Pradaxa product liability litigation involving hundreds of cases (if not more) was imminent. They argued this very fact before the MDL panel in June 2012. The Court is frankly amazed that the defendants could raise such an argument and now argue, before this Court, that they did not fully understand the broad scope of this litigation or the need to expand their litigation hold to *all* Pradaxa sales representatives, CSCs, and MSLs until March 2013 (sales representatives) and sometime after August 2013 (CSCs and MSLs) (*See* Doc. 311 pp. 12-13; Doc. 311 p. 13 ("Defendants expanded the scope of their sales representative preservation efforts as the litigation expanded in size"). Furthermore, there is nothing in any case management order nor can defendants point to any statement of the Court

[7] This argument is raised in the defendants' response, supplemental response and was raised by the defendants at oral argument.

that can be interpreted as suggesting such a tailored litigation hold was acceptable. Defendants did not receive from the Court a protection order tailoring the litigation hold or managing in increments classes of employees on some timeline or on some case specific landmark when the litigation hold would kick in. There have been no regionally based markers designed to apply the litigation hold to certain sales or consulting staff based on case filings. The defendants' efforts to suggest they and they alone decided to implement such a proportionality test to the litigation hold smacks of a post-debacle argument in desperation to salvage a failed strategy regarding production evasion.

The defendants also argue that because they have produced certain databases and/or document repositories that warehouse relevant sales representative, CSC and MSL material any failings with regard to these employees' custodial files is of little or no consequence (Doc. 311 p. 10). For instance, the defendants note that they have produced approximately 45,000 pages of documents from the TEMPO database, which contains the documents used to train sales representatives about Pradaxa and the promotional pieces that the sales force is approved to use in detailing health care providers on Pradaxa, along with earlier drafts of these materials (Doc. 311 p. 10). The defendants note sales representatives have consistently testified they are not permitted to use and do not use material outside of the TEMPO database when detailing physicians (i.e. they only used the approved TEMPO material) (Doc. 311 p. 10). Obviously, the defendants contend, the PSC doesn't really need material from the sales

representatives' custodial files, because the only material sales representatives used can be found in the TEMPO database.

This argument is ridiculous. The PSC is entitled to the requested material so they can determine for themselves whether the sales representatives only used approved material from the TEMPO database. In addition, they are entitled to review the files for other relevant information to utilize as a basis for cross examination. An example leaps to the fore, what if a sales representative has in his notes that he made some fraudulent representation about Pradaxa to a physician. Further, what if the rep said "as directed by so and so, I told Dr. X this and that" which is known by all to be patently false? Obviously, the training materials alone are not relevant and clearly the Court does not suggest that its hypothetical is accurate. However, if it were to prove true, the defendants' cannot deny such material is both relevant and discoverable.

C. The G Drive

The G Drive and T Drive are shared network drives made available to certain of defendants' employees. Defendants Letter to Court, October 7, 2013. According to the defendants, employees generally use these drives to store departmental data. *Id*. Within BIPI, this drive is known as the G Drive; within BII, it is known as the T Drive. Although potentially serious production issues have

been identified with both the G Drive and the T Drive, only the production issues associated with the G Drive are presently before the Court.[8]

The G Drive is not a single unified electronic storage area. It consists of over 1.8 million folders (Doc. 311 p. 17). Employees are granted access to the folders depending on the needs of their job (Doc. 311 p. 17). If an employee does not have access to a folder on the G Drive, it will not appear at all when he or she logs into the G Drive (Doc. 311 p. 17).

Pursuant to Case Management Order Number 17, the G Drive was scheduled to be produced on or before January 30, 2013 (Doc. 78 ¶ 14). In accord with the certification requirement imposed on the defendants as a result of earlier discovery violations (CMO 38 Doc. 231), the defendants provided an affidavit of completion of document production in relation to the G Drive on August 7, 2013 (Doc. 317-14 p. 43). The original G Drive production included approximately 3.5 million pages (Doc. 311 p. 18).

Shortly before the Court held a hearing on September 18, 2013 (to address the PSC's first motion for sanctions), the defendants alerted the PSC to potential problems with the G Drive production (October 7, 2013 Letter to the Court). The defendants indicated that approximately 500,000 documents/files (excluding attachments) from four out of the five G Drive directories were missed and, as a

[8] The defendants have reported similar issues with the T Drive production and have informed the Court and the PSC that they now realize that "large portions" of the T Drive were not included in the original T Drive collection (Doc. 311 p. 18).

result, were not produced to the PSC (October 7, 2013 Letter to the Court). The defendants further indicated that the number of missed documents/files was expected to increase slightly when the fifth directory was searched (October 7, 2013 Letter to the Court).

Ultimately, the defendants determined that the documents/files were missed because the defendants' IT department failed to provide the third party vendor conducting the G Drive collection proper access to the G Drive (Doc. 311 pp. 17-18). More specifically, the IT department was tasked with providing the third party vendor with logins that would give the third party vendor full access to all folders in the G Drive (Doc. 311 p. 17). The IT department, however, failed to do this (Doc. 311 p. 17). Instead, the IT department gave the vendor "default" logins of the sort typically granted to new employees (Doc. 311 p. 17). These default logins did not have access to all G Drive folders, meaning the vendor was not aware of the existence of some of the folders and did not collect files from them (Doc. 311 p. 18). The defendants eventually produced the missing documents. That supplemental production contained approximately 400,000 pages. This sort of "mistake" early in this litigation would have been looked upon by the Court as just that, but as the rationale of this order makes clear, the reasonable inferences to be drawn from the actions of the defendant at this point in time are that such maneuverers are by design.

The PSC contends that the production indicates that there are numerous new G Drive storage areas that should have been revealed during 30(b)(6)

depositions. It further contends that the late production has resulted in prejudice in that they do not yet know what is in it, it was produced in a disorganized manner, and they do not know who uses the new storage areas or what they are used for. The defendants contend that the production was not disorganized and complied with CMO 3 in all respects (with the exception of an error with a meta data field that has since been corrected) (Doc. 311 p. 18). The defendants further contend that no relevant documents from the G Drive have been lost because the G Drive does not have an auto delete function (Doc. 311 p. 18).

D. Text Messages

On June 28, 2012, before creation of the MDL, the PSC specifically requested that BIPI produce text messages (Doc. 302-9). The PSC made a similar request to BII on October 22, 2012 (Doc. 302-10). The defendants have admitted that the PSC did in fact request texts (Doc. 302-4 ("[t]exts were requested in discovery by both parties, and produced by neither, so far as we can tell."; Doc. 311 p. 14 (admitting that the PSC's document requests "included text messages in their boilerplate definition of 'document'"). Amazingly, the defendants' hold applicable to sales representatives, CSCs and MSLs did not expressly extend to text messages until October 18, 2013 or later (Doc. 302 p. 7). The defendants first alerted the Court and the PSC to the issue in a footnote in a letter dated October 25, 2013 (Doc. 302-5 p. 2 n.3). In the footnote, the defendants contend that they did not realize until mid-October that some employees had business related text messages on their cell/smart phones (Doc. 302-5 p. 2 n.3). The PSC (and the

Court) question the plausibility of this claim considering the defendants have produced a document showing that the defendants directed their sales force to use texts to communicate with their supervisors, district managers, and others (Doc. 302-2). Further, the deposition testimony of employee Emily Baier raises further questions on this issue.[9]

The defendants contend that they have "consistently included a broad definition of 'document' in the document preservation notices sent to potential custodians and – while the notices do not explicitly state 'text messages' – they do tell custodians to preserve all relevant documents in any form, particularly specifying that this includes electronic communications stored on hand held devices" (Doc. 311 p. 14). The defendants further contend that the late discovery of the existence of business related text messages on certain employees' phones is the fault of their employees (Doc. 311 p. 15 "Until October of 2013, however, BI custodians did not identify text messages among their responsive documents…"). The Court does not accept this explanation. As noted above, the duty to preserve is not a passive obligation; it must be discharged actively. The defendants had a duty to ensure that their employees understood that text messages were included in the litigation hold. The defendants' own documentation directs employees to utilize text messaging as a form of business related communication. Questions

[9] During oral argument, the PSC played Ms. Baier's testimony. Among other things, Ms. Baier stated as follows: (1) she utilized a company issued phone; (2) she utilized text messaging for work-related communications for years; (3) she was alerted to a litigation hold in September 2012 but she does not recall being asked to retain text messages; and (4) she received an email from counsel about one week prior to her deposition regarding the need to retain text messages.

should have been raised by the defendants prior to October 2013 when none of their employees were producing text messages.

Yet another, perhaps more egregious, example of the defendants failure to properly exercise a litigation hold with respect to employee text messages, is the revelation that the defendants failed to intervene in the automated deletion of employee text messages on company issued phones. The PSC has discovered that many employees utilized company issued cell phones. Apparently, the company issued cell phones were auto-programmed (by the defendants) to delete employee text messages.[10] The defendants' failure to intervene in this automatic process places them outside of the "safe-harbor" provision provided for in Federal Rule 37(e) and subjects them to sanctions for the loss of any electronically stored information resulting from that failure. *See* Committee Comments to Fed. R. Civ. Proc. 37(f)(now 37(e):

> Rule 37(f) applies to information lost due to the routine operation of an information system only if the operation was in good faith. Good faith in the routine operation of an information system may involve a party's intervention to modify or suspend certain features of that routine operation to prevent the loss of information, if that information is subject to a preservation obligation. A preservation obligation may arise from many sources, including common law, statutes, regulations, or a court order in the case. The good faith requirement of Rule 37(f) means that a party is not permitted to exploit the routine operation of an information system to thwart discovery obligations by allowing that operation to continue in order to destroy specific stored information that it is required to preserve. When a party is under a duty to preserve information because of

[10] The auto-delete function on company issued cell phones and the defendants' failure to halt the auto-delete function once a litigation hold was in place was revealed during the deposition of Emily Baier on November 14, 2013.

> pending or reasonably anticipated litigation, intervention in the routine operation of an information system is one aspect of what is often called a "litigation hold." Among the factors that bear on a party's good faith in the routine operation of an information system are the steps the party took to comply with a court order in the case or party agreement requiring preservation of specific electronically stored information.

In their supplemental response, the defendants argue that while sanctions might be appropriate for failure to turn off an auto-delete function in relation to email communications the same conduct with respect to text messages is not sanctionable (Doc. 317 p. 5). The basis for their argument seems to be that text messages are a less prominent form of communication and that the production of text messages is too burdensome (Doc. 317 p. 5). As to the former, text messages are electronically stored information, it does not matter that text messaging is a less prominent form of communication. Further, in the instant case, employees used text messaging – to some extent – for business related communication and text messages were expressly requested by the PSC. There is no question the defendants owed a duty to preserve this material. As to the latter, the Court has already addressed the issue of burden. If the defendants felt the PSC's request for text messages was overly burdensome they should have filed the appropriate motions with the Court. The defendants cannot simply make a unilateral decision regarding the burden of a particular discovery request and then allow the information that is the subject of the discovery request to be destroyed.

In their supplemental brief, the defendants also note the following: (1) although Ms. Baier utilized text messaging for work related communications, she

also testified that these text messages were non-substantive and (2) the company has a policy prohibiting substantive text messaging with physicians (Doc. 317 p. 6). As a result, the defendants argue, their failure to preserve text messages is harmless (Doc. 317 p. 6). Once again, the defendants do not get to choose which evidence they want to produce and from which sources. The PSC is not required to simply accept as true the assumption that all employees followed the "no substantive communications with physicians" policy. Nor is it required to accept as true a deponent's claim about the content of her electronic communications. It is certainly common knowledge that texting has become the preferred means of communication. The PSC is entitled to the discovery requested for, among other things, the purpose of impeaching the above claims.

Finally, the defendants argue that they do not believe they are required to produce text messages anyway (Doc. 311 p. 15). This is a classic example of conduct on behalf of the defendants that has become all too familiar in this litigation. The PSC refers to the practice as "better to beg forgiveness than ask permission." If the defendants felt they did not have an obligation to produce the text messages requested by the PSC, they should have responded with a specific objection to the request or otherwise sought relief from the Court. *See* Fed. R. Civ. Proc. 34(b) and 26(c).

The defendants raised the issue that some employees use their personal cell phones while on business and utilize the texting feature of those phones for business purposes yet balk at the request of litigation lawyers to examine these

personal phones. The litigation hold and the requirement to produce relevant text messages, without question, applies to that space on employees cell phones dedicated to the business which is relevant to this litigation. Any employee who refuses to allow the auto delete feature for text messages turned off or to turn over his or her phone for the examination of the relevant space on that phone will be subject to a show cause order of this Court to appear personally in order to demonstrate why he or she should not be held in contempt of Court, subject to any remedy available to the Court for such contempt.

VI. FINDINGS AND CONCLUSIONS

A. Findings as to Bad Faith and Otherwise Culpable Conduct

The Court finds the actions and omissions of the defendants, BIPI and BII, to be in bad faith. The defendants argue that their failure to produce the many thousands of documents they are now producing, and their inability to produce other documents at all, are the result of a good faith measured approach to the production of millions of documents over a fairly short period of time. They contend their failure to designate certain employees as subject to a hold is part of a reasonable hold strategy based on a measured and proportioned approach to cost benefit analysis dependant on scope of litigation. They base their failure to include one scientist in the litigation hold on a failure of their opponents to designate him and their own determination that he singularly was not important

enough in light of including his coworkers whose custodial materials were being provided.

As the Court mentioned hereinbefore, the question the Court has been asking over and over again has been answered. How can these problems keep happening? One of the problems to which the Court has been referring was that the defendants kept coming up with materials in an untimely manner. Materials were being turned over months and months late - often on the eve of a deposition. It is clear to the Court that the defendants have been pursuing a policy of turning over relevant material, or withholding relevant material, on their schedule and not the Court's. In doing so, they have violated the Court's case management orders. They have made misrepresentations to the Court in open court and in chambers. The defendants have caused the Court to believe that each defendant had a litigation hold, company-wide, on all relevant personnel and all relevant documentation and data (in their broadest definitions) at all relevant times.

The Court finds that BII has specifically not applied the hold to Dr. Lehr and now failed to produce certain of his "files." To fail to do so was in violation of the Court's case management orders and in bad faith.

The Court finds both defendants failed to ensure that the auto delete feature of their employee cell phones, company owned and personal, was disengaged for the purpose of preserving text messages and, as such, this allowed countless records to be destroyed. One can only speculate about the relevance or

lack thereof and what aspect of plaintiffs' case was harmed thereby. The Court finds this action to be in violation of its case management orders to produce relevant material by a date certain and in bad faith.

The Court finds the defendants failure to place a litigation hold on Sales Representatives, Clinical Science Consultants and Medical Science Liaisons at the earliest date and across the board of all such persons having any involvement with Pradaxa, and thereafter producing the relevant materials in a timely manner, in violation of the Court's case management orders, and in bad faith.

The Court finds that the failure to provide the vendor hired to provide the plaintiffs with discoverable material from the G drive with all relevant materials to be in violation of the Court's case management orders and in bad faith.

B. Sanctions Imposed

1. Professor Thorstein Lehr

The Court directs BII to produce all complete "files"[11]of Professor Lehr within 7 days. If that proves impossible because they have been destroyed due to the fact that he was not subject to the litigation hold, defendant shall so certify to the Court. Once the Court, knows for certain what defendant's response to this

[11] The Court will not endeavor to break down this word here or throughout this order any more specifically or technically than this, suffice it say defendant(s) shall interpret this in the broadest sense possible to mean all paper and electronic documents and data of every description. Further, complete is interpreted to mean going back in time from the inception of the keeping of any such relevant documentation or data by the individual.

order is in this regard, a further order will issue, allowing more time with possible conditions, or an order assessing sanctions pursuant to Rule 37 or the Court's inherent authority, if appropriate.

2. Inadequate Litigation Hold as to Sales Representatives, CSCs and MSLs

The defendants, BIPI and BII, are ordered to produce the complete files for those sales representatives, CSCs and MSLs that have been requested by the PSC within 14 days. If the defendants are unable to comply with this order, they shall so advise the Court and advise if more time is needed and the reason or if certain files are not available and the reason. The Court will then issue an order allowing more time with possible conditions, or an order assessing sanctions pursuant Rule 37 or the Court's inherent authority, if appropriate.

3. Failure to Preserve Text Messages

The defendants, BIPI and BII, are ordered to produce any text messages not otherwise covered by the order directed in number 2 immediately above that have been requested by the PSC within 14 days. If the defendants are unable to comply with this order, they shall so advise the Court and advise if more time is needed and the reason or if certain files are not available and the reason. The Court will then issue an order allowing more time with possible conditions, or an order assessing sanctions pursuant Rule 37 or the Court's inherent authority, if appropriate.

4. G Drive

The defendant, BIPI, is ordered to produce any relevant portions of the G drive that have been requested by the PSC within 30 days. If the defendant is unable to comply with this order, it shall so advise the Court and advise if more time is needed and the reason or if certain files are not available and the reason. The Court will then issue an order allowing more time with possible conditions, or an order assessing sanctions pursuant Rule 37 or the Court's inherent authority, if appropriate.

5. Financial Sanctions

The PSC requested a number of financial sanctions as a result of the defendants' transgressions. It asked for reimbursement for its fees and costs in pursuing the issue of the defendants' violations. The defendants agree they should be held accountable for that and the Court so orders and directs the PSC to submit an itemization with an affidavit.

The PSC requested that the Court revisit the issue raised by it through motion that the employee depositions scheduled or to be scheduled in Europe be scheduled in a place convenient to the PSC and defendants' United States counsel. This is a financial issue but also a timing issue because of the many delays caused by the defendants actions and the extraordinary time it takes to fly to Amsterdam and the logistics of setting up the necessary working space there. The Court has resisted multiple requests from the PSC on this issue, primarily on the basis that

the Court had an inadequate basis for requiring it. Based on the Court's findings above, the bad faith of the defendants in withholding discovery until well after it was required to be produced, by many months, the prejudice those delays have caused the litigation herein in postponing depositions and precipitating countless hours of chambers time and courtroom time discussing and advocating issues that did not need to occur, the Court finds an appropriate sanction pursuant to its inherent powers to be to require the defendants to produce all employees for deposition in the United States. Effective immediately or as close as logistically possible thereto, understanding that depositions and teams may already be in place, depositions shall take place in New York City or such other place as the PSC, and the defendants shall unanimously agree upon. If no alternative is unanimously agreed upon, they the Court's selection shall stand.

The PSC also requested a corporate fine as well as individual fines to be paid by each defense counsel. The corporate fine sought by plaintiffs is in the nature of $20 million. In the course of their advocacy, plaintiffs argued, in essence, that the Court's last sanction, was laughable and urged the Court to put some teeth in its sanction this time. The Court did note a sigh of relief on the faces of the corporate general counsel, though no laughs from the defense side of the courtroom. The Court is not moved by such advocacy. Moreover, the Court is not generally inclined to impose sanctions. In this judge's recollection, perhaps three times in seven years on the state bench and perhaps twice in fifteen years as a federal judge, this order being the third. No judge should relish the serious

obligation associated with a sanction, however, when a Court is confronted with a situation such as the instant one, it must act. But when it acts, it must do so in measured terms and in proportion to the wrongs and the prejudice before it. The wrongs here are egregious in the eyes of the Court. As hereinbefore provided, there may be more orders yet to come; orders which take actions designed to determine what aspects of the plaintiffs' case have been prejudiced or even so damaged as to interfere with their ability to prove what they legally have to prove and for the facts of this case to come out. Going forward, based on the findings heretofore, pursuant to the Court's inherent powers, and to encourage defendants to respect this Court and comply with its orders, the Court fines both defendants, jointly and severally, $931,500.00 ($500.00 per case). The last time the Court imposed a sanction it was based on a figure around $25,000.00. The Court assessed a figure at $20.00 per case for the number of cases then pending (the total ended up being $29,500.00). Then as now, the Court's imposition of a fine is a measured action, designed to let the defendants know that the Court's order and the Court deserve respect. If a somewhat forceful reminder of those tenants in the law must be sent to defendants for their misdeeds which demonstrate something to the contrary, so be it. Never should such reminders shock any one's conscience. Here, the first one was quite modest indeed. It did not send a sufficient message, but then most if not all the deeds the Court discussed herein were well underway, just not discovered. The fine imposed today, will not impact the defendants profit margins, but hopefully together with the potential future

actions the Court may be forced to take, once it learns whether the plaintiffs have been so prejudiced by this misconduct as to be unable to fully prosecute their cases, the defendants will understand once and for all time compliance with the Court's orders is not an optional part of litigation strategy. Just as the Court did not exhaust what it has available to it in this instance, as the plaintiffs urged in the first sanction hearing, its measured approach to behavior modification leaves remedies yet to be addressed should defendants continue on the path of wrong-headed litigation strategy as the Court has sanctioned herein.

SO ORDERED:

David R. Herndon
2013.12.09
13:49:34 -06'00'

Chief Judge
United States District Court

Date: December 9, 2013