

## In re Pradaxa Prods. Liab. Litig.

United States District Court for the Southern District of Illinois, East St. Louis Division

September 25, 2013, Decided; September 25, 2013, Filed

MDL No. 2385; 3:12-md-02385-DRH-SCW

### Reporter

2013 U.S. Dist. LEXIS 137235 \*; 2013 WL 5377164

IN RE PRADAXA (DABIGATRAN ETEXILATE)  
PRODUCTS LIABILITY LITIGATION. This Document  
Relates to: ALL CASES

**Subsequent History:** Motion granted by, Remanded by Zaite  
v. Long (In re Pradaxa Prods. Liab. Litig.), 2013 U.S. Dist.  
LEXIS 147302 (S.D. Ill., Oct. 11, 2013)

**Prior History:** In re Pradaxa (Dabigatran Etexilate) Prods.  
Liab. Litig., 2013 U.S. Dist. LEXIS 129506 (S.D. Ill., Sept.  
11, 2013)

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**Judges:** David R. Herndon, Chief United States District  
Judge.

**Opinion by:** David R. Herndon

## Opinion

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### CASE MANAGEMENT ORDER NUMBER 45

**Re: Motion to Compel Wa'el Hashad Custodial  
Documents**

**HERNDON, Chief Judge:**

### I. INTRODUCTION

This matter is before the Court on the PSC's motion to compel the production of Wa'el Hashad's (a former BIPI employee, employed at BIPI from May 2009 until August 2011) custodial documents (Doc. 257). In responding to the PSC's motion, BIPI has indicated that Wa'el Hashad's custodial documents were deleted from the company's system on November 22, 2011 — before the first post-launch Pradaxa product liability case was filed — in accord with the company's document retention policies (Doc. 264 and September 18, 2013 oral argument). The PSC contends that BIPI was under a pre-litigation duty to preserve evidence in November 2011 and therefore wrongfully destroyed Hashad's custodial documents. Accordingly, the PSC has asked the Court to sanction BIPI by imposing a spoliation inference (Doc. 270).

The Court heard oral argument on this matter on September 18, 2013. Thereafter, BIPI engaged in additional communications with Hashad to confirm that he did not have any documents subject to production in this [\*3] litigation. In an email dated September 23, 2013, counsel for BIPI notified the Court and the PSC regarding the result of those communications. Counsel for BIPI indicates that Hashad identified approximately 40 personal emails sent or received from his personal email account. Although a number of the

emails are reportedly personal and were reportedly sent or received after Mr. Hashad left his employment, BIPI informed the Court that it is "proceeding with producing any of [the emails] that reference Pradaxa to the Plaintiffs" (September 23, 2013 email to the Court).

On September 24, 2013, the PSC responded to BIPI's communication regarding the recently located Hashad emails (September 24, 2013 email to the Court). The PSC raised two issues in relation to BIPI's September 23rd email. First, the PSC noted that producing only those documents that "reference" Pradaxa is not the appropriate standard. Instead, BIPI should be producing all non-privileged documents pertaining to any matter that is relevant to any party's claim or defense. Second, the PSC noted the inconsistency between BIPI's email and statements made in Hashad's declaration to the Court (attached to BIPI's responsive pleading [\*4] (Doc. 264-4). In that declaration, Hashad, in relevant part, stated as follows: "I am not aware of any locations where my Pradaxa-related electronic or hard copy documents would currently be located. I did not take any Pradaxa-related electronic or hard copy documents with me when I left my employment with BIPI" (Doc. 264-4). In light of these concerns, the PSC requests that the Court order BIPI to (1) produce all 40 recently located emails and (2) inform the Court and the PSC whether the standard of producing only documents that "reference" Pradaxa has been used in other productions.

On September 25, 2013, counsel for BIPI notified the Court that it is presently sending approximately 200 disaster recovery tapes containing materials from August, 2011 (the month Hashad left the company), to an outside vendor to learn whether Hashad's electronic materials can be recovered (September 25, 2013 letter to the Court).

## II. BACKGROUND

Wa'el Hashad is a former BIPI employee. Hashad's employment with BIPI began in May of 2009 and ended in August of 2011. During this time, Hashad was BIPI's Vice-President of Cardiovascular and Metabolic Disease Marketing. There is no question that Hashad's custodial [\*5] file would have included documents relevant to the instant litigation. According to BIPI, however, Hashad's custodial file no longer exists. BIPI contends that Hashad's custodial documents were destroyed in November 2011, in accord with BIPI's document retention policies and before a duty to preserve documents relevant to this litigation arose.<sup>1</sup>

<sup>1</sup> BIPI contends that its duty to preserve arose — at the earliest — in February 2011 when the defendants received a demand letter in the first post-launch Pradaxa product liability case.

On September 4, 2013, the PSC filed a motion to compel Hashad's custodial file. The motion to compel asks the court, "pursuant to Federal Rule of Civil Procedure 37 and the inherent power of the Court" to enter an order "compelling Defendant [BIPI] to produce the custodial file of Wa'el Hashad, or in the alternative, for such other relief that the Court deems appropriate in the event that BIPI is not able to produce Hashad's custodial file or BIPI has permitted the destruction of the file" (Doc. 257 p. 1).<sup>2</sup>

With regard to sanctions, the PSC's motion to compel stated as follows: "While the PSC is not seeking sanctions at the current time, in the event that Hashad's file was destroyed, the PSC respectfully submits that the facts and circumstances of that destruction should be set out in detail — and under oath, perhaps via sworn testimony — by BIPI so that it can be evaluated whether sanctions are appropriate under the relevant case law" (Doc. 257 p. 3 n.1).<sup>3</sup>

In responding [\*7] to the PSC's motion to compel, BIPI addressed the questions raised by the PSC with respect to the existence and/or destruction of Hashad's custodial file. First, BIPI confirmed that, because Hashad is no longer employed with BIPI, his custodial documents were removed from BIPI's electronic system (Doc. 264 p. 3). Second, BIPI provided information regarding when his custodial documents were removed from the company's system. BIPI stated that Hashad's custodial file was destroyed — in accord with the company's document retention policies — on one of two dates: (1) 30 days after Hashad's employment ceased (i.e. on September 25, 2011) or (2) 24 hours after that litigation hold

<sup>2</sup> Further, the PSC's motion to compel identifies the following as potentially appropriate remedies:

- Ordering BIPI to conduct a new search for the Hashad file [\*6] and report back to the Court in 7 days with a detailed report of its conduct and findings (including details surrounding the destruction of the file if that is the conclusion BIPI reaches);
- Ordering a hearing on what was done with the Hashad file; or
- Ordering discovery on the issue of the existence or destruction of the Hashad file; and
- Ordering discovery surrounding the destruction of the Ask BI blog

(Doc. 257 p. 15)

<sup>3</sup> See also Doc. 257 p. 2 (noting that in CMO 17 the Court ordered BIPI to produce Hashad's file on November 30, 2012, asking the Court to enter an order directing BIPI to comply with CMO 17, and asking that if BIPI cannot comply requiring BIPI to provide an explanation for the purpose of assessing sanctions).

associated with *Academic Health Professionals Insurance Association v. BIPI* was lifted (i.e. in November 2011, at the latest — if Hashad's documents were part of that litigation hold) (in essence, BIPI's responsive briefing indicates that Hashad's custodial file was destroyed by September 25, 2011 or on an unspecified day in November 2011).<sup>4</sup>

BIPI contends that its duty to preserve evidence related to the instant litigation did not arise until BIPI knew or should have known that litigation was imminent. According to BIPI, this occurred — at the earliest — on February 1, 2012 — when BIPI received a demand letter related to the first post-launch Pradaxa product liability case (Doc. 264 p. 2). Thus, BIPI argues, whether Hashad's custodial documents were destroyed in September or November 2011, they were destroyed before the company had a duty to preserve evidence relevant to the instant MDL.

The PSC filed a reply to BIPI's responsive pleading (Doc. 270). In its reply, the PSC contends that BIPI's duty to preserve arose as soon as BIPI had reason to anticipate pending litigation and that imminence is not required (Doc. 270 [\*9] pp. 1-2). The PSC contends a number of events that pre-date the alleged destruction of Hashad's custodial documents put BIPI on notice that litigation was reasonably foreseeable. Accordingly, the PSC argues, the duty to preserve arose before Hashad's custodial documents were destroyed. Therefore, the PSC's reply brief asserts that sanctions are appropriate (Doc. 270 p. 5). Specifically, the PSC contends that imposition of an adverse inference is warranted (Doc. 270 p. 5).

At oral argument, on September 18, 2013, counsel for BIPI offered more specific information regarding the destruction of Hashad's custodial documents. Counsel stated Hashad's custodial documents were in fact part of the litigation hold put in place for the *Academic Health* case and that the litigation hold for that case was lifted on November 21, 2011 (after the case was settled).<sup>5</sup> Therefore, based on the representations made in court and in BIPI's responsive pleading, Hashad's file

would have been destroyed on November 22, 2011 (24 hours after the litigation hold associated with *Academic Health* litigation was lifted). See Doc. 264-5 ¶ 4 ("When a litigation hold is released, the document retention policy is to delete [\*10] all documents maintained exclusively under the hold within 24 hours.").

After considering the parties' written and oral arguments, as well as the progression of the parties' positions, the Court concludes the following matters are presently in issue:

- (1) Whether BIPI's duty to preserve documents relevant to this litigation arose before Wa'el Hashad's custodial file was destroyed on November 22, 2011.
- (2) Whether the admitted destruction of Wa'el Hashad's custodial file and the resulting inability to produce any documents from Wa'el Hashad's custodial file warrants the imposition of an adverse inference.
- (3) Whether to issue an order directing production of Hashad's custodial documents.

For the reasons discussed herein, the Court concludes that BIPI was not under a duty to preserve documents relevant to this litigation in November 2011, when Hashad's file was destroyed. Instead, the preservation obligation arose in February 2012, when BIPI received a demand letter pertaining to the first post-launch [\*11] Pradaxa product liability suit. Because no duty to preserve existed at the time of destruction, a spoliation inference is not appropriate. Further, even if a duty to preserve existed at the time of destruction, the PSC has not established that Hashad's custodial documents were destroyed in bad faith. Absent a showing of bad faith, the PSC is not entitled to a spoliation inference.

With regard to issuing an order directing the production of Hashad's custodial files, the Court orders as follows: BIPI is ORDERED to produce any and all Hashad documents that are still in existence within 7 days of entry of this Order.

BIPI must produce all nonprivileged material "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." Fed. R. Civ. P. 26(b)(1). It is not sufficient to produce only material that "references" Pradaxa. Further, the Court reminds BIPI that "[r]elevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." *Id.*

In [\*12] addition, the Court notes that BIPI is currently

<sup>4</sup> BIPI has attached employee declarations regarding BIPI's document retention policies. According to those declarations, when a person leaves employment at BIPI, "the company's [\*8] document retention policy is to leave all of the employee's email, user share and hard drive documents in place until 30 days after the employee's final day with BIPI. After those 30 days, the documents are deleted." (Doc. 264-5 ¶ 3). Further, "When a litigation hold is released, the document retention policy is to delete all documents maintained exclusively under the hold within 24 hours." (Doc. 264-5 ¶ 4).

<sup>5</sup> Initially counsel stated that the litigation hold was lifted on September 21, 2011. Counsel, however, later corrected that date and stated the litigation hold was lifted on November 21, 2011.

attempting to recover the destroyed custodial documents. BIPI is ORDERED to produce any material, discoverable under Federal Rule of Civil Procedure 26(b)(1), recovered as a result of those efforts. BIPI shall keep the Court and the PSC apprised of the status of those recovery efforts.

For the reasons discussed above, to the extent that BIPI is unable to produce any of Hashad's custodial documents — due to the November 2011 destruction of those documents — a spoliation inference will not be imposed.

Finally, the Court has reviewed *in camera* the custodial and non-custodial notices that were sent out by BIPI after the Court's September 18, 2013 hearing. The notices were complete and outlined the proper scope of production. Nonetheless, the Court ORDERS lead counsel for BIPI and BII to provide the Court with an attestation affirming or denying whether the defendants have been producing only those documents that "reference" Pradaxa. The attestation should also affirm or deny whether document production to date (and in the future) has included (and will include) all discoverable matter as defined by Federal Rule of Civil Procedure 26(b)(1). [\*13] The attestations should be filed with the Court, in the master docket, no later than Tuesday October 1, 2013.

### III. ANALYSIS

#### A. Destruction of Hashad's Custodial Documents and BIPI's Document Retention Policies

Hashad was employed with BIPI from May of 2009 until August of 2011 (Doc. 264-4 ¶ 3). According to declarations provided by BIPI, when a person ceases employment with the company, "the company's document retention policy is to leave all of the employee's email, user share and hard drive documents in place until 30 days after the employee's final day with BIPI. After those 30 days, the documents are deleted" (Doc. 264-5 ¶ 3). Further, when "a litigation hold is released, the document retention policy is to delete all documents maintained exclusively under the hold within 24 hours" (Doc. 264-5 ¶ 4). According to BIPI, in November 2011, Hashad's files had been maintained exclusively under the litigation hold related to the *Academic Health* litigation. Thus, his files were deleted on November 22, 2011, 24 hours after the *Academic Health* litigation hold was lifted.

The PSC contends that the above document retention policies conflict with the document retention policies disclosed during [\*14] the discovery process (Doc. 270 pp. 3-4). The PSC notes that, pursuant to discovery responses, "Microsoft office

email communications for U.S. employees are stored at a Regional Data Center in Virginia. A 90 day retention policy is assigned to the Inbox, Outbox, Deleted, and Sent Items, while a two year retention policy is assigned to the calendar, drafts, journal notes, tasks, and other root level folders" (Doc. 270 pp. 3-4). They further note the defendants stated that "backup and storage processes for documents and/or communications remain on a disaster-recovery file for 56 days after they become inactive" (Doc. 270 p. 4).

The Court finds that the document retention policies with regard to litigation hold documents and the documents of former employees do not necessarily conflict with the above discovery responses. In addition, the information presently available to the Court indicates that Hashad's files were destroyed in accord with BIPI's document retention policies.

Finally, as the PSC notes, by their calculations, the above document retention policies indicate that Hashad's emails would have existed until at least November 24, 2011 (Doc. 270 p. 4). For the reasons discussed below, [\*15] the Court finds that BIPI was not under a duty to preserve until February 2012. Accordingly, destruction of the documents any time in November 2011, in accord with the company's document retention policies, is not culpable conduct.

#### B. Authority to Impose Sanctions for the Pre-Litigation Destruction of Evidence

The duty to preserve evidence relevant to litigation is well recognized. *See e.g., Micron Technology, Inc. v. Rambus Inc.*, 645 F.3d 1311 (Fed. Cir. 2011); *Trask-Morton v. Motel 6 Operating L.P.*, 534 F.3d 672 (7th Cir. 2008); *Kronisch v. United States*, 150 F.3d 112, 130 (2d Cir. 1998). The duty to preserve "may arise from many sources, including common law, statutes, regulations, or a court order in the case." Fed. R. Civ. P. 37(f) Advisory Committee Note.

When a party neglects the duty to preserve evidence, a court has the authority to impose sanctions. *Chambers v. NASCO, Inc.*, 501 U.S. 32, 50-51, 111 S.Ct. 2123, 115 L.Ed.2d 27 (1991). In the federal system, this authority derives from two primary sources. First, a court may impose sanctions based on its inherent authority. *See Chambers*, 501 U.S. at 46; *Methode Electronics, Inc. v. Adam Technologies, Inc.*, 371 F.3d 923, 927 (7th Cir. 2004) [\*16] (district courts have inherent power to impose sanctions for abuse of the judicial system). A Court's inherent authority is based on the Court's power to manage and ensure the expeditious resolution of cases on their dockets. *Barnhill v. U.S.*, 11 F.3d 1360, 1368 (7th Cir. 1993). Second, if the destruction of evidence violates a court's discovery order or ruling, sanctions may be imposed under

Federal Rule of Civil Procedure 37. *See* Fed. R. Civ. P. 37(b)(2); *Brandt v. Vulcan, Inc.*, 30 F.3d 752, 756 (7th Cir. 1994).

Rule 37(b)(2)(A) provides as follows:

*For Not Obeying a Discovery Order.* If a party or a party's officer, director, or managing agent-or a witness designated under Rule 30(b)(6) or 31(a)(4) fails to obey an order to provide or permit discovery, including an order under Rule 26(f), 35, or 37(a), the court where the action is pending may issue further just orders. They may include the following:

- (i) directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action, as the prevailing party claims;
- (ii) prohibiting the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated [\*17] matters in evidence;
- (iii) striking pleadings in whole or in part;
- (iv) staying further proceedings until the order is obeyed;
- (v) dismissing the action or proceeding in whole or in part;
- (vi) rendering a default judgment against the disobedient party; or
- (vii) treating as contempt of court the failure to obey any order except an order to submit to a physical or mental examination.

Fed. R. Civ. P. 37(b)(2)(A).

Rule 37(e), which applies to electronically stored information lost through "routine good-faith operation" of an electronic information system rather than through intentional acts intended to make evidence unavailable in litigation, is also relevant. Rule 37(e) states: "Absent exceptional circumstances, a court may not impose sanctions under these rules on a party for failing to provide electronically stored information lost as a result of the routine, good-faith operation of an electronic information system." Fed. R. Civ. P. 37(e). This section only applies if the loss of information was in good-faith. Committee Comments to Rule 37.

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 [\*18] 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 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.

Fed. R. Civ. P. 37(f) Advisory Committee Note.

While a court may sanction a party pursuant to Rule 37 for discovery violations, such sanctions are limited to circumstances in which a party violates [\*19] a court order or discovery ruling. *Brandt v. Vulcan, Inc.*, 30 F.3d 752, 756 n. 7 (7th Cir. 1994). This limitation has led some courts to question whether Rule 37 provides authority to impose sanctions for spoliating evidence prior to a court order concerning discovery or a production request being served. *See e.g., Rimkus Consulting Group, Inc. v. Cammarata*, 688 F. Supp. 2d 598, 611 (S.D. Tex. 2010) (Rosenthal, J.) ("Allegations of spoliation, including the destruction of evidence in pending or reasonably foreseeable litigation, are addressed in federal courts through the inherent power to regulate the litigation process if the conduct occurs before a case is filed or if, for another reason, there is no statute or rule that adequately addresses the conduct."); *United Medical Supply Co., Inc. v. U.S.* 77 Fed. Cl. 257, 268 (Fed. Cl. 2007) (Allegra, J.) (questioning a court's authority to impose sanctions under Rule 37 for pre-litigation spoliation of evidence and concluding that the "majority view-and the one most easily reconciled with the terms of the rule-is that Rule 37 is narrower in scope and does not apply before the discovery regime is triggered).

Other courts, however, have found [\*20] that, if the pre-litigation/pre-order destruction of evidence results in failure to comply with a court's discovery orders, Rule 37 may be used to sanction the conduct. *See e.g., Turner v. Hudson Transit Lines, Inc.*, 142 F.R.D. 68, 72 (S.D.N.Y. 1991) (Francis, M.J.); *Dillon v. Nissan Motor Co., Ltd.*, 986 F.2d 263, 268-69 (8th Cir. 1993); *In re Air Crash Disaster near Chicago*, 90 F.R.D. 613, 620-621 (N.D. Ill. 1981) (Robson and Will, S.J.); *Alliance to End Repression v. Rochford*, 75 F.R.D. 438, 440 (N.D. Ill. 1976) (Kirkland, J). These courts proceed from the view that, failure to comply with a discovery order — resulting from culpable destruction of evidence prior to issuance of a discovery order — is sanctionable under Rule 37

because the noncompliance was self-inflicted.

The Seventh Circuit has not expressly addressed whether Rule 37 is an appropriate vehicle for sanctioning culpable pre-litigation destruction of evidence. In *Trask-Morton v. Motel 6 Operating L.P.*, 534 F.3d 672 (7th Cir. 2008), the Seventh Circuit considered allegations of wrongful pre-litigation spoliation of evidence as well as post-litigation bad faith discovery. At issue, among other things, was the district court's [\*21] denial of the plaintiff's motion for sanctions regarding the allegedly wrongful pre-litigation destruction of evidence and post-litigation bad faith discovery conduct. In assessing the allegedly wrongful pre-litigation destruction of evidence, the Seventh Circuit does not expressly address the source of authority for sanctioning such conduct.<sup>6</sup> The Appellate Court does, however, note that the plaintiff failed to establish "bad faith," a "prerequisite to imposing sanctions for the destruction of evidence." *Id.* at 681.

The imposition of a "bad faith" requirement leads the Court to consider several possibilities: The first possibility is that the appellate court is assessing the plaintiff's spoliation claim in relation to the [\*23] court's inherent authority and not under Rule 37. The Seventh Circuit has repeatedly held that the imposition of sanctions under Rule 37 does not necessarily require culpability. *See e.g. Halas v. Consumer Servs., Inc.*, 16 F.3d 161, 164-65 (7th Cir. 1994) (With regard to imposing sanctions under Rule 37, "[t]he simple failure to comply is

enough, notwithstanding a complete lack of culpability...."); *Id.* ("The weight of authority, however, holds that the culpability of a party who fails to comply with a court order determines only which sanctions the court should impose and not whether any sanctions are appropriate at all.") (internal citation omitted). Imposition of sanctions under a court's inherent authority, on the other hand, requires some level of culpability. *See e.g., Salmeron v. Enter. Recovery Sys.*, 579 F.3d 787, 793 (7th Cir. 2009) ("Sanctions meted out pursuant to the court's inherent power are appropriate where the offender has willfully abused the judicial process or otherwise conducted litigation in bad faith."); *Johnson v. Cherry*, 422 F.3d 540, 548-549 (7th Cir. 2005) ("a court has the inherent authority to impose sanctions for actions taken "in bad faith, vexatiously, [\*24] wantonly, or for oppressive reasons"). The second possibility is that "bad faith" is identified as a prerequisite because of the *type* of sanction in issue (an adverse inference). *See e.g., Faas v. Sears, Roebuck & Co.*, 532 F.3d 633, 644-45 (7th Cir. 2008) (adverse inference in relation to document destruction requires showing of bad faith); *Mathis v. John Morden Buick, Inc.*, 136 F.3d 1153, 1155 (7th Cir. 1998); (sanctioning a party for the destruction of evidence, outside of Rule 37, by imposing adverse inference requires a showing of "bad faith). The third possibility is that the requirement of bad faith relates to both the source of the court's authority (inherent) and the type of sanction being considered (adverse inference).

The distinction between a court's inherent authority to sanction and a court's authority to impose sanctions under Rule 37, although important, need not be resolved for purposes of this motion. The Court concludes that it has the authority to impose sanctions for the pre-litigation destruction of evidence (if not under Rule 37 then under the court's inherent authority or a combination of the two).

Further, in the instant case, there are two determinative issues: [\*25] (1) whether the destruction of Hashad's custodial file occurred before or after the duty to preserve was triggered and (2) whether the destruction of Hashad's custodial file warrants the imposition of an adverse inference. With regard to the former, common sense dictates that the standard for determining when a duty to preserve is triggered is the same, regardless of whether the Court is considering sanctions under its statutory authority or under its inherent power. With regard to the latter, Seventh Circuit authority unequivocally indicates that the imposition of an adverse inference for the destruction of evidence requires a finding of bad faith.<sup>7</sup> *See e.g., Bracey*

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<sup>6</sup>The Seventh Circuit merely refers to the decision not to impose sanctions. It does not specify what type of sanctions were in issue. The plaintiff's motion seeks the following sanctions: (1) judgment in favor of the plaintiff on the issue of liability; (2) adverse inference at trial related to the destroyed evidence; (3) an order denying the defendant's motion for summary judgment; (4) an award of certain attorney fees. *Trask-Morton v. Motel 6 Operating, L.P.*, No. 1:05-cv-01633-LJM-WTL, Motion for Sanctions for Spoliation of Evidence and Bad Faith Discovery (Doc. 50 p. 16). The district court's order denying the plaintiff's motion for sanctions addresses the "bad faith [\*22] destruction of evidence" and the standard for imposing an adverse inference at trial. *Trask-Morton v. Motel 6 Operating, L.P.*, No. 1:05-cv-01633-LJM-WTL, Doc. 102 pp. 7-8 (McKinney, C.J.). The relevant trial court pleadings do not make any reference to Rule 37. The plaintiff's motion for sanctions contends that the authority to sanction the alleged pre-litigation destruction of evidence and post litigation "bad faith" discovery derives from Rule 26, Rule 34, and a court's "inherent authority" to sanction bad faith conduct. *See Trask-Morton v. Motel 6 Operating, L.P.*, No. 1:05-cv-01633-LJM-WTL, Motion for Sanctions for Spoliation of Evidence and Bad Faith Discovery (Doc. 50). The district court's order denying the plaintiff's motion for sanctions implies that it considered the motion, at least as it related to the pre-litigation conduct, under the court's inherent authority. *See Trask-Morton v. Motel 6 Operating, L.P.*, No. 1:05-cv-01633-LJM-WTL, Doc. 102 pp. 7-8 (McKinney, C.J.).

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<sup>7</sup>The Court also notes that a number of district courts have concluded that the analysis for imposing sanctions under Rule 37 or under the Court's inherent authority is essentially the same. *See e.g.*

*v. Grondin*, 712 F.3d 1012, 1019-1020 (explaining that in the Seventh Circuit a finding of bad faith is required for an adverse inference instruction); *Id.* at 1020 ("Simply establishing a duty to preserve evidence or even the negligent destruction of evidence does not automatically entitle a litigant to an adverse inference instruction in this circuit. [The plaintiff] has not made the requisite showing of bad faith and we cannot conclude that the district court abused its discretion in declining to issue an adverse inference [\*26] instruction"); *Mathis v. John Morden Buick, Inc.*, 136 F.3d 1153, 1155 (7th Cir. 1998) (imposition of adverse inference for the destruction of evidence requires showing of bad faith) (in this case the Court specifically noted that it was not considering sanctions under Rule 37); *Trask-Morton v. Motel 6 Operating L.P.*, 534 F.3d 672, 681-82 (7th Cir. 2008) (affirming denial of spoliation sanction where no evidence of bad faith); *Park v. City of Chicago*, 297 F.3d 606, 615-616 (7th Cir. 2002) (affirming denial of spoliation sanction when records destroyed under routine record expungement policy); *Rummery v. Illinois Bell Telephone Co.* 250 F.3d 553, 558 (7th Cir. 2001) (While [the defendant] admits that the documents were destroyed intentionally, to draw an inference that the records favored [the plaintiff] requires us to conclude that the documents were destroyed in bad faith, *i.e.*, that the document destruction was for the purpose of hiding adverse information.") (internal citation omitted).

### **C. Considering the information presently available, BIPI did not owe a duty to preserve when Hashad's file was destroyed**

#### **1. When is the Preservation Obligation Triggered?**

The parties have proffered two standards for assessing when the duty to preserve — prior to the initiation of litigation — is triggered. BIPI contends that the duty to preserve arises when a litigant knew or should have known that litigation was *imminent* (Doc. 264). The PSC disagrees; arguing that imminence is not required (Doc. 270). Instead, the PSC asserts, the preservation obligation is triggered when a litigant knew or should have known that litigation was reasonably foreseeable (Doc. 270).

In its responsive briefing, BIPI relies primarily [\*28] on the Seventh Circuit's decision in *Trask-Morton v. Motel 6 Operating L.P.*, 534 F.3d 672 (7th Cir. 2000). Citing to *Trask-Morton*, BIPI asserts that the "Seventh Circuit clearly recognizes, the duty to preserve documents arises when the defendant 'knew, or should have known, that litigation was imminent'" (Doc. 264 p. 1). BIPI is correct. In *Trask-Morton*, the Seventh Circuit clearly acknowledges that a preservation obligation exists when litigation is imminent. The *Trask-Morton* decision, however, does not clearly establish that the duty to preserve is triggered *only* when litigation is imminent. Rather, as the PSC correctly notes, the Seventh Circuit merely acknowledged that other "courts have found a spoliation sanction to be proper only where a party has a duty to preserve evidence because it knew, or should have known, that litigation was imminent." *Trask-Morton*, 534 F.3d at 681. The Seventh Circuit then concluded that the alleged spoliator had no duty to preserve the destroyed evidence because it "had no reason to suspect litigation until — at the earliest — [the plaintiff's] attorney sent [the alleged spoliator] a demand letter." *Id.* at 681. The appellate court went on to state [\*29] that, under the circumstances of the case, the alleged spoliator "had no reason to anticipate litigation, and thus no duty to preserve anything." *Id.* Thus, while the Seventh Circuit acknowledged other courts have applied an imminent standard, it did not expressly accept or reject that standard.

As support for the contention that *Trask-Morton* did not adopt a requirement of imminence, the PSC points to *Micron Tech, Inc. v. Rambus Inc.*, 645 F.3d 1311 (Fed. Cir. 2011). In *Micron Tech, Inc.*, the Court of appeals for the Federal Circuit concluded that reading *Trask-Morton* as imposing a duty to preserve evidence *only* when litigation is *imminent* is "overly generous." *Id.* at 1320. *See also Id.* (in *Trask-Morton* the appellate court did not need to reach the issue because the alleged spoliator did not even have a reason to "suspect" litigation). The Court of Appeals for the Federal Circuit also addressed the Tenth Circuit Court of Appeals' decision in *Burlington N. & Santa Fe Ry. Co. v. Grant*, 505 F.3d 1013, 1032 (10th Cir. 2007) (cited by the Seventh Circuit in *Trask-Morton*). The appellate court explained that *Burlington* "merely noted that imminent litigation was sufficient, not that it was necessary [\*30] for spoliation." *Micron Tech, Inc.*, 645 F.3d at 1320.

As further support for its position, the PSC relies on the Advisory Committee Notes to the 2006 Amendments to FRCP 37(f), which state as follows: "When a party is under a duty to preserve information because of 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.'" According to the PSC, this indicates that a preservation obligation is triggered when

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[\*27] *Danis v. USN Communs., Inc.*, No. 98 C 7482, 2000 U.S. Dist LEXIS 16900, 2000 WL 1694325 (N.D. Ill. Oct. 20, 2000) (Schenkier, M.J.) (citing *Cobell v. Babbitt*, 37 F.Supp.2d 6, 18 (D.D.C.1999) (Lamberth, J.) ("Whether proceeding under Rule 37 of the Federal Rules of Civil Procedure or under a court's inherent powers, the analysis is essentially the same."); *Zang. V. Alliance Financial Services of Illinois, Ltd.*, 875 F.Supp.2d 865, 885 n.19 (N.D. Ill. 2012) (Mason, M.J.) (same).



litigation is "reasonably anticipated" and that imminence is not required.

The PSC also argues that the imminent standard would undermine the purpose of the duty to preserve evidence. The PSC notes that such a standard would "encourage destruction of relevant evidence whenever a party reasonably foresees, but is not certain, that it is likely to be sued, or even where a party knows litigation is certain to be filed — but not in the immediate future" (Doc. 270 pp. 2-3).

If *Trask-Morton* was the Seventh Circuit's only decision addressing when the preservation obligation is triggered, the Court might conclude that imminent litigation is sufficient but not necessary. As BIPI noted [\*31] in oral argument, however, the Seventh Circuit also addressed the issue in *Norman-Nunnery v. Madison Area Technical College*, 625 F.3d 422 (7th Cir. 2010). In *Norman-Nunnery*, the Seventh Circuit considered whether the plaintiff was entitled to a negative inference under the spoliation doctrine in relation to documents that were lost before any claim against the defendants had been filed. *Id.* at 428-429. In evaluating the issue and citing to *Trask-Morton*, the Seventh Circuit states as follows: "Some courts have found a spoliation sanction to be appropriate *only* where a party has a duty to preserve evidence because it knew, or should have known, that litigation was *imminent*." (emphasis added). *Id.* at 428.

At first glance, it appears that the Seventh Circuit may merely be acknowledging, once again, that the requirement of imminence has been adopted by "some" courts. The Court goes on to conclude, however, that the plaintiff was not entitled to a spoliation inference because "the documents were lost before [the alleged spoliator] knew or should have known that litigation was imminent." *Id.* at 429. There is no reference to the more flexible "reasonable anticipation" standard proposed by the [\*32] PSC.<sup>8</sup>

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<sup>8</sup>The Seventh Circuit does note that the destruction of evidence, in violation of a record retention policy, creates a rebuttable presumption that the missing record contained evidence adverse to the violator. That is not in issue in this case. The information presently before the Court indicates that the alleged destruction of Hashad's custodial files was in accord with BIPI's document retention policies regarding former employees and documents that are retained as part of a litigation hold. There is also a Seventh Circuit case which provides that "if, being sensitive to the possibility of a suit, a company then destroys the very files that would be expected to contain the evidence most relevant to such a suit, the inference arises that it has purged incriminating evidence." *Partington v. Broyhill Furniture Industries, Inc.* 999 F.2d 269, 272 (7th Cir. 1993). In the instant case, there is no indication that BIPI purged the files most relevant to the instant litigation. In fact, BIPI

In the Court's view, the Seventh Circuit's decision in *Norman-Nunnery*, tips the balance in favor of applying the standard proposed [\*33] by BIPI — that the duty to preserve is triggered only when a litigant knew or should have known that litigation was imminent (at least in the Seventh Circuit). In the instant case, however, whether the Court applies the "reasonable anticipation" standard or the "imminent litigation" standard, does not alter the Court's decision on whether to impose a spoliation inference. The reason for this is twofold: First, the Court finds that BIPI had no reason to anticipate litigation — imminent or otherwise in November 2011 (when Hashad's file was destroyed). Second, even assuming BIPI owed a duty to preserve in November 2011, there is no evidence of bad faith. Accordingly, a spoliation inference is not warranted.

## 2. No General Duty to Preserve in November 2011

The following is a chart summarizing events that are potentially relevant to the Court's analysis:

 [Go to table 1](#)

In [\*34] its briefing, BIPI indicated that Hashad's custodial documents were destroyed on September 25, 2011 (30 days after his employment ceased) or, assuming his custodial documents were part of the litigation hold put in place for the *Academic Health* litigation, on an unspecified date in November 2011 (24 hours after the litigation hold related to *Academic Health* was lifted). At oral argument, BIPI was able to provide more specific information regarding the destruction of Hashad's custodial documents. Counsel for BIPI informed the Court that Hashad's custodial documents were in fact part of the *Academic Health* litigation hold and would have been destroyed on November 22, 2011 (24 hours after the litigation hold was lifted).<sup>9</sup> Thus, the Court considers whether BIPI owed a duty to preserve evidence on November 22, 2011.

The PSC contends that certain events, taken together, triggered a duty to preserve before Hashad's custodial documents were destroyed. The events noted by the PSC can be grouped into four basic categories: (1) Clinical trial

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has produced millions of documents related to the instant litigation.

<sup>9</sup>Counsel for BIPI stated as follows: (1) Hashad left employment with BIPI in August 2011; (2) Hashad's custodial documents were retained as part of the *Academic Health* the litigation hold; (3) the *Academic Health* litigation settled on September 21, 2011; (4) the *Academic Health* litigation hold was lifted 30 days after the case settled (November 21, 2011); and (5) documents retained [\*35] in the *Academic Health* litigation hold were destroyed 24 hours after the litigation hold was lifted (November 22, 2011).



litigation; (2) privilege log entries; (3) adverse event reports, safety alerts, and other safety announcements; and (4) what BIPI refers to as "internet chatter".

Before November 2011, BIPI was a defendant in two cases associated with Pradaxa's clinical trials: (1) the *Hone* litigation (filed October 2008 and settled January 2009) and (2) the *Academic Health* litigation (filed January 2010 and settled September 2011). The *Hone* litigation related to a single patient that was part of the RE-LY clinical trial, before Pradaxa was approved by the FDA. In this case, Linda Hone, as personal representative of her deceased husband, commenced an action against BIPI. The complaint alleged that as a result of decedent's ingestion of Dabigatran Etexilate during a Phase III Clinical Trial — the RE-LY clinical trial — he suffered an adverse bleeding event and [\*36] was admitted to the hospital. The hospital was unable to stop the bleeding and the decedent died. The complaint alleged BIPI failed to warn of a potentially fatal risk of bleeding as a result of Dabigatran Etexilate and that there was no known antidote to reverse the effects of the drug. BIPI instituted a document hold in connection with the *Hone* litigation, but the hold was lifted in February of 2009 once the suit was settled (and before Hashad was employed with BIPI).

The PSC contends that the allegations in the *Hone* litigation are identical to the allegations at issue in this MDL and as such triggered a duty to preserve evidence relevant to potential Pradaxa product liability litigation. BIPI notes that the *Hone* litigation involved an injury that occurred in relation to taking Pradaxa during a clinical trial, before Pradaxa was approved by the FDA. Further, when Pradaxa was approved by the FDA it was approved with labeling information that warned about the risk of potentially fatal bleeding events and that included information about the lack of a known reversal agent.<sup>10</sup> BIPI argues that an isolated pre-launch litigation case, involving a patient who is injured while taking a pharmaceutical [\*37] company's product in a clinical trial, does not trigger a general duty to preserve relevant product liability evidence when the FDA later approves that product with a warning that references the very type of injury at issue in the pre-launch litigation. The Court, without commenting on the adequacy of Pradaxa's warning and/or labeling information, agrees with this contention. The *Hone* litigation did not give BIPI reason to anticipate that post-launch Pradaxa product liability was imminent or reasonably foreseeable. In fact, as BIPI points out, the first post-launch

Pradaxa product liability case was not filed until March 2012 — more than three years after the *Hone* litigation settled.

The *Academic Health* litigation also arose in the clinical context. The *Academic Health* litigation, however, was not a products-liability case. Rather, it named BIPI as a defendant in a case seeking indemnification for a malpractice suit arising out of the RECOVER clinical trial. In [\*38] the underlying case,<sup>11</sup> administrators of the RECOVER clinical trial were accused of malpractice and failure to obtain informed consent in relation to a patient who, allegedly, died after taking Pradaxa as part of the RECOVER clinical trial. Upon reviewing the underlying complaint, the Court is unable to locate (and the PSC does not point to) any allegations that Pradaxa itself was defective or that BIPI failed to warn of Pradaxa's risks. The Court fails to see how this indemnification suit put BIPI on notice that post-launch Pradaxa product liability litigation was "reasonably foreseeable" or imminent.<sup>12</sup>

The PSC also points to various privilege log entries that reference communications pertaining to Pradaxa product liability litigation and/or document preservation in relation to Pradaxa product liability litigation. BIPI contends that the referenced entries all concern documents connected with either the *Hone* or the *Academic Health* litigation. The Court [\*39] has reviewed the subject documents *in camera* and confirmed that all of the subject documents related to the *Hone* or *Academic Health* litigation. None of the documents indicate that BIPI's duty to preserve documents, relevant to potential post-launch Pradaxa product liability litigation, was triggered before Hashad's custodial documents were destroyed. Counsel for defendants revealed at oral argument that a couple of the privilege log entries mistakenly referred to entries as conversations regarding Pradaxa when they were actually about Mirapex and the Court was able to confirm that assertion.

The PSC contends that FDA adverse event reports and other safety announcements gave BIPI notice sufficient to trigger a general pre-litigation duty to preserve. For instance, the PSC cites to a report published by the Institute for Safe Medication Practices, published in October 2011. The report indicates that in the fourth quarter of 2010, "dabigatran (Pradaxa) was the suspect drug in 307 reported serious adverse events, outstripping 98.7% of the drugs we regularly monitor, as well as the drug it was intended to replace, warfarin (Coumadin),

<sup>10</sup> The Court wants to be clear — the Court is NOT making an assessment regarding the *adequacy* of the Pradaxa warning or other labeling information. It is merely acknowledging the label contained the information referenced above.

<sup>11</sup> *Torres v. Westchester County Health Care Corp.*, No. 09-06385 (N.Y. Sup. Ct., Westchester County).

<sup>12</sup> In addition, BIPI notes that it was later determined the decedent was not taking Pradaxa during the clinical trial (Doc. 264-7 ¶ 8).

with 202 reported cases" (Doc. 257-12 p. 11). The report [\*40] also states that during the fourth quarter of 2010 there were "paradoxically large numbers" of adverse event reports related to Pradaxa.<sup>13</sup> Other safety announcements referenced by the PSC include the following: (1) in August 2011, Japanese regulators issued a warning about potentially fatal bleeding episodes in some Pradaxa patients (Doc. 257-13); (2) in September 2011 an investigation was initiated in New Zealand when elderly patients died after experiencing internal bleeding; (3) numerous adverse event reports in the first quarter of 2011;<sup>14</sup> and (4) announcements attributed to BIPI regarding fatal bleeding episodes linked to Pradaxa.

As with the *Hone* litigation, the Court notes that the Pradaxa label referenced and warned against the risk of serious and sometimes fatal bleeding events as well as the lack of a known reversal agent.<sup>15</sup> Thus, the Court does not feel that the receipt of adverse event reports and other safety announcements regarding bleeding events was sufficient to trigger a general duty to preserve evidence relevant to future Pradaxa product liability litigation.

Finally, the PSC asks the Court to consider various postings that amount to "internet chatter." For instance, the PSC notes that On November 16, 2011, a plaintiffs' pharmaceutical injury firm (Parker Waichman Alonso LLP) published a blog about Pradaxa bleeding deaths on a website the firm operates. The Court does not agree that postings on a plaintiffs' blog or other media reports — at least not those referenced in the PSC's briefing — are sufficient to place a pharmaceutical company [\*42] in a litigation hold. As BIPI points out, if this were the standard, pharmaceutical companies would be in a perpetual litigation hold.

In conclusion, the events and publications identified by the PSC were not sufficient to trigger a general preservation obligation with regard to post-launch Pradaxa product liability

litigation in November 2011 — when Hashad's custodial documents were reportedly destroyed. Instead, the Court agrees, that under the circumstances present here, the duty to preserve did not arise until February 2012 — when the defendants' received a demand letter related to the first post-launch Pradaxa product liability case.<sup>16</sup>

#### D. The PSC has not Established Bad Faith

Finally, as already noted above, the spoliation inference requested by the PSC requires a showing of bad faith. Intentional conduct does not [\*43] establish bad faith. *Trask-Morton v. Motel 6 Operating L.P.*, 534 F.3d 672, 681 (7th Cir. 2008). Rather, bad faith "means destruction for the purpose of hiding adverse information." *Id.* In the instant case, there is no evidence of bad faith. The documents appear to have been deleted in accord with BIPI's document retention policies. Accordingly, even assuming BIPI was under a duty to preserve when Hashad's custodial documents were destroyed, a spoliation inference would not be appropriate.

#### IV. CONCLUSION

For the [\*44] reasons discussed herein, the Court concludes that BIPI was not under a duty to preserve documents relevant to this litigation in November 2011, when Hashad's file was destroyed. Instead, the preservation obligation arose in February 2012, when BIPI received a demand letter pertaining to the first post-launch Pradaxa product liability suit. Because no duty to preserve existed at the time of destruction, a spoliation inference is not appropriate. Further, even if a duty to preserve existed at the time of destruction, the PSC has not established that Hashad's custodial documents were destroyed in bad faith. Absent a showing of bad faith, the PSC is not entitled to a spoliation inference.

With regard to issuing an order directing the production of Hashad's custodial files, the Court orders as follows: BIPI is ORDERED to produce any and all Hashad documents that are still in existence within 7 days of entry of this Order.

BIPI must produce all nonprivileged material "relevant to any party's claim or defense—including the existence, description, nature, custody, condition, and location of any documents or

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<sup>13</sup> With regard to these adverse event reports, the report noted that "[t]he predominant reported adverse effects revolved around the drug's central pharmaceutical purpose, inhibiting the body's blood clotting function. However, the events reported were divided among cases indicating too much inhibition of clotting — hemorrhages — and not enough effect, including thromboembolic events such as pulmonary embolism and deep vein thrombosis" (Doc. 257-12 p. 2).

<sup>14</sup> The PSC discusses numerous adverse events reported in the first quarter of 2011 (Doc. 257 p. 9) [\*41] and cites to the Institute for Safe Medication Practices (Doc. 257-12). This exhibit, however, does not appear to reference the 2011 adverse events described by the PSC.

<sup>15</sup> Again, the Court is not commenting on whether this information provided an adequate warning.

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<sup>16</sup> The Court is not saying that events such as those noted by the PSC (i.e. adverse event reports, clinical trial litigation, other safety alerts, internet postings, and media stories) would never be enough to trigger a duty to preserve. It is simply concluding that, under the specific circumstances presented to the Court, a duty to preserve did not exist in November 2011.

other tangible things and the identity and location of persons who know of any discoverable [\*45] matter." Fed. R. Civ. P. 26(b)(1). It is not sufficient to produce only material that "references" Pradaxa. Further, the Court reminds BIPI that "[r]elevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." *Id.*

In addition, the Court notes that BIPI is currently attempting to recover the destroyed custodial documents. BIPI is ORDERED to produce any material, discoverable under Federal Rule of Civil Procedure 26(b)(1), recovered as a result of those efforts. BIPI shall keep the Court and the PSC apprised of the status of those recovery efforts.

For the reasons discussed above, to the extent that BIPI is unable to produce any of Hashad's custodial documents — due to the November 2011 destruction of those documents — a spoliation inference will not be imposed.

Finally, the Court has reviewed *in camera* the custodial and non-custodial notices that were sent out by BIPI after the Court's September 18, 2013 hearing. The notices were complete and outlined the proper scope of production. Nonetheless, the Court ORDERS lead counsel for BIPI and BII to provide the Court with an attestation affirming that [\*46] defendants have not been producing only those documents that "reference" Pradaxa. The attestation should also affirm that document production - to date and in the future - has included and will include all discoverable matter as defined by Federal Rule of Civil Procedure 26(b)(1). The attestations should be *filed* with the Court, in the master docket, no later than Tuesday October 1, 2013.

**SO ORDERED:**

/s/ David R. Herndon

**Chief Judge**

**United States District Court**

**Date:                    September                    25,                    2013**

Table1 ([Return to related document text](#))

Date	Event Description	Source
Oct./Dec. 2006	<ul style="list-style-type: none"> <li>• Privilege log entry indicates legal advice was provided by Beth Rose in anticipation of Pradaxa product liability litigation</li> <li>• At oral argument defendants indicated that this was a mistake and the privilege log should have referenced Mirapex</li> <li>• <i>In Camera</i> review of the subject privileged documents (PL00091) confirms that the documents did not relate to Pradaxa product liability litigation</li> </ul>	Doc. 257-7
2008	<i>Hone v. BIPI</i> , No. 3-08-cv-1002 (M.D. Fla.) - Lawsuit on behalf of decedent who died while on Pradaxa and participating in the RE-LY Clinical Trial filed and litigation hold put in place	Doc. 264-6
Apr./May/Nov. 2008	<ul style="list-style-type: none"> <li>• Privilege log entries reference email traffic involving anticipated Pradaxa Litigation</li> <li>• <i>In Camera</i> review of the subject privileged documents (PL00053, PL03928, PL00060) confirms that the emails related to the <i>Hone</i> litigation</li> </ul>	Doc. 257-7
Feb. 2009	<i>Hone v. BIPI</i> , No. 3-08-cv-1002 (M.D. Fla.) LITIGATION HOLD LIFTED	Doc. 264-7
May 2009	Wa'el Hashad begins employment at BIPI	Doc. 264 p.3 n.1
1/8/2010	<ul style="list-style-type: none"> <li>• <i>Academic Health Professionals Insurance Association v. BIPI</i>, No. 2657-10 (N.Y. Sup. Ct., Westchester Cnty.) FILED</li> <li>• Seeking indemnification for malpractice suit arising out of the RECOVER clinical trial</li> <li>• In the underlying case, administrators of the RECOVER trial were accused of malpractice and failure to obtain informed consent in relation to a deceased patient</li> <li>• Later determined that the patient did not take Pradaxa</li> </ul>	Doc. 257-10; Doc. 264-8; Doc. 264-7 ¶ 8
Oct. 2010	Pradaxa approved by the FDA	Doc. 264 p. 2
Dec. 2010	<ul style="list-style-type: none"> <li>• Privilege log entries re: Pradaxa product liability litigation</li> <li>• <i>In Camera</i> review of the subject privileged documents confirms that they related to the <i>Academic Health</i> litigation (PL00270; PL03041)</li> </ul>	Doc. 257-7
Fourth Quarter 2010	FDA receives adverse event reports involving Pradaxa	Doc. 257-12
First Quarter 2011	FDA receives adverse event reports involving Pradaxa	Doc. 257 p. 9
Jan./Apr. 2011	<ul style="list-style-type: none"> <li>• Privilege log entry re: Pradaxa legal advice</li> <li>• <i>In Camera</i> review of the subject privileged documents confirms that they do not relate to Pradaxa product liability litigation (PL00093)</li> </ul>	Doc. 257-7
Jan./Feb. 2011	<ul style="list-style-type: none"> <li>• Privilege log entry re: legal advice / document preservation in dabigatran litigation</li> <li>• <i>In Camera</i> review of the subject privileged documents confirms that the communication related to the <i>Academic Health</i> litigation (PL00564) (appears to relate to PL03041, which provides legal advice/document preservation regarding <i>Academic Health</i> litigation)</li> </ul>	Doc. 257-7
8/12/2011	Japanese regulators issue warning about potentially fatal bleeding in some Pradaxa patients	Doc. 257-13
8/26/2011	Wa'el Hashad's employment ceases	Doc. 264 p. 3
Sept. 2011	New Zealand Investigation into Pradaxa Deaths	Doc. 257-15
Oct. 2011	Various Internet discussions regarding Adverse Event Reports related to Pradaxa and plaintiffs pharmaceutical blogs relating	Doc. 257-22;

Date	Event Description	Source
	to serious bleeds associated with Pradaxa	Doc. 257-12
11/2/2011	Boehringer reports 50 bleeding related deaths	Doc. 257-16
11/16/2011	Blog states that Boeringer now reports that there have actually been 260 bleeding related deaths	Doc. 257-17
11/21/2011	<i>Academic Health</i> Litigation Hold LIFTED	Doc. 264-7 ¶ 5; counsel's representations during oral argument
11/22/2011	Date on which Wa'el Hashad's custodial documents were destroyed	Doc. 264-7 ¶ 5; counsel's representations during oral argument; Doc. 264-5 ¶ 4
Feb. 1, 2012	Demand Letter re: first Pradaxa post-launch product liability case	Doc. 264-2
Feb. 15, 2012	Litigation Hold Issued in relation to Feb. 1, 2012 Demand Letter	Doc. 264-3
March. 2012	First post-launch product liability case filed	Doc. 264 p. 1

**Table1** ([Return to related document text](#))