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WESTERN DISTRICT OF LOUISIANA
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:
All Cases

MAGISTRATE JUDGE HANNA

AMENDED¹ FINAL MEMORANDUM OPINION AND RULING
(TAKEDA ONLY)²

I. INTRODUCTION

As noted, this Court issued its initial written Ruling on the Motion for Sanctions on January 27, 2014 (Rec. Doc. 3925); an Amended Ruling was filed three days later, on January 30, 2014 (Rec. Doc. 3933), to correct typographical and other minor errors in the initial Ruling – no substantive changes were included. Jury selection in the first bellwether trial in this matter – *Allen v. Takeda Pharmaceuticals International, Inc., et al., Civil Action No. 6:12-cv-00064-*

¹¹ Upon review of the “filed” ruling, the Court noted the ruling which was ultimately filed, inexplicable, and once again, does not reflect the “final draft.” Consequently, this court issues this Amended Ruling, which makes no substantive changes whatsoever other than to correct those minor differences. These changes have no substantive impact on the ruling, but rather, address certain word omissions and one clarification, primarily found on page 18, wherein fn 30 was added to reflect the actual timing of Takeda’s motion.

² For purposes of the instant Ruling, the term “Takeda” refers to all of the Takeda defendants collectively, namely: Takeda Pharmaceuticals U.S.A., Inc., Takeda Development Center Americas, Inc. (f/k/a Takeda Global Research & Development Center, Inc.), Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals America, Inc., Takeda California, Inc., Takeda Pharmaceuticals International, Inc., and Takeda Pharmaceuticals, LLC. This Court adopts and incorporates its prior ruling and, specifically, the full factual background contained therein. However, this Court will reiterate certain facts and law which are relevant to this Court’s instant ruling. First, for purposes of the *Allen* case only, the parties agreed that all Takeda entities would be treated as one juridical entity, therefore, when it is necessary to refer to individual companies, Takeda Pharmaceutical Company, Ltd. (which is the Japanese parent company of all other Takeda companies named as defendants in this action) will be identified as “TPC” or, alternatively, as TCI (the acronym for Takeda Chemical Industries, the name under which TPC operated formerly), or as “Takeda Japan.” However, the parties and this Court have found that identification of the Takeda companies by their physical locations is easier to follow than acronyms. For this reason, the Takeda entities located in the United States will either be identified by their acronyms (“TPNA” for Takeda Pharmaceuticals North America or “TPA” for Takeda Pharmaceuticals America) or as “Takeda U.S.,” Takeda Global Research & Development (Europe), Ltd., “TGRD,” or “Takeda Europe,” and Takeda Pharmaceutical Company, Ltd., “Takeda Japan.”

RFD-PJH – began on January 27, 2014, however, opening statements and testimony were delayed by the Court to February 3, 2014.

As noted, on January 30, 2014, this Court issued an Amended Memorandum Opinion and Ruling (“Amended Ruling”)³ addressing the Motion for Sanctions. In that ruling at pp. 68-69, the Court noted,

[A]fter review of all of the evidence presented by the PSC, and the evidence and arguments presented by Takeda, this Court finds the PSC has carried its burden to establish both beneficial relevance and prejudice and that the PSC has made a strong and persuasive showing from the evidence of a ‘culpable state of mind’ on the part of Takeda in its destruction of evidence. Nevertheless, this Court, at this juncture, stops short of concluding the PSC has demonstrated sufficient bad faith to support the full breadth of onerous sanctions requested. Rather, . . . this Court . . . will allow all evidence of bad faith to go to the jury, and thereafter, will devise a jury instruction to be given to the jury on this point after hearing all evidence presented by each side. After having heard all the evidence, this Court will, at the final charge conference, determine what specific charge will be given to the jury as to what inference, if any, it might employ.”

This Court, after having heard all evidence at the trial, found the Plaintiffs’ Steering Committee⁴ had presented sufficient evidence to establish Takeda acted in bad faith in its destruction of documents and found Takeda did not present reliable and credible evidence to the contrary sufficient to meet Plaintiffs’ evidence. Nonetheless, with full appreciation of the gravity of the issue at hand, and ever mindful of the United States Supreme Court’s caution to district courts when considering the exercise of their inherent powers, the Court declined to provide the requested more onerous sanctions, in particular, a default judgment, the requested instruction to the jury that bad faith existed, or the mandatory inference argued by Plaintiffs.

Rather, the Court gave a permissive instruction to the jury containing certain findings of

³ Rec. Doc. 3933.

⁴ The Plaintiffs’ Steering Committee will hereafter be referred to as the “PSC.”

the Court.⁵ This Court now gives its supplemental reasons for its determinations and completes, clarifies, and supplements its prior preliminary ruling found in Rec. Doc. 3933. This Final Memorandum Opinion and Ruling, again, addresses the PSC's request for sanctions, however, only as to *Takeda as defendants* and specifically DEFERS the request for sanctions as against

⁵ Now, additionally, ladies and gentlemen, in this case you have heard certain evidence from both parties about certain documents and files that were destroyed by Takeda. I will now discuss with you the relevance of that evidence.

In general, companies often have policies to retain or destroy documents that are no longer current. These are called "document retention" policies. These policies permit the destruction of documents that the companies no longer need and that they do not have an obligation to maintain. Now, when a party develops, or should develop, a reasonable expectation that it might engage in litigation on a particular matter or issue, however, the law imposes an obligation for companies to keep and maintain all documents and evidence in its possession, or that might come into its possession, or that might be generated by that company that relate to that matter or issue.

Now, in this case, I instruct you that I have considered the evidence and I have determined Takeda, including the Takeda companies in America, the Takeda companies in Europe, and the Takeda company in Japan, had a duty to retain documents and files pertaining to their product, Actos. I instruct you, therefore, the Takeda companies in America and the Takeda company in Japan had a duty to retain documents and files pertaining to their product, Actos, as of July of 2002. The Takeda company in Europe had a duty to retain files and documents relating to their product, Actos, as of 2006.

Therefore, I further instruct you Takeda was legally obligated, no later than July of 2002 in America and Japan, to retain all information, files, and documents related to their product, Actos, and the Takeda companies in Europe were legally obligated to retain all information, files, and documents related to their product, Actos, as of 2006; so that those documents and files would be available within the litigation process and to the plaintiffs in this case. I instruct you that many of the files and documents were destroyed after the Takeda companies had the legal obligation to retain them. You have heard evidence those files and documents were on the computers of certain employees, including certain key Takeda executives whose positions would have placed them within a stream of information or in a decision making position as to Actos, its [sic] development, testing, or marketing within the respective Takeda companies. You have also heard evidence that certain employees, including certain key executives' computers' hard drives were erased and/or the documents and information on those computers were destroyed. I instruct you that many of those files and documents cannot be restored or reconstructed.

Now, the destruction or significant alteration of evidence or the failure to preserve property once the obligation arises to preserve such evidence is known as "spoliation" of evidence. I instruct you I have concluded that spoliation occurred in this case.

Because the majority of the documents and information initially destroyed was not available within the litigation process and to the plaintiffs in this case, we cannot know for sure whether the documents, if they had not been destroyed, would have helped plaintiffs prove their case against the defendants or not. However, because this Court has found Takeda destroyed documents and files in a manner such and at a time after they had an obligation to retain those documents and files, I instruct you that you are free to infer those documents and files would have been helpful to the plaintiffs or detrimental to Takeda, if you feel the evidence you have heard supports that inference.

See Transcript, Rec. Doc. 4210, at 6276:20-6279:5

Takeda's counsel.⁶ The latter will be addressed prior to disposition of these cases by way of settlement or remand. For convenience of the parties and the appellate court, the Amended Ruling, Rec. Doc. No. 3933, is attached as Exhibit A to the instant ruling and it is adopted and incorporated into this ruling. However, the instant ruling is designed to supplement, and, perhaps, clarify this Court's earlier analysis, expand upon its findings based upon evidence presented at trial, and finalize its ruling as to Takeda.

Again, this Court reminds it has deferred on Rule 37 as to attorney conduct, but had and will again make certain determinations as to the conduct of Takeda under Rule 37 and spoliation. Thus, within this ruling, the Court will finalize its findings, conclusions and rulings *as to the Takeda Defendants* under both Rule 37 and the law governing Plaintiffs' allegations of spoliation but will, again, DEFER as to attorney conduct until a later date.⁷

As noted, prior to trial, the PSC put forth evidence to support their argument of Takeda's violation of Rule 37, and of spoliation; that evidence and argument, as well as a discussion of applicable law, is addressed in this Court's prior ruling (Exhibit A) and is adopted and incorporated into this Ruling. During the trial, both parties put forth certain additional evidence to support their argument as to both violation of Rule 37 by Takeda, and spoliation by Takeda. Now having had benefit of trial testimony and evidence, this Court concludes the PSC, at trial, presented *additional* evidence to support their argument that information both relevant and the

⁶ Consequently, in this Ruling, the Court makes no determination as to the conduct of Takeda's counsel, pursuant to FED.R.CIV.P. 37, but does address the conduct of Takeda under FED.R.CIV.P. 37, as well as the jurisprudence surrounding the PSC's claim of spoliation – bad faith and subsequent willful abuse of the judicial process. Thus, this Court expressly DEFERS evaluating whether sanctions are warranted against Takeda's counsel under FED.R.CIV.P. 37(c) as the PSC argues, until after this Court has had opportunity to fully explore that conduct in its entirety and, also, notes that, to date, the majority of the argued counsel conduct occurred within Magistrate Judge Hanna's Court and within the context of his orders. Consequently, this Court reserves its right to refer that matter to the magistrate judge, if deemed appropriate.

⁷ See Rec. Doc. 3933, p. 27, fn 47.

absence of which is prejudicial to plaintiffs, was intentionally deleted by Takeda at times after the legal duty to preserve such evidence arose; therefore, after full review of the trial record, this Court, again, finds Takeda had an obligation to preserve certain information; Takeda deleted that information; the information deleted is relevant to Plaintiffs' claims in the multidistrict litigation;⁸ the absence of that information is prejudicial to Plaintiffs in the MDL; Takeda intentionally deleted the information; and that Takeda did so with bad faith. The Court will now turn its attention to its additional reasons for these findings and those matters remaining before the Court.

II. ADDITIONAL RELEVANT PROCEDURAL HISTORY

First, this Court notes, that as addressed in this Court's prior ruling, as a general matter, this case had progressed in an exceptional manner due to the continued and professional cooperation of the counsel, aided by the Special Masters and with input of the magistrate judge and oversight by this Court. Again, as noted, in the spirit of such cooperation, the PSC and Takeda had agreed to certain discovery schedules within which Takeda was to have produced certain custodial files. It is undisputed that multiple custodial files were not produced, leading to the allegations of violations of Rule 37 by Takeda, and the allegation that Takeda had engaged in intentional and bad faith spoliation. This Court made certain preliminary findings in its previous ruling, both under Rule 37 and the jurisprudence surrounding the PSC's claim of spoliation, as to Takeda's conduct and finding a violation of FED. R. CIV. P. 37 by Takeda, subsequently allowed evidence of Takeda's conduct to go to the jury, and, at the same time to be presented to the Court so that a final determination as to bad faith within spoliation, could be made either by the jury – upon proper instruction – or by the Court. This Court notes the Allen case was governed by New York law, which allows for punitive damages. Consequently, this Court was fully aware, and it

⁸ Multidistrict litigation will hereinafter be referred to as "MDL."

should be noted at the outset, the majority, if not all, of the anticipated evidence as to spoliation, also, would have been relevant and likely admissible as to punitive damages and this proved to be the case. The evidence which was actually presented to the jury to prove Mr. and Mrs. Allen's theory as to punitive damages, also, encompassed the evidence as to Takeda's bad faith conduct in its destruction of documents. Consequently, allowing the evidence as to spoliation to be presented to the jury added no undue prejudice to Defendants, as the same evidence would have, even without spoliation, gone before the jury to support Mr. and Mrs. Allen's punitive damages claim.

Second, throughout trial, counsel for Takeda made multiple comments, as asides to otherwise relevant arguments, that the timing of the issuance of the Court's formal ruling as to spoliation had created prejudice for Defendants at trial. This Court notes that at *no time before the trial* did Takeda's counsel *in any way suggest* prejudice or request a continuance, or provide the Court with any type of notice as to any claim of potential prejudice – and thus, this Court had no opportunity to address any such argument or make any adjustment. This Court suggests Takeda's failure to give such notice *prior to trial* is because *there was no such prejudice*. When one examines the procedural history surrounding spoliation, it is clear Takeda had knowledge of the issues surrounding spoliation and had meaningful notice of this Court's determinations as to the Plaintiffs' motion for sanctions arguing spoliation well in advance of trial, as this Court will now address.

Discovery was proceeding during the month of May, 2013, in accordance with orders issued by this Court,⁹ when Takeda notified the PSC several custodial files that had been

⁹ See First Amended Case Management Order: Discovery Protocol, at 4, 5 (Rec. Doc. 2656); Case Management Order: Protocol Relating to the Production of Electronically Stored Information ("ESI"), at 25 (Rec. Doc. 1539).

requested by the PSC were no longer available. The Special Masters, thereafter, made multiple efforts to ensure the Defendants fully disclosed the facts associated with the unavailable documents and encouraged the parties to amicably resolve the issues and questions that were triggered by Takeda's announcement. Despite the time invested and the laudable efforts of the Special Masters, no amicable resolution was reached. Eventually, however, the parties were able to agree *as to the scope* of the missing files. It is now undisputed there are a total of 46 custodial files that have been deleted and destroyed by Takeda.¹⁰ The missing 46 custodial files belonged to Takeda employees who include, among others, "company presidents to key officers." The PSC presented evidence before trial and supplemented that evidence at trial which established these key Takeda employees were privy to critical information regarding the development and marketing of Actos®.

In mid-June, 2013, the PSC noticed a Rule 30(b)(6) deposition of Takeda, identifying 21 topics they intended to address in the deposition.¹¹ Thereafter, Takeda notified the PSC that it

¹⁰ See Takeda's Opposition, Exhibit 1 (Rec. Doc. 3530). At this juncture, the Court notes the parties have used a variety of terms to describe the absence of the 46 custodial files at issue. The PSC argues the files in question have been "destroyed," "deleted," or "otherwise lost," while Takeda has used various phrasing concerning the location of the documents, arguing the files have "not been located" or are, in some cases (particularly in the case of the "backup tapes"), "inaccessible." For purposes of spoliation, this Court finds Takeda deleted the information contained within the 46 custodial files at issue. While Takeda has begun trying to fully restore the deleted electronic data in the U.S., it has not presented reliable or credible evidence of having succeeded in doing so, as of yet. Consequently, the Court concludes that regardless of the language used to describe the conduct of Takeda, it is clear Takeda deleted, and was unable to produce, relevant evidence in time for the first bellwether trial in these proceedings, all as more fully set forth in this Memorandum Ruling.

¹¹ The PSC sought to address the following topics, listed at Rec. Doc. 2942-1:

1. Custodial files requested by counsel in any litigation, whether state or federal, and in whatever form, whether paper or electronic, involving Actos® and any of its side effects, that have been destroyed or are no longer available, along with when they were destroyed, how they were destroyed, who destroyed them, and why they were destroyed.
2. For each destroyed custodial file, whether paper or electronic, requested by counsel in any litigation involving Actos® and any of its side effects, which applicable document retention policy applied at the time of the destruction, whether foreign or domestic.
3. For each destroyed custodial file, whether paper or electronic, details regarding whether similarly situated

employees' files were also destroyed and, if not, why not.

4. What efforts by whom and when, if any, have been undertaken to try to locate the destroyed or missing custodial files. What efforts have been undertaken to recreate destroyed or missing custodial files, such as searching to file archived emails, backup files, or the like.
5. For the individuals relating to the custodial files identified in response to Topic #1, the entity for which they worked, the date they left Takeda's employ, the reason for their separation, the location of their personnel files and their current employer and contact information.
6. When Takeda or any of its former or current employees or counsel or agents first learned that any requested custodial files described in Topic #1 were destroyed. This includes but is not limited to the ESI division or subsidiary of Nelson Mullins and the other 24 law firms enrolled as counsel for Takeda.
7. Who directed that electronic files in question be destroyed? All data respecting the destruction or retention of files, including the order(s) or memo(s) directing the destruction or retention.
8. Who directed that paper files in question be destroyed? All data respecting the destruction or retention of paper files, including the order(s) or memo(s) directing the destruction or retention.
9. When any Actos® litigation holds relating to the subject litigation were put into place, by whom, when and by what means the holds were distributed, what people and information were covered by such holds, and what was done to ensure compliance with the holds.
10. Whether any other litigation holds including but not limited to litigation stemming from criminal investigations, average wholesale pricing, and intellectual property, applied to the custodial files described in Topic #1 above.
11. The systems architecture used by Takeda to backup electronically stored information, including how often such backups are run, how and where the tapes are stored and catalogued, whether the data on the tapes is archived, whether any backup tapes have ever been accessed, together with the particulars of such access, whether any backups have been converted to any other media or form, and whether any backups have been destroyed.
12. If any data on backup tapes have been destroyed or deleted, the standard operating procedure for doing so.
13. The first time Takeda or anyone operating on its behalf put any third party on notice of potential litigation or the reasonable anticipation of litigation, either federal or state, involving Actos® and its side effects, including but not limited to insurers.
14. The earliest date on which any document Takeda asserted attorney-client or work-product privilege in anticipation of litigation in any litigation involving Actos® and its side effects.
15. Any holds associated with the European Union Article 20 for Actos®, including the date such a hold went into effect, to whom it was sent, what information it covered, and what was done to ensure its enforcement.
16. All information relating to Eli Lilly and any other entity regarding litigation holds concerning or mentioning Actos® and side effects, including all data as to whether a litigation hold was necessary or required, including the results of those communications, up to and until such a litigation hold was put into place.
17. The initial instance that Takeda, or anyone operating on its behalf, at its insistence or in its interest, contacted any lawyer or law firm in anticipation of the subject litigation (anywhere and in any court) or associated with the subject litigation, whether such litigation or contact was in the United States or elsewhere.

did not intend to designate anyone to appear at the deposition as noticed, and, therefore, two discovery cross-motions were filed: Takeda filed a Motion for Protective Order;¹² and the PSC filed a Motion to Compel FED.R.CIV.P. 30(B)(6) Deposition,¹³ including a specific PSC request for leave to take a 30(b)(6) corporate deposition of Takeda regarding issues associated with the unavailable custodial files. The subject matters covered by the deposition notice included, but were not limited to, the destruction of the files at issue; identification of all missing files; Takeda's issuance of a litigation hold; and the history of product liability litigation associated with Actos®. Takeda's Motion for Protective Order sought an order from the court either prohibiting the 30(b)(6) deposition in its entirety or, alternatively, limiting its scope. These matters initially sounded before the magistrate judge and prompted multiple hearings with the magistrate judge. Thus, the issue of the missing files and the reason for and circumstances surrounding those destroyed and deleted files was at this point fully in dispute, and immediately thrust into the forefront. The files which were at issue contained not only electronically

18. The dates and parties to any indemnity agreements, hold harmless agreements and/or joint defense agreements relating to the subject litigation.

19. The first time that Takeda notified or caused to be notified any insurer, underwriter or agent regarding anything related to the subject litigation or anticipation of same including but not limited to coverage issues relating to the subject litigation.

20. (a) The reasons, events, factors or data which caused Takeda or anyone acting on its behalf to impose a litigation hold in the United States in February 2011;

(b) The reasons, events, factors or data which caused Takeda or anyone acting on its behalf to impose a litigation hold in Japan in September 2011.

(c) The reasons, events, factors or data which caused Takeda or anyone acting on its behalf to impose different dates for a litigation hold in the United States as opposed to Japan.

21. Defendants are also required to produce all documents responsive to the topics included herein.

¹² Rec. Doc. 2881. The PSC's Opposition to Defendants' Motion for Protective Order is Rec. Doc. 2943.

¹³ Rec. Doc. 2884. Takeda's Brief in Response to Plaintiffs' Motion to Compel 30(b)(6) Deposition and in further support of their Motion for Protective Order Regarding Same is Rec. Doc. 2942. Plaintiffs' Supplemental Memorandum in Support of Motion to Compel FED. R. CIV. P. Rule 30(b)(6) Deposition on Litigation Hold Issue is Rec. Doc. 3182.

generated and electronically stored documents, but also “hard copy documents;” it is undisputed the non-electronic documents were destroyed and cannot be reproduced. The PSC presented evidence electronic files were deleted and destroyed and that those files cannot be fully reconstituted. Takeda – as will be discussed below – presented no evidence the deleted and destroyed electronically stored information has been, or can be fully reconstituted.

A. Magistrate Judge Hanna’s Rulings and Orders

As noted in this Court’s preliminary ruling, Rec. Doc. No. 3933, attached as Exhibit A, pp. 12-14, the magistrate judge held multiple hearings focused upon Takeda’s responses, or lack thereof, to the PSC’s discovery requests. On *July 3, 2013*, the Magistrate Judge conducted oral argument on both discovery motions and **concluded the PSC had presented *prima facie* evidence of “lost” or “destroyed” documents** [*See* “Ruling on Motion,” Doc. 2992]. *In his findings, the Magistrate Judge, also, noted Takeda had provided the PSC with inconsistent litigation hold dates.*¹⁴ The Magistrate Judge granted Plaintiffs’ request for a 30(b)(6) deposition of Takeda, but divided the 30(b)(6) deposition into two phases: the first phase to be directed toward answering the question of whether or not the unproduced documents were, in fact, destroyed and/or were otherwise unavailable to the PSC, while the second phase was to be directed toward the issuance of a litigation hold, its existence, enforcement, and nature; the second phase was to proceed only if it were determined that such document destruction had occurred in the first instance.¹⁵ Magistrate Judge Hanna consequently, ordered that a Takeda representative be prepared to testify: (a) regarding Topics 1 through 8 in the deposition notice; (b) on the topic of the routine, good-faith operation of an electronic information system as it

¹⁴ *See* “Ruling on Motion,” Rec. Doc. 2992, at 6-7.

¹⁵ *See* “Ruling on Motion,” Rec. Doc. 2992, at 8.

pertains to the destruction of the files at issue; and (c) on the retrieval and/or reconstruction of the lost or destroyed documents by itself or a third party.¹⁶ This Court notes that even as late as the Allen trial, Takeda had/has yet to produce the ordered representative who could or has been able to testify to many, if not all, of these issues; most glaringly the process and ability, if any, for Takeda to reconstruct the deleted electronically generated and/or stored documents and Takeda Japan's operation and conduct. As will be specifically addressed below, neither Mr. Regard, nor Ms. Calahan – the witnesses identified as Takeda's representatives to testify as to these issues at the 30(b)(6) deposition and at the Allen trial, respectively – could testify as to either of these issues. Thus, even at this writing, Takeda has yet to comply with pivotal aspects of the 30(b)(6) notice and the magistrate's order, creating not only delay as to overall discovery, but, also, specifically as to the Plaintiffs and PSC's allegations of spoliation.

As the Magistrate Judge deferred all other aspects of the Motion to Compel until after completion of the first phase of the 30(b)(6) deposition, that initial phase was critical to the timely and efficient progression of discovery. Of particular relevance as to delay and Takeda's conduct, the response Takeda made to the magistrate judge within Takeda's Motion for

¹⁶ See "Ruling on Motion," Rec. Doc. 2992, at 9. Topics 1 – 8: (1) Custodial files requested by counsel in any litigation, whether state or federal, and in whatever form, whether paper or electronic, involving Actos® and any of its side effects, that have been destroyed or are no longer available, along with when they were destroyed, how they were destroyed, who destroyed the, and why they were destroyed. (2) For each destroyed custodial file, whether paper or electronic, requested by counsel in any litigation involving Actos® and any of its side effects, which applicable document retention policy applied at the time of the destruction, whether foreign or domestic. (3) For each destroyed custodial file, whether paper or electronic, details regarding whether similarly situated employees' files were also destroyed and, if not, why not. (4) What efforts by whom and when, if any, have been undertaken to try to locate the destroyed or missing custodial files. What efforts have been undertaken to recreate destroyed or missing custodial files, such as searching to file archived emails, backup files, or the like. (5) For the individuals relating to the custodial files identified in response to Topic #1, the entity for which they worked, the date they left Takeda's employ, the reason for their separation, the location of their personnel files and their current employer and contact information. (6) When Takeda or any of its former or current employees or counsel or agents first learned that any requested custodial files described in Topic #1 were destroyed. This includes but is not limited to the ESI division or subsidiary of Nelson Mullins and the other 24 law firms enrolled as counsel for Takeda. (7) Who directed that electronic files in question be destroyed? All data respecting the destruction or retention of files, including the order(s) or memo(s) directing the destruction or retention. (8) Who directed that paper files in question be destroyed? All data respecting the destruction or retention of paper files, including the order(s) or memo(s) directing the destruction or retention. (Rec. Doc. 2884-2)

Protective Order, prompted the magistrate judge to initially limit the historical time period for inquiry under the 30(b)(6) deposition to that time period beginning January 1, 2010 – just before February 15, 2011, **the hold date Takeda had provided to both the PSC and the magistrate judge.**¹⁷ The magistrate judge, also, denied Takeda’s request to conduct discovery only through written interrogatories, as urged by Takeda; and deferred any additional ruling on the PSC’s motion, pending the completion of the first phase of the 30(b)(6) deposition. However, the dispute as to the 30(b)(6) deposition and Takeda’s conduct continued such that intervention by the magistrate judge was, again, required.

On July 25, 2013, before the scheduled first phase of the 30(b)(6) deposition, and at the request of the parties, the Magistrate Judge heard additional argument for the purpose of clarifying certain specific aspects of his ruling defining the scope of the 30(b)(6) deposition. At that hearing, the PSC now argues *Takeda’s counsel*, upon question by the Court, *for the first time, advised the Court that claims, settlements, and litigation involving Actos® product liability actually went back as far as 2002*, a date heretofore not disclosed by Takeda, notwithstanding valid discovery and order of the Court. Although Takeda argued a distinction *between and among certain maladies* as to the litigation hold(s), by way of subsequent written discovery responses, Takeda formally acknowledged, *for the first time*, that it had, in fact, instituted a “**general Actos® ‘products liability’** litigation hold” in July 2002 (the “2002 Litigation Hold”), and, notwithstanding the long outstanding discovery and orders of the Court, for the first time provided a schedule of Actos®-related personal injury claims and litigation.¹⁸

¹⁷ See Transcript of Motion Hearing by Telephone, Rec. Doc. 2977, at 28. This date was chosen by the magistrate judge because it was the earliest date Magistrate Judge Hanna believed - *based upon representations made to the Court during oral argument by Takeda* - the issuance of a litigation hold could have occurred.

¹⁸ See “Takeda’s Response and Objections to Plaintiffs’ Supplemental Interrogatory 2,” attached as Exhibit 15 to Plaintiffs’ Memorandum, and “Attachment A to Takeda’s Response to Plaintiffs’ Supplemental Interrogatory No. 2,” attached as Exhibit 6 to Plaintiffs’ Memorandum (Rec. Doc. 3484-2).

Thereafter, on *August 19 and 20, 2013*, the first two days of the Takeda 30(b)(6) deposition were held, as ordered. Thereafter, Magistrate Judge Hanna reviewed the transcripts of those two days' deposition testimony and, on August 23, 2013, issued yet another and Supplemental Order(s) on the Motion to Compel and Motion for Protective Order,¹⁹ noting many of the threshold questions the 30 (b)(6) deposition had been ordered to address had not been addressed *as Takeda's selected representative could not address those issues*. Because of the already experienced delays noted now mandating certain time constraints for the parties the Court ordered Takeda to file a supplemental brief to provide, formally, in writing, specific, listed categories of information regarding the missing files, the custodians of those files, and to provide cost estimates for retrieval and/or reconstruction of the missing files – as retrieval and/or reconstruction had been raised by Takeda during the 30(b)(6) deposition. Takeda submitted its Supplemental Brief, as ordered by Magistrate Judge Hanna, on September 5, 2013.²⁰

While awaiting the Supplemental Brief from Takeda, Magistrate Judge Hanna issued his Supplemental Ruling on Plaintiffs' Motion to Compel and Takeda's Motion for Protective Order²¹ to address those issues that had been deferred in his initial ruling. The magistrate judge at that point, August 29, 2013, found a *prima facie* case of spoliation by Takeda had been demonstrated by the PSC, and that this evidence justified the additional discovery the PSC was seeking in its Motion to Compel, and consequently Takeda, as of August 29, 2013, had full notice the Court had found evidence sufficient to support a *prima facie* showing of Takeda's having engaged in spoliation. Thereafter, the remaining portions of the Motion to Compel were

¹⁹ Rec. Doc. 3201.

²⁰ Takeda Defendants' Supplemental Brief in Support of their Motion for Protective Order ("Supplemental Brief") (Rec. Doc. 3270).

²¹ Rec. Doc. 3236.

granted, in part, and Takeda's request for a protective order precluding the remainder of the 30(b)(6) deposition was denied. Again, as of this time, Takeda was on full and complete notice a *prima facie* case had been established by the PSC for their claim of spoliation as to Takeda's conduct. Thus, at least as of this moment, if not before, Takeda was on full and complete notice it would have to provide testimony evidence at trial or before, to meet this *prima facie* finding or risk the consequence of such a finding becoming final. However, regrettably, even up to and through trial, Takeda failed to do so, rather engaged in delay, refusal to respond, or failure to present reliable, credible, and knowledgeable testimony and documentary evidence to meet the PSC *prima facie* showing.

In his supplemental ruling on the Motion for Protective Order, Magistrate Judge Hanna amended his ruling to now include, among other things, a revised beginning date for the PSC's discovery inquiries: January 1, 2002,²² thus, expanding the chronological limits as to discovery.

B. The 30(b)(6) Deposition of Takeda

For the ordered FED.R.CIV.P. 30(b)(6) deposition, Takeda chose to designate as its selected representative an "IT consultant," who had no independent personal or corporate knowledge of any of the Takeda entities or policies, who had never worked with or for, in any corporate capacity,²³ any of the Takeda entities prior to his being hired to assist Takeda in this litigation and who, consequently, had only a shallow, at best, understanding of only some of the ordered areas of inquiry and no knowledge of others. Ms. Calahan, Takeda's Assistant General Litigation Counsel, who testified at trial that she was involved in this choice of corporate

²² See Amended Order, Rec. Doc. 3056, at 2.

²³ In his deposition, Mr. Regard stated that he worked on a project for Takeda in 2010, wherein he was asked to do some analysis and provide some testimony regarding, he believes, a patent dispute. Deposition of Daniel Regard attached as Exhibit 8, to the Motion for Sanctions (Rec. Doc. 3484-2) at 32.

representative, testified at trial that in order to fully respond to the ordered areas of inquiry, multiple individuals would have had to have been produced. Consequently, Takeda chose to employ only one, Mr. Regard, to testify on behalf of all the Takeda entities.²⁴ It is of note Magistrate Judge Hanna had made specific determinations and issued specific orders to Takeda, repeatedly clarifying and elucidating Takeda's obligation pursuant to FED.R.CIV.P. 30(b)(6) and the notice issued. Thus, Takeda's actions are viewed not only in light of the Federal Rules of Civil Procedure, themselves, but, also, in the light of the Magistrate Judge's specific orders to Takeda, as to Takeda's obligation pursuant to FED.R.CIV.P. 30(b)(6) and the deposition notice issued by the PSC. The PSC argues the 30(b)(6) designation and the clear inadequacies of the resultant deposition of Takeda demonstrate, themselves, bad faith on the part of Takeda within the discovery process and constitute a direct violation of FED.R.CIV.P. 30(b)(6) and FED. R. CIV. P. 37, as well as being evidence of Takeda's deliberate and bad faith attempt to hide its preceding intentional document destruction in clear disregard of its legal obligation to preserve those documents, and as the Court agrees, a limited discussion of this argument is, therefore, appropriate at this juncture.²⁵

The 30(b)(6) deposition of Takeda was conducted over a period of four days, on August 19-20, 2013 and on September 18-19, 2013. Only one witness was selected by Takeda and presented as the designated representative of Takeda and that witness *had no personal or first-hand corporate knowledge of any kind of any of the topics about which he was questioned.*

²⁴ This choice, it would seem, was made pursuant to [an] "other person who consent[s] to testify on its behalf FED.R.CIV.P. 30(b)(6). However, this was not at all clear, nor was this provision under the rules directly referenced by Ms. Calahan.

²⁵ Whether Takeda's conduct as to the corporate deposition constitutes a violation of FED.R.CIV.P. 30(b)(6) by Takeda's *counsel*, is a matter this Court will give close attention when addressing FED.R.CIV.P. 37 and the alleged violations - a matter this Court, at this time, reserves for later consideration. However, whether *the nature of the selection* and information produced and testified to might, also, be evidence of bad faith on the part of Takeda as to spoliation, and constitutes a violation of FED.R.CIV.P. 37 as to the party, i.e. Takeda, are relevant to the inquiries now before the Court.

Rather, the PSC argues he was, in effect, merely a hired gun brought in by Takeda to provide a buffer and to obfuscate on Takeda's behalf - and this Court, after full review of the 30(b)(6) deposition, cannot disagree. Mr. Regard's testimony so obfuscated and avoided information ordered by Magistrate Judge Hanna to have been addressed, and which has since that time come to light, as to leave little doubt as to the veracity of the PSC's argument. After the initial two days of testimony, as noted, Magistrate Judge Hanna, again, addressed Takeda's obligations pursuant to his rulings and the Federal Rules of Civil Procedure, again, addressing the nine (9) specific topics of inquiry, and ordered supplemental written response on those issues.²⁶ The

²⁶ The nine topics for inquiry as ordered by the magistrate judge were:

- The name of the entity (or entities) which employed each of the 36 custodians identified in Mr. Saylor's August 15, 2013 correspondence to Mr. Bassett;
- The positions held by each of the foregoing custodians throughout their employment histories;
- The date of hire and the last date of employment for each custodian;
- The identity of any and all "successors" to the custodians as described in the 30(b)(6) depositions and whether the successors' custodial files have been produced;
- The degree to which Takeda contends materials that "would have been" in the custodians' files - which have not been located- either have already been produced to the PSC by other means (i.e. through "corporate records" or "successors" custodial files) or have been withheld as privileged;
- A **true** estimate of the **total** cost of retrieval/reconstruction of custodial files that have not been located for the custodians in the United States from the 2002 Litigation Hold to present day under any of the options presented in the testimony;
- A **true** estimate of the total cost of retrieving/reconstructing the EU custodians' files, unless it is accurate that there are no longer any missing EU custodial files;
- A **true** estimate of the **total** costs of retrieving/reconstructing the Japanese custodians' files, i.e. through metadata searches by sender, or a declaration that retrieval is simply not possible. Takeda is cautioned that incomplete or evasive answers to this Court's inquiry will be viewed as a failure to answer pursuant to FED.R.CIV.P. 37(a)(4);
- Whether any effort has been made to reconstruct the missing custodial files, and if so, the result of that effort.

(Rec. Doc. 3201).

issues focused primarily upon those issues Takeda's designated representative, Mr. Regard, either did not, or could not, address during the first two days of the 30(b)(6) deposition, notwithstanding Takeda's having been ordered to provide a representative(s) to address those issues. The selection and designation of a representative who could not or did not address issues Takeda was ordered to address, was wholly Takeda's – one made with full notice as to what the designated witness was to testify.

Suffice to say – as fully discussed in this Court's previous ruling, Rec. Doc. 3933, pp. 15-22 - Takeda's handling of the 30(b)(6) deposition, at best, created additional delay as to identification and resolution of the spoliation issue and, at its worst, appears as a deliberate attempt by Takeda to hide and avoid revealing evidence as to its previous destruction and deletion of files of key Takeda employees, who now have been proved to have been intimately involved in the development and marketing of Actos® during pivotal periods, and thus, an attempt to avoid and hide evidence as to the existence of the 2002 products liability Hold and documents deleted and destroyed thereafter.

Additionally, contrary to Mr. Regard's testimony that "backup tapes" were part of Takeda's compliance with its document retention policies and legal obligations, Takeda has argued to the contrary. Since May 22, 2013, within this MDL litigation, Takeda has argued Takeda should **not** be required to produce information from "backup tapes," as such tapes are "inaccessible."²⁷ Alternatively, Takeda, also, has argued that if this Court were to conclude the information on its backup tapes were determined to be "accessible," and, therefore, discoverable, the Court should entertain a cost-shifting analysis requiring the PSC to share some of the

²⁷ As discussed within this ruling, the distinctions among backup tapes, disaster, and business tapes, as argued by Takeda, has been fluid and obtuse at best.

financial burden associated with such production.²⁸ The apparent inconsistent interplay between the position taken by Takeda within the context of the ongoing discovery dispute and that found within Mr. Regard's testimony is glaring, and the PSC argues evidence of Takeda's bad faith. Furthermore, at trial, upon examination by the PSC, Takeda's designated representative, Ms. Calahan, admitted she did not know whether the "backup" tapes and/or "disaster tapes" could provide complete reconstruction of deleted material.²⁹ Thus, notwithstanding Takeda's argument the MDL's Plaintiffs have and will suffer no prejudice because Takeda is reconstituting the deleted electronic files – of course the destroyed hard copy files and documents are lost – Takeda's corporate representative testified she was not sufficiently knowledgeable to be able to testify whether this was correct and Takeda presented no other testimony – only unsupported argument – that complete reconstitution can be had.

Throughout discovery and motion practice leading up to the first bellwether trial, Takeda was fully aware spoliation was an issue; was fully aware the magistrate judge had ruled the PSC had made a *prima facie* showing that Takeda had engaged in spoliation and yet, Takeda did not amend its required witness list³⁰ to add a witness beyond Mr. Regard as to this issue until after this Court's pretrial conference, and even the witness Takeda then designated, herself, could not testify to critical aspects of Takeda's Argument – i.e. Takeda Japan's conduct and operations, and Takeda U.S.'s reconstitution of deleted and destroyed electronic files.

Soon after the pretrial conference where this Court gave counsel its preliminary ruling,

²⁸ See "Takeda Defendants' Legal Position in Opposition to Discovery from Backup Tapes for Former Employees of Takeda Pharmaceutical Company, Ltd." attached as Exhibit 16 to the Motion for Sanctions, at 4-5 (Rec. Doc. 3484). The Court notes Takeda has never formally requested a ruling that their backup files are actually "discoverable." Nevertheless, in response to the PSC's Motion for Sanctions, Takeda asked this Court to engage in a cost-shifting analysis to require the PSC to bear some of the costs associated with the production of information contained on Takeda's "backup files."

²⁹ Trial Tr. vol. V, 584-85 (Rec. Doc. 4176).

³⁰ Rec. Doc. 3879.

verbally on January 15, 2014, Takeda filed its motion to permit addition on one will-call witness.³¹ Thus, some ten days before jury selection began, Takeda had filed its motion to add Stacey Calahan, rather than Dan Regard, to address the spoliation issue. Thus, only on January 17, 2014, and for the first time, did Takeda add as a witness, for any purpose, Stacey Dixon Calahan, Assistant General Litigation Counsel for Takeda Pharmaceuticals USA, Inc., and designated Ms. Calahan, rather than Mr. Regard, would now testify at trial concerning spoliation-related topics. Ms. Calahan had, however, submitted a Declaration on behalf of Takeda after the 30(b)(6) addressing issues Takeda has been ordered to address in the 30(b)(6) deposition, in opposition to the PSC's motion for sanctions, which will be discussed below. The Court granted Takeda's request to add Ms. Calahan as a witness; thereafter, plaintiffs requested they be allowed to amend their witness list to, also, add Ms. Calahan as a witness; permission was granted; and ultimately, the plaintiffs led off their case on behalf of Mr. and Mrs. Allen with Ms. Calahan as their first witness, called as a hostile witness.

This Court had and continues to have concern as to the reliability and credibility of Ms. Calahan's testimony. However, the nature of her testimony, as well as the testimony itself, is quite enlightening to the Court's inquiry *as to Takeda's conduct*, beginning before litigation was filed, continuing through discovery, through motion practice, and up to and into the trial. First, this Court notes Ms. Calahan submitted – on behalf of Takeda and as an attorney of and for Takeda – the noted “Declaration of Stacey Dixon Calahan,” attached as Exhibit 3 to Takeda's opposition brief to Plaintiffs' motion for sanctions, Rec. Doc. 3530, at ¶13, wherein Ms. Calahan declares certain information as fact; gives legal opinions about which, from her trial testimony, it is clear, she had and has no personal knowledge or, at best, has a quite shallow, if any at all,

³¹ See Takeda Defendants' Opposed Motion for Leave to Amend Second Amended Scheduling Order Pilot Bellwether Program (First Trial) to Permit Addition of One Will-Call Witness (Rec. Doc. 3879).

institutional memory or knowledge as to Takeda U.S. and none, if any, as to Takeda Japan. When viewed in light of Ms. Calahan's trial testimony, Ms. Calahan's declaration is highly questionable, at the very best. The examination of Ms. Calahan by the PSC graphically illustrated Ms. Calahan had made factual assertions in her Declaration as to occurrences which predated her employment with Takeda and, therefore, about which she could have had no personal knowledge, and, also, established she had made factual assertions about which she, at best, had shallow institutional knowledge, if any at all, as to certain of the Takeda entities; and that she had almost none, if any, knowledge, personal or institutional, as to Takeda Japan. Thus, the Declaration, itself, is highly questionable, at best, and is argued by the PSC as further evidence of Takeda's bad faith, particularly as it was presented only after the 30(b)(6) deposition, and at trial her knowledge as to most of the assertions made and opinions given in the Declaration, were proven to be without foundation.

Next, the Court notes this Court did not find the majority of Ms. Calahan's testimony either reliable or often credible. Only upon persistent examination, and only when repeatedly faced with documents which undercut her prior testimony, would, and did, Ms. Calahan admit to knowledge and information she had, or did not have. Although Takeda presented Ms. Calahan to testify on behalf of "Takeda" – she repeatedly testified she had no knowledge of Takeda Japan's conduct – and yet, repeatedly had to recant when confronted with documentary evidence to the contrary. Also, Ms. Calahan, notwithstanding having been selected by Takeda to testify as to the spoliation issue and Takeda's repeated argument it had, and was continuing to reconstruct deleted files and, therefore, the PSC had and would suffer no prejudice – ultimately testified she *did not know whether a full reconstruction was actually possible, could be complete, and*

*speculated it was only a "snapshot."*³² Thus, in the face of the PSC's longstanding and persistent arguments and the magistrate judge's finding of a *prima facie* showing of spoliation, as well as this Court's determination in its preliminary ruling of the PSC's motion for sanctions that the documents deleted were relevant to Plaintiffs' case and that *the PSC had and would suffer prejudice as a result*, Takeda, once again, as with Mr. Regard, presented someone without the requisite knowledge to testify to the relevant issues or to grant factual support to their arguments. Consequently, the selection of Ms. Calahan to testify on Takeda's behalf as to spoliation in light of her limited corporate knowledge, limited personal knowledge, and lack of knowledge as to the argued restoration and limited knowledge of Takeda Japan, was at the very best regrettable, and at worst further support for this Court's finding Takeda has acted in violation of Rule 37 and in bad faith as to the destruction of its documents and files.

The PSC's examination of Ms. Calahan, almost in whole, grants further support for each element required in order for the PSC to prevail on its motion for sanctions pursuant to FED.R.CIV.P. 37 and the jurisprudence surrounding the PSC's claim of spoliation and, also, leave Defendants with no reliable or credible evidence to support their argument on this point, and this Court, hereby, cites that examination as additional support of this Court's factual findings and legal determinations made as to Rule 37 and spoliation, as to Takeda's conduct.³³

³² Trial Tr. vol. V, 625-26 (Rec. Doc. 4176).

³³ By way of illustration and example only and in no way complete the Court notes:

Ms. Calahan testified that she did not know for certain who in Takeda's Japan company issues legal holds. Trial Tr. vol. II, at 142 (Rec. Doc. 4173). In her "Declaration," however, she discussed with authority when holds were and were not issued in Japan. Calahan "Declaration" (Ex. 3 attached to Rec. Doc. 3530 at ¶¶ 4, 6, 11, 28, 33).

When asked if Takeda Japan was aware of the legal hold in July of 2002, Ms. Calahan replied she was not aware. Trial Tr. vol. III, at 227 (Rec. Doc. 4174). When confronted with verified interrogatory answers indicating the Japan entities were aware in July of 2002 of a legal hold, Ms. Calahan testified "that is when we believe they became aware" and inexplicably testified that was "consistent with what I just said." *Id.*, at 228.

When asked whether Japan ignored the 2002 hold, Ms. Calahan replied, "No, I don't know that they

Of particular and direct relevance, also, is that Ms. Calahan ultimately admitted, as Takeda's designated representative, facts that are *in direct contradiction with arguments made by Takeda throughout discovery and briefing to this Court*. Ms. Calahan admitted, under oath, the 2002 products liability hold was issued in 2002, refreshed on September 17, 2003, May 4, 2006, October 22, 2007, January 14, 2008, and February 15, 2011;³⁴ that it would have covered all maladies, including bladder cancer;³⁵ that the 2002 products liability Hold has not been

ignored the hold." *Id.*, at 228. When confronted with testimony that Japan did nothing to comply with the 2002 hold, she admitted that was true but then distinguished 'ignoring the hold' and 'not taking action' as being different because "each legal department in the entities of other countries make their own decisions based on their own policies and procedures about when and how they issue legal holds." *Id.*, at 229.

Ms. Calahan was then asked if she herself had issued legal holds from the United States instructing other companies, including companies in Japan, to hold all documents, to which she replied she had not. *Id.*, at 231. When confronted with a document she had written to Bozo Company in Japan instructing them to preserve documents, Calahan admitted the letter. *Id.*, at 234.

When asked whether the inclusion of a Takeda Japan entity on a release in a 2002 product liability case indicated that the Japan Takeda entity likely anticipated litigation, Calahan deflected the question by saying she did not work at the company in 2002. *Id.*, at 276; she also testified she did not know what was meant by the term "general form." *Id.*, at 281-82. She finally admitted that she thought the Release indicated Marlene Dubas thought it a possibility Takeda Japan could be in a product liability lawsuit. *Id.*, at 283-84.

Ms. Calahan denied having issued legal holds from the United States instructing other companies, including companies in Japan, to hold all documents. Trial Tr. vol. IV, at 377. When confronted with a legal hold she prepared that was sent to the Japan entity, Ms. Calahan semantically replied that she "issued a legal hold that included TPC, but I didn't instruct TPC to issue the legal hold." *Id.*, at 380.

When asked whether Takeda Global Research and Development Center, 2006, included Europe, Ms. Calahan replied that she did not know because she was not at the company in 2006. Trial Tr. vol. V, at 590. In her "Declaration," however, Ms. Calahan affirms to knowing considerable information about events at Takeda prior to her employment. Calahan "Declaration" (*Id.* at ¶¶ 12, 13, 24, 28, 33, 41).

Ms. Calahan was asked if the U.S. e-mail files had been fully restored as of today. She replied that she did not know. *Id.*, at 621. If Ms. Calahan did not know, she certainly should have known what the status was of the restoration of the U.S. files prior to submitting her "Declaration" and testifying at the trial.

Ms. Calahan does not acknowledge that Takeda Japan was named as a defendant in 2002. Calahan Declaration at ¶ 12 (attached as Exhibit 3 to Opposition, Rec. Doc. 3530); however, Exhibit 6 (attached to Plaintiffs' motion for sanctions, Rec. Doc. 3484) does indicate that Takeda Japan was named as a defendant in 2002.

³⁴ See "Declaration of Stacey Dixon Calahan," p. 3, ¶ 13, attached as Exhibit 3 to Takeda's responsive brief (Rec. Doc. 3530).

³⁵ Trial Tr., vol. VI, 729-731, 768 (Rec. Do. 4177).

rescinded;³⁶ and that no litigation hold specific as to one specific malady has been issued by Takeda.³⁷ Consequently, the regrettable evolution of Takeda's argument made to this Court, as to when and as to what Takeda issued their legal hold, when viewed against the admissions made by Takeda's Assistant General Litigation Counsel at trial, is regrettable and without factual support, and is further support for the PSC's argument of bad faith on the part of Takeda as to the destruction and deletion of its documents in the face of its legal obligations, and as to Takeda's violation of FED.R.CIV.P. 37.

Furthermore, as Ms. Calahan was Takeda's sole witness designated to testify as to spoliation at trial, and as Ms. Calahan testified she has no knowledge - personal, corporate or otherwise - as to how the reconstruction process is conducted and whether it can completely reconstitute a deleted file, thus, Takeda is left **with no evidence to support their argument they have and are fully reconstructing deleted and/or "destroyed" files** and, therefore, Plaintiffs have and will experience no prejudice as a result of Takeda's deleting and destroying files. To the contrary, Ms. Calahan's testimony was the reconstruction of electronically generated and electronically stored files is only a "snapshot," but, in fact, admitted she did not know one way or the other.³⁸ Additionally, as noted earlier, it is undisputed all hard copy documents which might have existed and which were destroyed, of course, cannot be reconstituted or reconstructed. Thus, Takeda is left with precious little beyond its own argument that what was destroyed has been or is capable of being fully reconstituted or reconstructed. This is particularly relevant when one recognizes the PSC, at trial, put forth an e-mail which was obtained from a non-destroyed individual's files, which on its face should, also, have been in a

³⁶ Trial Tr., vol. V, 583 (Rec. Doc. 4176).

³⁷ Trial Tr., vol. VI, 729 (Rec. Doc. 4177).

³⁸ Trial Tr., vol. V, 625-626 (Rec. Doc. 4176).

file of an individual whose files were destroyed, and one Takeda argues has been fully reconstituted from the much disputed and ever changing files, backup files, or disaster files, yet the e-mail – relevant to the issues at play – was not found within the files Takeda argues had been fully reconstituted. Thus, the evidence presented supports the reasonable inference the reconstruction, even as to electronically generated or stored information, is not and cannot be complete, notwithstanding Takeda's unsupported argument to the contrary. Thus, Takeda's argument that the PSC has not and cannot be prejudiced because Takeda has and continues to "reconstitute" the destroyed files is hollow at best. The "hard documents" of key Takeda employees involved in the development and marketing of Actos® are forever lost; the electronically generated and/or stored information has not been shown to have been or even be capable of full and complete reconstitution. Thus, those documents the PSC is unable to obtain from third parties within or without the Takeda corporate structure are lost to the PSC and the PSC has put forth a plethora of evidence showing those documents to have been of key Takeda employees intimately involved with the development and marketing of Actos® during key and pivotal periods. The PSC, through multiple witnesses pretrial and at trial, has presented credible evidence that notes of meetings, drafts of letters which were changed, power point presentations used, and other such information directly relating to the development and marketing of Actos® did exist, no longer exists, and cannot be fully reconstituted, if at all, as hard copies cannot be recreated, and a reasonable assumption can be made Takeda's efforts to reconstruct electronic evidence is not and cannot be fully successful. Thus, both relevance and prejudice have been further supported by evidence presented by the PSC at trial and Takeda has presented no credible, reliable evidence to the contrary at trial.

C. The PSC's Motion for Sanctions

In accordance with the deadline established by this Court, the PSC filed the Motion for Sanctions on October 21, 2013. Briefing was completed on December 14, 2013 when the PSC filed the Supplemental Authority.

The parties now agree that the following custodians' files are missing:

- Noriaka Hada (Japan). Position: Operation Control, Overseas Business Planning Department (Takeda Pharmaceutical Company). Employment dates: April 1, 1970 – July 1, 2008.
- Kiyoshi Kitazawa (Japan). Position: Managing Director (Takeda Pharmaceutical Company). Employment dates: April 1, 1971 – June 25, 2009.
- Masaomi Miyamoto (Japan). Position: Vice President, Pharmaceutical Research Division (Takeda Pharmaceutical Company). Employment dates: April 1, 1975 – March 9, 2010.
- Masahiro Miyazaki (Japan). Position: Associate Director, Pharmaceutical Research Division, Strategic Research Planning Department (Takeda Pharmaceutical Company). Employment dates: April 1, 1984 – April 1, 2011.
- Takashi Nonoyama (Japan) (Takeda Pharmaceutical Company). Position: Associate Director, Pharmaceutical Research Division, Research Management Department, Planning and Development. Employment dates: April 1, 1971 – April 1, 2005.
- Mikihiro Obayashi (Japan) (Takeda Pharmaceutical Company). Position: Director, Pharmaceutical Development Division. Employment dates: April 1, 1965 – February 1, 2001.
- Katsuhisa Saito (Japan). Position: Senior Director, Pharmaceutical Development Division, Strategic Development Department (Takeda Pharmaceutical Company). Employment dates: March 11, 1966 – April 1, 2004.
- Tsuyoshi Suzuki (Japan). Position: Associate Director, Pharmaceutical Research Division, Drug Safety Research Laboratories (Takeda Pharmaceutical Company). Employment dates: April 1, 1972 – February 3, 2002.
- Kunio Takeda (Japan). Position: Representative Director, Chairman of the Board (Takeda Pharmaceutical Company). Employment dates: April 1, 1962 – June 25, 2009.
- Brad Beltramea (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: September 3, 2002 – April 27, 2005.

- Carlos Borda (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: March 26, 2001 – November 26, 2004.
- Crystal Bowers (U.S.). Position: Sales Representative Intern (Takeda Pharmaceuticals America). Employment dates: January 4, 2005 – June 27, 2005.
- Alberto Claire (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: October 25, 2004 – March 2, 2007.
- Tom Eckstein (U.S.). Position: Senior Sales Representative (Takeda Pharmaceuticals America). Employment dates: July 26, 1999 – May 20, 2005.
- Denise Evans (U.S.). Position: Senior Sales Representative (Takeda Pharmaceuticals America). Employment dates: September 18, 2000 – June 15, 2006.
- Vivian Fernandez (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: September 18, 2000 – April 30, 2007.
- Wayne Fussell, Jr. (U.S.). Position: Senior Sales Representative (Takeda Pharmaceuticals America). Employment dates: May 3, 1999 – May 16, 2005.
- Yisel Galban (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: September 22, 2003 – September 17, 2004.
- Dean Hart (U.S.). Position: Senior Vice President - Sales (Takeda Pharmaceuticals America, Takeda Pharmaceuticals U.S.A.). Employment dates: January 17, 2000 – February 10, 2006.
- Markus Herzig (U.S.). Position: Vice President – Regulatory Affairs and Quality Assurance (Takeda Americas Research & Development Center Princeton). Employment dates: unknown (probably before 2001).
- Doug Joseph (U.S.). Position: Senior Manager – Product Safety (Takeda Development Corporation Americas, Takeda Pharmaceuticals U.S.A.). Employment dates: November 30, 1999 – January 14, 2005.
- Mike Lopez (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: October 18, 2004 – April 14, 2006.
- Michele Maldonado (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: September 18, 2000 – April 29, 2002.
- Bruce McCarson (U.S.). Position: Senior Sales Representative (Takeda Pharmaceuticals America). Employment dates: August 31, 2000 – August 3, 2007.
- Natalie Medina (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: August 1, 2005 – June 30, 2007.

- Lindsay Nguyen (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: October 9, 2000 – June 3, 2003.
- Donna Nunez (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: October 10, 2005 – February 22, 2008.
- Linda Peters (U.S.). Position: Director – Regulatory Affairs (Takeda Pharmaceuticals U.S.A.). Employment dates: April 19, 1999 – May 3, 2002.
- Stephanie Rais (U.S.). Position: Consultant, Regulatory Affairs and Quality Assurance (Takeda Americas Research & Development Center (Princeton)). Employment dates: unknown (probably before 2001).
- Luis Reyes (U.S.). Position: Senior Sales Representative (Takeda Pharmaceuticals America). Employment dates: December 8, 2003 – November 17, 2006.
- Elliott (Vernon) Sampley (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: November 17, 2006 – April 23, 2007.
- Roberta Schneider (U.S.). Position: TAH Senior Administrative Assistant (Takeda Americas Research & Development Center (Princeton)). Employment dates: January 1, 1998 – December 31, 2000.
- Zac Taylor (U.S.). Position: Director – Regional Sales (Takeda Pharmaceuticals America, Takeda Pharmaceuticals U.S.A.). Employment dates: February 1, 1999 – August 1, 2005.
- John Yates (U.S.). Position: President (Takeda Global Research & Development). Employment dates: January 1, 2004 – January 17, 2007.
- Amy Yates (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: August 1, 2005 – June 30, 2006.
- Jennifer Siwiec (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: September 22, 2003 – July 28, 2005.
- Annette Biederbeck (Europe). Position: Director, Epidemiology (Takeda Global Research & Development Center (Europe) Ltd.). Employment dates: November 1, 2007 – January 16, 2010.
- Iain Cockburn (Europe). Position: Vice President – Pharmacovigilance (Takeda Europe Research & Development Center, Ltd.). Employment dates: December 12, 2005 – September 13, 2006.
- Lesley McBurney (U.S.). Position: Sales Representative (Takeda Pharmaceuticals America). Employment dates: January 7, 2002 – March 5, 2004.

- Philip Collett (Europe) Position: Vice President, Regulatory Affairs (Takeda Europe Research and Development Centre, Ltd.). Employment dates: August 1998 – August 21, 2008.
- David Eckland (Europe). Position: Managing Director (Takeda Europe Research and Development Centre Ltd). Employment dates: October 28, 1998 – April 29, 2005.
- David Roberts (Europe). Position: Director – EU Marketing (Takeda Pharmaceuticals Europe Ltd.) Employment dates: May 1, 2000 – March 31, 2007.
- Kimberly Farrell (U.S.) Position: Director of Sales Training/Development (Takeda Pharmaceuticals America). Employment Dates: January 7, 1999 – October 26, 2001.
- Tony Jones (U.S.). Position: Senior District Manager (Takeda Pharmaceuticals America). Employment dates: July 6, 1999 – April 27, 2005.
- Eric Whitley (U.S.). Position: District Manager (Takeda Pharmaceuticals America). Employment dates: April 19, 1999 – March 31, 2005.
- Tanna Wyatt (U.S.). Position: District Manager (Takeda Pharmaceuticals America). Employment dates: September 18, 2000 – October 4, 2005.³⁹

In the foregoing list, there are 9 former employees of Takeda Japan; 5 former employees of Takeda Europe; and 32 former employees of Takeda US; of the latter group, 12 are sales representatives.

The PSC seeks an order from this Court imposing sanctions upon Takeda *and* its counsel, for spoliation of the missing custodial files listed above.⁴⁰ The PSC argued the foregoing custodians, as well as other custodians whose documents were destroyed, were all individuals whose files, it is reasonable to assume based upon evidence presented, contained relevant information as to development and marketing of Actos®, and therefore, whose documents,

³⁹ Rec. Doc. 3245-1 (Exhibit A to Takeda Defendants' Supplemental Brief in Support of Their Motion for Protective Order). At trial, Takeda presented evidence that eight of these custodians left Takeda's employ before the 2002 Hold was issued. Trial Tr., vol. VII, at 850-55 (Rec. Doc. 4178). Though the point has the potential to be a good one, Takeda did not follow-up with information about the destruction of these eight witness files. In the absence of information about the file destruction, this Court has no basis for removing their names from the list of no-file custodians agreed-to by the parties.

⁴⁰ As noted above, this Court is ruling only upon the request for sanctions against Takeda (the Defendants in this matter). The request for sanctions against defense counsel remains specifically deferred.

electronic and otherwise, should reasonably have been expected to reflect information critical to the plaintiffs' cases, and the absence of which would prejudice the PSC. The PSC, therefore, has argued and presented further evidence to support their argument at trial, as will be discussed below, that the witnesses whose files were destroyed were not peripheral to the issues in this case, but rather, were at the heart of the corporate discussions about Actos®, its development and risks, and, specifically – and most importantly – the need to “manage” those risks. The PSC further argues that based on the small sample of documents that escaped destruction or were located in third party files, and of which the PSC has had benefit of review, this Court should find the missing evidence to have been of a nature favorable to the plaintiffs in this case, as it concerned knowledge about bladder cancer long before warnings were provided, and illustrates a conscious effort by Takeda to conceal and downplay such risks and the evidence supporting such risks, based upon the evidence and testimony presented by both parties, and this Court agrees.⁴¹ The PSC argues that Takeda's obligation to preserve evidence concerning Actos® arose no later than 2000, a year during which the company received *three* product liability claims concerning Actos®,⁴² however, this Court has made its determination upon the actual hold issued by Takeda in 2002 – at this juncture. The PSC further argued and presented evidence at trial that Takeda failed to preserve all potentially relevant evidence as required by law after that point in time, and that documents were destroyed intentionally, and in bad faith, and that the PSC was prejudiced

⁴¹ While this Court understands Takeda's emphasis on the number of pages of documents that it has produced in this case - some 33 million pages - the relevance to this Court of this large and impressive number is somewhat limited within the immediate context of this motion. Takeda's acknowledged enthusiasm in producing documents is, in the context of the Motion for Sanctions, somewhat mitigated by its widespread failure to preserve large swaths of Actos®-related documents generated and held by very high-ranking officials who, at trial, were shown to have been involved in the development and marketing of Actos®.

⁴² Exhibit 14 to the PSC's Memorandum in Support is Takeda's Verified Response to Plaintiffs' Discovery Requests Served September 23, 2013, as amended September 24, 2013, With Question 1A (cardiovascular claims began in June 2001 and liver claims began in December 2000) (Rec. Doc. 3484).

by the document destruction that occurred; again based upon the evidence and testimony presented by both sides, this Court agrees for the reasons given in Rec. Doc. 3933 and herein. The PSC requests this Court sanction Takeda by entering a default judgment; requiring the Plaintiffs to submit evidence of spoliation to the jury and instructing the jury that it is required to conclude that the missing documents would have benefitted the Plaintiffs and harmed the Defendants' position in this litigation; and to impose fines and/or cost-shifting sanctions upon Takeda.⁴³ The PSC further argued an order requiring Takeda only to restore the missing electronic files (and to bear the cost of doing so) is insufficient because it is not possible to confect a complete restoration of missing electronic documents and, moreover, there is no restoration potential for the paper documents destroyed by Takeda, and, again, based upon the evidence and testimony presented by both sides, this Court agrees, for the reasons given in Rec. Doc. 3933 and herein.

In response, Takeda argued and argues, that it had no obligation to preserve documents that might benefit any of the Plaintiffs in these proceedings until June, 2011, when the first claim asserting bladder cancer (the specific medical malady at issue in this MDL) was filed. However,

⁴³ The full request is as follows:

Plaintiffs seek a default judgment to reflect the extreme severity of the conduct that occurred here. In the alternative, Plaintiffs seek a combination of sanctions: cost-shifting to reimburse plaintiffs for the discovery that was necessary to ferret out Takeda's wrong-doing; a fine to punish and deter Takeda from the conduct evidenced here; and an adverse inference to correct at least some of the prejudice that Plaintiffs have suffered. In particular, Plaintiffs seek an adverse inference in the form of the following jury instruction:

'Evidence involving 46 witnesses was destroyed by Takeda. You are hereby instructed to presume that the destroyed evidence would have been adverse to Takeda's position in this litigation.'

Finally, in addition to these sanctions, Plaintiffs seek an order requiring Takeda to restore at their expense whatever of the missing files can be restored from its backup tapes so that at least some portion of the missing evidence can be recovered.

(Rec. Doc. 3484-1)

Takeda admitted facts at trial, through their Assistant General Litigation Counsel, Ms. Calahan's testimony, that render this argument without factual support, when she admitted the litigation hold put in place in 2002 was *a general product liability hold and was not limited to or by possible resultant medical maladies* and was issued in 2002.⁴⁴ Takeda had argued that it did not engage in spoliation because no document was destroyed after the obligation arose, much less did it engage in any bad faith or intentional destruction of potentially relevant documents. In opposing the Motion for Sanctions, Takeda included a number of arguments in its briefing which this Court will acknowledge, but will not address at length:

- Takeda argues that its knowledge of risks associated with Actos® did not give rise to a duty to engage in document preservation efforts. However, the PSC has made no argument suggesting that the mere knowledge that Actos® causes side effects could, should, or did (in this instance) trigger an obligation to preserve documents.
- Takeda argues that events occurring during the course of the scientific development of a product do not automatically give rise to a duty of preservation, nor create a reasonable anticipation of litigation. Again, the PSC has made no such argument.

Finally, Takeda argues that there is not sufficient evidence of spoliation, nor of bad faith or intent on its part, to justify any sanction, whatsoever. This Court finds the evidence to be to the contrary, as will be fully discussed herein.

D. Certain Relevant Chronology

Spoliation and possible consequence resulting therefrom, have been issues vigorously debated since Takeda's first revelation that files and documents had been destroyed. Thus, as early as May, 2013, this issue has been at the forefront and has remained at the forefront of discovery since May, 2013, and ultimately culminated in the PSC's formal motion for sanctions being filed on October 22, 2013. The issue dominated the parties' interaction with the magistrate judge and the magistrate judge's orders and *prima facie* finding, and thereafter, was the subject

⁴⁴ Trial Tr. vol. II, at 153-54 (Rec. Doc. 4173); vol. VI, at 727-31, 768-69 (Rec. Doc. 4177).

of a 50 page explanation by this Court at the pretrial conference held on January 15, 2014, and as noted, this Court issued its initial written Ruling on the Motion for Sanctions on January 27, 2014.⁴⁵ Thus, Takeda had full notice of the PSCs' allegations of spoliation, the magistrate judge's rulings as to the issue, and had full benefit of this Court's explanation of its view of the issue and forthcoming ruling – all well before trial began. In fact, on January 17, 2014, after the pretrial conference, *yet before the formal written ruling was filed*, Takeda filed a motion to amend its witnesses list to add Stacey Calahan to testify for Takeda as to spoliation.⁴⁶ Furthermore, at no time before trial began did Defendants, in any way, suggest they might be or would be prejudiced by the trial's beginning as scheduled, nor did they request a continuance. Consequently, jury selection in the first bellwether trial in this matter – *Allen v. Takeda Pharmaceuticals International, Inc., et al.*, Civil Action No. 6:12-cv-00064-RFD-PJH – began on January 27, 2014, however, opening statements and testimony were delayed to February 3, 2014.

It is this Court's ordinary practice – and would have been its preference in these proceedings – to have issued its formal written ruling on the Motion for Sanctions far earlier than January 27, 2014. However, the delay in issuing the formal written ruling was unavoidable under the circumstances, as will be discussed below. Nonetheless, the Court gave full notice of the Court's likely determination multiple times, but in greatest detail and fully on the record at the pretrial conference held January 15, 2014. Record of the pretrial conference establishes this Court's full statement as to its view of the law, factual findings of the Court, and likely result. This Court's explanation runs from page 7 to page 58 of the record of the pretrial conference. Armed with full notice the parties, with the aid of the Special Master, had chosen to engage in

⁴⁵ The Amended Ruling was filed three days later on January 30, 2014, only to correct typographical and other minor errors in the initial Ruling.

⁴⁶ Rec. Doc. 3879.

negotiations to reach an agreed-to resolution of the “spoliation issue.”⁴⁷ This Court consulted the Special Masters – who, in turn, discussed the plethora of filed motions with counsel – in order to establish a desired prioritization of the large number of motions, and was informed the parties, with the able assistance of Special Master Russo, believed it would be in their best interest, collectively, to negotiate in an attempt to reach an amicable resolution of the dispute presented in the Motion for Sanctions and, thus, the Court was informed that it would behoove the negotiating process greatly were the Court to agree to delay its consideration of, and formal ruling on, the Motion for Sanctions, in order to allow the parties a meaningful opportunity to reach an agreement. Consequently, this Court agreed to delay formal ruling on the PSC’s motion for sanctions and to direct its attention to the plethora of other motions and objections also pending and informed counsel, through Special Master Russo, that this Court’s attention would, therefore, not be directed to the Motion for Sanctions *until and unless the parties concluded that no agreement would be reached*. This Court received notice from Special Master Russo on January 10, 2014, that *the parties had concluded their negotiations and the parties had*, at that time, *agreed that there would be no amicable resolution of the dispute presented in the Motion for Sanctions*. Consequently, at that time, this Court turned its attention to issuance of the formal written ruling on the Motion for Sanctions.

Approximately one week later, on January 15, 2014, this Court conducted the pre-trial conference; counsel for both the Plaintiffs and the Defendants participated in person. This Court, aware that its ruling on the spoliation motion was going to affect how both parties presented their case at trial, and in order to remove any possible prejudice to any party, spent a great deal of time during the pre-trial conference providing counsel with a full oral description of the anticipated

⁴⁷ In the period of time that began September 6, 2013 and ended October 21, 2013, the parties filed over 40 Motions in Limine, 11 *Daubert* motions, two Summary Judgment motions, innumerable objections to video deposition excerpts.

ruling. As the record of the pretrial conference reflects, this Court's framing of the issue, identification of the applicable law, and description of the possible sanctions that it intended to impose on Takeda, was thorough, extensive, and gave counsel full notice of the scope and content of the ruling that would be issued, so that all counsel could – with full knowledge of the anticipated written ruling - prepare their cases accordingly. Consequently, as of that time, counsel for both parties knew: (1) that this Court intended to allow the Plaintiffs to present evidence to the jury of the spoliation,⁴⁸ and (2) that this court would give instruction to the jury at the conclusion of the trial based upon evidence presented at trial, and (3) the likely nature of that instruction, and (4) that this Court would rely on the testimony and evidence presented by the parties at trial to determine the nature of the instruction and any other sanction requested. This Court's discussion of this issue comprises some 50 (fifty) pages of the extensive pretrial conference transcript.⁴⁹

Therefore, counsel and both parties had not only notice of the allegations of spoliation, the magistrate judge's *prima facie* finding, the PSC's request for sanctions, well before the pretrial, but, also, full notice of the substance of the Court's soon to be issued written ruling, two weeks prior to jury selection. Moreover, *Takeda acted on this notice* by seeking leave of court, by motion dated January 17, 2014 (two days after the pre-trial conference) to amend its witness list to add Stacey Dixon Calahan as a witness *whose identified purpose was to address spoliation-related issues from Takeda's perspective.*⁵⁰ The written Ruling on the Motion was

⁴⁸ Transcript of Pretrial Conference at 52 (Rec. Doc. 3894).

⁴⁹ This Court's discussion of the spoliation motion and its ruling comprises approximately 50 pages of the *Transcript of Proceedings (Pre-Trial Conference)* (January 15, 2014). See discussion at 7-58 (Rec. Doc. 3894).

⁵⁰ See Takeda Defendants' Opposed Motion for Leave to Amend Second Amended Scheduling Order Pilot Bellwether Program (First Trial) to Permit Addition of One Will-Call Witness (Rec. Doc. 3879).

formally issued shortly thereafter,⁵¹ and the matter proceeded to trial. Again, at no time prior to the trial did either party communicate to this Court any indication, of any nature, whatsoever, that they required more time to prepare for trial or desired a continuance; rather each side moved forward with trial preparation, presented for trial, and trial began.

Nonetheless, on several occasions during the trial, counsel for Takeda made statements implying they felt they had not had sufficient opportunity to adjust their trial strategy after this Court's ruling on the Motion for Sanctions. However, as illustrated above, spoliation had been an early and consistent issue argued by Plaintiffs, the magistrate judge had found the PSC had made a *prima facie* showing of spoliation, thus, the specter of spoliation had long haunted Takeda, even before the PSC filed its motion for sanctions. Takeda had full knowledge of the magistrate judge's rulings on this issue well before the pretrial conference, and had full knowledge of this Court's determinations as of the pretrial conference, and, had benefit of the actual written ruling before trial. Furthermore, again, it cannot be stressed enough, at no time did Defendants give the Court notice (in writing or otherwise) that counsel felt ill-prepared to respond to the spoliation issue at trial, indeed, counsel of Defendants did not inform the Court of any such concerns in any fashion prior to the commencement of trial. This Court points out the testimony and evidence concerning spoliation *is and was, also, relevant to the question of punitive damages, also put before the jury*, and, thus, such testimony and evidence, always, should have been anticipated. However, notwithstanding the clear and likely complete overlap of the two issues - spoliation and punitive damages - this Court, nonetheless, would have felt compelled to allow the Defendants, at least, the opportunity to argue prejudice, had they given any indication of prejudice before commencement of trial. However, in the absence of any such notice, of any kind, prior to trial or of a motion for continuance (or any other signal from

⁵¹ Rec. Doc. 3933.

counsel), and given the obvious overlap of the evidence required to support the two issues, spoliation and punitive damages, the Defendants' silence gave this Court no ability to understand, perceive, or address, prior to trial, that which counsel suggested as asides, during trial. Additionally, this Court finds Takeda's conduct did much to contribute to the delay obliquely complained of at trial, thus, any such oblique suggestion made by Defendant's counsel during trial is without merit.

Therefore, the trial commenced as scheduled and as foreshadowed by this Court in the initial and Amended Ruling, this Court and the jury heard the spoliation-related evidence presented at trial and, based upon that evidence, this Court gave the following instruction to the jury and the jury made its determinations:

Now, additionally, ladies and gentlemen, in this case you have heard certain evidence from both parties about certain documents and files that were destroyed by Takeda. I will now discuss with you the relevance of that evidence.

In general, companies often have policies to retain or destroy documents that are no longer current. These are called "document retention" policies. These policies permit the destruction of documents that the companies no longer need and that they do not have an obligation to maintain. Now, when a party develops, or should develop, a reasonable expectation that it might engage in litigation on a particular matter or issue, however, the law imposes an obligation for companies to keep and maintain all documents and evidence in its possession, or that might come into its possession, or that might be generated by that company that relate to that matter or issue.

Now, in this case, I instruct you that I have considered the evidence and I have determined Takeda, including the Takeda companies in America, the Takeda companies in Europe, and the Takeda company in Japan, had a duty to retain documents and files pertaining to their product, Actos. I instruct you, therefore, the Takeda companies in America and the Takeda company in Japan had a duty to retain documents and files pertaining to their product, Actos, as of July of 2002. The Takeda company in Europe had a duty to retain files and documents relating to their product, Actos, as of 2006.

Therefore, I further instruct you Takeda was legally obligated, no later than July of 2002 in America and Japan, to retain all information, files, and documents related to their product, Actos, and the Takeda companies in Europe were legally obligated to retain all information, files, and documents related to their product,

Actos, as of 2006; so that those documents and files would be available within the litigation process and to the plaintiffs in this case. I instruct you that many of the files and documents were destroyed after the Takeda companies had the legal obligation to retain them. You have heard evidence those files and documents were on the computers of certain employees, including certain key Takeda executives whose positions would have placed them within a stream of information or in a decision making position as to Actos, it's [sic] development, testing, or marketing within the respective Takeda companies. You have also heard evidence that certain employees, including certain key executives' computers' hard drives were erased and/or the documents and information on those computers were destroyed. I instruct you that many of those files and documents cannot be restored or reconstructed.

Now, the destruction or significant alteration of evidence or the failure to preserve property once the obligation arises to preserve such evidence is known as "spoliation" of evidence. I instruct you I have concluded that spoliation occurred in this case.

Because the majority of the documents and information initially destroyed was not available within the litigation process and to the plaintiffs in this case, we cannot know for sure whether the documents, if they had not been destroyed, would have helped plaintiffs prove their case against the defendants or not. However, because this Court has found Takeda destroyed documents and files in a manner such and at a time after they had an obligation to retain those documents and files, I instruct you that you are free to infer those documents and files would have been helpful to the plaintiffs or detrimental to Takeda, if you feel the evidence you have heard supports that inference.⁵²

This Court now completes its consideration of the PSC's request for sanctions against Takeda and adds factual and legal support for the instruction given, and sanctions now imposed.

III. FACTUAL BACKGROUND

This Court gave a full discussion of its factual finding in its initial ruling (Rec. Doc. 3933) and reminds the reader this Court adopts those findings herein. Consequently, this Court supplements those factual findings as follows:

A. Actos® and Takeda

It is undisputed Actos® – the brand name given by Takeda to pioglitazone – is used to

⁵² See Transcript, Rec. Doc. 4210, at 6276:20-6279:5.

treat diabetes. It has been on the market since 1999. During the 1980's and the 1990's, Takeda partnered with Upjohn during the development of Actos®; that partnership ended in 1993.⁵³ Approximately five years later, Takeda entered a co-promotion agreement with Eli Lilly & Company ("Lilly") for the purpose of marketing Actos® in the United States. Eli Lilly and Company is a named Defendant in the MDL suits, however, is not at issue in this motion.

The PSC has presented evidence which paints a picture of a company, who from the cessation of the Upjohn association; through each level of testing; and into its interplay with the governing regulatory agencies, along with its covert marketing techniques, exhibited a consistent pattern of conduct designed to obfuscate and conceal the potential health issues of its highly financially profitable product, Actos®, to protect that product and the billions of dollars it represented to the company from damage, whether by way of peer review within the medical community or adverse regulatory action, or more directly relevant here, product's liability litigation. The sheer volume of evidence presented by the PSC and Mr. and Mrs. Allen to support and establish this argument and pattern of conduct prohibits this Court from enumerating that evidence here. However, this Court notes, only by way of illustration, evidence of Takeda's blurring of the lines between marketing and science; its use of ghost writing in medical journals; its internal structure for marketing by seemingly impartial physicians; its obfuscation when reporting of test results; its disregard and manipulation of longstanding and customary scientific research protocol in its oft heralded ProActive study; its marked shift of position as to the possible dual P-PAR nature of Actos®; its sales representatives' documented refusal to inform doctors of potential risks of bladder cancer; and perhaps most distressing, the consistency of Takeda's conduct from the first indication of a possible association between Actos® and bladder

⁵³ See Exhibit 22 to PSC's Memorandum in Support (Rec. Doc. 3484-3).

cancer, throughout Takeda's entire history with Actos®. While it's not for this Court to judge Takeda's corporate conduct as a whole – the jury has done that – it is for this Court to determine whether Takeda acted with intent and bad faith when it deleted and destroyed the files of key Takeda employees intimately involved with the development of Actos® - from the inception of that development and forward.

Within that inquiry, Takeda's history and overall conduct in the development, regulation and marketing of Actos® is relevant when attempting to discern Takeda's motivation, intent and possible culpable state of mind when deleting and destroying files of key Takeda employees once Takeda had a reasonable anticipation of product's liability litigation and in the face of a valid litigation hold. And this Court finds, after, also, now having heard all evidence and argument put forth in an almost three month trial, that Takeda acted with deliberate intent and with focused purpose to eliminate evidence of the potential health risks of Actos®. Evidence of Takeda's history and pattern of corporate conduct designed to conceal, downplay, and obfuscate the evidence of those potential risks included the deletion of key Takeda employee's files, and extended to conduct designed to conceal that intent and conduct, even up to and within Takeda's conduct within this MDL, perhaps most graphically illustrated by Takeda's conduct as to the 2002 Hold.

B. The 2002 Hold

Takeda began receiving product liability *claims* concerning Actos® in July, 2000, and settled many of those claims before lawsuits were filed.⁵⁴ The first time certain Takeda entities were named as defendants in a product liability personal injury *lawsuit* was in July, 2002.⁵⁵

⁵⁴ See Takeda's Response to Plaintiffs' Supplemental Interrogatory 2, Exhibit A, which is attached as Exhibit 6 to the PSC's Memorandum in Support (Rec. Doc. 3484-2).

⁵⁵ Id.

According to Takeda, the specific entities named as defendants in the July, 2002 lawsuit were TPNA, TPA, and Takeda Japan.⁵⁶ In response to being named as defendants, the Takeda entity located in the country where suit was filed – i.e. the United States - issued a broadly-worded **General Product Liability Litigation Hold** (the “2002 Hold”). The **2002 Hold**, issued July 19, 2002 reads:

A motion has been filed to add Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. as defendants in a lawsuit. **The plaintiff in this lawsuit seeks damages for personal injury and wrongful death allegedly resulting from the use of certain prescription drugs, including Actos®.**

To be able to respond to discovery requests from the plaintiff, if that becomes necessary, we must take steps to preserve any documents that may be called for in this lawsuit.

Until further notice, you are instructed to preserve any and all documents and electronic data which discuss, mention, or relate to Actos®. This means do not destroy, delete, throw away or otherwise discard any such documents or electronic data. This includes correspondence, records, and data, contained in your paper and electronic files, regardless of form and including email correspondence and attachments and electronic data.

Action Steps:

Please interpret this directive in its broadest sense to prevent the deletion or destruction of any recorded information and data relating in any way to Actos®.

Please take steps immediately to preserve such documents and data within your department.

Please distribute this memo to members of your group and advise

⁵⁶ *Id.* Apparently contrary to this assertion by Takeda is *another* assertion by Takeda – this one by Stacey Calahan – that the 2002 lawsuit named two Takeda U.S. companies as defendants. *See* Calahan Declaration, at ¶ 12 (attached as Exhibit 3 to Opposition, Rec. Doc. 3530). Inasmuch as the possible conflict is only apparent – Ms. Calahan does not actively assert that Takeda Japan was not named in the 2002 lawsuit – Ms. Calahan testified she was not working at any Takeda entity until 2007 - this Court accepts the representation made by Takeda subject to FED.R.CIV.P. 11, in Exhibit 6 (attached to Plaintiffs’ motion for sanctions, Rec. Doc. 3484), as truthful and complete.

them of the importance of following these instructions.⁵⁷ (emphasis added)

By contrast – and despite having been given notice of the 2002 Hold and having been named as a defendant in the product liability personal injury lawsuit in 2002 – Takeda Japan did not comply with the 2002 Hold and only in 2011 issued another product liability personal injury litigation hold as to Actos® in Japan, on September 2, 2011.⁵⁸ Takeda has acknowledged TPC (Takeda Japan) *was aware through their employees of the 2002 Litigation Hold at the time of initial dissemination. Takeda U.S. had notified three employees of Takeda Japan – Saburo “Sam” Hamanaka, Teruyuki “Terry” Fukumoto, and Masatake Kashiya – of the 2002 Litigation Hold on or about July 19, 2002.*⁵⁹ Additionally, it is now clear that, although Takeda and Ms. Calahan, initially, did not acknowledge that Takeda Japan had been named as a defendant in the 2002 lawsuit; clearly, Takeda now acknowledges that TCI (n/k/a TPC) was named in that lawsuit. *See* Calahan Declaration at ¶ 12 (attached as Exhibit 3 to Opposition, Rec. Doc. 3530) and Exhibit 6 (attached to Plaintiffs’ motion for sanctions, Rec. Doc. 3484). Takeda further admits *the 2006 “refresher” of the 2002 Litigation Hold was made accessible to the European Takeda entities* through a Takeda company intranet site in April or May of 2006.⁶⁰

⁵⁷ See 2002 Litigation Hold, attached as Exhibit 13 to the Motion for Sanctions (Rec. Doc. 3484).

⁵⁸ Takeda’s Answer to Question 6(b). See Takeda’s Verified Response to Plaintiffs’ Discovery Requests served September 23, 2013, as amended September 24, 2013, with Question 1A (attached as Exhibit 14 to PSC’s Memorandum in Support)(Rec. Doc. 3484). See also Calahan Declaration, ¶ 14 (attached as Exhibit 3 to Opposition)(Rec. Doc. 3530).

⁵⁹ See “Takeda’s Verified Response to Plaintiffs’ Discovery Requests Served September 23, 2013, as Amended September 24, 2013, With Question 1A,” attached as Exhibit 14 to the Motion for Sanctions, at 2 (Rec. Doc. 3484).

⁶⁰ See “Takeda’s Verified Response to Plaintiffs’ Discovery Requests served September 23, 2013, as Amended September 24, 2013, with Question 1A” attached as Exhibit 14 to the Motion for Sanctions, at 3 (Rec. Doc. 3484), as follows.

1A a. On what date did TGRD EU or any of the European Takeda entities first become aware of the July 19, 2002 legal hold?

ANSWER: Takeda does not have a specific date when TGRD Europe (now known as

Thus, not only were Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. aware of and, as entities involved in the development and marketing of Actos®, subject to the broad hold put in place in 2002, TPC (Japan) was, also, made aware of the actual 2002 Hold issued.

Thus, the PSC established that – despite having received notice of the 2002 Hold, having been named in a lawsuit in 2002, and having been intimately involved within the development and marketing of Actos® – TPC, i.e. “Takeda Japan” failed to honor its legal obligations to preserve documents – a finding this Court will further discuss below. No credible explanation has been provided by Takeda for this failure. Takeda’s Assistant General Litigation Counsel, Stacey Calahan, who was designated by Takeda to testify as to these issues at trial, testified upon examination by the PSC that the 2002 Hold would have applied to cases of bladder cancer; it was established in 2002. The PSC put forth evidence to establish the 2002 Hold would have applied to “Takeda Japan” as well; that Takeda Japan was the primary developer and marketer of Actos®. Evidence also was presented Takeda Japan had, also, been named in the product liability lawsuit alleging personal injury from the use of Actos® in 2002,⁶¹ which spawned the 2002 Hold, thus, granting Takeda Japan a reasonable anticipation of products liability litigation –

Takeda Development Centre Europe, Ltd.) or the European Takeda Entities first became aware. TGRD Europe had access to the July 19, 2002 legal hold, in the form of the 2006 refresh notice, when the 2006 refresh notice was posted to Takeda’s Horizon intranet site in April or May 2006. To the best of Takeda’s knowledge and belief, no other European Takeda entity was aware of the July 19, 2002 legal hold before then.

The PSC has suggested the February 2010 “refresh” of the 2002 Litigation Hold was implemented after, and because of, the September 2010 bladder cancer “claim” (not a lawsuit), however, it is evident from Mr. Regard’s testimony that Takeda has attempted to distance itself from this notion, suggesting the February 2011 “refresh” was implemented “because it had been so long since a refresh had been issued.” See Deposition of Mr. Regard, Exhibit 8 at 680-81 (Rec. Doc. 3484).

⁶¹ See Takeda’s Response to Plaintiffs’ Supplemental Interrogatory 2, Exhibit A, which is attached as Exhibit 6 to PSC’s Memorandum in Support. (Rec. Doc. 3484). Although Calahan does not acknowledge that Takeda Japan was named as a defendant in 2002, Calahan did not begin working at Takeda until 2007. Exhibit 6 clearly identifies Takeda Japan was sued in 2002.

the language referenced in the 2002 Hold – as to Actos®, at least as of 2002. The PSC also proved Takeda Japan had knowledge and understanding of their legal obligations and of the possible consequence of violating litigation holds in the United States, as was illustrated by the litigation hold instituted as to earlier patent litigation concerning Actos®, which is undisputed to have applied to Takeda Japan.⁶² Consequently, this Court supplements its finding with the evidence presented by the PSC at trial that Takeda Japan was subject to the 2002 product liability Hold and had a reasonable anticipation of litigation as to product liability claims arising out of the use of Actos® at least as of 2002. Ms. Calahan’s testimony, also, supports this Court’s conclusion the 2002 general Actos® general products liability hold was “refreshed” several times over the relevant time period, September 17, 2003, May 4, 2006, October 22, 2007, January 14, 2008, and February 15, 2011.⁶³

Although the 2002 Hold was issued in response to a product liability lawsuit asserting that plaintiff had suffered liver damage, Takeda, through its Assistant General Litigation Counsel, Stacey Calahan, admitted at trial, the intentionally-broad scope of the **2002 Hold would have covered all maladies, including bladder cancer and thus, should have resulted in the immediate cessation of all destruction of documents related to Actos®, irrespective of the type of side effect alleged.**⁶⁴ *This admission by Takeda’s Assistant General Litigation Counsel is in direct contradiction to Takeda’s arguments made to this Court within discovery and the motion practice.*

Ms. Calahan’s further testimony established that **since 2000**, Takeda had received

⁶² Trial Tr. vol. V, at 549-53 (Rec. Doc. 4176).

⁶³ See “Declaration of Stacey Dixon Calahan,” attached as Exhibit 3 to Opposition, Rec. Doc. 3530, at ¶13.

⁶⁴ Trial Tr. vol. II, at 153-54 (Rec. Doc. 4173); vol. VI, at 727-31, 768-69 (Rec. Doc. 4177).

product liability *claims* asserting that Actos® had caused the following injuries: elevated liver enzymes, hepatitis, jaundice, abnormal liver function, congestive heart failure, neuropathy, liver failure and death, edema, weight gain, fatigue, weakness, shortness of breath, stomach problems, syncope, myocardial infarction, hypo-pigmentation, tooth abscess/loss, burning hands, blackout, impaired urination, pancreatic cancer, heart attack, renal failure, *as well as bladder cancer*. Ms. Calahan admitted and the holds, themselves, establish no *injury-specific hold* was ever issued by Takeda (on any continent) for any one of these Actos®-related health claims, rather by its own language, a *general product liability hold* was issued in 2002 for “personal injury and wrongful death” as to Actos®, i.e. a *product specific Hold* and it was that Hold which was refreshed multiple times. Thus, notwithstanding Takeda’s argument to the contrary, the evidence and testimony establishes that *no malady specific hold* was ever imposed.⁶⁵ Moreover, the 2002 products’ liability Hold was “refreshed” over time and remains in effect today, even though the litigation that prompted the issuance of the Hold was resolved long ago.⁶⁶ Thus, Takeda’s argument to the contrary is in no way supported by the facts in evidence, or their own Assistant General Litigation Counsel’s testimony given at trial.⁶⁷

Again, although Takeda has over the course of discovery and motion practice taken positions in direct contradiction to these facts, Takeda ultimately admitted the inescapable reality of these factual findings through the trial testimony of Takeda’s Assistant General Litigation Counsel, Ms. Calahan, who Takeda had selected as their witness to testify as to spoliation and who, also, is one of Takeda’s in house counsel in charge of this litigation. Takeda’s convoluted and contradictory path traveled through the positions Takeda took in discovery; and continuing

⁶⁵ Regard Deposition, at 675.

⁶⁶ Trial Tr. vol. II, at 146, 152 (Rec. Doc. 4173).

⁶⁷ Trial Tr. vol. II, at 153-54 (Rec. Doc. 4173); vol. VI, at 727-31, 768-69 (Rec. Doc. 4177).

into its positions taken by Takeda with this Court by way of motion practice, and culminating in the glaring contradiction between Takeda's positions taken, with the language of the holds themselves, when judged against Takeda's own Assistant General Litigation Counsel, Ms. Calahan, is further support for a finding Takeda, the corporate entity, engaged in spoliation, and Takeda, the corporate entity, attempted to conceal that conduct. These determinations further support this Court's determination to allow the evidence of spoliation to go to the jury; this Court's decision as to the jury instruction given; and, also, the sanctions now imposed. These determinations will be further discussed below.

IV. APPLICABLE LAW

This Court gave a full discussion of the applicable law as to FED.R.CIV.P. 37, spoliation and sanctions, in general, and the Fifth Circuit jurisprudence on this issue in its initial ruling and adopts and incorporates that discussion herein and thus, will not reiterate that full discussion. Rather, this Court, in this writing, focuses primarily on the deferred questions of bad faith and allowable sanctions.

The common law spoliation doctrine, its nuances and application – along with the duties it imposes on both litigants and prospective litigants, and the ramifications for failing to comply with its requirements – is in a state of development and flux throughout the nation, primarily triggered and fueled by the radical technological developments in information creation, storage, and sharing, none of which could have been imagined when the applicable Federal Rules of Civil Procedure were first contemplated. The internet, cloud, and computer programs, all are profoundly impacting discovery, its costs and management, particularly as businesses continue to change their manner and method of communicating; their creation and storage of information and documents, and their abilities to retain and delete that information at the touch of a button.

This technology continues to evolve at such a rapid pace it has far outreached the existing applicable law, both jurisprudential and statutory. The questions and inquiry of whether a party deliberately destroyed an alleged defective widget are quite different from those inherent in whether and how one might have failed to manage and maintain hard copies resting in a filing cabinet, which are quite different from those inherent in whether, or how, one might have failed to omit from the ordinary course of deletion, documents found only on a hard drive and, likely, will be quite different from those inherent in the question of whether or how document information existing only in the virtual reality of “the [a] cloud” or the next inevitable technological advance, was retained or eliminated. However, at the core of all such inquiries is, and will remain, the fundamental questions of what information is generated; how that information is stored; whether there was or should have been a legal obligation to retain that information; and if so, whether that legal obligation was honored; and, if not, why not; and ultimately, whether prejudice actually flows from that failure and how one goes about proving prejudice from the absence of information. The ever expanding universe of available information and documents possibly subject to discovery, and the ever expanding ways that information and those documents can be created, stored, transmitted, retained and omitted, and, in fact, perhaps exist in an ever more “virtual” world of information, would have been inconceivable only a few decades ago, however, have at their core certain common inquiries. The Fifth Circuit has not had the opportunity to consider these dramatic technological changes and their effects, if any, on the doctrines governing destruction of more tangible evidence, which, often by their nature, were not subject to sophisticated storage and “retention policies,” when determining application of these principles in this Circuit.⁶⁸ Therefore, this Court’s analysis will

⁶⁸ See, also, Consolidated Aluminum Corporation v. ALCOA, Inc., 244 F.R.D. 335 (M.D.La. 7/19/2006) (Noland, M.J.) (“Neither the Fifth Circuit Court of Appeal nor any district court within the Fifth Circuit has had the

address both longstanding jurisprudence, as well as the persuasive guidance found in opinions issued by its sister courts both in the Fifth Circuit and its sister Circuits, addressing the specific and unique interplay between information storage and destruction and the ever evolving technology as that interplay relates to the judicial process.

A. Spoliation

Again, this Court notes, spoliation is the intentional destruction, mutilation, alteration or concealment of evidence.⁶⁹ Spoliation of evidence, in this instance, *is an evidentiary question* grounded within a discovery dispute, and thus, in federal diversity cases such as the Allen case, this Court must *apply federal law* to the issue of discovery abuse, rather than state law.⁷⁰

This Court, again, notes and clarifies that the law of spoliation and sanctions as to electronically generated and stored information, is an area of the law that, to date, primarily, has grown out of certain general principles set forth in *The Sedona Principles: Best Practices, Recommendations & Principles for Addressing Electronic Document Discovery* (Sedona Conference Working Group Series 2003 and Second Edition 2007), which, primarily, addresses the handling of electronic evidence⁷¹ and has been incorporated to some degree within the Zubulake decisions from the Southern District of New York.

As a general matter, the PSC had the burden of proving the following loose elements in order to demonstrate that spoliation occurred in this matter (as opposed to what, if any, sanction

opportunity to directly address the standards for preservation of electronic evidence and applicable sanctions where such evidence has been spoliated. The court must therefore look to persuasive authority from other jurisdictions in deciding the present motion. The cases which have been recognized as setting the bench mark standards for modern discovery and evidence-preservation issues are the series of Zubulake decisions out of the Southern District of New York.”).

⁶⁹ Black’s Law Dictionary (9th ed. 2009).

⁷⁰ Condrey v. SunTrust Bank of Georgia, 431 F.3d 191, 203 (5th Cir. 2005), *citing* King v. Illinois Cent. R., 337 F.3d 550, 556 (5th Cir. 2003).

⁷¹ The PSC alleges the loss or destruction of paper documents, as well as electronic evidence.

should flow from a finding spoliation occurred.):

- there existed a duty to preserve the evidence due to litigation or the reasonable expectation of litigation;
- evidence was destroyed (or concealed) in violation of the preservation obligation;
- the destruction was intentional (rather than inadvertent);
- the destroyed evidence was relevant; and
- the unavailability of the destroyed evidence resulted in prejudice.

B. Sanctions

Within the analysis of spoliation, as an evidentiary matter, when the relevant conduct is not readily addressed by FED.R.CIV.P. 37, the Courts rely upon the inherent powers of the Court to govern their actions as to sanctions. Due to the self-evident apparent risks associated with the exercise of inherent powers by a Court, both the United States Supreme Court and the Fifth Circuit are clear, a Court should not impose *the nature of sanctions requested by the PSC*, unless there has been a specific finding of bad faith on the part of the person or entity against whom sanctions are being considered. See Roadway Express, Inc. v. Piper, 447 U.S. 752, 767, 100 S.Ct. 2455, 2465, 65 L.Ed.2d. 488 (1980) (“Similarly, the trial court did not make a specific finding as to whether *counsel’s* conduct in this case constituted or was tantamount to bad faith, a finding that would have to precede any sanction under the court’s inherent powers.”); Pressey v. Patterson, 898 F.2d 1018, 1021 (5th Cir. 1990) (“The trial court’s discretion to impose sanctions under its inherent power is even more limited. We have confined sanctions under the district court’s inherent power to *instances of bad faith or willful abuse of the judicial process*. We have also noted that in the context of the federal court’s inherent power, ‘bad faith’ is judged by ‘necessarily stringent’ standards.”); Toon v. Wackenhut Corrections Corporation, 250 F.3d 950,

952 (5th Cir. 2001)(emphasis added)(“The threshold for the use of the inherent power to impose sanctions is high. The court must make a specific finding of bad faith.”)

V. ANALYSIS AND DISCUSSION

This Court, in its initial ruling, noted the distinctions between FED. R. CIV. P. 37 and the jurisprudence surrounding the PSC’s claim of spoliation – the former usually not requiring a showing of bad faith or willful abuse of the judicial process for sanctions to be imposed when violated, the latter when grounded within the inherent powers, more often requiring a showing of bad faith or willful abuse of the judicial process for the type of sanctions requested by the PSC to flow. The former is more often directed to *attorney conduct*, but, also, embraces *party conduct*; the latter, more often embracing *party conduct*; the former, more often addressing conduct once the parties are before the Court by way of litigation, the latter, more often addressing conduct occurring before the parties are formally before the Court. However, the distinctions are not hard and fast rules.

Indeed, the facts of this matter act to blur these suggested distinctions. This Court finds for the reasons given in its preliminary ruling, and for reasons given in this ruling, as well as the evidence presented at trial, that Takeda, *the party*, engaged in conduct designed to hide certain information relevant to the risks of, development of, and marketing of its product Actos® that would be relevant to litigation surrounding the use of Actos® and to hide its conduct relevant to that destruction and deletion of files. Takeda’s conduct *both* preceded filing of suit in the Allen case – and any MDL suit – *and, also, continued* after the filing of the Allen suit, or the first filing among the MDL cases, and, also, continued into and through general discovery, motion practice, and the Allen trial. Additionally, certain of the noted conduct, but certainly not all, was presented to the Court by way of Takeda’s agents within the MDL litigation, i.e. Takeda’s

counsel. As noted, this Court has and continues to defer ruling on the PSC's allegations that Takeda's enrolled counsel – as distinct from Takeda's in-house counsel or Takeda as a corporate entity – violated FED.R.CIV.P. 37. Thus, this Court's focus, at this juncture, is Takeda's, as a corporate entity, alleged violations of FED.R.CIV.P. 37 and the jurisprudence surrounding the PSC's claim of spoliation and sanctions.

This Court found and finds the evidence the PSC presented both pretrial, as well as that presented during trial, has established Takeda violated both FED.R.CIV.P. 37 and engaged in bad faith destruction of files and documents. Takeda's conduct spanned both the period well before litigation was filed in any MDL case, and before the Allen case was filed, extended into the period after the first filing in this MDL and the Allen case, and continued through discovery and motion practice in the MDL, and into the first bellwether trial, the Allen case. Full reasons for this determination follow below.

In its prior ruling, this Court addressed that which was required in order to find spoliation had occurred and made certain initial findings as to each aspect required and adopts that discussion herein. Based upon full review of all evidence and argument presented by both parties at trial, this Court reiterates, and expands upon those factual findings and its determinations made.

The parties are in agreement that a duty to preserve litigation-related documents arises when litigation is filed or when a party reasonably anticipates litigation will be filed.⁷² The evidence establishes, both Takeda U.S. and Takeda Japan were sued in 2002 on products liability

⁷² See Trial Tr. vol. II, 160 (Rec. Doc. 4173). As noted above, both Takeda U.S. and Takeda Japan were named in a lawsuit in July 2002, clearly triggering a duty to preserve product liability-related documents on the part of both companies, and a products liability Hold was issued by Takeda U.S. in 2002. See Takeda's Response to Plaintiffs' Supplemental Interrogatory 2, Exhibit A, which is attached as Exhibit 6 to PSC's Memorandum in Support. (Rec. Doc. 3484). Although Calahan does not acknowledge that Takeda Japan was named as a defendant in 2002, Exhibit 6 clearly asserts that it was.

suits as to Actos®; a products liability hold was issued by Takeda U.S. in 2002; Takeda Japan had notice of that hold.⁷³ Thus, a litigation hold, which Takeda's Assistant General Litigation Counsel, Ms. Calahan, admits would have been applicable to bladder cancer claims, was issued by Takeda [U.S.] in 2002 and this Court has found both Takeda U.S. and Takeda Japan were subject to that hold – having been given notice of the hold and having been named in that suit. Thus, Takeda U.S. was bound by the Hold issued in 2002; Takeda Japan was bound by the 2002 Hold – and this Court now finds Takeda Japan had a reasonable anticipation of litigation for personal injury and death arising out of use of its product Actos® once it was sued in 2002; and Takeda Europe was bound by that Hold, at least, as of 2006 – therefore, Takeda had the legal obligation to retain documents relating to Actos® since 2002⁷⁴ (2006 in Europe) and all failed to do so. Evidence, including Assistant General Litigation Counsel, Stacey Calahan's testimony, clearly establishes Takeda U.S. and Takeda Japan failed to retain files covered by the 2002 Hold, furthermore, evidence establishes Takeda Japan made no effort to comply with its legal obligation to preserve evidence relevant to its product, Actos®, and Takeda U.S. gave only lip service to its legal obligations.

Again, the evidence established Takeda U.S. did not comply with its obligation to preserve Actos®-related documents; there was no evidence presented that Takeda Japan made any effort, whatsoever, to comply with its preservation duty prior to filing of this litigation and the Allen suit in particular; and evidence was presented supporting a finding that Takeda, in an effort to avoid the consequences of their actions enacted well before suit was filed, engaged in

⁷³ See "Takeda's Verified Response to Plaintiffs' Discovery Requests Served September 23, 2013, as Amended September 24, 2013, With Question 1A," attached as Exhibit 14 to the Motion for Sanctions, at p. 2 (Rec. Doc. 3484).

⁷⁴ Trial Tr. vol. III, at 247, 269 (Rec. Doc. 4174)

conduct to obfuscate and hide that failing, as was discussed in this Court's preliminary ruling, as well as, in this ruling, above.

Takeda primarily and repeatedly argued within discovery and motion practice that *it owed no duty to preserve documents associated with "bladder cancer" litigation prior to the summer of 2011*, arguing only then could Takeda have *reasonably* anticipated bladder cancer litigation. However, by example only, the evidence and testimony presented at trial wholly undercuts this argument. The factual basis for this argument is wholly contradicted by, not only, the clear language of the holds themselves as discussed in this Court's initial ruling - Rec. Doc. 3933 – but also, by the trial testimony of Takeda's Assistant General Litigation Counsel, Stacey Calahan, given upon examination by counsel for the PSC and Mr. and Mrs. Allen.⁷⁵

A. General Discussion

This Court will, at this juncture, address certain of Takeda's argument made within this litigation and at trial. Takeda argued to this Court it was not aware of bladder cancer litigation associated with Actos® until the filing of the first actual bladder cancer lawsuit in July 2011, and thus, Takeda argued it had no duty to preserve documents relating to Actos® and *bladder cancer* until 2011. However, the foregoing argument was fully undercut by the facts established by discovery and more so by the facts presented at trial, not the least of which is the testimony of their own in-house counsel, Ms. Calahan, complemented by the inescapable fact Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. *chose to institute a general product liability litigation hold, sweeping in its scope and breadth, and containing no such limitation to or identification of a particular malady, in 2002*. The 2002 Litigation Hold is, by its own language, general in nature and specifically instructs it is to be

⁷⁵ Trial Tr. vol. II, at 153-54 (Rec. Doc. 4173); vol. VI, at 727-31, 768-69 (Rec. Doc. 4177).

broadly interpreted to encompass “**any and all documents and electronic data which discuss, mention, or relate to Actos®;**” **no mention of any specific malady is found in the language of the Hold.**⁷⁶ Upon examination, Takeda’s Assistant General Litigation Counsel, Stacey Calahan, ultimately *admitted Takeda’s own language in no way limited the hold to, or referenced in any fashion, one specific malady above any other; rather, admitted the scope was and is defined as that “which discuss, mention, or relate to Actos®” and the language used specifically instructs the hold . . . to be interpreted “in its broadest sense.”* Indeed, **Takeda’s Assistant General Litigation Counsel**, Ms. Calahan, upon examination, ultimately **admitted the 2002 Litigation Hold in no way limits the hold to documents relating to liver injuries, as was initially argued by Takeda, but rather, keys to the involved drug, i.e. Actos®, and admitted that the Hold uses broad and inclusive language and instructs Takeda’s employees to preserve all documents relating to Actos® - not relating to Actos® and liver cancer as argued by Takeda to this Court in discovery and motion.** Takeda’s Assistant General Litigation Counsel, Ms. Calahan, also, admitted the 2002 Litigation Hold has not been lifted, and indeed has been “refreshed” at least five times, i.e. on September 17, 2003, May 4, 2006, October 22, 2007, January 14, 2008, and February 15, 2011.⁷⁷ She, also, admitted no malady specific hold had been issued.⁷⁸ Again, in sum, Takeda, itself, admitted at trial by way of the testimony of Ms. Calahan, that the 2002 Hold which was issued, was *a general product’s liability* hold, would

⁷⁶ See 2002 Litigation Hold, attached as Exhibit 13 to the Motion for Sanctions (Rec. Doc. 3484).

⁷⁷ See Declaration of Stacey Dixon Calahan, attached as Exhibit 3 to Takeda’s opposition brief, Rec. Doc. 3530, at ¶13., and trial testimony of Stacey Calahan, Trial Tr. vol. VI at 723 (Rec. Doc. 4177). The PSC argues Takeda’s duty to preserve arose as early as 2000 when Takeda began receiving product liability “claims” related to Actos®. However, because Takeda admits it implemented the 2002 Litigation Hold, and because the majority of “lost” documents were “destroyed” after this date, for these purposes only, this Court need not address whether Takeda should have implemented a litigation hold two years earlier.

⁷⁸ Trial Tr., vol. VI, 729 (Rec. Doc. 4177).

have *covered all maladies*, including bladder cancer, was “*refreshed*” multiple times and *remains in effect*. These admissions made by Takeda’s own Assistant General Litigation Counsel are in glaring contradiction with the positions taken and arguments made to this Court, by Takeda, throughout discovery and motion practice, but are supported by certain of Takeda’s responses to discovery within this MDL litigation. See “Takeda’s Response and Objections to Plaintiffs’ Supplemental Interrogatory 2,” attached as Exhibit 15 to the Motion for Sanctions, Rec. Doc. 3484-2, at p. 4.

The breadth of Takeda’s *arguments* made within discovery and within the motion practice, which have been proved by the documents and by Ms. Calahan’s trial testimony to be inaccurate, further support this Court’s finding of a violation by Takeda of FED.R.CIV.P. 37, and this Court’s finding Takeda engaged in spoliation and a willful abuse of the judicial process designed to hide the existence of and its earlier failure to honor the Hold put in place in 2002.

Takeda has, also, argued a distinction between Takeda U.S. and Takeda Japan – and, in fact, throughout this matter has presented no one who can or did testify or attest, knowledgably, to Takeda Japan’s conduct – this Court finds evidence has been presented showing this is a distinction without a difference. Takeda has acknowledged TPC (Takeda Japan) *was aware of the 2002 Litigation Hold at the time of initial dissemination. Takeda U.S. notified three employees of Takeda Japan – Saburo “Sam” Hamanaka, Teruyuki “Terry” Fukumoto, and Masatake Kashiyaie – of the 2002 Litigation Hold on or about July 19, 2002.* Takeda Japan was sued in a products liability suit arising out of the use of Actos® in 2002.⁷⁹ Takeda admits *the 2006 “refresher” of the 2002 Litigation Hold was made accessible to the European Takeda*

⁷⁹ See “Takeda’s Verified Response to Plaintiffs’ Discovery Requests Served September 23, 2013, as Amended September 24, 2013, With Question 1A,” attached as Exhibit 14 to the Motion for Sanctions, at p. 2. (Rec. Doc. 3484).

entities through a Takeda company intranet site in April or May of 2006;⁸⁰ and it is undisputed Takeda Japan was the dominant entity in the development and marketing of Actos.® Thus, not only were Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. aware of and subject to the broad hold put in place in 2002, TPC (Japan) was, also, made aware of that hold; therefore, the Takeda entities in the U.S., Europe, and Japan, all were aware of the 2002 hold, respectively Takeda U.S. and Takeda Japan – in 2002, and Takeda Europe – in 2006 and, yet the evidence is indisputable that files of key Takeda employees and documents of key Takeda employees shown to have been pivotally involved with the development, and marketing, and regulation of Actos® were deleted and destroyed **after 2002 in the U.S. and Japan**. Consequently, Takeda’s conduct occurring before the first suit was filed within the MDL, and in particular, before Mr. and Mrs. Allen’s suit was filed, is certainly relevant *as evidence as to Takeda’s culpable intent*, i.e. to the inquiry of Takeda’s good or bad faith as to the initial destruction and deletion, occurring before suit was filed, and to Takeda’s conduct within this MDL. However, Takeda’s conduct once suit was filed is, also, relevant to a determination of whether Takeda acted in good or bad faith in that destruction and deletion which occurred before

⁸⁰ See “Takeda’s Verified Response to Plaintiffs’ Discovery Requests served September 23, 2013, as Amended September 24, 2013, with Question 1A” attached as Exhibit 14 to the Motion for Sanctions, at 3, as follows.

1A a. On what date did TGRD EU or any of the European Takeda entities first become aware of the July 19, 2002 legal hold?

ANSWER: Takeda does not have a specific date when TGRD Europe (now known as Takeda Development Centre Europe, Ltd.) or the European Takeda Entities first became aware. TGRD Europe had access to the July 19, 2002 legal hold, in the form of the 2006 refresh notice, when the 2006 refresh notice was posted to Takeda’s Horizon intranet site in April or May 2006. To the best of Takeda’s knowledge and belief, no other European Takeda entity was aware of the July 19, 2002 legal hold before then.

The PSC has suggested the February 2010 “refresh” of the 2002 Litigation Hold was implemented after, and because of, the September 2010 bladder cancer “claim” (not a lawsuit), however, it is evident from Mr. Regard’s testimony that Takeda has attempted to distance itself from this notion, suggesting the February 2011 “refresh” was implemented “because it had been so long since a refresh had been issued.” See Deposition of Mr. Regard, at pp. 680-81. (Rec. Doc. 3484, Exhibit 8).

suit was filed in the MDL, as evidence of Takeda's motivation and argued attempt to conceal its failure to honor its legal obligation to retain documents covered by the 2002 Hold.

Thus, the factual and legal significance of Takeda's arguments made to this Court that its first *reasonable* anticipation of a *bladder cancer* litigation was *in July 2011* is, at best, unsupported when viewed in light of the evidence presented not only before trial, but also, that presented at trial and more particularly the admissions made by Takeda's Assistant General Litigation Counsel, Ms. Calahan, as well as the language of the holds themselves, and Takeda's attempts to conceal the very existence of those holds within this MDL. Thus, the reality *and existence* of an instituted hold undercuts Takeda's arguments as to when they *should* or *should not have* instituted a litigation hold; the fact is that in 2002 *Takeda did institute a litigation hold*; one by its own language general in nature, and of sweeping breadth, which was "refreshed" multiple time over the years and was never amended to cover bladder cancer or any of the known claims of injury - and despite this fact, Takeda failed to admit the very existence of this hold and its subsequent "refreshers," until the persistent involvement of the magistrate judge forced the issue.

It cannot be over emphasized that Takeda's Assistant General Litigation Counsel, Ms. Calahan, admitted the 2002 Hold would have applied to bladder cancer claims, and has not been lifted since the shift from suits claiming liver injury to suits claiming bladder cancer, nor has it been amended to, now, cover bladder cancer as opposed to liver cancer and yet, Takeda failed to admit even the existence of the 2002 Hold in its responses to discovery and the Court. Thus, Takeda's conduct within this MDL, when judged against the admissions of its own Assistant General Litigation Counsel, support a finding of a violation of FED.R.CIV.P. 37 and evidence of a willful abuse of the judicial process.

Moreover, Takeda's secondary argument that the 2002 Litigation Hold should not apply equally to all Takeda entities is unpersuasive in the face of clear evidence to the contrary. Evidence presented pretrial and at trial established *Takeda U.S., in fact, put the Japanese Takeda entities on notice of the sweeping 2002 Litigation Hold immediately following the implementation of this hold*, the Japan Takeda entities had, in fact, been named in the Actos® products liability lawsuit alleging personal injury in 2002, which had prompted the 2002 Hold, *and the European Takeda entities were, in fact, put on notice of the 2002 hold in 2006.*⁸¹ It is not disputed, and was fully established at trial, that each of the relevant identified Takeda entities⁸² bore involvement of significant nature, with the development and/or marketing of Actos® and yet, files of key Takeda employees, intimately involved in the development and marketing of Actos®, were destroyed and deleted after that time.

Again, over the unfortunate course of discovery, Takeda has made ever-shifting arguments as to the very existence of, the nature, importance, and character of the 2002 hold and its self-proclaimed “refreshers.” Takeda's argument that the 2002 Litigation Hold does not apply to *general products liability litigation* – and applies only to *liver injuries* – was abjectly disproved as discussed above.⁸³ Furthermore, Takeda, itself, within formal responses to this Court, referred to the 2002 hold as a “general Actos® ‘product liability’ litigation hold,”⁸⁴ in

⁸¹ See “Takeda's Verified Response to Plaintiffs' Discovery Requests Served September 23, 2013, as Amended September 24, 2013, With Question 1A,” attached as Exhibit 14 to the Motion for Sanctions, at pp. 2-3. (Rec. Doc. 3484).

⁸² However, for purposes of the Allen trial, only, the stipulation found at Rec. Doc. No. 512 [12-cv-00064] and Rec. Doc. No. 3880 [MDL No. 6:11-md-2299] instructs all Takeda entities are to be considered one juridical entity.

⁸³ Trial Tr. vol. II, at 153-54 (Rec. Doc. 4173); vol. VI, at 727-31, 768-69 (Rec. Doc. 4177); and “Takeda's Response and Objections to Plaintiffs' Supplemental Interrogatory 2,” attached as Exhibit 15 to the Motion for Sanctions, Rec. Doc. 3484-2, at p. 4.

⁸⁴ See “Takeda's Response and Objections to Plaintiffs' Supplemental Interrogatory 2,” attached as Exhibit 15 to the Motion for Sanctions, Rec. Doc. 3484-2, at p. 4.

direct contradiction to arguments made in discovery. Again, Takeda's trial admissions made by their Assistant General Litigation Counsel and the clear, unambiguous language of the 2002 Litigation Hold, and Takeda's instruction the Hold be broadly interpreted, and instructing Takeda employees to preserve "any and all documents and electronic data *which discuss, mention, or relate to Actos®*" all are **in direct factual contradiction to the positions taken by Takeda during this litigation**, and undercut Takeda's multiple after-the-fact attempts, when facing over 6,000 lawsuits across the country allegedly arising out of the use of Actos®, to read into the 2002 Hold, limitations not found in its clear language, and which are in glaring contradiction to its Assistant General Counsel's trial testimony. These facts are, again, supportive of a finding Takeda violated FED.R.CIV.P. 37, engaged in a willful abuse of the judicial process, and acted in bad faith in its conduct of and surrounding its destroying and deleting documents subject to the 2002 Hold.

Furthermore, from this Court's reading of the record, it appears Takeda indirectly argues a distinction between "claims" and "lawsuits" and, thereby, argues the September 2010 "claim" (but not lawsuit) for *bladder* cancer as falling under the 2002 Litigation Hold, which Takeda, also, argues should be limited only to liver injury law suits. The significance of this contradictory argument is apparent on its face. Furthermore, when one traces *the language and progression* of the litigation hold issued by Takeda with respect to Actos®, the following is clear:

- As this Court has noted, the language of the **2002 Litigation Hold** requires the recipient to "preserve any and all documents and electronic data which discuss, mention, or related to Actos®." The language of the hold itself mentions that the hold is being implemented because Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. are now defendants in a "**lawsuit**" alleging "personal injury and wrongful death."⁸⁵

⁸⁵ Ms. Calahan does not acknowledge that Takeda Japan was named as a defendant in the 2002 lawsuit. Calahan Declaration at ¶ 12 (attached as Exhibit 3 to Opposition, Rec. Doc. 3530); however, Exhibit 6 (attached to

- In 2006, Takeda issued a document entitled “Legal Hold Related to Actos® Products Liability Claims” (the “**2006 Litigation Hold**”), which states:

Takeda continues to be involved in a small number of **claims or lawsuits (“claims”)** relating to ACTOS®. . . As a result of these **claims**, all documents, materials, information and things that exist or continue to be developed *pertaining to ACTOS®* **have been and continue to be** subject to a Legal Hold. . . . **This means that all documents, materials, and computer files (including e-mails, word processing documents, slides, etc.) falling into this category must continue to be maintained until you are informed otherwise . . .**⁸⁶

- In 2011, Takeda issued yet another document, entitled “Actos® Product Liability Legal Hold” (the “**2011 Litigation Hold**”), which states:

Takeda Pharmaceuticals North America, Inc. **continues to be involved in product liability claims** regarding ACTOS®. As a result, for these **claims**, Takeda must take steps to ensure the preservation of all documents, as defined below, relating to this matter. . . . All documents that relate to **these claims** that you now possess or that come into your possession in the future must be preserved even if they would normally be destroyed in the ordinary course under Takeda’s document retention policy. . . . (emphasis added)

The foregoing document goes on to describe a variety of documents that must be preserved, including, but not limited to, “[d]ocuments relating to the safety or efficacy of ACTOS® or ACTOS® combination medicines,” and “[d]ocuments relating to the research and development of ACTOS® or ACTOS® combination medicines.”

And yet, in Takeda’s 30(b)(6) deposition, when addressing the 2006 Litigation Hold (as well as the 2007 Litigation Hold, the language of which this Court has not been supplied), Mr. Regard testified as follows:

Q: Okay. Well, the point we’re getting to here is, the February hold, the February 2011 hold that Ms. Calahan distributed –

Plaintiffs’ motion for sanctions, Rec. Doc. 3484) clearly identifies Takeda Japan as a named defendant in the 2002 suit.

⁸⁶ See document entitled “Legal Hold Related to Actos Products Liability Claims,” attached as Exhibit 20 to the Motion for Sanctions (certain emphasis added; certain emphasis in original) (Rec. Doc. 3484).

A: Yes, sir.

Q: – the language changed significantly, did it not, from the 2006 and 2007 version, which were the same?

A: It looks to be very different, yes.

Q: Okay. So why – when you talked to Ms. Calahan, when she said she was – this was just some sort of refresh unrelated to any bladder cancer or any particular event, why did she completely redraft the hold?

A: I did not ask her that question.

Q: Why not? Why didn't you ask her that?

A: It didn't occur to me at the time to ask her.⁸⁷

Ms. Calahan, at trial, testified each subsequent hold was, in fact, a refresher of the 2002 Hold.

Thus, Takeda's representative for the 30(b)(6) deposition selected to address these very issues, Mr. Regard, testified that Ms. Calahan stated that the 2011 Litigation Hold (apparently written by Ms. Calahan) was simply a "refresh" of the 2002 Litigation Hold,⁸⁸ as did Takeda's Assistant General Litigation Counsel, Ms. Calahan, with no change or distinction made as to the nature of the health malady – i.e. liver to bladder or any of the other maladies about which claims had been received. Notwithstanding positions taken, and argument made to this Court by Takeda, evidence establishes those positions and argument to be unsupported by the facts. What becomes apparent when one tracks the facts in the record and proven at trial against the evolution of Takeda's positions argued to this Court as to the existence and nature of the various litigation holds, is that Takeda's arguments made within discovery and to this Court in motion practice stand in direct contradiction to the evidence ultimately produced at trial, to the clear language of

⁸⁷ See Deposition of Daniel Regard, Exhibit 8, at 782-83 (Rec. Doc. 3484).

⁸⁸ The Court has not been provided all exhibits to Mr. Regard's deposition. Although it is unclear on what actual date the July 2011 lawsuit was filed, the February 2011 Litigation Hold was issued on February 15, 2011. See February 15, 2011 e-mail from Stacey Calahan to "Colleagues," attached as Exhibit 9 to the Motion for Sanctions (Rec. Doc. 3484).

the Holds themselves, and, specifically to the trial testimony of Takeda's Assistant General Counsel, Ms. Calahan.

The foregoing, also, is apparent when one reviews the evolution of the language of the various litigation holds, themselves, Mr. Regard's deposition testimony, and Ms. Calahan's trial testimony, along with Takeda's response to certain written discovery, such as that found below:

. . . the **"2010 Claim"** was received on or about September 21, 2010, when a patient made a spontaneous adverse event report via telephone to the call center operated on Takeda's behalf by [PPD]. . . . The patient who communicated the "2010 Claim" to PPD **did not file a lawsuit** seeking compensation for bladder cancer allegedly caused by Actos® **until July 2012**, at which time a complaint naming Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceutical Company Limited was filed in the Circuit Court of Cook County, Illinois. . . . The attorneys and law firms representing Takeda [in the instant MDL litigation] began representing Takeda with respect to the "2010 Claim" in July 2012, at the time the patient who communicated the "2010 Claim" to PPD filed and served a lawsuit in Cook County, Illinois seeking compensation for bladder cancer allegedly caused by Actos®. . . . **A general Actos® "product liability" litigation hold was in place at Takeda Development Center Americas, Inc. . . . Takeda Pharmaceuticals U.S.A., Inc. . . . and Takeda Pharmaceuticals America, Inc. at the time the "2010 Claim" was received, and was refreshed in February 2011 after the "2010 Claim" was received.**⁸⁹

And yet, when discussing the same 2002 Litigation Hold in her "Declaration," Ms. Calahan states:

Takeda entities in the United States **have refreshed the July 19, 2002 Actos-related legal hold at various times (e.g., September 17, 2003; May 4, 2006; October 22, 2007; January 14, 2008; February 15, 2011).**⁹⁰

And yet, Takeda, before this Court, repeatedly took the position the 2002 Hold was limited only to liver injury. Again, it cannot be overlooked the contradictory positions taken by

⁸⁹ See "Takeda's Response and Objections to Plaintiffs' Supplemental Interrogatory 1 Regarding 2010 Actor Bladder Cancer Claim," attached as Exhibit 8 to "Plaintiff's Supplemental Memorandum in Support of Motion to Compel FED.R.CIV.P. Rule 30(b)(6) Deposition on Litigation Hold Issue, (Rec. Doc. 3182), at 4-5. (emphasis added).

⁹⁰ See "Declaration of Stacey Dixon Calahan," p. 3, attached as Exhibit 3 to Takeda's responsive brief (Rec. Doc. 3530) (emphasis added).

Takeda are not legal in nature, nor do they argue language ambiguity, rather, they are factual assertions omitting relevant facts and made in direct contradiction to the facts ultimately admitted by Takeda at trial. Such conduct by Takeda is troubling at best and at worst, as the PSC argues, is evidence of Takeda's bad faith and willful abuse of the judicial process.

Consequently, Takeda's after-the-fact attempt to alter the clear and unambiguous language of its instruction and of the 2002 Hold, and the multiple "refreshers" of the 2002 Hold, in the face of its Assistant General Litigation Counsel, Ms. Calahan's testimony that the 2002 Hold applied, is additional support for a finding Takeda violated FED.R.CIV.P. 37, willful abuse of the judicial process and acted in bad faith as to its conduct surrounding the 2002 Hold.

1. Takeda's Destruction of Documents in Violation of its Duty

Ms. Calahan testified that certainly all U.S. employees knew of the litigation hold; knew of the importance of the hold; were instructed to move Actos® documents into a "hold" folder (which was held on each computer);⁹¹ and yet, they, nonetheless, did not do so and files were destroyed. By way of Ms. Calahan's trial testimony, and, also, the evidence presented by the PSC at trial, Takeda U.S. and Takeda Japan have, in effect, acknowledged that each is familiar with litigation holds, understands that they are very important, should issue holds in good faith, should deem compliance with litigation holds mandatory,⁹² and should expect cooperation by its employees.⁹³ And yet, even Ms. Calahan admitted at trial, and other documentary evidence establishes, the 2002 Hold was not complied with in the United States, Japan, or Europe.

By way of further example, the PSC's Exhibit 20 to their Memorandum in Support is an undated example of a "legal hold related to Actos® products liability claims." In pertinent part,

⁹¹ Trial Tr. vol. V, 619-20 (Rec. Doc. 4176).

⁹² Trial Tr. vol. II, 142 (Rec. Doc. 4173); Trial Tr. vol. V, 549-52 (Rec. Doc. 4176).

⁹³ Trial Tr. vol. V, 592 (Rec. Doc. 4176).

it reads as follows:

Takeda continues to be involved in a small number of claims or lawsuits (Claims) relating to Actos® (pioglitazone HCI). As a result of these claims, all documents, materials, information and things that exist or continue to be developed pertaining to Actos® have been and continue to be subject to a Legal Hold.

Additionally, all documents and materials that exist or continue to be developed pertaining to Combination medicines involving Actos®, whether a marketed or development medicine, also continue to be subject to a Legal Hold.

Each Takeda Employee or Contractor shall create an Outlook Folder entitled “Actos” beneath the “Legal Hold” folder provided as part of the implementation of CORP-B-019 “E-mail Management and Retention.” Contact the Help Desk if your Outlook file folder structure does not contain a “Legal Hold” folder.

This means that all documents, materials, and computer files (including e-mails, word processing documents, slides, etc.) falling into this category must continue to be maintained until you are informed otherwise, regardless of the specified record retention period that would apply to such materials under Takeda’s current Records Retention Schedules and Program. (emphasis in original)

You are reminded that you must follow the requirements of both BOP, CORP-B-019 “E-mail Management and Retention” for the retention of electronic materials, and “Best Practices For The Physical And Electronic Storage Of Materials That Must Be Retained For Legal Reasons”

IN ALL CASES, THE FOLLOWING INSTRUCTIONS APPLY TO DOCUMENTS, MATERIALS, INFORMATION, AND THINGS, IN HARD COPY OR ELECTRONIC FORMAT, THAT ARE REQUIRED TO BE RETAINED PURSUANT TO THIS LEGAL HOLD.⁹⁴ (emphasis in original)

Evidence further establishes Takeda’s Office of Ethics and Compliance, Records Management, used a “new employee training” power presentation to address records management compliance. It refers to the policy designated as CORP-B-019 (E-mail Management and Retention), compliance with legal hold directives, instructs employees to “never destroy any record without permission,” and contains extensive instruction on “Implementing the Legal Hold Directive.” New employees were to have been advised to

⁹⁴ Bates No. TAK-RIM-30b6-00000663 (Rec. Doc. 3484, Exhibit 20).

“review BOP-019 for more information” and provides a list of “records management resources,” which included sources of information, identified policies and standard operating procedures, and identified the corporate records group and provided information on how to contact its members.⁹⁵ And yet, it is undisputed the noted, relevant records were not retained, rather were deleted.

Takeda, also, has produced a document entitled “Best Practices for the Physical and Electronic Storage of Materials That Must Be Retained For Legal Reasons Independent of Corporate Record or Retention Guidelines or ‘Legal Holds.’”⁹⁶

These Best Practices are applicable to the employees of the following companies, and pertain to documents, records, and information that are **NOT** the “Official Records” of Takeda Pharmaceuticals North America, Inc., Takeda Global Research & Development Center, Inc., Takeda Pharmaceuticals America, Inc., and Takeda Finance LLC.

[Legal Hold] Advisories are periodically issued to Takeda employees and contractors by the Law Department and are continuously posted for their effective period in Vector under the Compliance tab. A “Legal Hold” is an instruction that requires mandatory compliance, and that is issued by Takeda Management to retain certain described document classes related to legal proceedings. Departure from these guidelines may only take place at the direction of Senior Counsel – Litigation.

To effectuate this Policy, the Outlook system has been configured to ensure that responsive materials that are accidentally deleted cannot be lost. Such materials, even to the extent that you empty your deleted items, will be captured in the bi-weekly-up tape. **HOWEVER, BECAUSE OF THE EXPENSE OF SEARCHING BACKUP MEDIA FOR A LEGAL HOLD OR RESPONSIVE MATERIALS, TAKEDA MANAGEMENT HAS MADE THE STORAGE OF SUCH MATERIALS WITHIN OUTLOOK BY EMPLOYEES AND CONTRACTORS MANDATORY. THEREFORE, RESPONSIVE MATERIALS SHALL NOT BE DELETED.**

⁹⁵ See Exhibit 19, PSC’s Memorandum in Support (Rec. Doc. 3484).

⁹⁶ See Bates No. TAK-RIM-30b6-00000926, Exhibit 18 (Rec. Doc. 3484).

The purpose for these particular Best Practices is to ensure that Legal Hold materials are stored and available on the local area network (LAN) and that Takeda, therefore, avoids the necessity of searching for such materials on employees' individual laptop computers, or on the period tape backup of Outlook.⁹⁷ (emphasis in original)

The ever shifting position as to whether and if tapes known as backup or disaster, business tapes – all or any - were to have been part of Takeda's document retention policy and, in fact, were or were not, a part of Takeda's document retention policy is, at its best, only distressing. Takeda business operating procedure known as CORP-B-019 has an effective date of May 1, 2006 and is entitled "E-mail Management and Retention." BOP-019 was approved by the associate general counsel, the general counsel, the Vice President – Chief Compliance Officer, the Vice President – Information Technology, Senior Vice President – Quality Assurance and Compliance, President of TGRD, and President of TPNA. The stated purpose of BOP-019 was "to describe the requirement for personnel of Takeda Pharmaceuticals North America, Inc., Takeda Global Research & Development Center, Inc., and their U.S. subsidiaries (collectively Takeda) to fulfill our legal, financial, regulatory, and organizational obligations as they relate to E-mail Management and Retention."⁹⁸ Employees were informed that the company *would not rely on backup tapes to fulfill the obligation to retain legal hold materials.* "Following implementation of this Operating Procedure, disaster recovery backup tapes and discs that are used for business continuity or disaster recovery purposes shall not be used for any other purpose, and shall not to be [sic] used to satisfy retention requirements for Company E-mail Records or Legal Hold Materials."⁹⁹ And yet, Ms. Calahan testified Takeda U.S. lacked the information technology infrastructure to implement its document retention programs and the

⁹⁷ Exhibit 18 to PSC's Memorandum in Support (Rec. Doc. 3484).

⁹⁸ Bates No. TAK-RIM-30b6-00000083, Exhibit 17 to PSC's Memorandum in Support (Rec. Doc. 3484).

⁹⁹ Bates No. TAK-RIM-30b6-00000089, Exhibit 17 to PSC's Memorandum in Support.

relevant document retention programs were not complied with.¹⁰⁰ And, Mr. Regard's very convoluted, ambiguous and seemingly internally contradictory testimony at Takeda's 30(b)(6) deposition as to the purpose, availability and nature of "backup tapes" or other not so aptly named storage, is wholly unhelpful to Takeda's position and did little to illuminate the issue and resolve the morass created by Takeda's earlier corporate positions on this point.¹⁰¹ Thus, Takeda's positions taken on the nature of and availability of any type of backup tapes have not been proven or supported by the evidence presented either before or during trial. Thus, Takeda's oft shifting positions as to the nature, and validity of their corporate document retention programs and specifically the use and ability to use any type of backup tapes – whatever their name - within any such retention program(s), are distressing. Such contradictory positions and argument made in the face of facts and testimony given at trial, support this Court's finding Takeda violated FED.R.CIV.P. 37, acted in bad faith as to the deletion and destruction of its documents, and thereafter, willfully engaged in abuse of the judicial process in order to attempt to conceal that destruction and deletion. Consequently, this Court finds Takeda's argument on this point not to be supported in fact or law.

2. Intentional (Rather Than Inadvertent) Destruction of the Evidence

Perhaps chief among Takeda's arguments is the argument that Takeda's deletion and destruction of evidence was at worst negligent and, at best, inadvertent. The jurisprudence makes a distinction between inadvertent document destruction (classically, a box of documents, sitting too close to a trash receptacle, is picked up by diligent housekeeping staff) and the intentional decision to destroy documents. Only the latter has the potential to support sanctions.

¹⁰⁰ Trial Tr. vol. V, 588-89, 602-05, 618 (Rec. Doc. 4176).

¹⁰¹ See Deposition of Daniel L. Regard, II, attached as Exhibit 8 to the Motion for Sanctions, at 726-31 (Rec. Doc. 3484).

There is no dispute in this case as to the intentional nature of the Defendants' document destruction. Ms. Calahan – Assistant General Counsel for Takeda U.S. – acknowledged as much when she testified that, to her belief, employees purposefully deleted documents, but did so against company policy because they were following document retention policy rather than litigation hold policy.¹⁰² However, Ms. Calahan's testimony, also, established the document retention policy, as written, was beyond the company's information technology's ("IT") capability to implement and thus, was one in name only. Thus, the document retention policies argued by Takeda in defense of their destruction and deletion of documents which were subject to a valid litigation hold, were policies completely incapable of retaining the very documents they were supposed to protect; and, thus, Takeda cannot find the safe harbor sought within a policy which existed in name only. However, the question goes beyond the intentional nature of the failure and into the *nature of Takeda's intention* as to those files actually deleted and destroyed.

The record reflects that through third party discovery and discovery obtained from less strategically placed Takeda employees whose files were not destroyed and deleted, the PSC was able to identify pivotal, albeit limited, missing information, much of which, on its face, argues it should have been within the files of those key Takeda employees whose files were deleted and destroyed. The plethora of evidence – documentary and testimonial - presented at trial by the PSC fully supports this Court's preliminary determination that the files of key employees who were intimately involved in the development, and marketing of Actos® would have been relevant to litigation involving Actos® and its development and marketing, and, therefore, the absence of such evidence can be reasonably assumed to be prejudicial to such litigation and, thus, will not be reiterated or itemized herein.

¹⁰² Trial Tr. vol. V, 597-98 (Rec. Doc. 4176).

Illustratively, however, this Court notes the following communications as further support for this Court's finding. Although not located in the custodial files of either the sender or the recipient, the following were located in the files of other Takeda employees who were copied on the e-mail correspondence or through third-party discovery:

- August 2005 email from Mick Roebel, Takeda Vice President of Regulatory Affairs, to (among others) Kiyoshi Kitazawa and Phillip Collett (Vice President of Regulatory Affairs at Takeda Global Research and Development Centre (Europe) Ltd.).¹⁰³ In this email, Mr. Roebel outlines the "Best Case Scenario," "Worst Case Scenario," and "Most Likely Scenario" concerning data connecting Actos® to bladder cancer and the drug's labeling. The foregoing email was not located in Mr. Kitazawa's file [which was deleted] but, rather, was found in the file of another Takeda employee.
- A series of emails dated January 2003 from Claire Thom to (among others) Mr. Kitazawa, discussing the marketing implications of labeling changes related to bladder cancer.¹⁰⁴ Again, Mr. Kitazawa's files were deleted.
- A September 22, 2004 email from David Eckland (Managing Director at Takeda Europe Research & Development Centre. Ltd.) to (among others) Masahiro Miyazaki, Phillip Collett, and Mr. Kitazawa. This email discusses the consequences of a medical paper describing pioglitazone as having a mixed gamma and alpha activity at clinical concentrations. Takeda has admitted deleting the custodial files of all four of the [noted] e-mail's recipients.¹⁰⁵

Even before the plethora of testimony and documentary evidence presented at trial by the PSC, it could not seriously have been questioned that, in fact, the deleted files belonged to both high-ranking Takeda officials heavily involved in the development, sales, marketing and/or promotion of Actos®, as well as rank-and-file sales representatives whose day-to-day work involved marketing and distributing Actos® in the marketplace. The titles of the employees

¹⁰³ See August 8, 2005 e-mail, attached as Exhibit 25 to the Motion for Sanctions (Rec. Doc. 3484).

¹⁰⁴ See January 2003 e-mails, attached as Exhibit 26 to the Motion for Sanctions (Rec. Doc. 3484).

¹⁰⁵ See September 2004 e-mail, attached as Exhibit 27 to the Motion for Sanctions (Rec. Doc. 3484).

whose files cannot be produced, themselves, evidence the potential importance and relevance of the deleted information. In Japan alone, employees whose files cannot be produced include:

1. Mikihiro "Ken" Obayashi (**Director, Pharmaceutical Development Division**);
2. Kiyoshi Kitazawa (**Managing Director, Board Member, and General Manager, Strategic Product Planning Department**);
3. Takashi Nonoyama (**Associate Director, Pharmaceutical Research Division, Research Management Department, Planning & Development**) (although some of Mr. Nonoyama's documents may have been produced because they are contained within the file of his successor);
4. Katsuhisa Saito (**Senior Director, Pharmaceutical Development Division, Strategic Development Department**);
5. Kunio Takeda (**Representative Director, Chairman of the Board**); and
6. Masaomi Miyamoto (**Vice President, Pharmaceutical Research Division**).
7. Masahiro Miyazaki (**Associate Director, Pharmaceutical Research Division**).

The titles of the following American and European Takeda employees, also, demonstrate the potential relevance of these former employees' missing files:

8. Harry (Dean) Hart (**Senior Vice President of Sales for Takeda Pharmaceuticals U.S.A., Inc.** (formerly Takeda Pharmaceutical North America Inc.) ("TPUSA");
9. Doug Joseph (**Senior Manager of Product Safety at a Takeda entity named Takeda Development Center Americas, Inc.** (f/k/a Takeda Global Research & Development Center, Inc.);
10. John Yates (**President at Takeda Global Research & Development Center Inc.** ("TGRD");
11. Phillip Collett (**Vice President of Regulatory Affairs at Takeda Global Research and Development Centre (Europe) Ltd.**);
12. Annette Beiderbeck (**Director of Epidemiology, Pharmacovigilance at Takeda Global Research and Development Centre (Europe) Ltd.**); and
13. David Eckland (**Managing Director at Takeda Europe Research & Development Centre. Ltd.**).

Even before trial, the potential relevance of the foregoing deleted and destroyed

information was obvious when evaluated within the context of those documents located, and those which related to Takeda's knowledge about the potential health concerns surrounding Actos®, and as those concerns might relate to bladder cancer, and to the sufficiency of the company's warnings and its labeling. Thus, even prior to trial, the PSC had located, from other sources, information which on its face established it should have been in the deleted custodial files of certain employees and established those employees were intimately involved with the development, regulatory administration, and marketing of Actos®, and thus, would have been both relevant to and beneficial to the claims challenging Takeda's handling of the development and marketing of Actos®.

Perhaps the most compelling evidence of potential beneficial relevance and prejudice to Plaintiffs, available before trial, however, was the correspondence of Tai Matsuzawa and Kiyoshi Kitazawa. Mr. Matsuzawa was a **Vice-President of the Pharmaceutical Group of Takeda Chemical Industries, Inc.** in Japan, while Mr. Kitazawa was a **Managing Director, Board Member, and General Manager of Takeda's Strategic Product Planning Department**, in Japan who worked for TPC from April 1, 1971 to June 25, 2009. Takeda has confirmed Mr. Kitazawa's e-mail account was deleted from active servers on October 1, 2009; his personal file share and all personal data was deleted by a Takeda information technology vendor on January 28, 2010, pursuant to a request dated January 20, 2010; and his business documents were discarded at the time of his departure. Thus, all of the foregoing deletions and destruction of documents were made *after the 2002 Litigation Hold was in place*.

As more fully discussed in its prior ruling, Rec. Doc. 3933, only through third-party discovery with Upjohn, did the PSC obtain correspondence to Mr. Matsuzawa from Dr. J.R. Mitchell, the president of Upjohn (as noted earlier Upjohn and Takeda were considering a

collaboration on Actos® in 1993), who wrote to Mr. Matsuzawa on September 21, 1993:

On September 20 our Pharmaceutical Executive Council, Upjohn's highest scientific decision-making body, carefully reviewed the results of the toxicology and clinical studies. The decision of the Council was that Upjohn will not go forward with pioglitazone in the clinic. **The Council decided that further clinical development of pioglitazone could not be justified based on their concern regarding pioglitazone's margin of safety.**¹⁰⁶

One month later, on October 25, 1993, Dr. Kitazawa – whose files were deleted and destroyed – wrote to Dr. Patricia Ruppel, the Project Manager Director for Upjohn, as follows:

Regarding Upjohn's statement for the development status of pioglitazone, **we would like to propose the following alternative or a similar [sic] instead of Upjohn's proposal in due consideration of our current development status.**

In the very preliminary clinical evaluation in the U.S.A., **pioglitazone did not show the reduction of blood glucose enough to satisfy Upjohn's in-house requirement.** Any considerable work that would be needed is not in line with our business needs for further development of Pioglitazone. Hence, all development on pioglitazone at Upjohn has ceased.¹⁰⁷

The foregoing correspondence reflects Upjohn withdrew from the Actos® development deal with Takeda over issues of “**pioglitazone's margin of safety.**” The Takeda correspondence one month later reflects Takeda's *attempt to shift the Upjohn explanation* and **omit Upjohn's express safety concerns** associated with Actos® **and substitute** references to concerns with the *efficacy of Actos® as a reducer of blood glucose*. The PSC argues Takeda's direct attempt to shift the focus away from safety concerns to the less damaging efficacy concerns, as well as Takeda's blatant attempt **to eliminate** language referencing Upjohn's *safety* concerns from not only the language used, but the stated reason Upjohn expressed for withdrawing from the collaboration, is clear evidence of Takeda's culpable intent to *conceal* the expressed *safety*

¹⁰⁶ See Letter from J.R. Mitchell to Tai Matsuzawa, dated September 21, 1993, attached as Exhibit 22 to the Motion for Sanctions (Rec. Doc. 3484) (emphasis added).

¹⁰⁷ See Letter from K. Kitazawa of Takeda to Patricia L. Ruppel, Director of Project Management at Upjohn, dated October 25, 1993, attached as Exhibit 23 to the Motion for Sanctions (Rec. Doc. 3484)(emphasis added).

concerns Upjohn associated with Actos®, and, therefore, is evidence of Takeda's bad faith in attempting to destroy these documents and such deliberate intent goes to the heart of the plaintiffs' failure to warn claims.

In response to the PSC's evidence, at trial, Takeda called Jerry Colca, a former employee of Upjohn, to address and counter this argument. Mr. Colca's testimony will be discussed in greater detail below, however, at this juncture, suffice it to say, this Court found Mr. Colca's testimony wholly unreliable, for the reasons that will be noted, not the least of which is the fact Mr. Colca was not involved in Upjohn's decision or in any communication with Takeda. Therefore, this Court finds both Takeda's evidence and argument in response to the PSC's evidence, wholly unpersuasive on this point. Although Takeda, also, presented certain testimony at trial of a meeting held in Osaka, which Takeda argues supports their argument as to the interpretation of the Upjohn Correspondence, the PSC, also, presented documentary evidence contradicting Takeda's argued interpretation *and it cannot be overlooked that due to Takeda's conduct, the PSC is without the very files of those Takeda employees who were involved in the response to Upjohn's decision to withdraw from the development of Actos® - files which should have been protected by the Litigation hold.* The witness Takeda chose to call on this issue – as will be discussed more fully below – did not attend the argued Osaka meeting; was not involved in Upjohn's decision; had no personal knowledge of those pivotal points, rather had only hindsight and assumption as to why Upjohn might have made its decision; and was in no way privy to the communication Upjohn had with Takeda Japan.¹⁰⁸ Thus, Takeda wholly failed to present reliable evidence to call into question the PSC's reliable evidence to the contrary; and provided no reliable evidence, at trial, to undercut this Court's initial finding and reliance upon the Upjohn document and Takeda's corporate response, and this Court, again, specifically refers

¹⁰⁸ Trial Tr. vol. XXIX, at 4648, 4656 (Rec. Doc. 4202).

to the extensive discussion of that issue in its earlier ruling found in Rec. Doc. 3933.

The fact that the foregoing evidence presented before, and at trial, on this issue is relevant to the PSC's arguments and to plaintiff's failure to warn claims cannot seriously be disputed. The efficacy of Actos® as a drug for the treatment of diabetes, and the safety of Actos® as a drug to be marketed to the public are two separate inquiries. Indeed, a drug may be wonderfully effective as a treatment for the medical problem for which it was developed, but, also, be highly toxic or even deadly to the individual taking it. Furthermore, specifically as to Mr. Allen, applicable New York law imposes a duty on a drug's manufacturer to warn of "all *potential* dangers." Upjohn declined to go forward with the development of Actos® in the clinic and clearly stated its specific concern and reasons for so declining: "**Upjohn's highest scientific decision-making body**" had reviewed results of "the toxicological and clinical studies" and **determined "Upjohn will not go forward with pioglitazone based on their concern regarding pioglitazone's margin of safety."** (emphasis added) Nonetheless, and in the face of Upjohn's scientific assessment and stated safety concerns, *Takeda attempted to convince Upjohn to abandon their "margin of safety" language in favor of language keying to pioglitazone's efficacy, i.e., wholly omitting any reference to concerns of Actos®' "margin of safety" and substituting in its place, language keying to efficacy, i.e., pioglitazone did not reduce blood glucose well enough to satisfy Upjohn.* Clearly, based on the clear language of the document itself, as well as supporting evidence presented by the PSC, Upjohn sought to disengage from the Actos® project for safety concerns. Yet, Mr. Kitazawa - *a General Manager at Takeda Japan's Pharmaceutical Development Division*, and, therefore, a highly-placed corporate employee speaking on behalf of Takeda with Upjohn - attempted to have Upjohn omit language reflecting Upjohn's safety concerns and substitute language concerning the efficacy of the drug as a blood

glucose reducer, **a totally separate and much less damaging statement** and Takeda deleted the very file which would have contained this very correspondence.

No evidence has been presented, Mr. Kitazawa - whose files were deleted and destroyed - was not *speaking on behalf of his employer Takeda when he wrote to the Project Manager for Upjohn*, and thus, Mr. Kitazawa's attempt to omit language of safety and substitute language of efficacy was reflective of Takeda's corporate attempt and the corporate position on this issue. That the missing files could evidence a corporate culture embracing attempts to remove mention of, or attempts to conceal, or to underplay expressed *safety* concerns surrounding the development of Actos® is clear; that Takeda destroyed all files within Takeda containing his correspondence is undisputed.

At trial, the PSC demonstrated, time and again, that the documents (electronic and paper) that had been destroyed were *relevant* to these proceedings because they were created by, for, or exchanged among people with significant responsibility for Takeda's response to health risks, including bladder cancer. Thus, the absence of those files can be reasonably assumed to have prejudiced Mr. and Mrs. Allen from presenting a full and complete picture of Takeda's actions and will prejudice the PSC within this MDL, as those documents are forever lost and the electronically generated or stored information was deleted and cannot be fully reconstituted. At trial, certain of the PSC's evidence was focused upon directly reinforcing evidence previously submitted through briefing, while other evidence was entirely new. The following are merely illustrative of the well-established relevance of the information contained in the deleted files:

- Destroyed documents in Japan include those in the files of high-ranking executive officers (including at least one member of the board of directors – Mr. Kitazawa) who were heavily involved in Takeda's response to the bladder cancer-related threats to Actos presented by the information submitted by Novo Nordisk to the FDA and the fall-out from the FDA's consideration of that evidence in 2002.¹⁰⁹ This evidence

¹⁰⁹ See, e.g., Trial Tr. vol. IV, 460, 473-74, 476, 497, 499, 500, 523-24 (Rec. Doc. 4175).

supports the finding that there were documents destroyed, that the destroyed documents included relevant information and that which was destroyed would have been prejudicial to Takeda's interest in any product liability litigation related to Actos. The files destroyed include personal computers, emails, personal files, paper files, and business documents.

- Communications with the high-ranking Japanese executives were coordinated and routed, and yet, all notes and other evidence of communications among certain of the most important involved Takeda employees up to and including the Japanese decision makers were deleted and destroyed.¹¹⁰
- There are no notes or other documentation relating to the meetings or correspondence between Upjohn and Takeda during the fall of 2003.¹¹¹
- The American members of the task force who sought to communicate with Japanese employees were required to submit their communications directly to Mr. Saito first and yet, those files were deleted and destroyed,¹¹² as well as all of Mr. Saito's files.¹¹³
- Phillips Collett presented "an outline of the Cohen hypothesis" at an August meeting to respond to the FDA; his outline is missing, presumably was destroyed with his files.¹¹⁴
- Mr. Miyazaki prepared documents for a meeting with the CEO on the bladder cancer issue – those files were destroyed.¹¹⁵
- The files of many of the Takeda Japan employees who were involved in negotiating Takeda's progress with the relevant regulatory agencies as to label changes, were deleted and destroyed.¹¹⁶
- Mr. Miyazaki was assigned to gather and review Japanese clinical data for the task force;¹¹⁷ Mr. Miyazaki's files were deleted and destroyed.

¹¹⁰ Trial Tr. vol. VII, 890 (Rec. Doc. 4178).

¹¹¹ Trial Tr. vol. IV, 437 (Rec. Doc. 4175).

¹¹² Id. at 482.

¹¹³ Id. at 474, 475-76.

¹¹⁴ Id. at 489.

¹¹⁵ Id. at 502-03.

¹¹⁶ Id. at 531.

¹¹⁷ Trial Tr. vol. X, 1265 (Rec. Doc. 4181).

- Although Takeda employees had open communications with those Takeda employees on Takeda's task force handling Takeda, all communication with the CEO was strictly controlled and went through Mr. Saito, whose files were destroyed and deleted.¹¹⁸
- Generally, minutes of meetings were created and kept, however, they no longer exist as the files of the pivotal meeting participants were deleted and destroyed.¹¹⁹

These cursory examples are in no way exhaustive or exclusive, rather, are merely illustrative of the plethora of testimony and evidence the PSC presented at trial to further support their argument and this Court's determination made in its initial ruling, Rec. Doc. 3933, that the deleted and destroyed files and documents were relevant and the loss of which is prejudicial to the PSC and in particular to Mr. and Mrs. Allen in attempting to establish the elements of their claims against Takeda. Furthermore, the evidence presented at trial by the PSC showed this conduct by Takeda to be only a small part of an overall pattern of conduct by Takeda.

Takeda's argument in response to the PSC's evidence is circular in nature, i.e. "we can never know what was inside the destroyed files" and, therefore, there can never be a showing of either relevance or prejudice. However, the PSC has established with credible, reliable, evidence obtained from third parties or from files not destroyed, that all of the 46 witnesses had critical information regarding the development and marketing of Actos. With regard to those witnesses, at the very least, the Plaintiffs have amply demonstrated both the relevance of the destroyed documents and the inevitable prejudice to their interests resulting from their inability to review the documents that should have been available. Additionally for Takeda to argue that because the documents have been destroyed, (albeit by Takeda) the PSC can never absolutely prove the benefit or nature of those destroyed documents, and thus the Plaintiffs cannot carry their burden,

¹¹⁸ Id. at 1268-69, 1296-97 (Rec. Doc. 4181).

¹¹⁹ Id. at 1290-91 (Rec. Doc. 4181).

would render Mr. and Mrs. Allen and Plaintiffs in future litigation wholly without remedy, and would act to both encourage and reward companies for their bad behavior, and, most importantly, would render impotent the underlying and established legal obligation owed to the judicial process. Thus, the Court finds this argument by Takeda wholly unpersuasive.

Considering the foregoing, this Court, again, concludes the plaintiffs have made a sufficient showing of relevance of and prejudice resulting from the loss of deleted information, and Takeda has not met that showing with sufficient credible and reliable evidence or persuasive argument.

Thus, for all of the foregoing reasons, this Court had and continues to find that Takeda engaged in spoliation of documents that it should have preserved pursuant to the 2002 Hold; that the files were shown to be relevant to the legal issues at hand, and the lack thereof can be reasonably assumed to prejudice the PSC in their claims. Consequently, this Court now turns its attention to the remaining and resultant issue, the legal consequences of Takeda's conduct.

B. Is the PSC Entitled to Sanctions? And, if so, Which Ones?

The PSC has requested this Court impose significant sanctions on Takeda as punishment for its acts of spoliation, its willful abuse of the judicial process, and its violation of Fed.R.Civ.P. 37, arguing separate and distinct, but at certain points overlapping in both time and nature, conduct by Takeda. District courts addressing the question of sanctions agree, once a court has determined evidence was spoliated, the court may, but is not compelled to, exercise its discretion to impose sanctions upon the responsible party, under its inherent authority, or by way of FED.R.CIV.P. 37. In exercising its discretion, particularly when acting pursuant to its inherent powers, district courts agree, a court should evaluate: (1) the degree of fault of the party who altered or destroyed the evidence; (2) the degree of prejudice suffered by the opposing party; and

(3) whether there is a lesser sanction that will avoid substantial unfairness to the opposing party. Alcoa, *supra* at 340, *citing* Menges v. Cliffs Drilling Co., 2000 WL 765082, *6 (E.D. La. 2000). In district courts within the Fifth Circuit, as a general rule, the “severe sanctions of granting default judgment, striking pleadings, or giving adverse inference instructions – as requested by the PSC - may not be imposed unless there is evidence of ‘bad faith.’” Rimkus, *supra* at 614, *citing* Condrey v. SunTrust Bank of Ga., 431 F.3d 191, 203 (5th Cir. 2005); King v. Ill.Cent. R.R., 337 F.3d 550, 556 (5th Cir. 2003); United States v. Wise, 221 F.3d 140, 156 (5th Cir.2000). Overriding the foregoing analysis is, however, the caution voiced by the United States Supreme Court to district courts when a court proceeds to impose sanctions pursuant to its inherent power, along with the jurisprudential suggestion that when imposing sanctions, the sanction should be only that necessary to redress conduct that abuses the judicial process. *See* Silvestri v. General Motors Corp., 271 F.3d 583, 590 (4th Cir. 2010), *citing* Chambers, *supra* at 45-46.

1. Should Sanctions Be Imposed?

This Court now turns its attention to that matter specifically reserved for final determination after this Court had full opportunity to hear all evidence and arguments at trial and, consequently, have the benefit of all evidence presented at trial – did Takeda act in bad faith or in willful abuse of the judicial process? And, if so, what consequences should flow as a result of Takeda’s conduct? By way of reiteration, the PSC has consistently argued, presented evidence, continued to argue, and continued to present evidence up to and through trial, that Takeda’s destruction of files was done in bad faith and its actions, which began before this litigation, and which continued into this litigation were an effort to conceal Takeda’s destruction of documents, and that Takeda’s positions taken and conduct engaged in within discovery,

motion practice, and trial were a willful abuse of the judicial process. The PSC argues all were done with the deliberate intent to impede this litigation and to cover up its intentional deletion and destruction of relevant documents covered by a valid litigation hold and after a time Takeda had a reasonable anticipation of litigation as to Actos®. This Court finds the PSC has fully carried its burden on these issues.

As noted, certain of Takeda's conduct is more directly relevant to the question of spoliation – for instance Takeda's conduct engaged in well before the first suit was filed in the MDL and well before Mr. and Mrs. Allen's suit was filed – whereas other of Takeda's conduct is more directly relevant to the question of a violation of FED.R.CIV.P. 37 and willful abuse of the judicial process – for instance Takeda's conduct which occurred within this MDL, but which might, also, be evidence not of the conduct itself, but of *the nature of* Takeda's earlier conduct. The *evidence of* Takeda's conduct overlaps when assessing *Takeda's possible willful intention and possible bad faith*, with Takeda's *actual conduct* both before this Court and having occurred before suit was filed. However, it is clear much of Takeda's conduct was engaged in well before Takeda came within the authority of this Court and, therefore, cannot be readily addressed by way of FED.R.CIV.P. 37. Additionally, this Court reminds, a finding of the violation of Rule 37 and a willful abuse of the judicial process more often addresses conduct occurring after suit has been filed and does not necessarily require a finding of bad faith, whereas the jurisprudence, although not as developed and clear as one might hope in this ever evolving electronic age, indicates a finding of spoliation and exercise of this Court's inherent powers, often addresses conduct which occurred before suit was filed and a finding of bad faith is often required for the type sanctions requested by the PSC, particularly a default judgment, and a mandatory instruction to the jury.

While Takeda argues this Court should demand “direct evidence” of its bad faith before *any* sanction can be imposed, under either mechanism, such a demand is not reflected in the applicable jurisprudence, nor required by FED.R.CIV.P. 37. Therefore, to embrace Takeda’s argument on this point would, in effect, be creating new law by imposing a heightened requirement of proof which is not supported by FED.R.CIV.P. 37, the applicable jurisprudence, nor the practical realities inherent in the questions surrounding a finding of spoliation and exercise of this Court’s inherent power, particularly when addressing electronic documents and files. Even outside, but certainly within, the context of deletion of electronic documents, rarely can bad faith be established by “direct evidence” or can a party find the “proverbial smoking gun,” particularly when the conduct in question is the company’s *deliberate attempt* to destroy any and all evidence *of its deliberate intent* and, therefore, to eliminate all “direct evidence” or “smoking guns.” If this Court were to accept Takeda’s argument, only the inept would be subject to policing by the law, as only the inept would have left “direct evidence” and/or a “smoking gun” behind after their deliberate attempts to destroy that very direct evidence. Rather, unfortunately, given the pragmatic realities of the inquiry, the courts are relegated to looking not at or for one act or one document or to “direct evidence” that a company, in effect, and against its interest, openly declares that it is acting in bad faith, but rather at the totality of the circumstances surrounding the company’s conduct. Thus, a court must look to the totality of the company’s actions, and the contextual basis of those actions in relation to the legal issues at hand.

After full review of all of the evidence and testimony presented by both the PSC and Takeda, both before and during trial, as well as Takeda’s evidence and argument both before and during trial, and, also, considering as evidence, Takeda’s conduct before suit was filed,

continuing after suit was filed, through the discovery and motion practice, and continuing on and into trial - this Court finds Takeda acted in bad faith and, also, a willful abuse of the judicial process in a deliberate attempt to destroy and, eliminate information concerning Actos and to obfuscate and hide its conduct and its knowledge of potential health risks of Actos® that might be relevant to future lawsuits and set about eliminating all files which might contain relevant evidence contained in Takeda's corporate files – electronic and otherwise - and thereafter acted before this Court to obfuscate and conceal that conduct. This Court's finding as to a violation of FED.R.CIV.P. 37 and Takeda's bad faith, deletion and destruction of files and documents, and subsequent willful abuse of the judicial process in an attempt to conceal that deletion and destruction, is further supported by those reasons given in Rec. Doc. 3933, those noted above, as well as the following conduct leading up to and continuing within this litigation:

- It has been established that Takeda U.S., Takeda Japan and Takeda Europe were subject to litigation Hold requiring retention of documents in anyway relating to Actos®.
- It is undisputed Takeda U.S., Takeda Japan and Takeda Europe deleted and destroyed files of key Takeda employees intimately involved with the marketing and development of Actos® after that Hold was in place.
- Within this litigation, the existence of Litigation Holds and lawsuits filed against Takeda have been the subject of discovery and interaction with the Court.
- ***Although asked by the Special Masters, Takeda failed to promptly identify litigation holds the company was fully aware of and, without explanation, changed the date submitted to the Court and, thereafter, argued as fact, facts directly contradicted by the clear language of the 2002 Hold and the trial testimony of Takeda's Assistant General Litigation Counsel, Stacey Calahan. Moreover, within discovery, when it became clear to Takeda that an improper date had been provided to this Court, through the Special Masters, Takeda failed to correct the record promptly***

By way of background, the Special Master and Deputy Special Master were charged by the Court to help manage and facilitate discovery on behalf of the Court. During a telephone conference among counsel conducted on May 28, 2013, the Special Masters, on behalf of the

Court, instructed, on behalf of the Court, Takeda to provide the applicable litigation hold date for the MDL cases to the PSC and Special Masters no later than June 6, 2013. On June 6, 2013, within the context of this MDL litigation, Takeda sent an e-mail to the Special Masters and PSC counsel advising them, in part, of the following:

Finally, our understanding is that ***Takeda issued its litigation hold notice for bladder cancer product liability litigation on February 15, 2011.*** The inquiry of Takeda's counsel into these matters continue and written supplemental information will be provided.¹²⁰ (emphasis added)

The June 6, 2013 e-mail, also, asserted that all of the Takeda employees for whom the PSC sought discoverable information had left Takeda's employment between February 2001 and April 2011, thus, the implication was that those employee's files would not have been impacted by Takeda's litigation hold and, therefore, would not be subject to discovery. Takeda claimed that all of the employees for whom files were requested had left their employment with Takeda *prior to the applicable litigation hold date*, except for one employee – Mashahiro Miyazaki. And, even as to Mr. Miyazaki, according to Takeda, Mr. Miyazaki's *actual* departure date was April 1, 2011, but deletion of data from his computer occurred on March 22, 2011, i.e., *prior to* his formal separation from employment, but *after* the declared litigation hold date of February 15, 2011 – as has been established by evidence presented, this assertion by Takeda was in no way accurate.

As foreshadowed in the June 6 e-mail, Takeda, thereafter, submitted a supplemental response by e-mail dated June 14, 2013 *declaring a different litigation hold date* without explanation:

¹²⁰ See e-mail dated June 6, 2013, attached as Exhibit 3 to the Motion for Sanctions (Rec. Doc. 3484) (emphasis added).

Our understanding is that **TPC** issued a litigation hold notice for bladder cancer product liability litigation on September 2, 2011.¹²¹
(emphasis added)

This supplemental e-mail did not address the earlier declared February 15, 2011 litigation hold date that had been provided by Takeda on June 6 or the interplay between the Takeda entity in the United States, Takeda Pharmaceuticals America (TPA), and the corporate entity in Japan, Takeda Pharmaceutical Company, Ltd. (TPC); rather, simply offered a *new* date, with no mention of the February 15, 2011 date which had been provided *only eight days earlier*. It cannot be overlooked the proper litigation hold date was pivotal to a vigorous discovery dispute and to anticipated discovery swirling around possible chronological limits to the PSC's discovery requests. No mention was made of the existence – whatever their argued application or lack thereof - of the 2002 Hold.

Having initially informed the Court that the pertinent litigation hold date was February 15, 2011 (this notice was provided to the Special Masters on June 7, 2013), Takeda had numerous opportunities to correct or clarify the record by identifying the date on which any and all litigation hold(s) was/were issued or to distinguish between or among the relevant Takeda entities if desired.¹²² Takeda did not do so, rather, Takeda filed a Motion for Protective Order without correction or clarification wherein Takeda, again, failed to correct or clarify in its Brief in Response to Plaintiffs' Motion to Compel 30(b)(6) Deposition filed on June 28, 2013. Takeda, yet again, failed to correct or clarify during the July 3, 2013 hearing conducted by Magistrate Judge Hanna, and, yet again, failed to correct or clarify during the July 25, 2013 status conference conducted by Magistrate Judge Hanna. The record reflects that only upon

¹²¹ See e-mail dated June 14, 2013, attached as Exhibit 4 to the Motion for Sanctions (Rec. Doc. 3484)(emphasis added).

¹²² Again, it cannot be overlooked that for purposes of the Allen trial – in which the motion for sanctions, also, was filed, by agreement of the parties “Takeda” encompassed all Takeda entities, domestic, European and Japanese unless specifically otherwise noted.

specific and direct question *of Magistrate Judge Hanna*, did Takeda, *for the first time*, admit to the very existence of earlier suits and earlier litigation holds.

At this juncture, this Court will step to the side of the primary discussion and note there is a distinct difference within discovery when faced with broad questions such as those posed by the PSC to Takeda and those posed by the Court, between *denying by omission the very existence of earlier lawsuits, claims, or/and earlier litigation holds*, and admitting that existence but, arguing those claims are not lawsuits, or the holds do not apply. Yet, Takeda *omitted the very fact of existence*, thus, depriving the PSC *of the possibility* of discovery which might – as was the case in this MDL – prove *the applicability and relevance* of the very documents and information whose existence was denied by way of omission. Takeda chose to overlook this pivotal distinction and refused to disclose *the existence of* lawsuits and litigation holds in the face of both discovery and order of the magistrate judge, which clearly called for its disclosure – not because they did not exist, but because Takeda might have believed they had argument that the lawsuits were not relevant and the holds not applicable and Takeda, therefore, unilaterally omitted disclosure of the very existence of the documents and claims. Thus, when the PSC presented their discovery requests, Takeda argued on grounds of overbreadth. At that point, the PSC and the magistrate judge attempted to discern when Takeda would have had a reasonable anticipation of litigation and whether litigation holds would have been put into place in order to determine the breadth of discovery to be allowed. Takeda's responses were pivotal to that inquiry at that time, yet Takeda chose not to disclose the existence of the 2002 litigation Hold, and certain earlier claims and lawsuits, for some time. Such a unilateral determination is not the purview of any party within discovery, rather is a determination to be made by the Court with benefit of argument by both sides and full review of the documents themselves. The end result

of this costly and time consuming unilateral determination and resultant omission and obfuscation by Takeda is, in and of itself, the proof of the importance of this distinction, particularly in light of the documents ultimately produced through discovery, the clear application of the 2002 Hold, and the clear relevance of the 2002 lawsuits and 2000 claims. But for Takeda finally admitting the *existence* of the earlier claims, suits, lawsuits and holds relating to Actos®, the clear language of the 2002 Hold and the “refreshers” would never have come to light, nor would discovery have been allowed which could have uncovered that very existence, and, perhaps, equally important, the PSC would, therefore, have been denied *any opportunity for the very discovery required to disprove Takeda’s unilateral determination and its after-the-fact arguments*. The actual existence and disclosure of the documents and information withheld by Takeda in the face of valid discovery requests and specific inquiry by the magistrate judge has been proven to be pivotal to defining the discovery necessary for the PSC and Mr. and Mrs. Allen to prove necessary elements of their claims. There is a clear and unassailable distinction between failing to disclose relevant information which exists, and disputing the applicability of that information; *a distinction Takeda deliberately chose to ignore*. It is not for a party such as Takeda to unilaterally decide to withhold the fact of the very existence of information which falls under a valid discovery request; rather, it is the purview of the Court – upon valid objection made – to determine whether the disclosed information and documents are applicable and relevant.

Again, notwithstanding Takeda’s earlier responses, on August 7, 2013, Takeda, again, gave response seemingly contradictory to its earlier position, in this instance to the PSC’s Supplemental Interrogatory 2, which had sought information about claims, settlements and litigation concerning personal injuries relating to Actos® as follows: “[A] **general Actos®**

‘product liabilities’ litigation hold was implemented at Takeda Pharmaceuticals U.S.A., Inc. (f/k/a Takeda Pharmaceuticals North America, Inc.) and Takeda Pharmaceuticals America, Inc. **in July 2002** when Takeda Pharmaceuticals U.S.A., Inc. (f/k/a Takeda Pharmaceuticals North America, Inc.) and Takeda Pharmaceuticals America, Inc. received notice of the first Actos® personal injury lawsuit, which was filed by Plaintiff Elizabeth McMillan in the Circuit Court of Jackson County, Missouri. **The general Actos® ‘product liability’ litigation hold** became applicable to Takeda Development Center Americas, Inc. (f/k/a Takeda Global Research & Development Center, Inc.) at the time of its incorporation in 2004 and has been refreshed periodically since that time.” (emphasis added). However, Attachment A to Takeda’s Responses to Plaintiffs’ Supplemental Interrogatory No. 2 shows a lawsuit naming both Takeda U.S. and Takeda Japan as defendants was filed and served on or about July 25, 2002,¹²³ and later response establishes Takeda Japan was also named in the 2002 lawsuit.

Therefore, not mentioned in this response, but later admitted by Takeda in their response to Plaintiffs’ Supplemental Interrogatory 2, is the fact that Takeda Japan was, also, named in the lawsuit in 2002.¹²⁴ All and each of these withheld disclosures have been proven to be pivotal to both discovery and the PSC’s ability to prove their cases as against Takeda.

i. Document destruction, particularly the significant amount that occurred in this case.

Takeda has presented little beyond unsupported argument to explain its selective document destruction in the face of Takeda U.S.’s and Takeda Japan’s having actually been named in an Actos® product liability suit in 2002 and in the face of the litigation Hold Takeda issued in 2002. The arguments made on this point before trial have been wholly undercut by the

¹²³ See Takeda’s Response to Plaintiffs’ Supplemental Interrogatory 2, Exhibit A, which is attached as Exhibit 6 to the PSC’s Memorandum in Support (Rec. Doc. 3484).

¹²⁴ Id.

actual language of the Hold itself and the testimony Takeda's Assistant General Litigation Counsel, Stacey Calahan, at trial as discussed above. At trial, Takeda, primarily, presented two witnesses to meet the magistrate judge's finding of a *prima facie* showing as to spoliation and this Court's preliminary ruling on this point – Stacey Calahan and Jerry Colca. This Court has, above, given and will below, give further reasons for finding Colca's testimony unreliable and speculative, at the very best, and Ms. Calahan's testimony supportive not of Takeda's position, but rather, of the PSC's position, and will not reiterate those reasons here. However, suffice to say, Takeda did not present credible and reliable evidence to meet the PSC's evidence or to support its arguments that the deletion and destruction were innocent and not done in bad faith.

As noted, but worthy of repeating here, at trial the PSC and counsel for Mr. and Mrs. Allen presented evidence Mr. Katsuhisa Saito, the Senior Director, Pharmaceutical Development Division, Strategic Development Department was the hub for and of all information concerning Actos® during critical periods of development and crises for Takeda as to Actos®. All information was routed to and through him and he was the ultimate and final arbiter. There is no dispute Mr. Saito's files were destroyed and cannot be reconstructed, as were the files of all of the more significant employees involved in the flow of information to Mr. Saito, during the critical junctures within challenges posed to Actos®' development, governmental regulation and marketing. In effect, the files of Takeda's commanding general as well as his front line generals and direct aides in the battles waged by Takeda in its development, regulation of, and marketing of Actos® were deleted and destroyed – all in the face of a valid and applicable litigation hold having been issued and Takeda Japan having had full notice of that hold and a full understanding of its legal obligations in the United States as to that hold. Such select and methodical destruction, under these facts, strongly supports the reasonable inference and factual finding the

deletion and destruction was not incidental or random, rather, was intentional, and done with deliberate intent, to eliminate evidence of Takeda's conduct, which would be relevant in product liability suits as to Actos® and thus, was done in bad faith.

ii. Failure to comply with the litigation hold established in 2002.

Although this Court has found and, again finds, the PSC submitted sufficient evidence prior to trial to establish that all Takeda entities failed to comply with the litigation Hold that had been established in 2002, and at a time when all had a reasonable anticipation of litigation, this point was further solidified by the evidence presented by the PSC at trial. Even Takeda's Assistant General Litigation Counsel, Stacey Calahan, admitted that the litigation Hold had not been complied with by any Takeda entity. Although Takeda argued that the failure to comply was the result of compliance with otherwise put in place document retention policies, as discussed above, the evidence presented at trial, both by Takeda and the PSC, did not support this argument; rather, the evidence supported the PSC's argument to the contrary. Of note is evidence establishing that the actual document retention policies testified to by Ms. Calahan were not capable of being operational as information technology could not implement the corporate retention policy.¹²⁵ As noted above, it is a hollow argument, at best, for Takeda to suggest that the document destruction, in the United States, was a result of a document retention policy which Takeda, itself, admits it knew could not be implemented, and thus, could not protect the required documents. Additionally, Ms. Calahan admitted in her testimony, upon questioning, that soon after assuming her position in 2007, she, in fact, realized that "a problem" existed as the litigation Holds had not been followed even in the U.S.¹²⁶ Perhaps one of the most

¹²⁵ Trial Tr., vol. V, 588 (Rec. Doc. 4176).

¹²⁶ Trial Tr., vol. VI, 744 (Rec. Doc. 4177).

telling documents is Stacey Calahan's February 15, 2011 e-mail sent to numerous individuals in Takeda Pharmaceuticals, Inc., Takeda Pharmaceuticals North America, Inc., and Takeda Global Research & Development, Inc. regarding "Actos® product liability legal hold."¹²⁷

Dear Colleagues:

To ensure compliance with Takeda's **ongoing legal obligations to retain information subject to a Legal Hold**, I am **once again issuing to you** the following ACTOS® **Product Liability Legal Hold**. (emphasis added)

As you are aware, Takeda is involved in several product liability claims regarding ACTOS®. I am writing because you may be in possession of electronic and physical documents relevant to these matters. It is critical that all such documents continue to be preserved and retained. Please see the attached Legal Hold, which described the documents (electronic and paper) that **MUST** continue be [sic] retained at this time for use in these matters.

Also, please forward this message (with a copy to me) to anyone in your organization who might possess relevant documents and who is not shown as a recipient of this message. (emphasis in original)

Actos® Product Liability Legal Hold attached to Stacey Calahan's February 15, 2011 e-mail.¹²⁸

Takeda Pharmaceuticals North America, Inc. continues to be involved in product liability claims regarding ACTOS®. As a result of these claims, Takeda must take steps to ensure the preservation of all documents, as defined below, relating to this matter. Failure of Takeda and its employees and contractors to retain any potentially relevant documents may have serious consequences. The preservation of relevant documents for these claims is of paramount importance.

All documents that relate to these claims that you now possess or that come into your possession in the future must be preserved even if they would normally be destroyed in the ordinary course under Takeda's document retention policy. For purposes of identifying documents to be preserved, the term "relate to" should be construed as broadly as possible and any doubts concerning particular documents should be resolved in favor of preservation. Takeda's Legal Department personnel may contact you in connection with the collection process for this investigation. Please cooperate in that collection process.

¹²⁷ Exhibit 9 attached to the PSC's Memorandum in Support, Bates No. TAK-RIM-30b6-00000695 (Rec. Doc. 3484).

¹²⁸ Exhibit 9 attached to the PSC's Memorandum in Support, Bates No. TAK-RIM-30b6-00000696-697 (Rec. Doc. 3484).

It is also of note that within the United States Takeda entities, Takeda made the argument that CORP-B-019 was in fact applicable, when the evidence shows it could not be enforced because the information technology infrastructures were never put in place to facilitate its implementation. And yet, Takeda's obligation to retain files and information pursuant to the referenced legal holds were arguably in effect prior to and after CORP-B-019.

It is undisputed Takeda Japan did not honor the 2002 Hold. Takeda Japan destroyed documents of key Takeda employees and yet, the corporate retention policy, if any, at place in Japan remains a great mystery, *as Takeda has not chosen to present – even within the face of valid discovery request, order of the magistrate judge, the PSC's argument and evidence, and this Court's preliminary ruling – anyone knowledgeable to testify as to the policies of Takeda Japan.* In fact, Ms. Calahan specifically denied any such knowledge as to Takeda Japan and it remains difficult to determine whether Mr. Regard actually had any such knowledge or not. Of course, Mr. Regard, it is clear, had no personal knowledge at all, and whether he possessed any *corporate* knowledge, and if so, whether from any reliable corporate source, is impossible to determine. Takeda has had full opportunity to present representatives who could, and, *in fact, were ordered to* present representatives who could discuss the retention policies of the Takeda entities in the U.S., Europe, and Japan, and have failed to do so. In the face of evidence argued by the PSC as evidence of Takeda's willful and bad faith conduct, Takeda had full opportunity to present to the Court, evidence to support its arguments of innocent destruction and Takeda has failed to do so by way of the Allen trial or before. Armed with the PSC's evidence, argument, and this Court's preliminary determinations made pursuant to that evidence as to spoliation and Takeda's conduct vis à vis Rule 37, Takeda chose to present Stacey Dixon Calahan, its Assistant General Litigation Counsel, to testify on behalf of Takeda as to these issues and yet, Ms. Calahan

testified she had no knowledge as to Takeda Japan. Regrettably, Ms. Calahan repeatedly declared that she had no knowledge, or limited knowledge at best, as to Takeda Japan's internal operations vis à vis corporate document retention policies, and handling of litigation holds. Consequently, *Takeda, through its own choice, and notwithstanding multiple opportunities and orders to do so*, failed to present anyone who could testify on its behalf with reliable knowledge of Takeda Japan's corporate policies, conduct, or awareness as it relates to document retention, notwithstanding full knowledge Takeda Japan was intimately involved in the development and marketing of Actos®, and the fact this issue was paramount to the PSC's case and to Takeda's arguments.

In contrast, at trial, the PSC presented a plethora of credible, reliable evidence that the 2002 Hold applied to Takeda Japan; that Takeda Japan was aware of the 2002 Hold; that Takeda Japan was aware of the legal implications and consequences of that Hold; and yet in the face of that evidence, that Takeda Japan destroyed, in a methodical and selective fashion, key employees' files as they related to their involvement with Actos®. Furthermore, specifically as to the Japanese Takeda entity's knowledge and understanding, the PSC presented evidence by way of a preexisting patent litigation hold involving Actos®, admitted to be applicable to Takeda Japan, involving patent litigation which granted Takeda Japan complete knowledge of the legal obligations and consequences which flow from litigation holds within the United States. Additionally, the PSC presented evidence Takeda Japan destroyed documents covered by this hold – which has not been lifted – which, had they been retained as required by the patent litigation hold, would have been available for the 2002 product liability Hold and would have fallen under the 2002 product liability hold. The foregoing demonstrates, again, an unexplained and seemingly blatant disregard of their legal obligations by Takeda Japan under otherwise

undisputed litigation holds, and yet, Takeda presented no one knowledgeable to testify as to Takeda Japan's conduct.

iii. The Upjohn affair.

As noted above, in the early 1990's, Takeda Chemical Industries Limited – the predecessor to Takeda Pharmaceutical Company, i.e. Takeda Japan – was engaged in a loose joint undertaking with the Upjohn company to develop pioglitazone from which Upjohn withdrew citing inadequate “margins of safety.” By letter dated September 21, 1993, Upjohn informed Takeda Japan that its “highest scientific decision-making body” had carefully reviewed the results of the toxicology and clinical studies to date and concluded that Upjohn would not proceed further with clinical studies of pioglitazone. “The council decided that further clinical development of pioglitazone could not be justified based on their concern regarding pioglitazone's margin of safety.”¹²⁹ In response, Mr. Kitazawa, General Manager of the International Development Department in the Pharmaceutical Development Division of Takeda Chemical Industries Limited, i.e. Takeda Japan, responded to Upjohn's notice and requested that, rather than indicating that Upjohn's decision was based upon its “concern regarding pioglitazone's margin of safety,” that Upjohn issue a statement linking its decision to the efficacy of pioglitazone, rather than its safety.

In response to Takeda's request that Upjohn explain its decision in terms of its own business needs and the efficacy of pioglitazone – rather than in terms of the “margin of safety” that had been exhibited thus far – e-mail from Peter J. Daniels (an unidentified Upjohn employee) indicated that he and some of his colleagues were concerned about the “lack of

¹²⁹ Exhibit 22 to PSC's Memorandum in Support (Rec. Doc. 3484).

frankness (and honesty?) of the Takeda statement.”¹³⁰ In response, Takeda submitted an e-mail of Patricia Ruppel which indicated that the statement drafted by Takeda – indicating that there was a large amount of pre-clinical work that needed to be done – and the clinical efficacy was limited and, thus, did not justify such a large investment, “reflects pretty accurately”¹³¹ the stand taken in Osaka. However, Ms. Ruppel did not testify and the PSC, also, presented e-mails and argument undercutting the motivation behind this argument and argued, again, that there should have existed notes on the Osaka meeting within the files of those Takeda employees who attended and Takeda had – in violation of the 2002 Hold – deliberately deleted and destroyed those files, and consequently, Takeda should not now be allowed to hide behind that conduct.

Specifically, in September 1993, Dr. J.R. Mitchell, the president of Upjohn, had written to Dr. Tai Matsuzawa, a Vice President of the Takeda Pharmaceutical Group at Takeda Chemical Industries, Ltd. (another Japanese Takeda entity), as follows:

On September 20 our Pharmaceutical Executive Council, **Upjohn’s highest scientific decision-making body**, carefully reviewed the results of the **toxicology and clinical studies**. The decision of the Council was that **Upjohn will not go forward with pioglitazone in the clinic. *The Council decided that further clinical development of pioglitazone could not be justified based on their concern regarding pioglitazone’s margin of safety.***¹³²

In response, Dr. Kitazawa responded to Dr. Patricia Ruppel, the Project Manager Director for Upjohn, suggesting revision of “Upjohn’s statement,” as follows:

Regarding Upjohn’s statement for the development status of pioglitazone, **we would like to propose the following alternative or a similar [sic] instead of Upjohn’s proposal** in due consideration of our current development status.

¹³⁰ Exhibit 24 to PSC’s Memorandum in Support (Rec. Doc. 3484).

¹³¹ *Id.*

¹³² See Letter from J.R. Mitchell to Tai Matsuzawa, dated September 21, 1993, attached as Exhibit 22 to the Motion for Sanctions (Rec. Doc. 3484)(emphasis added).

In the very preliminary evaluation in the U.S.A., *pioglitazone did not show the reduction of blood glucose enough to satisfy Upjohn's in-house requirement.* Any considerable work that would be needed is not in line with our business needs for further development of Pioglitazone. **Hence, all development on pioglitazone at Upjohn has ceased.**¹³³

This Court relied heavily upon this evidence in its prior ruling as to the Upjohn matter in making a determination, in its prior ruling, that Takeda had acted in a manner to support the PSC's argument. Takeda, fully armed with this Court's preliminary determination and the PSC's evidence presented prior to trial, selected primarily, Jerry Colca to testify on Takeda's behalf at trial as to the true nature and their argued interpretation of the Upjohn matter. And yet, Mr. Colca's testimony established he: was not involved in the communication between Upjohn and Takeda; was not involved in Upjohn's decision to withdraw; was not a part of Upjohn's "highest scientific decision-making body"; was only informed of Upjohn's decision after the fact and, thus, had no personal knowledge as to the matter; had not attended a meeting in Osaka, Japan; had vested emotional ties to Actos® and was at the time of trial, actively courting Takeda's financial backing for his new TZD type diabetes drug. As noted above, this Court found Mr. Colca's testimony to be wholly unreliable. This Court does not question that much, if not all, of the testimony of Mr. Colca was his individual truth, however, Mr. Colca clearly did not have sufficient personal knowledge to support his testimony, opinions, and assumptions made; thus, this Court finds Mr. Colca's testimony *unreliable*. Additionally, the PSC established a strong and convincing challenge to his *credibility* as well. Mr. Colca is no longer with Upjohn, has founded a new company attempting to find financial backing from drug companies, Takeda in particular, for another "TZD" type drug of a similar nature to Actos®, and Mr. Colca was at the time of his testimony actively engaged in courting Takeda's backing for this project.

¹³³ See Letter from K. Kitazawa of Takeda to Patricia L. Ruppel, Director of Project Management at Upjohn, dated October 25, 1993, attached as Exhibit 23 to the Motion for Sanctions (Rec. Doc. 3484)(emphasis added).

Additionally, it is without question, after having heard Mr. Colca's testimony, Mr. Colca had, and continues to have, a personal and emotional connection to this type of medical approach to the containment of diabetes and was quite upset by Upjohn's decision to withdraw from the Takeda, Upjohn project. In fact, Mr. Colca indicated that when the involved corporate governance of Upjohn came to notify him of Upjohn's decision not to go forward with development of this drug, Mr. Colca "went ballistic."¹³⁴

Both the chronology of Upjohn's decision, and Mr. Colca's learning of that decision, as well as the strength of his emotional reaction are relevant to this Court when evaluating Mr. Colca's testimony. Again, it is clear from his testimony that Mr. Colca was not involved in the decision by Upjohn officials to terminate its association with Takeda and to terminate Upjohn's development of a drug with which Mr. Colca clearly had a strong emotional attachment. Mr. Colca was neither privy to the contemporaneous corporate conversations to discontinue or the communication between Takeda and Upjohn surrounding the decision to be made, nor was he informed of the decision before the decision was actually made – only after the decision had been made, nor was he sent or invited by Upjohn to go to the Osaka meeting. Although Mr. Colca testified efforts were made – after the fact - to explain Upjohn's decision to withdraw, even he admitted that those conversations were only after the fact, and in response to his having gone "ballistic."

Takeda chose to present the trial testimony of Dr. Jerry Colca, the senior researcher who had been employed by Upjohn in the 1980's and 1990's for the purpose of working on the development of Actos® to meet the PSC's evidence and argument. As referenced above, Takeda, with Dr. Colca's assistance, attempted to demonstrate that the PSC and this Court's interpretation of the Upjohn events and correspondence described *supra* represents an error on

¹³⁴ Trial Tr. vol. XXIX, 4711-12 (Rec. Doc. 4202).

the part of the Court and the PSC. Takeda argues business concerns – not abandonment of a project due to safety concerns – led to Upjohn’s decision. However, as noted, Dr. Colca’s testimony revealed that he was a researcher, not directly involved in any of the actual decision-making meetings about Upjohn’s future involvement with pioglitazone, either in the U.S. or in Japan.¹³⁵ As a result, his impressions of Upjohn’s “real” reason for ending its involvement with Actos are founded on hearsay, rumors, and his attempt to reconcile Upjohn’s decision with his emotional attachment to a particular class of drug to which he still holds allegiance and is attempting to develop and at the time of trial he was courting Takeda for financial backing.

Thus, Takeda chose to support its argument as to Upjohn’s actual reason for withdrawing and to meet the PSC’s evidence and argument with a witness who no longer works for Upjohn, was not involved or privy to Upjohn’s decision, was not involved or privy to Upjohn’s communication with Takeda Japan, and who had and still has a strong emotional attachment to TZD type drugs – of which Actos® is one - and who was at the time of his testimony attempting to convince Takeda to provide financial backing for yet, another TZD type drug of his design.

As noted above, Takeda, also, argued a meeting in Osaka, Japan supports their argument that their interpretation of the statement contained in Mr. Kitazawa’s letter is, in fact, correct, i.e. that Upjohn’s decision was a business choice and not based upon the absence of sufficient safety margins. However, again, Takeda’s testamentary evidence on this point was weak, at best, and was contradicted by documentary evidence presented by the PSC. However, even if accepted, the evidence presented by Takeda on this point would not change the documentary evidence presented by the PSC and, furthermore, perhaps of equal if not greater significance, Takeda cannot escape the undisputed fact that Takeda destroyed the very files of the very Takeda

¹³⁵ Trial Tr. vol. XXIX, 4678-79; 4714-15; 4716 (Rec. Doc. 4202).

employee involved in the Upjohn exchange and who attended the Osaka meeting in the face of a valid litigation hold and after Takeda Japan clearly had a reasonable anticipation of litigation arising out of its product, Actos®. This Court did not hear from Mr. Kitazawa, himself, at trial and his files were deleted, nor did this Court hear from any actual participant of the argued Osaka meeting. Thus, and again, this Court finds the PSC presented sufficient evidence by way of documents and testimony to fully support their argument and this Court's earlier interpretation of the "Upjohn Affair" and Takeda did not meet that evidence with sufficient credible and reliable evidence to support their argument.

In sum, the PSC, through evidence and testimony presented before and at trial, has painted a picture of a company motivated by a desire to solidify its move into the international drug market and reap the enormous financial gains available to it in that market, which set out to not only disregard, but bury and eliminate all evidence which could have thwarted their purpose or could be used in litigation and, thus, harm that goal, i.e. expose Takeda's prior knowledge of possible risks inherent in the development, marketing and use of Actos®. The PSC presented much evidence – both by way of documents and testimony of the promise and projection of enormous financial gain to a company wishing to move into a new market through the development and marketing of Actos® which, for much of the relevant time, was the company's sole drug/product and its flagship product. The PSC's evidence established Takeda was a company which was in transition and moving into the international drug market, with the hope Actos®, its flagship product, would and, in fact did, financially anchor. Again, the PSC presented evidence, in point of fact, that Actos® for much of the early and relevant period, was the only drug and product of U.S. Takeda. Consequently, the PSC presented evidence to support their argument that Takeda had financial gain and the desire to protect their flagship product

from the harm litigation could wreak as the underlying motivator in deleting all evidence which could be used against Takeda in litigation and thus, protect Actos®' position in the lucrative international drug market. Takeda presented little, if any, credible evidence to counter this argument and evidence put forth by the PSC. Consequently, this Court finds when the design of their flagship product was called into question by the reasonable anticipation of claims of health risks and anticipated litigation, Takeda engaged in a deliberate attempt to eliminate all evidence of knowledge of, and evidence of the risks themselves, and engaged in a deliberate attempt to conceal that conduct within the MDL. Thus, this Court finds the PSC presented evidence establishing a pattern of conduct carefully constructed, deliberately carried out, reflective of bad faith and a willful abuse of the judicial process.

iv. Further support

By way of illustration only, in no way exclusive or exhaustive, prior to trial and supported by the evidence put forth in their case-in-chief at trial, the PSC alleged and this Court agrees, the following evidence further supports the findings of this Court:

- Despite Takeda having actual knowledge of its duty to preserve evidence, files of at least forty-six witnesses were destroyed, deleted or otherwise lost. These employees played a critical role in the development and marketing of Actos®. Employees whose files were deleted were at the heart of discussions about bladder cancer and the need to "manage" the bladder cancer risk as a marketing problem.
- The sheer number of custodians whose documents were destroyed after the 2002 Litigation Hold was put into place suggests a deliberate disregard of that hold. Even a company diligently attempting to preserve evidence might mistakenly destroy a small number of files, or even all of the files of a single document custodian. But the wholesale destruction of the files of at least 46 relevant custodians -- *after a litigation hold was instituted* -- cannot be considered accidental. In spite of the 2002 Litigation Hold, Takeda deleted key employees' electronic files, erased hard drives, and destroyed paper files. 38 of the 46 custodians whose files are "missing" were deleted after 2002, when Takeda had issued its 2002 Litigation Hold.

- The scale of the spoliation in this case is further evidence that the documents were destroyed in bad faith. Takeda destroyed documents of relevant custodians on three continents over a period of approximately ten years. This repeated, systemic, and wide-spread destruction can only be the result of a willful and intentional failure to preserve; *i.e.*, a bad faith refusal to preserve evidence in the face of a known obligation to do so.
- In addition to not timely implementing and enforcing litigation holds, Takeda failed to follow its own document retention policies. Takeda admitted this fact in its 30(b)(6) deposition. Takeda also failed to index its backup tapes.

Again, this Court agrees and further notes Ms. Calahan admitted Takeda U.S.'s information technology lacked the infrastructure to actually implement the argued document retention policy.

- As part of the spoliation, Takeda made repeated material misrepresentations regarding litigation holds which continue to this date. The misleading June 6, 2013 e-mail (which was in specific response to the Special Masters' request) was sent to five additional counsel representing Takeda. The misleading nature of the June 6, 2013 e-mail was compounded by the fact that Takeda allowed the Court to labor under the false impression that the February 2011 reminder was "the" hold until such time as additional disclosures were compelled by a series of more specific questions by the Court and discovery propounded by the PSC. Since that time, Takeda has made a variety of inconsistent disclosures, not always voluntary. At the July 3, 2013 hearing, defense counsel continued to embrace the June e-mail and the February 2011 date as the applicable litigation hold date.

Again, this Court agrees and further notes, that prior to Ms. Calahan's testimony at trial admitting the 2002 Hold applied, at least as to Takeda U.S., Takeda had continued to argue the 2002 Hold did not apply to Takeda U.S.

- On June 14, 2013, eight days after the June 6, 2013 e-mail, instead of correcting the obvious misrepresentation, Takeda, now through different counsel, sent a "supplement" which again compounds the misrepresentation.

This Court notes the facts fully support this point.

- Instead of the continuing "inquiry" promised by the June 6, 2013 e-mail Takeda continued to claim none of the files of the Japanese custodians were deleted after a legal hold was issued in Japan.

This Court agrees and further notes, in light of Ms. Calahan's trial testimony, the February 15, 2011 was actually a reminder of a much earlier Actos Products Liability Litigation hold.

- The decision to designate Dan Regard as the document destruction 30(b)(6) representative as opposed to one or more witnesses who had direct personal or corporate institutional knowledge of the document destruction and litigation holds is evidence of obfuscation and bad faith.

This Court agrees and has included full discussion of this point, herein.

- Takeda has reversed its position regarding file deletion and inaccessibility. After taking a contrary position, Daniel Regard testified no files had been deleted and it had been Takeda's plan all along to use backup tapes to comply with its hold obligations. Regard also testified it was acceptable to delete files because of backup tapes. However, he could provide no evidence of a written policy to that effect and ignored Corp-B-019, a best practices memorandum and language in the Actos® hold itself which contradicted him.

This Court agrees, and further notes the apparent contradiction between Mr. Regard's and Ms. Calahan's testimony and Takeda's own internal documents as has been discussed herein.

- Takeda did not selectively destroy files pertaining to bladder cancer, while retaining files relating to other problems with Actos®, nor did it destroy files of employees whose involvement with Actos® was limited to bladder cancer. Rather, it destroyed files of executives with overall Actos® responsibility and sales representatives, who would have dealt with *any* Actos® defect.

This Court agrees the evidence submitted support this argument.

- When Plaintiffs became aware the files of certain document custodians were missing, rather than coming forward with a full explanation, Takeda began a campaign of concealment and obfuscation - in short, a cover-up.

This Court has included herein full discussion of this point and agrees.

This Court finds the foregoing PSC arguments were fully supported by evidence the PSC placed into the record preceding trial and at trial, and further finds these arguments were not contradicted by reliable or credible evidence presented by Takeda.

Again, as noted above, the PSC presented correspondence between Mr. Kitazawa and Upjohn, which they had to obtain through third-party discovery with Upjohn as it did not exist in the information presented by Takeda. Again, this correspondence suggests Upjohn withdrew from a development deal with Takeda over issues of “**pioglitazone’s margin of safety**,” but that Mr. Kitazawa, acting on behalf of Takeda, nevertheless, attempted to shift the Upjohn explanation from their express *safety concerns* associated with the drug to the *efficacy of Actos® as a reducer of blood glucose*. This Takeda correspondence, along with the plethora of evidence presented by the PSC at trial as to Takeda’s corporate culture, evidences a corporate culture which engages in and embraces conduct to conceal or remove mention of, or to underplay evidence of expressed safety concerns surrounding the development of Actos® in order to move forward with the development, marketing, and sale of Actos® and to protect the enormous profits generated by Actos®.

Also, urged by the PSC as evidence of Takeda’s bad faith as to its document destruction is the company’s conduct within discovery within the MDL, and chief among that conduct the designation of Daniel Regard as Takeda’s 30(b)(6) deponent in the face of the PSC’s discovery requests and the magistrate judge’s orders as discussed above. As noted, this Court reviewed the tortured 30(b)(6) deposition of Daniel Regard in connection with this Court’s earlier ruling and found a careful reading of the transcript revealed Daniel Regard had no personal or first-hand corporate knowledge of any Takeda entity’s corporate history; was never an employee of any Takeda entity other than as a consultant; and, on its face, his testimony is rife with deliberate obfuscation, and selective and shallow corporate investigation, at best. This Court, also, noted Magistrate Judge Hanna, in his discovery order, specifically ordered a Takeda representative be prepared to testify regarding, among other things, inquiry related to document retention systems;

inquiry related to the destruction of files at issue; and inquiry into the retrieval and/or reconstruction of the lost or destroyed documents.¹³⁶ And yet, Takeda clearly failed to do so.

Nonetheless, Daniel Regard's actual testimony is directly relevant to the issue now at hand. For example, despite testifying he "conducted dozens of employee interviews, went on site visits, and reviewed numerous Takeda documents and policies in preparation for the deposition," it is clear from a review of his deposition transcript this is at its very best hyperbole. Review establishes the interviews conducted by Mr. Regard were select and limited, at best. Mr. Regard did not interview many of the pivotal Takeda employees who might have had knowledge as to certain pivotal document retention issues at hand. For example, it is not at all clear from the record that Mr. Regard spoke to the relevant information technology employees at each of the Takeda various entities, and his testimony does not illustrate a strong grasp of the information technology procedures and their interplay with litigation hold policy each of those entities, nor could he testify with knowledge as to the corporate history of those holds or as to Takeda Japan's conduct, nor did he have a meaningful discussion with Ms. Calahan.

Perhaps, most telling is the seemingly cursory nature of his interview of Stacey Calahan, Assistant General Litigation Counsel for Takeda Pharmaceuticals USA, Inc. - whose "Declaration" Takeda submitted, after the 30(b)(6) deposition, in support of Takeda's opposition to this motion and whom, at trial, Takeda chose to designate as its designated corporate representative witness as to spoliation.

This Court notes, again, that portion of Mr. Regard's deposition where he acknowledges it did not occur to him to ask Ms. Calahan certain vital questions, as follows:

Q: Okay. Well, the point we're getting to here is, the February hold, the February 2011 hold that Ms. Calahan distributed –

¹³⁶ See "Ruling on Motion," Rec. Doc. 2992, at p. 9.

A: Yes, sir.

Q: – the language changed significantly, did it not, from the 2006 and 2007 version, which were the same?

A: It looks to be very different, yes.

Q: Okay. So why – when you talked to Ms. Calahan, when she said she was – this was just some sort of refresh unrelated to any bladder cancer or any particular event, why did she completely redraft the hold?

A: I did not ask her that question.

Q: Why not? Why didn't you ask her that?

A: It didn't occur to me at the time to ask her.¹³⁷

Indeed, it is clear from the deposition transcript there were a number of important issues related to the litigation holds that Mr. Regard simply did not question Ms. Calahan about, including the discrepancy between the two litigation hold dates provided to the PSC on June 6, and 14, 2013 by Takeda. Additionally, Takeda, after failing to present Ms. Calahan in response to the 30(b)(6) subpoena and the magistrate judge's orders – submitted not Mr. Regard's Declaration – but Ms. Calahan's to address the PSC's motion for sanctions. As Mr. Regard had *no personal knowledge or first-hand corporate knowledge* concerning these issues himself – having never worked for Takeda other than as a consultant and having only been retained to answer questions at Takeda's 30(b)(6) deposition - the Court is perplexed as to how Mr. Regard could have been expected to provide the definitive and comprehensive answers to the many questions specifically ordered by the magistrate judge and, in fact, a careful review of his deposition shows that in large part, he did not.

Even more important, as noted, Takeda submitted the "Declaration" of Ms. Calahan

¹³⁷ See Deposition of Dan Regard, attached as Ex. 8 to Motion for Sanctions, at 782-83 (Rec. Doc. 3484-2).

under 28 U.S.C. §1746¹³⁸ after the 30(b)(6) deposition of Takeda and later designated her as Takeda's corporate representative to testify, at trial, as to those issues subject to the 30(b)(6) notice surrounding spoliation and yet, Ms. Calahan's trial testimony established she, also, lacked either personal or corporate institutional knowledge to support many, if not most of the factual attestations made in her Declaration which Takeda had submitted to this Court to support Takeda's opposition to the PSC's Motion for Sanctions.¹³⁹ First, this Court notes the "Declaration" was presented after the 30(b)(6) depositions on behalf of Takeda, as to certain issues which were to have been addressed in Takeda's 30(b)(6) deposition, and, therefore, was submitted by Takeda and on behalf of Takeda, after the PSC would have had any opportunity to challenge or conduct discovery as to the opinions or assertions made within the Declaration. If, in fact, Ms. Calahan was the Takeda representative best suited to testify on behalf of Takeda as to these issues, she should have been presented at the 30(b)(6) deposition when the PSC would have had fair opportunity to question her as to the basis of her opinions and knowledge or, at the

¹³⁸ 28 U.S.C. §1746 states:

§1746. Unsworn declarations under penalty of perjury

Wherever, under any law of the United States or under any rule, regulation, order, or requirement made pursuant to law, any matter is required or permitted to be supported, evidenced, established, or proved by the sworn declaration, verification, certificate, statement, oath, or affidavit, in writing of the person making the same (other than a deposition, or an oath of office, or an oath required to be taken before a specified official other than a notary public), such matter may, with like force and effect, be supported, evidenced, established, or proved by the unsworn declaration, certificate, verification, or statement, in writing of such person which is subscribed by him, as true under penalty of perjury, and dated, in substantially the following form:

(1) If executed without the United States: "I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature)".

(2) If executed within the United States, its territories, possessions, or commonwealths: "I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)".

¹³⁹ This Court notes Ms. Calahan's tenure at Takeda would not grant her individual knowledge before July 2007, when she began her employment with Takeda Pharmaceuticals U.S.A., Inc., and thus, she, too, lacks the necessary personal or first-hand corporate knowledge to fully enlighten this Court to matters predating July of 2007.

very least the selected Takeda representative, Mr. Regard, should have asked the relevant questions of Ms. Calahan at his interview. Clearly, he did not. From Ms. Calahan's testimony at trial, it is clear such challenge and discovery as to the underlying foundation and basis of the facts and self-serving legal opinions contained in the Declaration submitted by Takeda on its behalf, was clearly needed, as her trial testimony established Ms. Calahan, also, lacked sufficient personal or corporate knowledge to support many, if not most, of that attested to in Takeda's self-serving Declaration.¹⁴⁰

Thus, the PSC's argument that Takeda attempted to insulate itself from meaningful questioning and discovery by choosing Mr. Regard to respond to the 30(b)(6) in order to hide Takeda's earlier conduct within the MDL as to the 2002 Hold and as to its document destruction is persuasive. And, after full review of Mr. Regard's tortured deposition, and now having benefit of Ms. Calahan's trial testimony, this Court specifically finds Mr. Regard's testimony that he was comprehensively prepared to answer questions about the very critical issues outlined by the 30(b)(6) notice and contained within Magistrate Judge Hanna's order, is not credible, and, perhaps, more importantly, undercuts Takeda's arguments that it acted in good faith in designating Mr. Regard to speak for Takeda at the deposition in the face of the heated ongoing

¹⁴⁰ Furthermore, this Court notes Ms. Calahan's Declaration was rife with legal opinions, which could not have been relevant to any Takeda conduct before she came to Takeda in July 2007, but purport to address that time frame. Thus, this Court has grave question as to whether such unsolicited legal opinions of one who was not present when the underlying corporate decisions were made, are in any way relevant to the inquiry at hand or appropriate even for such a self-serving Declaration. However, this Court notes both parties to this motion submitted additional expert opinion evidence by way of declaration. (*See* Plaintiffs' Exhibit 7 (Declaration of Darrell Long, expert in storage systems research and computer science generally)(Rec.Doc. 3484), and Defendants' Exhibit 6 (Declaration of Daniel L. Regard, II, expert in electronic technology and document production in a litigation context)(Rec. Doc. 3530)). This Court has not considered the substantive substance of either declaration, in the context of this motion, for two very important reasons. First, neither complies with the requirements of FED.R.CIV.P. 26(b) and FED.R.EVID. 702. Second, the expert opinions proffered are of very limited assistance to this Court under these circumstances, Dr. Long's opinions about the sufficiency of Takeda's computer storage systems have not become relevant because this Court's ruling does not turn on any finding about Takeda's computer storage system. Similarly, the considered opinion of Takeda's professional consultant that the company has done a "swift, broad and effective" job of preserving documents seemingly is directed at replacing this Court's opinion with his own; an occurrence which would be wholly inappropriate.

discovery dispute and Magistrate Judge Hanna's orders; this Court finds it did not.

Takeda, also, vehemently challenges the assertions of the PSC, that Takeda's conduct reflects sufficient culpable intent to support sanctions, arguing it has steadfastly maintained good faith in both its document retention policies and its participation in discovery in this matter and points to the massive number of documents actually presented in support of that argument. Again, in a case of this magnitude with corporate conduct extending over as many years as this one, and in this age of technology, one must expect a plethora of discoverable documents and commends Takeda's trial counsel for their laudable participation in discovery. However, the number of documents produced cannot overshadow or justify such a pervasive and widespread failure by Takeda to preserve such large swaths of Actos®-related files and documents generated and held by so many high-ranking key Takeda officials, all of whom were directly involved with the development and marketing of Actos®. Therefore, after full review of all argument and evidence presented before and at trial and for the reasons noted herein and in its previous ruling, this Court finds Takeda acted in bad faith as to the deletion and destruction of documents, and engaged in willful abuse of the judicial process in an attempt to conceal that deletion and destruction. This Court further finds Takeda's conduct constituted a violation of FED.R.CIV.P. 37.

2. Consideration of Sanctions

This Court now having finalized its finding as to Takeda's conduct now turns its attention to the requested sanctions.

The PSC requests a variety of sanctions, the most serious of which are a default judgment or a mandatory adverse inference at trial. Because the issue of Takeda's conduct was so hotly contested in this litigation and is so pivotal to the issue of the remedy to be granted, the Court

awaited final determination of this element until the Court had had full benefit of all evidence and argument presented by both parties at the first bellwether trial. Now having full benefit of all evidence and argument presented by all parties, this Court turns its attention to sanctions and in so doing, will revisit certain and select aspects of the case law and analysis discussed in its preliminary ruling, in some depth.

Generally, the jurisprudence instructs that to obtain even the less serious sanction of an adverse inference imposed pursuant to the inherent power of the Court a party seeking such sanction must establish the evidence in question was destroyed with a “culpable state of mind.” Alcoa, 244 F.R.D. at 340, *citing* Zubulake IV, 220 F.R.D. at 220. In the Fifth Circuit, the imposition of the severe sanctions requested for spoliation, heretofore has required a showing of bad faith. *See, e.g.,* Condrey v. SunTrust Bank of Georgia, 431 F.3d 191, 203 (5th Cir. 2005) (“The Fifth Circuit permits an adverse inference against the destroyer of evidence only upon a showing of “bad faith” or “bad conduct.”); King v. Illinois Cent. R. R., 337 F.3d 550, 556 (5th Cir. 2003) (“An adverse inference based on the destruction of potential evidence is predicated on the “bad conduct” of the defendant.”); Ford v. Potter, 354 Fed.Appx. 28, 33 (5th Cir. 2009) (unpublished) (“ . . . an [adverse] inference is predicated on the “bad conduct” of the defendant.”); United States v. Wise, 221 F.3d 140, 156 (5th Cir. 2000) (“An adverse inference drawn from the destruction of records is predicated on bad conduct”); Vick v. Texas Employment Com’n, 514 F.2d 734 (5th Cir. 1975) (“The adverse inference to be drawn from destruction of records is predicated on bad conduct of the defendant. Moreover, the circumstances of the act must manifest bad faith. Mere negligence is not enough, for it does not sustain an inference of consciousness of a weak case.”).¹⁴¹

¹⁴¹ As pointed out in Rimkus:

However, this Court's exhaustive research has shown the majority of cases addressing the discreet issue of bad faith within the context of spoliation, including those by the Fifth Circuit Court of Appeals, are unpublished, do not address the issue within the context of the spoliation of *electronically stored information*, or do not set forth a framework under which to analyze the varying degrees of culpable conduct which might be sufficient to trigger the severe remedy of a default judgment, an adverse inference, or the varying degrees of the other remedies sought by the PSC. Indeed, the analysis appears to be highly fact-based, requiring a court faced with the issue of sanctions made pursuant to its inherent powers to reconcile the conduct of the spoliator with a sanction that appropriately – but not unnecessarily severely – punishes the conduct, all the while keeping in mind the distinction between sanctions flowing from a violation of FED.R.CIV.P. 37 and sanctions flowing from an exercise of this Court's inherent power; again, the former likely not requiring a finding of actual “bad faith” and the latter likely requiring a showing of “bad faith” in order to support the nature of sanctions requested by the PSC. Because issues relating to discovery are primarily handled at the district court and magistrate judge level, the lack of Fifth Circuit and appellate case law setting forth a comprehensive framework for the bad faith analysis is not necessarily surprising. Consequently, again, this Court looked to the experiences of its sister courts for guidance from their experience within which to analyze the issue of bad faith and a willful abuse of the judicial process. In so doing, this Court however, is, also, and always must be, mindful of the jurisprudential overlay of caution set forth by the United States Supreme Court in Chambers, *i.e.*, and the exhortation to “exercise caution in

Other circuits have also held negligence insufficient for an adverse inference instruction. The Eleventh Circuit has held that bad faith is required for an adverse inference instruction. The Seventh, Eighth, Tenth, and D.C. Circuits also appear to require bad faith. The First, Fourth, and Ninth Circuits hold that bad faith is not essential to imposing severe sanctions if there is severe prejudice, although the cases often emphasize the presence of bad faith. In the Third Circuit, the courts balance the degree of fault and prejudice.

688 F.Supp.2d at 614 (internal citations omitted).

invoking its inherent power” to sanction, Chambers, 501 U.S. at 50, as well as the need to employ “the least possible power adequate to the end proposed.” Natural Gas Pipeline Co. Of America v. Energy Gathering, Inc., 86 F.3d 464 (5th Cir. 1996). And this Court’s mindfulness of this caution was instructive when fashioning the sanctions to be imposed.

This Court gave a full discussion of all of the available jurisprudence in its earlier ruling, Rec. Doc. 3933, and discussed certain of the jurisprudence in more depth earlier in this ruling and, thus, will not revisit such full discussion here, rather, merely reminds the reader this Court has adopted and incorporated its earlier ruling, Rec. Doc. 3933, and discussion of applicable jurisprudence within this ruling, herein.

VI. Determination

This Court, for all reasons stated herein and in its earlier ruling, has found Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals America, Inc., and Takeda Japan had a duty to preserve “any and all documents and electronic data which discuss, mention or relate to Actos®,” as of implementation of the 2002 Litigation Hold, and that Takeda Europe had the same duty as of 2006.¹⁴² This Court has found the same Takeda entities breached that duty by the deletion of files and destruction of documents, including electronic data, after those dates and that the information deleted and destroyed has been proven relevant to proof of legal issues now before this Court in this MDL and in Mr. and Mrs. Allen’s case, and that a reasonable inference flows that the deleted and destroyed evidence would have been beneficial to Mr. and Mrs. Allen’s case and to MDL claimants. Furthermore, this Court finds that all hard copy evidence destroyed cannot be reproduced and the PSC has presented evidence to support a reasonable inference that the deleted and destroyed electronically generated and electronically

¹⁴² Whether any or all Takeda entities might have had a reasonable anticipation of litigation earlier is not pivotal to this ruling and, therefore, will not be fully discussed at this juncture.

stored information has not and cannot be fully reconstituted and Takeda has submitted no evidence to support its argument to the contrary. This Court has found the deletion of documents was intentional and conducted in bad faith. Thus, this Court finds the PSC has presented sufficient evidence to prove each of the threshold elements required to establish their claim as to spoliation and to support sanction by this Court.¹⁴³

Therefore, this Court finds the PSC has presented sufficient evidence to prove conduct by Takeda worthy of sanction. However, this factual finding is relevant to two separate legal inquiries, i.e. whether Takeda, as a corporate entity before this Court, violated FED.R.CIV.P. 37 and also, whether Takeda engaged in bad faith destruction of information which constitutes spoliation? And each inquiry is answered in the affirmative. First, this Court, again, emphasizes its findings are as to *Takeda, the corporate entity* and not Takeda's counsel within this MDL; this Court finding genuine distinction as between the two.

As noted, the PSC argues bad faith and culpable intent on the part of Takeda, both before Mr. and Mrs. Allen filed suit and before litigation in the MDL was instituted, and after litigation in the MDL was instituted and Mr. and Mrs. Allen filed suit and argue the conduct predating the MDL filings cannot adequately be dealt with under the Rules (*i.e.*, Takeda's conduct before this litigation began), and, therefore, requests sanctions, not only under FED.R.CIV.P. 37, but also

¹⁴³ In general, the PSC focused on five factors which they argued established spoliation:

- the existence of a duty to preserve evidence;
- the destruction (or concealment) of evidence in violation of the duty;
- that the destruction was intentional (rather than inadvertent or negligent);
- the relevance of the destroyed evidence; and
- prejudice resulting from the unavailability of the destroyed evidence.

under the inherent powers of this Court and cites overlapping evidence to prove up the necessary “culpable intent” both for FED.R.CIV.P. 37 and for the requisite “bad faith” required to trigger exercise of this Court’s inherent powers in a way resulting in the sanctions requested by the PSC. The overlap *of evidence* both chronological and corporate, presents yet an additional challenge for the Court for, undisputedly, a violation of Rule 37 is not necessarily and perhaps not properly equated to a finding of spoliation; although the evidence to prove the two may well overlap, and in this case clearly does. Jurisprudence implies that which can be addressed by operation of FED.R.CIV.P 37 should not, also, be the basis for exercise of this Court’s inherent power. However, that is not to say certain conduct – which can be addressed under FED.R.CIV.P 37, cannot, also, be evidence of an ongoing intent, of a company to hide or conceal its earlier deliberate destruction of potentially damaging evidence, by way of argument that the conduct engaged in before the Court is a mere extension of the company’s culpable intent to hide the underlying information they had earlier – before suit was filed – deleted and destroyed. In the one instance the evidence supports actual violation of FED.R.CIV.P. 37, while in the other, the same is evidence of an ongoing intent which, although extending into the litigation, was born well before suit was actually filed.

Nonetheless, in either case, this Court agrees with my sister Courts, “whether preservation or discovery conduct is acceptable in a case depends **on what is reasonable.**” Rimkus, 688 F.Supp. 2d at 613 (emphasis added).

Under the factual circumstances of this case, the *reason* for the destruction of evidence was vehemently contested and in no small part depended upon Takeda’s explanation for the deletion and destruction of the evidence, an explanation Takeda has failed to provide – in the face of evidence presented by the PSC - by way of any credible or persuasive evidence. This

Court notes the determination of Takeda's actual intent has been greatly exasperated by Takeda's failure to present credible representatives knowledgeable as to Takeda U.S., Europe and, particularly, Japan's corporate operations, policies and history, and in particular, information technology. Based upon the evidence presented, this Court finds the evidence and argument presented by Takeda, as to Takeda's *corporate* conduct, to be unpersuasive. Rather, this Court finds Takeda's *corporate* conduct grounded in bad faith and constitutes a willful abuse of the judicial process. In particular, based upon all evidence and argument presented throughout this matter, this Court finds the PSC has established, and Takeda has not disproved a finding that Takeda's *corporate* conduct was not innocent, inadvertent, or merely negligent in its destruction, deletion, and attempt to conceal relevant information and evidence. Consequently, this Court now turns its attention to the specific sanctions requested by the PSC.

VII. CONCLUSION

Thus, for all the reasons given herein, this Court allowed evidence of spoliation to go to the jury based upon Takeda's violation of Rule 37 as well as Takeda, the corporate entity's, willful abuse of the judicial process under the Court's inherent power. This Court notes, again, the majority of evidence supporting the issue of spoliation also supports the issue of punitive damages and would, for that reason, have gone before the jury in that context.

As noted, the PSC requested sanctions which begin with the Draconian default judgment and include, in the alternative, "a combination . . . of cost shifting, a fine, an adverse inference jury instruction, restoration of deleted files and attorneys' fees and costs." As this Court must be ever mindful of the United States Supreme Court's caution to district courts when exercising their inherent powers, the Court will not enter a default judgment against Takeda, as the Court believes such a sanction would be beyond that which is required to address the conduct proven

and violative of the Supreme Court's voiced caution. Therefore, this request is DENIED.

The PSC, also, requested "an adverse inference jury instruction;" this Court, also, DENIES that request, again mindful of the United States Supreme Court's caution issued to district courts. Rather, this Court will better and more narrowly tailor the sanction to the conduct and will give a permissive instruction allowing the jury to make its own ultimate determination as to *the nature of* Takeda's conduct. Thus, this Court will give – and did give, an instruction to the jury which instructed as to certain aspects of the PSC's argument, but which culminated in:

... I instruct you that you are free to infer those documents and files would have been helpful to the plaintiffs or detrimental to Takeda, if you feel the evidence you have heard supports that inference I instruct you that you are free to infer those documents and files would have been helpful to the plaintiffs or detrimental to Takeda, if you feel the evidence you have heard supports that inference.¹⁴⁴

This instruction was narrowly tailored pursuant to the Court's inherent powers based upon Takeda's bad faith in its destruction of documents and also upon its willful abuse of the judicial process.

The PSC, also, urges fines, attorney's fees, and cost shifting. Based upon the foregoing, and as this Court finds, Takeda, the corporate entity itself, also, violated FED.R.CIV.P. 37 with the positions taken with this Court within this litigation – all fully discussed above – this Court further ORDERS the following:

1. Takeda shall continue at its sole cost to reconstruct all deleted files and a timeline and review process for oversight by the Court shall be established with the involvement of the Special Masters, the PSC, and Takeda. This timeline and review process shall contain periodic reporting by both parties to the Special Masters and periodic review by this Court by way of reporting by the Special Masters to the Court. Consequently, this Court directs all parties and the **Clerk of Court** to direct all future discovery disputes to the

¹⁴⁴ Trial Tr., vol. XXXVII, at 6279 (Rec. Doc. 4210).

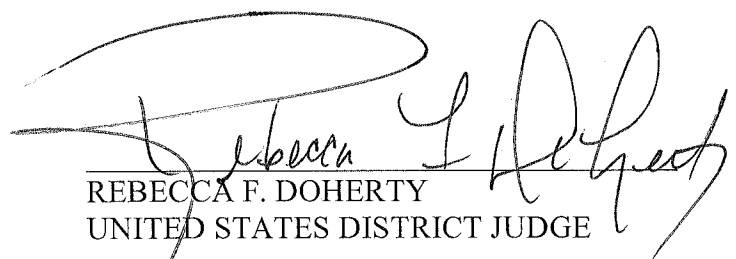
Article III Court and this Court will refer discovery matters to the magistrate judge on an issue by issue basis.

2. The Court DEFERS, until completion of the above noted process and determination of the final impact and cost of Takeda's conduct, a determination of attorney's fees arising out of Takeda's violation of FED.R.CIV.P. 37 and bad faith spoliation of evidence, allowing the PSC, at the appropriate time, when full knowledge is available as to those costs, to re-urge this issue.
3. The Court will, however, at this juncture, entertain within a separate filing and request by the PSC, for shifting to Takeda, the specific costs, including attorney's fees, incurred by the PSC of all third party discovery – that would not have otherwise been conducted – and which was required to establish the violation of FED.R.CIV.P. 37 or to establish spoliation.
4. Should the PSC determine a more meaningful 30(b)(6) deposition is required, this Court will so order and orders that all reasonable costs of this deposition, including attorney's fees, shall be borne by Takeda. Furthermore, Takeda's designation of representative(s) shall be submitted to this Article III Court no later than one month before the deposition(s) in order for this Court to ensure the representative(s) selected have the requisite personal corporate knowledge to respond to the areas of inquiry identified. After the conclusion of that/those 30(b)(6) deposition(s) – should the PSC deem it appropriate, after a careful comparison of the responses then given, against those given by Mr. Regard, the Court would entertain a request that all or part of all reasonable costs, including attorney's fees, as well as all costs of the Special Master's participation, directly incurred by the PSC in the actual taking of the 30(b)(6) deposition(s) to which

Mr. Regard responded, as well as relevant participation in the discovery interplay surrounding the 30(b)(6) deposition with the magistrate judge, be shifted from the PSC to Takeda.

5. All attorney's fees shifted, for these purposes only and exclusively, shall be at an agreed to rate, or at the equivalent defense counsel rate charged for their participation in the noted matters.
6. All other requests for sanctions as to Takeda's *counsel* – remain DEFERRED.
7. All other requests for sanctions against Takeda, itself, are at this time, pursuant to this motion, DENIED.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 23 day of June, 2014.


REBECCA F. DOHERTY
UNITED STATES DISTRICT JUDGE