UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

In re Actos (Pioglitazone) Product Liability Litigation	* * *	6:11-md-2299
This Document Relates to: *Terrence and Susan Allen v. Takeda Pharmaceuticals International, Inc., et al.*, No. 6:12-cv-0064-RFD-PJH	* * * * *	JUDGE DOHERTY MAGISTRATE JUDGE HANNA

DEFENDANTS' RULE 59 MOTION FOR FOR A NEW TRIAL

May It Please The Court:

Defendants Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International, Inc., Takeda Pharmaceuticals LLC, Takeda Development Center Americas, Inc., Takeda California, Inc. (collectively, "Takeda"), and Eli Lilly and Company ("Eli Lilly") (collectively with Takeda, "Defendants"), respectfully move this Court, pursuant to Fed. R. Civ. P. 59, for a new trial on all of Plaintiffs' claims and on Plaintiffs' demand for punitive damages. As grounds for this Motion, Defendants state:

- Defendants are entitled to a new trial because the jury's multi-billion dollar punitive damages awards are unconstitutional and so excessive as to *per se* demonstrate passion and prejudice. At the very least, the Court should remit the punitive damages awards to amounts that total no more than compensatory damages.

- Defendants are entitled to a new trial because the Court committed prejudicial errors in its evidentiary rulings and its instructions to the jury.

Further support and grounds for this Motion are set forth in the accompanying Memorandum of Law in Support of Defendants' Rule 59 Motion for a New Trial, and exhibits thereto,[1] which are incorporated herein by reference.

WHEREFORE, Defendants respectfully pray that this Motion be granted in Defendants' favor as to each of Plaintiffs' claims and on Plaintiffs' demand for punitive damages.

DATED: June 27, 2014

Respectfully Submitted,

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[1] Defendants are submitting an omnibus set of exhibits in support of their Rule 50(b) motion and their Rule 59 motion.

CERTIFICATE OF SERVICE

I hereby certify that on June 27, 2014, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to Plaintiffs' Steering Committee, Lead Defense Counsel and Defendants' and Plaintiffs' designees. The designees will forward the NEFs to the appropriate attorneys as outlined by the Court's Case Management Order: Notice of Procedure [D.E. 3398].

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MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' RULE 59 MOTION FOR A NEW TRIAL

May It Please The Court:

Defendants Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International, Inc., Takeda Pharmaceuticals LLC, Takeda Development Center Americas, Inc., Takeda California, Inc. (collectively, "Takeda"), and Eli Lilly and Company ("Eli Lilly") (collectively with Takeda, "Defendants"), respectfully submit this Memorandum of Law in Support of Their Rule 59 Motion for a New Trial.

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INTRODUCTION

Defendants have filed a motion for judgment as a matter of law under Rule 50(b). If the Court does not grant the Rule 50(b) motion in its entirety, the Court should grant Defendants a new trial under Rule 59(a) because the jury's combined $9 billion punitive damages awards, which are more than 6,100 times larger than the jury's compensatory damages awards, are unconstitutional under Supreme Court and Fifth Circuit precedent and was the product of passion and prejudice. The Court also should grant Defendants a new trial because the Court committed prejudicial errors in its evidentiary rulings and instructions to the jury. If the Court does not grant Defendants a new trial, the Court should remit the punitive damages awards to a total of no more than the amount of the compensatory damages awards.

STANDARD

After a jury trial, a district court may grant a new trial "for any reason which a new trial heretofore has been granted in an action at law in federal court." Fed. R. Civ. P. 59(a). The reasons for a new trial include grossly excessive punitive damages awards, *see, e.g.*, *Auster Oil & Gas, Inc. v. Stream*, 835 F.2d 597, 603 (5th Cir. 1988) (remanding for new trial where jury's punitive damages award was "so excessive as to indicate inherent passion and prejudice"), as well as prejudicial evidentiary errors and instructional errors. *See, e.g.*, *Willitt v. Purvis*, 276 F.2d 129, 132 (5th Cir. 1960) (a district court is "under a duty to grant a new trial" when it has "admitted irrelevant and prejudicial evidence"); *Aero Intern. v. United States Fire Ins. Co.*, 713 F.2d 1106, 1113 (5th Cir. 1983) ("A new trial is the appropriate remedy for prejudicial errors in jury instructions.").

ARGUMENT

I. Defendants Are Entitled To A New Trial Because The Jury's Multi-Billion Dollar Punitive Damages Awards Are Unconstitutional And So Excessive As To *Per Se* Demonstrate Passion And Prejudice.

A. The Punitive Damages Awards Violate Defendants' Rights To Due Process and New York Law.

"The Due Process Clause of the Fourteenth Amendment prohibits the imposition of grossly excessive or arbitrary punishments" including punitive damages awards, "on a tortfeasor." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003). Excessive and arbitrary punitive damages awards are prohibited because "[e]lementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also the severity of the penalty that a State may impose." *BMW of N. America, Inc., v. Gore*, 517 U.S. 559, 574 (1996). *See also State Farm*, 538 U.S. at 417 ("To the extent [a punitive damages] award is grossly excessive, it furthers no legitimate purpose and constitutes an arbitrary deprivation of property.").

The Supreme Court has established three guideposts to determine whether a punitive damages award violates a defendant's constitutional right to due process: (1) "the degree of reprehensibility of" the defendant's conduct; (2) "the disparity between the harm or potential harm suffered by" the plaintiff "and his punitive damages award"; and (3) "the differences between the" punitive damages award "and the civil penalties authorized or imposed in comparable cases." *Gore*, 517 U.S. at 574-75. New York courts apply the same guideposts to determine whether a punitive damages award is excessive under New York law. *See, e.g.*, *Western N.Y. Land Conservancy, Inc. v. Cullen*, 886 N.Y.S.2d 303, 306 (App. Div. 2009). *See also Bi-Economy Market v. Harleysville Ins. Co.*, 886 N.E.2d 127, 131 (N.Y. 2008) (noting that

the amount of a punitive damages award "should bear some reasonable relation to the harm done and the flagrancy of the conduct causing it"). The Supreme Court's guideposts point in only one direction when applied to this case: the jury's punitive damages verdict is unconstitutional and cannot stand.

1. The punitive damages awards bear no reasonable relationship to the compensatory damages awards.

The "most commonly cited indicium of an unreasonable or excessive punitive damages award is its ratio to the actual harm inflicted on the plaintiff." *Gore*, 517 U.S. at 580. Although the Supreme Court has declined to adopt a "mathematical bright line between the constitutionally acceptable and the constitutionally unacceptable that would fit every case," *id.* at 582-83, it has made it clear that "few awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process," *State Farm*, 538 U.S. at 425. *See also Exxon Shipping Co. v. Baker*, 554 U.S. 471, 514-15 (2008) ("[i]n *State Farm*, we said that a single-digit maximum is appropriate in all but the most exceptional of cases"). Indeed, "[w]hen compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *State Farm*, 554 U.S. at 425; *see also Rubinstein v. Administrators of the Tulane Educational Fund*, 218 F.3d 392, 408 (5th Cir. 2000) (holding that punitive damages of $75,000 with compensatory damages of $2,500 were constitutionally excessive, finding the 30:1 ratio to be "clearly outside even the gray areas of the demarcation between acceptable levels of damages and unacceptable levels").

The ratio between the combined punitive damages awards and the compensatory damages awards in this case is a staggering 6,101 to 1. Plaintiffs can cite no authority for the proposition that such a ratio withstands constitutional muster.

2. Defendants' conduct was not reprehensible.

"[T]he most important indicium of the reasonableness of a punitive damages award is the degree of reprehensibility of the defendant's conduct." *Gore*, 517 U.S. at 575. "That conduct is sufficiently reprehensible to give rise to tort liability, and even a modest award of exemplary damages, does not establish the high degree of culpability that warrants a substantial punitive damages award." *Id.* *See also State Farm*, 538 U.S. at 419-20 ("While we do not suggest there was error in awarding punitive damages based upon [defendant's] conduct toward [plaintiffs], a more modest punishment for this reprehensible conduct could have satisfied the State's legitimate objectives, and the Utah courts should have gone no further.").

When determining "the reprehensibility" of a defendant's conduct, courts consider whether: (1) "the harm caused was physical as opposed to economic"; (2) the defendant's "conduct evinced an indifference to or a reckless disregard of the health or safety of others"; (3) "the target of the conduct had financial vulnerability"; (4) "the conduct involved repeated actions or was an isolated incident"; and (5) "the harm was the result of intentional malice, trickery, or deceit, or mere accident." *State Farm*, 538 U.S. at 419. "The existence of any one of these factors weighing in favor of a plaintiff may not be sufficient to sustain a punitive damages award." *Id.* In this case, Plaintiff suffered physical injury (factor 1). However, none of the other factors establishes that Defendants acted so reprehensibly as to warrant the imposition of any punitive damages award, let alone multi-billion dollar ones.

First, as is explained more fully in their Rule 50(b) motion, Defendants did not engage in conduct indifferent to or in reckless disregard of health or safety.[1] Defendants marketed a life-saving prescription medicine that Mr. Allen's own physicians still prescribe for some of their patients because it is effective in combating type 2 diabetes – a disease that Plaintiffs described

[1] Defendants incorporate all of their Rule 50(b) arguments on punitive damages as if set forth herein.

as "a horrific" and "nasty, nasty, deadly disease." (Ex. 45, Dr. Reilly Testimony, P7512A at 50:7-12; Ex. 46, Dr. Lamb Testimony, P7514A at 51:07 – 52:24; Ex. 47, Dr. Wnek Testimony, D2781A at 30:5-18; Ex. 22, Vol. II, 02/03/14 Tr. at 36:2, 42:17 (opening statement)).[2] Plaintiffs' expert witnesses testified that Actos presents a "low" absolute risk of bladder cancer, and Plaintiffs did not claim that this low risk should preclude the selling of Actos. To the contrary, Plaintiffs told the jury that they believe Actos should stay on the market. (Ex. 22, Vol. II, 02/03/14 Tr. at 24:17-18 (Plaintiffs telling jury in opening statement that "this is not a case where we're saying, take Actos off the market")).

Plaintiffs' allegation against Defendants was that they did not adequately warn prescribing physicians about the low risk of bladder cancer from Actos. However, it is undisputed that the Actos label (which is written for physicians) has always contained FDA-approved information about bladder cancer since the FDA first approved the drug.[3] The evidence also showed that the FDA recommended the language in the Actos label about human bladder cancer data after the FDA reviewed a wealth of information, including, among other things, data from Actos clinical trials (including the PROactive trial) and the first interim report

[2] Defendants are submitting an omnibus set of exhibits in support of their Rule 50(b) motion and their Rule 59 motion. The exhibits cited herein refer to that set of exhibits.

[3] The Precautions section of the very first Actos label, approved by the FDA in 1999, stated that bladder tumors "were observed in male rats" given doses "approximately equal to the maximum recommended human oral dose." (Ex. 6, 07/99 Actos Label, D1067 at 12). In 2006 – approximately four and a half years before Mr. Allen was diagnosed with bladder cancer – Takeda added human bladder cancer data to the Precaution section of the Actos label, noting that in the two 3-year clinical trials of Actos (the longest clinical trials of Actos) "there were 16/3656 (0.44%) reports of bladder cancer in patients taking" Actos "compared to 5/3679 (0.14%) in patients not taking" Actos, and that "[a]fter excluding patients in whom exposure to study drug was less than one year at the time of diagnosis of bladder cancer, there were six (0.16%) cases on" Actos "and two (0.05%) on placebo." (Ex. 14, 08/06 Actos Label, D1626 at 16). In 2009 – more than a year before Mr. Allen was diagnosed with bladder cancer – Takeda revised the Actos Medication Guide (which is written for patients), to state: "In studies of pioglitazone (the medicine in ACTOS), bladder cancer occurred in a few more people who were taking pioglitazone than in people who were taking other diabetes medicines. There were too few cases to know if the bladder cancer was related to pioglitazone." (Ex. 15, 09/09/09 letter from FDA to Takeda, D1916 (approving addition of bladder cancer language to Medication Guide)).

from the KPNC study – an ongoing, long-term epidemiological study of bladder cancer in Actos patients approved by the FDA.[4] Those facts are flatly inconsistent with a finding that Defendants were indifferent to or recklessly disregarded patient safety. *See, e.g.*, *DeLuryea v. Winthrop Labs.*, 697 F.2d 222, 230-31 (8th Cir. 1983) (stating "there was no evidence to support" a finding that a prescription drug manufacturer had acted with "reckless indifference" to safety where the drug label's Precautions section and Adverse Reactions section mentioned the risk at issue (tissue damage) at the time plaintiff took the drug).[5]

Plaintiffs cannot defend the jury's profoundly unconstitutional punitive damages awards by pointing to Takeda's alleged spoliation of documents. As Takeda has noted in its Rule 50(b) motion, no reasonable jury could find that Takeda's failure to preserve custodial files of various Takeda employees who left the company was done with the intent to hide evidence that Actos increases the risk for bladder cancer. Indeed, Plaintiffs said in their opening statement that they were not accusing Takeda of deliberately shredding documents as part of a cover up. (Ex. 22, Vol. II, 02/03/14 Tr. at 52:21-25). In any event, *State Farm* shows that the Supreme Court does not consider spoliation of evidence (even intentional spoliation of evidence that deals directly

[4] (*See* Ex. 7, 02/04/03 Memorandum of Meeting Minutes, D1218 (summarizing meeting between Takeda and FDA that included discussion of, among other things, conducting the KPNC study); Ex. 8, 03/24/04 Takeda letter to FDA, D1330 (responding to FDA's comments on original proposed KPNC protocol); Ex. 9, 08/31/05 Takeda submission of bladder cancer data to FDA, D1501; Ex. 10, 06/01/06 Takeda submission of bladder cancer data to FDA, D1584; Ex. 11, 06/19/06 Contact Report Form, D1591 (summarizing telephone call from FDA's Dr. Robert Misbin during which Dr. Misbin stated that a label change regarding bladder cancer was needed); Ex. 12, 07/28/06 FDA Approval Package for Duetact (a product containing Actos), D1621 at 4, 25-26, 45-46, 53-64, 170-74 (stating that Actos human clinical trial data regarding bladder cancer should be added to the Precautions section of the Actos label after that section's discussion of rat bladder cancer data); Ex. 13, 08/30/06 letter from FDA to Takeda, D1639 (approving the addition of Actos human clinical trial data regarding bladder cancer to the Precautions section of the Actos label)).

[5] In *DeLuryea*, the plaintiff took the drug at issue from August 1968 to June 1974. *Id.* at 224, 227. From September 1968 to May 1974, the drug label's Adverse Reactions section mentioned tissue damage. *Id.* at 230 n.7. In May 1974 – the month before plaintiff stopped taking the drug – the manufacturer added tissue damage to the Precautions section of the label. *Id.*

with the plaintiff and occurs during the pendency of plaintiff's case) to be the kind of conduct that warrants a large punitive damages award.

In *State Farm*, the Utah Supreme Court determined that a $145 million punitive damages award was constitutional based, in part, on evidence that "State Farm engaged in deliberate concealment and destruction of all documents related to [its] profit scheme." *Campbell v. State Farm Mut. Auto. Ins. Co.*, 65 P.3d 1134, 1148 (Utah 2001). The Utah Supreme Court noted that "State Farm's own witnesses testified that documents were routinely destroyed so as to avoid their potential disclosure through discovery requests," and that "[s]uch destruction even occurred while this litigation was pending." *Id.* *See also Campbell v. State Farm*, 840 P.2d 130, 133 (Utah Ct. App. 1992) (noting that a State Farm claims adjuster testified that his supervisor directed him to "destroy" and "redraft" a report about the Campbells' car accident in order to justify State Farm's refusal to settle the third-party claim against the Campbells).

The U.S. Supreme Court explicitly referenced State Farm's spoliation of evidence when the Court analyzed the "reprehensibility" of State Farm's conduct. *See State Farm*, 538 U.S. at 419 ("The trial court found that State Farm's employees altered the company's records to make the Campbells appear less culpable."). Yet, even though State Farm had intentionally spoliated evidence about the plaintiffs while the plaintiffs' case was pending, the Court found that any punitive damages award would have to be "more modest" in order to withstand constitutional scrutiny. *Id.* at 419. Indeed, the Court said that "under the principles outlined in [*Gore*], this case [was] neither close nor difficult." *Id.* at 418.

Again, Takeda denies that it deleted files with the intent of shielding those files from discovery in litigation. But, even the Plaintiffs' allegations of spoliation against Takeda are no

match for the spoliation seen in *State Farm* – spoliation that the Supreme Court said did not justify a large punitive damages award.

Finally, spoliation cannot justify a punitive damages award against Lilly because Plaintiffs did not allege that Lilly spoliated documents. And, a finding of indifference or reckless disregard is particularly inappropriate against Lilly because – as explained in Defendants' Rule 50(b) motion – federal law prevented Lilly from making any changes to the Actos label.

Second, there is no evidence that Defendants targeted Plaintiffs because of financial vulnerability, and Plaintiffs have never made that argument.

Third, there is no evidence of recidivist conduct (*i.e.*, "evidence that a defendant has repeatedly engaged in prohibited conduct while knowing or suspecting that it was unlawful," *Gore*, 517 U.S. at 576). In fact, although the Court originally proposed a punitive damages jury instruction that would have told the jury to consider "[h]ow often the defendant had committed similar acts of this type in the past," Plaintiffs agreed to strike that language from the instruction "because there's no such evidence in the record." (Ex. 39, Vol. XXXVI, 04/04/14 Tr. at 6011:11 – 6012:22 (final charge conference)). Moreover, no prescription drug manufacturer would suspect that it is behaving unlawfully by conducting an epidemiological study approved by the FDA or making label changes that were directed by the FDA.

Fourth, there was no evidence that Plaintiffs' injury was the result of intentional malice, trickery, or deceit. To the contrary, during argument on the appropriate amount of punitive damages, Plaintiffs' counsel conceded that Defendants' actions did not reflect "vindictiveness." (Ex. 40, Vol. XXXVII, 04/07/14 Tr. 6326:11). And, given the fact that the Actos label contained information about bladder cancer the entire time that Mr. Allen took Actos – including language

recommended by the FDA – Defendants cannot be found to have "tricked" or "deceived" either Mr. Allen's physicians or Mr. Allen about a potential risk of bladder cancer.

3. The punitive damages awards are vastly greater than civil penalties imposed in similar cases.

The Supreme Court's third guidepost for determining if a punitive damages award violates due process is whether the award is substantially greater than the statutory fines available for similar conduct. *Gore*, 517 U.S. at 583-84 (finding due process violation where Alabama jury awarded $2 million in punitive damages for conduct that would have resulted in a $2,000 fine under Alabama's Deceptive Trade Practices Act).

The jury found that Defendants failed to adequately warn Mr. Allen's prescribing physicians about a potential risk of bladder cancer from Actos. While New York has not adopted statutory penalties for this precise conduct, its statutory penalty for analogous consumer-related conduct – $5,000 to $10,000 – is tiny when compared to the multi-billion punitive damages awards in this case. *See* N.Y. Gen. Bus. Law §§ 349, 350-a, 350-d ($5,000 fine for violating consumer protection statute); *see also, e.g.*, 21 U.S.C. § 333(a)(2) (providing for a $10,000 civil penalty for the "misbranding of any . . . drug in interstate commerce"). Indeed, the ratio of punitive damages to statutory penalty (using the largest such penalty) is a mindboggling *900,000* to one.

New York's civil penalty for violations of consumer protection standards cannot reasonably be viewed as giving fair notice to prescription drug companies like Defendants that violating analogous tort law standards might subject them to multi-billion dollar penalties. Deference to the New York legislature's judgment concerning appropriate sanctions for this type of conduct weighs heavily in favor of vacating the punitive damages awards.

4. The punitive damages awards are inappropriately based on conduct that did not involve Plaintiffs' injuries.

In addition, the punitive damages awards are inappropriate because they are not limited to the conduct that injured Plaintiffs. It is well settled that in order for a defendant's actions to be a basis for an award of punitive damages, those actions must be related to plaintiff's injuries. "A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business," and "due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant." *State Farm*, 538 U.S. at 423. The staggering size of the punitive damages awards, and the evidence admitted at trial, show that the awards were improperly based on conduct that had no bearing on the Plaintiffs' injuries in two critical respects: (1) they were improperly based on potential harm to other users of Actos; and (2) they were improperly based on alleged spoliation of evidence.

First, the awards were improperly based on "other parties' hypothetical claims" against Takeda and Lilly for bladder cancer. Over Defendants' objection, Plaintiffs' counsel repeatedly referred at trial to harm that Actos allegedly caused to others, at one point asserting that there were "thousands of lawsuits" brought by people claiming that Actos caused their bladder cancer. (Ex. 23, Vol. III, 02/04/14 Tr. 292:17). And, during argument on the appropriate amount of the punitive damages awards, Plaintiffs' counsel encouraged the jury to issue Defendants a "fine" for "causing 9,000 cancers a year," and implied to the jury that a $1 billion fine would be letting Defendants off easy. (Ex. 40, Vol. XXXVII, 04/07/14 Tr. at 6328:23 – 6329:7). (*See also id.* at 6333:9-21 (Plaintiffs' counsel arguing that a $100 million punitive damages award would be insufficient and noting that there have been "other Actos trials"). The size of the punitive

damages awards can only rationally be explained as reflecting this alleged harm to third parties, not the harm to Plaintiffs alone.

Second, as discussed, the awards were improperly based on the alleged spoliation of evidence that was completely unrelated to Plaintiffs' harm (and that took up five days of the trial). There is no evidence that Takeda deliberately destroyed documents in order to hide from Plaintiffs a potential risk of bladder cancer from Actos. Plaintiffs speculated that the missing files (employee files that Takeda failed to retain after those employees left Takeda) may have contained emails or other documents showing that Takeda should have provided stronger warnings about bladder cancer in the Actos labeling. But, the evidence presented at trial is inconsistent with any inference that the missing files contained anything like a "smoking gun" concerning liability. Plaintiffs' own experts repeatedly told the jury that randomized clinical trial data is the "gold standard" for determining whether a drug causes a disease,[6] and that the next two best forms of evidence on general causation are meta-analyses of randomized clinical trial data and the results of epidemiological studies.[7] Plaintiffs offered no evidence that employee custodial files would contain randomized clinical trial data or epidemiological data not already included in Takeda's filings with the FDA (all of which were provided to Plaintiffs during discovery).[8]

[6] (*See, e.g.*, Ex. 30, Vol. XVI, 02/24/14 Tr. at 2315:21-22 (Plaintiffs' expert statistician, Dr. Madigan, testifying: "Randomized trials, everyone agrees, is the gold standard of evidence.") (*See also* Ex. 26, Vol. VIII, 02/11/14 Tr. at 1005:19-25 and Ex. 27, Vol. IX, 02/12/14 Trial Tr. at 1085:4-6 (Dr. Kessler describing randomized clinical trials as the "gold standard" for determining causation)).

[7] (Ex. 31, Vol. XVII, 02/26/14 Tr. at 2422:5 – 2423:18 (Dr. Delacroix testifying that after randomized clinical trials, the next best evidence on the issue of causation is meta-analyses of randomized clinical trials, followed by epidemiological studies)).

[8] As Defendants explain in their Rule 50(b) motion, a meta-analysis would have made no difference in this case.

In sum, the extreme size of the punitive damages awards, and the amount of time spent at trial on attacks against Defendants' character, reveal plainly that the punitive awards were not limited to conduct that caused Plaintiffs' harm, and were instead improperly based on conclusions about Defendants' character that are constitutionally forbidden.

B. The Punitive Damages Award Against Lilly Is Unconstitutional For Additional Reasons.

The $3 billion award against Lilly exceeds constitutional limits for several additional reasons.

First, in terms of the ratio between punitive damages and compensatory damages, the jury found Lilly responsible for 25% of the compensatory damages ($368,750) but imposed 33% of the total punitive damages ($3 billion) on Lilly. The ratio between punitive and compensatory damages is a truly staggering, and plainly unconstitutional, 8,136 to 1. More generally, the discrepancy in the jury's verdict, and the outlandish ratio between punitive and compensatory damages, demonstrates that the jury's punitive damages award against Lilly is "grossly excessive and arbitrary."

Second, in terms of the reprehensibility of Lilly's conduct, as explained in the Defendants' Rule 50(b) motion, Lilly has never been the holder of the new drug application for Actos. Thus, it never had any authority to change the Actos label. Lilly's failure to change the label, an action that it was legally prohibited from taking, cannot be the basis of a finding of liability, much less support a massive award of punitive damages.

Third, Lilly is not alleged to have engaged in any spoliation of documents. While basing any part of the punitive damages awards on spoliation is impermissible for the reasons explained above, it is clearly unlawful to punish Lilly for another party's conduct.

C. The Grossly Excessive Punitive Damages Awards Mandate An Entire New Trial on Liability And Damages.

In the Fifth Circuit, "when a jury verdict results from passion or prejudice, a new trial, not remittitur, is the proper remedy." *Wells v. Dallas Independent School Dist.*, 793 F.2d 679, 683 (5th Cir. 1986). *See also Consolidated Companies, Inc. v. Lexington Ins. Co.*, 616 F.3d 422, 435 (5th Cir. 2010) ("When the district court deems a jury award excessive it may remit the award rather than order a new trial, so long as the award does not result from passion or prejudice on the part of the jury.") (quotations and citation omitted). And, "at some point a verdict can be so excessive as to constitute a *per se* indication of prejudice or passion, and require a new trial." *Auster Oil & Gas, Inc. v. Stream*, 853 F.2d 597, 603 n.5 (5th Cir. 1988). *See also Wells*, 793 F.2d at 684 (stating that an award can be "so exaggerated as to indicate bias, passion, [or] prejudice" and that in such circumstances "remittitur is inadequate and the only proper remedy is a new trial"); Wright & Miller, 11 *Federal Practice and Procedure* § 2815, at 218 (2012) ("One limitation on the use of remittitur remains. It is not proper to use it if the verdict was the result of passion and prejudice, since prejudice may have infected the decision of the jury on liability, as well as on damages. In those instances a complete new trial is required.").

The Fifth Circuit has found verdicts to be the product of passion or prejudice where those verdicts were several times larger than rationally supportable. For example, in *Auster*, the jury rendered punitive damages verdicts against four defendants totaling $5 million, and the district court remitted the awards by a total of $4.3 million. *Auster*, 835 F.2d at 600, 603. The Fifth Circuit found that the "ratios of the punitive damages awards to remittiturs," which "ranged from 5 to 1 for" one defendant "to a stunning 50 to 1 for" another defendant," led to "the inescapable conclusion that the jury was motivated by passion and prejudice in their award of punitive

damages," requiring a new trial. *Id.* at 603-04. In *Wells*, the jury rendered a verdict of $1.9 million, and the district court remitted the award to $250,000. *Wells*, 793 F.2d at 683. The Fifth Circuit found that the district court abused its discretion in denying defendant's motion for a new trial: "We conclude that today's case, in which the district court felt compelled to reduce a $1.9 million award by more than an order of seven, is one in which the jury award was so large that it reflected passion or prejudice." *Id.* at 684. The Fifth Circuit added: "[W]e find it difficult to regard the quarter-million dollar remnant of a virtual two-million verdict as in any significant sense a product of the jury. It was the judge's verdict; a new trial is called for." *Id.*

In the present case, any plausible reductions of the punitive damages awards would be massive, and would dwarf the 50 to 1 ratio in *Auster* that the Fifth Circuit described as "stunning" and that mandated a new trial. In short, the size of the punitive damages awards here – totaling more than 6,100 times the compensatory damages – are "so excessive as to constitute a *per se* indication of prejudice or passion, and require a new trial." *Auster*, 835 F.2d at 603 n.5.

In this case, the new trial should be on all issues, not just punitive damages. It is well settled that "[c]ourts must order a complete retrial of issues 'unless it clearly appears that the issue to be retried is so distinct and separable from the others that a trial of it alone may be had without injustice." *Brooks v. Great Lakes Dredge-Dock Co.*, 754 F.2d 539, 540 (5th Cir. 1985) (quoting *Gasoline Prods. v. Champlin Refining*, 283 U.S. 494, 500 (1931)). The "distinct and separable" test is not met "when the issues subject to retrial are so interwoven with other issues in the case that they 'cannot be submitted to the jury . . . without confusion and uncertainty.'" *Colonial Leasing v. Logistics Control Intern.*, 770 F.2d 479, 481 (5th Cir. 1985) (quoting *Gasoline Prods.*, 283 U.S. at 500). In this single-phase trial, there was no separate evidence on punitive damages, other than a brief stipulation regarding Defendants' net worth and Actos sales

figures. The conduct that purportedly supported punitive damages was the same that purportedly supported compensatory liability, making the two issues inseparable. Under the circumstances, because a new trial limited to punitive damages would be impractical, Defendants are entitled to a new trial on all issues.

D. At The Very Least, The Court Should Remit The Punitive Damages Awards To Amounts That Total No More Than Compensatory Damages.

If the Court decides to remit the punitive damages verdicts in this case, the amount of the punitive damages verdicts should be reduced to amounts that total no more than the total compensatory damages awards. The jury's compensatory damages awards of $1,475,000 are substantial. And, the Supreme Court has stated that "[w]hen compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *State Farm*, 554 U.S. at 425.

While there is no basis for any punitive damages award in this case, there is likewise no basis for punitive verdicts that total more than the compensatory damages awards. In short, if the Court enters punitive damages judgments in this case, those combined judgments should not exceed a 1-to-1 ratio with the total compensatory awards.

II. Defendants Are Entitled To A New Trial Because The Court Committed Prejudicial Errors In Its Rulings On Spoliation.

A. The Court Erred In Giving An Adverse Inference Instruction.

In the Fifth Circuit, a district court may give an adverse inference instruction against a defendant based on spoliation of evidence only if the plaintiff establishes that (1) the defendant destroyed relevant evidence at a time when it had a legal duty to preserve evidence for pending or potential litigation by the plaintiff; (2) the defendant destroyed the evidence in bad faith – *i.e.*, with the intent of preventing the evidence from being used against the defendant in litigation;

and (3) the destruction of the evidence is prejudicial to the plaintiff.[9] The Court erred in finding that these elements were met.

First, the Court erred in its determination that Takeda had a legal duty to preserve documents for the Allens and other bladder cancer plaintiffs beginning in 2002. As Takeda argued in its Opposition to the PSC's Spoliation and Rule 37 Motion for Sanctions, Takeda did not have a legal duty to preserve documents for bladder cancer plaintiffs until the summer of 2011 – the point at which Takeda first reasonably anticipated the possibility of bladder cancer litigation. Takeda did not create a legal duty to preserve documents for the Allens or other future bladder cancer plaintiffs through its issuance of a broadly-worded products liability litigation legal hold in 2002. (*See* Ex. 43, *Van Treeck v. Klinck*, No. 12-cv-007359, slip op. at 11-17 (Wis. Cir. Ct. Jun. 16, 2014) (finding that Takeda's 2002 litigation hold did not create a legal duty to preserve Actos documents for future bladder cancer plaintiffs)). *See also In re Ethicon, Inc. Pelvic Repair Systems Prods. Liab. Litig.*, -- F.R.D. --, 2014 WL 439785, at *11 (S.D. W. Va. 2014) (Eifert, M.J.) ("[t]he undersigned is not persuaded by Plaintiffs' argument that Ethicon's duty to preserve evidence relevant to this MDL began with the 2003 document preservation notice. . . . [A]n isolated lawsuit, or even two, would not reasonably lead Ethicon to believe that large scale nationwide products liability litigation was down the road"); *In re Pfizer Inc. Securities Litig.*, 288 F.R.D. 297, 316-17 (S.D.N.Y. 2013) (defendant's duty to preserve documents for the plaintiffs at issue arose when those plaintiffs filed suit, not when defendant was subject to an earlier lawsuit "that raised different factual issues from the instant action"); *Stanfill v. Talton*, 851 F. Supp. 2d 1346, 1365-66 (M.D. Ga. 2012) (rejecting a "shifting duty" to

[9] *See Pressey v. Patterson*, 898 F.2d 1018, 1021-22 (5th Cir. 1990); *King v. Ill. Cent. R.R.*, 337 F.3d 550, 556 (5th Cir. 2003); *Condrey v. SunTrust Bank of Georgia*, 431 F.3d 191, 203 (5th Cir. 2005); *Consolidated Aluminum Corp. v. Alcoa, Inc.*, 244 F.R.D. 335, 343, 347 (M.D. La. 2006).

preserve evidence). The issuance of a legal hold does not create a legal duty to all potential beneficiaries of that hold. It is the reasonable anticipation of litigation against certain parties that creates a duty to preserve which is owed to those parties.

Second, the Court's finding that Takeda destroyed documents in bad faith – *i.e.*, with the intent of preventing the evidence from being used against Takeda in litigation – was clearly erroneous. Plaintiffs presented no evidence to support a finding that Takeda's failure to preserve custodial files (emails, PowerPoint presentations, *etc.*) of various Takeda employees when those employees left Takeda was done with the intent to hide evidence that Actos increases the risk of bladder cancer.

To the contrary, as discussed above, Takeda had no reasonable anticipation of bladder cancer litigation until the summer of 2011. The custodial files, however, were deleted prior to that date. Takeda therefore could not have destroyed the files with the requisite bad faith intent of preventing their use in bladder cancer litigation. The fact that Takeda had a litigation hold in place beginning in 2002 does not change this analysis, as it is undisputed that the litigation hold was not entered due to anticipation of bladder cancer litigation. As *Van Treeck* explains, "[i]f Takeda pledged to preserve *all* information relating to Actos, and for no particular purpose (*i.e.*, not just for purposes of preserving evidence relating to bladder cancer, or to liver failure, or to any other particular malady whose alleged association with Actos triggered a litigation hold), then what does the deletion of some of that information say about Takeda's motives? Not much." (Ex. 43, *Van Treeck*, No. 12-cv-007359, slip op. 14) (emphasis in original).

Further, as Takeda noted in its Rule 50(b) motion, evidence that use of a drug increases the risk for a disease comes in the form of *scientific data*, such as randomized clinical trial data

and epidemiological data, not employee emails or PowerPoint presentations.[10] And, it is undisputed that: (1) Takeda stores its scientific data regarding Actos in databases; (2) Takeda produced the data from those databases to Plaintiffs;[11] and (3) Plaintiffs have made no allegation, let alone presented evidence, that data was missing from those databases.

Even if evidence of causation came from employee custodial files, any scheme to cover up that evidence over a period of several years through employee attrition (*i.e.*, by deleting custodial files when employees leave the company) would be spectacularly ill-conceived because there would be no way to know whether all key employees with documents relevant to the issue of bladder cancer would leave the company before bladder cancer litigation ensued. Indeed, it is undisputed that a number of key Takeda employees with documents relevant to bladder cancer did not leave Takeda before the bladder cancer litigation hold was put in place in 2011 and that Takeda produced those employees' custodial files.[12]

Moreover, it is common knowledge that deleting an email from a person's email files does not necessarily permanently destroy that email (or any documents attached to that email) because the email is also likely to be in the email files of at least one other person (in the "in-

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[10] *See generally*, Federal Judicial Center, *Reference Manual on Scientific Evidence* 549-632 (3d ed. 2011). (*See also* Ex. 26, Vol. VIII, 02/11/14 Tr. at 1005:19-25 and Ex. 27, Vol. IX, 02/12/14 Tr. at 1085:4-6 (Dr. Kessler describing randomized clinical trials as the "gold standard" for determining causation)).

[11] (*See* Ex. 20, Exhibit A to 06/03/13 Declaration of Stacey Dixon Calahan, D2690 at 8-9 (list of Takeda databases produced to Plaintiffs); Ex. 25, Vol. VII, 02/10/14 Tr. at 847:25 – 848:17 (Ms. Calahan discussing production of Takeda databases)).

[12] For example, Dr. Claire Thom – whom Plaintiffs called as an adverse witness in their case-in-chief to testify about Takeda's interactions with the FDA regarding Actos and bladder cancer – remained with Takeda or a Takeda affiliate until 2013, (*See* Ex. 28, Vol. X, 02/13/14 Tr. at 1239:14-17 (Thom)), and Takeda preserved her custodial files and produced them to Plaintiffs. Takeda also preserved the custodial files of some of the other key employees involved with Actos who left Takeda before the summer of 2011. For example, Takeda preserved and produced Dr. Bhattacharya's custodial file. As Dr. Bhattacharya testified (via deposition) at trial, she worked on drug safety issues at Takeda from 2002 to 2008, including the issue of a potential association between Actos and bladder cancer. (*See, e.g.*, Ex. 44, Bhattacharya 1A at 451:11 – 452:4, 454:19 – 485:20).

box" or the "sent-box"). So, no rational actor would try to hide a "smoking gun" email by simply deleting an employee's email file when that employee leaves the company. In fact, several thousand emails and attachments of the former employees at issue (the "no file custodians" ("NFCs")) were preserved because those emails and attachments were also located in the email files of at least one other Takeda employee (and Takeda produced those documents to Plaintiffs).[13] For example, although Mr. Miyazaki's custodial files were not preserved when he left the company, over 81,000 emails and email attachments (totaling nearly 500,000 pages) for which Mr. Miyazaki was the sender or a recipient were retained in the email files of other employees.[14] Any alleged "cover up" would also be ill-conceived given the existence of back up retention tape systems in the United States and the EU from which emails could be retrieved.[15] In short, the facts in this record do not support the Court's finding of bad faith. *See Pressey*, 898 F.2d at 1022 (district court erred in finding that defendant's employee acted in bad faith in destroying an audio tape where the employee knew that the information on tape could be obtained through other sources; "a decision to destroy the tapes in hopes of preventing the information contained on them from being used as evidence would have been an entirely irrational act"); *Alcoa*, 244 F.R.D. at 346 ("even if Alcoa failed to preserve all emails that it had a technical duty to preserve, the likelihood that information relevant to this matter is contained in other sources, which have been preserved and produced, weighs in favor of finding that Alcoa acted only negligently rather than in bad faith").

[13] (*See* Ex. 21, No File Custodian Summary Sheets List Updated Sept. 14, 2013, P5303).

[14] (*Id.* at 16; Ex. 25, Vol. VII, 02/10/14 Tr. at 859:22 – 860:4 (Calahan)).

[15] (*See* Ex. 24, Vol. V, 02/06/14 Tr. at 638:2-7 (Calahan)).

Takeda also denies the Court's assertions that Takeda's conduct during this litigation has been part of a long-running cover-up of the potential risks of Actos or that Takeda has otherwise acted inappropriately. Takeda and its lawyers (both inside and outside counsel) have acted properly, professionally, and zealously within the bounds of the law at all times. The Court's conclusions to the contrary are simply wrong.

By way of example only, there was nothing inappropriate about Takeda's decision to designate Mr. Regard, an electronic evidence and case management expert, to serve as its Rule 30(b)(6) corporate designee witness. Rule 30(b)(6) does not require a corporate designee to testify based on personal knowledge, and the Rule permits a corporation to designate a non-employee to testify on its behalf. In fact, at no time did the PSC object to Takeda's designation of Mr. Regard. Moreover, as Ms. Calahan testified at trial, no current Takeda employee had the personal knowledge necessary to address the laundry list of topics in the PSC's Rule 30(b)(6) deposition notice – topics that covered events occurring more than a decade earlier and on three continents. Retaining a single outside individual with expertise on electronic evidence issues who could conduct a thorough investigation was the most appropriate and efficient way to proceed – especially in light of the compressed timeframe which Takeda was given to produce a Rule 30(b)(6) witness. (Ex. 25, Vol. VII, 02/10/14 Tr. at 866:20 – 867:15). Indeed, Mr. Regard spent hundreds of hours on his investigation, including conducting interviews of 50 witnesses across three continents. (*Id.* at 867:22 – 868:3). Takeda met its obligation to present a witness to testify about "information known or reasonable available to the organization." Fed. R. Civ. P. 30(b)(6).

Third, the Court's finding that Plaintiffs were prejudiced by the deletion of the files at issue was also clearly erroneous. As is discussed above, evidence of whether a drug presents a

potential safety risk comes from scientific data – not emails and PowerPoint presentations – and Takeda produced all of its scientific data regarding Actos to Plaintiffs. And, even if evidence of whether a drug presents a safety risk comes from emails, several thousand NFC emails (and attachments) were contained within the custodial files of other employees and produced to Plaintiffs. *See Alcoa*, 244 F.R.D. at 347 ("even assuming every email deleted during the time period in question had some relevance to this lawsuit, it is doubtful that Consolidated will be sufficiently prejudiced in its ability to put on its case to warrant an adverse inference instruction, considering the overwhelming amount of documentary evidence and emails already produced by Alcoa"). (*See also* Ex. 42, *In Re Actos Litig.*, No. 11-L-010011, slip op. at 4-5 (Ill. Cir. Ct. Apr. 18, 2014) (denying plaintiff's motion for sanctions because "plaintiff has failed to show prejudice from Takeda's destruction of custodial files").

B. The Court Erred In Admitting Evidence Regarding Takeda's Alleged Spoliation of Evidence.

The Court also erred in admitting evidence regarding Takeda's alleged spoliation of evidence, including the actions of defense counsel during the litigation in dealing with the spoliation dispute. As Defendants predicted in their written objections to the Court's pretrial spoliation ruling, this was not a trial on the merits; it was a trial about alleged spoliation. (*See* ECF Doc. 3963 at 2). *See also Wallace v. Ford Motor Co.*, 2013 WL 3288435, at *7 (S.D. Miss. Jun. 28, 2013) (warning of the possibility that the issue of spoliation could "overwhelm the merits of the trial"). Indeed, Plaintiffs spent the first week of the trial on the issue of spoliation.

C. The Court's Rulings On Spoliation Prejudiced Not Only Takeda, But Also Lilly.

Lilly was unfairly prejudiced throughout trial by the admission of adverse evidence, and that prejudice was exacerbated by the jury instruction on spoliation. At several points during the

trial, the Court admitted evidence on the ground that admission was justified by the Court's spoliation opinion. The Court said it was balancing the probative and prejudicial value of such evidence vis-à-vis Takeda and setting a higher threshold for prejudice based on the Court's Takeda-specific findings. For example, in denying Defendants' motion to strike a reference to "thousands" of Actos lawsuits being filed, the Court stated: "[T]he reason the Court is granting such leeway here is by way of sanction to Takeda. . . . So, yes, there's going to be some prejudice to Takeda. The jury will get to decide what they think about all this." (Ex. 23, Vol. III, 02/04/14 Tr. at 324:25 – 325:6; *see also id.* at 263:4 – 265:5, 324:4-10, 349:16-19). Lilly was in no way involved in the spoliation opinion, yet admission of this type of adverse evidence was unfairly prejudicial to Lilly. Moreover, the Court's jury instructions on spoliation failed to alleviate this unfair prejudice. To the contrary, the Court instructed the jury "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," (Ex. 40, Vol. XXXVII, 04/07/14 Tr. at 6279:3-5 (emphasis added)), without indicating that the jury could not draw the same inferences in deciding the counts against Lilly.

III. Defendants Are Entitled To A New Trial Because The Court Committed Other Prejudicial Errors In Its Evidentiary Rulings And Its Instructions To The Jury.

Defendants respectfully submit that the Court committed a number of additional prejudicial errors in its evidentiary rulings and instructions to the jury. Each of those errors in and of itself warrants granting Defendants a new trial.

First, the Court erred in denying Defendants' *Daubert* motions to exclude the testimony of Plaintiffs' expert witnesses – Drs. Delacroix, Kessler, Southgate, and Schneeweiss – and in admitting the testimony of those witnesses. Defendants incorporate herein all of the arguments made in their written *Daubert* motions and replies, oral arguments on the motions, and

arguments made at trial regarding the inadmissibility of the testimony of Plaintiffs' expert witnesses.

Second, the Court erred in denying Defendants' Motion To Exclude Testimony of Plaintiffs' Experts That Actos Can Cause Bladder Within One Year Of Use, and in admitting the testimony of Plaintiffs' experts that Actos can cause bladder cancer within one year of use. Defendants incorporate herein all of the arguments made in their written motion and reply, oral arguments on the motion, and arguments made at trial regarding the inadmissibility of the testimony of Plaintiffs' expert witnesses on whether Actos can cause bladder cancer within one year of use.

Third, the district court erred in instructing the jury that the burden of proof for punitive damages is preponderance of the evidence. As Defendants have previously argued to the Court and therefore incorporate by reference here, the proper standard under New York law is clear and convincing evidence, and any punitive damages instruction to the jury should have included only the clear and convincing standard. Defendants incorporate herein all of their previous briefing and arguments.

CONCLUSION

If the Court does not grant Defendants' Rule 50(b) motion for judgment as a matter of law on all of Plaintiffs' claims and Plaintiffs' demand for punitive damages, the Court should grant Defendants a new trial on liability and damages. If the Court does not grant Defendants a new trial, the Court should remit the punitive damages awards to amounts that (when combined) total no more than the amount of compensatory damages.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 27, 2014, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to Plaintiffs' Steering Committee, Lead Defense Counsel and Defendants' and Plaintiffs' designees. The designees will forward the NEFs to the appropriate attorneys as outlined by the Court's Case Management Order: Notice of Procedure [D.E. 3398].

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