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BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE: PROTON-PUMP INHIBITOR PRODUCTS LIABILITY LITIGATION	MDL DOCKET NO. 2757

TAKEDA'S RESPONSE IN OPPOSITION TO MOTION FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF LOUISIANA PURSUANT TO 28 U.S.C. § 1407 AND JPML 7.2 FOR COORDINATED AND CONSOLIDATED PRETRIAL PROCEEDINGS

ORAL ARGUMENT REQUESTED

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Defendants Takeda Pharmaceuticals U.S.A., Inc. (f/k/a Takeda Pharmaceuticals North America, Inc.), Takeda Pharmaceuticals International, Inc., Takeda Development Center America, Inc. (f/k/a Takeda Global Research & Development Center Inc.), Takeda California, Inc. (f/k/a Takeda San Diego, Inc.), and Takeda Pharmaceuticals America, Inc. (collectively "Takeda"),[1] oppose the Motion of Plaintiffs for Transfer of Actions to the United States District Court for the Middle District of Louisiana Pursuant to 28 U.S.C. § 1407 and JPML 7.2 for Coordinated and Consolidated Pretrial Proceedings ("Plaintiffs' Motion"). In the event that Plaintiffs' Motion is granted, Takeda requests that the Judicial Panel on Multidistrict Litigation ("JPML" or "Panel") transfer the actions to the Honorable Dale Fischer in the United States District Court for the Central District of California, who presided over the *In re Nexium (Esomeprazole) Products Liability Litigation*, MDL No. 2404 (J.P.M.L. 2012), in which she adjudicated product liability claims involving some of the same proton pump inhibitors at issue here.

INTRODUCTION

Prevacid® and Dexilant®, marketed by Takeda Pharmaceuticals U.S.A., Inc., received approval from the Food and Drug Administration in 1995 and 2009, respectively, and belong to the class of drugs called proton pump inhibitors ("PPIs"), which function by reducing the acid content in the stomach to treat conditions such as gastroesophageal reflux disease and ulcers. The complaints from the initial fifteen cases in the Schedule of Actions attached to Plaintiffs' Motion and the thirteen cases that since have been filed (as of November 21, 2016) reveal allegations against five different manufacturers regarding at least five different PPIs, and claims

[1] These are the Takeda entities that have been named and served in the cases that are subject to the motion requesting centralization. Other Takeda-named entities that have not been served and/or are not legitimate entities are not appearing before the JPML.

that those manufacturers failed to adequately warn of the risk of certain kidney related injuries from PPI use, including acute interstitial nephritis (AIN), acute kidney injury (AKI), acute renal failure (ARF); chronic kidney disease (CKD); and end stage renal disease (ESRD). Those PPIs—Prevacid® (lansoprazole); Dexilant® (dexlansoprazole); Nexium® (esomeprazole); Zegerid® and Prilosec® (omeprazole)—have distinct chemical compositions. Out of the twenty-seven actions, Takeda entities have been named as defendants in only four of them and have not yet responded to the complaints in the two actions in which they were served.

The Panel should deny Plaintiffs' Motion. First, centralization is a last resort after all other options have been considered. At this early stage before the parties have explored alternative ways to effectively and efficiently manage the pending actions, centralization would be premature. Even if centralization was not premature, the common facts shared by these actions are greatly outweighed by those which are uncommon among multiple claims against multiple PPI manufacturers regarding multiple PPI products under multiple states' laws.

To the extent the Panel concludes that centralization is appropriate, the four actions against Takeda should be excluded and remanded. Transferring those actions against Takeda to multidistrict litigation for coordinated and consolidated proceedings would not be convenient or promote the just and efficient conduct of the small number of actions.

If Plaintiffs' Motion is granted and the claims against Takeda are not severed and remanded, centralization should occur with the Honorable Dale Fischer in the Central District of California. Judge Fischer has experience managing centralized actions and recently presided over the *In re Nexium (Esomeprazole) Products Liability Litigation*, MDL No. 2404 ("*In re Nexium* MDL"), which involved product liability claims over some of the same PPIs. Her particular knowledge and experience make her uniquely qualified to preside over any centralized litigation.

Furthermore, in contrast to other judges proposed by plaintiffs, her experience would benefit the parties and promote judicial efficiency.

ARGUMENT

I. Transfer and Centralization Will Not Serve the Convenience of the Parties and Witnesses or Promote the Just and Efficient Conduct of The Pending Actions.

a. Centralization is Premature.

The Panel should deny centralization because it is premature. When considering a motion for transfer, the Panel has made clear that "centralization under Section 1407 should be the ***last solution*** after considered review of all other options." *In re Comcast Corp. Employee Wage & Hour Employment Practices Litig.*, No. MDL 2710, 2016 WL 3101837, at *1 (J.P.M.L. June 2, 2016) (emphasis added). Currently, there are only twenty-seven actions pending, and only four of those include Takeda entities as defendants. Takeda has not yet responded to either of the complaints in the two actions in which it has been served. A review of the dockets reveals that none of the twenty-seven cases has advanced in any significant fashion. Based on the current posture of these cases, centralization cannot be considered the ***last solution***.

Centralization is appropriate if it will "serve the convenience of the parties and witnesses or promote the just and efficient conduct" of the pending actions. *See In re Scientific Drilling Intern Inc., Fair Labor Standards Act (FLSA) Litig.*, 24 F. Supp. 3d 1364, 1365 (J.P.M.L. 2014). Aside from being too early for the parties and Panel to determine whether centralization is the only remaining solution, a centralization of the pending actions will not make the administration of the four actions filed against Takeda more efficient or convenient for Takeda.

Plaintiffs attempt to bolster their request for centralization by speculating about the number of cases that could be filed in the future. (*See* Pls.' Mem. at 1 (stating that Plaintiffs' counsel have over 5,000 possible PPI cases "under investigation" with additional potential

clients asking for information).) However, the "mere possibility" of additional actions being filed is insufficient to require centralization of the current pending cases. *See In re Mirena Ius Levonorgestral-Related Products Liability Litig.*, 38 F. Supp. 3d 1380, 1381 (J.P.M.L. 2014) ("Although plaintiffs assert that the number of actions is likely to expand substantially, the mere possibility of additional actions does not convince us that centralization is warranted."). Moreover, the Panel has explained that the "possibility of future filings" is not considered in the "centralization calculus." *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litig.*, 959 F. Supp. 2d 1375, 1376 (J.P.M.L. 2013) ("Although plaintiffs suggest that the number of Lipitor cases is likely to expand considerably, we are disinclined to take into account the mere possibility of future filings in our centralization calculus."). Plaintiffs may very well be investigating additional cases. However, the *mere possibility* of the filing of additional cases does not warrant centralization of the pending twenty-seven actions, nor is it something that the Panel should consider in its analysis.

The *In re Nexium* MDL reveals why centralization would be premature. In 2012, the plaintiffs in that litigation, in part based on the suggestion that additional actions would be filed, obtained transfer and centralization but ultimately only one action against Takeda was incorporated into the MDL. With only twenty-seven cases filed and only four against Takeda, it is too soon to know whether centralization would serve the convenience of the parties and witnesses, or promote the just and efficient conduct of the pending PPI actions.

Instead, the parties can avail themselves of "alternatives to Section 1407 transfer to minimize whatever possibilities there might be of duplicative discovery and/or inconsistent pretrial rulings." *In re Shoulder Pain Pump—Chondrolysis Prods. Liab. Litig.*, 571 F.Supp.2d 1367, at 1368 (J.P.M.L. 2008). The Panel has recognized that "[t]hese options include transfer

pursuant to 28 U.S.C. § 1404, as well as voluntary cooperation and coordination among the parties and the involved courts to avoid duplicative discovery or inconsistent pretrial rulings." *In re Comcast Corp. Employee Wage & Hour Employment Practices Litig.*, No. MDL 2710, 2016 WL 3101837, at *1 (J.P.M.L. June 2, 2016); *see also In re Dollar Tree Stores Inc., Fair Labor Standards Act (FLSA) and Wage & Hour Litg.*, 829 F. Supp. 2d 1376, 1377 (J.PM.L. 2011) ("The Panel is convinced that cooperation among the parties and deference among the courts can easily minimize the possibilities of duplicative discovery or inconsistent pretrial rulings in the actions now before the Panel" and adding that "informal cooperation to avoid duplicative proceedings is appropriate where most plaintiffs share counsel.").

At this early stage, cooperation among the parties is a better option than centralization, particularly where some common discovery already occurred with respect to AstraZeneca and Takeda in the *In re Nexium* MDL. Here, the Takeda entities are represented by the same counsel and are willing to coordinate discovery and other case efforts with the plaintiffs in the four cases in which they have been named, and any others to be filed.[2] Plaintiffs' counsel already are engaging in coordination to some extent, as evidenced by the five plaintiffs' firms that expressly supported Plaintiffs' Motion. (*See* Pls.' Mem. at 14.)

[2] The Panel's Briefing Schedule instructed the parties to include in their briefs "what steps they have taken to pursue alternatives to centralization (including, but not limited to, engaging in informal coordination of discovery and scheduling, and seeking Section 1404 transfer of one or more of the subject cases)." (*See* Dkt. 4.) At the time of Plaintiffs' Motion, Takeda had been served in only one of the PPI cases, *Buzbee*, No. 16-2934, in the Eastern District of New York. Takeda's counsel spoke with *Buzbee's* counsel prior to the filing of Plaintiffs' Motion about a potential personal jurisdiction challenge in that Court based on the facts of that particular action. However, no resolution was reached. The *Buzbee* case has since been stayed until March 1, 2017, pending the Panel's decision on Plaintiffs' Motion. Takeda was not served in a second action, *Thomas*, in the Eastern District of California, until November 1, 2016. The parties in that case have similarly moved for a stay pending the Panel's decision. Otherwise, Takeda has not been approached about potential alternatives or informal coordination of discovery by any of the counsel who filed or support Plaintiffs' Motion.

b. Factual Issues That Are Not Common Will Predominate.

Even if the Panel decides that it is not premature to consider centralization, before any transfer the Panel must determine whether the cases subject to potential centralization share "common questions of fact." *See* 28 U.S.C. § 1407(a). Here, any common issues of fact regarding claims that PPIs cause kidney-related injuries are overshadowed by the issues that are not common: multiple defendants, different products, different formulations, different clinical histories, different regulatory histories, and different injuries. Because of those "non-common" issues, a transfer of the actions would be inconvenient and inefficient and should be denied.

Numerous PPI products are available in branded and generic forms, and in prescription and over-the-counter formulations. Indeed, PPIs are among the most commonly used medications in the world, with reportedly 20 million people in the United States using PPIs each year.[3] Actions such as these with diverse PPI defendants and distinct PPI products do not have the commonality of facts and efficiency of process required to support centralization.

The Panel recently confronted analogous circumstances in *In re Cordarone (Amiodarone Hydrochloride) Marketing, Sales Practices and Products Liability Litig.*, -- F.3d –, 2016 WL 3101841 (J.P.M.L. June 2, 2016), where plaintiffs alleged injuries from the compound amiodarone in nine actions filed against multiple generic manufacturer defendants and Wyeth, which manufactured the branded version of amiodarone known as Cordarone. The Panel concluded that centralization was unlikely to serve the convenience of a substantial number of parties and their witnesses because of the different defendants sued across the nine actions. 2016 WL 3101841 at *1. Similarly, in *In re Shoulder Pain Pump—Chondrolysis Products Liability Litig.*, 571 F.Supp.2d 1367 (J.P.M.L. 2008), the Panel was asked to consolidate thirteen actions

[3] *See Proton Pump Inhibitors* (last visited Nov. 7, 2016), https://www.drugwatch.com/proton-pump-inhibitors/.

in which plaintiffs alleged that the use of ambulatory pain pumps and/or the anesthetic drugs used in the pumps caused chondrolysis. Despite identifying some commonality, the Panel observed that there was an indeterminate number of pain pumps made by different pain pump manufacturers and that many defendants were sued in only a minority of the actions. *In re Shoulder Pain Pump*, 571 F.Supp.2d at 1368. The Panel was not convinced "that the efficiencies that might be gained by centralization would not be overwhelmed by the multiple individualized issues (including ones of liability and causation) that these actions appear to present." *Id.*

This Panel has denied centralization and transfer for similar reasons in other cases as well. *See, e.g., In re Children's Personal Care Prods. Liab. Litig.*, 655 F. Supp. 2d 1365, 1366 (J.P.M.L. 2009) (denying plaintiffs' motion for transfer and holding that although the claims "generally revolve around allegations that certain children's care products . . . are contaminated . . . [a]ny common issues, however, are overshadowed by the non-common ones" such as multiple defendants and baby products with differing formulations); *see also In re Pfizer Inc. Marketing and Sales Practices Litig.*, 657 F. Supp. 2d 1367, 1367-68 (J.P.M.L. 2009) (holding centralization inappropriate where "each of the eleven drugs necessarily has a different clinical, regulatory, medical, and promotional history"); *In re Tropicana Orange Juice Marketing and Sales Practices Litig.*, 867 F.Supp.2d 1341, 1342 (J.P.M.L. 2012) (denying industry-wide centralization because separate discovery would be necessary as to different products and manufacturing processes and the introduction of competing defendants into the litigation would complicate case management, resulting in inefficiencies and delay).

In the ambulatory pain pump litigation where centralization was denied many defendants were named in only a few actions, while other defendants were named in almost all the actions. *In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d 1375, 1377

(J.P.M.L. 2010). The same is true here. AstraZeneca entities are defendants in twenty-five of the twenty-seven PPI cases subject to Plaintiffs' Motion, while Proctor & Gamble entities are defendants in seven, Takeda in four, and Pfizer in one. Under circumstances such as these where defendants are not uniformly named, transfer is inappropriate. *See, e.g., In re Children's Personal Care Prods. Liab. Litig.* 655 F. Supp. 2d at 1366 (noting while denying motion for transfer that "[o]nly J&J is named as a defendant in all actions. Only two other defendants are named in two of the four actions; remaining defendants are named in one action each."); *see also In re Watson Fentanyl Patch Prods. Liab. Litig.*, 883 F. Supp. 2d 1350, 1351 (J.P.M.L. 2012) (noting a hesitancy to "centralize litigation against multiple, competing defendants which marketed, manufactured and sold similar products."). This case is distinguishable from in *In re Bextra and Celebrex Marketing, Sales Practices and Prods. Liability Litig.*, 391 F. Supp. 2d 1377 (J.P.M.L. 2005), where the Panel approved the centralization of claims regarding multiple anti-inflammatory medications. Unlike this litigation, which involves multiple manufacturers and both prescription and over-the-counter medications, *In re Bextra* involved two prescription medications, both of which were produced by Pfizer. 391 F. Supp. 2d at 1379.

Plaintiffs assert that common issues of fact exist because there are "similar causes of action" and "similar factual allegations." (Pls.' Mem. at 4.) At the same time, Plaintiffs acknowledge that the initial PPI cases include different manufacturer defendants and that PPIs treat at least five different gastric acid-related conditions. (*See id.* at 4 – 5.) While Plaintiffs might choose to ignore the factual issues that are not common, these different manufacturers, products and conditions, combined with the individualized issues unique to each plaintiff, are what would predominate in any centralization. After the initial denial of centralization in the ambulatory pain pump litigation the number of actions grew to over 100, yet the Panel again

denied centralization because individual issues of causation and liability appeared to predominate, including the different medical histories of the individual plaintiffs, regardless of how many cases were filed. *In re Ambulatory Pain Pump-Chondrolysis Prods. Liab. Litig.*, 709 F. Supp. 2d at 1377; *see also In re Cordarone*, 2016 WL 3101841 at *2.

Here, different discovery will be pursued relating to distinct testing and research in connection with the PPIs identified in the initial twenty-seven cases—Prevacid, Dexilant, Nexium, Zegerid and Prilosec—which are manufactured, marketed and distributed by different pharmaceutical companies. There also will be individual regulatory histories; different communications with the Food and Drug Administration; and different decisions involving the promotion of these products. There will not likely be similarities in discovery concerning any disclosures made by each company to members of the medical community, the reliance of the medical community on any alleged representations, and the company's awareness concerning the drug's purported adverse effects. These and other factual issues will require different discovery from different pharmaceutical company employees and witnesses. Moreover, the divergent types of kidney injuries claimed by plaintiffs, which range from the acute AIN condition to the chronic CKD injury, demonstrate the predominance of particularized factual inquiries. Based on all of the differing factual issues, centralization is inappropriate.

II. Claims Against Takeda Regarding Prevacid Or Any Other of Its PPI Products Should be Excluded from Centralization in Any MDL That Is Established.

Although Takeda opposes centralization, in the event the Panel grants Plaintiffs' Motion, Takeda asks the Panel to separate and simultaneously remand the claims against the Takeda defendants to their respective transferor courts. Pursuant to 28 U.S.C. § 1407(a), the Panel may order centralization and transfer actions to an MDL for coordinated and consolidated proceedings and simultaneously separate and remand certain claims that do not involve common

questions of fact. *See* 28 U.S.C. § 1407(a) ("the panel may separate any claim, cross-claim, counter-claim, or third-party claim and remand any of such claims before the remainder of the action is remanded"); *see also In re 1980 Decennial Census Adjustment Litig.*, 506 F. Supp. 648, 650 (J.P.M.L. 1982) ("The Panel is empowered by statute to couple its order of transfer with a simultaneous separation and remand of any claims in an action.").

The Panel has separated and simultaneously remanded claims involving different pharmaceutical drug products that were part of the same class. The Panel was unwilling, for example, to transfer cases involving prescription drugs other than Vioxx into an MDL involving Vioxx. *See In Re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005) (holding that "claims involving a prescription drug other than Vioxx . . . do not share sufficient questions of fact to warrant inclusion of these non-Vioxx claims in MDL-1657 proceedings."); *see also In re Celexa and Lexapro Prods. Liab. Litig.*, 416 F. Supp. 2d 1361 (J.P.M.L. 2006) (separating and simultaneously remanding claims relating to a drug other than Celexa or Lexapro because these claims "do not share sufficient questions of fact . . . to warrant inclusion" in the MDL proceedings); *In re Seroquel Prod. Liab. Litig.*, 447 F. Supp. 2d 1376, 1378 (J.P.M.L. 2006) ("the claims involving prescription drugs other than Seroquel do not share sufficient questions of fact with claims relating to Seroquel to warrant inclusion" in the Seroquel MDL).

Should the Panel order centralization, Takeda requests that the Panel exclude the two cases filed solely against Takeda entities, and separate, sever and remand the claims against Takeda in the other two cases in which Takeda entities were named with other manufacturers. In *Thomas v. Takeda Pharmaceuticals U.S.A., Inc., et al.* (E.D. Cal. No. 16-865) and *Moore v. Takeda Pharmaceuticals U.S.A., Inc., et al.* (W.D.N.C. No. 16-364), plaintiffs sued only Takeda entities and only lodged claims against Takeda regarding their PPI products. As occurred with

the Vioxx, Celexa and Seroquel litigations discussed above, the Panel should separate *Thomas* and *Moore* from any centralization and remand those cases to the jurisdictions where they were filed because they do not share sufficient common questions of fact with the cases in which Takeda is not a defendant. That would leave two cases against Takeda: *Buzbee v. AstraZeneca Pharmaceuticals LP, et al.* (E.D.N.Y. No. 16-2934), where plaintiffs sued PPI manufacturers AstraZeneca and Takeda; and *Crandell v. AstraZeneca Pharmaceuticals, LP, et al.* (W.D. La. No. 16-1460), where plaintiffs sued AstraZeneca, Takeda and Proctor & Gamble. The Panel should sever the claims against Takeda from the claims against the other manufacturers in *Buzbee* and *Crandell* and remand them, respectively, to the transferor jurisdictions.

In addition, inclusion in a massive, coordinated proceeding would place a significant burden on defendants such as the Takeda entities, who are named in just four actions. If the Panel orders centralization, Takeda further requests that any future PPI claims against Takeda which are joined with PPI claims against other PPI manufacturers and the subject of future tag-along notices, be likewise separated and remanded to their respective transferor courts.

III. If Plaintiffs' Motion is Granted and the Claims Against Takeda Are Not Severed and Remanded, Centralization Should Occur With the Honorable Dale Fischer in the Central District of California.

Should this Panel deem transfer appropriate, and in the event that Takeda's cases are not excluded from centralization, Takeda agrees with AstraZeneca and the other manufacturer defendants that the cases should be transferred to the Honorable Dale Fischer in the United States District Court for the Central District of California. In support of its position, Takeda incorporates the arguments in the AstraZeneca Brief in Opposition (the "AZ Brief"). *See* AZ Brief at II.A.

a. Judge Fischer Is the Only Judge in the Country With Significant Multidistrict Litigation Experience Regarding PPIs.

Any MDL should be assigned to Judge Fischer in the Central District of California, who handled the *In re Nexium* MDL that involved other product liability claims from certain PPI usage. As this Panel has recognized, an MDL judge's familiarity with the subject matter and the unique issues presented by the litigation promotes the just and efficient conduct of the consolidated actions. In *In re Effexor (Venlafaxine Hydrochloride) Products Liability Litigation)*, this Panel centralized claims in Eastern District of Pennsylvania because it viewed Judge Rufe as "in a unique position to guide" the litigation to an efficient resolution. The Panel explained that "the claims regarding Effexor in this litigation parallel the claims as to the drug Zoloft in MDL No. 2342 – which is already before Judge Rufe and also involves Pfizer as [a] common defendant. . . ." 959 F. Supp. 2d 1359, 1360 (J.P.M.L. 2013); *see also In re Pella Corp. Architect and Designer Series Windows Marketing, Sales Practices and Prods. Liab. Litig.*, 996 F. Supp.2d 1380, 1383 (J.P.M.L. 2014) (choosing a transferee district that would enable assignment to Judge David C. Norton, "who has been handling . . . MDL No. 2333, which, similar to this docket, involves allegations involving defects in various different windows . . . In our view, Judge Norton's experience overseeing MDL No. 2333 is likely to benefit the parties here"); *In re Train Derailment Near Tyrone, Okl., On April 21, 2005*, 545 F. Supp. 2d 1373, 1374 (J.P.M.L. 2008) (finding the Southern District of New York an appropriate transferee district because Judge Barbara S. Jones "has already developed familiarity with the issues involved as a result of presiding over motion practice and other pretrial proceedings for the past two years").

Judge Fischer's experience presiding over the *In re Nexium* MDL would similarly benefit the parties and promote judicial efficiency more so than any other judge proposed by plaintiffs.

Judge Fischer can apply the experience and knowledge she gained during the *In re Nexium* MDL should the Panel determine that transfer is appropriate here. As this Panel has explained, an MDL judge "of necessity, acquires an unusually high degree of familiarity with not only the involved parties, counsel, and claims but also the litigation's underlying subject matter. As a result, that judge is uniquely well-positioned to recognize and dispose of spurious claims quickly." *In re Lipitor (Atorvastatin Calcium) Marketing, Salespractices and Prods. Liab. Litig. (No. II)*, 997 F. Supp. 2d 1354, 1356 (J.P.M.L. 2014). For example, in the *In re Nexium* MDL, Judge Fischer utilized case management techniques designed to fairly and efficiently distinguish plaintiffs with a *prima facie* case of product identification and ingestion. Assignment to Judge Fischer will promote judicial efficiency, as she is "uniquely well-positioned" to apply her knowledge and case management techniques to the claims in this litigation.

While no actions are currently pending in the Central District of California, this Panel has afforded little weight to that factor in national litigation when a judge's prior experience with pertinent issues advocates transfer to a particular district. *See In re Pella Corp.*, 996 F. Supp.2d at 1382 – 83 (finding "no impediment" to the selection of a transferee district where "no constituent action currently is pending" when the litigation was "nationwide in scope" and the selection would facilitate assignment to a judge who had already handled an MDL involving a similar product). Plaintiffs' Motion anticipates that this litigation will be nationwide in scope (*see* Pls.' Mem. at 12),[4] so the absence of any actions pending in the Central District of California should similarly prove "no impediment" to transfer there.

[4] Plaintiffs specifically state that "[t]hese drugs have been sold and consumed across the nation so there will be no single congregation of constituents in any one district." (Pls.' Mem. at 12.)

b. The Central District of California is More Appropriate for Centralization Than the Middle District of Louisiana.

Plaintiffs' Motion proposes the Middle District of Louisiana (Baton Rouge) as the most appropriate district for centralization allegedly because it is "easily accessible" with a "low-volume docket" and available resources to preside over a multidistrict litigation. (Pls.' Mem. at 7.) However, the plaintiffs whose cases are subject to Plaintiffs' Motion do not even agree on centralization in the Middle District of Louisiana. None of the five interested plaintiff responses primarily advocates for centralization there. (*See* Dkts. 10, 40, 43, 46 and 51.) Indeed, the reasons proffered by Plaintiffs in favor of the Middle District of Louisiana do not hold water.

First, the Middle District of Louisiana is not convenient for all parties. Plaintiffs admit that to get to Baton Rouge for most people around the country requires a flight to a southern hub airport where a direct flight can be taken to Baton Rouge. In other words, two flights are necessary to reach Baton Rouge, except for from a handful of southern airports. Takeda is located in Chicago, IL, and its lead counsel is located in Baltimore, MD, and there are no direct flights to Baton Rouge from either of those cities. But centralization in Baton Rouge would not only be inconvenient for Takeda, it would be for other parties as well. AstraZeneca is located in Wilmington, DE, and its lead counsel are in Delaware and Indianapolis, IN, so they also would have to take two flights to reach Baton Rouge (Takeda assumes that the same may be true for Pfizer and Proctor & Gamble and their counsel). In addition, four of the six plaintiffs' lawyers who signed or supported Plaintiffs' Motion (*see* Pls.' Mem. at 14-15) would require two flights to reach Baton Rouge from their locations in San Francisco, CA, Leawood, KS, Pensacola, FL and New York, NY. Even if any of the parties could take a direct flight into New Orleans, it is an over 80 mile drive from New Orleans to Baton Rouge, which is not convenient on the heels of what would be a multi-hour flight for most travelers.

Centralization in Los Angeles with Judge Fischer, on the other hand, would be more convenient. For Takeda, Astra Zeneca and their counsel, and for all but two of the six plaintiffs' lawyers (those in Alexandria, LA and Pensacola, FL), multiple direct flights on different airlines are available to Los Angeles, which has three large airports (LAX, LA/Ontario International, and John Wayne) and three smaller airports (Bob Hope, Palm Springs International, and Long Beach). In addition, Weitz & Luxenberg, who filed the Motion and represented that they have over 5,000 possible PPI cases under investigation (*see* Pls.' Mem. at 1), has an office in Los Angeles. Similarly, Takeda's lead counsel also has an office in Los Angeles.

While the Middle District of Louisiana may be less busy overall than the Central District of California that does not mean it is better suited for an MDL. Plaintiffs reference federal court statistics stating that the Middle District of Louisiana was the 60th-busiest district court out of 89 from 2015-2016 in terms of civil filings per judge. (*See* Pls.' Mem. at 9, n.11.) The Central District of California was 12th based on that same metric, but that metric does not tell the complete story because the Central District was also 4th in the country in terms of the shortest time from the filing of a civil case to disposition at a median time of 5 months. The Middle District of Louisiana, on the other hand, ranked 78th at 11.7 months. In other words, the Central District of California may have more civil cases filed per judge each year, but those cases are disposed of more than twice as fast as cases in the Middle District of Louisiana. In addition, the Central District of California has thirty-eight district judges but only twelve pending MDLs, a low amount given the size of the Court.

Plaintiffs' Motion also touts the under-utilization of the Middle District of Louisiana and the fact that is has never been granted an MDL. (*See id.* at 10.) With all due respect to the judges of the Middle District of Louisiana, having the time and resources to devote to the

management of a complex multidistrict product liability litigation without any experience in doing so is not a factor that weighs in favor of that Court over the Central District of California and Judge Fischer, who already has handled a complex multidistrict product liability litigation regarding certain PPI medications. In addition, the Central District of California is not one of the small group of district courts identified in Plaintiffs' Motion as the "go-to" jurisdictions for product liability MDLs, so it is not "over-utilized" or subject to a glut of complex product liability litigations. (*See id.* at 10, n.15.)

Any centralization of the PPI cases should occur with Judge Fischer in the Central District of California based on her prior and unique experience, the convenience of travel to Los Angeles compared to Baton Rouge, the fact that lead counsel on Plaintiffs' Motion has an office in Los Angeles, and the fact that the Central District of California swiftly handles civil matters and is not over-burdened with complex product liability litigations.

c. Centralization in the Alternative Venues Proposed by Plaintiffs Would Not Promote the Just and Efficient Conduct of the Actions as Effectively as the Central District of California.

Plaintiffs' Motion advocates for four other alternative jurisdictions—the Western District of Louisiana, the Southern District of Illinois, the District of New Jersey and the District of Kansas. (*See* Pls.' Mem. at 13-14.) None of those jurisdictions has a large number of PPI cases, none of the PPI cases in those jurisdictions has progressed appreciably, none of the manufacturer defendants are headquartered or developed their PPIs in those jurisdictions, and no relevant company witnesses or documents are located in those jurisdictions. In short, none of those jurisdictions is preferable to Judge Fischer in the Central District of California.

The Western District of Louisiana requires special mention because of the prejudice to Takeda that would result if the cases are centralized there in front of the Honorable Rebecca

Doherty as Plaintiffs alternatively have proposed. Judge Doherty previously presided over the *In re Actos (Pioglitazone) Products Liability Litigation*, MDL No. 2299, which involved claims that Takeda failed to warn that its life-saving diabetes drug, Actos, caused bladder cancer. On the eve of the first bellwether trial, and after Takeda had won defense verdicts in the first three Actos cases that went to trial in state courts in California, Nevada and Maryland, Judge Doherty issued a novel spoliation of evidence ruling in which she determined that Takeda's duty to preserve documents for the bladder cancer litigation arose in 2002—nine years before any bladder cancer case was filed—because Takeda had issued a broadly-worded litigation hold in another case that had nothing to do with bladder cancer. Judge Doherty concluded that Takeda had a culpable state of mind in the destruction of evidence and that the evidence it put on to rebut spoliation allegations was not reliable or credible, and she allowed evidence of bad faith to go to the jury in the first bellwether trial in her Court. *See* Ex. 2, *In re Actos*, No. 11-md-2299, Amended Memorandum Opinion and Ruling at 68 – 69 (W.D. La. January 30, 2014.) Based on that ruling, the focus of the first bellwether case turned to spoliation and resulted in a staggering $9 billion jury verdict against Takeda and its co-defendant, Eli Lilly. With other options for centralization available, transferring these PPI actions to the Western District of Louisiana on the heels of what occurred in the Actos litigation would potentially be prejudicial to Takeda.[5]

Takeda also opposes centralization in the Southern District of Illinois. Indeed, the statistics cited in Plaintiffs' Motion (*see* Pls.' Mem. at 9, n.11) reveal that while moderately busy in terms of civil filings per judge from 2015-2016 (ranked 44th), the Southern District of Illinois

[5] The Plaintiffs in *Crandell*, which was filed in the Western District of Louisiana, filed an Interested Party Response advocating for centralization in the Western District of Louisiana in front of Judge Doherty or, alternatively, in the Middle District of Louisiana. (*See generally* Interested Party Response, Dkt. 10; *see also Moore* Interested Party Response, Dkt. 51 (advocating for the Middle District of Louisiana).) Plaintiffs' counsel in *Crandell* also was one of the lead plaintiffs' lawyers in the *In re Actos (Pioglitazone) Products Liability Litigation.*

ranked 94th in the median time for a civil case to go from filing to disposition at 30.6 months. The JPML's litigation statistics as of November 15, 2016 also reveal that the Southern District of Illinois currently has two pharmaceutical product liability multidistrict litigations, but those statistics do not include the consolidated pharmaceutical product liability litigation *In re Depakote*, which is pending in that court in front of Judge Nancy Rosenstengel and includes approximately 700 cases. Whether it's because of the burden caused by a crowded product liability litigation docket or for other reasons, only one Depakote case has been tried in the Southern District of Illinois in the past 3.5 years; however, Judge Rosenstengel recently entered an order stating that she intends to resolve the majority of cases by the end of 2017, which she called a "a massive undertaking involving all of this district's resources." *See* Ex. 2, *In re Depakote*, No. 12-52, Order at 1 – 2 (S.D. Ill. July 6, 2016.) In addition, the Panel is scheduled on December 1, 2016 to hear the motion for centralization in the *In re Invokana (Canagliflozin) Products Liability Litigation*, MDL No. 2750, where certain plaintiffs are seeking consolidation in the Southern District of Illinois before the same judge plaintiffs are proposing here, the Honorable Staci Yandle, while other plaintiffs and the defendants in that MDL seek centralization in the District of New Jersey, one of these Plaintiffs' other choices. Any centralization and transfer of these cases should not be to the Southern District of Illinois.[6]

Plaintiffs also alternatively proposed the District of New Jersey, which currently has seventeen multidistrict litigations pending across its three vicinages, seven of which are complex

[6] Two plaintiffs are advocating for centralization in the Southern District of Illinois (*see Mason* (Dkt. 43) and *Bekins* (Dkt. 46) Interested Party Responses), in part on the basis that the first PPI case, *Mason v. AstraZeneca, et al.*, was filed there in May 2016. However, no additional cases have been filed in the Southern District of Illinois and *Mason*, which only involves the AstraZeneca defendants, has not advanced in any material way. A review of the *Mason* docket shows that AstraZeneca's motion to dismiss the complaint has been briefed but not decided and a scheduling order was issued, only to be extended on October 18, 2016. Otherwise, *Mason* is in its infancy, just like the other PPI cases that have been filed.

product liability litigations. (*See* Pls.' Mem. at 10, n.15.) For that reason combined with Judge Fischer's prior experience, the Central District of California would be more likely to promote the "just and efficient conduct of the actions" in accordance with 28 U.S.C. § 1407(a). Finally, Plaintiffs' Motion gives no reason why centralization should occur in the last of their alternative proposed venues—the District of Kansas—except to say that one PPI case is pending there before the Honorable Daniel Crabtree and another judge of the Court, the Honorable Kathryn Vratil, recently handled an MDL in 2015. Again, those reasons do not overcome the relevance and importance of Judge Fischer's prior unique experience, and no other interested party response advocates for the District of Kansas.

d. Takeda Agrees With AstraZeneca That if The Panel Orders Centralization and Judge Fischer is Unavailable, the PPI Cases Should Be Transferred to the District of Delaware.

If Judge Fischer is unavailable, Takeda agrees with AstraZeneca that transfer of the cases to the District of Delaware would be appropriate and incorporates the arguments in the AZ Brief in that regard. *See* AZ Brief at II.B.

CONCLUSION

For the reasons set forth above, Takeda hereby respectfully requests that the JPML deny the pending Plaintiffs' Motion in its entirety or, in the alternative, that the Panel exclude the four cases against Takeda from the MDL. Should the Panel determine that centralization is appropriate, Takeda respectfully requests that the Panel select the Honorable Judge Dale Fischer in the United States District Court for the Central District of California as the presiding judge.

Dated: November 22, 2016

Respectfully submitted,

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PROOF OF SERVICE

I hereby certify that on this 22nd day of November 2016, a copy of the foregoing RESPONSE IN OPPOSITION TO MOTION FOR TRANSFER OF ACTIONS TO THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF LOUISIANA PURSUANT TO 28 U.S.C. § 1407 AND JPML 7.2 FOR COORDINATED AND CONSOLIDATED PRETRIAL PROCEEDINGS was filed using CM/ECF, which will effectuate service on all counsel of record.

Dated: November 22, 2016

Respectfully submitted,

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EXHIBIT 1

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

AMENDED MEMORANDUM OPINION AND RULING

I. Introduction

This multidistrict litigation arises from product liability claims against the manufacturer and marketer of Actos® and other drugs containing pioglitazone. Currently pending before the Court is the "Plaintiffs' Steering Committee's ("PSC") Spoliation and Rule 37 Motion for Sanctions" [Doc. 3484].[1] In its motion, the PSC argues the Takeda entities (defendants Takeda Pharmaceuticals U.S.A., Inc., Takeda Development Center Americas, Inc. (f/k/a Takeda Global Research & Development Center, Inc.), Takeda Pharmaceutical Company, Ltd. ("TPC"), Takeda Pharmaceuticals America, Inc., Takeda California, Inc., Takeda Pharmaceuticals International, Inc., and Takeda Pharmaceuticals, LLC (collectively, Takeda)) intentionally destroyed documents relevant to the instant litigation in bad faith, resulting in prejudice to the plaintiffs. The PSC seeks a default judgment, or in the alternative, a combination sanction of cost-shifting, a fine, an adverse inference jury instruction, restoration of the deleted files, and attorneys' fees and costs. Takeda filed

[1] Upon review of the "filed" ruling, the Court noted the ruling which was ultimately filed, inexplicably, 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 formatting, one typographical error, and other minor clarifications primarily found in fn 27. The Spoliation Motion was filed on October 1, 2013. Briefing on the motion was completed on November 5, 2013. During the following two months, this Court understood that counsel for both parties were engaged in voluntary negotiations in an effort to achieve an amicable resolution to the dispute presented in the Spoliation Motion. This Court used the intervening two month period to work up, address, and rule on a large number of pending motions (including *Daubert* motions, motions in limine, and summary judgment motions). All rulings on those motions were completed and filed by January 15, 2014. Shortly before the last of these numerous rulings was issued, this Court was informed that negotiations on the Spoliation Motion had ended without success, and this Court turned its attention to the Spoliation Motion

designated to testify and additionally, that Takeda and Ms. Calahan selected the content of her "Declaration." And, after full review of Mr. Regard's tortured deposition, this Court cannot help but question 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 Magistrate Judge Hanna's order, but more importantly, must question 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 discovery dispute and Magistrate Judge Hanna's orders.

In addition to the noted "evidence" presented and arguing it had no duty to preserve evidence before 2011, Takeda 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. Again, in a case of this magnitude 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 for its laudable participation in discovery. However, the number of documents produced cannot fully justify the widespread failure to preserve large swaths of Actos - related documents generated and held by so may high-ranking officials. After reviewing the arguments of the parties, the breadth of the "lost" information, and the job titles of those whose files were lost, as well as the Upjohn incident, when coupled with the ever-evolving arguments made by Takeda to the magistrate judge and the seemingly internally inconsistent testimony of Daniel Regard as to "backup tapes," as well as Ms. Calahan's "Declaration," this Court, admittedly, has grave concerns about Takeda's pure intent.

Considering the foregoing, and after 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, as sister courts have permitted, this Court determines it 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.[89] 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.[90]

V. Determination

This Court 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. This Court has found the same Takeda entities breached that duty by the destruction of documents and electronic data after those dates and that the information destroyed is deemed relevant to proof of legal issues now before this Court and, likely, beneficial to plaintiffs' case, and, therefore, the absence of which is, likely, prejudicial to the plaintiffs. This Court does not, at this juncture - reserving that determination until after this Court

[89] This Court is also mindful that a majority of the evidence related to spoliation will likely be relevant to other issues in the trial, particular the issue of punitive damages, and, thus, will not inordinately delay the trial of this matter by virtue of its presentation.

[90] *See* fn 88.

has heard all evidence at trial - however, make a determination as to the full extent of culpability of Takeda in that breach of their duty, and therefore, the nature or strength of the instruction to be given the jury.

The PSC, also, requests 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." The Court will not enter a default judgment against Takeda, as the Court believes such a sanction is too severe. Therefore, this request is DENIED. Furthermore, this Court finds the requests for cost-shifting, a fine, and the restoration of deleted files are better addressed under the purview of Fed.R.Civ.P. 37, or as to spoliation after all evidence has been heard at trial. Therefore, this Court expressly DEFERS ruling upon the request for cost shifting or fines, as well as the request for sanctions pursuant to Rule 37 and will await the unfolding trial phase, without prejudice to Plaintiffs' right to raise the issue(s) for immediate determination at any time they might deem appropriate. However, counsel are cautioned that the requested remedy of "restoration of deleted files" -- where possible -- with cost-shifting and attorneys' fees and costs are well within the Court's consideration and authority under both Rule 37 and spoliation.

As noted, the PSC argues sufficient bad faith and culpable intent on the part of Takeda, which they argue cannot adequately be dealt with under the Rules (*i.e.*, Takeda's conduct before this litigation began), and requests sanctions within the inherent powers of this Court. 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 circumstances of this case, the *reason* for the destruction of evidence is vehemently contested and in no small part

depends upon the *explanation* for the absence of the evidence, rather than testimony as to whether that absence exists. This Court notes its determination is exasperated by Takeda's evidence presented in opposition to the PSC's motion, i.e., its choice to provide a witness to respond for it in its 30(b)(6) deposition who was not then, and at no time had been, an employee of any of the Takeda entities (other than to serve as a consultant) and whose corporate "investigation" appears cursory at best and thus, who could shed precious little, if any, relevant light upon the reasons for the actual destruction of files which occurred at Takeda and the litigation holds at play and Takeda's choice to provide a self-serving "Declaration," from one whose employment history belies her possible personal knowledge and, therefore, which provides precious little relevant factual information to this Court as to the issues at hand. It is not lost on this Court these decisions rested solely with Takeda. Nonetheless, the fact remains this Court finds itself on the eve of the first bellwether trial without persuasive, credible, and informed explanation as to why the destruction of files actually occurred. Nonetheless, and in the face of such absence of relevant information, this Court must determine what is "reasonable" given the unique circumstances at hand, while bearing in mind the remedy must be tailored to the conduct and should impose the least onerous sanction available that addresses the level of conduct at hand. Nonetheless, based upon the evidence and argument presented by both sides, this Court finds it wholly reasonable to allow the jury to hear all evidence and argument establishing and bearing on the good or bad faith of Takeda's conduct and after hearing all such evidence, the instruction to be given the jury in a manner congruent with that evidence.

This Court is not unmindful of the gravity of the requests made, and is of the opinion the Court can benefit from hearing and seeing all of the evidence at trial before determining what actual instruction should be given the jury; that determination to be made at the final charge conference

of the first bellwether trial.

The PSC, also, requests fines and attorneys' fees. Again, this Court is of the opinion it will benefit from hearing the testimony concerning this issue at trial before determining if any further sanction is appropriate, however, invites the PSC to raise the issue of fines or attorneys' fees after this Court has had benefit of all testimony at the first bellwether trial.

VI. CONCLUSION

This Court will, for the full reasons given above, allow all evidence of and relating to Takeda's conduct as to documents and electronic data destruction to go before the jury and will, after having heard all evidence, determine what instruction to give the jury. Additionally, the request for a default judgment is DENIED, and this Court DEFERS on the PSC's request for attorneys' fees and costs until having had benefit of hearing trial testimony.

Additionally, this Court DEFERS on the Rule 37 determination until after the bellwether trial process is completed.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 30 day of January, 2014.

REBECCA F. DOHERTY
UNITED STATES DISTRICT JUDGE