No. 16-1513

IN THE
Supreme Court of the United States

PLIVA, INC.,
Petitioner,
v.
SUPERIOR COURT OF CALIFORNIA,
SAN FRANCISCO COUNTY
(JERRYANN MILLER, *Real Party in Interest*),
Respondents.

On Petition for a Writ of Certiorari
to the California Court of Appeal,
First Appellate District

BRIEF IN OPPOSITION

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COUNTERSTATEMENT OF QUESTIONS PRESENTED

The present petition presents an identical question to the pending petition brought by Petitioner PLIVA, Inc.'s sister company, Teva Pharmaceuticals USA, Inc. (No. 16-1364) PLIVA and Teva's petitions arise out of the same coordinated proceeding pending since 2010 and involving numerous plaintiffs and manufacturers and distributors of name-brand and generic metoclopramide, and now is on the verge of resolution by settlement agreements amongst the parties. As with Teva, the trial court determined twice that PLIVA explicitly consented to personal jurisdiction and waived personal jurisdiction challenges in Real Party's case based on the lengthy historical record in the case. This Court previously denied certiorari review of these issues in 2016 as to both PLIVA and Teva (No. 15-1209), and the law on consent and waiver has not changed since then. It is not the law in dispute here, but rather the trial court's determination of the facts. The questions presented by the petition are inappropriately framed to incorporate PLIVA's version of the facts, which were disputed and resolved against it by the trial court.

Therefore, the question presented by the petition should be reframed as:

> Whether there is substantial evidence supporting the trial court's factual determinations that petitioner PLIVA explicitly consented to the court's jurisdiction, and waived challenges to personal jurisdiction by its actions taken with regard to Real Party's individual case.

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INTRODUCTION

According to Petitioner PLIVA, Inc.'s ("PLIVA") Rule 29.6 Statement, PLIVA is an indirect wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc. ("Teva"). Not surprisingly, PLIVA's petition is substantially identical to the petition filed by Teva on the same issue in the same litigation. No. 16-1364. It is anticipated both Teva's and PLIVA's petitions will be considered at the Court's September 26, 2017 conference.

Both petitions should be denied for the reasons set forth in the Brief in Opposition to Teva's petition that was filed on July 12, 2017, namely:

- The petitions do not implicate either a federal question, a conflict among the various courts or any Supreme Court Rule 10 consideration warranting review.
- The petitions essentially seek review of claimed erroneous factual findings regarding waiver and consent. Such petitions are disfavored under Rule 10.
- The petitions present straightforward legal questions and factual determinations concerning consent to jurisdiction and waiver of personal jurisdiction challenges that were correctly decided by Respondent Court and are amply supported by the record.
- The petitions are based on false and misleading assertions and omissions of key facts.
- All 18 defendants in the coordinated litigation entered into global settlement agreements with the plaintiffs, including

> Teva and PLIVA. Therefore, this petition almost certainly will be moot as Real Party Jerryann Miller has accepted the settlement terms, and the overall conditions are being met and the settlements are funding.

This Court already denied Teva and PLIVA's identical petition on consent and waiver of personal jurisdiction just over a year ago, on June 27, 2016. No. 15-1209. Since their first petition was denied, there has been no change in the law concerning consent and waiver that warrants review. Nor is this Court's recent decision in *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773 (2017) implicated, since the substantive issue of personal jurisdiction neither was reached nor decided in this case due to Respondent Court's findings regarding consent and waiver.

In short, the record reflects PLIVA was provided ample opportunity and instructed by Respondent Court at the outset of the coordination in 2010 and 2011 to address personal jurisdiction issues, and PLIVA was silent. PLIVA then explicitly agreed to Respondent Court's jurisdiction as part of the case management system it negotiated with the plaintiffs, and then actively and vigorously litigated Ms. Miller's and the other plaintiffs' cases by seeking their dismissal on preemption grounds pursuant to *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), while simultaneously seeking discovery from the plaintiffs in their individual cases. PLIVA also told the California court of appeal and Supreme Court on petitions for review of Respondent Court's *Mensing* decision if they did not grant review and direct Respondent Court to dismiss all 3098 pending cases

(including Ms. Miller's case, who was listed as a real party PLIVA's petition), PLIVA would be required to litigate her case – and all non-resident cases – through trial before Respondent Court. *See* Appendices C and D, App. 8-18 (with Ms. Miller listed at App. 18).

Thus, Respondent Court found consent and waiver of jurisdiction (twice now by two different judges), and the California court of appeal and Supreme Court and this Court previously denied review, with the court of appeal issuing its written decision denying PLIVA's mandamus petition the second time around. The Respondent Court's and the court of appeal's decisions are fully in line with this Court's seminal decision on waiver and consent in *Ins. Corp. of Ir. v. Compagnie Des Bauxites De Guinee,* 456 U.S. 694 (1982), which held a defendant may consent to jurisdiction explicitly by consent or stipulation, or constructively through the voluntary use of state procedures. *Id*. at 703-04.

Other than the Teva and PLIVA defendants, none of the other 18 defendants in this litigation challenged personal jurisdiction, and for good reason given all the parties' consent to jurisdiction and active litigation of these cases. For these reasons, as set forth below and in the opposition to Teva's petition, PLIVA's petition must once again be denied.

BACKGROUND

The factual background for this case is set forth in detail in the Brief in Opposition to petitioner Teva's petition for certiorari (No. 16-1364), and is equally applicable with regard to PLIVA's petition here. This brief will summarize the salient aspects of the factual background raised specifically in PLIVA's brief, as

well as additional actions taken by PLIVA's counsel with regard to PLIVA's consent to personal jurisdiction and conduct waiving personal jurisdiction challenges.

A. Ms. Miller's Action against PLIVA

Ms. Miller's action arises out of injuries she sustained as a result of ingesting PLIVA's generic metoclopramide drug product. Metoclopramide (also known by its brand name Reglan) is used to treat heartburn caused by gastroesophageal reflux. Use of metoclopramide more than 90 days greatly increases the risk of contracting a serious and potentially permanent condition known as tardive dyskinesia, which is a neurological disorder that causes uncontrollable, rapid movements of the face and body.

After the manufacturer for the name-brand version of the drug changed its label in 2004 warning not to use the drug more than 90 days, federal drug regulations allowed the generic drug manufacturers to update their labels to reflect this change. Despite the fact PLIVA was the largest manufacturer of metoclopramide at the time (generic or brand), PLIVA never updated its generic metoclopramide label nor made any attempt to inform doctors of the change. And since the brand manufacturer had ceased publishing the label in the Physician's Desk Reference in 2003 after purchasing the brand rights from the original manufacturer (Wyeth, Inc.) in 2002, doctors were unaware of the label change and continued prescribing the drug to patients more than 90 days, including to Ms. Miller who, consequently, developed tardive dyskinesia.

Ironically, PLIVA's parent Teva has been developing a drug to treat tardive dyskinesia – the very condition caused by its years of sale of its generic metoclopramide products without adequate warnings and communications to doctors not to use their products more than 90 days. In fact, in a June 2015 press release Teva gloated it was in the final phases of developing the drug, that there were no approved therapies for the drug, and that tardive dyskinesia is a debilitating disorder affecting about 500,000 people in the United States as a result of treatment of certain medications including metoclopramide. So Teva not only profited handsomely from selling its metoclopramide products without an adequate warning, but it sought to profit from development of a drug it intended to treat that condition.

B. The Initial Coordination in California

A petition was filed in June 2010 to coordinate the California cases before Respondent Court, and Respondent Court stayed all pending cases while it considered the petition. The Court ultimately determined coordination was appropriate, and all the individual actions pending and later filed in California were transferred to Respondent Court to coordinate litigation and discovery in the cases.

Respondent Court had its first hearing in the cases on September 8, 2010. PLIVA wrongly asserts in its brief the stay remained in place until it was lifted to decide the *Mensing* issue in July 2011, but in fact Respondent Court at the September 8 hearing "lift[ed] the stay as to all purposes except discovery effective today," and set a two day hearing on January 5 and 6, 2011 for all motions filed by the parties in

response to the individual case complaints. Appendix G, App. 28-31. The complaints at the time included numerous non-resident plaintiffs, and many named PLIVA since it had been the largest manufacturer of generic metoclopramide until it sold its rights in 2008 after being bought by Teva.

After the hearing, counsel for the parties conferred and determined one of the biggest issues in the case was product identification. Most of the plaintiffs had ingested a generic version of the drug, and most often from multiple generic manufacturer defendants. The parties including PLIVA therefore determined that rather than launching into motions, responses and answers for individual cases, it would be in the best interest of the parties to negotiate an efficient and orderly case management system whereby the generic defendants would only be required to answer complaints once their products were positively identified through the pharmacy records or other sources.

In order for such a case management system to work, all the parties would have to and in fact did agree to the jurisdiction of the court, and not to file forum non-conveniens challenges once their products were identified and they were required to file their answers. The plaintiffs in agreeing to undergo the considerable time and expense of providing substantial discovery and litigating the cases at the outset, while deferring responses by the defendants until their products were positively identified, needed to ensure that once the defendants were brought into the case that all parties had agreed to the jurisdiction of the court and that they could continue to litigate their cases there without challenge.

On October 1, 2010, the parties wrote a joint letter to Respondent Court outlining their proposed case management system. Appendix F, App. 25-27. The parties further informed the Court in the October 1, 2010 letter that the parties' tentative agreements on the case management system would eliminate "some, if not all, motions," and the parties asked the Court to vacate the dates for filing responses and motions to the individual complaints as well as the January 5 and 6, 2011 hearing dates, to allow time to negotiate their final agreements to the case management system. The Court agreed to the request, and vacated the hearing dates and instead set January 5, 2011 as a case management conference.

C. The Case Management Negotiations

On November 30, 2010, the parties presented eight agreed case management orders ("CMOs") to the Court they had negotiated. The first CMO was aptly and importantly named "CMO 1: APPOINTMENT OF LIAISION COUNSEL, JURISDICTION AND STAY OF DISCOVERY." CMO-1 formally appointed Teva's counsel as Lead Counsel for the generic manufacturer defendants. The parties also agreed explicitly in CMO-1 to Respondent Court's jurisdiction over all the parties, cases and counsel in the JCCP coordinated proceedings:

> **IV. Jurisdiction**. This Court retains sole and complete jurisdiction over the parties, cases and counsel in this coordinated proceeding, including each and every case filed in (or coordinated into) this coordinated proceeding.

CMO-1 and its jurisdiction agreement ultimately were submitted by the parties, and the CMO was signed and entered by Respondent Court on April 25, 2011. Appendix E, App. 20-21.

Several of the remaining CMOs were amended after discussions with Respondent Court, and were circulated along with a proposed Master complaint to defendants' counsel on December 2, 2010.

On December 5, 2010, while the parties were negotiating the provisions of the CMOs and a master complaint, PLIVA's national counsel and co-counsel in the California coordinated proceedings, Rex Littrell, raised a new issue with regard to PLIVA's foreign (non-U.S.) indirect parent, PLIVA d.d., that had been named in the master complaint and in the individual complaints. Mr. Littrell acknowledged that, "because agreements to jurisdiction play such a large role in the overall agreements between the parties, I need be very careful about the allegations." (Emphasis added.) Consequently, he stated "I am not authorized to consent to the jurisdiction of the California court on behalf of PLIVA d.d., a foreign corporation." Mr. Littrell also raised a personal jurisdiction issue with regard to another PLIVA parent, a U.S.-based defendant called Barr Pharmaceuticals, LLC, stating Barr "never manufactured, sold or distributed metoclopramide. It is merely a holding company, and PLIVA, Inc. and Barr Laboratories, Inc. are indirect wholly-owned subsidiaries of it."

Mr. Littrell, while acknowledging the supreme importance of their "agreements to jurisdiction" to the case management system being negotiated by the parties, made no mention of any issue with regard to the jurisdiction of the California court over petitioner

PLIVA, Inc. (the U.S.-based manufacturer), which he also represented in the proceedings.

By mid-December 2010, Teva withdrew from its agreement for a tolling provision to allow the plaintiffs to refrain from naming it in the action until product identification was firmly established. This meant the parties had to renegotiate the case management system to accommodate Teva's withdrawal of the tolling provision. At the January 5, 2011 conference, the parties informed the Court Teva withdrew from the tolling agreement, but they remained optimistic they could work around this development.

By February 2011, the parties had revised the case management framework without the tolling. The parties, however, were at an impasse with the CMO language to address PLIVA, d.d.'s (PLIVA's non-U.S. parent) and Barr's (PLIVA's U.S.-based parent) assertion they would not consent to jurisdiction before the California courts. When the parties updated the Court on February 22, 2011 with regard to the PLIVA d.d. and Barr jurisdiction issue, the Court informed the parties it "want[ed] to know up front who is challenging personal jurisdiction," and an effort was made by the parties to identify any parties who intended to challenge jurisdiction. Mr. Littrell confirmed the Respondent Court judge "made clear he wants these issues resolved up front before other matters move forward." The only defendants that came forward in addition to PLIVA, d.d. and Barr were several other non-U.S. parent companies of their U.S.-based generic manufacturer defendant counterparts (including Teva's non-U.S. parent, Teva Industries, Ltd.). Plaintiffs' counsel conferred with counsel for these defendants, including Mr. Littrell for

PLIVA d.d. and Barr, to work out the personal jurisdiction issues to those defendants' satisfaction.

On April 25, 2011 the parties submitted their agreed CMO-1 (with its agreement to jurisdiction), which Respondent Court signed. Appendix E, App. 20-21.

On April 28, 2011, the parties submitted additional agreed CMOs with regard to Master Pleadings (CMO-2), a process for of adoption of those pleadings in the individual cases and plaintiffs' preliminary discovery disclosures (CMO-3), and later exchanges of Plaintiff and Defendant Fact Sheet discovery (CMO-4). CMO-3 was especially relevant here, because the parties specifically agreed that once a defendant was named in an action, all the defendant could do was contest identification of its product or answer. There was no provision for challenging jurisdiction, as the parties had already agreed to jurisdiction in CMO-1. PLIVA also had agreed to take out a motion to quash provision they had inserted in their attempt to preserve PLIVA d.d.'s and the other objecting non-U.S. and holding company defendants' right to challenge jurisdiction, since the jurisdictional issues had been resolved at the court's request. What remained was the defendant's right only to answer or object as to whether the proffered product identification discovery adequately identified its product before it was brought into the action.

At the April 29, 2011 case management hearing, the Court requested several changes to CMO-3 which the parties indicated would not be an issue. The parties negotiated those changes and agreed to the final form of the remaining CMOs, which they planned to submit to the Court.

In short, the case management system developed by the parties placed the initial pleading, expense and production burden on the plaintiffs while the generic defendants including PLIVA were able to defer answers and filing fees until they received product usage evidence, medical authorizations and a notice of adaption of a master complaint, which they were allowed to review and approve first. The plaintiffs also had to produce preliminary disclosure information and later a Plaintiff Fact Sheet in every case. In exchange, the defendants including PLIVA agreed to the jurisdiction of the Respondent Court and the defendants waived the right to bring forum non conveniens motions.

D. Defendants Sought Complete Dismissal of Ms. Miller's Case under *Mensing*

After agreeing to jurisdiction and the case management plan, PLIVA and the other defendants vigorously litigated the cases.

This Court decided *PLIVA, Inc. v. Mensing*, 564 U.S. 604 in June 2011. In the defendants' July 25, 2011 case management report, PLIVA and the other generic defendants contended "that the *Mensing* decision decisively ends the Generic Defendants' involvement in this litigation and that all Generic Defendants immediately should be dismissed from all cases pending in this consolidated litigation." Appendix E, App.23. They then requested "a procedure whereby the Generic Defendants are permitted to seek dismissal of all claims against them." *Id*. at App.24. PLIVA made no mention in its report or at the July 26, 2011 conference of any intention to challenge jurisdiction for any of the cases

(nearly 90% of which PLIVA admitted to be non-resident plaintiffs), let alone request a procedure to do so. With all the Plaintiffs now corralled into the JCCP coordination barrel, PLIVA was intent on utilizing Respondent Court's jurisdiction and the JCCP processes to dismiss all the individual cases based on its *Mensing* argument.

PLIVA and the other defendants also requested in their July 25, 2011 case management report that the Court enter an order requiring all plaintiffs (including Real Parties) to serve "Preliminary Disclosure" discovery responses on defendants (through Teva's counsel), including records documenting their product use; all records of their injuries; all medical and pharmacy records; all documents the Plaintiffs' doctors relied upon in prescribing their drug; and HIPAA-compliant medical authorizations for additional medical records. Appendix E, App. 22-23. Respondent Court agreed to the request, and signed the requested Preliminary Disclosure order at the July 26, 2011 conference. No defendant at that hearing informed the Court it was contesting jurisdiction and should not receive those discovery responses.

In adopting PLIVA's and the other generic defendants' proposal to proceed with their *Mensing* dismissal challenges, the court at the July 26 conference made clear it wanted its ruling to apply to each pending individual case, stating "my expectation is that … all the necessary bells and whistles to make that complaint operative in each case will also be submitted." The parties already had agreed to a process of filing a master complaint, and utilized that process as a vehicle to challenge all the plaintiffs'

cases. This process was not concocted by Respondent Court and imposed on PLIVA, as PLIVA would have this Court believe – it was a process and mechanism negotiated and agreed to by the parties and presented to the Court by them to resolve the *Mensing* issue as to all the individual cases.

E. PLIVA Asked the Court of Appeal to to Direct Respondent Court to Dismiss Ms. Miller's Case

On April 17, 2012, Respondent Court overruled the *Mensing* demurrer, holding the failure to warn claims asserted by the plaintiffs were not violative of *Mensing* and the impossibility preemption doctrine because it was possible under the allegations for Petitioners to have issued warnings and communications about safety issues after those warnings were put into the name-brand Reglan labels in 2003 and 2004.

PLIVA and the other petitioners sought review of the *Mensing* decision from the California court of appeal, and as referenced above specifically named Ms. Miller as a real party in Addendum B to the petition, and asked the court of appeal to reverse the decision and direct Respondent Court to dismiss all their individual cases. Appendix D, App.13 and 18. This relief was in keeping with Respondent Court's directive that its ruling apply to all cases in the JCCP. PLIVA further informed the court of appeal and the California Supreme Court in its petitions that if review was not granted and Respondent Court's decision was not reversed, PLIVA would be required to litigate the plaintiffs' cases – including Ms. Miller's and the other non-resident cases – in Respondent Court through trial. *Id.* at App.13; Appendix C, App.

8-9. That, of course, is the opposite of what PLIVA is arguing now.

By the time the California Supreme Court denied review of the *Mensing* decision on December 12, 2012, the California court of appeal had granted Teva's petition for review of an identical decision against Teva in the Fosamax JCCP litigation pending in Orange County Superior Court. The court of appeal decided that case against Teva in June 2013. *Teva Pharmaceuticals v. Superior Court,* 217 Cal.App.4th 96 (2013), *cert. denied,* 2015 U.S. LEXIS 687 (U.S., Jan. 20, 2015). This Court denied review after the Solicitor General filed its invited *amicus* brief supporting the court of appeal's decision. No. 13-956.

F. The First Time Any Defendant Informed Respondent Court It Intended to Challenge Jurisdiction Was Three Years after Ms. Miller Filed Her Case

It is indisputable that the first time any defendant (including PLIVA) expressed to Respondent Court any intention to challenge personal jurisdiction as to any U.S.-based manufacturer defendant was at the February 11, 2014 conference. That is three years after Ms. Miller filed her case in February 2011.

When the issue was raised at the hearing, Teva's counsel stated only: "Yes. I guess, Your Honor. I'd say there are – there's the master complaint issue" and "Yes. There are potential – I guess there are a variety of potential attacks to individual, specific cases, including personal jurisdiction and substantive issues, potentially." PLIVA's counsel was silent on the

issue. Not surprisingly, the court went on to address the matter at hand, namely, the next set of demurrers Petitioner wanted to bring on yet another preemption issue, and deferred on the issue until "later."

It was not until the May 1, 2014 conference that PLIVA's counsel, Mr. Littrell, did a better job explaining to the court that PLIVA and Teva, at least, wanted to challenge personal jurisdiction based on the residency status of the plaintiff. The plaintiffs asserted Petitioner and PLIVA had long ago waived any such challenges in the case. It is apparent from the record the court and plaintiffs' counsel were unclear about the nature of the intended challenges until PLIVA's counsel explained them with clarity at this May 1 conference.

PLIVA asserts that "personal jurisdiction was raised during an unrecorded informal conference … held on July 25, 2011" by its counsel, Mr. Littrell, and that he "explained that *Goodyear* was impactful on actions in the JCCP." PLIVA Brief, pp. 12-13. This assertion is astonishing because:

- The purported assertion is uncorroborated in any document or court record or by any other witness.
- The purported assertion took place on the same day (July 25, 2011) PLIVA filed its report with the Court raising and attaching the *Mensing* decision and asking Respondent Court for a process to dismiss all cases under that decision. Yet no mention is made of personal jurisdiction challenges or *Goodyear* in the report, or by PLIVA's counsel or any attorney on the record at the July 26, 2011 conference.

- Mr. Littrell on December 5, 2010 acknowledged he had to be careful in preserving PLIVA d.d.'s and Barr's challenges to personal jurisdiction "because agreements to jurisdiction play such a large role in the overall agreements between the parties." Yet for such an important issue, he failed to inform Respondent Court on the record at any time until May 1, 2014 that PLIVA, Inc. intended to challenge personal jurisdiction as to any plaintiff.
- After Respondent Court ruled against PLIVA on the *Mensing* issue, PLIVA informed the California court of appeal and Supreme Court it would be required to litigate all the non-resident cases in the California courts through trial if review was not granted. Appendices C and D, App. 8-18. If PLIVA was conveying to those Courts that Respondent Court had personal jurisdiction in those cases, how can PLIVA credibly claim it conveyed the opposite position in the unrecorded meeting with Respondent Court?
- And even taking Mr. Littrell's claimed statements at face value, an off-the-record statement PLIVA did not even bother to put in its papers or assert at the recorded hearing "raising" personal jurisdiction and stating *Goodyear* was "impactful" is hardly an expression of any intent by PLIVA to challenge personal jurisdiction.

Thus, it remains indisputable neither PLIVA nor any defendant informed Respondent Court of any intent to challenge personal jurisdiction until

February 11, 2014. The speech Mr. Littrell finally made on May 1, 2014 explaining PLIVA intended to challenge personal jurisdiction as to the non-resident plaintiffs could easily have been made when PLIVA raised its *Mensing* challenges at the July 26, 2011 hearing and earlier. But PLIVA had simply stayed silent and did not give Respondent Court that opportunity to address the personal jurisdiction issue then, which it had indicated it wished to do when it lifted the stay on September 8, 2010 and again when it directed the parties to resolve all personal jurisdiction issues on February 22, 2011. And as Respondent Court explained at the initial April 10, 2015 hearing on the consent and waiver issue, "we could have tackled it [the jurisdiction issue] then." Appendix A, App. 2.

G. Respondent Court Found PLIVA Consented to Jurisdiction and Waived Jurisdictional Challenges

Respondent Court gave PLIVA and Teva ample opportunities to contest the consent and waiver issues once it did raise its jurisdictional challenges in 2014.

The first opportunity was at the April 10, 2015 hearing on the plaintiffs' motion on the consent and waiver issue as to PLIVA and Teva, and PLIVA's and Teva's concurrent "test" motion to quash, after full briefing. None of the other 18 defendants unrelated to PLIVA filed jurisdictional challenges, even though those defendants were in the same position as Teva and PLIVA. In fact, the other lead counsel for the generic defendants wrote to Teva's counsel and Mr. Littrell on May 19, 2016 reminding them that "All parties agreed to CMOs 1, 2 and 3 and presented them jointly to the Court as Exhibits to the Joint Case

Management Conference statement for the April 29, 2011 hearing which identified 'Agreed-On Case Management Orders.' Qualitest kept its agreement with plaintiffs …."

Respondent Court granted the plaintiffs' motion and denied defendants' motion. The court found the parties agreed in CMO-1 that it had jurisdiction over all the cases and parties in the litigation, that such jurisdiction was fundamental to the parties' case management system they had negotiated and presented to him, and that he would have expected any party that disagreed with the Court's jurisdiction over it to have raised the issue "[a]nd we could have tackled it then, before many of the procedures that were put in place and relied on by me and relied on by everybody else here. All of that would have stopped and we would have figured out who's playing and who's not." Appendix A, App. 2. Respondent Court also found waiver in that PLIVA sought dismissals of all the cases under *Mensing*, without ever informing it, the court of appeal or the California Supreme Court their rulings would not be applicable to the non-resident cases because the court had no jurisdiction.

Even PLIVA's counsel Mr. Littrell agreed at the hearing on the waiver issue, when pressed, "If we would have won, Your Honor would have had to apply your ruling on the demurrer on the master complaint to the individual cases." Appendix A, App. 3. PLIVA's counsel's statement is an admission PLIVA understood its *Mensing* demurrer was operative as to every single case in the litigation, including non-resident cases such as Ms. Miller's.

The California court of appeal and the California Supreme Court denied review, and this Court on June 27, 2016 denied Petitioner's petition for certiorari. No. 15-1209. But shortly after, PLIVA and Teva filed their motions to quash as to Ms. Miller's and other non-residents' cases claiming again the court had no personal jurisdiction. The motions were heard by a different JCCP coordination judge after the original judge retired. After full re-briefing of the issue by the parties, the court denied the motions based on the same consent and waiver findings made by the JCCP judge who decided the prior motions.

The California court of appeal again denied PLIVA and Teva's petitions, but this time issued short written decisions setting forth the bases for its denials and its denial of the 2015 petition on the same issue. The California Supreme Court denied review, and Teva and PLIVA filed their current petitions for certiorari with this Court on May 12 and June 16, 2017, respectively.

REASONS FOR DENYING THE PETITION

The reasons for denying PLIVA's petition are the same as the reasons stated in the Brief in Opposition to Teva's petition. *See* No. 16-1364. Since it is anticipated the Court will be considering both petitions at the same conference, the reasons will be briefly stated.

I. There Is No Conflict of Law among the Courts Warranting Review of Certiorari under Supreme Court Rule 10.

There is no conflict among the courts on the jurisdiction waiver and consent issue that warrants review under Rule 10. There is no conflict among the

circuits on any issue, nor with any state court of last resort, nor any state court for that matter.

The statutory process for challenging personal jurisdiction in California is extremely straightforward and well-established. A defendant that wishes to challenge personal jurisdiction must file a motion to quash prior to or simultaneously with an answer, demurrer or motion to strike. Cal. Code Civ. Proc. §418.10(a) and (e). Once a motion to quash is filed, no action taken by the defendant, "including filing an answer, demurrer or motion to strike constitutes an appearance, unless the court denies the motion made under this section." *Id.* at subdiv. (e)(1). If the motion to quash is denied, the statute allows the moving party an opportunity to seek immediate appellate review before the decision becomes final and a general appearance is deemed to have been made. *Id.* at subdivs. (c) and (e)(2). And, importantly here, the statute provides that "Failure to make a motion under this section at the time of filing a demurrer or motion to strike constitutes a waiver of the issues of lack of personal jurisdiction." *Id.* at subdiv. (e)(3).

The case law is equally straightforward with regard to consent and waiver of jurisdictional challenges. The seminal California case is *Roy v. Superior Court,* 127 Cal.App.4th 337 (2005), which held the following: A defendant "waives any objection to the court's exercise of personal jurisdiction," unless it files a timely motion to quash under section 418.10. *Id.* at 341. Personal jurisdiction is not an affirmative defense that can be preserved in a responsive pleading. *Id.* at 342, n.5; *see also Neihaus v. Superior Court*, 69 Cal.App.3d 340, 345 (1977). "Nothing could be clearer: a defendant may move to quash coupled

with any other action without being deemed to have submitted to the court's jurisdiction. However, the motion to quash remains essential." *Roy,* 127 Cal.App.4th at 345. The reason for requiring the personal jurisdiction issue to be raised at the outset of the litigation is for judicial economy, "because all other objections become moot if the motion to quash is granted." *Id.* at 344.

Thus, a party making a general appearance without filing a preceding or concurrent motion to quash in essence acknowledges the trial court's jurisdiction in the case and waives any jurisdictional challenge. *Roy,* 127 Cal.App.4th at 341. A defendant generally appears in a case when it explicitly agrees to the court's jurisdiction. *General Ins. Co. v. Superior Court,* 15 Cal.3d 449, 453 (1975). A defendant also generally appears by filing a demurrer or motion to strike (Code Civ. Proc. §1014), seeking discovery in a case (*Factor Health Management, LLC v. Superior Court,* 132 Cal.App.4th 246, 250 (2005)), or otherwise seeking resolution of the case or taking part in the action in such a manner as to recognize the authority of the court to proceed in the particular action (*id.*; *Hamilton v. Asbestos Corp.,* 22 Cal.4th 1127, 1147 (2000)).

The California court of appeal here reviewed the facts and found no error in their application to the law on consent and waiver. It concluded, among other things, PLIVA made a general appearance by agreeing to the jurisdictional provision of CMO-1 which it participated in drafting; filed demurrers and a motion to strike challenging the court's subject matter jurisdiction under the *Mensing* decision; sought writ review with appellate review of the denial

of the *Mensing* demurrer; and obtained the benefits of the discovery process which it requested. PLIVA Appendix B, App. 2-4.

Respondent Court's and the court of appeal's decisions are completely congruent with this court's seminal decision on consent and waiver. In *Ins. Corp. of Ir. v. Compagnie Des Bauxites De Guinee,* 456 U.S. 694 (1982), the Court held an individual may submit to a court's jurisdiction through appearance or by agreement or stipulation. *Id*. at 703. The Court also upheld state court procedures which "find constructive consent to the personal jurisdiction of the state court in the voluntary use of certain state procedures." *Id.* at 704, citing *Adam v. Saenger*, 303 U.S. 59 (1938) (which states personal jurisdiction in the state court is "the price which the state may exact as the condition of opening its courts" to the objecting party). The Court further noted the trial court's waiver decision is a fact-based inquiry, and that waiver can be voluntary or involuntary if warranted by the defendant's conduct.

In sum, the law on the proper manner of challenging jurisdiction, making a general appearance in a particular case and consent and waiver are straightforward and easily applied to the factual findings in this case.

II. The Issues Raised by PLIVA Essentially Consist of Claims of Erroneous Factual Findings by Respondent Court.

Rule 10 provides "[a] petition for writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." The

petition essentially consists of claims Respondent Court made erroneous factual findings based on the historical record concerning consent and waiver, which is even further reason to deny the petition here.

A trial court's determination a party made a general appearance in a case, thereby waiving challenges to personal jurisdiction, are questions of fact, and must be upheld if there is substantial evidence supporting those findings. *Hamilton,* 22 Cal.4th at 1147; *Mansour v. Superior Court,* 38 Cal.App.4th 1750, 1756 (1995).

As detailed above, there is nothing in the record indicating PLIVA informed Respondent Court of any intent to challenge personal jurisdiction before the February 11, 2014 conference. The Court gave PLIVA ample opportunity to challenge personal jurisdiction as to non-resident plaintiffs or request process to do so before signing the first case management order, and in fact on February 22, 2011 expressly requested the parties raise and resolve all personal jurisdiction challenges before it took any further action. PLIVA not only stayed silent, but invoked the Court's jurisdiction by negotiating and agreeing to the case management system set up by the parties (including agreeing to jurisdiction), by seeking dismissal of the individual plaintiffs' cases on substantive grounds (including Ms. Miller's case), and by requesting discovery in the individual cases.

In short, there is ample evidentiary support in the record for Respondent Court's findings on consent and waiver. The extensive record and briefing by PLIVA on these issues has been raised before two judges in Respondent Court who made the same findings and came to the same conclusions, the

California court of appeal which reviewed the matter twice and issued a written opinion by a three justice panel the second time (as well as a similar one on Teva's petition), and the California Supreme Court which denied review twice and this Court which denied review of the consent and waiver issue last year.

III. PLIVA's Factual Narrative Is False and Misleading.

Mindful of Supreme Court Rule 15(2)'s admonition of counsel's "obligation to the Court to point out in the brief in opposition, and not later, any perceived misstatement made in the petition," Ms. Miller sets forth below the true facts refuting the most glaring misstatements in PLIVA's narrative:

1. The Court and the Parties First Discussed Filing Motions on September 8, 2010, Not July 2011 as PLIVA asserts.

PLIVA asserts the July 2011 conference was "the first time since the JCCP's inception, the JCCP and the parties discussed filing motions or demurrers." PLIVA Brief, p.12. PLIVA's assertion is false.

At the September 8, 2010 conference, the court set a two day hearing for January 4 and 5, 2011 and lifted the stay for any initial motions the defendants wanted to file (what it termed a "motion-o-rama"), stating:

> What I'm going to do is I'm going to lift the stay for all purposes except discovery effective today; so that if you haven't responded to the complaint, responded in the sense of answered or filed another

> appropriate response, the time starts running today.

Appendix G, App.30.

After the September hearing, the parties, including PLIVA, then informed the Court that they had worked out a case management framework and that the motions would not be necessary. Appendix F, App. 25-27. And by April 2011, the parties successfully reached agreement to a series of CMOs for resolution of these initial pleading issues and other issues, including jurisdiction.

2. PLIVA First Informed Respondent Court in 2014 It Wanted to Challenge Personal Jurisdiction, Not "Every Step of the Way" as PLIVA asserts.

PLIVA asserts "At every step of the way, Petitioner raised personal jurisdiction and repeatedly was assured that the defense was preserved …." PLIVA Brief, p.27. PLIVA also claims it "repeatedly asserted its intent to challenge the court's jurisdiction over it in cases of non-resident plaintiffs …." PLIVA Brief, p.34. PLIVA's assertions are false.

As referenced in the section above, the Court on September 8, 2010, lifted the stay for any defendant to file any response to the individual responses, and set a two day "motion-o-rama" for January 5 and 6, 2011. Appendix G, App. 28-31. And after PLIVA's counsel raised the issue of personal jurisdiction for PLIVA d.d. and Barr (but not petitioner PLIVA, Inc.), Respondent Court in February 2011 directed the parties to resolve all personal jurisdiction issues before it would sign any of the CMOs negotiated by the parties. Those issues were resolved, and the court

in April 2011 signed CMO-1 with the parties' agreement to the court's jurisdiction.

In both instances, PLIVA could have asserted Respondent Court had no personal jurisdiction over PLIVA in non-resident cases, but PLIVA did not raise any jurisdiction issue (other than for PLIVA, d.d. and Barr), did not file any motions and did not request a process to do so. Instead, PLIVA stayed silent and negotiated a case management system to litigate the cases before Respondent Court, agreed to jurisdiction in CMO-1, and vigorously litigated the non-resident cases including Ms. Miller's case before Respondent Court.

And it cannot be disputed that the first time any defendant informed the Court of any intent to challenge jurisdiction was when Teva did so at the February 10, 2014 conference, and the first time PLIVA did so was at the May 1, 2014 conference, the day before the court was to hear the third set of demurrers and other challenges.

3. The Parties Agreed to Respondent Court's Jurisdiction for All Cases in CMO-1 in April 2011.

PLIVA claims the CMO-1 jurisdiction provision was some sort of oblique reference to courts in other California counties and to the New Jersey and Pennsylvania coordinations, and did not mean the Court had jurisdiction over PLIVA for all the cases in the JCCP coordination. PLIVA Brief, p.11. PLIVA also asserts its "consent" to jurisdiction was "based on action taken by the court itself, and not petitioner." PLIVA Brief, p.31. PLIVA's assertions are false.

The CMO-1 jurisdiction provision was negotiated by PLIVA and the parties as an essential component of a case management system designed to delay PLIVA's and the other defendants' answers until their products were conclusively identified in the case, and was submitted by the parties to the Court for signature on April 25, 2011. The jurisdiction provision states: "Jurisdiction: This court retains sole and complete jurisdiction over the parties, cases and counsel in this coordinated proceeding, including every case filed in (or coordinated into) this coordinated proceeding."

PLIVA knew very well and intended this language to reflect its agreement to personal jurisdiction of the Court in all the cases. PLIVA's counsel's (Mr. Littrell's) December 5, 2010 email sent during the negotiations acknowledged "because agreements to jurisdiction play such a large role in the overall agreements between the parties," he could not agree to personal jurisdiction over PLIVA's non-U.S. parent (PLIVA d.d.) and a PLIVA U.S. holding company he represented (Barr). (Emphasis added.) CMO-1 is the resultant "agreement to jurisdiction," which Mr. Littrell agreed to and submitted jointly to the Court for signature on April 25, 2011.

And that is precisely how Respondent Court reasonably understood CMO-1's jurisdiction provision at the time it was entered, and when it ruled on the consent issue on April 10, 2015:

> First of all, I see it as pretty simple, CMO 1 says I have jurisdiction over the parties, the cases and counsel, all of them, and that got served on everybody.

> As a matter of fact, some of the participants on the defense side as liaison counsel are counsel in these motions here [referring to Teva's counsel]. And everybody knew at that time what we were about to embark on was an absolutely massive administrative odyssey is the only way to describe it and that this Court was getting organized and helping to organize you folks, and you were helping to organize me as to what we were going to do with this massive set of cases.
>
> And fundamental to that was I had to have jurisdiction over the participants.

Appendix A, App. 1-2.

4. **PLIVA, not Respondent Court, Requested the Process to Decide the *Mensing* Issue First and to Obtain Discovery in Each Case.**

PLIVA asserts "the JCCP Court directed the course of the proceedings and the manner and sequence in which the parties should address the issues"; "Petitioner was ordered to engage in the proceedings giving rise to the supposed waiver"; and "Petitioner could not refrain from litigating *Mensing* until after personal jurisdiction was challenged in non-resident cases …." PLIVA Brief, pp. 23-24. PLIVA also asserts "The JCCP Court chose to address *Mensing* challenges before personal jurisdiction challenges. Petitioner followed the JCCP Court's instructions on the manner and order in which to address issues applicable to the coordinated actions."

PLIVA Brief, pp. 28-29; *see also* pp. 2-3. PLIVA's assertions are false and misleading.

After *Mensing* was decided on June 26, 2011, PLIVA and the other generic defendants asserted that *Mensing* ended the litigation against them, and that they should be dismissed from all the cases. Consequently, in their July 25, 2011 conference statement, PLIVA raised the *Mensing* issue and attached the *Mensing* case to the statement, and requested "a procedure whereby the Generic Defendants are permitted to seek dismissal of all claims against them." Appendix E, App.24.

PLIVA's July 25, 2011 statement made no mention of any personal jurisdiction issue, and did not attach the Court's *Goodyear* personal jurisdiction decision which was decided the day after *Mensing*. PLIVA also did not request a procedure whereby it would be permitted to make personal jurisdiction challenges as it did for the *Mensing* issue, despite the fact it admits there were over 3800 plaintiffs in the litigation at the time and nearly 90% were non-resident plaintiffs. Nor did PLIVA's or any defendant's counsel mention personal jurisdiction or declare any intention to challenge personal jurisdiction at the July 26, 2011 conference.

The Court obliged PLIVA's and the other generic defendants' request, and ordered the parties to proceed on the *Mensing* issues. Respondent Court made clear its "expectation is that … all the necessary bells and whistles to make that complaint operative in each case will also be submitted."

Thus, it was the Court that followed PLIVA's request to decide the *Mensing* issue in July 2011, and

not the other way around. There was no "sequencing" of the *Mensing* decision with personal jurisdiction challenges because no defendant including PLIVA raised any such challenge. And there is no reason Respondent Court would suspect personal jurisdiction challenges would be made, since the parties had agreed to personal jurisdiction in CMO-1, and since the Court in February 2011 had directed the parties to resolve all personal jurisdiction issues before it would sign the first CMO. And, indisputably, it was not until February 10 and May 1, 2014 that Teva and PLIVA finally informed Respondent Court they wanted to challenge personal jurisdiction in any of the cases.

5. Respondent Court Never "Assured" Petitioner It Could Challenge Personal Jurisdiction after the *Mensing* Issue Was Resolved.

PLIVA states it was assured repeatedly by Respondent Court it could file motions to quash after its *Mensing* challenges were resolved. Petition pp. 3, 15, 28, 31-32. This assertion is false.

It is indisputable no defendant including PLIVA ever expressed any intention to challenge personal jurisdiction until the February 11, 2014 conference. How could Respondent Court be assured about something PLIVA never asked for prior to that date? Respondent Court rightfully assumed all personal jurisdiction challenges had been cleared up after it directed the parties to do so on February 22, 2011, and after the parties agreed in April 2011 to the court's jurisdiction over all the cases in CMO-1. Under these facts, it is impossible to comprehend how PLIVA could have been assured by Respondent Court that

PLIVA, while pressing its *Mensing* challenges, could later file motions to quash challenging the court's jurisdiction in nearly 90% of the cases.

PLIVA, rather than relying on the statements of its own counsel prior to February 11 and May 1, 2014, instead relies on snippets of out of context statements in the record by the court and plaintiffs' counsel to support its view that it was continuously assured it could raise personal jurisdiction challenges after the court decided its *Mensing* and other challenges.

For example, the petition points to Amended CMO-1 and other statements that the *Mensing* issue could proceed but that all other motions were preserved. PLIVA Brief, p.15. The context of these statements is that California precludes a party from filing piecemeal demurrers, and the court was trying to preserve any "non-*Mensing*" issues for later demurrer. This did not mean filing motions to quash challenging jurisdiction, which had been resolved by the parties and in CMO-1.

PLIVA also references a statement by plaintiffs' counsel in 2013 that jurisdiction arguments are preserved, but a review of the full transcript indicates the statement was made in the context of preserving subject matter and not personal jurisdiction.

Such oblique statements by the Court and plaintiffs' counsel, which have other contexts and meanings, are no substitute for a direct statement by PLIVA of its intent to challenge jurisdiction and a request for a process to do so. PLIVA's counsel certainly knew how to make such a request – he did

so for PLIVA's parent, PLIVA d.d., in December 2010, and he finally asserted PLIVA's intent to challenge jurisdiction on May 1, 2014 and later suggested a "test case" to do so, which it brought in 2015. And if the issue had in fact been raised by him at the outset, as Respondent Court said at the April 10, 2015 hearing on the consent and waiver issue, "we would have stopped and we would have figured out who's playing and who's not." Appendix A, App.2.

6. Jurisdiction Challenges Cannot Be "Reserved" in a Demurrer Footnote.

Petitioner claims it "reserved" its personal jurisdiction challenges in its demurrer papers in a footnote. PLIVA Brief, pp. 14-15, 16 and Appendix H, App.59 (the footnote). But the law is clear a defendant cannot reserve such challenges in its responsive pleadings, and then vigorously litigate the case. *Roy,* 127 Cal.App.4th at 342, n.5; *see also Neihaus v. Superior Court*, 69 Cal.App.3d at 345.

IV. PLIVA's Due Process Rights Were Not Violated.

PLIVA claims its Due Process rights were violated by the California courts in finding consent and waiver of its personal jurisdictional challenges. To the contrary, there is no Due Process violation. PLIVA has been treated fairly and justly, and PLIVA should be estopped through its consent and waiver from belatedly claiming Respondent Court has no personal jurisdiction for the majority of cases in the litigation.

As this Court stated, unlike for subject matter jurisdiction where "consent is irrelevant" and "principles of estoppel do not apply," "[t]he requirement that a court have personal jurisdiction

flows not from Art. III, but from the Due Process clause." *Ins. Corp.*, 456 U.S. at 702. And since such right is not a matter of sovereignty but rather of "individual liberty," "the test for personal jurisdiction requires that 'the maintenance of the suit … not offend 'traditional notions of fair play and substantial justice.'" *Id.* at 702-03 (quoting *International She Co. v. Washington*, 326 U.S. 310, 316 (1945)).

Respondent Court's decisions finding consent and waiver do not violate Due Process and do not offend the notions of fair play and substantial justice here. As discussed above, Respondent Court provided PLIVA ample opportunities to challenge jurisdiction at the early stages of the litigation, and PLIVA stayed silent and chose instead to proceed with substantive challenges and discovery in the individual cases. When PLIVA and Teva finally informed the court years later they wanted to challenge personal jurisdiction (after losing on the *Mensing* issue), the court gave them two opportunities before two different judges to make their case, and to run the court's decisions up the appellate ladder.

In short, California opened its courts to PLIVA at its behest to vigorously and actively litigate the individual cases, including Ms. Miller's case, through its coordination process as a vehicle to efficiently obtain discovery and seek dismissal of the individual cases on substantive grounds. After explicitly consenting to the jurisdiction of the California courts and so actively litigating the cases, and after Ms. Miller and the other plaintiffs and Respondent Court relied on PLIVA's consent to jurisdiction and substantive challenges to the cases, PLIVA cannot now claim years later it was treated unfairly and its

Due Process rights were violated when its belated challenge to the court's jurisdiction was denied.

V. Ms. Miller Accepted PLIVA's Global Settlement Offer and Expects This Petition Will Be Moot.

After seven years of litigation, this matter is about to come to a close as all 18 defendants have reached global settlements with the California plaintiffs and plaintiffs in coordinations in Pennsylvania and New Jersey and as to other cases filed nationally. Ms. Miller accepted the terms of all the settlements applicable to her including PLIVA's settlement. The conditions for these settlements are being met and most defendants have funded. Teva and PLIVA were the last to settle, and it is anticipated all conditions of the global settlement will be met. As a consequence, it is anticipated this petition should be moot by the time this Court would make any final decision in the case, and for this further reason the petition should be denied.

CONCLUSION

For the foregoing reasons, Real Party Jerryann Miller respectfully requests the Court deny the petition.

Respectfully submitted,

August 16, 2017

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APPENDIX A

SUPERIOR COURT OF CALIFORNIA
COUNTY OF SAN FRANCISCO
HONORABLE RICHARD A. KRAMER,
JUDGE PRESIDING
DEPARTMENT NUMBER 303

Coordination Proceeding
Case No.: CJC-10-004631

[Dated April 10, 2015]

COORDINATION PROCEEDING	)
SPECIAL TITLE [RULE 1550 (b)]	)
	)
REGLAN/METOCLOPRAMIDE CASES	)
	)

Excerpts From Reporter's Transcript of Proceedings

Friday, April 10, 2015

REPORTED BY:
MARY ANN SCANLAN-STONE, CPR-RPR-CCRR
CLR CSR NO. 8875

* * *

[p.15]

* * *

THE COURT: First of all, I see it as pretty simple, CMO1 says I have jurisdiction over the parties, the cases, and counsel, all of them, and that

got served on everybody. As a matter of fact, some of the participants on the defense side as liaison counsel are counsel in these motions here. And everybody knew at that time what we were about to embark on was an absolutely massive administrative odyssey is the only way to describe it and that this Court was getting organized and helping to organize you folks, and you were helping to organize me as to what we were going to do with this massive set of cases.

And fundamental to that was I had to have jurisdiction over the participants.

So the order says that and, to me, that recitation alone resolves the issues here, because if anybody disagreed with that, whether or not they individually signed on to it -- but if anybody disagreed with that, they had to say, hey, wait a minute, not us, not us.

And we would have tackled it then, before many

* * *

[p.16]

* * *

THE COURT:....

of the procedures that were put in place and relied on by me and relied on by everybody else here. All of that would have stopped and we would have figured out who's playing and who's not. That all by itself, in my view, is sufficient to constitute a waiver of the judicial claims.

* * *

[p.30]

* * *

THE COURT: the way the law works is if the demurring parties had won, all the cases would have been thrown out, all of the generic cases would be gone, and everybody would be out of this Court, and then the Court of Appeal, on the plaintiffs' appeal from the sustaining of a demurrer, would have impacted all of the cases.

* * *

[p.42]

* * *

THE COURT: If a judge tells you, by the way, I think I have jurisdiction over all of you, every bit of all of you, if a judge says that to you in writing as an order, somebody ought to stand up and say, hey, wait a minute, with all due respect, that's the way it would come out.

* * *

[p.43]

* * *

MR. LITTRELL: If we would have won, Your Honor would have had to apply your ruling on the demurrer on the master complaint to individual cases.

* * *

[p.44]

* * *

THE COURT: Do you have authority for the fact that I would have had to have several thousand hearings to see if that ruling from, say, the Supreme Court applied to each and every one of those cases? Do you have any authority for that?

Because that's not how I do it and I've been doing it for a long time. What I do is I say, how about we Xerox the Court of Appeal opinion, stick it in all the files, and electronically get rid of all the cases.

* * *

APPENDIX B

SUPERIOR COURT OF CALIFORNIA
COUNTY OF SAN FRANCISCO
HONORABLE RICHARD A. KRAMER,
JUDGE PRESIDING
DEPARTMENT NUMBER 303

Coordination Proceeding
Case No.: CJC-10-004631

[Dated February 26, 2015]

COORDINATION PROCEEDING	)
SPECIAL TITLE [RULE 1550 (b)]	)
	)
REGLAN/METOCLOPRAMIDE CASES	)
	)

Excerpts From Reporter's Transcript of Proceedings

Thursday, February 26, 2015

REPORTED BY:
MARY ANN SCANLAN-STONE, CPR-RPR-CCRR
CLR CSR NO. 8875

* * *

[p.53]

* * *

THE COURT: Is part of what will be involved in this jurisdictional thing, … that this was waived?

MR. SKIKOS: Yes.

MR. OETHEIMER: Yes, I'm sure.

THE COURT: So that could go forward.

MR. SKIKOS: Yes.

* * *

[p.56]

* * *

THE COURT: Would it make any sense to go forward on the waiver argument anyway?

MR. SKIKOS: I think it would.

MR. OETHEIMER: We don't believe so.

THE COURT: But it would have to be done anyway, no matter what the result is of the supreme court -- whichever supreme court we're talking about, if the supreme court says we hereby abolish international shoes and we hereby abolish specific jurisdiction except…

* * *

[p.57]

* * *

THE COURT: in the following limited situations, a complete victory for out-of-state defendants, there would still be a need to have the hearing on whether personal jurisdiction was waived. No matter what, that would have to happen.

Conversely, if personal jurisdiction was waived, there's no need to wait for what the supreme courts do. If it was not waived, then whatever happens in the supreme courts would happen and its impact would be determined anyway.

* * *

[p.79]

* * *

THE COURT: But I think be we have to resolve at least the question of waiver in order to avoid what looks to me like it could be a two- to four-year delay in whether or not there's jurisdiction over anybody who might have waived it.

Whether or not what's pending is in front of the California Supreme Court is sufficiently identical to what would be here in the non-waiver arguments remains to be seen, because nobody has told me exactly what it is.

So here's what I'm going to do. I've decided.

I'm going to lift the stay as to all of the cases in the JCCP, to the extent that any party who wishes to can file a motion regarding the jurisdiction of this Court to proceed in any one or more of the cases, and you do whatever you want.

* * *

APPENDIX C

IN THE SUPREME COURT OF CALIFORNIA

After A Summary Denial By The Court of Appeal, First Appellate District Division One – No. A135804

EXCERPTS FROM PETITION FOR REVIEW

[Dated October 9, 2012]

GENERIC DEFENDANTS, Petitioners,	)
	)
v.	)
	)
THE SUPERIOR COURT OF SAN FRANCISCO COUNTY, Respondent	)
	)

* * *

[p.3]

* * *

Despite this tidal wave of authority, the Superior Court hearing these consolidated cases in San Francisco refused to follow *Mensing* and overruled petitioners' demurrer in its entirety. Left intact, that sharp deviation from this overwhelming nationwide consensus will allow nearly 3,000 plaintiffs (the overwhelming majority of whom are not California residents) to continue pursuing claims against the generic drug manufacturers-petitioners in

California state court-even though those plaintiffs' claims are exactly the same as the ones pressed and rejected by the U.S. Supreme Court in *Mensing*.

* * *

[p.5]

* * *

No factual development is necessary to enable judicial review; yet allowing these cases to proceed will push this state's courts to the breaking point with full-blown discovery, motions practice, and the prospect of literally thousands of trials in a resource-strapped judicial system-particularly in San Francisco, where months ago the…

* * *

[p.6]

* * *

…superior court barely averted an emergency plan to close 25 courtrooms, lay off 40 percent of its workforce, and shutter the very same complex litigation department from which this petition (which involves over 2,000 claims by out-of-state plaintiffs) arises.

Dated: October 9, 2012 Respectfully submitted,

/s/ Joshua S. Goodman

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APPENDIX D

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA FIRST APPELLATE DISTRICT DIVISION _____

(From the Superior Court for San Francisco County, JCCP 4631, Case No. CJC-10-004631 Richard A. Kramer, Judge)

Excerpts From PETITION FOR WRIT OF MANDATE AND/OR PROHIBITION OR OTHER APPROPRIATE RELIEF

[Dated June 26, 2012]

GENERIC DEFENDANTS, Petitioners,	)
	)
v.	)
	)
THE SUPERIOR COURT OF SAN FRANCISCO COUNTY, Respondent	)
	)
COORDINATED PROCEEDING SPECIAL TITLE [RULE 3.550]	)
	)
REGLAN/METOCLOPRAMIDE CASES	)
	)

* * *

[p.6]

* * *

Given this state of affairs, the trial court's apparent decision to have these thousands of cases proceed to trial despite *Mensing* not only is wrong on the merits; deferring review would impose an extraordinary and unreasonable burden on this State's already-strained judicial system.[2]

* * *

[p.10]

* * *

A. Petitioners, Respondent and Real Parties in Interest.

1. The petitioners are defendants in hundreds of personal injury actions brought by approximately 3,000 plaintiffs now pending under rule 3.550 of the California Rules of Court as JCCP 4631 in respondent court entitled In re Reglan/Metoclopramide Cases, San Francisco Superior Court Case No. CJC-10-004631. (For a complete list of petitioners, …

* * *

[p.11]

* * *

…please see Addendum A to this petition.) The plaintiffs are named here as the real parties in

---

[2] Petitioners also note that approximately 90 percent of the plaintiffs in these coordinated cases are out-of-state residents, which presumably impacts the California court system's ability to accommodate Californians.

interest. (For a complete list of plaintiffs, please see Addendum B to this petition.)

* * *

[p.53]

* * *

CONCLUSION

For the foregoing reasons, petitioners respectfully request that this court grant the writ and issue a decision directing the superior court to vacate its order overruling petitioners' demurrers and directing the superior court to sustain the demurrers in their entirety and to dismiss these cases as against petitioners in their entirety; or, in the alternative, directing the superior court to vacate its order denying petitioners' motion to strike and directing the superior court to reconsider that motion in accordance with this court's decision.

Dated: June 26, 2012

Respectfully submitted,

HOROVITZ & LEVY LLP
JON B. EISENBERG

GOODMAN NEUMAN HAMILTON LLP
JOSHUA S. GOODMAN

KIRKLAND & ELLIS LLP
JAY P. LEFKOWITZ, P.C.

By: /s/ Joshua S. Goodman
Attorneys for Petitioners

ADDENDUM A

PETITIONERS

Actavis Elizabeth LLC

Acura Pharmaceuticals, Inc. f/kJa/ Halsey Drug Company, Inc.

ANI Pharmaceuticals

Barr Laboratories, Inc.

Beach Products, Inc.

Bedford Laboratories, a division of Ben Venue Laboratories, Inc.

Boehringer Ingelheim Roxane, Inc., f/k/a Roxane Laboratories, Inc.

Bristol-Myers Squibb and Apothecon

Generics Bidco I, LLc

Hospira, Inc.

Ipca Pharmaceuticals, Inc.

King Pharmaceuticals, Inc.

McKesson

Morton Grove Pharmaceuticals, Inc.

Mutual Pharmaceutical Company, Inc. & United Research Laboratories, Inc.

Northstar RX, LLC

Paco Pharmaceutical Services, Inc.

Pharmaceutical Associates, Inc.

Pliva, Inc.

Qualitest Pharmaceuticals, Inc.

Ranbaxy, Pharmaceuticals, Inc.

Richmond Pharmaceuticals, Inc

Rugby Laboratories, Inc.

Sandoz Inc.

Silarex Pharmaceuticals, Inc.

Smith and Nephew, Inc.

Teva Pharmaceuticals USA, Inc.

The Harvard Drug Group LLC dba Major Pharmace

Vintage Pharmaceuticals, LLC

VistaPharm, Inc.

Watson Laboratories, Inc.

Wochkardt USA, LLC

ADDENDUM B

CA MCP Litigation – Active Plaintiffs

* * *

[Addendum B, p.49]

* * *

1887	Miller, Jerryann	Gold v. Wyeth	CGC-11-507473	1/20/11

[Note: The above represents an excerpt referencing Real Party Jerryann Miller taken from "Addendum B" of the California court of appeal petition for a writ of mandate concerning the trial court's ruling on Petitioners' *Mensing* demurrer (without the counsel name column). The un-excerpted portion of "Addendum B" lists the remaining 3098 Real Parties until the Addendum ends at entry 3098 at page 79.]

APPENDIX E

SUPERIOR COURT OF CALIFORNIA
COUNTY OF SAN FRANCISCO

[Dated July 25, 2011]

COORDINATION PROCEEDING	)
SPECIAL TITLE [RULE 1550 (b)]	)
	)
	)
REGLAN/METOCLOPRAMIDE CASES	)
	)

DEFENDANTS' CASE MANAGEMENT CONFERENCE STATEMENT

Date: July 26, 2011
Time: 9:30 a.m.
Dept.: 304
The Honorable Richard A. Kramer

AGENDA

A. Case Management Orders

- CMOs Previously Entered
  - CMO-1: Appointment of Liaison Counsel, Jurisdiction and Stay of Discovery
  - Order re Electronic Service
  - Protective Order

- CMO re Plaintiffs' Initial Disclosures

B. Status of San Francisco Superior Court Management and Judge Kramer's continued over sight of these coordinated proceedings.

C. Process for Streamlining the Add-On Procedure

- Request to add on recent cases pending
- Transfer of cases previously coordinated

D. The *Mensing* Opinion

E. Defendant Hospira's Motion and Demurrer

CASE MANAGEMENT ORDERS

The Court previously entered a set of pretrial orders on various issues, including the following:

1. CMO-1: Appointment of Liaison Counsel, Jurisdiction, and Stay of Discovery;
2. Order re Electronic Service; and
3. Protective Order

The Defendants submit the following process governing the preliminary disclosures required of each plaintiff and submit the [Proposed] Order re Plaintiffs' Preliminary Disclosures for the Court's approval (Exhibit A). Following the disposition of the issues relating to the *Mensing* decision (see below), the parties will continue to meet and confer on a process initialing the filing of a Master Complaint and a short

form pleadings relating thereto. In the interim, Defendants also request that the Court address issues raised by the recent United States Supreme Court in *PLIVA, Inc. v. Mensing*, ---U.S. ---, 131 S.Ct. 2567 (June 23, 2011) (slip op.) (a copy of this opinion is attached as Exhibit B).

Position

a. Preliminary Disclosures

Defendants recommend a two-pronged approach in light of the recent U.S. Supreme Court holding in *Mensing*. First, defendants have proposed to the Plaintiffs Liaison Committee a scaled-down version of the draft case management order the parties have been negotiating for several months. Defendants' proposal (Exhibit A) is as follows: Plaintiffs provide preliminary disclosures in each, including the following documents and information, within six months:

1. All pharmaceutical and other records that document the Plaintiff's use of each metoclopramide product with which the Plaintiff alleges that his/her metoclopramide prescriptions were filed.

2. All medical and other records that document any metoclopramide-related injury or otherwise support the allegation that the Plaintiff incurred an injury as a result of ingestion of metoclopramide.

3. All medical and pharmacy records in the possession of Plaintiff or Plaintiff's counsel,

other than those records that are privileged (e.g., they pertain to psychiatric care) and those that pertain to experts and consultants.

4. All records and information available to Plaintiff as to what his or her prescribing physician relied on in prescribing metoclopramide to him or her when said prescribing physician first learned about the metoclopramide and from what source.

5. HIPAA-compliant authorizations for any of the pharmacies or healthcare providers identified in the documents produced in response to Requests Nos. 1 to 3 above.

b. Procedure for Briefing and Argument re *Mensing*

Second, Defendants request that the Court address the issues raised in the *Mensing* opinion and set a briefing schedule therefor. The Generic Defendants maintain that the Supreme Court found unequivocally in *Mensing* that claims against generic drug companies are preempted under the Supremacy Clause of the United States Constitution. Therefore, the Generic Defendants maintain that the *Mensing* decision decisively ends the Generic Defendants' involvement in this litigation and that all generic defendants immediately should be dismissed from all cases pending in this consolidated litigation.

However, based upon statements made by plaintiffs' counsel in the Pennsylvania and New

Jersey coordinated metoclopramide proceedings – many of whom also represent plaintiffs in this coordinated litigation – the Generic Defendants anticipate some plaintiffs may attempt to assert that some limited claims against generic defendants may not be preempted despite the *Mensing* decision. The swift resolution of this threshold issue will enable the Court to proceed with the coordinated actions before it in an efficient and timely manner.

Accordingly, the defendants request the Court authorize a procedure whereby the Generic Defendants are permitted to seek dismissal of all claims against them. The procedure may be dependent upon whether the plaintiffs (1) intend to stand on their claims asserted in the various individual complaints currently pending before the Court or (2) wish to amend their claims in an attempt to assert causes of action not previously asserted against the Generic Defendants. The procedure also maybe dependent upon whether the Court wishes to address such issues via independent motions filed by each Generic Defendant in each case or via some representative challenge to plaintiffs' claims against the Generic Defendants.[1] Nevertheless, the Defendants believe a procedure should be discussed and authorized at the case management conference.

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[1] The defendants note that, on July 8, 2011, Defendant Hospira, Inc., filed a demurrer in the case of *Corte v. Wyeth, LLC, et al.*, No CGC-11-509518, in which, inter alia, Hospira cites the *Mensing* decision and maintains that all claims against it are preempted by federal law. The defendants understand that demurrer is scheduled for hearing before this Court on August 1, 2011.

Dated: July 25, 2011 /s/ Stuart M. Gordon
Stuart M. Gordon, Esq.
James R. Reilly, Esq.
Brand-Name Manufacturers'
Liaison Counsel

Dated: July 25, 2011 /s/ Joshua Goodman
Joshua Goodman, Esq.
Generic Manufacturers'
Liaison Counsel

Dated: July 25, 2011 /s/ Tammara Tukloff
Tamara Tukloff, Esq.
Generic Manufacturers'
Liaison Counsel

APPENDIX F

Excerpts From Parties' October 1, 2010 Joint Letter to Court (from Skikos Declaration, Vol. IV, Exh. 146, pp. 3532-34 of Petitioner's Court of Appeal Appendix)

* * *

The parties have tentatively agreed on many of the procedures for the California Coordinated Litigation in line with what has been agreed upon and adopted in the PCCP pending in Philadelphia and the Gadolinium litigation over which you are currently presiding.

This litigation will have master pleadings, including a Master Complaint the plaintiffs' attorneys will draft and send to defense liaison counsel to share with their constituents and discuss any appropriate revisions. Defendants will file a Master Answer which will include a general denial and reserve all available defenses.

Plaintiffs will file a Notice Re: Adoption of Master Complaint containing product identification and other pertinent information as we agreed upon. Each Notice Re: Adoption of Master Complaint shall have its own action number, making motions to sever unnecessary. Simultaneous with filing their Notices Re: Adoption of Master Complaint, plaintiffs will serve the defendants named therein with pharmacy records or other records containing product

identification and medical authorizations for the defendants to obtain all pertinent records associated therewith.

If any of the plaintiffs are not prepared to file Notices Re: Adoption of Master Complaint, they will initially serve defendants' liaison counsel with a Notice of Intention to File an Adoption in order to toll the statute of limitations as to any new plaintiffs who have not already filed complaints or who are not named in the Master Complaint, after which plaintiffs will file their adoptions within an agreed period of time.

The defendants will file Notices Re: Adoption of Master Answer within 60 days from the date they are served with the Notice Re: Adoption of Master Complaint

The parties are very close to agreeing on the Plaintiffs' and Defendants' Fact Sheets. The respective fact sheets will very closely follow those that have been agreed upon and adopted in the Philadelphia PCCP.

The parties are also very close to agreeing on a Protective Order similar to the Philadelphia PCCP but tailored for California and being mindful of what you approved in the Gadolinium litigation.

The parties are working on a Case Management Order for Non-preference Case Protocol and one for Preference Case Protocol and should have those finalized soon. The parties will also work on

the issue of electronic service to determine if it is necessary and, if so, how best to utilize it.

Defendants will agree to waive their rights to file forum non conveniens motions as part of the overall agreement.

Because of all of the tentative agreements we are working on, all have agreed it is not necessary for defendants to file answers or other responsive pleadings by October 8, 2010 or to have a deadline of November 1, 2010 to file motions because we are trying our best to eliminate some, if not all, motions if possible.

We agreed to continue the date for the cookie lunch on October 13, 2010 for a few weeks until we are far enough along to meet with you to show you our progress and, hopefully, the majority of the final agreements referenced above. We will coordinate a date that is convenient for the Court and all counsel who want to attend the cookie lunch. The liaison counsel promise to outshine all other counsel in their cookie selection for that cookie lunch.

We also agreed it will be unnecessary to have a motion-o-rama on January 4 and January 5, 2011, but we would like to keep the date of January 5, 2011 for a case management conference.

Lastly, in our discussion, we advised you we would prepare an appropriate stipulation for tolling the statute of limitations where appropriate and as agreed upon.

* * *

APPENDIX G

Excerpts From September 8, 2010 Reporter's Transcript of Proceedings (from Skikos Declaration, Vol. IV, Exh. 146, pp. 3535-36 of Petitioner's Court of Appeal Appendix)

* * *

For Defendant Teva Pharmaceuticals USA Inc.:

GOODWIN PROCTER LLP BY: MICHAEL J. MOLONEY III, Attorney at Law Three Embarcadero Center, Suite 2400 San Francisco, CA 94111 JENKINS GOODMAN NEWMAN & HAMILTON LLP BY: JOSHUA S. GOODMAN, Attorney at Law 417 Montgomery Street, 10th Floor San Francisco, CA 94104-1192

For Defendants PLIVA, Inc., fka PLIVA USA, Inc.; Barr Laboratories, Inc.; and Watson Pharmaceuticals, Inc.:

HASSARD BONNINGTON LLP BY: THOMAS M. FRIEDER, Attorney at Law Two Embarcadero Center, Suite 1800 San Francisco, CA 94111-3993 ULMER BERNE LLP BY: REX A. LITTRELL, Attorney at Law 88 East Broad Street, Suite 1600 Columbus, OH 43215-3581

* * *

[pp. 14-15]

* * *

THE COURT: Back on the record. We discussed off the record what I called the motion-o-rama which was probably an apt term because we're going to have a number of motions in a number of cases here including motions which will either be similar or identical to motions in other cases. So what I'm going to do is set two hearing dates for the motions and then filing motions, if they haven't already been filed, and briefing will work off of the two hearing dates.

* * *

[p.15]

* * *

THE COURT: What I'd like to do is get similar or identically cast of issues heard together. It will be easier for me. It will be easier for you. It will be easier to brief them. If anybody wants to put together, say, a master brief or a challenge to the X cause of action for a master response to, say, a motion for stay or dismissal or forum non conveniens, you may do that, save me reading, and you can also add additional material for individualized cases.

* * *

[p.16]

* * *

MR. GOODMAN: Your Honor, Josh Goodman for Teva Pharmaceuticals. The all-day hearings on the 20th and the 5th, what time does all day begin?

THE COURT: 9:30.

MR. GOODMAN: And the lifting of the stay for filing motions on pleadings, does that require parties who have been served and who have not answered because

there's a stay, does it require them to file an answer or other responsive pleading?

THE COURT: Yes, that's correct. What I'm going to do is I'm going to lift the stay for all purposes except discovery effective today; so that if you haven't responded to the complaint, responded in the sense of answered or filed another appropriate response, the time starts running today. It's as if you were served today. All the time that existed in the past doesn't count, okay?

MR. GOODMAN: Okay.

* * *

[p.16]

* * *

MR. GORDON: Your Honor, is there a reason not to continue the stay on just filing answers until we're all set as to what the pleadings look like? I can see why it would be maybe necessary to file these motions now, but it seems like there would be a whole a lot of answers from a whole a lot of parties if we don't need to do that now unless you want us to and then we'll do it.

THE COURT: Well, we might as well get it going. That's the way I would do it if this was one case, and we will be talking about discovery. I'd like to get answers. Certainly, if there are cross-complaints, I doubt it, but if there are, I'd like to get other parties in sooner rather than later.

* * *

[p.17]

* * *

MR. SKIKOS: Your Honor, that's excellent. Can we ask one favor before -- since Larry and I will be working on coordinating all of this, can we get a list of motions people intend to make before our cookie lunch so maybe we can discuss the organization of these motions at the cookie lunch.

THE COURT: I think we ought to do that, to the extent it's possible. . . . Also, let's set them all for hearing on the first of the two days and then I'll organize what gets heard when, with the help of counsel. (Ex. 96, 9/8/10 transcript at pp. 17:27-18:11)

* * *