SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEPARTMENT 305

COORDINATION PROCEEDING SPECIAL TITLE [RULE 3.550(c)] **PRADAXA® CASES** **This Order Relates to:** *Allred, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al.*, No. CGC-16-555734; *Alvarez, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al.*, No. CGC-17-557643; *Bangert, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al.*, No. CGC-17-557925; *Barnes, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al.*, No. CGC-16-554001; *Berg, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al.*, No. CGC-16-554395; *Bingham, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al.*, No. CGC-16-555340; *Bradford, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al.*, No. CGC-16-554245; *Fourzon, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al.*, No. CGC-16-554586;	Case No. CJC-16-004863 JUDICIAL COUNCIL COORDINATION PROCEEDING NO. 4863 ORDER GRANTING DEFENDANTS BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM USA CORPORATION, BOEHRINGER INGELHEIM CORPORATION, AND BOEHRINGER INGELHEIM VETMEDICA, INC'S SECOND RENEWED MOTION TO QUASH SERVICE OF SUMMONS

Harvey, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al., No. CGC-16-555875;

Kemp, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al., No. CGC-17-557608;

Keppel, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al., No. CGC-16-554701;

Lopez, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al., No. CGC-16-554821;

Miranda-Herrera, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al., No. CGC-16-554607;

Moe, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al., No. CGC-16-555631;

Morgan, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al., No. CGC-16-552292;

Sacay, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al., No. CGC-17-557000;

Sardo, et al. v. Boehringer Ingelheim Pharmaceutical, Inc., et al., No. CGC-16-554031

Defendants Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), Boehringer Ingelheim USA Corporation ("BI USA"), Boehringer Ingelheim Corporation ("BIC"), and Boehringer Ingelheim Vetmedica ("BIVI") (collectively, "BI" or "BI defendants") moved the Court for an order quashing service of summons based on lack of personal jurisdiction over the claims of the "Non-California Plaintiffs" in the above-referenced actions.[1] The motion came on for hearing on January 25, 2019, and appearances are as noted in the record. After fully considering the matter and good cause appearing, the Court grants the motion.

I. RELEVANT FACTS AND EVIDENCE

As part of this judicially coordinated proceeding, the Non-California Plaintiffs in the above-referenced actions assert causes of action for strict liability failure to warn, negligent failure to warn, and

[1] BI previously submitted in connection with its First Renewed Motion to Quash Service of Summons a list which identifies the names and state of residence of all "Non-California Plaintiffs" in the above-referenced actions.

negligent and intentional misrepresentations, against BI in connection with injuries allegedly sustained from taking Pradaxa, an anticoagulant drug manufactured by BI. The Non-California Plaintiffs specifically allege in their respective Complaints that BI "failed to adequately disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa;" "failed to adequately disclose to patients that Pradaxa has a narrow therapeutic window, and that it should be dose-adjusted to patients to minimize the risk of bleeding; and "failed to disclose to patients that the risks of Pradaxa outweigh the benefits in patients 80 years of age or older." In addition, the Non-California Plaintiffs allege that BI "failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa" and "failed to provide adequate warnings about the true safety risks associated with the use of Pradaxa."

On August 14, 2017, this Court granted plaintiffs' motion to conduct discovery specific to the issue of whether this Court may exercise personal jurisdiction over the BI defendants. Plaintiff has since conducted jurisdictional discovery. BI now renews its motion to quash service of summons based on a lack of personal jurisdiction. The following facts and/or evidence are relevant to the instant motion:

None of the BI defendants are incorporated in California, or own, lease, or maintain any property or bank accounts in California.[2] *See* Declaration of Mario Horwitz ISO Renewed Motion to Quash Service of Summons, filed June 30, 2017, Ex. 3. According to BI, BIPI "never designed, developed, formulated, manufactured, labeled, or produced Pradaxa in California" and "never made any decisions concerning the design, development, formulation, manufacture, labeling, or production of Pradaxa in California;" and BIC, BI USA, and BIVI did not have any role in the design, development, formulation, manufacture, labeling, or production of Pradaxa. *Id.* Further, the Non-California Plaintiffs do not allege that they were prescribed, ingested, and suffered their injuries in California.

Between 2005 and 2009, however, BI conducted the "RE-LY" clinical trials worldwide and nationwide, including in California. Of the 950 RE-LY study locations worldwide, 32 were located in California. Declaration of Wayne Wolff ISO Motion to Quash ("Wolff Decl."), ¶ 2. Moreover, of the

[2] BI incorporates by reference the declarations previously submitted by Frank A. Pomer, Assistant Secretary for BIPI and BIC, and Michael Herman, Assistant Secretary for BIVI, in connection with the First Renewed Motion to Quash Service of Summons.

18,113 RE-LY patients worldwide, 5,383 were from the United States and, among that number, 478 were from California RE-LY sites. *Id.* The RE-LY clinical trial was a "randomized trial designed to compare two fixed doses of [Pradaxa]...with open-label use of warfarin in patients who had atrial fibrillation and were at an increased risk for stroke." Declaration of Amy Eskin ISO Opposition to Motion to Quash ("Eskin Decl."), Ex. C. Paul Reilly, Ph.D., who participated in the development and management of the trial, testified that the RE-LY trial was an "18,000 patient clinical trial that formed the major basis for the safety and efficacy claims for Pradaxa." *Id.*, Ex. D at 25:2-20, 26:2-11, 35:12-15. The results of the RE-LY trial were published in the New England Journal of Medicine, and were used nationally to promote Pradaxa.

In connection with the RE-LY trials, BI sought out California physicians to act as principal investigators for its 32 California RE-LY sites. *See* Eskin Decl., Ex. E. BI also conducted periodic on-site visits to the California RE-LY sites to monitor, among other things, the data collection and "adverse event" reporting at the sites. *See id.*, Exs. K-O. An "adverse event" or "safety outcome event" includes instances of major bleeding, death, or myocardial infarction, which site personnel are supposed to document as part of the RE-LY study's goal of determining the safety and efficacy of Pradaxa.

In 2010, BI re-examined the RE-LY database for potentially unreported events in the RE-LY trial. *Id.*, Ex. D at 27:4-29:2. BI thereafter submitted a correction to the New England Journal of Medicine which disclosed that 81 unreported events relating to the safety and efficacy of Pradaxa were discovered in 80 patients, and that there were 28 additional events that should have been reported as safety outcome events. *Id.*, Ex. W. In 2014, BI again re-examined the RE-LY database, and issued a correction regarding the RE-LY trial, indicating a least 20 missed episodes of major bleeding. *Id.* Ex. LL. This number includes four unreported safety and efficacy outcome events from the California RE-LY sites, dating back to 2007, which are comprised of two deaths (one from a stroke/intracranial hemorrhage and one from a major gastrointestinal bleed), a major bleed and ulcer. In the same year, changes were made to the Pradaxa label to account for this new data. A comparison of the original label and the 2014 label, which supposedly reflects additional data from the RE-LY trials in California, demonstrates that the late discovered data resulted only in changes to the percentages contained in the label pertaining to the data

collected from the entire RE-LY trials. *See id.*, Ex. MM. For example, under Section 6.1 titled "Bleed Events," the original label reflected a "hazard ratio" of 0.80 for "life-threatening bleed" and 0.93 for "major bleed," whereas the 2014 label reflected a "hazard ratio" of 0.81 for "life-threatening bleed" and 0.94 for "major bleed." *Id.*

II. LEGAL STANDARD

A defendant may move to quash service of summons on the ground that the court lacks personal jurisdiction over him or her. Code Civ. Proc. § 418.10(1). In such a motion, the plaintiff bears the burden to demonstrate facts, as to each nonresident defendant, justifying the exercise of jurisdiction by a preponderance of evidence. *Strasner v. Touchstone Wireless Repair & Logistics, LP* (2016) 5 Cal.App.5th 215, 221-22.

Personal jurisdiction is governed by California's long-arm statute, which permits a court to exercise jurisdiction "on any basis not inconsistent with the Constitution of this state or of the United States." *See DVI, Inc. v. Sup. Ct.* (2002) 104 Cal.App.4th 1080, 1089. "To comport with federal and state due process, California courts may only exercise jurisdiction when a defendant has sufficient minimum contacts with the state to satisfy 'traditional notions of fair play and substantial justice.'" *Strasner, supra,* 5 Cal.App.5th at 221. There are two types of personal jurisdiction: general jurisdiction and specific jurisdiction. *DVI, Inc., supra,* 104 Cal.App.4th at 1090. General jurisdiction over a defendant exists where the defendant's contacts are substantial, continuous and systematic. *Id.* Specific jurisdiction, on the other hand, requires the plaintiff to show that the defendant purposefully availed himself of forum benefits with respect to the matter in controversy; that the controversy is "related to or arises out of" the defendant's contacts with the forum; and that the exercise of jurisdiction would comport with fair play and substantial justice. *Id.*

In *Bristol-Myers Squibb Co. v. Sup. Ct.* ("*BMS*") (2017) 137 S.Ct. 1773, non-California residents sued Bristol-Myers Squibb Co. for injuries allegedly sustained as a result of taking Plavix, a drug manufactured by defendant. *Id.* The United States Supreme Court noted that the nonresident plaintiffs were not prescribed Plavix in California, did not purchase Plavix in California, did not ingest Plavix in California, and were not injured by Plavix in California. *Id.* at 1781. Moreover, the court found that all

the conduct giving rise to the nonresidents' claims occurred outside of California, as BMS did not develop, manufacture, label, package or work on the regulatory approval of Plavix in California. *Id.* at 1778, 1782. Accordingly, the court held that California did not have specific jurisdiction over defendant. *Id.* at 1782.

III. ANALYSIS

The Non-California Plaintiffs do not contend that California has general jurisdiction over the BI defendants. Instead, they contend that the BI defendants are subject to the specific jurisdiction of this Court because their claims arise out of or relate to BI's conduct with respect to the RE-LY clinical trials conducted in California. For the reasons stated below, however, the Court concludes that California does not have specific jurisdiction over the BI defendants.

The Non-California Plaintiffs rely solely on BI's conduct with respect to the RE-LY clinical trials in California in support of their claim that California has specific jurisdiction over BI. In particular, they argue that BI's conduct of collecting and analyzing data from the RE-LY trials in California for the primary purpose of assessing the overall safety and efficacy profile of Pradaxa gives rise or relates to their claims, which revolve around the safety and efficacy profile of the drug. Additionally, the Non-California Plaintiffs contend that but for BI's conduct in failing to ensure the accuracy and reliability of the RE-LY data, or failing to timely discover all safety and adverse event outcomes, the data relating to those "missed adverse events" would have been incorporated in the original label, and prescribing physicians would have been able to consider this additional data in connection with their risk benefit analysis and/or informed consent discussion with their patients. Opp. at p. 10.

However, the Court finds that any connection between BI's activities with respect to the California RE-LY trials and the Non-California Plaintiffs' claims is too attenuated to support the exercise of specific jurisdiction over BI. Although the Non-California Plaintiffs argue that both their claims and the RE-LY trials revolve around the overall safety and efficacy profile of the drug, the Non-California Plaintiffs' claims are based on *specific* allegations of BI's failure to warn, namely, that BI "failed to adequately disclose to patients that there is no drug, agent or means to reverse the anticoagulation effects of Pradaxa," "failed to adequately disclose to patients that Pradaxa has a narrow therapeutic window, and

that it should be dose-adjusted to patients to minimize the risk of bleeding," and "failed to disclose to patients that the risks of Pradaxa outweigh the benefits in patients 80 years of age or older." The Non-California Plaintiffs failed to demonstrate how any of BI's activities with respect to the RE-LY trials, much less the RE-LY trials in California, give rise or sufficiently relate to the specific failures to warn alleged in the Complaints.

Moreover, with respect to the Non-California Plaintiffs' argument regarding the "missed adverse events," the Court does not find that BI's conduct in failing to timely discover certain information from the RE-LY trials in California gives rise or sufficiently relates to the claims asserted in this case. Indeed, a comparison of the original label and the 2014 label, which supposedly reflects additional data from the RE-LY trials in California, demonstrates that the late discovered data resulted only in negligible changes to the label's description of the results from the entire RE-LY trial. The Non-California Plaintiffs failed to demonstrate how these negligible changes in the data relate to their specific claims. As such, there is no indication that BI's conduct with respect to the RE-LY trials in California serves as an "adequate link" between California and the Non-California Plaintiffs' claims. *BMS*, *supra*, 137 S.Ct. at 1781.

As in *BMS*, all of the conduct giving rise to the Non-California Plaintiffs' claims occurred outside of California. As indicated in the declarations of Frank Pomer and Michael Herman, officers at BI, BIPI "never designed, developed, formulated, manufactured, labeled, or produced Pradaxa in California," and "never made any decisions concerning the design, development, formulation, manufacture, labeling, or production of Pradaxa in California;" whereas BIC, BI USA, and BIVI did not have any role in the design, development, formulation, manufacture, labeling, or production of Pradaxa. Declaration of Mario Horwitz ISO Renewed Motion to Quash Service of Summons, filed June 30, 2017, Ex. 3. Moreover, none of the Non-California Plaintiffs allege that they were prescribed, ingested, and suffered their injuries in California. Apart from their evidence and argument relating to the RE-LY clinical trials, the Non-California Plaintiffs did not present any other evidence to show that BI has contacts in California that give rise to or are related to the Non-California Plaintiffs' claims.

Because the Non-California Plaintiffs failed to identify an "adequate link" between their claims and the State of California, California courts cannot exercise specific jurisdiction over the BI defendants.

Id. at 1782.

IV. CONCLUSION

For the foregoing reasons, the Court grants the BI defendants' Motion to Quash Service of Summons for Lack of Personal Jurisdiction.

IT IS SO ORDERED.

Dated: January 31, 2019

Mary E. Wiss
Judge of the Superior Court

Superior Court of California
County of San Francisco

COORDINATION PROCEEDING SPECIAL TITLE [RULE 3.550]	JUDICIAL COUNCIL COORDINATION PROCEEDING NO. **4863**
PRADAXA CASES	Case Number: **CJC-16-004863**
	CERTIFICATE OF ELECTRONIC SERVICE (CCP 1010.6(6) & CRC 2.260(g))

I, T. Michael Yuen, Clerk of the Superior Court of the County of San Francisco, certify that I am not a party to the within action.

On January 31, 2019, I electronically served the ORDER GRANTING DEFENDANTS BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM USA CORPORATION, BOEHRINGER INGELHEIM CORPORATION, AND BOEHRINGER INGELHEIM VETMEDICA, INC'S SECOND RENEWED MOTION TO QUASH SERVICE OF SUMMONS via File&ServeXpress® on the recipients designated on the Transaction Receipt located on the File&ServeXpress® website.

Dated: January 31, 2019

T. Michael Yuen, Clerk

By: _____
Sean Kane, Deputy Clerk