BEFORE THE
UNITED STATES JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

IN RE: PRADAXA PRODUCT LIABILITY LITIGATION	§ § § § §	MDL - _____

BRIEF IN SUPPORT PLAINTIFF'S MOTION FOR TRANSFER OF ACTIONS PURSUANT TO 28 U.S.C. § 1407

MAY IT PLEASE THE COURT:

Pursuant to 28 USC § 1407 and Rule 7.2(a) of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, Plaintiff Vera Lee Sellers submits this memorandum of law in support of her motion for transfer of all currently filed cases identified in the included Schedule of Actions ("Actions"), as well as any cases subsequently filed involving similar facts or claims ("tag along cases") to the United States District Court for the Southern District of Illinois, and to consolidate and coordinate all cases for pretrial proceedings before the Honorable David R. Herndon, United States District Judge, Southern District of Illinois. Presently, there are at least 21 substantially similar actions pending in 12 different judicial districts in the United States alleging similar wrongful conduct on the part of Defendants. Likewise, because of the scope of Defendants' conduct, it is likely that hundreds (or thousands) of other actions will be filed in jurisdictions throughout the United States. Transfer for consolidation and coordination is proper because each of these Actions and tag along cases arise out of the same or similar nucleus of operative facts, arise out of the same or similar alleged wrongful conduct, will involve the resolution of the same or similar questions of fact and law, and discovery will be substantially similar and will involve the same documents and witnesses.

I. Background

A. The Basis of Litigation

Pradaxa® is a direct thrombin inhibitor used to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation, which carries an increased risk of stroke. On October 19, 2010, Pradaxa® was approved by the Food and Drug Administration ("FDA") as the first new oral anticoagulation medication in the U.S. in more than 50 years. Prior to the FDA's approval of Pradaxa®, warfarin was the only oral anticoagulant available in the U.S. for reducing stroke and systemic embolism in patients with atrial fibrillation. Unlike patients who use Pradaxa®, users of warfarin must follow dietary restrictions and regularly monitor their blood levels (INR) by undergoing blood tests and potentially adjusting the dose of their medication multiple times during their course of treatment.

Defendants promoted Pradaxa® as a novel medicine for patients with non-valvular atrial fibrillation. Defendants' marketing campaign for Pradaxa® included promoting it as being more effective than warfarin in preventing stroke and systemic embolism, providing a convenient alternative to warfarin therapy because it does not require blood monitoring or dose adjustments, and does not require any dietary restrictions. In promoting Pradaxa®, Defendants spent significant money, which included $67,000,000.00 spent during 2010 (although Pradaxa® was not approved for sale until October 19, 2010). [1]

During 2011, Defendants reportedly undertook 1.5 million Pradaxa® "detailing sessions" (marketing/sales visits by Defendants' sales force) with U.S. primary care physicians, internists, group practitioners, cardiologists, and practice nurses, spending a

[1] Deborah Weinstein, Study: Sales Support is Dwindling, Not Dead, March 14, 2012, Medical Marketing and Media.

staggering $464,000,000.00 during this 12 month period to promote Pradaxa® in the United States.[2] As part of their Pradaxa® marketing efforts, Defendants widely disseminated direct-to-consumer advertising campaigns designed to influence patients, including Plaintiff, to inquire about and/or request prescriptions for Pradaxa® from their prescribing physician. In their direct to consumer advertisements, Defendants overstated the efficacy of Pradaxa® with respect to preventing stroke and systemic embolism and failed to adequately disclose to patients that there is no reversal agent or adequate means by which to reverse the anticoagulation effects of Pradaxa®, and that such irreversibility could have permanently disabling, life-threatening and fatal consequences.

In addition, Defendants also failed to warn emergency room doctors, surgeons and other critical care medical professionals, including Plaintiff's physician, that there is no effective means to reverse the anticoagulation effects of Pradaxa®, which is a dramatic departure from all other blood thinners. In fact, Defendants failed to warn that it is not even possible to monitor Pradaxa® levels in the blood. Pradaxa® treatment, therefore, leaves trauma professionals without effective means with which to treat and stabilize patients who experience uncontrolled or excessive bleeding while taking Pradaxa®. Further, the Pradaxa® Medication Guide, prepared and distributed by Defendants and intended for U.S. patients to whom Pradaxa® has been prescribed, failed to warn and disclose to patients that there is no agent to reverse the anticoagulation effects of Pradaxa® and that if serious bleeding occurs, it may be excessive, irreversible, permanently disabling, and life-threatening.

[2] Id.

From October 2010 until the end of March 2011, approximately 272,119 prescriptions for Pradaxa® were written in the United States. During that same period, there were 932 Pradaxa®-associated "Serious Adverse Event" ("SAE") Medwatch reports filed with the U.S. Food and Drug Administration, including at least 120 deaths and over 500 reports of severe, life-threatening bleeding. As of December 31, 2011, the U.S. Food and Drug Administration received over 500 reports of deaths of people in the U.S. linked to Pradaxa® which, at that point, had been available in the U.S. for approximately 14 months. In addition, there were over 900 reports of gastrointestinal hemorrhages, over 300 reports of rectal hemorrhages, and over 200 reports of cerebrovascular accidents suffered by U.S. citizens associated with Pradaxa®.

During the Defendants' 2011 fiscal year, worldwide Pradaxa® sales eclipsed the $1 billion threshold, achieving what is commonly known in the pharmaceutical industry as "blockbuster" sales status. Death and serious injury to patients being prescribed Pradaxa® have continued to mount in the wake of Defendants successful marketing and over promotion of Pradaxa®.

ARGUMENT

II. Transfer and Consolidation or Coordination of All Actions Is Appropriate Under 28 U.S.C. § 1407

The purpose of the multidistrict litigation process is to "eliminate the potential for contemporaneous pretrial rulings by coordinating district and appellate courts in multidistrict related civil actions." *In re Multidistrict Private Civ. Treble Damages Litig.*, 298 F. Supp. 484, 491-92 (J.P.M.L. 1968). Accordingly, pursuant to 28 U.S.C. § 1407, transfer of actions to one district for coordinated or consolidated pretrial proceedings is appropriate where: (1) actions pending in different districts involve one or more common questions of fact and (2) the transfer of such actions will be for the convenience

of the parties and witnesses and will promote the just and efficient conduct of such actions. 28 U.S.C. § 1407(a). Consolidation is especially important in multidistrict litigations where "the potential for conflicting, disorderly, chaotic" action is greatest. *Id.* at 493.

Here, transfer, coordination and consolidation is appropriate because many common questions of fact and law exist, including, but not limited to:

- Whether Pradaxa® was defective;
- Whether Defendants conducted adequate testing of Pradaxa®;
- Whether Defendants breached their duty of care to Plaintiffs;
- Whether Defendants had knowledge regarding the existence of a defect in Pradaxa®;
- Whether Defendants failed to warn about their product as alleged in the various Actions;
- Whether Defendants beached any warranty, express or implied, related to their sale of Pradaxa®;
- Whether Plaintiffs relied on Defendants' claims as to the safety and efficacy provided by Pradaxa®; and
- Whether Plaintiffs are entitled to compensatory and exemplary damages.

Determination of these and other common issues in a single district will benefit the parties and witnesses and serve to promote the efficient prosecution and resolution of these Actions. Notably, this Panel has routinely ordered the transfer and consolidation of multidistrict product liability actions involving drug products, often over the objections of one or more parties. *See, e.g., In re Bextra and Celebrex Prods. Liab. Litig.*, 391 F. Supp. 2d 1377 (J.P.M.L. 2005); *In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352 (J.P.M.L. 2005); *In re Accutane Prods. Liab. Litig.*, 343 F. Supp. 2d 1382 (J.P.M.L. 2004); *In re Ephedra Prods. Liab. Litig.*, 314 F. Supp. 2d 1373 (J.P.M.L. 2004); *In re Zyprexa Prods. Liab. Litig.*, 314 F. Supp. 2d 1380 (J.P.M.L. 2004); *In re Paxil Prods. Liab. Litig.*, 296 F. Supp. 2d 1374 (J.P.M.L. 2003); *In re Prempro Prods. Liab. Litig.*, 254 F. Supp. 2d 1366 (J.P.M.L. 2003); *In re Meridia Prods. Liab. Litig.*, 217 F. Supp. 2d 1377 (J.P.M.L. 2002); *In re*

Serzone Prods. Liab. Litig., 217 F. Supp. 2d 1372 (J.P.M.L. 2002); *In re Baycol Prods. Liab. Litig.*, 180 F. Supp. 2d 1378 (J.P.M.L. 2001); *In re Phenylpropanolamine Prods. Liab. Litig.*, 173 F. Supp. 2d 1377 (J.P.M.L. 2001); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, 990 F. Supp. 834 (J.P.M.L. 1998); *In re Richardson-Merrell Inc. "Bendectin" Prods. Liab. Litig.*, 533 F. Supp. 489 (J.P.M.L. 1982); *In re the UpJohn Co. Antibiotic "Cleocin" Prods. Liab. Litig.*, 450 F. Supp. 1168 (J.P.M.L. 1978).

Without transfer, coordination and consolidation of these Actions and tag along cases, there exists a real and significant hazard of inconsistent rulings, in addition to judicial inefficiency, overlapping discovery, and unnecessary expense to all parties. Moreover, transfer, coordination and consolidation are especially appropriate here because formal discovery has not yet commenced and no responsive pleadings have been filed in any of the 21 pending Actions. Most concerning, however, there currently are motions to dismiss pending in 8 of the 21 filed Actions. These motions to dismiss are largely uniform in nature and could result in disparate rulings if not consolidated for consideration before a single district. Accordingly, transfer, coordination and consolidation of the Actions and tag along cases to a single district are appropriate for the just and efficient prosecution of the Actions and convenience of the parties and witnesses.

III. The Southern District of Illinois Is the Most Appropriate Forum for Transfer and Consolidation for Coordination.

Currently, there are 8 (of 21 total) active Pradaxa cases filed in the Southern District of Illinois. The district courthouse is located in East St. Louis, Illinois; in close proximtiy to mass transit, an international airport and hotels. For these and other reasons further detailed below, the Actions and tag along cases should be transferred and consolidated before the Honorable David R. Herndon, United States District Judge,

the Southern District of Illinois, who is currently presiding over all 8 of the Pradaxa cases filed in the Southern District of Illinois.

A. East St. Louis, Illinois Is a Convenient and Efficient Location for Consolidated Proceedings.

The Southern District of Illinois courthouse is centrally located for all parties and witnesses, particularly in light of the fact that this litigation will unquestionably involve parties and witnesses located in a variety of areas throughout the United States. Additionally, traveling to this central location is much more convenient and efficient than traveling to other destinations in the United States. For instance, the Southern District of Illinois courthouse is located only 15 minutes from the Lambert International Airport in St. Louis, Missouri. Lambert International Airport is one of the most central travel hubs in the nation with 250 daily departures, making the Southern District of Illinois an appropriate choice to serve as the transferee court for this multidistrict litigation. In addition, access to Lambert Airport is publicly available through Metrolink, St. Louis's light rail transit system. Metrolink likewise conveniently stops just blocks away from the district courthouse. Finally, there exist numerous reasonably priced hotels within the immediate vicinity of the courthouse. The cost of lodging, food and gas within the Southern District of Illinois area is at or below the national average.

B. The Southern District of Illinois Is Well-Equipped to Manage a Multi-District Litigation.

The Southern District of Illinois provides an ideal venue for managing this litigation in the most efficient and expeditious manner. The Southern District of Illinois is currently handling two multi-district litigations: *In re: Profiler Products Liability Litigation* (MDL-1748) and *In re: Yasmin and Yaz (drospirenone) Marketing, Sales Practices and Relevant Products Liability Litigation* (MDL-2100). This district has likewise handled at least 4 multi-district litigations involving over 8,700 filed cases. The staff and Clerk's

office of the Southern District of Illinois, therefore, are well equipped and experienced to provide the necessary support services for managing this litigation.

C. Judge David R. Herndon Is Amply Qualified to Manage Multi-District Litigation.

Appointed to the Southern District of Illinois fifteen years ago, Judge Herndon is an excellent choice for managing this complex litigation. He has served as Chief Judge for the Southern District of Illinois since 2007. Further, Judge Herndon has gained significant experience in managing complex litigation, as well as consolidated, mass tort litigation in an efficient manner. Among other complex cases, he has presided over *In re: MCI Non-Subscriber Telephone Rates* (MDL-1275) as well as *In re: Yasmin and Yaz (drospirenone) Marketing, Sales Practices and Relevant Products Liability Litigation (MDL-2100)*. Judge Herndon efficiently resolved the *MCI MDL* and has efficiently moved the *Yasmin MDL* into a posture where the parties are engaged in active and productive settlement discussions with more than a thousand cases having been settled, with many others cases being negotiated and resolved on an ongoing basis. In addition to his well-rounded qualifications and his experience with complex litigation, Judge Herndon, upon information and belief, is able to handle an additional MDL in light of the current posture of the *Yasmin MDL*. Judge Herndon is an appropriate choice for managing this MDL in a manner that will facilitate this litigation for the benefit of all parties. Moreover, Judge Herndon has an experienced and talented staff and law clerks that have managed the *Yasmin MDL* with great efficiency.

IV. Conclusion

For the reasons discussed above, Plaintiff respectfully requests that the Panel transfer the above-mentioned actions and all subsequently filed tag along cases for coordinated and consolidated pretrial proceedings before the Southern District of

Illinois, and assign the matter to Chief Judge David R. Herndon.

Dated this 30th day of May, 2012

Respectfully submitted,

s/ Ryan L. Thompson

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ATTORNEYS FOR PLAINTIFFS IN THE FOLLOWING ACTIONS :

Case No. 3:12-cv-00615; *Vera Lee Sellers vs. Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Corporation; Boehringer Ingelheim USA Corporation; and Boehringer Ingelheim Vetmedica, Inc.*; In the United States District Court for the Southern District of Illinois, East St. Louis Division.

Case No. 5:12-cv-00266-W; *Jerald R. Radcliff and Debbie Radcliff vs. Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Pharma GMBH & Go. KG; Boehringer Ingelheim International GMBH; and Bidachem S.P.A.*; In the United States District Court for the Western District of Oklahoma.

Case No. 6:12-cv-00061-GFVT; *Janet Cornelius, Individually and as Administrator of the Estate of Floyd Cornelius, Deceased vs. Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Pharma GMBH & Go. KG; Boehringer Ingelheim International GMBH; and Bidachem S.P.A.*; In the United States District Court for the Eastern District of Kentucky, London Division.

Case No. 3:12-cv-00131-JGH; *Donald Ray Pawley and Sheila M. Pawley vs. Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Pharma GMBH & Go. KG; Boehringer Ingelheim International GMBH; and Bidachem S.P.A.*; In the United States District Court for the Western District of Kentucky, Louisville Division.

Case No. 6:12-cv-00572; *Garland James Lege and Patricia A. Lege vs. Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Pharma GMBH & Go. KG; Boehringer Ingelheim International GMBH; and Bidachem S.P.A.*; In the United States District Court for the Western District of Louisiana.

Case No. 6:12-cv-00045-GFVT; *Helen Jean Hawkins and John Edward Hawkins vs. Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Pharma GMBH & Go. KG; Boehringer Ingelheim International GMBH; and Bidachem S.P.A.*; In the United States District Court for the Eastern District of Kentucky, London Division.

Case No. 3:12-cv-00103; *Bertha Bivens, Individually and as Representative of the Estate of Nancy Brummett, Deceased vs. Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Pharma GMBH & Go. KG; Boehringer Ingelheim International GMBH; and Bidachem S.P.A.*; In the United States District Court for the Eastern District of Tennessee, Northern Division.

Case No. 3:12-cv-00116; *Edward Stair, Jr. vs. Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim Pharma GMBH & Go. KG; Boehringer Ingelheim International GMBH; and Bidachem S.P.A.*; In the United States District Court for the Eastern District of Tennessee, Northern Division.

Case No. 3:12-cv-00480; *Amanda Scott, Individually and as Representative of the Estate of Ray Herndon Celsor, deceased vs. Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, Boehringer Ingelheim USA Corporation, Boehringer Ingelheim Vetmedica, Boehringer Ingelheim Pharma GMBH & Co. KG, and Boehringer Ingelheim International GMBH*; In the United States District Court for the Middle District of Tennessee, Nashville Division.