

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE: PRADAXA (DABIGATRAN ETEXILATE) PRODUCTS LIABILITY LITIGATION))))	3:12-MD-0235-DRH-SCW MDL No. 2385
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This Document Relates to:

ALL CASES

CASE MANAGEMENT ORDER No. 12
REGARDING FOREIGN DEFENDANTS
AND DIRECT FILING/
WAIVER OF SERVICE OF PROCESS
FOR FEDERAL COURT CASES AGAINST
BOEHRINGER INGELHEIM INTERNATIONAL GmbH

Herndon, Chief Judge:

Pursuant to Paragraph 10(d) of CMO # 1, the parties met and conferred and, after extensive negotiation and the agreement of counsel, have proposed the following plan to address jurisdictional and other issues related to the Foreign Defendants.

The Court hereby **ORDERS AS FOLLOWS:**

A. JURISDICTIONAL ISSUES

1. Retention of BII as a Party

The Foreign Defendants, Boehringer Ingelheim International GmbH (“BII”), Boehringer Ingelheim Pharma GmbH & Co. KG (“Pharma KG”), Boehringer Ingelheim GmbH (“BI GmbH”) and Bidachem S.p.A. (“Bidachem”) and other foreign Boehringer entities, have been named as parties in Complaints filed in federal and state court involving the drug

Pradaxa®. The Foreign Defendants assert that they are not subject to the jurisdiction of any U.S. Court. To avoid unnecessary motion practice and to streamline the proceedings in *In Re: Pradaxa (Dabigatran Etexilate) Products Liability Litigation*, MDL No. 2385 (“MDL Proceedings”) and related state court actions (collectively “Pradaxa® Litigation”), BII has agreed not to contest jurisdiction in any Pradaxa® case and to appear in such cases (without prejudice and subject to the provisions of Section C(2) below, which allows them to revoke this consent in specific cases).

2. Dismissal without prejudice of Pharma KG, BI GmbH, Bidachem and other foreign Boehringer entities

a. In consideration of BII’s agreement not to contest the jurisdiction of any U.S. federal or state court in the Pradaxa® Litigation and within 30 days of entry of this Order, Plaintiffs shall voluntarily dismiss *without prejudice* defendants Pharma KG, BI GmbH, and Bidachem (“Dismissed Foreign Defendants”) and any other foreign Boehringer entity¹ from the following actions:

¹¹ As used throughout this CMO, the phrase “other foreign Boehringer entity” does not include BII.

- (i) *Pawley v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.*, U.S. District Court for the Western District of Kentucky, Cause No. 3:12-cv-131;
- (ii) *Ecklund v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.*, U.S. District Court of the Eastern District of New York, Case No. 12-cv-2936;
- (iii) *Hole v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.*, U.S. District Court for the Southern District of Florida, Case No. 12-cv-61004;
- (iv) *Sessoms v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.*, U.S. District Court for the District of South Carolina, Case. No. 2:12-cv-1698; and
- (v) Any other Pradaxa® case pending in federal court in which plaintiffs claim to have effected service on some or all of the Foreign Defendants.

b. The Dismissal Order as to *Pawley, Ecklund, Hole* and *Sessoms* shall state as follows: "Subject to CMO #12, Plaintiff(s) hereby dismisses without prejudice Boehringer Ingelheim Pharma GmbH & Co. KG and Bidachem S.p.A." A Dismissal Order for a case covered by Section A(2)(a)(v) will similarly identify the entities being dismissed.

c. In the event a plaintiff does not effectuate an Order dismissing the Dismissed Foreign Defendants and any other foreign Boehringer entity without prejudice as stated in Section A(2)(a) and/or refuses to comply with the other terms of this Order, BII may seek relief from the Court. At the request of counsel for BII and in support of BII's application, Lead Counsel for Plaintiffs will submit an affidavit to the Court attesting to the following: (i) that this Order is the product of extensive negotiations between Lead Counsel for Plaintiffs and counsel for BII, Lead Counsel for Plaintiffs understanding of the risk of the inability to establish jurisdiction over BII, the Dismissed Foreign Defendants, and/or any other foreign Boehringer entity; and (ii) neither this CMO nor any others

referenced herein was intended to be a general appearance for BII, the Dismissed Foreign Defendants, or any other foreign Boehringer entity.

3. Cooperation with State Courts

This Order is being entered in reliance on representations of Lead Counsel for the Plaintiffs and counsel for plaintiffs in state court Pradaxa® cases presently pending in California, Connecticut and Illinois, that the plaintiffs in those state court actions, including those that may be filed after the date of the entry of this Order: (a) will not, in the future, name the Dismissed Foreign Defendants or any other foreign Boehringer entity as defendants in state court Pradaxa® cases; and (b) intend to cooperate with Lead Counsel for Plaintiffs in these MDL Proceedings regarding all discovery sought from BII.

Plaintiffs acknowledge that the Direct Filing and Service of Process provisions of this Order do not apply to Pradaxa® cases filed in state court.

B. ACCESS TO RELEVANT PHARMA KG, BI GmbH & BIDACHEM INFORMATION AND DEPOSITIONS OF WITNESSES

1. BII stipulates that it shall not object to the deposition testimony of employees from the Dismissed Foreign Defendants or documents produced by the Dismissed Foreign Defendants being considered an admission of a party opponent pursuant to Fed. R. Evid. 801(d)(2) and similar state evidentiary rules, provided that the testimony and documents would otherwise be considered an admission of a party if the Dismissed Foreign Defendants were parties in the Pradaxa® Litigation. Subject to the terms of this Order, BII reserves the right to object to the admissibility of such documents and testimony on all grounds other than on the basis that such documents and testimony are not the statements of a party.

2. BII stipulates that for purposes of discovery served on BII, it shall not be a valid objection to Plaintiffs' Notice to Produce Documents that relevant non-privileged documents are in the physical possession of a Dismissed Foreign Defendant.

3. BII stipulates that it shall not be a valid ground to challenge a discovery Order regarding foreign documents and witnesses on the grounds that the Dismissed Foreign Defendants are not parties in the Pradaxa® Litigation.

4. BII stipulates and agrees that at trial it will not object to the authenticity of documents it produces on the basis that such documents have been provided to BII by one of the Dismissed Foreign Defendants; such documents created by BII or Dismissed Foreign Defendants shall be presumed to be authentic under Fed.R.Evid. 901, absent good cause shown.

5. BII stipulates that it shall not be a valid objection to a deposition notice to BII to produce an employee of one of the Dismissed Foreign Defendants that the proposed deponent is not an employee of BII.

6. BII stipulates that it and the Dismissed Foreign Defendants are affiliated companies, and BII shall not argue that its affiliated companies are at fault instead of BII.

7. Consistent with the terms of this Order, BII reserves the right to object to the admissibility of documents and testimony it and the Dismissed Foreign Defendants produced on any basis other than those stated in Paragraphs 1-6 above. All objections as to relevance are preserved.

C. DIRECT FILING OF CASES IN MDL 2385

1. To eliminate delays associated with transfer to this Court of cases filed in or removed to other federal district courts and to promote judicial efficiency, any plaintiff whose case would be subject to transfer to the MDL Proceedings may file his or her case directly in the MDL Proceedings in the Southern District of Illinois. No action filed directly in the MDL Proceedings shall name the Dismissed Foreign Defendants or any other foreign Boehringer entity. No case may name more than a single plaintiff, except that the

Complaint may also include consortium plaintiffs permitted by law and, in the event of a wrongful death action, the appropriate representative(s) of the estate, may be filed directly into the MDL Proceedings pursuant to this Order.

2. Plaintiffs are instructed not to name the Dismissed Foreign Defendants or other foreign Boehringer entity as defendants in future Complaints filed in or transferred to these MDL Proceedings. Complaints naming any of the Dismissed Foreign Defendants or other foreign Boehringer entity cannot avail themselves of the direct filing procedure established by this Order. In the event a plaintiff files a Complaint naming any of the Dismissed Foreign Defendants or other foreign Boehringer entity in contravention of this Direct Filing Order, neither BII, the Dismissed Foreign Defendants nor other foreign Boehringer entity will be deemed to have consented to the jurisdiction of the Court for that particular plaintiff.

3. Each case filed directly in the MDL Proceedings by a plaintiff who resides in a federal district other than the Southern District of Illinois may be filed in the MDL Proceedings for purposes of pretrial proceedings, consistent with the Judicial Panel on Multidistrict Litigation's August 8, 2012, Transfer Order. Any complaint filed directly in the MDL proceedings shall identify: (i) the residence of plaintiff at the time of filing; and (ii) the residence of plaintiff at the time he/she was allegedly injured by the use of Pradaxa®.

4. Solely for purposes of pre-trial proceedings, BII will not challenge the venue of any action filed directly in the MDL Proceedings in the Southern District of Illinois. The direct filing of actions in MDL No. 2385 in the Southern District of Illinois is solely for purposes of consolidated discovery and related pretrial proceedings as provided by 28

U.S.C. § 1407. Upon the completion of all pretrial proceedings applicable to a case directly filed in the MDL Proceedings, and subject to any agreement that may be reached concerning a waiver of the requirements for transfer pursuant to *Lexecon v. Milberg Weiss et al.*, 523 U.S. 26 (1998), this Court, pursuant to the Rules of the Judicial Panel on Multidistrict Litigation and 28 U.S.C. §1404(a), will transfer that case to a federal district court of proper venue as defined by 28 U.S.C. § 1391, based on the district where the plaintiff resided at the time of alleged injury by use of Pradaxa®, where the plaintiff resided at the time of prescription and ingestion, the recommendations of the parties to that case, or on its own determination after briefing from the parties if they cannot agree. Utilization of the procedure set forth in this Order for directly filing a case in the MDL Proceedings shall not result in this Court being deemed the “transferor court” for any such directly filed case.

5. This Order does not preclude the parties from agreeing, at a future date, to try in this District cases filed pursuant to this Order.

6. The inclusion of any action in MDL 2385, whether such action was or will be filed originally or directly in the Southern District of Illinois, shall not constitute a determination by this Court that jurisdiction or venue is proper in this District.

7. The fact that a case was filed directly in the MDL Proceedings pursuant to this Order will have no impact on choice of law, including the statute of limitations that otherwise would apply to an individual case had it been filed in another district court and transferred to this Court pursuant to 28 U.S.C § 1407.

8. The caption for any complaint that is directly filed in MDL 2385 before this Court shall bear the following caption:

about a pending case number unless special circumstances exist or if counsel has not received a case number within 24 hours.

11. Plaintiffs' Leadership Counsel shall make reasonable efforts to ensure that the Court does not receive an excessive number of directly filed actions on any given day. To this end, the Court asks that Plaintiffs' Leadership Counsel make reasonable efforts to limit direct filings to approximately 40 per day.

12. The attorney who has electronically signed the complaint will receive an email notifying his/her office of the assigned case number. After plaintiff's counsel receives the case number by email, the complaint can be filed. The system will ask whether there are any exhibits to the document; check "YES" and attach the civil cover sheet as an exhibit.

13. When electronically filing the pleadings, the signature block shall follow the below format:

RESPECTFULLY SUBMITTED,

 /s/ Jane Doe

Jane Doe
NAME OF LAW FIRM
ADDRESS
TELEPHONE
FAX
EMAIL@EMAIL.com
Attorney for Plaintiff

14. Filing Fees: Internet credit card payments shall be required for all complaints and are made online through Pay.gov. Plaintiff's counsel will be prompted to pay the required filing fee at the time the complaint is filed. The Clerk's Office will be electronically notified when the complaint is filed and will review it for errors or omissions.

After the complaint is filed, plaintiff's counsel shall draft the summonses and send them to the Court by email to newcases_eaststlouis@ilsd.uscourts.gov. In the email, plaintiff's counsel shall provide his or her name, the case number, and his or her mailing address. The Clerk will file and send originals via mail to the office of plaintiff's counsel so that plaintiff's counsel can effectuate service of process.

D. TOLLING AS TO CERTAIN DEFENDANTS

1. BII, the Dismissed Foreign Defendants and other foreign Boehringer entities maintain that they are not subject to the jurisdiction of United States courts. Plaintiffs do not agree to the same. However, in an effort to streamline the case, and to obtain documents and depositions of the Dismissed Foreign Defendants quickly, plaintiffs have agreed at this time to sue only BII, and BII has agreed to accept service in cases filed pursuant to this Order, and to conditionally appear before this Court.

2. Accordingly and stated above, plaintiffs are instructed not to name the Dismissed Foreign Defendants or any other foreign Boehringer entity as Defendants in future complaints filed directly or transferred into the MDL Proceedings pursuant to this Order. If any plaintiff desires an exemption from this prohibition, said plaintiff shall file a motion requesting an exemption from the prohibition contained in this Order and seek a ruling from this Court that the Foreign Dismissed Defendants or other foreign Boehringer entity may be added to the plaintiff's complaint. Plaintiff must establish good cause to receive an exemption from this Order.

3. In the event any plaintiff obtains an exemption from the prohibition in this Order, the provisions of Section E (Service of Process) will not apply to such plaintiff's

Complaint. Such a plaintiff agrees to serve BII, the Dismissed Foreign Defendants and any other foreign Boehringer entity in accordance with the Federal Rules of Civil Procedure and the Hague Convention. Neither BII, the Dismissed Foreign Defendants nor any other foreign Boehringer entity agrees to waive of service of process for any Pradaxa® case for which an exemption has been granted.

4. Provided that the statute of limitations applicable to each plaintiff's claim has not already expired upon the filing of a complaint against BII, in exchange for not being named/served in Pradaxa cases subject to this Order, the Dismissed Foreign Defendants agree that the statute of limitations shall be tolled as to them. The Dismissed Foreign Defendants agree, and this Court hereby orders, the statute of limitations applicable to any plaintiff's claims against the Dismissed Foreign Defendants that are filed or otherwise transferred to the MDL Proceedings will not expire until the later of: (i) the expiration of the then existing statute of limitations; (ii) on October 3, 2013; or (iii) as extended by agreement of the parties in writing. The parties agree, and this Court hereby Orders, that these tolling provisions do not apply to cases filed prior to the entry of this Order that did not name any Foreign Defendants in the Complaint.

5. The Dismissed Foreign Defendants and any other foreign Boehringer entity expressly reserve all jurisdictional defenses. The tolling of the statute of limitations is without waiver of the jurisdictional defenses raised by the Dismissed Foreign Defendants, and any other foreign Boehringer entity and each plaintiff who files an action in the MDL Proceedings expressly agrees that the tolling of such limitations period shall not be raised in an effort to assert jurisdiction over the Dismissed Foreign Defendants or any other foreign Boehringer entity in state or federal court.

6. Nothing in this Order regarding the Foreign Defendants shall act as a waiver of the Dismissed Foreign Defendants or any other Boehringer entity's jurisdictional defenses. In the event plaintiffs seek to rejoin and/or serve the Dismissed Foreign Defendants or any other foreign Boehringer entity, they will not argue to any court that any terms in this CMO including BII's agreement not to contest jurisdiction in the Pradaxa® Litigation and/or participation in these MDL Proceedings acts as a waiver of BII's, the Dismissed Foreign Defendants' or any other foreign Boehringer entity's jurisdictional defenses.

E. SERVICE OF PROCESS

1. BII states it is the owner of the intellectual property for Pradaxa®. BII has granted an exclusive non-transferable license to Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") to distribute and market Pradaxa® in the United States. BII will not claim that any United States headquartered Boehringer Ingelheim entity other than BIPI is an indispensable party to claims filed in the MDL Proceedings. Nor will BII claim that any of the Dismissed Foreign Defendants or any other foreign Boehringer entity is an indispensable party to the claims filed in the MDL Proceedings.

2. BII agrees, without waiver of any defenses, to accept service of process solely on its own behalf in all Pradaxa® cases filed directly in this MDL, in accordance with the direct filing procedures set forth in this Order, subject to the provisions of Fed. R. Civ. P. 4(d) (as modified herein). The process for the acceptance of service in this Order relates solely to BII and no other defendant(s), and nothing herein is

intended to modify the requirements of the Federal Rules of Civil Procedure with regard to effecting service on any other defendant(s).

3. For cases filed directly into the MDL Proceedings pursuant to this Order, the Complaint and notice required under Rule 4(d) shall be provided to counsel for BII by e-mailing the documents to vlodato@sillscummis.com or by mailing them with an email address for return confirmation to:

Vincent Lodato, Esq.

Sills Cummis & Gross P.C.

One Riverfront Plaza, Newark, New Jersey 07102

BII is not required to return the waiver forms contemplated by Rule 4(d), but shall instead send a confirmation of first receipt of a complaint to plaintiff's counsel by email or otherwise and shall respond to the complaints as set forth herein. A plaintiff who files his/her complaint directly into the MDL Proceedings pursuant to the terms of this Order and effects service pursuant to this paragraph is not required to file a return of service with the Court.

4. Service will be effective only if effected and confirmed as set forth above by confirmation email from Sills Cummis & Gross P.C. General mailing to Boehringer Ingelheim International GmbH or use of other methods of transmission (e.g., Federal Express or DHL) will not be sufficient to effect service. This Order does not prevent any plaintiff from effecting service pursuant to any other method authorized under the Federal Rules of Civil Procedure.

5. For complaints filed directly in this MDL, BII shall have sixty (60) days from the date of confirmation of receipt of the complaint to answer or otherwise plead. Plaintiff's counsel will meet and confer with counsel for BII prior to initiating any default proceedings and will provide twenty-one (21) business days to cure any alleged default.

6. For cases in which plaintiffs have named the Dismissed Foreign Defendants or any other foreign Boehringer entity, any applicable time limitations in Federal Rule of Civil Procedure 4(m) are extended such that plaintiffs need not serve any other Dismissed Foreign Defendants or any other foreign Boehringer entity until the earlier of: (i) October 3, 2013, (ii) further order of this Court, or (iii) by written agreement of the parties. Neither BII, the Dismissed Foreign Defendants nor any other foreign Boehringer entity shall move to dismiss a complaint as to an un-served Dismissed Foreign Defendant or any other foreign Boehringer entity prior to October 3, 2013 or as otherwise ordered by the Court.

F. DEPOSITIONS MADE AVAILABLE PURSUANT TO THIS ORDER

MDL and state court plaintiffs who do not agree to and follow the provisions of this Order will not be entitled to receive the transcripts of depositions taken pursuant to the

Deposition Protocol Order absent further order of this Court. It is the intent of the parties and the Court that plaintiffs and their counsel fully adhere to this Order and the purpose for which it is being entered. More specifically, the intent is that all plaintiffs' counsel not name and/or effectuate service on the Dismissed Foreign Defendants. Such actions, if sought without first obtaining an exemption, may be met with opposition from the PSC and stern judicial disapproval.

SO ORDERED:

  David R. Herndon
2012.10.19
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**Chief Judge
United States District Court**

Date: October 19, 2012