

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

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IN RE: PRADAXA (DABIGATRAN)	3:12-md-02385-DRH-SCW
ETEXILATE) PRODUCTS)	
LIABILITY LITIGATION)	MDL No. 2385
)	

This Document Relates to:

ALL CASES¹

AMENDED CASE MANAGEMENT ORDER NUMBER 2
Confidentiality Order
Vacating and Replacing Doc. 5

Herndon, Chief Judge:

On May 2, 2013, the Court entered Sealed Case Management Order Number 33 (Doc. 176), granting in part and denying in part the defendants' motion (Doc. 130) to modify Case Management Number 2 (Doc. 5). Case Management Order Number 33 directed the parties to submit a proposed amended Case Management Order Number 2 consistent with the Court's rulings in Case Management Order Number 33. The parties were unable to present the Court with an agreed order consistent with the terms of Case Management Order Number 33. Accordingly, the parties submitted individual proposed orders (Doc.

¹ This Order was originally entered as an agreed order in member actions 3:12-cv-50001 through 3:12-cv-50008. The provisions of this Order are now applicable to "All Cases" Pursuant to MDL 2385 Case Management Order Number 1.

195 and Doc. 196). After reviewing the parties proposed orders, the Court issues the following Confidentiality Order relating to the parties' proprietary and confidential information that may be subject to protection pursuant to Fed. R. Civ. P. 26(c):

1. Discovery in this case, including any appeal, may involve the production of information containing trade secrets, proprietary commercial or business information, intellectual property or financial information for which special protection from public disclosure and from use for any purpose other than this proceeding is warranted.

2. This Order shall govern all hard copy and electronic documents, the information contained therein, and all other information produced or disclosed during this case, whether revealed in a document, deposition, other testimony, discovery responses or otherwise, by a party to this proceeding (the "Producing Party") to any other party (the "Receiving Party").

3. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Order and thereby become a Producing Party for purposes of this Confidentiality Order.

4. The entry of this Order does not prevent any party from seeking a further order of this Court pursuant to Fed.R.Civ.P.26(c).

5. Nothing in this Order shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony or other evidence.

6. "Confidential Information," as used herein, means information, documents, things or data of any type, kind or character that the Producing Party believes in good faith constitutes, reflects, discloses, or contains information subject to protection under Fed. R. Civ. P. 26(c) or other applicable law, whether it is a document, information contained in a document, information revealed during a deposition or other testimony, information revealed in an interrogatory response, or information otherwise revealed. Any transcript of an in camera hearing shall be treated as confidential pursuant to this Order.

7. "Highly Confidential Information," as used herein, means highly sensitive Confidential Information which, if disclosed to a competitor or the general public, could result in substantial business harm by revealing trade secrets, manufacturing processes, proprietary design, drug formulation, drug development, sequencing, chemical stability and characteristics, analytical methods used in manufacturing, quality control processes, CMC information exchanged with the FDA and not the subject of a patent, source and specifications for drug components and raw materials, manufacturing plans, unpublished patent applications, strategic intellectual property plans, notices of invention, including but not limited to confidential intellectual property and patentable data, information, products or processes.

8. In designating materials as "Confidential Information" or "Highly Confidential Information," the Producing Party shall do so in good faith, consistent with the provisions of this Order. Nothing contained herein shall be

construed to allow global designations of all materials or documents as "Confidential Information" or "Highly Confidential Information."

9. Specific documents and discovery responses produced by a Producing Party may be designated as containing Confidential Information or Highly Confidential Information by marking the first page of the documents with the words "Confidential Information - Subject to Confidentiality Order" or "Highly Confidential Information - Subject to Confidentiality Order" without obscuring any part of the text. Such a designation shall subject the document and its contents to this Order. In lieu of marking the original of a document, the Producing Party may mark the copies that are produced or exchanged.

10. To the extent that information stored or recorded in the form of electronic or magnetic media is produced in such form, the Producing Party may designate such information as Confidential Information or Highly Confidential Information by cover letter generally referring to such information. The Receiving Party shall mark any storage medium containing such Confidential Information or Highly Confidential Information with the legend "Confidential Information - Subject to Confidentiality Order" or "Highly Confidential Information - Subject to Confidentiality Order." Information designated as "Highly Confidential Information" which is stored in electronic form must be maintained in a secure password protected environment with limited access to be set by a member of the Plaintiffs' Leadership Council so as to maintain the limitations provided in Paragraph 12 of this Order. Any Highly Confidential Information provided to

experts (subject to the provisions of Paragraphs 12 and 14 of this Order) in electronic format on removable storage media must be subject to password protection, with the password being provided separately from the removable storage media containing the Highly Confidential Information. Whenever any Receiving Party reduces any such information to hard copy form, that Receiving Party shall mark the hard copy form with the "Confidential Information - Subject to Confidentiality Order" or "Highly Confidential Information - Subject to Confidentiality Order" designation.

11. Information designated as Confidential Information pursuant to this Order may only be shown and delivered to the following people:

- (i) the Receiving Party;
- (ii) counsel for the parties, including their clerical, secretarial and other staff employed or retained by such counsel;
- (iii) in house counsel for the Defendants, including the clerical, secretarial and other staff working in the legal department;
- (iv) experts and consultants retained by a party to this proceeding or the party's counsel for purposes of assisting the party and its attorneys of record in the preparation and/or presentation of its claims or defenses, provided that the proposed recipient executes the attestation attached as Exhibit A;
- (v) judges, court reporters, court personnel, or videographers present at trial, conferences, hearings, arguments or depositions held in this case;
- (vi) Plaintiff's treating physicians, nurse practitioners, or other medical

professionals who treated Plaintiff (and their respective staffs), provided the proposed recipient executes the attestation attached as Exhibit A.

Counsel for the parties may show Confidential Information to any Defendant witness during a deposition, hearing or trial. Counsel for the parties may show Confidential Information to any non-Defendant witness during a deposition, hearing or trial if such person or persons execute the attestation attached as Exhibit A or otherwise affirms on the record that he/she has familiarized him/herself with the contents of this Order and agrees to be bound by it. Confidential Information shown to any witness during a deposition shall not lose its confidential status through such use, and counsel shall use their best efforts and take all steps reasonably required to protect its confidentiality during such use.

12. Information designated as Highly Confidential Information pursuant to this Order may only be used for purposes of preparation, trial and appeal of this litigation and not for any other purpose. Highly Confidential Information may be shown and/or delivered only to the following persons, provided that such persons are made aware of the terms of this Order and agree to be bound by its provisions:

(i) counsel for the Plaintiffs, including their clerical, secretarial and other staff employed or retained by such counsel, provided that the proposed recipient executes the attestation attached as Exhibit A, and further provided that the procedure set forth in Paragraph 13 of this Order is followed;

(ii) experts and consultants retained by Plaintiffs or the Plaintiffs' counsel for purposes of assisting the Plaintiffs and their attorneys of record in the preparation and/or presentation of its claims or defenses, provided that the proposed recipient executes the attestation attached as Exhibit A, and further provided that the procedure set forth in Paragraph 14 of this Order is followed;

(iii) judges, court reporters, court personnel, or videographers present at trial, conferences, hearings, arguments or depositions held in this case;

(iv) treating physicians of plaintiffs provided that the proposed recipient executes the attestation attached as Exhibit A, and further provided that the procedure set forth in Paragraph 14 of this Order is followed;.

Counsel for the parties may show Highly Confidential Information to any Defendant witness during a deposition, hearing or trial. Counsel for the parties may show Highly Confidential Information to any treating physician witness or any non-Defendant expert witness during a deposition, hearing or trial, if such person or persons execute the attestation attached as Exhibit A.

Highly Confidential Information shown to any witness during a deposition shall not lose its confidential status through such use, and counsel shall use their best efforts and take all steps reasonably required to protect its confidentiality during such use.

13. Prior to receiving any material designated as "Highly Confidential Information," the requesting attorney must sign an attestation stating that he or

she is not currently affiliated with or employed by any of the Defendants' direct competitors. A "direct competitor" for purposes of this order is defined as any company involved in the development or manufacturer of direct thrombin inhibitors. No "Highly Confidential Information" shall be disclosed to an attorney who has not signed such an attestation. No attorney who has access to "Highly Confidential Information" shall disclose, in writing or orally, or use in any way at any time in the future outside of the present litigation, any "Highly Confidential Information." An attorney who is affiliated with or employed by one of the Defendants' direct competitors may not gain access to material designated as "Highly Confidential Information" except upon a finding by this Court, after the issue has been briefed by both sides, that although he or she is affiliated with or employed by one of the Defendants' direct competitors, he or she is not a "competitive decision maker" within that company.

14. Prior to providing any material designated as "Highly Confidential Information" to an expert or consultant or to a treating physician, Plaintiffs' Leadership Counsel has an affirmative duty to inquire of the expert, consultant, or treating physician whether he or she is currently affiliated with or employed by one of the Defendants' direct competitors (as defined above), and the expert or consultant must sign an attestation stating that he or she is not currently affiliated with or employed by any of the Defendants' direct competitors. No "Highly Confidential Information" shall be disclosed to an expert or consultant who has not signed such an attestation. No expert or consultant who has access

to “Highly Confidential Information” shall disclose, in writing or orally, or use in any way at any time in the future outside of the present litigation, any “Highly Confidential Information.” Inadvertent or mistaken production of any document or information without a designation of Confidential Information or Highly Confidential Information will not be deemed to waive a later claim to its confidential nature or preclude the Producing Party from designating said document or information at a later date. A Producing Party may designate as Confidential Information or Highly Confidential Information or withdraw such a designation from any material that it has produced, provided that such re-designation shall become effective only after such re-designation. Upon such re-designation, the Receiving Party shall: treat such document or information as re-designated pursuant to the terms of this Order; take reasonable steps to notify any persons known to have possession of such material of such re-designation under this Order; and promptly endeavor to procure all copies of such materials from persons known to have possession of such material who are not entitled to receipt of it pursuant to this Order.

15. Inadvertent or Mistaken Disclosure of Privileged Documents. "Clawback" Procedure: Inadvertent or mistaken production of documents or electronically stored information ("ESI") (collectively "Inadvertently Produced Documents") subject to work-product or attorney-client privilege, or other legal privilege protecting information from discovery, shall not constitute a waiver of the privilege, provided that the producing party shall notify the receiving party in

writing as set forth herein. In the event that a party inadvertently or mistakenly produces documents or ESI subject to a claim of privilege, the producing party shall, within ten (10) days of the discovery of the inadvertent or mistaken disclosure, notify the other party in writing of the inadvertent or mistaken disclosure. The producing party may, in the notice, request a "clawback" of the inadvertently or mistakenly disclosed material. The party receiving such clawback notice shall immediately and diligently act to retrieve the Inadvertently Produced Documents, and all copies, including any loaded to databases, and return them to the producing party or destroy them as agreed between the parties. All notes or other work product of the receiving party reflecting the contents of such materials shall be destroyed and not used.

If the receiving party elects to file a motion as set forth below, the receiving party, subject to the requirements below, may retain possession of the Inadvertently Produced Documents as well as any notes or other work product of the receiving party reflecting the contents of such materials pending the resolution by the Court of the motion below, but shall segregate and not use them pending resolution of the motion. If the receiving party's motion is denied, the receiving party shall promptly comply with the immediately preceding provisions of this paragraph. No use shall be made of such Inadvertently Produced Documents during depositions or at trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them unless otherwise ordered by the Court.

The party receiving such Inadvertently Produced Documents may, after receipt of the producing party's notice of inadvertent or mistaken production, move the Court to dispute the claim of privilege.

16. A Receiving Party may challenge a Producing Party's confidentiality designation by notifying the Producing Party, in writing, of its good faith belief that the confidentiality designation was not proper and must give the Producing Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain, in writing within fourteen (14) business days of receiving such a challenge, the basis of the designation. If that does not resolve the dispute over the designation, then either party may apply to the Court for a determination as to whether the designation is appropriate. The burden of proof as to a designation of Confidential Information or Highly Confidential Information rests on the Producing Party to demonstrate that such designation is proper.

17. At the time of deposition or within 30 days after receipt of the final deposition transcript, a party may designate as Confidential Information or Highly Confidential Information specific portions of the transcript which contain confidential matters under the standards set forth above. This designation shall be in writing and served upon all counsel. No objection shall be interposed at deposition that an answer would elicit confidential information. Transcripts will be treated as confidential until the expiration of this time period. Any portions of a transcript designated confidential shall thereafter be treated as confidential in

accordance with this Order.

18. In filing materials with the court in pretrial proceedings, counsel shall file under seal only those specific documents and that deposition testimony designated as Confidential Information or Highly Confidential Information, and only those specific portions of briefs, applications, and other filings that contain verbatim Confidential Information or Highly Confidential Information, or that set forth the substance of such information.

19. Within forty-five (45) days after conclusion of this proceeding, including any appeals related thereto, at the written request of the Producing Party, such attorney and any person to whom he/she disclosed Confidential Information or Highly Confidential Information shall, at the Receiving Party's option, either (a) destroy or (b) return and surrender all Confidential Information or Highly Confidential Information produced pursuant to this Order, to the Producing Party. If returning the materials, such persons shall return any Confidential Information or Highly Confidential Information and any and all copies (electronic or otherwise), summaries, notes, compilations, and memoranda related thereto (excluding privileged communications, attorney work product, and documents filed with the Court, but such documents shall remain subject to the terms of this Order). Upon the return of all such Confidential Information or Highly Confidential Information the Receiving Party shall certify in writing that reasonable, good faith efforts were made to assure that all such information and any and all copies (electronic or otherwise), summaries, notes,

compilations and memoranda related thereto have been delivered to the Producing Party in accordance with the terms of this Order. In lieu of returning the materials described in this paragraph (including copies, summaries, notes, compilations and memoranda related thereto) the Receiving Party may destroy the materials in a manner that will protect the Confidential Information or Highly Confidential Information and the destroying party shall certify by affidavit that it has done so.

20. Nothing contained in this Order shall preclude any party from using its own Confidential Information or Highly Confidential Information in any manner it sees fit, without prior consent of any party or the Court. Notwithstanding any other provision herein, nothing in this Order shall affect or modify the Defendant's (a) ability to utilize and review Plaintiff's information and report such information as is required by law to the FDA or other regulatory agencies, or (b) its right to provide information to its insurer(s), as applicable, for purposes of evaluating Plaintiff's claims or as may be required for reporting purposes.

21. **Discovery Material Protected under German Law.** Any entity subject to the jurisdiction of German law producing documents in this litigation may designate as CONFIDENTIAL those documents (including electronic or paper form) containing "personal data" within the meaning of the German Federal Data Protection Act (the "Act") if such documents would otherwise fall within the jurisdiction and scope of the Act. "Personal data" consists of any and all

information concerning the personal or material circumstances of an identified or identifiable natural person. In particular, this provision applies to the following documents:

(i) any correspondence (electronic or paper form) that identifies or through recourse to other sources of information available to the data processor allows identification of its author(s)/sender(s) and/or its addressees/recipients (e.g., all email correspondence, letters and faxes, including transmission reports);

(ii) any document, such as memoranda, notes, and presentations, if it identifies or allows identification of its author/sender and/or its addressee/recipient through recourse to other information available to the data processor;

(iii) minutes of internal or external meetings as far as they include information about which individual(s) did or did not attend the meeting; and

(iv) personnel records and information.

22. To the extent the same documents are produced by both a U.S.-based entity and a Germany-based entity in this litigation, and one version of the document is protected by the Act and the other is not, the fact that one version has been designated confidential under the Act shall not confer any privileges of confidentiality under this Order upon the second version of the document that has no basis to be designated confidential. Any entity based outside of the Federal Republic of Germany shall not be permitted to send data into the Federal Republic of Germany for the purpose of making it confidential, provided that this

shall not prohibit any such entity subject to this Order that prior to the beginning of this litigation had been storing or transmitting data to recipients or electronic systems within the Federal Republic of Germany in the ordinary course of their business from continuing to do so.

23. It is expressly understood by and between the parties that in producing Confidential Information or Highly Confidential Information in this proceeding, the parties shall be relying upon the terms and conditions of this Order.

24. By written agreement of the parties, or upon motion and Order of this Court, the terms of this Order may be modified. This Order shall continue in force until amended or superseded by express order of the Court, and shall survive and remain in effect after the termination of this proceeding.

SO ORDERED:

 Digitally signed by
David R. Herndon
Date: 2013.06.10
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**Chief Judge
United States District Court**

Date: June 10, 2013