

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF ILLINOIS**

---

**IN RE: PRADAXA (DABIGATRAN  
ETEXILATE) PRODUCTS LIABILITY  
LITIGATION**

---

)  
) **3:12-md-02385-DRH-SCW**  
)  
)  
)  
)

**MDL No. 2385**

**This Document Relates to:**

**ALL CASES**

**CASE MANAGEMENT ORDER NUMBER 17**  
**Production Schedule for BIPI<sup>1</sup>**

**HERNDON, Chief Judge:**

After conferring with the parties on November 19, 2012, the Court

Orders as follows:

1. Paper and Pradaxa-Specific Electronic Custodial files
  - a. 28 custodians identified by BIPI on October 12<sup>th</sup> – productions to be made on **November 30<sup>th</sup>** (both paper and Pradaxa-specific files).
  - b. Six custodians identified on Nov. 11<sup>th</sup> – to be produced on **December 17<sup>th</sup>** (both paper and Pradaxa-specific files).
  
2. Electronic Materials Subject to Search Terms
  - a. Category “A” Custodians of the 28 custodians identified by BIPI on October 12<sup>th</sup> by **November 30<sup>th</sup>**.
  - b. Category “B” and “C” Custodians of the 28 custodians identified by BIPI on October 12<sup>th</sup> by **December 17<sup>th</sup>**.
  - c. Six Custodians Identified on November 11<sup>th</sup> by **December 17<sup>th</sup>**.
  
3. TEMPO Database (Marketing and Educational Materials)
  - a. Will be produced on **December 30<sup>th</sup>**.

---

<sup>1</sup> Amended CMO #3 shall be complied with for all aspects of the production.

- b. If issues with regard to meeting this production deadline arise, those issues shall be brought to the Court, as needed, on or before the status conference scheduled for December 13, 2012.
- c. Both Drafts and Final versions of all responsive and non-privileged material contained in TEMPO shall be produced.

4. VISTA Database

- a. BIPI shall produce the full VISTA database as it relates to Pradaxa to the PSC on or before **December 17th** (this production shall include all entries through December 1<sup>st</sup> and shall be produced all at one time).
- b. The parties shall meet and confer regarding the production of incremental updates of the VISTA database and the format of the deliverable export. The parties will update the Court regarding the status of these matters, as needed, on or before the status conference scheduled for December 13, 2012.

5. ARISg Database

- a. BIPI shall produce the full ARISg database as it relates to Pradaxa to the PSC on or before **December 17th** (this production shall include all entries through December 1<sup>st</sup> and shall be produced all at one time). BIPI shall be permitted to withhold the production of any patient or reporter identifying information in order to comply with federal regulations.
- b. The parties shall meet and confer regarding the production of incremental updates of the ARISg database, the format of the deliverable export, and the production of source files for adverse events. The parties will update the Court regarding the status of these matters, as needed, on or before the status conference scheduled for December 13, 2012.

6. IDEA for Submission

- a. BIPI shall assess matters pertaining to the production of responsive and non-privileged data related to Pradaxa within IDEA for Submission.
- b. The parties will update the Court regarding the status of these matters, as needed, on or before the status conference scheduled for December 13, 2012.

7. IDEA for General and IDEA for Controlled Documents

- a. BIPI shall produce all responsive and non-privileged data within IDEA for General and IDEA for Controlled Documents by **January 14, 2013**.

- b. BIPI's production shall include data from both the "work in progress" and the "archive" part of IDEA for General and IDEA for Controlled Documents as testified to by Ms. Peacock on November 15, 2012.
- c. BIPI does not have to re-produce the PDF files that it has already produced, however, BIPI shall produce the non-PDF version of any document in IDEA for General and IDEA for Controlled Documents regardless of whether it has already produced the PDF version.

8. Oracle Clinical

- a. BIPI shall produce all raw data for all clinical trials related to Pradaxa and/or Dabigatran Etexilate by **December 17th**. The production shall be made in such a manner to permit the PSC to determine what study or test the data is related to.
- b. In addition to all raw data related to Pradaxa, BIPI shall produce any data set that was provided to the FDA or other regulatory agency shall be provided to the PSC as a complete data set just as it was submitted to the FDA or other regulatory agency by **December 17th**.
- c. If issues with regard to meeting the December 17th production deadlines arise, those issues shall be brought to the Court, as needed, on or before the status conference scheduled for December 13, 2012.
- d. The parties shall meet and confer regarding the format and scope of this production. The parties will update the Court regarding the status of these matters, as needed, on or before the status conference scheduled for December 13, 2012.

9. BRAIN and CEREBUS

- a. BIPI shall produce all raw data for all pre-clinical studies related to Pradaxa and/or Dabigatran Etexilate by **January 14th**. The production shall be made in such a manner to permit the PSC to determine what study or test the data is related to.
- b. In addition to all raw data related to Pradaxa, BIPI shall produce any data set that was provided to the FDA or other regulatory agency shall be provided to the PSC as a complete data set just as it was submitted to the FDA or other regulatory agency by **January 14th**.
- c. If issues with regard to meeting the January 14th production deadlines arise, those issues shall be brought to the Court, as needed, on or before the status conference scheduled for December 13, 2012.

- d. The parties shall meet and confer regarding the format and scope of this production. The parties will update the Court regarding the status of these matters, as needed, on or before the status conference scheduled for December 13, 2012.
10. SAS Data
- a. BIPI shall produce all SAS data for all pre-clinical studies and clinical trials related to Pradaxa and/or Dabigatran Etexilate by **January 14th**. The production shall be made in such a manner to permit the PSC to determine what study or test the data is related to.
  - b. In addition to all SAS data related to Pradaxa, BIPI shall produce any data set that was provided to the FDA or other regulatory agency shall be provided to the PSC as a complete data set just as it was submitted to the FDA or other regulatory agency by **January 14th**.
  - c. The parties shall meet and confer regarding the scope of this production. The parties will update the Court regarding the status of these matters, as needed, on or before the status conference scheduled for December 13, 2012.
11. Materials Responsive to Boston Request for Production or PSC's First Request for Production that will be Produced from Sources Other than those Sources Identified Above
- a. Any such responsive materials shall be produced **December 30th**.
12. Responses to PSC's Second Request for Production and Second Set of Interrogatories (Served on November 8, 2012)
- a. BIPI anticipates filing objections to the PSC's Second Request for Production and Second Set of Interrogatories. The parties will update the Court regarding the status of these matters, as needed, on or before the status conference scheduled for December 13, 2012.

13. Z-Drive:  
a. Production relating to the Z-Drive is being reviewed by BIPI. The parties will update the Court regarding the status of this matter, as needed, on or before the status conference scheduled for December 13, 2012.

**IT IS SO ORDERED.**

  
  
David R. Herndon  
2012.11.20  
11:31:15 -06'00'

**Honorable David R. Herndon  
Chief Judge, United States District Court**

**Date: November 20, 2012**