

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

<b>IN RE PRADAXA (DABIGATRAN ETEXILATE) PRODUCTS LIABILITY LITIGATION</b>	<b>) ) ) )</b>	<b>3:12-md-02385-DRH-SCW  MDL No. 2385</b>
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**This Document Relates to:**

**ALL CASES**

**AMENDED CASE MANAGEMENT ORDER No. 3  
Order Governing the Format of Production  
(Striking and Replacing Case Management Order No. 3 MDL 2385 Doc. 6)**

**HERNDON, Chief Judge:**

**With Regard to** the procedures and format relating to the production of documents and things, the Court hereby **Orders as Follows:**

**A. GENERAL**

1. In the event this Order does not otherwise provide for the method of production, the parties shall meet and confer in good faith on a manner of production that balances the needs for production to be efficient, cost effective and reasonably useable and in a manner that will avoid cumulative or duplicative document discovery attempting to minimize the burdens and costs on the producing party.

2. Except as specifically limited herein, the Order governs the production of discoverable documents by the parties during the Litigation. This Order will not enlarge or affect the proper scope of discovery in this Litigation, nor imply that discovery produced under the terms of this Order is properly discoverable, relevant, or admissible in this or in any other litigation. Nor does this Order alter or expand the preservation obligations of the parties. This order does not address the manner in which documents are selected and filtered prior to

review by the parties. The parties agree to meet and confer regarding such issues with the understanding that, in an effort to comply with anticipated production deadlines and produce documents to plaintiffs as soon as reasonably possible, the defendants have commenced collecting, processing, reviewing and producing certain document populations including but not limited to regulatory files (e.g., INDs and NDA) and custodial paper documents. Prior to the entry of this Amended Order, the Plaintiffs have not been involved in Defendants' collection process. Entry of this order does not imply that Plaintiffs consent to Defendants' selection and filtering processes to date. The parties are directed to meet-and-confer about such issues.

3. The parties are reminded of their respective obligations to preserve relevant information as required under federal law.

4. All documents that are responsive to discovery requests and not designated as privileged (i.e., subject to the attorney-client privilege and/or work product doctrine) will be produced, subject to objections and responses, and subject to the parties' Protective Order and/or Confidentiality Order, in the manner provided herein. Conversely, nothing in this Order will be interpreted to require disclosure of materials that a party contends are protected from disclosure by the Protective Order, Confidentiality Order, or the attorney-client privilege and/or the attorney work-product doctrine. Nothing in this Order will be deemed to limit or modify in any way the terms of the parties' Protective Order or Confidentiality Order.

## **B. PRODUCTION PROTOCOLS**

1. General Format of Production. All documents produced in this litigation shall be produced as electronic TIFF images with associated text (OCR or extracted text as set forth herein), metadata, and objective coding, unless another production format is designated herein or otherwise agreed to by the parties.

2. Production of Electronic Images and Associated Data. Except as limited in this paragraph or as described herein, all documents that originally existed in electronic or hard-copy form that are produced in these proceedings shall be produced in electronic image form in the manner provided herein. To the extent exceptions to the foregoing are required, the parties will meet and confer to discuss alternative production requirements, concerns, or formats. Except for redacted documents, each document produced pursuant to this Order shall convey the same information in the electronic image(s) produced as the original document. Documents that present other imaging or formatting problems shall be promptly identified by the receiving party and the parties shall meet and confer to attempt to resolve the problems.

a. Document Image Format. All production document images, whether scanned from hard copy documents or generated from native electronic documents, shall be provided as single-page Tagged Image File Format (“tiff format”), using Group 4 compression at 300 dpi resolution, and shall reflect, without visual degradation, the full and complete information contained in the original document, unless redacted. Reasonable efforts will be used to scan the pages at or near their original size and so that the image appears straight and not skewed. Physically oversized originals, however, may appear reduced. In addition, reducing image size may be necessary to display Bates numbers without obscuring text. The documents shall be logically grouped together and produced in accordance with Rule 34 of the Federal Rules of Civil Procedure. The parties shall meet and confer to the extent reasonably necessary to facilitate the import and use of the produced materials with commercially available document management or litigation support software.

b. Load Files: Load file means an electronic file provided with a production set of document images that facilitates the loading of such information into a receiving party’s

document review platform, and the correlation of such data in the platform. A properly delimited ASCII text file containing Metadata and any objective coding required to be provided pursuant to this Order, an IPRO (LFP file) or OPTICON load file for tiff images, and document level ASCII OCR or Extracted text files named with the corresponding StartBates or BegBates document ID. The receiving party will provide the producing party with load file specifications 14 days in advance of the date of the first production. The producing party will have the right to request a sample load file and deliver a small first production to ensure the load file works and avoid any unnecessary costs associated with a faulty large-scale production.

c. Document Unitization. Each page of a hard copy document shall be scanned into an image and if a document is more than one page, the unitization of the document and any attachments shall be maintained as it existed in the original when creating the image file. For documents that contain fixed notes, the pages will be scanned with the notes and those pages will be treated as part of the same document. The relationship of documents in a document collection (*e.g.*, cover letter and enclosures, email and attachments, binder containing multiple documents, or other documents where a parent-child relationship exists between the documents) shall be maintained. If more than one level of parent-child relationship exists, documents will be kept in order, but all will be treated as children of the initial parent document. Such information shall be produced in the load file and metadata or objective coding, as set forth herein, in a manner to enable the parent-child relationship among documents in a document collection to be reconstituted by the receiving party in commercially available document management software, such as Concordance. If a parent-child exists for an email string an Email Thread ID shall be provided in the metadata. All documents produced shall have a character that delineates page breaks in the OCR text so that the receiving party can determine where one page ends and

another page begins. Parent-Child as well as other document family relationships and document unitization relationships shall be maintained even if that results in the production of documents considered to be duplicate documents as defined in paragraph B(2)(3) below.

d. Color. If an original document contains color, the producing party shall not deny reasonable requests for color copies of the original. Reasonable requests for color versions of documents originally produced in black-and-white shall not be denied. Upon receipt of a request for a color copy of a document originally produced in black-and-white, the producing party shall (a) provide a color image by e-mail to the requesting party and (b) provide a replacement image and load file bearing the same Bates number for that previously produced document with its next production. The parties agree to meet and confer regarding which party shall bear the cost of color copies.

e. Duplicates. Each party will take reasonable steps to de-duplicate electronic documents and other ESI in accordance with the terms of this Order. The parties will de-duplicate across all sources (i.e., global or horizontal de-duplication). The producing party will maintain references to all removed duplicate files in an index field titled "Duplicate Custodian". See Attachment A. Near duplicates or similar documents will be produced. Duplicated electronic files will be identified based upon calculated MD5 Hash values for binary file content. File contents only will be used for MD5 Hash value calculation and will not include operating system metadata (filename, file dates) values. All files bearing an identical MD5 hash value make a duplicate group. The document reviewed by Defendants for privilege, relevance, or confidentiality shall be deemed the primary duplicate document within the group. Upon receipt of a primary document, the receiving party may make reasonable requests for the production of

certain duplicates of the primary document on showing of good cause. The parties will meet and confer in good faith regarding disagreements related to such requests.

f. Messaging Files: Duplicate messaging files will be identified based upon MD5 Hash values for the message family, including parent object and attachments. Duplicate messaging materials will be identified at a family level, including message and attachment(s).

g. E-mail Threading: The producing party may identify e-mail threads where all previous emails that make up the thread are present in the body of the final e-mail in the thread. Any party electing to use this procedure must notify all receiving parties that e-mail thread suppression has been proposed to be performed on a specified production and the Parties agree to meet and confer regarding the format of this production, which shall established such that the objective coding fields for all previous emails shall be produced. The producing party may replace the image file, and text fields for all previous emails with the image file and text field for the final email. The parties reserve the right to seek Court guidance on the issue should agreement not be reached. If redactions have been applied to subject or text fields, Defendants may substitute and replace the subject and text fields with those reviewed by Defendants' counsel for the final email in the thread. Any email that has been subject to e-mail threading shall be identified by the field "EmailThreading" as described in Attachment A.

h. Bates Numbering and Source Index. Each page of a produced document shall contain a legible, unique identification number ("Bates number") and confidentiality notice, where applicable, which will be electronically burned onto the page image in a manner that does not obliterate, conceal, obscure, or interfere with any information from the source document. No other stamp or information will be placed on a document other than Bates-number, confidentiality notice, and any redactions as may be required. This provision does not apply to databases or documents produced in native electronic format. With each production, the

Producing Party shall provide a chart identifying the source, start bates range, and end bates range for each category of documents being produced (the "Production Index"). The Producing Party shall certify that, to the best of its knowledge, the information contained in the Production Index is accurate as to both the bates ranges and the source of the documents identified by such bates ranges. The Production Index shall be updated with each production by the Producing Party.

i. File Naming Conventions. Each page image file shall be named with the unique Bates number of the page of document, followed by the extension ".TIF." In the event the Bates number contains a symbol and/or character that cannot be included in a file name, the symbol and/or character will be omitted from the file name.

j. Production Media. Document productions will be made on CD-ROM, DVD, external hard drive, or such other readily accessible computer or electronic media as the parties may hereafter agree upon (the "Production Media"). Each piece of Production Media shall be marked with a specific identifying number, like a Bates number, as well as the following: production number, production date, and the Bates number range(s) of the materials on the Production Media.

k. Objective Coding. The producing party will provide objective coding as set forth in Attachment A in a load file included on the production discs with each production. If Defendant chooses to objectively code any hard copy documents with index fields in additions to those required in Attachment A, it shall provide the additional objective coding at the time of production to Plaintiff, or as soon as the objective coding is available. The producing party may review and, where necessary, revise or redact objective coding if it contains privileged or work

product information, or other protected information, so long as all revisions or redactions are individually noted on the privilege log.

l. Metadata: Metadata means corresponding data about an electronic document that is generally not seen on the face of the document or when the document is printed (e.g., date created, date sent, author, recipient, etc.). For electronic documents, e-mails and hardcopy documents, the parties agree to produce metadata as set forth in "Attachment A", to the extent such metadata is responsive, not privileged, available and applicable. The producing party may redact, or remove from production, protected and/or privileged metadata, so long as all revisions or redactions are individually noted on the privilege log.

m. OCR/Extracted Text: The producing party shall produce corresponding Optical Character Recognition (OCR) text files for hard-copy documents and any electronic documents that require redaction prior to production. For electronic documents that require redaction, the process shall be that the producing party shall export the document to a TIFF image and perform the OCR process off that TIFF image. Printing electronic documents to paper for the purpose of performing the OCR scan shall not be permitted by this Order. For documents that exist in electronic format that have not been redacted and that are produced as images, the producing party shall produce extracted text files reflecting the full text that has been electronically extracted from the original, native electronic files. The parties shall coordinate regarding the specifics for delivering OCR and extracted text as part of productions, including any load files specifications. Defendant shall identify the program being used to create the OCR file to the PSC. Redactions shall be clearly recorded in the index field of the document. *See* Attachment A. For any document that will undergo the OCR process and contain a redaction, the producing party shall burn a Bates number onto the image or document prior to the OCR

process such that the Bates number becomes part of the OCR file. In the event the Producing Party updates the OCR to include the production Bates numbers into the OCR text for its own use, the producing party shall provide an identical production to the Receiving Party.

n. Native Format Productions. Native production means electronic documents that are produced in the format in which they were created and used (also referred to in terms of "Native Format"). The parties will produce Excel and PowerPoint files in native format, unless redacted. The parties will also produce Microsoft Word (and similar word processing documents) documents in native format unless redacted. Any native files that are produced shall be produced with a Bates-numbered TIFF image slip-sheet stating "Document [Begin Bates number] to [End Bates number] is a [document type] that has been produced in native format." The slip-sheet shall also contain a MD5 hash generated for the produced native file. Any native files that are produced shall be produced with the source file path provided, as well as all extracted text and applicable metadata fields set forth in Attachment A. The parties shall meet-and-confer regarding a request for the production of any other materials, including documents in native file format.

o. Databases. Database means electronic data organized (often structured data, organized in rows, columns and tables) in an electronic environment for a particular purpose. Prior to production of any database, the Parties will meet and confer regarding the discoverability and feasibility of any request for production of a database including the form and content of any such production. The producing party reserves the right to object to the production of requested databases. The parties will cooperate to produce responsive, non-duplicative electronic data from relevant databases in a reasonably usable production format where practical and feasible. Where such production is not practical or feasible, the Parties will

confer upon an appropriate form of production. The Court's assistance regarding the discoverability, form, and scope of production of data from a database may only be sought after the parties have failed to reach agreement after good-faith discussion.

p. Video, Audio, other electronic media that cannot be rendered as Tiff images. Except as subject to redaction or other protection, the producing party shall produce requested relevant video, audio and other electronic media that cannot easily be rendered as Tiff images in their original media format, i.e., CD Audio, DVD Video, etc. unless the original format is unreasonable, or unduly burdensome or costly, in which situation the parties will meet and confer on the format for producing this type of information. Audio and video files may be edited, only after consultation with the opposing party, if redactions are required, subject to appropriate identification of any such modification to the original audio or video file.

q. Original Documents. The producing parties shall retain the original hard-copy and native source documents in their original format (together with, except as may be otherwise expressly agreed among the parties, the means to access, retrieve, and view such documents; however, the original hardware does not have to be kept) for all documents produced in this proceeding. Producing parties shall maintain the original native electronic source documents in a manner so as to preserve the "metadata" associated with these electronic materials in the event review of such metadata becomes necessary. Subject to preservation of appropriate privileges and other protections of Defendant's information from production in accordance with applicable law, upon a showing of good cause or particularized need, after reasonable request and any necessary meet and confer, where a document existed originally in only hard copy format, Defendant will make originals of any produced document available for inspection by the requesting party in the form in which such documents are kept in the ordinary course of business.

3. Translated Documents. If any document produced by a producing party has an English language translation in the custodial or source file from which the document was produced, the producing party will produce both the original non-English document as well as the translation. Otherwise, foreign language documents will be produced in their original language and not translated. The index field for Foreign Language Documents will note “yes” if a document contains content in one or more foreign languages. *See* Attachment A for a list of index fields.

4. Replacement Images. If a document produced by a producing party has an error or the images must be replaced due to inadvertent or mistaken production, a change in confidentiality, or other reason the replacement production must be marked as a replacement, and the producing party must provide a reason for the replacement. The load file of the replacement document(s) must be separately produced in a complete replacement file and clearly marked as such in the production index.

5. Clawback. The parties understand that document discovery in this Litigation may involve the production of large volumes of documents in a short time period and, thus, the inadvertent or mistaken production of privileged, confidential, private or otherwise protected information is possible. As the parties wish to protect such information against use in the Litigation or further disclosure, the parties acknowledge that the producing party may claw back such inadvertently or mistakenly produced documents, and that nothing in this Order waives, restricts or eliminates any “claw back” rights that may be included in any Protective Order or Confidentiality Order to which the parties may become subject, or governing law, rules (e.g., F.R.C.P. 26(b)(5)(B) & F.R.E. 502), orders or agreements regarding inadvertently or mistakenly

produced documents. The procedures for opposing any attempt to “claw back” a document that is established in CMO #2 shall not be altered by anything in this Order.

6. Costs: While each party will bear, by default, its own document production costs, each party reserves the right to pursue cost-shifting or cost-sharing pursuant to the Rules (e.g., Rule 26(b)(2)) and other applicable law.

7. Disputes: The parties will meet and confer in good faith, in person or by phone, and endeavor to resolve any dispute related to this Order before submitting such disputes to the Court for determination, or otherwise moving for relief.

8. Relief and Modification: After an appropriate meet and confer in good faith, either party may apply to the Court for relief or modification of this Order.

**SO ORDERED**

 Digitally signed by  
David R. Herndon  
Date: 2012.10.25  
10:53:18 -05'00'

**Chief Judge  
United States District Court**

**Date: October 25, 2012**

	FIELD NAME	Field Description	Electronic Documents	E-mail	Hardcopy Documents	Comments
1	SOURCE	Custodian or other source of document	X (index)	X (index)	X (index)	
2	BEGDOC	Bates Number of first page in document	X (index)	X (index)	X (index)	
3	ENDDOC	Bates Number of last page in document	X (index)	X (index)	X (index)	
4	BEGATTACH	BegDoc# of parent record	X (index)	X (index)	X (index)	
5	ENDATTACH	EndDoc# of last attached document in family	X (index)	X (index)	X (index)	
6	APPLICANAMED	Metadata collected from MS office files and PDFs.	X (metadata)			
7	Date Last Modified	Last modified date	X (metadata)			all fields related to a date shall be uniformly created in the format mm/dd/yyyy
7a	Time Last Modified	Last modified time	X (metadata)			
8	DATESENT	Sent date of email message (e.g. Month dd yyy)		X (metadata)		
9	TITLE	Metadata collected from MS office files and PDFs.	X (metadata)			
9a	FileName	Metadata collected from MS office files and PDFs	X (metadata)			
10	From	Author or sender of e-mail message or email string		X (metadata)		Where party names are available or reconcilable as fully qualified domain addresses (e.g. name@domain.com), then they will be supplied in such format. Some addresses may not be reconcilable due to distribution lists, expired accounts or other technical impedances.
11	To	Recipient(s) of e-mail message		X (metadata)		Where party names are available or reconcilable as fully qualified domain addresses (e.g. name@domain.com), then they will be supplied in such format. Some addresses may not be reconcilable due to distribution lists, expired accounts or other technical impedances.
12	CC	Recipient(s) of "Carbon Copies" of e-mail message		X (metadata)		Where party names are available or reconcilable as fully qualified domain addresses (e.g. name@domain.com), then they will be supplied in such format. Some addresses may not be reconcilable due to distribution lists, expired accounts or other technical impedances.
13	BCC	Recipient(s) of "Blind Carbon Copies" of e-mail message		X (metadata)		Where party names are available or reconcilable as fully qualified domain addresses (e.g. name@domain.com), then they will be supplied in such format. Some addresses may not be reconcilable due to distribution lists, expired accounts or other technical impedances.

FIELD NAME	Field Description	Electronic Documents	E-mail	Hardcopy Documents	Comments
14	DtLastAccessed	X (metadata)			
15	AUTHOR	X (metadata)			
16	DateLastSaved	X (metadata)			
17	EDFOLDER/EDSOURCE	X (metadata)	X (metadata)		
18	EMAIL_SUBJECT		X (metadata)		
19	EmbeddedDoc	X (metadata)			
20	HasNotes	X (metadata)			
21	TrackedChanges	X (metadata)			
22	OLEComments	X (metadata)			
23	DATECREATED	X (metadata)			
24	DOCEXT	X (metadata)			
25	FileSize	X (metadata)			
26	EmailDateCreate		X (metadata)		
27	DATERCVD		X (metadata)		
28	TIMESENT		X (metadata)		
29	CONFIDENTIALITY	X (index)	X (index)	X (index)	
30	REDACTION	X (index)	X (index)	X (index)	
31	FOREIGN LANGUAGE	X (index)	X (index)		
32	MESSAGE-ID		X (metadata)		
33	DUPLICATE CUSTODIAN	X (index)	X (index)		
34	DuplicatePath	X (metadata)	X (metadata)		Will include multiple entries.
35	OLEAuthor	X (metadata)			
36	OLECreate Dt	X (metadata)			
37	OLESubject	X (metadata)			

FIELD NAME	Field Description	Electronic Documents	E-mail	Hardcopy Documents	Comments
38	OLETitle	X (metadata)			
39	FromDomain		X (metadata)		
40	InternetMessageID		X (metadata)		
41	FileSystemDateCreate	X (metadata)			
42	AttachmentCount		X (metadata)		
43	AttachmentNames		X (metadata)		
44	Color	X (index)			
45	RevisionNumber	X (metadata)			
46	LastPrintedDate	X (metadata)			