

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA**

<b>IN RE: XARELTO (RIVAROXABAN)</b>	)	<b>MDL No. 2592</b>
<b>PRODUCTS LIABILITY LITIGATION</b>	)	
	)	<b>SECTION: L</b>
_____	)	
	)	<b>JUDGE FALLON</b>
<b>THIS DOCUMENT RELATES TO:</b>	)	<b>MAG. JUDGE NORTH</b>
<b>ALL ACTIONS</b>	)	
_____	)	

**PRE-TRIAL ORDER NO. 12  
(STIPULATED PROTECTIVE ORDER)**

Plaintiffs and Defendants before this Court in MDL No. 2592 (sometimes hereinafter referred to as “Plaintiffs” and/or “Defendants,” or collectively, the “Parties”) have advised the Court that they hereby stipulate and agree, through their respective attorneys of record as follows:

1. The Parties, by and through their counsel, stipulate and agree that this Stipulated Protective Order – and any designation of a document, material or information (whether written, graphic, or electronic) as being a “PROTECTED DOCUMENT” subject to this Stipulated Protective Order – is intended solely to facilitate prompt discovery and the preparation for trial in the above-captioned action.

2. This Stipulated Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, produced or disclosed by any party to this proceeding (the “Supplying Party”) to any other party (the “Receiving Party”). This Stipulated Protective Order is binding upon all Parties at the time it is entered including their respective corporate parents, subsidiaries, and affiliates and their respective attorneys, principals, experts, consultants, representatives, directors, officers, employees, and others as set forth in this Order.

If additional parties are added other than parents, subsidiaries or affiliates of current parties to this litigation, then their ability to receive “PROTECTED INFORMATION” as set forth in this Stipulated Protective Order will be subject to them being bound, by agreement or Court Order, to this Stipulated Protective Order. Third Parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Stipulated Protective Order and thereby become a Supplying Party and/or Receiving Party for purposes of this Stipulated Protective Order.

3. Nothing herein shall be construed to affect or restrict in any manner the use or admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

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

5. This Protective Order does not confer blanket protections on all documents, disclosures, or responses to discovery and the protection it affords extends only to specific information or as set forth herein.

6. A Supplying party may designate as “PROTECTED INFORMATION” any documents, things and information, it produces in this litigation to a Receiving Party if such Supplying Party or counsel for such Supplying party believes in good faith that such PROTECTED INFORMATION is subject to protection under Fed. R. Civ. P. 26(c)(1)(G) or other applicable law. Plaintiffs shall be permitted to designate materials that contain personal information as “PROTECTED INFORMATION” pursuant to this Order.

7. A Supplying Party may also designate as “PROTECTED INFORMATION – HIGHLY PROTECTED ” any document or information which, if potentially disclosed to a competitor or the general public, could result in substantial business harm. Nonexclusive

examples include materials that may reveal 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, strategic plans, marketing plans, brand plans, documents setting forth marketing and sales tactics and strategies, sales data, and documents revealing pricing or other contractual data so long as the material is also protected under Fed. R. Civ. P. 26(c)(1)(G). In designating discovery materials as “PROTECTED INFORMATION – HIGHLY PROTECTED”, the Supplying Party shall do so in good faith consistent with the provisions of this Protective Order and rulings of the Court. Paragraphs 19 and 20 herein set forth the terms regarding disclosure of discovery material designated as “PROTECTED INFORMATION” or “PROTECTED INFORMATION – HIGHLY PROTECTED.”

Additionally, certain information that may be designated as “PROTECTED INFORMATION - DEFENDANT RESTRICTED”, such as protected internal financial data from the Janssen defendants or Bayer defendants, is not and would not be shared or disclosed as between the respective defendants for legal and other reasons. To the extent such information is required to be produced in this matter, if a Receiving Party proposes to disclose such information to a co-defendant, the Receiving Party and Supplying Party shall meet and confer prior to any such disclosure, and the Supplying Party shall have the right to seek an Order that the disclosure not be made. It is the obligation of the Supplying Party to notify the Receiving Party at the time

of production and identify with specificity any documents that the Supplying Party contends should not be disclosed to a co-defendant. This paragraph does not restrict and will not delay the production of such materials to Plaintiffs.

8. Any entity organized under the laws of the Federal Republic of Germany that becomes a party to this litigation may designate as “PROTECTED INFORMATION” those documents (including electronic or paper form) containing “personal data” within the meaning of the German Federal Data Protection Act, which is protected under German law. “Personal data” consists of any and all data that concerns an identified person or a person who is identifiable with recourse to additional information available to the data processor (*e.g.*, reference to an individual by his/her title or position with the company whose identity is specified in other available sources of information). In particular, this provision applies to the following documents:

- a. any correspondence (electronic or paper form) that identifies or through recourse to other source 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);
- b. 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;
- c. minutes of internal or external meetings as far as they include information which individual(s) did or did not attend the meeting;
- d. personnel records and information; and
- e. any document containing private medical information.

9. No items or information, including but not limited to summaries of items or information designated as “PROTECTED INFORMATION” shall be produced or disseminated orally, or by any other means, except as permitted by this Stipulated Protective Order. As used in all following paragraphs, the phrase “PROTECTED INFORMATION” also includes the PROTECTED INFORMATION – HIGHLY PROTECTED” and “PROTECTED INFORMATION - DEFENDANT RESTRICTED” designations unless the specific paragraph contains additional or different provisions for the latter designations.

10. Any designation of “PROTECTED INFORMATION” under this Stipulated Protective Order shall not be construed as an admission or an agreement by any party that any document, material or information, or any portion thereof, constitutes competent, material, relevant, or admissible evidence in this case.

11. Documents not designated as “PROTECTED INFORMATION” are not protected as that term is used herein.

12. This Protective Order shall not be construed to protect from production or to permit the designation as “PROTECTED INFORMATION” of any document or other material that (a) the party has not made reasonable efforts to keep confidential, or (b) is at the time of production or disclosure, or subsequently becomes, through no wrongful act on the part of the Receiving Party, generally available to the public through publication or otherwise.

13. This Stipulated Protective Order shall not be construed as a waiver by any party of the right to contest the designation of “PROTECTED INFORMATION” under this Stipulated Protective Order. Any party desiring to contest the designation of specific “PROTECTED INFORMATION” may do so at any time and shall give the Supplying Party notice in writing (a letter to liaison counsel delivered by email shall be sufficient), including the listing of any such

information or document(s) or the Bates ranges for the information or document(s), and shall provide a brief explanation of the basis for contesting the “PROTECTED INFORMATION” designation (the “Notice”). If the same document in the Notice appears in the production at other Bates numbers, the Notice shall be deemed to be sufficient for all such documents and information. The Notice shall be sufficient if it identifies documents being challenged and states the basis for the challenge. If the Parties cannot stipulate to the designation as “PROTECTED INFORMATION” within fourteen (14) days of the Supplying Party’s receipt of such written notice, then the Supplying Party has the burden of making an application to the Court for an order directing that the contested document(s) or information is entitled to protection under applicable law. The Supplying shall have thirty (30) days to file and serve an application unless the parties agree to a shorter time or the Court orders a different time period. If no such application is filed within the requisite time period, the information shall not be afforded protected status, unless the Court subsequently orders otherwise. All references in motions or briefs seeking to confirm the confidentiality designation “PROTECTED INFORMATION” shall be filed under seal to the extent permitted by applicable Court rules and procedure as set forth herein below in paragraphs 25 and 26. Pending a Court determination, no document or information designated as “PROTECTED INFORMATION” under this Order shall be disseminated other than as provided by this Order unless otherwise ordered by the Court or as stipulated by the Parties.

14. The fact that the Parties have agreed to this Protective Order shall not be used against either party in any subsequent challenge to the designation of material as protected information. The challenge shall be decided on the merits pursuant to the applicable law.

15. Pursuant to the terms and requirements of this Stipulated Order, the Supplying Party may designate as “PROTECTED INFORMATION” all or any part of documents or information produced by it in the course of litigation or in response to various interrogatories and requests for production of documents, as well as documents, electronic files and data compilations, and deposition transcripts, or portions thereof, that contain or constitute protected information.

16. The designation of information shall be made by placing or affixing on the material in a manner that will not interfere with its legibility the words “PROTECTED INFORMATION. SUBJECT TO PROTECTIVE ORDER” as long as the designation is conspicuously placed on produced documents, media or information in a uniform manner. The designation shall be made prior to, or contemporaneously with, production or disclosure of that material.

17. Information disclosed at a deposition taken in connection with this action may be designated as Protected Information by designating the portions of the transcript in a letter to be sent to the court reporter and Liaison Counsel within fifteen (15) days of the date the court reporter makes the transcript available for the Producing Party’s review. The letter shall direct the court reporter to indicate the portions designated as Protected Information and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the fifteen (15) day period as “Protected – Subject to Further Protective Review.” Such transcripts will be treated as Protected Information and shall be fully subject to this Protective Order, until after the expiration of the fifteen (15) days after the transcript was made available by the court reporter. If the Producing Party does not send a designation letter within the fifteen

(15) day period, then the transcript will be not be treated as “PROTECTED INFORMATION” unless upon application to the Court, the Court orders otherwise. The parties may agree to a reasonable extension of the fifteen (15) day period or may seek an extension from the Court for sending the designation letter.

18. A party may not file in the public record in this action any “PROTECTED INFORMATION” without written permission from the Supplying Party or a court order secured after appropriate notice to the parties. Material or information designated as “PROTECTED INFORMATION” under this Stipulated Protective Order shall not be used or disclosed by any party, or their counsel or any person acting on his/her behalf to any other persons except as provided for hereinafter, and shall not be used for any business or competitive purpose, or for any other purposes whatsoever, other than the preparation and trial of this action and any appeal in connection with this action.

19. In the absence of written permission from the Supplying Party or an order of the Court, material or information designated as “PROTECTED INFORMATION” under this Stipulated Protective Order may only be shown and delivered to the following people:

- a. Counsel for the Parties, including in-house for Defendants, and all employees of such counsel who have responsibility for assisting in the preparation and trial of this action or any appeal herein;
- b. Any attorney of record for plaintiffs in other pending U.S. litigation alleging personal injury or economic loss arising from the alleged use, purchase, or payment of Xarelto for use in such other Xarelto action, provided that the proposed recipient is: (a) already operating under a Protective or Confidentiality Order in another jurisdiction where the



Xarelto action is pending; or (b) agrees to be bound by this Order and executes the Acknowledgment that is attached hereto as Exhibit A;

- c. The Parties to the extent required for assisting in the preparation and trial of the case or any appeal herein. To the extent such disclosure is made, such Party shall be advised of, shall become subject to, and shall agree in advance of disclosure to, the provisions of this Stipulated Protective Order;
- d. The Court, any Special Master appointed by the Court and court personnel (including the court having jurisdiction over any appeal);
- e. Court reporters used in connection with the litigation;
- f. Any person who (i) wrote or received a copy of the document before it was furnished in this litigation, or (ii) was present or participated in a meeting or discussion of the protected information before it was furnished in this litigation;
- g. Any mediators, secretaries, paraprofessional assistants, and other employees of such mediators who are actively engaged in assisting the mediators in connection with this matter;
- h. Employees of outside copying, document imaging, litigation and trial support, and facsimile services;
- i. 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 (including undisclosed consulting experts), provided that the proposed

recipient executes the attestation attached as Exhibit A. A copy of each executed acknowledgement shall be maintained for Plaintiff's consultants or experts by Plaintiff's Liaison Counsel and for Defendants' consultants or experts by Counsel for Defendants during the course of the litigation. At the conclusion of the litigation, counsel for Receiving Party shall confirm in writing with counsel for Supplying Party that it will have any documents designated as "PROTECTED INFORMATION" or "HIGHLY PROTECTED INFORMATION" that were provided to consultants or experts returned to counsel for the Receiving Party.

- j. To the extent the Defendants desire that any former employee whose deposition is to be taken in this matter execute the Acknowledgement attached as Exhibit A, it shall be the Defendants' burden to obtain such an agreement prior to the deposition. If a former employee refuses to execute the Acknowledgment, the parties will meet and confer on the issue. If the parties cannot reach an agreement and the Defendants continue to desire to preclude the former employee from receiving "PROTECTED INFORMATION" at his or her deposition, the Defendants shall move for a protective order in a timely fashion so that the issue may be resolved by the Court prior to the deposition. Without such an additional protective order, nothing in this Order shall prevent Plaintiffs' Counsel from showing "PROTECTED INFORMATION" to the witness at the deposition of any former employee of Defendants who currently works for a company that may otherwise preclude the receipt of "PROTECTED INFORMATION"

by that witness had he or she had not been formerly employed by Defendants. If the Receiving Party intends on disclosing “PROTECTED INFORMATION” to a former employee outside of a deposition, trial or other formal proceeding under oath, the former employee must execute the Acknowledgment attached as Exhibit A prior to disclosure.

- k. Disclosure may be made to witnesses or deponents in the course of this litigation if such person or persons execute the Acknowledgement that is attached as Exhibit A.
- l. The Parties will continue to meet and confer regarding the disclosures to plaintiffs’ prescribing and treating physicians, nurse practitioners, or other medical professionals who treated plaintiffs (and their respective staffs) and the conditions upon which those disclosures may be made outside of a deposition.

20. In addition to the persons and entities identified above, material or information designated as “PROTECTED INFORMATION – HIGHLY PROTECTED” under this Stipulated Protective Order may only be disclosed to the following individuals in the manner set forth below:

- a. As used herein, a “competitor” shall be defined as any pharmaceutical company that manufactures or has as one of its products a new oral anticoagulant (“NOAC”) indicated for the treatment of reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, treatment of DVT, treatment of PE, reduction in the risk of recurrence of DVT and/or PE following

initial 6 months treatment for DVT and/or PE, or prophylaxis of DVT, which may lead to PE, in patients undergoing knee or hip replacement surgery.

- b. Subject to Paragraph 19(j) above, prior to disclosure to anyone who is, independent of this litigation a current director, officer, employee of, or counsel for a competitor, or anyone who at the time of disclosure is pursuing an opportunity to become an employee, officer, or director of any competitor of Defendants;
- c. the Receiving Party shall identify the Bates range of documents that may be provided to such person without disclosing the identity of the person. Within fourteen (14) days of the disclosure of the Bates range of documents, any party in good faith may deem any document in the above Bates range as a document that may not be disclosed to such person if that party considers the document to contain information that if potentially disclosed to a competitor of Defendants, such disclosure would cause Defendants significant competitive harm. If such a designation is not made within fourteen (14) days, the documents in the Bates range may be provided to the individual pursuant to this Stipulated Protective Order so long as Exhibit A is signed as set forth above. A party may object to the designation of non-disclosure above within fourteen (14) days of the designation.

21. All counsel shall keep all material or information designated as “PROTECTED INFORMATION” which is received under this Stipulated Protective Order within its exclusive possession and control, except as provided in paragraphs 19 and 20, and shall take reasonable steps to maintain such material in a secure manner.

22. Any person having access to material or information designated as a “PROTECTED DOCUMENT” under this Stipulated Protective Order, including consultants and experts, are permitted to make copies, extracts, summaries, or descriptions of the material or information or any portion thereof as necessary for the preparation and trial of this litigation.

23. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted shall be protected, regardless of whether the document containing such names is designated as “PROTECTED INFORMATION”. No such person shall be contacted, either directly or indirectly, based on the information so disclosed without the express written permission of the Supplying Party.

24. This Protective Order does not address the offering of Protected Information in evidence at trial or any court hearing, but nothing contained in this Protective Order shall preclude any party from moving the Court at an appropriate time for an order that evidence be received *in camera* or under other conditions to prevent unnecessary disclosure.

25. The Parties will use the following procedure for submitting to the Court papers consisting of, relating to, containing, incorporating, reflecting, describing or attaching Protected Information: any such material shall be filed in a sealed envelope, labeled with the case name, case number, the motion to which the documents relate, and a listing of the titles of the documents in the envelope, and shall bear the legend: THIS DOCUMENT CONTAINS PROTECTED INFORMATION COVERED BY A PROTECTIVE ORDER OF THE COURT AND IS SUBMITTED UNDER SEAL PURSUANT TO THAT PROTECTIVE ORDER. THE PROTECTED CONTENTS OF THIS DOCUMENT MAY NOT BE DISCLOSED WITHOUT EXPRESS ORDER OF THE COURT. Such material shall be kept under seal until further order

of the Court; however, such materials shall only be available to the Court and counsel of record, and to all persons entitled to receive such information under the terms of this Order. When serving such material, the parties shall select the “Sealed, electronic” option to ensure that on-line access is restricted as contemplated by this Order. That parties shall take reasonable steps to minimize such sealing.

26. Within seven (7) days of the submission of any material under seal, the parties shall confer to determine if the Producing Party objects to the filing of the Protected Information in unsealed form. To the extent of the parties’ agreement concerning the treatment of the Protected Information, the filing party may file the subject materials in unsealed form. To the extent the parties are unable to reach agreement, either party may file a motion to address the appropriate treatment of the subject materials. On such motion, the Supplying Party shall have the burden of proving the material is Protected Information. The material shall remain sealed unless the Court orders otherwise.

27. When submitting deposition testimony pursuant to the previous Paragraph that has been designated as Protected Information, the submitting party shall submit, to the extent reasonably possible, only those pages of the deposition transcript that are cited, referred to, or relied on by the submitting party.

28. If another court or an administrative agency subpoenas or otherwise orders production of “PROTECTED INFORMATION” obtained under this Stipulated Protective Order, the person to whom the subpoena or other process is directed shall promptly notify liaison counsel for the designating party in writing via electronic and overnight delivery of all of the following: (1) the “PROTECTED INFORMATION” that is requested by the subpoena; (2) the date on which compliance with the subpoena is requested; (3) the location at which compliance

with the subpoena is requested; (4) the identity of the party serving the subpoena; and (5) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or other designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena or other process has been issued. In no event shall “PROTECTED INFORMATION” be produced before the expiration of fifteen business days after written notice to counsel for the designating party unless required to do so by the order seeking the documents. Furthermore, the person receiving the subpoena or other process shall cooperate with the producing party in any proceeding related thereto.

29. If any party learns of any unauthorized disclosure of documents or information designated as “PROTECTED INFORMATION” by Parties or counsel in this litigation, it shall immediately inform the Court in writing of all pertinent facts relating to such disclosure.

30. Inadvertent production of any document or information without a designation of “PROTECTED INFORMATION” will not be deemed to waive a later claim to its protected nature or preclude a party from designating said document or information as “PROTECTED INFORMATION” pursuant to this Order at a later date. Any party may designate as “PROTECTED INFORMATION” or withdraw “PROTECTED INFORMATION” designation from any material that it has produced, provided, however, that such re-designation shall be effective only as of the date of such re-designation. A party must treat such documents and things with the noticed level of protection from the date such notice is received. Such re-designation shall be accomplished by notifying counsel for each party in writing of such re-designation and providing replacement images bearing the appropriate description. Upon receipt of any re-designation and replacement image that designates material as “PROTECTED INFORMATION,” all Parties shall (1) treat such material in accordance with this Order; (2) take

reasonable steps to notify any persons known to have possession of any such material of such re-designation under this Stipulated Protective Order; and (3) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Stipulated Protective Order .

31. Inadvertent production of documents or information (hereinafter “Inadvertently Produced Documents”) subject to work-product immunity, the attorney-client privilege, or other legal privilege protecting information from discovery shall not constitute a waiver of the immunity or privilege, provided that the party producing the documents shall notify all Parties in writing within a reasonable period of time from the discovery of the inadvertent production. If such notification is made, such Inadvertently Produced Documents and all copies thereof shall, upon request, be returned to the party making the inadvertent production, all notes or other work product of the Receiving Party reflecting the contents of such materials shall be destroyed, and such returned or destroyed material shall be deleted from any litigation-support or other database. If the party receiving the production disputes in writing the claim of privilege or the claim of inadvertence they 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. The party receiving such Inadvertently Produced Documents may, after receipt of the notice of inadvertent production, move the Court to oppose the request for return of the subject materials. If the Receiving Party’s motion is denied, the Receiving Party shall promptly comply with the immediately preceding provisions of this paragraph or such other directives as may be issued by the Court. 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.

32. Upon final termination of this action, whether by judgment, settlement or otherwise, counsel for the Receiving party shall destroy or return to counsel for the Designating party all “PROTECTED INFORMATION” in their possession or subject to their control (including but not limited to materials furnished to consultants and/or experts), and execute an affidavit or declaration affirming based on personal knowledge that all such “PROTECTED INFORMATION”, including copies upon which any notes have been made, have been destroyed or returned.

33. The terms of this Stipulated Protective Order shall survive and remain in effect after the termination of this lawsuit. To the extent permitted by local rules and governing law, counsel for the designating party shall be entitled to contact the Court to claim and retrieve documents containing “PROTECTED INFORMATION” that were submitted to the Court.

34. Any party for good cause shown may apply to the Court for modification of this Stipulated Protective Order, or the Order may be modified by consent of the Parties in writing. This Stipulated Protective Order shall remain in full force and effect and each person subject to this Order shall continue to be subject to the jurisdiction of this Court, for the purposes of this Order, in perpetuity, and the Court shall not be divested of jurisdiction of any person or of the subject matter of this Order by the occurrence of conclusion of this case, or by the filing of a notice of appeal, or other pleading which would have the effect of divesting this Court of jurisdiction of this matter generally.

The Court approves the aforesaid stipulations and memorializes them in this Court order.

New Orleans, Louisiana this 4th day of May, 2015.

A handwritten signature in black ink, reading "Eldon C. Fallon". The signature is written in a cursive style with a large initial "E" and a distinct "C" before the last name.

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United States District Judge