UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN) PRODUCTS LIABILITY LITIGATION	**MDL No. 2592**
	SECTION L
THIS DOCUMENT RELATES TO:	**JUDGE ELDON E. FALLON**
ALL CASES	**MAGISTRATE NORTH**

IN THE FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
PHILADELPHIA COURT OF COMMON PLEAS
TRIAL DIVISION – CIVIL

IN RE: XARELTO® PRODUCTS LIABILITY LITIGATION	**January 2015**
	No. 002349
This document relates to all actions	

AGREEMENT BETWEEN MDL PSC, PCCP LIASION COUNSEL AND DEFENDANTS ON ADDITIONAL DISCOVERY

Whereas, Plaintiffs and Defendants ("Parties") disagree as to the remaining allowable discovery on Defendants Bayer and Janssen in the MDL and PCCP, the parties have reached the following compromise.

A. In exchange for Defendants' agreement to produce the following discovery, Plaintiffs shall agree to seek no additional discovery on such matters in the MDL or PCCP.

B. The parties further agree there shall be no additional discovery in the MDL or PCCP beyond the specific discovery set forth in this agreement without a prior showing of good cause.

C. PCCP Lead Counsel acknowledges and agrees to the terms of this agreement.

1) **Discovery related to the 2017 Kreutz/Kubitza article.** Bayer shall Agree to supplement the Kubitza custodial from the date of prior production collection thru December 31, 2017 in order to produce any drafts of the 2017 Kreutz/Kubitza article,

including any emails transmitting such drafts along with any emails contained within such strings, i.e., related emails, including replies and forwards. There is no discovery from Janssen on this topic or further discovery from Bayer; Plaintiffs reserve the right to ask questions in this area during future fact and expert depositions

2) **Health Canada & EMA discovery.** Bayer shall produce the Xarelto Health Canada regulatory file and correspondence file and update the Xarelto EMA contact reports since the last complete EMA contact report productions through December 31, 2017 regarding the following issues:

a. VTE Recurrence Prevention indication, including communications related to CHOICE
b. Use of Xarelto in patients taking dual antiplatelet therapy (DAPT), triple therapy, including the ATLAS TIMI 46, ATLAS TIMI 51, and the PIONEER studies.
c. The use of PT to measure the anticoagulation status of a patient under any circumstances.

There is no discovery from Janssen on this topic; Plaintiffs reserve the right to ask questions in this area during the depositions authorized in this Agreement.

3) **Strikethrough/Preemption Discovery.** Janssen and the PSC negotiated this item, with the remaining issues resolved by the MDL Court in its April 24, 2018 Order & Reasons. There is no discovery against Bayer on this topic.

4) **Discovery related to the draft manuscript produced as Xarelto_*BHCP*_11884161 (Lensing Depo. Exhibit 86) including any and all internal and external communications, drafts, final manuscripts, submissions to journals, underlying data and any analyses of such data:** Bayer will provide a sworn interrogatory answer as to the status of this manuscript. There shall be no separate deposition on this topic and there shall be no further discovery on this topic beyond the sworn interrogatory answer. There is no discovery from Janssen on this topic; Plaintiffs reserve the right to ask questions in this area during the depositions authorized in this Agreement.

5) **Discovery related to the secure email system identified as the source of emails to and from the FDA in the Mingo trial by counsel for Janssen.** Janssen has produced FDA emails from custodians -requested by plaintiffs for the time period covered by the prior production. Janssen shall also produce such emails from Huy Truong, along with the custodial file of Truong, -including documents related to the VTE Recurrence Prevention and VTE Treatment indications and the EINSTEIN CHOICE study in the custodial file. There is no discovery against Bayer on this topic.

6) **Discovery related to Dr. Lensing's e-mail account and the preservation thereof, Dr. Lensing's personal e-mail account, the planet.nl address, Dr. Lensing's laptop and its hard drive, and the existence of e-mail and Xarelto related data on such laptop** Agreed discovery shall consist of the following

a. Bayer agrees to produce discovery deemed responsive under the existing ESI Protocol for the time period applicable to Lensing's initial production from three additional custodians selected by the PSC:
    i. Corinna Weidt;
    ii. Akos Ferenc Pap; and
    iii. Gerlind Holberg
b. Bayer agrees to provide a statement regarding the retention period for Dr. Lensing's Inbox, Sent Items and Deleted
c. Bayer agrees to produce e-mail messages from Dr. Lensing's personal account deemed responsive under the existing ESI Protocol for the time period applicable to Lensing's initial production. To the extent that Bayer can manually de-duplicate from existing production documents, Bayer will provide Bates identifiers or will otherwise produce documents if not previously produced.
d. Bayer agrees to provide a statement on the results of the PC drive search.

There is no discovery on Janssen on this topic. Neither party is waiving any rights to pursue potential appropriate and relevant relief or remedies that emanate from this issue.

7) **Discovery related to the EINSTEIN CHOICE study, and the regulatory approval of the 10mg dose for VTE Recurrence prevention.** Bayer and Janssen shall produce custodial files from a narrow set of custodians defined as 4 Bayer custodians and 1 additional Janssen custodian related to EINSTEIN CHOICE, and regulatory approval of the study, and the 10mg dose for VTE recurrence prevention indication (Plaintiffs already have Mr. Truong's custodial files from paragraph 5 above). Plaintiffs and Defendants shall agree on a narrow list of search terms related to this topic. Plaintiffs shall name the 5 custodians and their proposed list of search terms by seven business days from the entering of this agreement. If the custodians were previously produced, the collection and production shall only be a supplement to the prior production from the date of prior production collection thru December 31, 2017. Production shall be on a rolling basis, beginning 60 days after agreement on the agreed search terms, or immediately after the Cooney trial is over, whichever is later, and shall be completed by 120 days after agreement on the search terms.

8) **Discovery related to the use of Xarelto in patients on DAPT, as well as discovery related to the PIONEER study and related manuscripts:** Bayer and Janssen shall produce custodial files from a narrow set of custodians up to 4 custodians (2 from Bayer and 2 from Janssen) related to use of Xarelto with DAPT, PIONEER study, and regulatory approval of the study. Plaintiffs and Defendants shall agree on a narrow list of search terms related to this topic. Plaintiffs shall name the 4 custodians and their proposed list of search terms by seven business days from entering of this agreement. If the custodians were previously produced, the collection and production shall only be a supplement to the prior production from the date of prior production collection thru December 31, 2017. Production shall be on a rolling basis beginning 60 days after agreement on the agreed search terms, and shall be completed by 120 days after agreement on the search terms.

9) **Depositions on Paragraphs 7 & 8.** With respect to the topics addressed in Paragraphs 7 & 8, above, Plaintiffs shall be entitled to take 6 total depositions; 3 Bayer, and 3 Janssen, either as custodial depositions or 30(b)(6) at Plaintiffs' choice, with the following limitations:

a. The Bayer corporate deposition agreed to in the Cooney case in PCCP, per Paragraph 2 of the April 20, 2018 Stipulation and Order, shall count as one of these depositions; that deposition is currently set to occur in mid-July in Europe. Under the current schedule in this agreement, the custodial productions will not be completed prior to that deposition. As such, if plaintiffs proceed with the corporate designee/30(b)(6) deposition in the Cooney case prior to the completion of the custodial file productions in this agreement, plaintiffs shall not be entitled to any additional corporate designee/30(b)(6) depositions of Bayer on the topics covered by the Cooney deposition.
b. The depositions shall be limited to 7 hours (if in English).
c. Beyond the Cooney deposition, no other depositions covered under this paragraph shall occur prior to the Cooney trial.

10) **Updating Discovery.** Plaintiffs may select up to six (6) custodians – no more than 3 Bayer custodian and 3 Janssen custodians -- on January 1, 2019 and January 1, 2020 -- for updating their prior custodial file productions. The parties will separately negotiate the applicable search terms and the production times based on the volume of the files at issue. The collection and production shall only be a supplement from the date of prior production collection. The parties will meet and confer over admissibility requirements (authenticity, foundation, hearsay exception, and statements of a party-opponent) related to these production, in an effort to avoid the need for additional depositions. There will be no depositions of these custodians or corresponding 30(b)(6) depositions without a showing of good cause.

11) **Admissibility Requirements.** Plaintiffs and Defendants will meet and confer over admissibility requirements (authenticity, foundation, hearsay exception, and statements of a party-opponent) related to prior document productions. Resolution of this topic, including, if necessary, motion practice will not expand the scope of additional discovery set forth in this agreement.

Date: June 15, 2018

Respectfully submitted,

MDL PLAINTIFFS' STEERING COMMITTEE	**PCCP PLAINTIFFS' LIAISON COUNSEL**
By: /s/ *Andy D. Birchfield Jr.* Andy D. Birchfield, Jr. (Co-Lead Counsel) 234 Commerce Street Post Office Box 4160 Montgomery, Alabama 36103-4160 Phone: (334) 269-2343 Fax: (334) 954-7555 Andy.Birchfield@BeasleyAllen.com By: /s/ *Brian H. Barr* Brian H. Barr (Co-Lead Counsel) 316 Baylen Street, Suite 600 Pensacola, FL 32502 Phone: (850) 435-7045 Fax: (850) 436-6044 bbarr@levinlaw.com	By: /s/ *Michael M. Weinkowitz* Michael M. Weinkowitz, Esquire Levin Sedran & Berman 510 Walnut Street, Suite 500 Philadelphia, PA 19106 mweinkowitz@lfsblaw.com By: /s/ *Daniel N. Gallucci* Daniel N. Gallucci, Esquire NastLaw LLC 1101 Market Street, Suite 2801 Philadelphia, PA 19107 dgallucci@nastlaw.com By: /s/ *Laura Feldman* Laura Feldman, Esquire Feldman & Pinto PC 6706 Springbank Street Philadelphia, PA 19119 lfeldman@feldmanpinto.com
Defendants Janssen Pharmaceuticals, Inc. and Janssen Research & Development, LLC DRINKER BIDDLE & REATH LLP By: /s/ *Susan M. Sharko* Susan M. Sharko Drinker Biddle & Reath LLP 600 Campus Drive Florham Park, NJ 07932-1047 Telephone: (973) 549-7000 susan.sharko@dbr.com Rodney M. Hudson DRINKER BIDDLE & REATH LLP 50 Fremont Street, 20th Floor San Francisco, CA 94105-2235 Telephone: (415) 591-7500 Rodney.hudson@dbr.com Chanda A. Miller Drinker Biddle & Reath LLP One Logan Square, Suite 2000 Philadelphia, PA 19103-6996 Telephone: (215) 988-2500 Chanda.Miller@dbr.com IRWIN FRITCHIE URQUHART & MOORE LLC By: /s/ *James B. Irwin*	**Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG** ARNOLD & PORTER LLP By: /s/ *Andrew K. Solow* Andrew K. Solow Steven Glickstein ARNOLD & PORTER LLP 250 West 55th Street New York, New York 10019-9710 Telephone: (212) 836-8485 andrew.solow@arnoldporter.com steven.glickstein@arnoldporter.com William Hoffman ARNOLD & PORTER LLP 601 Massachusetts Ave., NW Washington, D.C. 20001 Telephone: (202) 942-5000 william.hoffman@arnoldporter.com CHAFFE MCCALL L.L.P. By: /s/ *John F. Olinde* John F. Olinde Chaffe McCall L.L.P. 1100 Poydras Street, Suite 2300 New Orleans, LA 70163

James B. Irwin
Kim E. Moore
Irwin Fritchie Urquhart & Moore LLC
400 Poydras Street, Suite 2700
New Orleans, LA 70130
Telephone: (504) 310-2100
jirwin@irwinllc.com

Telephone: (504) 585-7241
olinde@chaffe.com

/s/ *Albert G. Bixler*
ECKERT SEAMANS CHERIN & MELLOTT, LLC
Albert G. Bixler
abixler@eckertseamans.com
Attorney Identification No. 45639
Leslie A. Hayes
lhayes@eckertseamans.com
Attorney Identification No. 35975
Two Liberty Place
50 South 16th Street, 22nd Floor
Philadelphia, PA 19102
Telephone: (215) 851-8400
Facsimile: (215) 851-8383

/s/ *Judy L. Leone*
DECHERT LLP
Robert C. Heim
robert.heim@dechert.com
Attorney Identification No. 15758
Judy L. Leone
judy.leone@dechert.com
Attorney Identification No. 41165
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
Telephone: (215) 994-2570
Facsilime: (215) 665-2570