GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP

WRITER'S DIRECT DIAL
312.881.5947
scook@goldmanismail.com

June 5, 2017

BY EMAIL AND ECF

Honorable Paul A. Engelmayer
United States District Judge
Southern District of New York
Thurgood Marshall
United States Courthouse
40 Foley Square
New York, NY 10007

***Re: In re Mirena IUS Levonorgestrel-Related Products Liability Litigation (No. II),* 17-MD-2767 (PAE), and 17-MC-2767 (PAE)**

Dear Judge Engelmayer:

Pursuant to this Court's Order No. 1, the parties jointly submit this letter concerning the proposed agenda for the Initial Conference on June 13 and the parties' positions on the four subjects identified in Order No. 1.

A. Proposed Agenda

The parties' proposed agenda for the June 13 conference is as follows:

I. Introductions

II. Plaintiffs' Lead and Liaison Counsel Structure: The parties set forth their positions in letters submitted on May 19 and 26.

III. Brief Explanation of the Case by Plaintiffs and Defendants

A. Relationship to MDL 2434
B. Prior Litigation History

IV. Production of Pre-MDL 2767 Discovery, including Electronically Stored Information ("ESI"), Deposition Transcripts and Expert Reports: Defendants are prepared to produce pre-MDL 2767 discovery to Plaintiffs upon the entry of the orders discussed below.

V. Proposed Schedules and Case Trajectory: The parties' proposed schedules are discussed below and attached as Exhibits 1 and 2.

VI. **Proposed Orders Related to Document Production (Confidentiality Stipulation and Protective Order; Protocol for Document Production Format; and Order Regarding Documents Claimed to Be Privileged)**: The parties are currently discussing these proposed Orders.

VII. **Document Preservation Order**: The parties submitted letters to the Court on May 10, 15 and 16 setting forth their positions on preservation.

VIII. **Proposed Direct Filing Order**: The parties have agreed on a proposed Order regarding direct filing, which was filed on May 11 (Exhibit 3).

IX. **Master Pleadings**: The parties are currently discussing a procedure for a Master and Short-Form Complaint and Master Answer.

X. **Proposed Order Related to Streamlined Service of Foreign Defendants**: The parties are currently discussing this proposed Order.

XI. **Plaintiff and Defendant Fact Sheet and Timing**: The parties are currently discussing Fact Sheets and related Orders.

XII. **Schedule for Future Status Conferences**: The parties request that the Court calendar regular conferences for the next six months.

B. Discovery

The parties' positions on discovery are set forth below.

Interim PSC's Position

a. Production of Discovery Already Taken. The Bayer Defendants have agreed to make "discovery already taken" available to the Interim PSC, but only if the Interim PSC will agree to be bound by several orders (Confidentiality and Protective Order, Electronically Stored Information Protocol, and Order Regarding Documents to Be Claimed as Privileged/Protected) proposed by the Bayer Defendants. While the Bayer Defendants have suggested that they may be agreeable to "minimal changes" in the proposed orders, they have also indicated that they will not entertain any proposal that substantively alters any provision of their proposed orders. The Interim PSC members, however, believe that substantive changes to the protective order are necessary.

The Interim PSC also believes that it is unnecessary at this time to execute the Bayer Defendants' ESI Protocol and Order Regarding Documents to Be Claimed as Privileged/Protected as a prerequisite to receiving discovery that has already been gathered by the Bayer Defendants and which has already been marked as privileged/protected. In the normal course, ESI orders and privilege protocol are negotiated *before* the documents are collected and produced. In essence, the Bayer Defendants seek to have the Interim PSC bless their methods after the fact in hopes of binding the Interim PSC to those same methods for all future document productions.

The Interim PSC has proposed the attached Confidentiality and Protective Order to govern its members' handling of the already existing production, as well as all future productions. *See* Exhibit 4. As it relates to future productions, the Interim PSC intends to continue discussions with the Bayer Defendants in hopes of achieving an agreed upon ESI Protocol and process for handling attorney-client privilege and work product designations.

b. Anticipated Discovery Disputes

As the Court points out, the litigation efforts of the Jones Ward firm and the Miller DellaFera firm reveal significant areas of dispute with the Bayer Defendants. However, MDL 2767 involves many additional firms and clients who have conducted no discovery and have never been given access to the confidential case documents and depositions from the pre-MDL 2767 litigation. Therefore, it is difficult for the Interim PSC to anticipate all anticipated discovery disputes.

i) Initial ESI Production

The Bayer Defendants' ESI production consists of documents preserved, gathered, and collected in 2013 for purposes of MDL 2434, before a single PTC/IH case had been filed. As far as the Interim PSC is aware, the Bayer Defendants have engaged in no efforts to prepare a separate production for the PTC/IH litigation and have engaged in only very minimal supplementation of the production over the last three years in the individual PTC/IH cases.

As the Federal Rules of Civil Procedure envision, the Interim PSC has attempted to engage the Bayer Defendants in discussions about the sources of potential ESI and how this proposed production of documents was preserved, gathered, and collected for purposes of the PTC/IH litigation. The Bayer Defendants refuse to engage or entertain any questions from the Interim PSC, except to point to correspondence that the Bayer Defendants sent to the plaintiffs' leadership in MDL 2434, broadly explaining their methods. *See* Exhibit 5 (November 19, 2013 Letter).

The Interim PSC has many questions and concerns about the ESI that the Bayer Defendants intend to produce. In fact, using the November 2013 letter as a guide, the Interim PSC articulated the following questions to the Bayer Defendants on May 30, 2017 (*see* Exhibit 6) about their "preservation, collection and review" process but the Bayer Defendants have refused to answer:

1) Who were the litigation holds (2009, 2011, 2012) issued to?
   a) How was it determined who received the hold letter?
   b) Did it go to all Women's HealthCare or Female HealthCare employees?
   c) Were documents gathered from each of the employees who received the hold letter?
   d) Were documents produced from each employee who received the hold letter?
   e) Were documents gathered or preserved at the time of the hold or were the employees trusted to preserve the documents until they were gathered?

f) Were the documents gathered at supplemental periods?

2) Who comprised the "limited group of employees" who received the 2009 hold letter?
   a) The letter says it was limited to "Mirena and papilledema." Was it really that narrow?
   b) What was the exact instruction to employees in the 2009 hold letter?

3) At the "interview" stage, how was it determined who had been "significantly involved with Mirena"?
   a) Why such a narrow definition?
   b) What does that mean?
   c) What is the metric used for determining significant involvement?
   d) Why not significant involvement with WHC or FHC products or contraceptive products or LARCS?
   e) Have documents been gathered and/or preserved from those who were not "significantly involved" with Mirena?
   f) Have documents been produced from anyone who was not significantly involved?

4) Were the initial documents subjected to a "relevance" review?
   a) When?
   b) What were the parameters for determining relevance?
   c) Who did such a review?
   d) Were the reviewers aware of the PTC/IH issues?

5) Other than search terms in Relativity, were the documents subjected to any other sort of review or culling prior to being sent to Kroll Ontrack?
   a) Which collections of potentially discoverable data comprised the corpus of documents upon which the Relativity key word search was applied?
   b) Were document added to that corpus over time?
   c) If documents were added to the corpus, was the Relativity search re run?

6) "When a decision is made to collect an employee's custodial file …"
   a) What is the decision-making process?
   b) Who makes the decision?

7) What email boxes were collected?
   a) Employees only?
   b) What about group email boxes?

8) Does all of the Robocopy data still exist?
   a) If so, how much data was gathered?

b) Of the data gathered, how much has been produced?

9) Were sources of structured data or databases gathered?
   a) Which sources of structured data or databases?
   b) How were such decisions made?
   c) What was the process for searching sources of structured data or databases for information?
   d) For each source of structured data or database, was the full structure or database preserved?
   e) For each source of structured data or database, what methods were used for searching the source or database (i.e., keywords, concept searches, etc.)?
   f) For each source of structured data or database, how was the information collected and transferred to a review platform?

10) The November 13, 2013 letter notes that the documents were "deduplicated" and then loaded into the Relativity review platform prior to being sent to Kroll Ontrack for review. While in Relativity, the letter states that the documents were subjected to "keyword" searches.
   a) Who performed the keyword searches?
   b) Prior to subjecting the documents to a keyword search method, what was the volume of data?
   c) After subjecting the documents to a keyword search method, what was the volume of data sent to Kroll Ontrack?
   d) Was the de-duplication process looking for exact duplicates or did it include near duplicates?

11) After being sent to Kroll Ontrack, the November 13, 2013 letter indicates that the documents were subjected to a second "de- duplication" process.
   a) Why were the documents again de-duplicated?
   b) What was the volume of data before the de-duplication process?
   c) What was the volume of data after the de-duplication process?
   d) Was the de-duplication process looking for exact duplicates or did it include near duplicates?

12) Following the de-duplication process performed by Kroll Ontrack,the November 13, 2013 letter indicates that the documents were placed in Kroll Ontrack's review platform, known as Inview.
   a) Were the documents subjected to another round of keyword searches before production in MDL 2434?
   b) Were the documents subjected to a "relevance review" at this time, before being produced in MDL 2434?

c) Were the documents subjected to any technology assisted review or concept searching in the Inview review platform?
d) Were any documents contained in the Inview review platform withheld in MDL 2434 due to a determination that such documents were not "relevant" to the litigation?

13) Have the plaintiffs in the PTC/IH litigation received an "exact copy" of the documents produced in MDL 2434?
a) Before being produced in the PTC/IH litigation, was the original corpus of preserved documents subjected to any additional search term reviews?
b) Before being produced in the PTC/IH litigation, was the original corpus of documents subjected to a new relevance review, separate from the relevance review performed for the MDL 2434 production?

14) For the custodial files produced in both MDL 2434 and those produced in the individual PTC/IH litigations, has every custodial file has been updated and upplemented since originally produced?
a) If not, which custodial files have been supplemented, the date of the supplementation(s) and the latest date for which documents have been gathered and produced for the custodian?
b) In preparing any supplementation(s), was the same process used for the "preservation, collection and review" as the original MDL 2434 production?

The Interim PSC believes these are legitimate questions to which the plaintiffs should be entitled to answers. Should the Bayer Defendants not want to answer these questions at this stage of the litigation, the Interim PSC believes a FRCP 30(b)(6) deposition is necessary.

The second issue with the ESI can be characterized as a "search term" issue. Again, none of the lawyers involved in MDL 2767 were involved in the creation of the "search terms" used in MDL 2434. The "search terms" did not even account for issues clearly relevant to the PTC/IH litigations, including the signs, symptoms, and injuries associated with PTC/IH.

Search terms are inherently unreliable. When combined with the failure to include even the most relevant search terms for a particular litigation, the results can be nothing short of abysmal. The Interim PSC strongly encourages the Bayer Defendants to produce the original document corpus, plus all supplementations, (with an appropriate "clawback" agreement for privileged materials) to allow the Interim PSC to conduct "concept searches" and "technology assisted review" tools to discover the documents relevant to this litigation. Alternatively, the Interim PSC proposes that the parties cooperatively engage in the use of such tools to help streamline the time and costs associated with discovering the relevant case documents.

The third issue can be characterized as an "improper redaction" issue. The documents produced in the individual PTC/IH cases contain hundreds of thousands of redactions for categories such as: Redacted: Manufacturing/CM&C and Redacted: Other Bayer Product. Such redactions were made despite the fact that the parties to the individual PTC/IH cases entered into an agreed protective order intended to protect such information from disclosure to third parties outside the litigation. With such protective measures in place, the Bayer Defendants have no basis to redact or withhold such information. The Interim PSC respectfully requests that any such redactions be removed from documents produced in MDL 2767.

The fourth issue involves the Bayer Defendants' overuse of the confidentiality designation. It appears as though the Bayer Defendants have designated every single document produced to date as "Confidential" and subject to the protective and confidentiality order. Certainly, the Bayer Defendants cannot reasonably believe that every document they have produced is "confidential" within the meaning of the Federal Rules of Civil Procedure. Indeed, with the agreement of the Bayer Defendants, numerous documents have been publicly filed and used in individual PTC/IH litigations. Overuse of confidentiality designations places undue costs and burdens on the courts, their respective clerks' offices, and the parties. Therefore, the Interim PSC respectfully requests that the Bayer Defendants begin the process of de-designating those documents that are not properly designated as confidential pursuant to the Federal Rules of Civil Procedure.

Finally, another area of concern about the initial production is the lack of audio and video files. Despite the fact that prior discovery has revealed the existence of audio and video files, no such files have ever been produced. For instance, the Bayer Defendants engaged in television advertising for the Mirena product. Rather than producing any videos, the Bayer Defendants claimed that any such videos would likely be found on YouTube. This is not an appropriate response to a discovery request. The Interim PSC also anticipates requesting relevant audio and video files. If such files are not produced, this issue will need to be addressed with the Court.

ii) Scope of Relevant Information

As the Interim PSC discussed in its May 15th letter to the Court, the parties have widely different views on what is relevant for purposes of discovery in this case.

iii) Requests for Production of Documents and Other Things

The individual plaintiffs in the PTC/IH litigations served written requests for production of documents and other things. The requests were met with over 200 pages of boilerplate objections. The Interim PSC intends to serve similar requests and hope that the Bayer Defendants do not take a similar approach in this MDL. To the extent that the Bayer Defendants intend to do so, this issue will need to be raised with the Court at the appropriate time.

Defendants' Position:

With the production of more than 11 million pages of discovery, certain supplements of key non-custodial sources and several custodial files, and the removal of certain redactions requested by Plaintiffs, Plaintiffs will have all the evidence they need to understand the claims and defenses in this litigation. Outside of the supplements and unredacted documents, additional generic discovery in this litigation is not proportional to the needs of the case and should not be permitted. The basis for Defendants' position follows:

Defendants' comprehensive 11-million-page production of Mirena-related documents and data in MDL 2434 ("Mirena I") and the New Jersey multi-county consolidated litigation ("MCL") was not limited to any alleged injury and included documents related to IIH. In Mirena I, Plaintiffs claim that the hormone in Mirena caused uterine perforation after insertion; the MCL is not limited to any injury and in fact includes 11 IIH cases. Defendants have provided details of this comprehensive Mirena collection and production to the Interim PSC on multiple occasions and have never refused to provide additional information. In short, Defendants, working with plaintiffs' attorneys and Judges Seibel and Martinotti, identified the current and former employees who were most substantially involved with Mirena generally. This group included individuals whose Mirena-related documents spanned nearly 20 years, individuals from all three defendant companies, and individuals who worked in the five major departments important in product liability cases: 1) Medical/Clinical; 2) Regulatory; 3) Pharmacovigilance; 4 Marketing; and 5) Sales. The raw custodial files of these individuals, including hard copy and ESI, were collected. There was no filtering at the collection stage. After collection, a keyword filter (see Attachment 3 to Defendants' June 5, 2017 Status Letter) was applied to the documents. Defendants designed the keywords to identify Mirena documents in the raw custodial files with no regard to any specific aspect of Mirena or alleged injury. The search terms were so broad that they captured many documents that were unrelated to Mirena. Thus, a team of attorneys reviewed the documents that were identified by the keyword search for relevancy. The focus of this review was again whether the documents were related to Mirena, with no regard to injury. The reviewers were instructed to mark a document relevant if it regarded Mirena. Exact duplicates within the custodial files were removed from the documents identified during the relevancy review and the remaining documents were produced.

At the same time, Defendants, plaintiffs' attorneys, and Judges Seibel and Martinotti worked together to identify non-custodial sources of Mirena documents. The owners/managers of those non-custodial sources were instructed to design queries that would identify Mirena-related documents without regard to any specific aspect or injury. The queries were run and the Mirena-related documents were identified and produced.

After production of the custodial and non-custodial documents, the plaintiffs in Mirena I and the MCL took 30(b)(6) depositions to determine if there were any other custodians whose files needed to be collected or non-custodial sources that needed to be mined to find missing Mirena documents. After the 30(b)(6) depositions, Defendants produced the files of additional custodians whom plaintiffs thought may have Mirena-related documents. Plaintiffs did not seek any additional non-custodial files. The additional files were collected, reviewed, and produced as described above. In all, 41 custodians' files were produced. These custodians include the Bayer employees most integral to Mirena generally,

including all regulatory, medical, and pharmacovigilance issues related to Mirena; therefore, any documents related to IIH and Mirena within their files were produced.

Defendants have produced that exact set of documents to the Jones Ward (Temporary Lead Counsel) and Miller DellaFera (Interim PSC) firms in 62 IIH/PTC cases. Never have those IIH plaintiffs filed a motion to compel arguing that Defendants' Mirena-related productions were inadequate. In fact, the adequacy of the comprehensive productions have been clearly demonstrated by those two firms' ability to litigate their cases. Jones Ward and Miller DellaFera attorneys have taken expert and fact depositions, served expert reports in 25 cases, and conducted *Daubert* and summary judgment briefing in more than ten IIH cases based substantially on the set of documents that Defendants, plaintiffs' attorneys, and Judges Seibel and Martinotti identified as described above. IIH plaintiffs have even prepared cases for trial, with Jones Ward bringing multiple cases to within weeks of trial without citing a need for additional discovery. In addition to the prior productions, Bayer, in the spirit of compromise, has offered to provide supplements of the main non-custodial sources of discovery, supplements of the custodial files of several employees significantly involved with Mirena, and documents with redactions of two other products removed.

It is clear that full discovery of Bayer's materials and witnesses related to Mirena has already been conducted. Bayer intends to make all of those materials available to Plaintiffs in this MDL as soon as the Court enters the Stipulated Confidentiality Agreement, the Document Production Protocol, and the Order on Privileged Materials (Exhibits 7, 8 and 9). Courts have entered this same or similar Confidentiality Order in the IIH cases where the comprehensive Mirena production was provided. Such an Order is required by applicable EU data protection laws before the documents can be produced. Defendants sent drafts of these proposed Orders to the Interim PSC on May 19 and asked for comments during multiple telephone calls, but the Interim PSC did not send proposed changes to the Orders until the day this letter was due. Defendants have not had the opportunity to consider these changes or meet and confer with Plaintiffs and does not believe these Orders are ripe for the Court's adjudication.

Defendants have engaged in several calls with the Interim PSC and asked Plaintiffs to identify what specific discovery they believe is lacking from prior productions. Despite the Jones Ward and Miller DellaFera firms (who collectively represent nearly three-fourths of the Plaintiffs in this MDL and are on the Interim PSC) having Bayer's discovery materials for years and litigating 25 cases through the completion of fact discovery and service of expert reports, and despite all Plaintiffs' counsel knowing which custodians were searched and the search terms used, the Interim PSC maintains they are unable to make specific discovery requests at this time. Without such requests, the Defendants are unable to inform the Court of any specific discovery disputes. Defendants stand ready to address any narrowly tailored and specific discovery requests Plaintiffs may make, but they oppose wholesale discovery of other products in this Mirena litigation. Such discovery is not necessary and is not proportional to the needs of the case.

Defendants intend to meet and confer with the Interim PSC about the issues related to ESI identified above, which were first shared with Defendants less than a week ago, but note that many of the requests call for clearly privileged information and that the requests focus on "discovery about discovery" instead of substantive discovery, which is a major step backward given the advanced stages of a large number of cases in this MDL. In addition, the Interim PSC has mischaracterized the parties'

prior discussions; for example, Defendants have not categorically refused to produce any video files; instead, Defendants asked Plaintiffs to specify which videos were seen by Plaintiffs or their healthcare providers and they have not done so. Defendants will be prepared to address any specific questions at the initial status conference, but none of these issues are ripe for the Court at this time.

C. Relationship to Prior MDL

Interim PSC's Position:

It is the position of the Plaintiffs' Interim PSC ("Interim PSC") that *In re: Mirena IUD Products Liability Litigation* (MDL 2434), overseen by Judge Seibel, has no relationship to *In re: Mirena Levonorgestrel-Related Products Liability Litigation (No. II)* (MDL 2767) other than the fact that the two MDL's involve a common product that caused substantial numbers of women to suffer an injury. Not only are the injuries claimed in MDL 2767 quite different, but the injuries were caused by the "drug" (levonorgestrel) component of the Mirena product; whereas, MDL 2434 was specifically limited to injuries caused by the "device" component of the Mirena product. Moreover, MDL 2434 specifically excluded cases that did not involve the "migration" of the device itself.

As a result, the injuries are different, the mechanism of injury is different, the experts are different, the causation issues are different, the key documents are different, and even the key witnesses are largely different.

Importantly, none of the Interim PSC members (including the proposed Co-Lead Counsel) were involved in the MDL 2434 leadership; none of the Interim PSC members (including the proposed Co-Lead Counsel) were involved in the negotiations that preceded the Bayer Defendants' preservation, collection and production of documents in MDL 2434; none of the Interim PSC members (including the proposed Co-Lead Counsel) were involved in the selection of deponents in MDL 2434. Given the substantial differences between the two cases, it is the Interim PSC's position that the MDL 2434 discovery is largely unrelated to MDL 2767.

Defendants' Position:

In Mirena I (MDL 2434), Plaintiffs claimed that Defendants failed to warn of the possibility that uterine perforation could occur after and unrelated to Mirena's insertion, which Plaintiffs called "secondary perforation" or "spontaneous migration." *In re Mirena*, 159 F.Supp.3d 396, 409 (S.D.N.Y. 2016). Plaintiffs' theory in that litigation, like this one, centered on the hormone in Mirena, levonorgestrel. Specifically, in Mirena I, Plaintiffs argued levonorgestrel causes changes in the uterus that lead to spontaneous migration. *Id*. at 428-29. Defendants challenged that position as lacking any scientific basis. Judge Cathy Seibel excluded Plaintiffs' general causation expert testimony and granted summary judgment, finding "no evidence in the record from which a jury could find that secondary perforation exists and is capable of causing Plaintiffs' injuries." *In re Mirena*, 202 F.Supp.3d 304, 327-28 (S.D.N.Y. 2016).

The fact discovery propounded in Mirena I is related to the litigation at hand. The parties engaged in generic fact discovery for nearly two years, which included an extensive document

production from 41 custodial files and numerous non-custodial/database sources. Importantly, the document production was not in any way limited to a particular injury; the search terms targeted ***any*** Mirena-related documents. Nor were the custodians whose files were produced injury-specific; instead, these custodians' work related to Mirena generally. In addition, the entire FDA regulatory file for Mirena was produced and supplemented multiple times, as were Mirena studies. Plaintiffs deposed a number of Bayer witnesses in the U.S. and abroad; Plaintiffs' Temporary Lead Counsel Jones Ward participated in 20 of those depositions. Interim PSC members Jones Ward, Davis Crump, and Peter Miller represented plaintiffs in Mirena I and were subject to the Court's Orders there.

D. Substantive Motions and Case Trajectory

Interim PSC's Position:

a) Anticipated Nondiscovery Motions: It is anticipated that both the Interim PSC and the Bayer Defendants will each file *Daubert* motions at the appropriate time. Moreover, it is anticipated that the Bayer Defendants will file an omnibus motion for summary judgment at the appropriate time.

b) Anticipated Trajectory, Timetable, and Efficient Sequencing of Litigation: Given that most of the Interim PSC members and their clients have not yet been given access to the pre-MDL 2767 discovery, have not taken any depositions of their own, have not reviewed the approximately 12 millions of pages of documents and have not secured litigation experts of their own, the timetable for this litigation should mirror a traditional MDL schedule. The Interim PSC's proposed Discovery Plan is attached as Exhibit 1.

The Interim PSC anticipates retaining additional expert witnesses, taking additional depositions and potentially supplemental depositions, and serving written discovery requests. Additionally, while the Interim PSC is willing to accept the Bayer Defendants' document production to the Jones Ward firm and the Miller DellaFera firm (which is almost exclusively the exact production from MDL 2434), the Interim PSC believes there are serious deficiencies with the initial production as discussed above. Resolving those ESI issues and determining the scope of what is deemed to be relevant for purposes of this litigation will prove to be one of the early and most important issues for the Court to address.

Notably, neither the Jones Ward firm nor the Miller DellaFera conducted any FRCP 30(b)(6) depositions of the Bayer Defendants. The Jones Ward firm conducted only seven full depositions of the Bayer Defendants' witnesses as part of the PTC/IH litigation –two of which occurred before the Jones Ward firm was provided with the foreign defendants' documents by the Bayer Defendants. For its part, the Miller DellaFera firm did not conduct any full depositions of the Bayer Defendants' corporate witnesses. Additional depositions, therefore, are necessary and appropriate for MDL 2767.

Additionally, the Interim PSC anticipates replacing, adding or supplementing expert witnesses for MDL 2767. However, developing expert witnesses and providing them with the time and documents (which the Interim PSC has not yet reviewed) necessary to formulate their reports takes substantial time; otherwise, the expert witnesses will most certainly be accused in a *Daubert* context of not spending

ample time considering the issues.

The Interim PSC submits that the Bayer Defendants' proposal provides for an expedited schedule at the expense of judicial efficiency, and the plaintiffs' ability to sufficiently prepare their case. As explained above and in the Interim PSC's separate status letter, plaintiffs anticipate significant additional fact and expert discovery prior to the disclosure of experts, expert depositions, and the filing of dispositive motions. Additionally, in the event that the Bayer Defendants are unsuccessful in their *Daubert* challenges, the parties and the Court will need to start anew with general discovery, creating further unnecessary delay of the litigation. Given the history of *Daubert* rulings to date in individual PTC/IH cases, the Interim PSC submits that the Bayer Defendants' confidence in their position is premature and unmerited. The Interim PSC has voiced this opinion to the Bayer Defendants in advance of this filing.

Defendants' Position:

As set forth in the Status Letter filed today, Defendants propose the early disposition of causation issues that are fundamental to Plaintiffs' claims. Under Defendants' proposal (Exhibit 2), the parties would have six months to seek limited supplemental discovery related to general causation issues, after which the parties would engage in expert discovery and *Daubert* briefing. The core general causation *Daubert* issues, as well as recurring problems with Plaintiffs' case-specific experts' methodology already fully briefed in eight cases that have been transferred to this Court, will be ripe for the Court's consideration within a year. This proposal is consistent with the purposes of the MDL statute in promoting the just and efficient conduct of litigation, the Manual of Complex Litigation's recognition that resolution of the admissibility of general causation evidence may be central to the disposition of a litigation, and the JPML's observation regarding this MDL that "discovery and pretrial motions concerning the issue of general causation have been, or will be, at the center of all actions." (Apr. 6, 2017 Transfer Order, at 3.)

In contrast, Plaintiffs' proposed schedule is unduly slow, is one-sided, and is impractical. It includes no deadlines whatsoever for the first year of the MDL and would not ripen the general causation issues for the Court for two years. Meanwhile, their proposal would require the parties to engage in costly general and case-specific discovery in 30 cases – nearly 20 percent of the cases in the entire MDL, not counting the 40-plus cases where discovery occurred before transfer – and to file motions *in limine* and serve deposition designations and exhibit lists in six cases before any dispositive or *Daubert* motions can be adjudicated. This delay in resolution of the core causation issues in these cases serves neither the parties' interests nor judicial economy.

Defendants have a number of additional objections to Plaintiffs' proposed schedule, including the requirement that the parties choose discovery cases without Defendants having full information about Plaintiffs from Plaintiff Fact Sheets, the limitations on treating physicians who can be deposed, the simultaneous exchange deadline for expert reports despite Plaintiffs' burden of proof on all issues, and the overlapping trial-related deadlines with summary judgment and *Daubert* briefing deadlines. Defendants will be prepared to discuss these in more detail at the Initial Status Conference if the Court desires.

E. Trial-Ready Cases and Relationship to MDL

The *Miller* and *Sellers* cases, the two "trial-ready" cases referenced by the JPML, were dismissed on June 1, 2017 and will be refiled in MDL 2767 within thirty days after the Court enters the parties' agreed direct filing order.

Respectfully submitted,

/s/ Lawrence L. Jones II
Lawrence L. Jones II
Temporary Lead Counsel for Plaintiffs
On behalf of Plaintiffs' Interim PSC

/s/ Shayna S. Cook
Shayna S. Cook
Co-Lead Counsel for Defendants
Bayer HealthCare Pharmaceuticals Inc., Bayer OY, and Bayer Pharma AG

Paul W. Schmidt
Covington & Burling LLP
One CityCenter, 850 Tenth Street, NW
Washington, DC 20001-4956
Co-Lead Counsel for Defendants
Bayer HealthCare Pharmaceuticals Inc., Bayer OY, and Bayer Pharma AG

E. James Shepherd
Shook, Hardy & Bacon L.L.P.
JPMorgan Chase Tower
600 Travis Street, Suite 3400
Houston, Texas 77002-2926
Counsel for Defendants
Bayer HealthCare Pharmaceuticals Inc., Bayer OY, and Bayer Pharma AG

CC (via ECF):
All Counsel registered via ECF

EXHIBIT 1

TO

JUNE 5, 2017 JOINT LETTER

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE:

MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO. II)
This Document Relates To All Actions

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ORDER NO. __

17-MD-2767 (PAE)
17-MC-2767 (PAE)

PRETRIAL ORDER #__
(Master Scheduling Order)

1. *Identity of cases.* Discovery Group 1 will consist of cases filed on or before **May 14, 2018.**

2. *Discovery Pool Cases.* By **August 13, 2018**, the parties shall submit a list of a total of thirty (30) cases, fifteen (15) chosen by each side, to be included in the Discovery Pool. In order to be considered for the Discovery Pool, a plaintiff must have served a substantially completed Plaintiff Profile Form (PPF) by **June 25, 2018.**

3. *Discovery Pool Cases – Case – Specific Discovery.* Case-Specific Discovery for Discovery Pool Cases commences on **August 20, 2018**. Case-Specific Depositions shall be limited to: (1) Plaintiff(s); (2) implanting physician; (3) diagnosing physician; (4) one additional fact witness, which may include an additional physician; (5) sales representative or distributor directly associated with the sale of the product to implanting physician.

4. *Plaintiff Fact Sheets.* By **September 21, 2018**, each Plaintiff in the Discovery Pool must serve a substantially completed Plaintiff Fact Sheet (PFS).

5. *Defendant Fact Sheets.* By **October 12, 2018,** Defendants shall serve a substantially completed Defendant Fact Sheet (DFS) for each case in the Discovery Pool (30 cases). The defendants will disclose the identity and locations of all sales representatives for each case in the Discovery Pool in the Defendant Fact Sheets.

6. *Trial Pool Cases.* By **December 10, 2018,** the parties shall submit a list of a total of sixteen (16) cases, eight (8) for each side, to be included in the Trial Pool.

7. *Bellwether Cases.* Parties will make presentations to the Court on **December 14, 2018** on all Trial Pool cases, and the Court shall select a total of six (6) cases to be Bellwether trial cases. The Court shall complete its selection for the final six (6) Bellwether trial cases no later than **December 21, 2018.**

8. *Expert Reports.*

    a. On **January 25, 2019,** the parties shall serve expert reports in each of the six bellwether trial cases.

    b. The parties shall serve rebuttal expert reports by **March 11, 2019** for all Bellwether cases.

9. *Written Discovery.* Parties shall serve any and all final, non-duplicative written discovery in the six Bellwether trial cases no later than **March 11, 2019.**

10. *Expert Discovery.* Expert Discovery for Bellwether cases shall be completed by **April 1, 2019**. Rebuttal expert discovery shall be completed by **April 15, 2019**.

11. *Case-Specific Discovery.* Discovery on all Bellwether cases shall be completed by **April 8, 2019**.

12. *Motion Practice*.

    a. Daubert Motions and Dispositive Motions shall be filed in the six Bellwether trial cases by **April 19, 2019**. Response briefs shall be filed by **May 17, 2019**. Reply briefs shall be filed by **May31, 2019**.

    b. Motions in limine shall be filed in the six Bellwether trial cases by **April 26, 2019**. Response briefs shall be filed by **May 24, 2019**. Reply briefs shall be filed by **June 7, 2019**.

    c. Dates for summary judgment and *Daubert* hearings, if any, will be set at an upcoming status conference.

13. *Pretrial.* The Court shall conduct pretrial and final settlement conferences at dates to be determined at an upcoming status conference. The Court will issue future orders related to conduct of the pretrial conference and submission of a Proposed Pretrial Order.

14. *Deposition Designations*. Deposition designations shall be filed by **May 17, 2019**. Any objections to an opposing party's designations and any counter-designations shall be filed by **June 7, 2019**. Any objections to the counter-designations, and any counter-designations to an opposing party's counter-designations, shall be filed by **June 28, 2019**.

15. *Exhibit and Witness Lists*. The parties will exchange exhibit and witness lists by **June 7, 2019**.

16. The parties shall file proposed jury instructions in charge form on substantive theories of recovery or defense, on damages and on evidentiary matters peculiar to the case, and special interrogatories, if any be appropriate to the case, along

with a proposed verdict form on **June 24, 2019**. The court requests that the parties email the proposed jury instructions to the court's law clerk in Word format.

17. *Trial.* The parties will have three (3) cases ready for trial on **August 5, 2019**.

SO ORDERED.

Dated: June __, 2017

New York, New York

PAUL A. ENGELMAYER
UNITED STATES DISTRICT JUDGE

EXHIBIT 2

TO

JUNE 5, 2017 JOINT LETTER

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------x

IN RE:

MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO. II)

This Document Relates To All Actions

----------x

17-MD-2767 (PAE)
17-MC-2767 (PAE)

ORDER NO. ____
(Scheduling Order)

PROPOSED CASE MANAGEMENT ORDER RE: SCHEDULING ORDER

Engelmayer, P.

The following scheduling order is adopted:

1. Within seven business days of the entry of (1) a Confidentiality Stipulation and Protective Order; (2) a Protocol for Document Production Format; and (3) an Order Regarding Documents Claimed to be Privileged/Protected, Defendants shall make available to Plaintiffs' Lead Counsel the documents and data produced in certain member cases before transfer to this MDL. This production includes all data produced in Mirena I (MDL 2434) and additional data specifically requested by and produced to certain member Plaintiffs including adverse event report data. Defendants will also produce all transcripts and exhibits from depositions of current or former Bayer employees that were taken in MDL 2434 or Mirena IIH cases.

2. By August 14, 2017, Defendants will supplement its productions of the IND/NDA, the FDA contacts database, and Bayer's Study Reports. Defendants will also supplement the data previously collected from the adverse event report database.

3. By July 14, 2017, all Plaintiffs who are currently members of this MDL shall produce completed Plaintiff Fact Sheets. Plaintiffs in later-filed cases shall produce completed Plaintiff Fact Sheets 45 days after their lawsuits are directly filed in or transferred to this MDL.

4. All generic discovery pertinent to general causation expert reports and *Daubert* briefing

shall be completed by December 15, 2017. All remaining generic discovery is stayed until after general causation *Daubert* motions are adjudicated.

5. Plaintiffs' general causation expert reports are due January 5, 2018. All experts giving general causation opinions in this MDL shall be disclosed by this date.

6. Depositions of Plaintiffs' general causation experts shall be complete by February 10, 2018.

7. Defendants' general causation expert reports are due February 17, 2018. All experts giving general causation opinions in this MDL shall be disclosed by this date.

8. Depositions of Defendants' general causation experts shall be complete by March 23, 2018.

9. General causation *Daubert* motions are due April 27, 2018; responses are due May 18, 2018; and reply briefs are due June 1, 2018.

10. On April 27, 2018, the parties shall file specific causation *Daubert* motions in the cases already ripe for *Daubert* disposition (*i.e.*, cases with expert discovery complete and *Daubert* motions pending before transfer to this MDL). Responses are due May 18, 2018 and reply briefs are due June 1, 2018.

11. The Court will schedule a hearing on the *Daubert* motions at a later date.

12. If the Court excludes Plaintiffs' general causation expert testimony, Defendants shall file an omnibus summary judgment motion within 30 days of the Court's Order.

13. In the event that any of Plaintiffs' general causation experts survive *Daubert* challenges, the Court will randomly select 16 cases to be part of an Initial Disposition Pool ("IDP").

14. Within 14 days of IDP selection by the Court, Plaintiffs and Defendants may select three cases per side to strike from the IDP. Any voluntary dismissals from the IDP will be replaced by cases selected by Defendants for inclusion in the IDP.

15. Defendants shall produce completed Defense Fact Sheets within 40 days of the parties'

strike selection.

16. The parties shall proceed with case-specific discovery in the remaining 10 IDP cases for 90 days following strikes. Any remaining generic discovery will also be completed during that time.

17. At the end of the 90-day discovery period, Plaintiffs shall serve case-specific expert reports in the IDP cases. Defendants shall depose Plaintiffs' experts within 30 days after service of case-specific reports.

18. Defendants' case-specific expert reports are due in the IDP cases 45 days after Plaintiffs' reports. Plaintiffs shall depose Defendants' case-specific experts within 30 days after reports are served.

19. Dispositive and *Daubert* motions are due in the IDP cases 30 days after expert depositions are completed. Responses are due 21 days later, and reply briefs 7 days after responses. The Court will schedule any dispositive and *Daubert* motion hearing in the IDP cases at a later date.

20. The Court will enter a separate Order pertaining to pretrial deadlines and trial case selection.

SO ORDERED.

_____
PAUL A. ENGELMAYER
United States District Judge

Dated: _____
New York, New York

EXHIBIT 3

TO

JUNE 5, 2017 JOINT LETTER

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------x
IN RE:

ORDER NO. __

MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO. II)
This Document Relates To All Actions

17-MD-2767 (PAE)
17-MC-2767 (PAE)

----------x

ORDER NO. __

AGREED ORDER REGARDING DIRECT FILING OF ACTIONS IN THE SOUTHERN DISTRICT OF NEW YORK

ENGELMAYER, J.

I. Scope of the order

This Order applies to claims brought by a U.S. citizen or resident based on usage or purchase of MIRENA® (levonorgestrel-releasing intrauterine system) within the United States in which the claimed injury is consistent with the Judicial Panel on Multidistrict Litigation's April 6, 2017 Transfer Order and (i) currently are pending in this centralized multidistrict litigation ("MDL No. 2767") or (ii) will be filed in, removed to or transferred to this Court (collectively, "the MDL Proceedings").

II. Direct Filing of Cases in MDL 2767

A. Any plaintiff whose case would be subject to transfer to MDL No. 2767 may file her case directly in the MDL Proceedings in the Southern District of New York for pretrial proceedings only, consistent with the Judicial Panel on Multidistrict Litigation's April 6, 2017 Transfer Order.

B. Defendants will not challenge the venue of any action filed directly in the MDL Proceedings in the Southern District of New York.

C. No *Lexecon* Waiver. For cases filed directly into MDL No. 2767, the Parties preserve and do not waive any and all rights under *Lexecon Inc. v. Milberg Weiss,* 523 U.S. 26 (1998) to have each case remanded to the district of traditional venue for trial.

D. The direct filing of any action in MDL 2767, pursuant to this Order, shall have no impact on choice of law that otherwise would apply to an individual case had it been originally properly filed in another district court and transferred to this Court pursuant to 28 U.S.C. § 1407.

E. Complaints that include multiple Plaintiff users of Mirena may not be direct filed.

F. The inclusion of any action in *In Re: Mirena IUS Levonorgestrel-Related Products Liability Litigation (No. II),* whether such action was or will be filed originally or directly in the Southern District of New York, shall not constitute a determination by this Court that jurisdiction or venue is proper in this District.

G. Nothing in this order shall preclude the parties from agreeing, at a future date, to try cases filed pursuant to this order in this District.

H. Any complaint that is directly filed in MDL No. 2767 before this Court shall bear the following caption:

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------x	
IN RE:	
	17-MD-2767 (PAE)
MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO. II)	MDL No. 2767
----------x	COMPLAINT
JANE DOE,	AND JURY DEMAND
Plaintiff,	Civil Action No.: _____
vs.	
XYZ CORPORATION and ABC COMPANY,	
_____	

Defendants.

----------x

I. Each case filed directly in the MDL Proceedings in the Southern District of New York shall contain the following language concerning jurisdiction and venue:

> *Plaintiff(s) aver(s) that the federal judicial district in which Plaintiff's Mirena was inserted was [___]; and the federal judicial district in which Plaintiff currently resides is [ ]. But for the Order permitting direct filing into the Southern District of New York pursuant to Order No. __, plaintiff(s) would have filed her/their case(s) in the United States District Court for the* [Insert Name of Court].

When electronically filing the pleadings, the signature block shall follow the below format:

> RESPECTFULLY SUBMITTED,
> _____/s/ Jane Doe_____
> Jane Doe
> NAME OF LAW FIRM
> ADDRESS
> TELEPHONE
> FAX
> EMAIL@EMAIL.com
> Attorney for Plaintiff

J. All Defendants stipulate and agree that the proper filing of a complaint directly in MDL No. 2767 pursuant to this order shall stop the running of any statute of limitations, statute of repose, or prescriptive or preemptive period as if the complaint had been filed in an appropriate venue.

K. The Clerk of this Court shall set forth the procedure and protocol by which direct filing of a matter in MDL No. 2767 may be commenced.

L. The allowance of direct filing in MDL 2767 does not extend to cases that do not include an allegation of a claimed injury identified in the Judicial Panel on Multidistrict Litigation's April 6, 2017 Transfer Order. Upon notice from Bayer of an injury facially inconsistent with the Judicial Panel on Multidistrict Litigation's April 6, 2017 Transfer Order, a plaintiff has 14 days to provide a written statement that the claimed injury is consistent with the Transfer Order. If a plaintiff fails to comply, her case shall be transferred to the proper venue pursuant to 28 U.S.C. § 1404(a). All contested issues will be brought before the Court pursuant to a motion for suggestion of remand.

SO ORDERED.

Dated: May __, 2017

New York, New York

_____

PAUL A. ENGELMAYER
UNITED STATES DISTRICT JUDGE

EXHIBT 4

TO

JUNE 5, 2017 JOINT LETTER RE: PROPOSED AGENDA FOR THE JUNE 13, 2017 INITIAL CONFERENCE, AND POSITION STATEMENTS

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:

MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO.II)

17-MD-2767(PAE)
17-MC-2767 (PAE)

This Document Relates to All Actions

PAUL A. ENGELMAYER, District Judge:

CONFIDENTIALITY STIPULATION AND PROTECTIVE ORDER

IT IS HEREBY STIPULATED AND AGREED, by and between plaintiffs and defendants BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER PHARMA AG ("BPAG") and BAYER OY ("BOY") through their respective counsel and subject to the approval of this Court, that the following Confidentiality Stipulation and Protective Order shall be entered in this action. This Order shall govern the production of documents by Plaintiffs and ~~all properly served~~ Defendants in this case and any future amendments thereto.

1. **Discovery Materials**. This Confidentiality Stipulation and Protective Order applies to all products of discovery and all information derived there from, including but not limited to all documents and deposition testimony and any copies, excerpts or summaries thereof ("Discovery Materials"), obtained by any party pursuant to the requirements of any court order, requests for production of documents, requests for admissions, interrogatories or subpoenas.

2. **Identification of Confidential Discovery Materials**. "Confidential Information" shall mean information, recorded, stored, or maintained for any reason in any medium, including but not limited to print, electronic, or digital, that the party designating the

information as confidential (the "Designating Party") reasonably believes to fall within the following definition:

a. "Trade secret," as set forth in the Uniform Trade Secrets Act, meaning information, including a formula, pattern, compilation, program, device, method, technique, or process that:

i. Derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use; and

ii. Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

b. Research, development, or commercial information that is of a highly competitively sensitive nature and that a reasonably prudent business person in the applicable field would not release to or share with the public in the ordinary course of business, and the release of which would likely cause proprietary, competitive, or economic harm.

c. Personal information protected from disclosure under [state] or federal law, or where disclosure of that information would be highly offensive to a reasonable person and is not of legitimate public concern.

3. Notwithstanding any other provision in this Protective Order, the Order shall not apply to:

a. information that is publicly available, including

i. information or material that, prior to disclosure, was public information or knowledge;

ii. information and material that were, or after designation became, -public information or knowledge (other than by an act or omission of a Party or others subject to this Protective Order); or

iii. information that is legitimately and independently acquired from a source not subject to this Protective Order;

b. information that has been widely disseminated (whether outside or within an organization or corporation);

c. information that is more than 15 years old.

~~2.~~4. All Discovery Materials containing confidential information, as defined above, ~~that contain trade secrets and other confidential research, development, or commercial information, or personal and medical information~~ may in good faith be stamped "Confidential" by the producing party and shall be subject to the provisions of this Confidentiality Stipulation and Protective Order. Such stamping or marking will take place prior to production by the producing person, or subsequent to selection by the receiving party for copying but prior to the actual copying. The stamp shall be affixed in such manner as not to obliterate or obscure any written matter. Confidential Discovery Materials shall be used solely for the purposes of this case and for no other purpose without the prior written approval from the Court or the prior written consent of the producing party.

~~3.~~5. Subject to the provisions of paragraph 8 of this Order, disclosure of any Confidential Discovery Materials shall be limited to:

a. the Court and its staff;

b. "counsel," including inside Counsel and Outside Attorneys and their office attorneys, legal assistants, and clerical staffs;

c. persons shown on the face of the document to have authored or received it;

d. court reporters and videographers retained to transcribe testimony;

e. the parties;

f. retained experts or vendors who are expressly retained by or on behalf of any party to provide assistance or testimony with respect to this case;

g. any witness during deposition in this case; and

h. Plaintiffs' healthcare providers.

4. **Foreign Confidential Information produced by BPAG**. In addition, BPAG may designate as "Confidential" those documents (hereafter referring to any data in electronic form or in paper form) containing "personal data," within the sense of the German Federal Data Protection Act, the confidentiality of which is protected under German law. Personal data consists of: any and all data which 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 position within the company such as "Head of Finance" whose identity results from other sources of information). In particular, this applies to the following documents:

a. any correspondence (electronic or on paper) which identifies or through recourse to other sources of information available to the data processor allows identification of its author/sender and/or its addressee/recipient, i.e., for example all email correspondence, letters and faxes (including transmission reports);

b. any document such as memoranda, notes, and presentations if they identify or allow 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 about which individual(s) did or did not attend the meeting; and

d. personnel records and information.

5. **Foreign Confidential Information produced by BOY**. In addition, BOY may designate as "Confidential" those documents (hereafter referring to any data in electronic form or in paper form) containing "personal data," within the sense of the Finnish Data Protection Act, or "electronic message," within the sense of the Constitution of Finland, the Finnish Act on the Protection of Privacy in Electronic Communications, and the Act on the Protection of Privacy in Working Life, the confidentiality of which is protected under Finnish law. Personal data means any information on a private individual and any information on his/her personal characteristics or personal circumstances where these are identifiable (e.g. with recourse to additional information available to the data processor) as concerning him/her or the members of his/her family or household. Electronic message means e-mail messages or any comparable message transmitted between parties in a communications network. In particular, this applies to the following documents:

a. any electronic message such as e-mail messages or any comparable message or printout thereof transmitted between parties in a communications network;

b. any document such as memoranda, notes, letters and presentations if they identify or allow 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 about which individual(s) did or did not attend the meeting; and

d. personnel records and information.

6. Where a document has been designated as "Confidential" in accordance with paragraphs 2, 4 or 5 above and a party believes that: (a) the document conveys an attachment or contains information that would not be deemed confidential under this paragraph and (b) the document could be redacted to omit material protected by this paragraph in such a manner that the remaining non-confidential material would not be confusing or misleading, that party shall meet and confer with counsel for BHCP, BPAG and/or BOY to determine whether the document can be produced in a redacted format without a confidential designation. (For instance, an email transmitting a publicly released document might be subject to redaction under this provision. Alternately, an email setting forth the sender's opinion would likely not be subject to redaction, because severing the opinion from the identity of the sender could be misleading.) If the parties cannot agree on redaction of a particular document, the party seeking redaction and non-confidential production may file a request with the Court. A producing party shall not make any redactions pursuant to this paragraph without agreement from the receiving party.

~~7.~~6. **Challenging Confidential Designation.** Counsel for a party to whom Confidential Discovery Materials are being produced may challenge the "Confidential" designation made by the producing party by first requesting a "meet and confer" with the producing party in an attempt to amicably resolve the challenge. Any such meet and confer shall occur within 10 days of the notification of a challenge to the "Confidential" designation. In the event agreement cannot be reached, the proponent of confidentiality may apply by motion for a ruling as to whether the designated discovery material may, in accordance with this Order, be treated as confidential. This motion shall be made ~~within 30 days from the date on which the parties,~~at any time, ~~after good faith attempt, agree that they cannot~~ if the Parties are unable to resolve the dispute, after good faith attempt, ~~or~~ such other time period agreed to by the parties. The party seeking to maintain the materials as "Confidential" shall have the burden of proof on such motion to establish the propriety of its confidential designation. The Discovery Materials designated "Confidential" shall continue to be treated as such and subject to the provisions of this Confidentiality Stipulation and Protective Order pending determination by the Court of the merits of any such motion. In the event that the Court enters an order that particular Discovery Materials are not entitled to the designation "Confidential" the Discovery Materials shall nevertheless continue to be treated as "Confidential" and subject to the terms of this Confidentiality Stipulation and Protective Order for ~~30~~ 10 days following the service of Notice of Entry of such order to enable the producing party to seek review and a stay of such order.

~~8.~~7. **Disclosure of Confidential Discovery Material.**

a. The disclosure of the Discovery Materials designated as "Confidential" by counsel for a party in this case to legal assistants, paralegals and clerical staff employed by the disclosing counsel's office and the Court is

allowed under the terms of this Confidentiality Stipulation and Protective Order without limitation and without the need to execute an Affidavit. Such disclosure shall not constitute a violation or a waiver of the protections afforded by the Confidentiality Stipulation and Protective Order. Said assistants, paralegals and clerical staff, as employed agents of the disclosing counsel, are bound by this Order to the same extent as the parties and attorneys are bound.

b. Disclosure by counsel for a party in this case to any of the other individuals/entities identified in sections 3.~~–~~g. ~~c~~-g of Discovery Materials designated as "Confidential" by another party shall not constitute a violation or waiver of the protections afforded by this Confidentiality Stipulation and Protective Order to the extent that such disclosure is necessary to assist in the prosecution or defense of this case and so long as the individual/entity (or, in the event that an entity is not a natural person, the entity's employees) to whom disclosure is made has executed an Affidavit in the form attached hereto as Exhibit A. Copies of each executed Affidavit shall be maintained by the disclosing counsel.

~~c. Disclosure by counsel to a plaintiff's healthcare provider and/or that healthcare provider's counsel, outside of a deposition setting, of Discovery Materials designated as "Confidential" by another party shall not constitute a violation or waiver of the protections afforded by this Confidentiality Stipulation and Protective Order to the extent that such disclosure is necessary to assist in the prosecution or defense of this case and so long as the individual/entity (or, in the event that an entity is not a natural person, the entity's employees) to whom~~

~~disclosure is made has executed an Affidavit in the form attached hereto as Exhibit A. Copies of each executed Affidavit shall be maintained by the disclosing counsel. Such disclosure, outside of a deposition setting, shall be limited to the following categories of documents:~~

~~i. All documents (including call notes) referencing the healthcare provider to whom the disclosure is being made.~~

~~ii. All promotional materials identified as being used for the purposes of sales call visits with the healthcare provider to whom the disclosure is being made.~~

~~iii. All approved promotional materials used for the purposes of sales call visits with healthcare providers found within the custodial file of a sales representative who called on the healthcare provider to whom the disclosure is being made.~~

~~iv. All documents and materials presented during educational seminars (i.e. continuing medical education lectures and other similar lectures/meetings).~~

~~v. All "Dear Doctor" and "Dear Healthcare Provider" letters sent to healthcare providers in the United States.~~

~~vi. All documents publicly available.~~

~~d.~~c. During a deposition, disclosure by counsel to a witness and/or that witness's counsel, if any, of Discovery Materials designated as "Confidential" by another party shall be permitted so long as the witness to whom the disclosure is made has executed the Affidavit or orally agreed on the record to the terms of the

Affidavit attached hereto as Exhibit A. ~~Under no circumstances shall copies of Discovery Materials designated as "Confidential" used at a deposition be left in the possession of the witness or his/her counsel. Further, copies of Discovery Materials designated "Confidential" shall not be attached to or included with any original or copy of the transcript of a deposition sent to the witness or his/her counsel.~~

~~e.~~d. In addition, within thirty (30) days after the completion of a deposition session, counsel may designate ~~the entirety or any~~ a specified portion of the transcript or exhibits thereto as "Confidential" by letter to the opposing party, identifying each such designation by page number and line number. A deposition may not be designated in its entirety as confidential. Until such thirty (30) day period expires, the ~~entirety of such transcripts and all exhibits thereto shall be~~ designated deposition sections and exhibits shall be treated as Confidential and subject to this Order. After such thirty (30) day period expires, such transcripts, exhibits or portions designated as "Confidential" shall be treated as such under this Order. If no such designation is made within thirty (30) days, such transcripts or exhibits shall not be treated as "Confidential" under this Confidentiality Stipulation and Protective Order.

~~f.~~e. Discovery Materials designated as "Confidential" produced by any defendant in this case may be disclosed to the named plaintiff(s) ~~in other Mirena® lawsuits~~ and their counsel who have executed Exhibit B acknowledging that they are a plaintiff or counsel of record in a case filed in MDL 2767. ~~: (i) they have filed and properly served Bayer HealthCare Pharmaceuticals Inc.; Bayer Pharma~~

~~AG; and Bayer OY, (ii) the claimed injury in their lawsuit allegedly resulted from the use of Mirena®, and the subsequent alleged injury of idiopathic intracranial hypertension, (iii) a protective order has been entered in the lawsuit that would protect the Discovery Materials designated as "Confidential" from disclosure and that the Protective Order entered specifically covers Bayer HealthCare Pharmaceuticals Inc.; Bayer Pharma AG; and Bayer OY, and (iv) all counsel for plaintiff who receive the documents agree to be governed by the terms of this Order.~~ Upon execution, Exhibit B shall be provided to the Lead Plaintiffs' Counsel for MDL 2767, who shall maintain the executed Exhibit B at his or her office.~~counsel for the Defendant(s).~~

~~g.~~f. Any materials provided to an insurer or its counsel shall not be used for any purpose other than evaluation of the claims asserted in this case and shall not be used outside the claims asserted in this case.

~~9.~~8. Except as provided for herein, nothing in this Confidentiality Stipulation and Protective Order shall prevent or restrict counsel for any party in any way from inspecting, reviewing, using or disclosing any Discovery Materials produced or provided by that party, including Discovery Materials designated as "Confidential." The parties reserve all their respective rights concerning whether or not there has been a waiver of confidentiality in the event that the producing party shares such Discovery Materials designated as Confidential with third parties other than as provided for elsewhere in this Confidentiality Stipulation and Protective Order.

~~10.~~9. Disclosure of Discovery Materials designated as "Confidential" other than in accordance with the terms of this Confidentiality Stipulation and Protective Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate.

~~11.~~10. All persons receiving or given access to Discovery Materials designated as "Confidential" in accordance with the terms of this Confidentiality Stipulation and Protective Order consent to the continuing jurisdiction of this Court for the purposes of enforcing this Confidentiality Stipulation and Protective Order and remedying any violations thereof. All parties and their respective counsel, paralegals and the employees and assistants of all counsel, and experts receiving Discovery Materials designated as "Confidential" shall take steps reasonably necessary to prevent the disclosure of Confidential Discovery Materials other than in accordance with the terms of this Confidentiality Stipulation and Protective Order.

~~12.~~11. This Order does not automatically seal court records in this case or apply to the disclosure of Confidential Discovery Material at court hearings and/or trial. It is only intended to facilitate the prompt production of discovery materials. A party that seeks to file with this Court any material that contains, describes, identifies, discloses, discusses, refers to or attaches any Discovery Materials designated as "Confidential" shall first file a motion for leave to file under seal seeking permission from the Court to do so. If the Court grants the party's request to file certain materials under seal, the documents filed under seal with the Clerk of the Court shall be kept under seal until further order of the Court.

~~13.~~12. The producing party of any Confidential Discovery Materials attached to or referenced in a document filed with the Court under seal may assent to the unsealing of the document at any juncture without waiving its assertion of confidentiality as to any other Discovery Materials.

~~14.~~13. Nothing shall prevent disclosure beyond that required under this Confidentiality Stipulation and Protective Order if the producing party consents in writing to such disclosure, or if the Court, after notice to all affected parties, orders such disclosure and that Order is not subject to an appellate stay within 30 days after Notice of Entry of the Order is served on the producing party.

~~15.~~14. Any party who inadvertently fails to identify documents, including deposition transcripts, as "Confidential" shall, promptly upon discovery of its oversight, provide written notice of the error and substitute appropriately designated documents produced in the same format as the incorrectly designated document was initially produced. Any party receiving such inadvertently unmarked documents shall, following receipt of notice of the error, treat such documents as confidential as if they had initially been designated as such, make good faith and reasonable efforts to retrieve documents distributed to persons not entitled to receive documents with the corrected "Confidential" designation and, upon receipt of the substitute documents, promptly return or destroy the improperly designated document(s) and/or the electronic media on which such document(s) reside.

~~16.~~15. **Procedure for Use in Court**. Discovery Material received by the Court or entered into evidence in non-trial proceedings shall not lose its status as "Confidential" Discovery Materials as a result. The use of any Discovery Material designated as "Confidential" at trial will be addressed in the Court's Pretrial Order.

~~17.~~16. This Confidentiality Stipulation and Protective Order shall be binding until the resolution of this litigation.

~~18.~~17. Unless otherwise ordered or agreed in writing by the producing party, and if requested by the producing party, each receiving party must return all Discovery Material to

the producing party or provide a certification to the producing party that all Discovery Material in their possession has been destroyed after the final termination of this action including copies of materials provided to third parties under the provisions of this Order. Notwithstanding this provision, Counsel are entitled to retain an archival copy of all pleadings, motion papers, transcripts, legal memoranda, correspondence or attorney work product, even if such materials contain Confidential Discovery Material. Any such archival copies that contain or constitute Confidential Discovery Material remain subject to this agreement as set forth in Paragraph 16 above.

~~19.~~18. Any party may apply to the Court for a modification of the Confidentiality Stipulation and Protective Order, and nothing in this Confidentiality Stipulation and Protective Order shall be construed to prevent a party from seeking such further provisions enhancing or limiting confidentiality as may be appropriate.

~~20.~~19. No action taken in accordance with the Confidentiality Stipulation and Protective Order shall be construed as a waiver of any claim or defense in this case or of any position as to discoverability or admissibility of evidence.

~~21.~~20. If a receiving party or its counsel or expert is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization that calls for production of any Confidential Discovery Materials produced by another party, the party to whom the subpoena or other process is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such documents or information until 10 business days after notifying counsel for the producing party in writing of all of the following: (i) the information and documentation requested for production in the subpoena; (ii) the date on which compliance with the subpoena is requested; (iii) the location at which compliance with the

subpoena is requested; (iv) the identity of the party serving the subpoena; and (v) 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 has been issued.

~~22.~~21. Nothing in this Confidentiality Stipulation and Protective Order shall be construed to prevent this Court from disclosing any facts relied upon by it in making or rendering any finding, ruling, order, judgment or decree of whatever description.

~~23.~~22. ~~E~~Unless ordered by the Court, each party shall bear its own costs for complying with this Confidentiality Stipulation and Protective Order. Nothing in this paragraph shall prevent a party from asking for sanctions for improper designation of documents.

SO ORDERED

Dated: _____, 2017~~–~~

New York, New York

_____

PAUL A. ENGELMAYER, District Judge

United States District Court

Southern District of New York

In Re:

17-MD-2767(PAE)

Mirena IUS LEVONORGESTREL-RELATED Products Liability Litigation (NO.II) **17-MC-2767 (PAE)**

This Document Relates to All Actions

PAUL A. ENGELMAYER, District Judge:

EXHIBIT A

AGREEMENT TO MAINTAIN CONFIDENTIALITY

STATE OF _____)
)
COUNTY OF _____)

_____, being duly sworn, deposes and says:

1. I am over the age of 18 years and make this Affidavit based upon my personal knowledge, and I am competent to testify to the matters stated herein.

2. I am aware that United States District Judge Paul A. Engelmayer entered a Confidentiality Stipulation and Protective Order in the litigation identified above. A copy of that

Confidentiality Stipulation and Protective Order has been shown to me, and I have read and understand its contents.

3. By signing this Affidavit, I promise that I will not use the materials and contents of the materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order for any purpose other than this litigation.

4. By signing this Affidavit, I also promise that I will not communicate, disclose, discuss, identify, or otherwise use materials or the contents of materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order with, to, or for any person or entity other than the Court, a party to the above-described case, counsel for a party to the above-described case, including other counsel, paralegals, and staff employed in his or her office, persons permitted by the above-described Confidentiality Stipulation and Protective Order to attend depositions taken in this case, and persons or entities assisting such counsel who have executed an affidavit in the same form as this Affidavit.

5. By signing this Affidavit, I also promise that I will not copy, transcribe, or otherwise reproduce, or cause to be copied, transcribed, or otherwise reproduced, by any means whatsoever, any materials or the contents of any materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order except to the extent to which I am directed to do so by counsel for a party to this litigation, in which case all such copies, transcriptions, or reproductions shall be made solely for my own use in connection with my work or assistance in the above matter. I further promise at the conclusion of this litigation to deliver upon request all materials designated "Confidential" (originals and copies) to the counsel who originally directed that said materials be provided to me.

6. I understand that, by signing this Affidavit, I am agreeing to subject myself to the jurisdiction of this Court.

7. I understand that any use or distribution of the materials or contents of the materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order in any manner contrary to the provisions of the Confidentiality Stipulation and Protective Order will subject me to remedies as this Court may deem appropriate.

Dated: _____,
_____, 201_

_____
Signature of Affiant

Subscribed and sworn to before me,
this _____ day of _____

_____
Notary Public

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:

MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO.II)

17-MD-2767(PAE)
17-MC-2767 (PAE)

This Document Relates to All Actions

PAUL A. ENGELMAYER, District Judge:

EXHIBIT B

AGREEMENT TO MAINTAIN CONFIDENTIALITY

STATE OF _____)
)
COUNTY OF _____)

_____, being duly sworn, deposes and says:

1. I am an attorney and make this Affidavit based upon my personal knowledge, and I am competent to testify to the matters stated herein.

2. I am aware that a Confidentiality Stipulation and Protective Order has been entered in the litigation identified above. A copy of that Confidentiality Stipulation and Protective Order has been shown to me, and I have read and understand its contents.

3. By signing this Affidavit, I promise that I will not use the materials and contents of the materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order for any purpose other than this litigation.

4. By signing this Affidavit, I agree to be bound by all terms of the above-described Confidentiality Stipulation and Protective Order.

5. I understand that, by signing this Affidavit, I am agreeing to subject myself to the jurisdiction of this Court.

6. I understand that any use or distribution of the materials or contents of the materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order in any manner contrary to the provisions of the Confidentiality Stipulation and Protective Order will subject me to remedies as this Court may deem appropriate.

7. By signing this affidavit, I am verifying under oath that I am a named plaintiff or counsel for a named plaintiff in a Mirena lawsuit that has been filed in or transferred to this Court for inclusion ~~previously been filed ("the Lawsuit") where (a) all the claimed injury(ies) in the Lawsuit allegedly result from the use of Mirena® and the subsequent alleged injury of idiopathic intracranial hypertension, (b) Bayer HealthCare Pharmaceuticals Inc.; Bayer Pharma AG; and Bayer OY have all been properly served in the Lawsuit, and (c) a protective order has been entered in the Lawsuit that would protect the Discovery Materials designated as "Confidential" from disclosure and that the Protective Order entered in the Lawsuit specifically covers Bayer HealthCare Pharmaceuticals Inc.; Bayer Pharma AG; and Bayer OY.~~in MDL 2767.

8. By signing this affidavit, I agree to only access and review Discovery Materials produced by parties that I have sued and properly served in the Lawsuit.

Dated: _____,
_____, 201_

_____
Signature of Affiant

Subscribed and sworn to before me,
this _____ day of _____

_____
Notary Public

EXHIBIT 5

TO

JUNE 5, 2017 JOINT LETTER

Shook, Hardy & Bacon L.L.P.
www.shb.com

James Shepherd

JPMorgan Chase Tower
600 Travis Street, Suite 3400
Houston, Texas 77002
713.227.8008
713.546.5610 DD
713.227.9508 Fax
eshepherd@shb.com

November 19, 2013

BY ELECTRONIC MAIL

James R. Ronca
252 Boas Street
Harrisburg PA 17102
jronca@anapolschwartz.com

Matthew J. McCauley
6 Harbor Park Drive
Port Washington, New York
mmccauley@yourlawyer.com

Fred Thompson
28 Bridgeside Blvd.
Mt. Pleasant, SC
fthompson@motleyrice.com

Dion Kekatos
77 Water Street, 26th Floor
New York, NY 10005-4401
dkekatos@seegerweiss.com

Re: Mirena® MDL Discovery for Bayer Pharma AG and Bayer Oy

Dear Jim, Fred, Matt, and Dion:

Pursuant to United States District Court, Southern District of New York Standing Order M10-468, *In re: Pilot Project Regarding Case Management Techniques for Complex Civil Cases in the Southern District of New York*, Bayer Pharma AG ("BPAG") and Bayer Oy ("BOY") provided the following discovery related information regarding Mirena® ("Mirena"). By doing so, BPAG and BOY relieve their obligations under the Standing Order.

Preservation, Collection, and Review:

BPAG and BOY issued a legal hold on May 19, 2009 for a case in which the plaintiff alleged that Mirena caused papilloedema. That hold was limited to documents and data related to Mirena and papilloedema and to a limited group of employees.

The scope of the legal hold was extended to all documents and data relating to the marketing, distribution, sale, production, manufacture, research, or development of Mirena. This extended legal hold was sent to employees of BPAG on December 7, 2011 and to employees of BOY on January 3, 2012. In addition, it was sent to a group of temporary employees of BOY on January 19, 2012. Reminder notices were sent periodically thereafter.

In-house and outside counsel of BPAG and BOY have interviewed current and former employees to determine individuals who are or have been significantly involved with Mirena. When a decision is made to collect an employee's custodial file, counsel works with that employee to determine the existence and location(s) of potentially responsive

documents. When the employee's hard drive is identified as a source, BPAG and BOY collect the data from that employee's hard drive using Robocopy to collect the following file types:

*.doc
*.docx
*.docm
*.docxml
*.dochtml
*.xls
*.xlsx
*.xlsm
*.xlsxml
*.xlshtml
*.ppt
*.pptx
*.pptm
*.pps
*.ppsm
*.ppsx
*.pptxml
*.ppthtml
*.sldm
*.sldx
*.mpp
*.mdb
*.pdf
*.nsf
*.rtf
*.txt
*.wpd
*.vdx
*.vdw
*.vsd
*.zip
*.one
*.onepkg
*.odt
*.ods
*.odp
*.csv
*.xml

*.7Z
*.xps
*.msg
*.prn
*.eml
*.pst
*.pub

For e-mail, the employee's e-mail box is collected directly from the e-mail server. In addition, counsel works with the employee to collect potentially relevant hard copy and media files, if any, and those documents are collected, scanned/copied, and returned to the custodian.

BPAG and BOY process the collected documents and data internally to meet the requirements of the German Federal Data Protection Act, the Finnish Data Protection Act, the Finnish Act on the Protection of Privacy in Electronic Communications, and the Act on the Protection of Privacy in Working Life. This processing includes the use of ImageMaker to de-duplicate within a custodial file using MD5 hash values and Relativity to perform a keyword search for the following terms:

Mirena OR
Merena OR
Merino OR
"LNG 20" OR
"LCS 20" OR
"ICS 20" OR
"LNG-20" OR
"LCS-20" OR
"IUS-20" OR
"21-225" OR
Intrauterine OR
Interuterine OR
"Inter-uterine" OR
Interuterus OR
"Inter-uterus" OR
Intrauterus OR
"Intra-uterus" OR
"Intra-uterine" OR
IUD OR
IUS OR
IUC OR
levonorgestrel OR

Levonorgestrol OR
Levonorgesterone OR
Levonorgestin OR
Levo OR
Norgrestrel OR
"Levo-norgestrel" OR
"Levo-norgesterol" OR
"Levo-norgestin" OR
"LNG-IUS" OR
"Levonorgrestrel interuterine contraceptive system" AND NOT
((Skyla OR Jaydess OR "Low-dose Levonorgestrel Contraceptive System" OR LCS)
AND NOT (Mirena OR Merena OR Merino OR "LNG 20" OR "LCS 20" OR "ICS 20"
OR "LNG-20" OR "LCS-20" OR "IUS-20"))
Levonova OR
LNG20 OR
mirena-us OR
mirenas OR
mirenae OR
mirenao OR
imirena OR
ind 22,697 OR
IND w/2 Report OR
lng-releasing OR
lng-iud OR
ing-iuds OR
lng-containing OR
iuds OR
lng-iud OR
iud-related OR
iud-associated OR
lng-ius OR
iuss OR
ingius OR
ius-related OR
iucs OR
iucd OR
levonorgrestrel-releasing OR
levonorgestrelcontaining OR
levonorgrestrel-iud OR
levonorgrestrel-intrauterine OR
“adhesion formation” OR
“uterine perforation” OR

perforat! OR
Migrat! OR

To the extent there is a hit based on this keyword search, the document and its family are sent to Kroll Ontrack ("Kroll"). Kroll processes the data to prepare it for loading to its review platform, Ontrack Inview. Kroll's processing includes de-duplication of the data across custodians using SHA (160-bit hash value). The de-duplication done by Kroll and BPAG and BOY identifies exact duplicates.

Custodians:

Following is a list of key BPAG and BOY employees who we believe, based on our current information, have or had relevant knowledge and core responsibility for Mirena. For each of these individuals, BPAG and BOY will produce a custodial file, as applicable and available, from hard copy files maintained by the individual, the computer hard drive and other media (CDs, DVDs, jump drives) of the individual, the individual's e-mail file, and the individual's home share file on file share servers.

Dr. Pirjo Inki - Dr. Inki is currently a Senior Global Medical Affairs physician at Bayer Oy in Turku, Finland. She joined Schering Oy in April 2003 as a Medical Advisor for Mirena. In 2006, when Bayer acquired Schering AG, Dr. Inki's title changed to Global Medical Affairs Physician, Mirena. Since joining Schering Oy, Dr. Inki's duties have included global medical support for Mirena, including consulting on medical questions with Bayer HealthCare Pharmaceuticals Inc.'s Medical Affairs department and review and evaluation of scientific studies and data regarding Mirena.

Pirjo Sallinen - Ms. Sallinen is the Global Program Head for IUSs for Bayer Pharma AG in Berlin, Germany. She joined Leiras Oy in 1992 as the Project Manager for Mirena and her involvement with Mirena continues today. Ms. Sallinen was the project manager who oversaw the approval of Mirena in many countries included the United States. She started working on the U.S. approval in 1997. Ms. Sallinen was involved in pre and post-marketing studies of Mirena, the original FDA New Drug Application for Mirena, and Mirena labeling changes.

Ilka Schellschmidt - Ms. Schellschmidt has been the Vice-President, Head Global Medical Affairs Women's Healthcare for Bayer Pharma AG in Berlin, Germany since 2010. In that role, she oversees the medical support efforts related to Mirena. Prior to 2010, Ms. Schellschmidt was responsible for the clinical development of certain LNG IUSs, a role she began in 2007.

Dr. Juliane Schöndorf - Dr. Schöndorf is a Bayer Oy employee in Espoo, Finland. She has been one of the Global Safety Leads for Mirena since 2005. The Global Safety Lead

is responsible for the monitoring of the safety of Mirena. Dr. Schöndorf's responsibilities include the evaluation of safety signals and the compilation of aggregate safety reports (e.g. PSURs).

Dr. Carol Ann Wilson - Since 2007, Dr. Wilson has been the Head of Global Medical Coding for Bayer Pharma AG in Berlin, Germany. In 2000, as a Schering AG employee, Dr. Wilson was responsible for implementing the new medical terminology, MedDRA, to code safety information, including adverse events. The MedDRA coding conventions were implemented as part of the project and later further developed at Bayer Pharma AG. Dr. Wilson has been responsible for those coding conventions since their development.

Non-Custodian Sources:

As I explained during our call on October 21, 2013, BPAG and BOY share many of the non-custodian sources of documents and data that Bayer HealthCare Pharmaceuticals Inc. ("BHCP") agreed to produce. BHCP will produce:

1. Investigational New Drug Application ("IND"), New Drug Application ("NDA"), and Supplemental New Drug Applications for Mirena;
2. Communications and contacts with the FDA regarding Mirena;
3. Published and unpublished reports of Bayer's preclinical and clinical studies involving Mirena;
4. Company Core Data Sheets for Mirena;
5. Periodic Safety Update Reports ("PSURs") for Mirena;
6. Investigator's brochures contained in the NDA and its supplements;
7. Mirena U.S. package inserts;
8. Documents related to patents for Mirena that are contained in the NDA;
9. Mirena-related Dear Healthcare Provider letters issued in the U.S.;
10. Documents submitted to the FDA related to BfArM's inquiries related to Mirena;
11. Documents submitted to the FDA related to the French regulatory authority's inquiries related to Mirena;

12. Interim reports of the EURAS study involving Mirena that are contained in the PSURs;

13. Information from the PSURs reflecting the number of patients to whom Mirena has been administered; and

14. U.S. Mirena Adverse Event Data involving reports of perforation, embedment, or migration from the ARGUS database.

BPAG and BOY do not intend to re-produce these materials.

BPAG and BOY will produce documents or data from the following from non-custodian sources that will not be produced by BHCP:

1. Non-U.S. Adverse Event Data involving reports of perforation, embedment, or migration from the ARGUS database.

2. Mirena-related documents from the Global Labeling Committee team room; and

3. Mirena-related documents from the Global Safety Committee team room.

The custodial files and documents from non-custodian sources listed above to be produced by BPAG and BOY, will be produced pursuant to the Protocol For Document Format Production. The production will begin on a rolling basis after review and the parties agree upon a revised Confidentiality Stipulation and Protective Order that complies with the German Federal Data Protection Act, the Finnish Data Protection Act, the Finnish Act on the Protection of Privacy in Electronic Communications, and the Act on the Protection of Privacy in Working Life.

Sincerely,

James Shepherd

EXHIBIT 6

TO

JUNE 5, 2017 JOINT LETTER

JONES WARD PLC

TRIAL ATTORNEYS

May 30, 2017

VIA ELECTRONIC MAIL

Shayna S. Cook
GOLDMAN ISMAIL TOMASELLI
BRENNAN & BAUM LLP
564 West Randolph Street, Suite 400
Chicago, Illinois 60661

RE: In re: Mirena Levonorgestrel-Related Products Liability Litigation (No. II), 17-MD-2767 (PAE) and 17-MC-2767 (PAE)

Dear Shayna:

In follow up to our call on Friday, I am writing to discuss some of the discovery-related issues that I believe will need to be addressed either by the Bayer Defendants, the Court, or both. I am hopeful that this provides you with ample information to discuss and evaluate the issues we will be confronting in the near future.

As I reminded you on Friday's call, Martin Crump and the other lawyers who are "new" to this case have not had an opportunity to review the Bayer Defendants' confidential document production or the depositions taken in my cases, unless such documents or depositions have been publicly filed. Thus, the majority of the Interim PSC members are handicapped by their inability to review such information and many of the views below are thus mine.

As this matter advances, and the other lawyers are given access to the confidential production, I suspect that the Plaintiffs' PSC will raise additional issues and make additional requests for documents or depositions. Nonetheless, in the spirit of trying to resolve issues that I believe are outstanding from my experience litigating PTC/IH cases, I have attempted to detail such issues below.

Documents Produced

As an initial matter, I, along with the Interim PSC, have several issues with the electronic discovery produced by the Bayer Defendants in the individual PTC/IH cases.

The first issue can be broadly characterized as the "preservation, collection and review" process outlined in the Bayer Defendants' November 13, 2013 correspondence to the MDL 2434 leadership, none of whom are involved in MDL 2767. Among the questions the Interim PSC has about the "preservation" and "collection" processes are the following:

The Pointe
1205 East Washington Street, Suite 111
Louisville, Kentucky 40206

Telephone: (502) 882-6000
Facsimile: (502) 587-2007
Web: www.jonesward.com

1) Who were the litigation holds (2009, 2011, 2012) issued to?

   a) How was it determined who received the hold letter?

   b) Did it go to all Women's HealthCare or Female HealthCare employees?

   c) Were documents gathered from each of the employees who received the hold letter?

   d) Were documents produced from each employee who received the hold letter?

   e) Were documents gathered or preserved at the time of the hold or were the employees trusted to preserve the documents until they were gathered?

   f) Were the documents gathered at supplemental periods?

2) Who comprised the "limited group of employees" who received the 2009 hold letter?

   a) The letter says it was limited to "Mirena and papilledema." Was it really that narrow?

   b) What was the exact instruction to employees in the 2009 hold letter?

3) At the "interview" stage, how was it determined who had been "significantly involved with Mirena"?

   a) Why such a narrow definition?

   b) What does that mean?

   c) What is the metric used for determining significant involvement?

   d) Why not significant involvement with WHC or FHC products or contraceptive products or LARCS?

   e) Have documents been gathered and/or preserved from those who were not "significantly involved" with Mirena?

   f) Have documents been produced from anyone who was not significantly involved?

4) Were the initial documents subjected to a "relevance" review?

   a) When?

   b) What were the parameters for determining relevance?

   c) Who did such a review?

d) Were the reviewers aware of the PTC/IH issues?

5) Other than search terms in Relativity, were the documents subjected to any other sort of review or culling prior to being sent to Kroll Ontrack?

a) Which collections of potentially discoverable data comprised the corpus of documents upon which the Relativity key word search was applied?

b) Were document added to that corpus over time?

c) If documents were added to the corpus, was the Relativity search re-run?

6) "When a decision is made to collect an employee's custodial file …"

a) What is the decision-making process?

b) Who makes the decision?

7) What email boxes were collected?

a) Employees only?

b) What about group email boxes?

8) Does all of the Robocopy data still exist?

a) If so, how much data was gathered?

b) Of the data gathered, how much has been produced?

9) Were sources of structured data or databases gathered?

a) Which sources of structured data or databases?

b) How were such decisions made?

c) What was the process for searching sources of structured data or databases for information?

d) For each source of structured data or database, was the full structure or database preserved?

e) For each source of structured data or database, what methods were used for searching the source or database (i.e., keywords, concept searches, etc.)?

f) For each source of structured data or database, how was the information collected and transferred to a review platform?

10) The November 13, 2013 letter notes that the documents were "de-duplicated" and then loaded into the Relativity review platform prior to being sent to Kroll Ontrack for review. While in Relativity, the letter states that the documents were subjected to "keyword" searches.

a) Who performed the keyword searches?

b) Prior to subjecting the documents to a keyword search method, what was the volume of data?

c) After subjecting the documents to a keyword search method, what was the volume of data sent to Kroll Ontrack?

d) Was the de-duplication process looking for exact duplicates or did it include near duplicates?

11) After being sent to Kroll Ontrack, the November 13, 2013 letter indicates that the documents were subjected to a second "de-duplication" process.

a) Why were the documents again de-duplicated?

b) What was the volume of data before the de-duplication process?

c) What was the volume of data after the de-duplication process?

d) Was the de-duplication process looking for exact duplicates or did it include near duplicates?

12) Following the de-duplication process performed by Kroll Ontrack, the November 13, 2013 letter indicates that the documents were placed in Kroll Ontrack's review platform, known as Inview.

a) Were the documents subjected to another round of keyword searches before production in MDL 2434?

b) Were the documents subjected to a "relevance review" at this time, before being produced in MDL 2434?

c) Were the documents subjected to any technology assisted review or concept searching in the Inview review platform?

c) Were any documents contained in the Inview review platform withheld in MDL 2434 due to a determination that such documents were not "relevant" to the litigation?

13) Have the plaintiffs in the PTC/IH litigation received an "exact copy" of the documents produced in MDL 2434?

a) Before being produced in the PTC/IH litigation, was the original corpus of preserved documents subjected to any additional search term reviews?

b) Before being produced in the PTC/IH litigation, was the original corpus of documents subjected to a new relevance review, separate from the relevance review performed for the MDL 2434 production?

14) For the custodial files produced in both MDL 2434 and those produced in the individual PTC/IH litigations, has every custodial file has been updated and supplemented since originally produced?

a) If not, which custodial files have been supplemented, the date of the supplementation(s) and the latest date for which documents have been gathered and produced for the custodian?

b) In preparing any supplementation(s), was the same process used for the "preservation, collection and review" as the original MDL 2434 production?

We hope you can agree that these are legitimate questions to which the plaintiffs should be entitled to answers. Should the Bayer Defendants not want to answer these questions at this stage of the litigation, the Interim PSC intends to seek answers to these questions and more by way of a FRCP 30(b)(6) deposition.

The second issue can be characterized as a "search term" issue. As you know, the lawyers involved in MDL 2767 were not involved in the creation of the "search terms" used in MDL 2434. As you also know, the "search terms" did not account for issues that are relevant to the PTC/IH litigations, including the signs, symptoms, and injuries associated with PTC/IH. Moreover, among other "search terms" that were not included are progestin, progesterone (or any variation thereof), "serum," "plasma," "obesity," "weight gain," "Norplant," "Norplant-2," Jadelle," or anything related to thrombosis.

Search terms are inherently unreliable. When combined with the failure to include even the most relevant search terms for a particular litigation, the results can be nothing short of abysmal. The Interim PSC strongly encourages the Bayer Defendants to produce the original document corpus, plus all supplementations, (with an appropriate "clawback" agreement for privileged materials) to allow the Interim PSC to conduct "concept searches" and "technology assisted review" tools to discover the documents relevant to this litigation. Alternatively, the Interim PSC proposes that the parties cooperatively engage in the use of such tools to help streamline the time and costs associated with discovering the relevant case documents.

Additionally, Plaintiffs will be reviewing the documents in the Relativity platform, the same platform indicated in Defendants' November 13, 2013 letter. As you are aware, the Relativity review platform provides tools for "concept searching" and "computer-assisted learning" for purposes of culling a document corpus. Prior to transferring the original corpus of documents to Kroll Ontrack, did Defendants use either or both of these tools in addition to conducting keyword searches for purposes of deciding which documents would be reviewed on the Kroll Ontrack Inview platform?

Scope of Preservation and Production

As you know, the parties have different views about the scope of preservation and the scope of production in these cases. Rather than rehash the arguments here, I assume we will agree to disagree and present the issues to the Court.

Audio and Video Files

Another area of concern about the initial production is the lack of audio and video files. Among other things, I am personally aware that sales representatives received part of their training from audio and video files. Nonetheless, no such files have ever been produced.

Additionally, as you know, I have requested television commercials for the Mirena product. Rather than producing all such videos, the Bayer Defendants claimed that any such videos would likely be found on YouTube. This is not an appropriate response to a discovery request. The Interim PSC also anticipates requesting relevant audio and video files. If such files are not produced, this issue will need to be addressed with the Court.

Written Discovery

As you know, no written interrogatories were served by the plaintiffs in the individual PTC/IH cases. The Interim PSC anticipates preparing and serving interrogatories in MDL 2767.

Corporate Representative Depositions

As you know, despite requests from the individual plaintiffs in the PTC/IH litigations, no FRCP 30(b)(6) depositions have been taken. The Interim PSC anticipates serving FRCP 30(b)(6) deposition notices and taking such depositions.

Depositions

To date, the Jones Ward law firm took seven depositions of Bayer witnesses for the PTC/IH litigations: Costales, Konnerth, Korner, Plouffe, Schoendorf, S. Thomas, and Walsh. In a handful of MDL 2434 depositions, the Jones Ward law firm conducted a limited examination of the witnesses.

Because the Interim PSC has not had the opportunity to review those depositions because of confidentiality designations, it cannot make a determination of whether or not those witnesses will need to be re-deposed or simply subjected to supplemental depositions. Nonetheless, the Interim PSC does anticipate that a review of the documents will necessitate additional depositions of current and former Bayer employees, as well as Bayer "key opinion leaders."

Privilege Determinations

As you know, during the course of the individual PTC/IH litigations, plaintiffs raised the issue of attorney-client privilege and work product designations, particularly with respect to attachments designated as protected. At this time, the Interim PSC would respectfully request that Bayer review its privilege logs and the corresponding documents to confirm that the

attachments contain an independent basis for the privilege designation. It is the Interim PSC's position that attachments to e-mails do not become privileged simply by virtue of being attached to a communication that may be privileged. Nor does a document merely "cc:'d" to a lawyer become protected by the privilege.

As MDL 2767 proceeds, the Interim PSC anticipates that there will be additional challenges to the privilege log but resolving the issues above will go a long way toward resolving the bulk of the disputes.

Redactions

As you know, the documents produced in the individual PTC/IH cases contain hundreds of thousands of redactions for categories such as:

Redacted: Manufacturing/CM&C
Redacted: Other Bayer Product

Such redactions were made despite the fact that the parties to the PTC/IH cases entered into an agreed protective order intended to protect such information from disclosure to third parties outside the litigation. With such protective measures in place, the Bayer Defendants have no basis to redact or withhold such information. The Interim PSC respectfully requests that any such redactions be removed from documents produced in MDL 2767.

Over-Designation of Confidentiality

It appears as though the Bayer Defendants have designated every single document produced to date as "Confidential" and subject to the protective and confidentiality order. Certainly, the Bayer Defendants cannot reasonably believe that every document they have produced is "confidential" within the meaning of the Federal Rules of Civil Procedure. Indeed, with the agreement of the Bayer Defendants, numerous documents have been publicly filed and used in individual PTC/IH litigations.

While it is true that documents are often designated as "Confidential" in a wholesale manner for purposes of expediting a litigation production, the Bayer Defendants have clearly reviewed each and every document produced to date. Therefore, in addition to reviewing the documents for purposes of relevance, as well as designating privileges and redacting documents as discussed above, the Interim PSC does not understand why such documents cannot be (or were not) subjected to a "Confidentiality" decision at the same time –allowing the documents to be properly designated as confidential or not.

Overuse of confidentiality designations places undue costs and burdens on the courts, their respective clerks' offices, and the parties. Therefore, the Interim PSC respectfully requests that the Bayer Defendants begin the process of de-designating those documents that are not properly designated as confidential pursuant to the Federal Rules of Civil Procedure.

Requests for Production of Documents and Other Things

As you know, the individual plaintiffs in the PTC/IH litigations served written requests for production of documents and other things. The requests were met with hundreds of pages of form objections. The Interim PSC intends to serve similar requests and hope that the Bayer

Defendants do more than simply object and refer to their previous production of documents. To the extent that the Bayer Defendants intend to do so, this issue will need to be raised with the Court.

Please let me know if you have any questions regarding the areas I have identified. I would suggest that we not wait until Friday afternoon to discuss these matters. Instead, I would propose that we attempt to discuss these issues on Thursday afternoon in order to allow us time to prepare for the joint filing due on June 5, 2017. I can be available anytime on Thursday afternoon so please let me know what works best for you and your team.

I look forward to hearing from you.

Sincerely,

JONES WARD PLC

/s/ Lawrence L. Jones II

EXHIBIT 7

TO

JUNE 5, 2017 JOINT LETTER

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:

MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO.II)

17-MD-2767(PAE)
17-MC-2767 (PAE)

This Document Relates to All Actions

PAUL A. ENGELMAYER, District Judge:

CONFIDENTIALITY STIPULATION AND PROTECTIVE ORDER

IT IS HEREBY STIPULATED AND AGREED, by and between plaintiffs and defendants BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER PHARMA AG ("BPAG") and BAYER OY ("BOY") through their respective counsel and subject to the approval of this Court, that the following Confidentiality Stipulation and Protective Order shall be entered in this action. This Order shall govern the production of documents by Plaintiffs and all properly served Defendants in this case and any future amendments thereto.

1. **Discovery Materials**. This Confidentiality Stipulation and Protective Order applies to all products of discovery and all information derived there from, including but not limited to all documents and deposition testimony and any copies, excerpts or summaries thereof ("Discovery Materials"), obtained by any party pursuant to the requirements of any court order, requests for production of documents, requests for admissions, interrogatories or subpoenas.

2. **Identification of Confidential Discovery Materials**. All Discovery Materials that contain trade secrets and other confidential research, development, or commercial information, or personal and medical information may in good faith be stamped "Confidential"

by the producing party and shall be subject to the provisions of this Confidentiality Stipulation and Protective Order. Such stamping or marking will take place prior to production by the producing person, or subsequent to selection by the receiving party for copying but prior to the actual copying. The stamp shall be affixed in such manner as not to obliterate or obscure any written matter. Confidential Discovery Materials shall be used solely for the purposes of this case and for no other purpose without the prior written approval from the Court or the prior written consent of the producing party.

3. Subject to the provisions of paragraph 8 of this Order, disclosure of any Confidential Discovery Materials shall be limited to:

a. the Court and its staff;

b. "counsel," including inside Counsel and Outside Attorneys and their office attorneys, legal assistants, and clerical staffs;

c. persons shown on the face of the document to have authored or received it;

d. court reporters and videographers retained to transcribe testimony;

e. the parties;

f. retained experts or vendors who are expressly retained by or on behalf of any party to provide assistance or testimony with respect to this case;

g. any witness during deposition in this case ; and

h. Plaintiffs' healthcare providers.

4. **Foreign Confidential Information produced by BPAG**. In addition, BPAG may designate as "Confidential" those documents (hereafter referring to any data in electronic form or in paper form) containing "personal data," within the sense of the German Federal Data Protection Act, the confidentiality of which is protected under German law. Personal data consists of: any and all data which 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 position within the company such as "Head of Finance" whose identity results from other sources of information). In particular, this applies to the following documents:

a. any correspondence (electronic or on paper) which identifies or through recourse to other sources of information available to the data processor allows identification of its author/sender and/or its addressee/recipient, i.e., for example all email correspondence, letters and faxes (including transmission reports);

b. any document such as memoranda, notes, and presentations if they identify or allow 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 about which individual(s) did or did not attend the meeting; and

d. personnel records and information.

5. **Foreign Confidential Information produced by BOY**. In addition, BOY may designate as "Confidential" those documents (hereafter referring to any data in electronic form or in paper form) containing "personal data," within the sense of the Finnish Data Protection Act, or "electronic message," within the sense of the Constitution of Finland, the Finnish Act on the Protection of Privacy in Electronic Communications, and the Act on the Protection of Privacy in Working Life, the confidentiality of which is protected under Finnish

law. Personal data means any information on a private individual and any information on his/her personal characteristics or personal circumstances where these are identifiable (e.g. with recourse to additional information available to the data processor) as concerning him/her or the members of his/her family or household. Electronic message means e-mail messages or any comparable message transmitted between parties in a communications network. In particular, this applies to the following documents:

a. any electronic message such as e-mail messages or any comparable message or printout thereof transmitted between parties in a communications network;

b. any document such as memoranda, notes, letters and presentations if they identify or allow 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 about which individual(s) did or did not attend the meeting; and

d. personnel records and information.

6. Where a document has been designated as "Confidential" in accordance with paragraphs 2, 4 or 5 above and a party believes that: (a) the document conveys an attachment or contains information that would not be deemed confidential under this paragraph and (b) the document could be redacted to omit material protected by this paragraph in such a manner that the remaining non-confidential material would not be confusing or misleading, that party shall meet and confer with counsel for BHCP, BPAG and/or BOY to determine whether

the document can be produced in a redacted format without a confidential designation. (For instance, an email transmitting a publicly released document might be subject to redaction under this provision. Alternately, an email setting forth the sender's opinion would likely not be subject to redaction, because severing the opinion from the identity of the sender could be misleading.) If the parties cannot agree on redaction of a particular document, the party seeking redaction and non-confidential production may file a request with the Court.

7. **Challenging Confidential Designation.** Counsel for a party to whom Confidential Discovery Materials are being produced may challenge the "Confidential" designation made by the producing party by first requesting a "meet and confer" with the producing party in an attempt to amicably resolve the challenge. In the event agreement cannot be reached, the proponent of confidentiality may apply by motion for a ruling as to whether the designated discovery material may, in accordance with this Order, be treated as confidential. This motion shall be made within 30 days from the date on which the parties, after good faith attempt, agree that they cannot resolve the dispute or such other time period agreed to by the parties. The party seeking to maintain the materials as "Confidential" shall have the burden of proof on such motion to establish the propriety of its confidential designation. The Discovery Materials designated "Confidential" shall continue to be treated as such and subject to the provisions of this Confidentiality Stipulation and Protective Order pending determination by the Court of the merits of any such motion. In the event that the Court enters an order that particular Discovery Materials are not entitled to the designation "Confidential" the Discovery Materials shall nevertheless continue to be treated as "Confidential" and subject to the terms of this Confidentiality Stipulation and Protective Order for 30 days following the service of Notice of Entry of such order to enable the producing party to seek review and a stay of such order.

8. **Disclosure of Confidential Discovery Material.**

a. The disclosure of the Discovery Materials designated as "Confidential" by counsel for a party in this case to legal assistants, paralegals and clerical staff employed by the disclosing counsel's office and the Court is allowed under the terms of this Confidentiality Stipulation and Protective Order without limitation and without the need to execute an Affidavit. Such disclosure shall not constitute a violation or a waiver of the protections afforded by the Confidentiality Stipulation and Protective Order. Said assistants, paralegals and clerical staff, as employed agents of the disclosing counsel, are bound by this Order to the same extent as the parties and attorneys are bound.

b. Disclosure by counsel for a party in this case to any of the other individuals/entities identified in sections 3.c-g of Discovery Materials designated as "Confidential" by another party shall not constitute a violation or waiver of the protections afforded by this Confidentiality Stipulation and Protective Order to the extent that such disclosure is necessary to assist in the prosecution or defense of this case and so long as the individual/entity (or, in the event that an entity is not a natural person, the entity's employees) to whom disclosure is made has executed an Affidavit in the form attached hereto as Exhibit A. Copies of each executed Affidavit shall be maintained by the disclosing counsel.

c. Disclosure by counsel to a plaintiff's healthcare provider and/or that healthcare provider's counsel, outside of a deposition setting, of Discovery Materials designated as "Confidential" by another party shall not constitute a violation or waiver of the protections afforded by this Confidentiality Stipulation

and Protective Order to the extent that such disclosure is necessary to assist in the prosecution or defense of this case and so long as the individual/entity (or, in the event that an entity is not a natural person, the entity's employees) to whom disclosure is made has executed an Affidavit in the form attached hereto as Exhibit A. Copies of each executed Affidavit shall be maintained by the disclosing counsel. Such disclosure, outside of a deposition setting, shall be limited to the following categories of documents:

i. All documents (including call notes) referencing the healthcare provider to whom the disclosure is being made.

ii. All promotional materials identified as being used for the purposes of sales call visits with the healthcare provider to whom the disclosure is being made.

iii. All approved promotional materials used for the purposes of sales call visits with healthcare providers found within the custodial file of a sales representative who called on the healthcare provider to whom the disclosure is being made.

iv. All documents and materials presented during educational seminars (i.e. continuing medical education lectures and other similar lectures/meetings).

v. All "Dear Doctor" and "Dear Healthcare Provider" letters sent to healthcare providers in the United States.

vi. All documents publicly available.

d. During a deposition, disclosure by counsel to a witness and/or that witness's counsel, if any, of Discovery Materials designated as "Confidential" by another party shall be permitted so long as the witness to whom the disclosure is made has executed the Affidavit or orally agreed on the record to the terms of the Affidavit attached hereto as Exhibit A. Under no circumstances shall copies of Discovery Materials designated as "Confidential" used at a deposition be left in the possession of the witness or his/her counsel. Further, copies of Discovery Materials designated "Confidential" shall not be attached to or included with any original or copy of the transcript of a deposition sent to the witness or his/her counsel.

e. In addition, within thirty (30) days after the completion of a deposition session, counsel may designate the entirety or any specified portion of the transcript or exhibits thereto as "Confidential" by letter to the opposing party. Until such thirty (30) day period expires, the entirety of such transcripts and all exhibits thereto shall be treated as Confidential and subject to this Order. After such thirty (30) day period expires, such transcripts, exhibits or portions designated as "Confidential" shall be treated as such under this Order. If no such designation is made within thirty (30) days, such transcripts or exhibits shall not be treated as "Confidential" under this Confidentiality Stipulation and Protective Order.

f. Discovery Materials designated as "Confidential" produced by any defendant in this case may be disclosed to the named plaintiff(s) in other Mirena® lawsuits and their counsel who have executed Exhibit B acknowledging that: (i)

they have filed and properly served Bayer HealthCare Pharmaceuticals Inc.; Bayer Pharma AG; and Bayer OY, (ii) the claimed injury in their lawsuit allegedly resulted from the use of Mirena® and the subsequent alleged injury of idiopathic intracranial hypertension, (iii) a protective order has been entered in the lawsuit that would protect the Discovery Materials designated as "Confidential" from disclosure and that the Protective Order entered specifically covers Bayer HealthCare Pharmaceuticals Inc.; Bayer Pharma AG; and Bayer OY, and (iv) all counsel for plaintiff who receive the documents agree to be governed by the terms of this Order. Upon execution, Exhibit B shall be provided to counsel for the Defendant(s).

g. Any materials provided to an insurer or its counsel shall not be used for any purpose other than evaluation of the claims asserted in this case and shall not be used outside the claims asserted in this case.

9. Except as provided for herein, nothing in this Confidentiality Stipulation and Protective Order shall prevent or restrict counsel for any party in any way from inspecting, reviewing, using or disclosing any Discovery Materials produced or provided by that party, including Discovery Materials designated as "Confidential." The parties reserve all their respective rights concerning whether or not there has been a waiver of confidentiality in the event that the producing party shares such Discovery Materials designated as Confidential with third parties other than as provided for elsewhere in this Confidentiality Stipulation and Protective Order.

10. Disclosure of Discovery Materials designated as "Confidential" other than in accordance with the terms of this Confidentiality Stipulation and Protective Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate.

11. All persons receiving or given access to Discovery Materials designated as "Confidential" in accordance with the terms of this Confidentiality Stipulation and Protective Order consent to the continuing jurisdiction of this Court for the purposes of enforcing this Confidentiality Stipulation and Protective Order and remedying any violations thereof. All parties and their respective counsel, paralegals and the employees and assistants of all counsel, and experts receiving Discovery Materials designated as "Confidential" shall take steps reasonably necessary to prevent the disclosure of Confidential Discovery Materials other than in accordance with the terms of this Confidentiality Stipulation and Protective Order.

12. This Order does not automatically seal court records in this case or apply to the disclosure of Confidential Discovery Material at trial. It is only intended to facilitate the prompt production of discovery materials. A party that seeks to file with this Court any material that contains, describes, identifies, discloses, discusses, refers to or attaches any Discovery Materials designated as "Confidential" shall first file a motion for leave to file under seal seeking permission from the Court to do so. If the Court grants the party's request to file certain materials under seal, the documents filed under seal with the Clerk of the Court shall be kept under seal until further order of the Court.

13. The producing party of any Confidential Discovery Materials attached to or referenced in a document filed with the Court under seal may assent to the unsealing of the document at any juncture without waiving its assertion of confidentiality as to any other Discovery Materials.

14. Nothing shall prevent disclosure beyond that required under this Confidentiality Stipulation and Protective Order if the producing party consents in writing to such disclosure, or if the Court, after notice to all affected parties, orders such disclosure and that Order is not subject to an appellate stay within 30 days after Notice of Entry of the Order is served on the producing party.

15. Any party who inadvertently fails to identify documents, including deposition transcripts, as "Confidential" shall, promptly upon discovery of its oversight, provide written notice of the error and substitute appropriately designated documents produced in the same format as the incorrectly designated document was initially produced. Any party receiving such inadvertently unmarked documents shall, following receipt of notice of the error, treat such documents as confidential as if they had initially been designated as such, make good faith and reasonable efforts to retrieve documents distributed to persons not entitled to receive documents with the corrected "Confidential" designation and, upon receipt of the substitute documents, promptly return or destroy the improperly designated document(s) and/or the electronic media on which such document(s) reside.

16. **Procedure for Use in Court**. Discovery Material received by the Court or entered into evidence in non-trial proceedings shall not lose its status as "Confidential" Discovery Materials as a result. The use of any Discovery Material designated as "Confidential" at trial will be addressed in the Court's Pretrial Order.

17. This Confidentiality Stipulation and Protective Order shall be binding until the resolution of this litigation.

18. Unless otherwise ordered or agreed in writing by the producing party, and if requested by the producing party, each receiving party must return all Discovery Material to

the producing party or provide a certification to the producing party that all Discovery Material in their possession has been destroyed after the final termination of this action including copies of materials provided to third parties under the provisions of this Order. Notwithstanding this provision, Counsel are entitled to retain an archival copy of all pleadings, motion papers, transcripts, legal memoranda, correspondence or attorney work product, even if such materials contain Confidential Discovery Material. Any such archival copies that contain or constitute Confidential Discovery Material remain subject to this agreement as set forth in Paragraph 16 above.

19. Any party may apply to the Court for a modification of the Confidentiality Stipulation and Protective Order, and nothing in this Confidentiality Stipulation and Protective Order shall be construed to prevent a party from seeking such further provisions enhancing or limiting confidentiality as may be appropriate.

20. No action taken in accordance with the Confidentiality Stipulation and Protective Order shall be construed as a waiver of any claim or defense in this case or of any position as to discoverability or admissibility of evidence.

21. If a receiving party or its counsel or expert is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization that calls for production of any Confidential Discovery Materials produced by another party, the party to whom the subpoena or other process is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such documents or information until 10 business days after notifying counsel for the producing party in writing of all of the following: (i) the information and documentation requested for production in the subpoena; (ii) the date on which compliance with the subpoena is requested; (iii) the location at which compliance with the

subpoena is requested; (iv) the identity of the party serving the subpoena; and (v) 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 has been issued.

22. Nothing in this Confidentiality Stipulation and Protective Order shall be construed to prevent this Court from disclosing any facts relied upon by it in making or rendering any finding, ruling, order, judgment or decree of whatever description.

23. Each party shall bear its own costs for complying with this Confidentiality Stipulation and Protective Order.

SO ORDERED

Dated: _____, 201_

New York, New York

_____

PAUL A. ENGELMAYER, District Judge

United States District Court

Southern District of New York

In Re:

17-MD-2767(PAE)

Mirena IUS LEVONORGESTREL-RELATED Products Liability Litigation (NO.II) **17-MC-2767 (PAE)**

This Document Relates to All Actions

PAUL A. ENGELMAYER, District Judge:

EXHIBIT A

AGREEMENT TO MAINTAIN CONFIDENTIALITY

STATE OF _____)
)
COUNTY OF _____)

_____, being duly sworn, deposes and says:

1. I am over the age of 18 years and make this Affidavit based upon my personal knowledge, and I am competent to testify to the matters stated herein.

2. I am aware that United States District Judge Paul A. Engelmayer entered a Confidentiality Stipulation and Protective Order in the litigation identified above. A copy of that

Confidentiality Stipulation and Protective Order has been shown to me, and I have read and understand its contents.

3. By signing this Affidavit, I promise that I will not use the materials and contents of the materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order for any purpose other than this litigation.

4. By signing this Affidavit, I also promise that I will not communicate, disclose, discuss, identify, or otherwise use materials or the contents of materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order with, to, or for any person or entity other than the Court, a party to the above-described case, counsel for a party to the above-described case, including other counsel, paralegals, and staff employed in his or her office, persons permitted by the above-described Confidentiality Stipulation and Protective Order to attend depositions taken in this case, and persons or entities assisting such counsel who have executed an affidavit in the same form as this Affidavit.

5. By signing this Affidavit, I also promise that I will not copy, transcribe, or otherwise reproduce, or cause to be copied, transcribed, or otherwise reproduced, by any means whatsoever, any materials or the contents of any materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order except to the extent to which I am directed to do so by counsel for a party to this litigation, in which case all such copies, transcriptions, or reproductions shall be made solely for my own use in connection with my work or assistance in the above matter. I further promise at the conclusion of this litigation to deliver upon request all materials designated "Confidential" (originals and copies) to the counsel who originally directed that said materials be provided to me.

6. I understand that, by signing this Affidavit, I am agreeing to subject myself to the jurisdiction of this Court.

7. I understand that any use or distribution of the materials or contents of the materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order in any manner contrary to the provisions of the Confidentiality Stipulation and Protective Order will subject me to remedies as this Court may deem appropriate.

Dated: _____,
_____, 201_

_____
Signature of Affiant

Subscribed and sworn to before me,
this _____ day of _____

_____
Notary Public

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:

MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO.II)

17-MD-2767(PAE)
17-MC-2767 (PAE)

This Document Relates to All Actions

PAUL A. ENGELMAYER, District Judge:

EXHIBIT B

AGREEMENT TO MAINTAIN CONFIDENTIALITY

STATE OF _____)
)
COUNTY OF _____)

_____, being duly sworn, deposes and says:

1. I am an attorney and make this Affidavit based upon my personal knowledge, and I am competent to testify to the matters stated herein.

2. I am aware that a Confidentiality Stipulation and Protective Order has been entered in the litigation identified above. A copy of that Confidentiality Stipulation and Protective Order has been shown to me, and I have read and understand its contents.

3. By signing this Affidavit, I promise that I will not use the materials and contents of the materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order for any purpose other than this litigation.

4. By signing this Affidavit, I agree to be bound by all terms of the above-described Confidentiality Stipulation and Protective Order.

5. I understand that, by signing this Affidavit, I am agreeing to subject myself to the jurisdiction of this Court.

6. I understand that any use or distribution of the materials or contents of the materials designated "Confidential" pursuant to the above-described Confidentiality Stipulation and Protective Order in any manner contrary to the provisions of the Confidentiality Stipulation and Protective Order will subject me to remedies as this Court may deem appropriate.

7. By signing this affidavit, I am verifying under oath that I am a named plaintiff or counsel for a named plaintiff in a Mirena lawsuit that has previously been filed ("the Lawsuit") where (a) all the claimed injury(ies) in the Lawsuit allegedly result from the use of Mirena® and the subsequent alleged injury of idiopathic intracranial hypertension, (b) Bayer HealthCare Pharmaceuticals Inc.; Bayer Pharma AG; and Bayer OY have all been properly served in the Lawsuit, and (c) a protective order has been entered in the Lawsuit that would protect the Discovery Materials designated as "Confidential" from disclosure and that the Protective Order entered in the Lawsuit specifically covers Bayer HealthCare Pharmaceuticals Inc.; Bayer Pharma AG; and Bayer OY.

8. By signing this affidavit, I agree to only access and review Discovery Materials produced by parties that I have sued and properly served in the Lawsuit.

Dated: _____,
_____, 201_

_____
Signature of Affiant

Subscribed and sworn to before me,
this _____ day of _____

_____
Notary Public

EXHIBIT 8

TO

JUNE 5, 2017 JOINT LETTER

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:

MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO.II)

17-MD-2767(PAE)
17-MC-2767 (PAE)

This Document Relates to All Actions

PAUL A. ENGELMAYER, District Judge:

PROTOCOL FOR DOCUMENT PRODUCTION FORMAT

I. GENERAL

This Order governs the format of Documents, Data, and/or Tangible things that will be produced in this litigation. This Order does not govern the scope of production of Documents, Data, and/or Tangible things in the Litigation. All parties reserve their rights with respect to the scope of the document production.

II. PRODUCTION FORMAT

A. Hard copy documents. Hard copy documents and their attachments will be produced as follows:

1. Single page Group IV TIFF format (black and white, 300 dpi). Each image should have a unique file name, which is the Bates number of the page. Where possible, original document orientation should be maintained (i.e., portrait to portrait and landscape to landscape) and the Bates number shall be outside of the margins of the imaged pages.

2. OCR Text Files. Defendant will provide Plaintiff with the name of the OCR software and the settings of that software used to create the OCR. OCR text files shall be provided as a single text file for each hard copy document, not one text file per page. The filename itself should match its respective TIFF filename, which is the Bates number. The text

files will not contain the redacted portions of the documents. For foreign language "hard" copy documents being produced, in addition to the metadata fields required for English language documents, the Unicode values will be produced in a corresponding metadata field.

3. Coding Fields. The following information shall be produced with the OCR text files accompanying hard copy documents:

a. Beginning Document Bates Number;

b. Ending Document Bates Number;

c. Attachment Beginning Bates Number;

d. Attachment Ending Bates Number;

e. Custodian or Source;

f. Custodian ID;

g. Document Type;

h. Confidentiality (Y/N);

i. Page Count;

j. Redaction (Y/N);

k. Replacement (Y/N); and

l. OCR Text File Name.

4. Database Load Files/Cross-Reference Files. Documents will be provided with a Concordance delimited file with an IPRO delimited file and an Opticon delimited file, as detailed in Exhibit B. Each TIFF in a production must be referenced in the corresponding load file. The total number of documents referenced in a production's load file should match the total number of TIFF files in the production.

5. Bates Numbering. All images must be assigned a Bates/control number that must always: (1) be unique across the entire document production; (2) maintain a constant length (0-padded) across the entire production; (3) contain no special characters or embedded spaces; and (4) be sequential within a given document. If a Bates number or set of Bates numbers is skipped in a production, the producing party will note which Bates numbers are skipped and the reason why in a cover letter accompanying the production.

6. Unitizing of Documents. In scanning paper documents, documents are to be produced as they are kept in the normal course of business. For documents found in file folders and other containers that have labels or tabs or other identifying information, such labels and all sides of such file folders and tabs shall be scanned. In the case of an organized compilation of separate documents — for example, a binder containing several separate documents behind numbered tabs — the document behind each tab should be scanned separately, but the relationship among the documents in the binder should be reflected in proper coding of the beginning and ending document and attachment fields. Documents will be unitized at the lowest possible level and attachment information preserved. For example, if a folder contains two documents, the folder and each document will constitute a separate document, but they will have the same attachment start and end.

B. Electronically Stored Information ("ESI")

1. Non-standard and Microsoft PowerPoint documents agreed on by the parties pursuant to Sections I.B.2.k and I.B.2.n, audio and video files as provided in section I.B.2.m, and Microsoft Excel Spreadsheets as provided in section I.B.2j will be produced in native format with a link in the "NativeLink" field, along with all extracted text and applicable metadata fields set forth in Exhibit A.

2. All ESI documents other than those identified above in section I.B.1 will be produced in single page Group IV TIFF format (black and white, 300 dpi) with extracted text, along with the metadata and coding fields set forth in Exhibit A that exist for a particular item, to be provided in a standardized load file compatible with Concordance (default delimiter), with a Bates number field included in the load file so that text and metadata can be matched with TIFF images. Original document orientation should be maintained (i.e., portrait to portrait and landscape to landscape) when possible.

a. Text Files. For each document, the text of native files will be extracted directly from the native file and provided as a single text file for each document. The text filename itself should match its respective TIFF filename, which is the Bates number. However, if a document has been redacted, OCR of the redacted text will suffice.

b. System Files. Common system and program files as defined by Kroll's NIST library (a copy of which is attached as an Appendix to this Production Format) need not be processed, reviewed, or produced.

c. De-Duplication. A party is only required to produce a single copy of a responsive standalone document and a party may de-duplicate (based on MD5 or SHA-1 hash values at the document level) across custodians, except that any document which is part of a family group that includes a produced document cannot be withheld as a duplicate. The identity of other custodians of de-duplicated documents must be listed in the "Other Custodians" field of any copies of the document that are produced. The load file will identify the de-duped custodian or source and provide the ProgBeg of the produced copy.

d. Unproduced Duplicates. A produced copy of an unproduced duplicate may be used, and shall be treated as if it were, the unproduced document for any purpose in this action.

e. Parent-Child Relationships. Parent-child relationships (the association between an attachment and its parent document or between embedded documents and their parent) should be preserved.

f. Family Groups. A document and all other documents in its attachment range constitute a family group. If any document which is part of a family group is produced, then all documents in that family group, except for documents which are withheld in their entirety for privilege will be produced. No document which is part of a family group that contains a document which is produced, can be withheld as a duplicate.

g. Database Load Files/Cross-Reference Files. Documents should be provided with a Concordance delimited file with an IPRO delimited file and an Opticon delimited file, as detailed in Exhibit B. Each TIFF in a production must be referenced in the corresponding load file. The total number of documents referenced in a production's load file should match the total number of TIFF files in the production.

h. Bates Numbering. All images must be assigned a Bates/control number that must always: (1) be unique across the entire document production; (2) maintain a constant length (0-padded) across the entire production; (3) contain no special characters or embedded spaces; and (4) be sequential within a given document. If a Bates number or set of Bates numbers is skipped in a production, the producing party will note which Bates numbers are skipped and the reason why in a cover letter accompanying the production.

i. Embedded Documents shall be extracted and produced as standalone files along with corresponding attachment metadata to the parent document.

j. Microsoft Excel Spreadsheets shall be produced as native files with the source file path provided along with the extracted text and metadata identified in Exhibit A. If a spreadsheet requires redactions it can be produced as a TIFF image with all rows and columns expanded and capable of being viewed within the TIFF image.

k. Microsoft PowerPoint presentations or slide shows will be converted to TIFF images as follows: a conversion to black and white will be done utilizing PowerPoint's print feature; background will be turned off so all text is visible; hidden slides will be revealed; and if any slides in the presentation contain speaker notes, then all slides will be printed in Slide and Notes view (one slide per page) with the slide appearing at the top of the page and the notes appearing at the bottom of the page. For those presentations or slide shows in which the black and white TIFF affects the ability to interpret the document, the parties will meet and confer regarding a reasonable alternative form of production (i.e., a color copy or native format).

l. Microsoft Word documents will be converted to TIFF images with comments and track changes exposed. Embedded images or documents will be extracted and produced as TIFFs with the source file path provided along with the extracted text and metadata identified in Exhibit A.

m. Audio and Video Files in any form including but not limited to all VCR, DVD, Blu-ray or web/internet files shall be produced as native files with the source file path, extracted text and metadata, as applicable and as identified in Exhibit A.

n. **Non-Standard Files**. For documents and ESI that convert with errors to TIFF (e.g., oversized drawings, picture files, etc.), the producing party will either produce the document in native format or will ask the receiving party to meet and confer regarding a reasonable alternative form of production. A Bates-numbered placeholder will be inserted in production sets for documents produced in native form.

o. **Color**. For those color documents for which the black and white TIFF image affects the ability to interpret the document, the parties will meet and confer regarding the production of the document in color.

p. **Replacement files**. Any documents that are replaced in later productions shall be clearly designated as such, by appending a "- R" to the production prefix and by a letter communication accompanying the production clearly designating such documents as replacements.

q. **Time Zone**. GMT should be selected as the time zone.

r. **Dynamic Fields**. Documents with dynamic fields for file names, dates, and times will be processed to show the field code (e.g., "[FILENAME]" or "[AUTODATE]"), rather than the values for such fields existing at the time the file is processed.

s. The parties will meet and confer if needed regarding the production of potentially relevant structured data sources.

t. **Compressed files**. Compression file types (i.e., .CAB, .GZ, .TAR, .Z, .ZIP) shall be decompressed in a reiterative manner to ensure that a zip within a zip is decompressed into the lowest possible compression resulting in individual folders and/or files.

C. MISCELLANEOUS PROVISIONS

1. Documents and ESI that contain information that identifies patients or any other information protected by law will be redacted from any documents produced.

2. Any practice or procedure set forth herein may be varied by agreement of the parties, confirmed in writing, where such variance is deemed appropriate to facilitate the timely and economical exchange of documents or ESI.

3. The parties understand that this protocol contemplates the production of large volumes of documents and that productions will be made on a rolling basis.

4. The parties further acknowledge that nothing in this Order waives, restricts or eliminates the parties' "claw-back" rights pursuant to the Protective Order(s) in this case or governing law, rules, orders, or agreements regarding inadvertently produced documents.

5. The parties shall meet and confer and endeavor to resolve any disputes arising hereunder before submitting such disputes to the Court for determination.

SO ORDERED

Dated: _____, 2017

New York, New York

_____

PAUL A. ENGELMAYER, District Judge

EXHIBIT A

Field Name	Populated For (Email, Edoc, or Both	Field Description
ProdBeg	Both	Control Numbers
ProdEnd	Both	Control Numbers
BegAttach	Both	Control Numbers (First production Bates number of the first document of the family)
EndAttach	Both	Control Numbers (Last production Bates number of the last document of the family)
PgCount	Both	Page Count
Source	Both	Name of party producing the document
Custodian	Both	Custodian name (ex. John Doe)
NativeFile	Both	Native File Link
EmailSubject	Email	Subject line of email
DateSent	Email	Date and time email was sent — Format: (mm/c1d/yyyy hh:mm:ss AM)
DateMod	Edoc	Date and time the document was modified — Format: (mm/dd/yyyy hh:mm:ss AM)
To	Email	All recipients that were included on the “To” line of the email
From	Email	The name and email address of the sender of the email
CC	Email	All recipients that were included on the “CC” line of the email
BCC	Email	All recipients that were included on the “BCC” line of the email
Attach	Email	The file name(s) of the attached documents
DateCreated	Edoc	Date and time the document was created — Format: (rnm/dd/yyyy hh:mm:ss AM)

Field Name	Populated For (Email, Edoc, or Both	Field Description
FileName	Both	File name of the edoc or email (for email this is the subject line of the email with a .htm extension)
Title	Edoc	Any value populated in the Title field of the document properties
Subject	Edoc	Any value populated in the Subject field of the document properties
Author	Edoc	Any value populated in the Author field of the document properties
DocExt	Both	File extension of the document
Applic	Edoc	Commonly associated application for the specified file type.
Text	Both	Text extracted from the email or edoc
Confidentiality	Both	Y/N — Yes or No Indicates if document has been designated as "Confidential" or "Highly Confidential" under the Protective Order
FileSize	Both	File size
TextPath	Both	Filepath for OCR or extracted text files
AttachBates	Email	Bates numbers of the first pages of each attachment, separated by semicolons
AttachCount	Email	Number of email attachments
AttachNames	Email	Names of the attachments as listed in the email, separated by semicolons
DateReceived	Email	Date and time received - Format: (mm/dd/yyyy hh:mm:ss AM)
Importance	Email	Indicates Important of the e-mail message
HashValue	Both	MD5 or SHA1 hash value
LastModBy	Edoc	Last person who modified a document

Field Name	Populated For (Email, Edoc, or Both	Field Description
DocumentType	Both	Descriptor for the type of document: "E-document" for electronic documents not attached to emails; "Emails" for all e-mails Physicals" for hard copy physical documents that have been scanned and converted to an electronic image.
Redacted	Both	"yes" if document was redacted
Replacement	Both	"Yes" if document was a Replacement
ProdVol	Both	Name of production media
OtherCustodians	Both	Names of any other custodians whose copy of the document was not produced as a duplicate in format last name, first names with each name delimited by semicolons
OtherCustodianID	Both	Each OtherCustodian will be assigned a unique numeric identifier that will be maintained throughout productions. Where data is collected from an archive, the archive will be listed as custodian; Multi-valued, separated by semicolons
CustodianID	Both	Name of person or data source (non-human) from where documents/files are produced. Each Custodian will be assigned a unique numeric identifier that will be maintained throughout productions. Where data is collected from an archive, the archive will be listed as custodian. **Where redundant names occur, individuals should be distinguished by an initial which is kept constant throughout productions (e.g., Smith, John A. and Smith, John B.)* *** Defendant will use reasonable means to determine if a custodian changed his/her name for work purposes during the relevant time period (e.g., Jane Doe got married, changed her name to Jane Smith and used her married/hyphenated name at work). Defendant will notifyplaintiffs of any and all name changes in production cover letters*.
Relative FilePath Append	Email	File Path in which the attachments were stored
EmailDateSort	Email	Sent Date of the parent email (physically top email in a chain, i.e. immediate/direct parent email)

Field Name	Populated For (Email, Edoc, or Both	Field Description
Read/Unread	Email	Whether the Outlook item was read or unread at the time of collection. Values provided will be "Yes" for read, "No" for unread, and a null value where the read/unread flag value is unavailable.

EXHIBIT B

FILE FORMATS

Image Load Files

- The name of the image load file should mirror the name of the delivery volume, and should have an .LFP or an OPT extension (i.e., ABC001.LFP; ABC000.OPT)
- The volume names should be consecutive (i.e., ABC001, ABC002, et. seq.)
- There should be one row in the load file per TIFF image.
- Every image in the delivery volume should be contained in the image load file.
- The image key should be named the same as bates number of the page.
- Load files should not span across media (e.g., CDs, DVDs, Hard Drives, Etc.), i.e., a separate volume should be created for each piece of media delivered.
- Files that are the first page of a logical document should include a "D" where appropriate. Files that are the first page of an attachment to an e-mail should include a "C" where appropriate. Subsequent pages of all documents (regular document, e-mail, or attachment) should include a blank in the appropriate position.

IM,VN00000001,D,0,@29502601;295026001\0000;VN00000001.TIF;2
IM,VN00000002, ,0,@29502601;295026001\0000;VN00000002.TIF;2
IM,VN00000003, ,0,@2950260 1;295026001\0000;VN00000003.TIF;2
IM,VN00000004, ,0,@29502601;295026001\0000;VN00000004.TIF;2
IM,VN00000005,D,0,@29502601;295026001\0000;VN00000005.TIF;2
IM,VN00000006, ,0,@29502601;295026001\0000;VN00000006.TIF;2
IM,VN00000007, ,0,@29502601;295026001\0000;VN00000007.TIF;2
IM,VN00000008, ,0,@29502601;295026001\0000;VN00000008.TIF;2
IM,VN00000009,D,0,@29502601;295026001\0000;VN00000009.TIF;2
IM,VN00000010, ,0,@29502601;295026001\0000;VN00000010.TIF;2

Opticon Delimited File:

MSC000001,MSC001,D:\IMAGES\001\MSC000001.TIF,Y,,,3
MSC000002,MSC001,D:\IMAGES\001\MSC000002.TIF,Y,,,,
MSC000003,MSC001,D:\IMAGES\001\MSC000003.TIF,Y,,,,
MSC000004,MSC001,D:\IMAGES\001\MSC000004.TIF,Y,,,2
MSC000005,MSC001,D:\IMAGES\001\MSC000005.TIF,Y,,,,

Concordance Delimited Files:

þBegDocþþEndDocþþBegAttachþþEndAttachþþCustodianþ

- The data load file should use standard Concordance delimiters:
  - Comma ¶ (ASCII 20)
  - Quote — þ (ASCII 254)
  - Newline — ® (ASCII 174)
- The first record should contain the field names in the order of the data;
- All date fields should be produced in mm/dd/yyyy format;
- Use carriage-return line-feed to indicate the start of the next record;
- Load files should not span across media (e.g., CDs, DVDs, Hard Drives, Etc.); a separate volume should be created for each piece of media delivered;
- The name of the data load file should mirror the name of the delivery volume, and should have a .DAT extension (i.e., ABC001.DAT);
- The volume names should be consecutive (i.e., ABC001, ABC002, et. seq.)

EXHIBIT 9

TO

JUNE 5, 2017 JOINT LETTER

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:

MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO.II)

17-MD-2767(PAE)
17-MC-2767 (PAE)

This Document Relates to All Actions

PAUL A. ENGELMAYER, District Judge:

ORDER REGARDING DOCUMENTS CLAIMED TO BE PRIVILEGED/PROTECTED

1. This Order is entered to provide guidelines that govern claims the parties make to withhold information otherwise discoverable by claiming that the information is privileged/protected, the protocols that shall be followed with regard to privilege logs for documents fully withheld and those redacted for a claim of privilege ("privilege redactions"), and the method of determining privilege and/or privilege redaction disputes.

2. Pursuant to a claim of attorney-client privilege, work product protection, or other applicable privilege or immunity, the designating party shall produce one or more privilege logs in a Microsoft Excel Spreadsheet or a comparable electronic format that allows text searching and organization of data. The designating party will produce a privilege log within 75 days following the production of documents from which the privileged or privilege redactions are withheld. The log will be accompanied by a glossary of the names and affiliations of the legal personnel named in the log. In the affiliation column, the designating party will indicate whether the legal personnel is an inside or outside counsel. If the individual is outside counsel, his/her law firm's name will be provided. If the individual is inside counsel, the designating party will identify the type of attorney (e.g., litigation, patent, etc.) where possible.

3. The log will contain the following information for each item not produced or redacted for reasons of privilege, to the extent providing this information will not destroy the privilege:

a. the name(s) of the person(s) who created and received the document or a copy of it, including the To; From; CC and BCC fields, when applicable. The producing party will place a star to indicate if an individual identified is an attorney and two stars to indicate an attorney agent. If a distribution list is included in the To; CC; or BCC fields, the names of all persons included in the distribution list must be disclosed;

b. the date on which the document was created and/or received;

c. the time the document was sent, if applicable;

d. a description of the nature of the document sufficient to enable the receiving party to assess the applicability of the privilege or protection;

e. the privilege(s) claimed; and

f. the Bates range of the document.

4. With respect to emails, when there is a chain of privileged or privilege redacted emails the designating party need include only one entry on the log to identify withheld e-mails that constitute an uninterrupted dialogue between or among individuals; provided, however, that disclosure must be made that the e-mails are part of an uninterrupted dialogue. Moreover, the beginning and ending dates and times (as noted on the e-mails) of the dialogue and the number of e-mails within the dialogue must be disclosed, in addition to other requisite privilege log disclosure, including the names of all of the recipients of the communications.

5. With respect to the e-mails collected from the custodial files of the individuals whose files were produced in Kelli Baugh and Justin Baugh v. Bayer Corporation, et al. in the United States District Court for the District of South Carolina, Civil Action No. 4:11-cv-00525_RBH/Florence Division, Jo-Ann Ruane, Antonio Costales, Catherine Holtz, John Rotondo, and Charles Walsh, when there is a chain of privileged or privileged redacted e-mails

the designating party need only include one entry on the privilege log to identify withheld e-mails that constitute an uninterrupted dialogue between or among individuals. Moreover, the beginning and ending dates and times (as noted on the e-mails), as well as the number of e-mails in the string, will be provided in addition to the other requiste privilege log disclosure, including the names of all of the recipients of the communications. This section is only applicable to those documents already produced in the *Baugh* matter and does not apply to any subsequent productions for custodial files of Jo-Ann Ruane, Antonio Costales, Catherine Holtz, John Rotondo, and Charles Walsh.

6. Presumptively, neither party is required to include in their privilege logs:

   a. communications exclusively between a party and its counsel;

   b. work product created by trial counsel, or by an agent of counsel other than a party, after commencement of the action; and

   c. internal communications within: i) a law firm or ii) a legal department of a corporation or of another organization.

7. The parties shall meet and confer and endeavor to resolve any disputes arising hereunder before submitting such disputes to the Court for determination. If no resolution is reached, a party or person who raises a question as to the assertion of a privilege, privilege redaction, or work product protection with respect to documents (including electronically stored information) may request a ruling from the Court as follows:

   a. The requesting party or person will submit to the Court, in a manner permitted by the Judge's Individual Practices, and to opposing counsel by hand delivery, fax or email, a letter of not more than 3 single-spaced pages (a) setting forth its position and including a glossary of the names and affiliations of all individuals named in the disputed document(s) and (b) certifying that it has in good faith conferred with the opposing party or person in an effort to resolve the issues without court action.

   b. If the requestor is the party or person invoking privilege or work product protection, it may attach to its letter to the Court no more than 5 representative documents that are the subject of its request. The documents are to be attached only to the copy of

the letter directed to the Court, for *in camera* review, and not to the copy of the letter directed to the opposing party.

c. Any opposing party or person may submit a responsive letter of no more than 3 single-spaced pages within 3 business days with a copy to opposing counsel.

d. If the Court permits a reply, it should not exceed 2 single-spaced pages and should be submitted within 2 business days of the responding letter.

e. Unless the Court requires a more extensive submission, within fourteen days from the receipt of the responsive letter or, if later, its receipt of the documents, the Court will make its best effort to determine whether the submitted documents must be produced. The Court may issue its decision prior to its receipt of the responsive letter if it has otherwise provided any opposing party or person an opportunity to be heard.

8. Pursuant to Federal Rule of Civil Procedure 26(b)(5) and Federal Rule of Evidence 502(e), a party who inadvertently discloses documents that are privileged or otherwise immune from discovery shall, promptly upon discovery of such inadvertent disclosure, so advise the receiving party and request that the documents be returned. The receiving party shall return such inadvertently produced documents, including all copies, within 10 days of receiving such a written request. The party returning such inadvertently produced documents may thereafter seek re-production of any such documents pursuant to applicable law.

SO ORDERED

Dated: _____, 201_

New York, New York

_____

PAUL A. ENGELMAYER, District Judge