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BRIAN R. MARTINOTTI, J.S.C.

IN RE: MIRENA® LITIGATION *This Document Relates to All Actions*	**SUPERIOR COURT OF NEW JERSEY** **LAW DIVISION: BERGEN COUNTY** **CASE NO. 297** **MASTER DOCKET NO.:** **BER-L-4098-13**

SECOND REVISED 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 Revised Confidentiality Stipulation and Protective Order shall be entered in this action. This Order shall govern the production of documents by Plaintiffs and the proper Defendants as identified in the Agreed Order Regarding Proper Party Defendant and any future amendments thereto.

1. **Discovery Materials.** This Revised 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 Revised Confidentiality Stipulation and Protective Order. Such stamping or marking will take place prior to production

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

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 litigation 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 the underlying litigation;

g. any witness during deposition in this Litigation; 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"

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 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 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 Revised 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 Revised 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 to the Litigation to legal assistants, paralegals and clerical staff employed by the disclosing counsel's office and the Court is allowed under the terms of this Revised 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 Revised 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 the Litigation 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 Revised Confidentiality Stipulation and Protective Order to the extent that such disclosure is necessary to assist in the prosecution or defense of the Litigation 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 Revised Confidentiality Stipulation and Protective Order to the extent that such disclosure is necessary to assist in the prosecution or defense of the Litigation 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 Revised Confidentiality Stipulation and Protective Order.

f. Discovery Materials designated as "Confidential" produced by any defendant in this *In Re: Mirena® Litigation, Superior Court of New Jersey, Law Division, Bergen County, Case No. 297* may be disclosed to the named plaintiff(s) in other non-New Jersey MultiCounty Litigation Case No. 297 Mirena® lawsuits and their counsel who have executed Exhibit B acknowledging that: (i) they have filed and properly served the defendant who produced the Discovery Materials to which they would like access, (ii) the Plaintiff alleges injury from the use of Mirena® in their non-New Jersey MultiCounty Case No. 297 lawsuits; (iii) a protective order has been entered in the non-New Jersey MultiCounty Case No. 297 litigation that would protect the Discovery Materials designated as "Confidential" from disclosure, 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). Nothing in the paragraph shall be construed to govern access to documents by counsel with lawsuits pending in this *In Re: Mirena® Litigation, Superior Court of New Jersey, Law Division, Bergen County, Case No. 297.*

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 litigation and shall not be used outside the claims asserted in this litigation.

9. Except as provided for herein, nothing in this Revised 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 Revised Confidentiality Stipulation and Protective Order.

10. Disclosure of Discovery Materials designated as "Confidential" other than in accordance with the terms of this Revised 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 Revised Confidentiality Stipulation and Protective Order consent to the continuing jurisdiction of this Court for the purposes of enforcing this Revised 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 Revised 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 file such Discovery Materials under seal in compliance with applicable law and shall only file same upon the entry of a Court Order permitting the documents to be filed under seal in accordance with the procedure set forth in Paragraph 13 of this Order. Documents filed under seal with the Clerk of the Court shall be kept under seal until further order of the Court, so long as the Court permits, in a sealed envelope with information required by the Court as well as the following statement endorsed on it:

> Confidential
>
> This envelope contains documents that are subject to a Protective Order entered by the Court in this action governing the use of Confidential Discovery Material. All such material so filed shall be maintained by the Clerk of the Court separate from the public records in this action, and shall be released only upon further Order of the Court.

13. If, in connection with any motion or court filing, any party intends to submit or offer into evidence any Discovery Material designated as "Confidential" by either Plaintiffs or Defendants, the party shall abide by R. 1:38 and shall only file such evidence following the entry of an order to seal the Discovery Material designated as "Confidential". Except as otherwise directed by the Court, and subject to the approval of the Court, when the submission of the Discovery Material designated as "Confidential" is anticipated in connection

with any motion, the parties shall set a schedule that is sufficient to allow ten (10) days after the completion of briefing by all parties for any party to file a motion to seal all or part of the papers. For all motions, the parties shall exchange their respective motion papers, opposition papers and reply papers in accordance with the schedule set by the Court or the Rules of Court (with service of a courtesy copy to chambers), but shall not file these papers until ten (10) days after the service of the moving party's reply papers and then only if no party has notified all other parties that it intends to file a motion to seal any of the papers in support or in opposition to the pretrial motions. Upon resolution of the sealing motion, within five (5) days the Party who produced the Discovery Material designated as "Confidential" shall file with the Clerk of Court a copy of the motion, opposition, reply, or other submission, together with all supporting memorandum and exhibits, in such form as directed by the Court (under seal or otherwise) on the sealing motion. In connection with any application to seal records in accordance with R.1:38-11, the Party who produced the Discovery Material designated as "Confidential" shall be deemed the movant in connection with such request, and it shall be that Party's burden to demonstrate good cause to seal such Discovery Material. Nothing in this Order shall be deemed to alter the Party's burdens under R. 1:38-11. To the extent the provisions of this Protective Order are inconsistent with New Jersey law, New Jersey law shall trump them.

14. 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.

15. Nothing shall prevent disclosure beyond that required under this Revised 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.

16. 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.

17. **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.

18. This Revised Confidentiality Stipulation and Protective Order shall be binding throughout and after final adjudication of this action, including but not limited to any final adjudication of any appeals and petitions for extraordinary writs.

19. 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 17 above.

20. Within thirty (30) days after final adjudication of this action, including but not limited to, any final adjudication of any appeals and petitions for extraordinary writs, Plaintiffs or Defendants may request that the Clerk return under seal to counsel for the producing party all Discovery Materials designated "Confidential" including, without limitation, all transcripts or other things that were subject to the provisions of this Revised Confidentiality Stipulation and Protective Order.

21. Any party may apply to the Court for a modification of the Revised Confidentiality Stipulation and Protective Order, and nothing in this Revised 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.

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

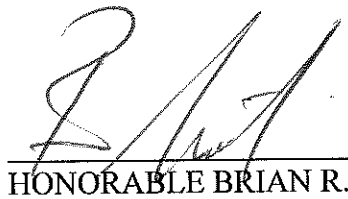
23. If a receiving party or its counsel or expert is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization that calls for production of any Confidential Discovery Materials produced by

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.

24. Nothing in this Revised 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.

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

IT IS SO ORDERED



HONORABLE BRIAN R. MARTINOTTI, J.S.C.

IN RE: MIRENA® LITIGATION *This Document Relates to All Actions*	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY CASE NO. 297 MASTER DOCKET NO.: BER-L-4098-13

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 a Revised Confidentiality Stipulation and Protective Order has been entered in this case, *In Re: Mirena® Litigation, Superior Court of New Jersey, Law Division, Bergen County, Case No. 297.* A copy of that Revised 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 Revised 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 Revised Confidentiality Stipulation and Protective Order with, to, or for any person or entity other than the Court, a party to the above-described Litigation, counsel for a party to the Litigation, including other counsel, paralegals,

and staff employed in his or her office, persons permitted by the above-described Revised Confidentiality Stipulation and Protective Order to attend depositions taken in the Litigation, 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 Revised Confidentiality Stipulation and Protective Order except to the extent to which I am directed to do so by counsel for a party to the 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 the Litigation to deliver upon request <u>all</u> 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 Revised Confidentiality Stipulation and Protective Order in any manner contrary to the provisions of the Revised 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

IN RE: MIRENA® LITIGATION *This Document Relates to All Actions*	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY CASE NO. 297 MASTER DOCKET NO.: BER-L-4098-13

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 Revised Confidentiality Stipulation and Protective Order has been entered in this case, *In Re: Mirena® Litigation, Superior Court of New Jersey, Law Division, Bergen County, Case No. 297* Litigation. A copy of that Revised 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 Revised 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 Revised 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 Revised Confidentiality Stipulation and Protective Order in any manner contrary to the provisions of the Revised 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 results from perforation, embedment or migration of the Mirena®, and (b) a protective order has been entered in the Lawsuit that would protect the Discovery Materials designated as "Confidential" from disclosure.

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