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Carol E. Higbee, P.J.Cv.

In re PELVIC MESH LITIGATION/BARD,	SUPERIOR COURT OF NEW JERSEY LAW DIVISION, ATLANTIC COUNTY CIVIL ACTION Case No. 292 CT Master Case 6339-10 Hon. Carol E. Higbee, P.J. Cv. **STIPULATED PROTECTIVE ORDER REGARDING CONFIDENTIALITY OF DOCUMENTS**

WHEREAS New Jersey Court Rule 4:10-3(g) authorizes the entry of an Order to limit disclosure of certain confidential information; and

WHEREAS, the parties, through their counsel, have stipulated and agreed to give effect to this Stipulation and Order of Confidentiality ("Protective Order") as set forth below to protect the designated confidential information from use in any manner inconsistent with this Protective Order;

WHEREAS, the Court finds that there is good cause for the entry of this Order within the meaning of New Jersey Court Rule 4:10-3(g)

I. Scope of Order

Disclosure and discovery in this proceeding may involve production of confidential, proprietary, and private information for which special protection from public disclosure and from any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the court to enter their Stipulated Protective Order ("Protective Order") in this matter. Upon entry of this Stipulated Protective Order, the Protective Order will apply to all actions that are or become a part of Case No. 292 CT, Master Number 6339-10.

II. The Order

A. By signing this Protective Order (the "Order"), the parties have agreed to be bound by its terms and to request its entry by the presiding district or magistrate judge. It is hereby ORDERED as follows:

B. **DISCOVERY PHASE**

1. For purposes of this Order, the following definitions shall apply: (a) The term "Confidential Discovery Material" as used in this Protective Order means all information designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL, as those designations are defined in Paragraphs II.B.2 and II.B.3, produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is designated in good faith by the party producing the material in accordance with the terms of this Protective Order (the "producing party") as being entitled to protection under New Jersey Court Rule 4:10-3(g) or other applicable case law, or as ordered by the Court; (b) the term "document" shall have the full meaning ascribed to it by the New Jersey Court Rules; and (c) the term "producing party" shall be defined as any party or non-party who produces or provides materials or testimony containing Confidential Discovery Material.

2. A Producing Party may designate as "**CONFIDENTIAL**" any material the producing party believes in good faith constitutes or discloses information or that qualifies for protection pursuant to R. 4:10-3(g) including information that is trade secret or other confidential research,

development, or commercial information, and materials that are deemed confidential under Federal Drug Administration ("FDA") regulations and Health Insurance Portability and Accountability Act ("HIPAA") statutes and/or regulations.

3. Confidential information may be further designated as "**HIGHLY CONFIDENTIAL**" if a Defendant produces materials that it believes in good faith would, if disclosed, cause substantial economic harm to the competitive position of the entity from which the information was obtained because it is **HIGHLY CONFIDENTIAL** information relating to research and development material on a product currently under development or materials that reflect a party's price competitiveness in the market or business strategies of a party concerning a current or new product. The plaintiff(s) will inform the producing party of its intent to disclose such information to any individual who is currently, or who at any time during the pendency of this litigation becomes, a consultant to a competitor of the Producing Party in the pelvic mesh business, and plaintiff(s) will follow the procedures for disclosure of such materials to such individual as provided in Paragraph II. B. 8 of this Protective Order. A "competitor" for purposes of this Paragraph is defined as a company currently involved, or actively investigating becoming involved, in the development, sale, marketing and/or distribution of any type of pelvic mesh product.

4. Challenges to Designations or Redacted Information: Challenges to Designations or Redacted Information: Any party may at any time challenge the redaction or the designation of information as CONFIDENTIAL or HIGHLY CONFIDENTIAL by providing written notice of its objection to the designating party, or, in the case of a deposition, either on the record at a deposition or in writing later. Within 10 days after such a challenge, the designating party shall respond in writing. If, after a meet-and-confer process, the parties cannot reach agreement, the designating party shall apply for an appropriate ruling from the Court within 20 days. The disputed material shall continue to be treated as designated, or redacted, until the Court orders otherwise or unless the designating party fails to move the Court within 20 days, at which point the material at issue shall be re-designated consistent with the designation challenge. In any such application concerning a ruling on confidentiality or redacted information, the party claiming the designation of confidentiality or redaction has the burden of establishing that such confidential designation or redaction is proper.

5. No person or party subject to this Order shall distribute, transmit, or otherwise divulge any material marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, except in accordance with this Order.

6. Use of Confidential Material Limited to this Action: Any document or other material which is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, or the contents thereof, may be used by a party, or a

party's attorney, expert witness, consultant, or other person to whom disclosure is made, only for the purpose of this action. Nothing contained in this Order shall prevent the use of any document or the contents thereof, at any deposition taken in this action. If a party intends to use material that has been marked as **HIGHLY CONFIDENTIAL** at the deposition of an employee or former employee of a non-producing party in this litigation, then the party shall notify the Producing Party ten (10) days in advance of the deposition that it intends to use that category of material. If the parties cannot agree on parameters for usage of the material at the deposition, then the parties will seek the direction of the Court as to the utilization of that category of material in the deposition.

7. Access to Confidential Material: If a party or attorney wishes to disclose any document or other material which is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, or the contents thereof, to any person actively, or retained to, work on this action (e.g., expert witness, paralegal, associate, consultant), the person making the disclosure shall do the following:

   (a) Provide a copy of this Order to the person to whom disclosure is made;

   (b) Inform the person to whom disclosure is made that s/he is bound by this Order;

   (c) Require the person to whom disclosure is made to sign an acknowledgment and receipt of this Order;

(d) Instruct the person to whom disclosure is made to return or, in the alternative and with permission of the producing party, at the conclusion of the case to destroy any document or other material which is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, including notes or memoranda made from **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** material;

(e) Maintain a list of persons to whom disclosure was made and the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** materials which were disclosed to that person;

(f) At the conclusion of this action, gather the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** materials, copies thereof, and related notes and memoranda, and return them to the party or attorney who originally disclosed them, or destroy them, providing a certificate of compliance with the terms of this Protective Order; and

(g) Only "Designated In-House Counsel" of Defendants may have access to information designated as **HIGHLY CONFIDENTIAL** by another producing party. "Designated In-House Counsel" shall mean: (1) Brian Leddin, Brian L. Burlew, Greg A. Dadika, and Stephen J. Long for C. R. Bard, Inc.; (2) Marc Polk, Michael W. Lyons, and Mark Farber for Sofradim Production or Tissue Science Laboratories Limited, as appropriate; and (3) paralegal and/or clerical employee for each such Designated In-House

Counsel to provide administrative support. Each Designated In-House Counsel shall complete and sign a copy of the Undertaking in Exhibit A, and each such completed, signed form shall be transmitted by e-mail to counsel for the other parties before disclosure of any such other party's **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** information to the Designated In-House Counsel.

(h) The parties may disclose CONFIDENTIAL or HIGHLY CONFIDENTIAL material to any attorney of record for claimants in other pending U.S. litigation alleging personal injury or economic loss arising from the alleged use, purchase, or payment of pelvic mesh products in this or such other action, provided that the proposed recipient is (i) already operating under a stipulated Confidentiality Order and (ii) agrees to be bound by this Order and signs the attestation described in paragraph 11 that is attached hereto as Exhibit A.

8. Disclosure Requirements for **HIGHLY CONFIDENTIAL** information to Competitor Related Consultants: Prior to disclosure, plaintiff(s) will inform the Producing Party of its intent to disclose **HIGHLY CONFIDENTIAL** material to anyone who is currently, or who at any time during the pendency of this litigation becomes, an employee, officer, director or consultant to a competitor in the manner set forth below. "Competitor" is defined in Paragraph II.B.3 above. "Consultant" is defined

as a person who is currently during the pendency of these matters engaged as a contractor, subcontractor, non-litigation consultant, or counsel for a competitor in connection with that competitor's development and marketing plans for pelvic mesh products.

(a) Give at least ten (10) days notice in writing to counsel for the party who designated such information as **HIGHLY CONFIDENTIAL** of the intent to so disclose that information, although the disclosing party is not required to identify the intended recipient of such materials.

(b) Within ten (10) days thereafter, counsel for the parties shall attempt to resolve any disputes between them regarding the production of the **HIGHLY CONFIDENTIAL** material to the intended individuals.

(c) If the parties are unable to resolve any dispute regarding such production, within an additional seven (7) days, the party who designated the information in question as **HIGHLY CONFIDENTIAL** shall file a motion objecting to the proposed disclosure. In making such motion, it shall be the Producing Party's burden to demonstrate good cause for preventing the disclosure pursuant to R. 4:10-3.

(d) If the Court permits disclosure of the material designated as **HIGHLY CONFIDENTIAL** at issue, the information remains designated as **HIGHLY CONFIDENTIAL** and the individual

receiving such information shall be bound by the requirements of Paragraph II.B.7.

9. Redaction of Confidential Material: The parties recognize that certain FDA, other governmental agencies, and certain federal statutes require redaction of certain information prior to production of certain information by Defendants and that Defendants will comply with those requirements and redact such information as directed, subject to a separate stipulation that will be submitted by the parties regarding FDA redaction requirements. Any party challenging information that has been redacted may do so in accordance with Paragraph II.B.4 of this Protective Order, or otherwise in accordance with New Jersey Court Rule 1:38-7(e).

10. Use of Confidential Material at Depositions: All transcripts and exhibits shall be treated as if designated **CONFIDENTIAL** for a period of thirty (30) days after the transcript is available from the court reporter. Counsel for any party may designate during the deposition or during the thirty day period after the transcript is available from the court reporter any portion of the transcript as **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** by denominating by page and line, and by designating any exhibits, that are to be considered **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** pursuant to the criteria set forth in this Order. Such designation shall be communicated to all parties. Transcript portions and exhibits designated in accordance with this paragraph shall be disclosed only in accordance with this Order. A party may challenge the **CONFIDENTIAL** or **HIGHLY**

CONFIDENTIAL designation or portions thereof in accordance with the provisions of Paragraph II.B.4 above.

11. Inadvertent Failure to Properly Designate Confidential Material: Inadvertent production of any document or information without a designation of **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** will not be deemed to waive a party's claim to its confidential nature or estop said party from designating said document or information as **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** at a later date. Disclosure of said document or information by another party prior to such later designation shall not be deemed a violation of the provisions of this Order.

12. Inadvertent Disclosure of Privileged Documents, "Clawback" Procedure: Inadvertent production of documents or electronically stored information ("ESI") (collectively "Inadvertently Produced Documents") subject to work-product or attorney-client privilege, or other legal privilege protecting information from discovery, shall not constitute a waiver of the privilege, provided that the Producing Party shall notify the receiving party in writing as set forth herein. In the event that a party inadvertently produces documents or ESI subject to a claim of privilege, the producing party shall, within ten (10) days of the discovery of the inadvertent disclosure, notify the other party in writing of the inadvertent disclosure. The Producing Party may, in the notice, request a "clawback" of the inadvertently disclosed material. The party receiving such clawback

notice shall immediately and diligently act to retrieve the Inadvertently Produced Documents, and all copies, including any loaded to databases, and return them to the Producing Party or destroy them as agreed between the parties. All notes or other work product of the receiving party reflecting the contents of such materials shall be destroyed and not used.

If the receiving party elects to file a motion as set forth below, the receiving party, subject to the requirements below, may retain possession of the Inadvertently Produced Documents as well as any notes or other work product of the receiving party reflecting the contents of such materials pending the resolution by the Court of the motion below, but shall segregate and not use them pending resolution of the motion. If the receiving party's motion is denied, the receiving party shall promptly comply with the immediately preceding provisions of this paragraph. No use shall be made of such Inadvertently Produced Documents during depositions or at trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them unless otherwise ordered by the Court.

The party receiving such Inadvertently Produced Documents may, after receipt of the producing party's notice of inadvertent production, move the Court to dispute the claim of privilege.

13. Pursuant to New Jersey Court Rule 4:10-2(g) and New Jersey Rule of Evidence 504, there is no waiver of privilege or work product protection in this matter or any other matter in any other jurisdiction for

any document clawed-back under this clause, or for the subject matter of any such document, whether the privileged document was inadvertently provided following review or as part of a "Quick Peek" production. In the event that any party receives information produced in discovery from any other party that reasonably appears to be Inadvertently Produced Documents, the receiving party shall promptly notify the producing party in writing of the apparent inadvertent production.

C. **PROCEDURE FOR SUBMITTING CONFIDENTIAL DISCOVERY MATERIAL TO THE COURT**

1. To the extent that any pleading, brief or memorandum or other document filed with the Court contains Confidential Discovery Material or portions thereof, or any purporting to reproduce, paraphrase or summarize any such confidential information, the pleading, brief, or memorandum shall be filed in accordance with the following procedures:

(a) For discovery-related motions, the notice of motion will be filed with the Clerk. All other papers will be served on the parties, will be served via Lexis/Nexis in the specific matter to which the motion applies, but not filed with the Court. Instead, courtesy copies shall be provided to the Court for *in camera* use. Following the disposition of the motion, the Court will destroy the papers or return them to the party filing them.

(b) For pre-trial non-discovery-related motions, only the notice of motion initially will be filed with the clerk of the court. All other papers will be served via Lexis/Nexis in the specific matter to which the motion

applies, but not filed with the Court. Courtesy copies of all other motion papers will be provided to the Court for in camera use. The parties shall set a schedule during a conference with the Court 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 pre-trial nondiscovery motions, the parties shall exchange their respective moving papers, opposition papers, and reply papers in accordance with the schedule set by the Court pursuant to the conference, 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 of the other parties that it intends to file a motion to seal any of the papers in support or in opposition to the pretrial nondiscovery-related motion. Courtesy copies shall be provided to the Court for *in camera* use at the time they are exchanged between the parties. A cover letter shall indicate that these papers are for *in camera* use only. In the event that a party moves to seal any of the motion papers, it shall file its notice of motion, and any brief, affidavit, or certification in support directly with the Honorable Carol E. Higbee, P.J. Cv. After the Court disposes of the motion to seal, the Clerk will file the papers on both motions in accordance with the Court's order.

(c) In motion practice concerning the designation of materials CONFIDENTIAL as or HIGHLY CONFIDENTIAL, the parties shall make every effort to limit the submission of material to include only that information that is in dispute and not extraneous.

2. If Confidential Discovery Material is filed under seal, as required by paragraph II.C.1, in connection with a discovery motion, or is filed in connection with a non-discovery motion, pursuant to paragraph II.C.1, and is ordered by the Court to be maintained under seal, the Confidential Discovery Material and/or other papers shall be kept under seal until further order of the Court. However, said Confidential Discovery Materials and other papers filed under seal shall be available to the Court and counsel of record, and to all other persons entitled to receive the confidential information contained therein under the terms of this Protective Order.

D. **POST DISCOVERY PHASE**

1. Survival of Protective Order: Throughout and after the conclusion of this litigation, including any appeals, the restrictions on communication and disclosure provided for herein shall continue to be binding upon the parties and all other persons to whom **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material has been communicated or disclosed pursuant to the provisions of this Order or any other order of the Court.

2. This Protective Order does not prohibit the use of CONFIDENTIAL or HIGHLY CONFIDENTIAL material at any trial. If any party or attorney wishes to file, or use as an exhibit or as testimonial evidence at a hearing or trial, any **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** material, the parties shall attempt to resolve the matter of continued confidentiality by conferring about methods to avoid or limit public disclosure of such

information during testimony. If an amicable resolution proves unsuccessful, the parties may present the issue to the Court for resolution.

3. Return or Destruction of Confidential Material Upon Termination of Litigation: Within sixty (60) days after the final termination of this action, each party, upon request of the other party, shall either return to the producing party, or destroy, all **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material designated by any other party (including any such material disclosed to third persons), except for any attorneys' work-product for the party returning the material, and shall provide confirmation in writing to opposing counsel if such materials are destroyed.

4. Modification of this Order: Nothing in this Order shall prevent any other party from seeking amendments broadening or restricting the rights of access to or the use of **CONFIDENTIAL** and/or **HIGHLY CONFIDENTIAL** material or otherwise modifying this Order; and this Order may be amended without leave of the Court by the agreement of the undersigned attorneys for the parties in the form of a Stipulation that shall be filed in this case.

ENTER:

Dated: 11/2/11

HON. CAROL E. HIGBEE, P.J. Civ.

Parties and Counsel:

Jonathan D. Orent
Motley Rice LLC
321 S. Main Street Suite 200
Providence, RI 02860
401-457-7700
Liaison counsel for Plaintiffs

Richard B. North, Jr.
Nelson Mullins Riley & Scarborough, LLP
Atlantic Station
201 17th St. NW, Suite 1700
Atlanta, GA 30363
404-322-6155
Lead counsel for Defendant C. R. Bard, Inc.

Sandra A. Bresnick
Quinn Emanuel Urquhart & Sullivan, LLP
51 Madison Avenue 22nd Floor
New York, NY 10010
212-849-7000
Lead counsel for Defendants Covidien, Inc. and Sofradim Production S.A.S

EXHIBIT A

In re PELVIC MESH LITIGATION/BARD,	SUPERIOR COURT OF NEW JERSEY LAW DIVISION, ATLANTIC COUNTY CIVIL ACTION Case No. 292 CT Master Case 6339-10 Hon. Carol E. Higbee, P.J. Cv. **PROTECTIVE ORDER** **BARD ONLY CASES**

AGREEMENT TO BE BOUND BY PROTECTIVE ORDER

I have read and understand the Protective Order entered in the above-captioned litigation, and I agree to be bound by its terms. Specifically, and without limitation upon such terms, I agree not to use or disclose any Confidential Information made available to me other than in accordance with this Protective Order.

I hereby agree to submit to the Superior Court of New Jersey Law Division, Atlantic City for enforcement of the undertaking I have made herein.

Dated: _____

_____
Signed name

_____
Printed name