

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

IN RE: DePUY ORTHOPAEDICS, INC.) MDL Docket No. 1:10 md 2197
ASR HIP IMPLANT PRODUCTS)
)
)
) **AMENDED**
This Document Relates To:) **STIPULATED PROTECTIVE**
) **ORDER OF CONFIDENTIALITY**
)
ALL CASES)

Plaintiffs and Defendants before this Court in MDL 2197 (sometimes hereinafter referred to as "Plaintiffs" and/or "Defendants", or collectively, the "Parties") hereby stipulate and agree, through their respective attorneys of record as follows:

1. The Parties, by and through their counsel, stipulate and agree that this Stipulated Protective Order of Confidentiality – and any designation of a document, material or information (whether written, graphic, or electronic) as being a "PROTECTED DOCUMENT" subject to this Stipulated Protective Order of Confidentiality – is intended solely to facilitate prompt discovery and the preparation for trial of the ASR hip implant litigation.

2. This Protective Order shall govern all hard copy and electronic materials, the information contained therein, and all other information including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, produced by any party to this proceeding (the "Supplying Party") to any other party (the "Receiving Party"). This Protective Order is binding upon all Parties and their counsel in the MDL, including their respective corporate parents, subsidiaries, and affiliates and their respective attorneys, principals, experts, consultants, representatives, directors, officers, employees, and others as set forth in this Protective Order. If additional parties are added other than parents, subsidiaries or affiliates of current parties to this

litigation, then their ability to receive a "PROTECTED DOCUMENT" as set forth in this Protective Order will be subject to them being bound, by agreement or Court Order, to this Protective Order.

(a) Third Parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Supplying Party for purposes of this Protective Order.

(b) The entry of this Protective Order does not preclude any party from seeking a further order of this Court.

(c) Nothing herein shall be construed to affect in any manner the admissibility at trial or in any other Court proceeding of any document, testimony, or other evidence.

(d) This Protective Order does not confer blanket protections on all documents, disclosures or responses to discovery and the protection it affords extends only to the specific information or items that are entitled to protection under the applicable legal principles for treatment as confidential after individual review by the producing party.

3. The term "PROTECTED DOCUMENT" refers to information protected by Rule 26 of the Federal Rules of Civil Procedure, or other applicable laws or rules as a "trade secret" (as defined in the Uniform Trade Secrets Act) or privacy laws, including personal or medical information. "PROTECTED DOCUMENTS" containing confidential information as used in this Order means documents containing trade secrets and other information that is of a proprietary, business, financial or technical nature and not readily known or available to competitors, potential competitors, or the public, the value of which arises from its being confidential and the disclosure of which (whether separately or in conjunction with other information being produced) is believed in good faith by the Supplying Party to have the potential, if disclosed, for

causing competitive harm to it or giving a competitive advantage to others. Plaintiffs shall be permitted to designate materials that contain personal information as a "PROTECTED DOCUMENT" pursuant to this Order.

4. Examples of "PROTECTED DOCUMENTS" containing such confidential information, which is of a proprietary, business, financial, or technical nature and not readily known or available to competitors, potential competitors, or the general public, include but are not limited to:

a. Engineering drawings showing the dimensions, specifications, tolerances, and similar information related to the design of the ASR components and/or system or other hip systems;

b. Raw material specifications and certifications and manufacturing process descriptions and records which provide details of the way in which DePuy manufactures the ASR components and/or system or other hip systems; and

c. Documents related to DePuy's internal development, design, manufacturing, testing, and marketing processes, sales statistics, marketing plans, cost and pricing structures, customer lists, distributor lists, competitors and analysis of competitor products, independent contractors, complaint investigation, recall plans and processes, and similar matters which are confidential and proprietary and have independent economic value because they are not known to DePuy competitors or potential competitors or the general public and have entailed substantial cost to develop and are necessary for a medical device company to compete in a heavily regulated industry and comply with governing FDA regulations.

5. No person who examines any item produced pursuant to a discovery request, or information that is protected by this Protective Order, shall disseminate orally, or by any other means, any protected information other than as permitted by this Order.

6. Any designation of "PROTECTED DOCUMENT" under this Stipulated Protective Order of Confidentiality shall not be construed as an admission or an agreement by any party:

(a) That the designated disclosure constitutes or contains confidential information; or

(b) That any document, material or information, or any portion thereof, constitutes competent, material, relevant, or admissible evidence in this case.

This Stipulated Protective Order of Confidentiality is entered into solely to facilitate a reasonable and prompt disclosure of discovery materials to facilitate preparation and trial of ASR hip implant litigation.

7. This Stipulated Protective Order of Confidentiality shall not be construed as a waiver by any party of the right to contest the designation of documents as a "PROTECTED DOCUMENT" under this Stipulated Protective Order of Confidentiality. Any party desiring to contest the protected designation of specific documents as a "PROTECTED DOCUMENT" may do so at any time and shall give the producing party notice in writing (a letter to both lead counsel delivered by email shall be sufficient) including the listing of any such document(s) or the bates ranges for the document(s), and shall provide a brief explanation of the basis for contesting the "PROTECTED DOCUMENT" designation (the "Notice"). If the same document in the Notice appears in the production at other bates numbers, the Notice shall be deemed to be sufficient for all such documents. The Notice shall be sufficient if it identifies documents being challenged and states the basis for the challenge. If the Parties cannot stipulate to the designation

as a "PROTECTED DOCUMENT" within thirty (30) days of the Supplying Party's receipt of such written notice, the Supplying Party has the burden of making an application to the Court for an order directing that the contested document(s) shall remain a "PROTECTED DOCUMENT" under the terms of this Stipulated Protective Order of Confidentiality. All references in motions or briefs to information in a PROTECTED DOCUMENT or any PROTECTED DOCUMENT shall be filed under seal to the extent permitted by applicable Court rules and procedure. Pending a Court determination, no document designated as a "PROTECTED DOCUMENT" under this Order shall be disseminated other than as provided by this Order unless otherwise ordered by the Court or as stipulated by the Parties. Failure of the party claiming that a document is a "PROTECTED DOCUMENT" to move for an Order to establish confidentiality within thirty (30) days of receipt of the Notice will operate as a waiver of the confidentiality designation. To the extent that a document designated as a "PROTECTED DOCUMENT" under this Order has been produced in another action and determined by a court of competent jurisdiction not to be confidential, then said document will be considered non-confidential and non-protected for purposes of this litigation.

8. Pursuant to the terms and requirements of this Stipulated Order of Confidentiality, the Supplying Party may designate as a "PROTECTED DOCUMENT" all or any part of documents produced by it in the course of litigation or in response to initial disclosures, and various interrogatories and requests for production of documents, as well as documents, electronic files and data compilations, and deposition transcripts, or portions thereof, that contain or constitute confidential information.

9. The designation of confidential information shall be made by placing or affixing on the material in a manner that will not interfere with its legibility the words "PROTECTED DOCUMENT. DOCUMENT SUBJECT TO PROTECTIVE ORDER" as long as the

designation is conspicuously placed on produced documents in a uniform manner. The designation shall be made prior to, or contemporaneously with, production or disclosure of that material. Deposition testimony or any portion thereof may be designated "Confidential" on the record at the time of the deposition. If the party seeking to maintain a deposition transcript as Protected does not serve a letter on the court reporter and Plaintiffs' Liaison Counsel within 30 days of receipt of the deposition transcript, then the entire transcript shall be deemed not to contain any Protected Information and any legend stating Protected Information shall be removed. All copies, duplicates, extracts, summaries or descriptions (hereinafter referred to collectively as copies) of documents designated as "PROTECTED DOCUMENT" under this Order, or any portion of such a document, shall be immediately affixed with the designation "PROTECTED DOCUMENT" if the word does not already appear on the copy. All such copies shall be afforded the full protection of this Order.

10. A party may not file in the public record in this action any "PROTECTED DOCUMENT", without written permission from the Supplying Party or a court order secured after appropriate notice to all interested persons. Material or information designated as a "PROTECTED DOCUMENT" under this Stipulated Protective Order of Confidentiality shall not be used or disclosed by any party, or their counsel or any person acting on his/her behalf to any other persons except as provided for hereinafter, and shall not be used for any business or competitive purpose, or for any other purposes whatsoever, other than the preparation and trial of an action involving an ASR Hip Implant and any appeal herein.

11. Material or information designated as "PROTECTED DOCUMENT" under this Stipulated Protective Order of Confidentiality shall not be disclosed to any other person or entity, except in the following circumstances:

(a) Disclosure may be made to employees of counsel for Plaintiffs or Defendants who have direct functional responsibility for assisting in the preparation and trial of this action or any appeal herein. Any employee to whom disclosure is made shall be advised of, shall become subject to, and shall agree in advance of disclosure to, the provisions of this Stipulated Protective Order requiring that the material and information be held in confidence.

(b) Disclosure may be made to consultants or experts (hereinafter, "expert") employed by Plaintiffs or Defendants, or their counsel to assist in the preparation and trial of this litigation. However, prior to disclosure to any expert (including undisclosed consulting experts), the expert must agree to be bound by the terms of this Stipulated Protective Order of Confidentiality by executing the acknowledgement annexed hereto as Exhibit "A." With respect to experts, a copy of each executed acknowledgement shall be maintained for Plaintiffs by Plaintiffs' Liaison Counsel, and for Defendants by Counsel for Defendants, during the course of the litigation. At the conclusion of the litigation, counsel for Receiving Party shall confirm in writing with counsel for Supplying Party that it will seek to have any documents designated as PROTECTED DOCUMENTS that were provided to experts returned to counsel for the Receiving Party. In no event shall any disclosure be made to current employees, officers, directors or consultants of any competitors of DePuy, or to anyone who, at the time of disclosure, is anticipated to become an employee, officer, director or consultant of any competitor of DePuy, irrespective of whether they are retained as an expert for Plaintiffs. A "competitor" shall be defined as any medical device manufacturer that manufactures artificial hip joints.

(c) Disclosure may be made to the Parties to the extent required for assisting in the preparation and trial of this matter or any appeal herein. To the extent such

disclosure is made, such Party shall be advised of, shall become subject to, and shall agree in advance of disclosure to, the provisions of this Stipulated Protective Order of Confidentiality requiring that the material and information be held as confidential.

(d) Disclosure may be made to the Court and court personnel (including the court having jurisdiction over any appeal).

(e) Disclosure may be made to Court reporters used in connection with the litigation.

(f) Disclosure may be made to any person who (i) wrote or received a copy of the document designated confidential before it was furnished in this litigation, or (ii) was present or participated in a meeting or discussion of the protected information before it was furnished in this litigation.

(g) Disclosure may be made to any mediators, secretaries, paraprofessional assistants, and other employees of such mediators who are actively engaged in assisting the mediators in connection with this matter.

(h) Disclosure may be made to employees of outside copying, document imaging and facsimile services.

(i) Disclosure may be made to witnesses or deponents in the course of this litigation, only as necessary for the litigation and only after the person to whom such disclosure is made has been informed of the Stipulated Protective Order of Confidentiality and has agreed in writing to be bound by it, by signing the form of acknowledgement annexed as Exhibit "A". The executed acknowledgement shall be retained by counsel for the Receiving Party, with a copy provided to counsel for the Supplying Party on a showing of good cause where providing a copy does not violate the attorney-client privilege, the work-product privilege or any other privilege.

12. All counsel shall keep all material or information designated as a "PROTECTED DOCUMENT" which is received under this Stipulated Protective Order of Confidentiality within its exclusive possession and control, except as provided in paragraph 11, and shall take reasonable steps to maintain such material in a secure manner. Except as provided in paragraph 11 above, no person shall have access to the foregoing material and information.

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

14. If, in connection with any motion or other proceeding except trial, any party intends to offer into evidence any documents designated a "PROTECTED DOCUMENT" by either Plaintiffs or Defendants, such evidence shall be submitted in camera and in accordance with the applicable local court rules, and unless otherwise ordered by the Court, shall be sealed with any proceedings involving disclosure of the evidence held in camera. The Parties shall be entitled to identify and use documents for trial purposes regardless of a "PROTECTED DOCUMENT" designation, provided that for any documents identified on Exhibit Lists for use at trial, the Parties shall be entitled to seek appropriate protection, by motions in limine or otherwise, for any document so identified.

15. If another court or an administrative agency subpoenas or otherwise orders production of a "PROTECTED DOCUMENT" that a person has obtained under the terms of this Order, the person to whom the subpoena or other process is directed shall promptly notify liaison counsel for the Supplying Party in writing via fax and overnight delivery of all of the following: (1) the "PROTECTED DOCUMENT" that is requested for production in the subpoena; (2) the

date on which compliance with the subpoena is requested; (3) the location at which compliance with the subpoena is requested; (4) the identity of the party serving the subpoena; and (5) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or other designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena or other process has been issued. In no event shall a "PROTECTED DOCUMENT" be produced prior to the expiration of fifteen (15) days following transmission of written notice to liaison counsel for the Supplying Party unless required to do so by the order seeking the documents.

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

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

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

18. Inadvertent production of documents (hereinafter "Inadvertently Produced Documents") subject to work-product immunity, the attorney-client privilege, or other legal privilege protecting information from discovery shall not constitute a waiver of the immunity or privilege, provided that the party producing the documents shall notify all Parties in writing within a reasonable period of time from the discovery of the inadvertent production. If such notification is made, such Inadvertently Produced Documents and all copies thereof shall, upon request, be returned to the party making the inadvertent production, all notes or other work product of the Receiving Party reflecting the contents of such materials shall be destroyed, and such returned or destroyed material shall be deleted from any litigation-support or other database. If the party receiving the production disputes in writing the claim of privilege they may retain possession of the Inadvertently Produced Documents as well as any notes or other work product of the Receiving Party reflecting the contents of such materials pending the resolution by the Court of the motion below. If the Receiving Party's motion is denied, the Receiving Party shall promptly comply with the immediately preceding provisions of this paragraph or such other directives as may be issued by the Court. No use shall be made of such Inadvertently Produced Documents during depositions or at trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them. The party receiving such Inadvertently Produced Documents may, after receipt of the notice of inadvertent production, move the Court to oppose the request for return of the subject materials. Each party retains all rights and arguments as to any proceeding regarding Inadvertently Produced Documents.

19. Upon final termination of this action, whether by judgment, settlement or otherwise, upon written request from counsel for the Supplying Party, counsel for all Parties shall return to counsel for the Supplying Party all materials and all copies thereof in his/her possession that were designated by Supplying Party as a "PROTECTED DOCUMENT" in accordance with this Stipulated Protective Order of Confidentiality and/or, in the alternative, provide a written statement to counsel for the Supplying Party that all copies of such materials in his or her possession, including copies upon which any notes have been made, have been destroyed.

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

IT IS SO ORDERED:

s/ David A. Katz

Honorable David A. Katz

AGREED TO BY COUNSEL OF RECORD:

s/ Ellen Relkin

Counsel for MDL Plaintiffs

s/ Robert Tucker

Counsel for MDL Defendants

DATED: _____, 2011

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

IN RE: DePUY ORTHOPAEDICS, INC.)	MDL Docket No. 1:10 md 2197
ASR HIP IMPLANT PRODUCTS)	
)	
)	EXHIBIT A TO AMENDED
This Document Relates To:)	STIPULATED PROTECTIVE
)	<u>ORDER OF CONFIDENTIALITY</u>
ALL CASES)	

CONFIDENTIALITY AGREEMENT

The undersigned hereby acknowledges that he/she has read the Stipulated Protective Order of Confidentiality executed by the attorneys of record for the Parties and entered by the court in the action presently pending in United States District Court for the Northern District of Ohio entitled *In Re: DePuy Orthopaedics, Inc. ASR Hip Implant Products*, Case No. 1:10 MD 2197, and understands the terms thereof and agrees, upon threat of penalty of contempt, to be bound by such terms.

Date: _____

Signature: _____

Printed Name: _____