#### UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO

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IN RE:

HEPARIN PRODUCTS LIABILITY LITIGATION MDL Docket No. 1953

CHIEF JUDGE JAMES G. CARR CASE NO. 1:08-60000

ALL CASES

# First Amended Pretrial Order No. 7 PROTECTIVE ORDER

WHEREAS, the parties in the above-entitled action, believe that parties and non-parties may be asked to produce documents, provide testimony or otherwise supply information that contains trade secrets, confidential or proprietary information in connection with discovery in the aboveentitled litigation; and

WHEREAS, the parties believe that it is appropriate for this Court to issue a protective order to permit the disclosure of such trade secret, confidential or proprietary information in connection with the above-entitled litigation, but to protect that information from public disclosure;

IT IS HEREBY STIPULATED AND AGREED by and between plaintiffs and defendants Baxter International Inc., Baxter Healthcare Corporation, Baxter Healthcare Corporation of Puerto Rico, and Scientific Protein Laboratories LLC, Changzhou SPL Co., Ltd., through their respective Lead and Liaison Counsel, that, during this action, with respect to the disclosure of any information, documents or things obtained by any party to this action, where such items are asserted to contain or comprise trade secret, confidential, or proprietary information, the following procedures shall be employed and the following restrictions shall govern:

1 **Definitions**: For purposes of this Protective Order, the following definitions shall apply:

(a) The term "document" shall mean each and every writing within the meaning of Rule 1001 of the Federal Rules of Evidence, and shall consist of letters,

words, or numbers, or their equivalent, set down by handwriting, typewriting, printing, photostating, photographing, magnetic impulse, mechanical or electronic recording, or other form of data compilation.

(b) The term "Disclosing Party" is defined herein as any party or nonparty who is requested to produce or produces documents, materials or testimony containing CONFIDENTIAL INFORMATION.

(c) The term "Receiving Party" is defined herein as any party to whom documents, materials or testimony containing CONFIDENTIAL INFORMATION is provided.

(d) The term "CONFIDENTIAL INFORMATION" is defined herein as trade secrets, or other confidential or proprietary research, development, manufacturing, sales, marketing, or commercial or business information, including customer names; proprietary licensing, distribution, sales, marketing, design, development, research, and manufacturing information—not publicly filed with any federal or state regulatory authority—regarding products and medicines, whether currently marketed or under development; clinical studies not publicly filed with any federal or state regulatory authority; information concerning competitors; production information; personnel records and information; financial information not publicly filed with any federal or state regulatory authority, and personal medical information.

(e) "Outside Service Organization" is defined herein as an individual or organization that provides photocopying, document processing, translation, jury or trial consulting, or graphics services to counsel as part of discovery or preparation and trial of this action.

(f) "Support Staff" is defined herein as employees of counsel for the parties or their Consultants, including paralegals, clerical personnel and secretarial personnel.

2. Applicability of Protective Order: If, in the course of this litigation, a party undertakes or is caused to disclose what the Disclosing Party contends is CONFIDENTIAL INFORMATION, the procedures set forth herein shall be employed and the disclosure thereof shall be subject to this Protective Order. CONFIDENTIAL INFORMATION shall be used solely in the preparation, prosecution or trial of this litigation.

**3. Other Cases:** By entering this Order and limiting the disclosure of information in this litigation, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Order who becomes subject to a motion to disclose another party's information designated under one of the categories of confidentiality pursuant to this Order, shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

4. **Disclosure Prohibited:** CONFIDENTIAL INFORMATION or the substance or context thereof, including any notes, memoranda or other similar documents relating thereto, shall not be disclosed or summarized, either in writing or orally, by a Receiving Party to anyone other than persons permitted to have access to such information under this Order. Nothing in this Protective Order shall limit disclosure or use by a designating party of its own CONFIDENTIAL INFORMATION.

**5. Designating and Marking Confidential Material**: Materials to be designated "CONFIDENTIAL" pursuant to this Protective Order shall be designated and marked as follows:

(a) **Documents:** Documents may be designated as "CONFIDENTIAL" by placing the following legend, or equivalent thereof, on any such document:

#### "CONFIDENTIAL"

Such legend shall be placed upon every page of each document containing CONFIDENTIAL INFORMATION. In lieu of marking the originals of documents, the party may mark the copies that are produced or exchanged.

(b) Non-Paper Media: Where CONFIDENTIAL INFORMATION is produced in a non-paper medium (e.g., video tape, audio tape, computer disks, etc.), the appropriate confidentiality notice as described in  $\P$  5(a) above should be placed on the medium, if possible, and its container, if any, so as to clearly give notice of the designation. To the extent that any Receiving Party prints any of the information contained on non-paper media that is designated as containing CONFIDENTIAL INFORMATION, such printouts will be marked as described in  $\P$  5(a) above by the Receiving Party.

(c) **Physical Exhibits:** The confidential status of a physical exhibit shall be indicated by placing a label on said physical exhibit with the appropriate confidentiality notice as

described in  $\P$  5(a) above.

(d) Written Discovery: In the case of CONFIDENTIAL INFORMATION incorporated in answers to interrogatories or responses to requests for admission, the appropriate confidentiality notice as described in  $\P$  5(a) above shall be placed only on the first page of the document and on each answer or response that actually contains CONFIDENTIAL INFORMATION.

**Deposition Proceedings:** Counsel for the parties agree that the Designating Party shall make a good faith effort to designate as "CONFIDENTIAL" those specific portions of a deposition transcript that contain CONFIDENTIAL INFORMATION. The entire transcript of a deposition shall be treated as CONFIDENTIAL until 30 days after receipt of the deposition transcript by counsel for the witness, after which the information revealed during the deposition shall cease to be treated as CONFIDENTIAL unless, at the deposition and on the record, or in writing before the 30 days have expired, the witness, his or her employer or his or her counsel designate those portions of the deposition transcript (including exhibits) as "CONFIDENTIAL." In the case of non-party witnesses, any party or the non-party witness, his or her employer, or his or her counsel may designate information revealed as CONFIDENTIAL INFORMATION either by a statement to such effect on the record in the course of the deposition, or in writing within 30 days of receipt of the deposition by the non-party witness' counsel.

Counsel for any Disclosing Party shall have the right to exclude from oral depositions, other than the deponent, deponent's counsel, the reporter, and videographer (if any), any person who is not authorized by this Protective Order to receive documents or information designated "CONFIDENTIAL." Such right of exclusion shall be applicable only during periods of examination or testimony directed to or comprising CONFIDENTIAL INFORMATION of the Disclosing Party.

With regard to designations made within thirty (30) days after receipt of the deposition transcript of a deposition, counsel shall make such designations by sending written notice to the Court Reporter, to counsel for the parties, and to any other person known to have a copy of said transcript. The notice shall reference this Protective Order, identify the appropriate level of confidentiality, and identify the pages and/or exhibits so designated. All copies of transcripts designated in this fashion shall be marked with a notice indicating the appropriate level of confidentiality of the material and shall be governed by the terms of this Protective Order.

**7 Designating Inspections of Documents and Tangible Items:** Where discovery is provided by allowing access to the documents or tangible things for inspection instead of delivering copies of them, all items being inspected shall be deemed CONFIDENTIAL INFORMATION until the party allowing access to them indicates otherwise in writing or delivers copies of them to the party seeking discovery with no "CONFIDENTIAL" designation, in which case the provisions of paragraph 8 shall also apply. If a party believes that inspection, measuring, testing, sampling, or photographing of that party's processes, products, equipment, premises, or other property pursuant to Rule 34 of the Federal Rules of Civil Procedure will reveal or disclose information that is in good faith deemed CONFIDENTIAL INFORMATION, that party shall advise in advance the party seeking such discovery that the inspection, measuring, testing, sampling, or photographing will be permitted only on a confidential basis, and that the information discovered, and any information derived from that information, shall be treated as CONFIDENTIAL INFORMATION.

8. Inadvertent Nondesignation: The failure to designate CONFIDENTIAL INFORMATION as "CONFIDENTIAL" before or at the time of disclosure shall not operate as a waiver of a Disclosing Party's right to designate said information as "CONFIDENTIAL." In the event that CONFIDENTIAL INFORMATION is designated as "CONFIDENTIAL" after disclosure, a Receiving Party shall employ reasonable efforts to ensure that all such information is subsequently treated as "CONFIDENTIAL" pursuant to the terms of this Protective Order. Disclosure of such CONFIDENTIAL INFORMATION to persons not authorized to receive that information before receipt of the confidentiality designation shall not be deemed a violation of this Protective Order. However, in the event the document has been distributed in a manner inconsistent with the designation, a Receiving Party will take the steps reasonably necessary to conform distribution to the designation: i.e., returning all copies of the "CONFIDENTIAL" document, or notes or extracts thereof, to the persons authorized to

possess such documents. In the event distribution has occurred to a person not under the control of a Receiving Party, a request for return of the document, and for an undertaking of confidentiality, shall be made in writing. In the event the request is not promptly agreed to in writing, or in the event there is no response, or in the event that the party deems the making of the request to be a futile act, the party shall promptly notify the Disclosing Party of the distribution and all pertinent facts concerning it, including the identity of the person or entity not under the control of the Receiving Party.

**9. Misdesignation:** A Disclosing Party will use reasonable efforts to avoid designating, or to de-designate in a reasonable time after request, any document or information as "CONFIDENTIAL" that is not entitled to such designation or that is generally available to the public.

10. Challenging Designation of Materials: Any Receiving Party disagreeing with the designation of any document or information as "CONFIDENTIAL" shall notify the Disclosing Party in writing. The Disclosing Party shall then have a reasonable period, not exceeding thirty (30) days, from the date of receipt of such notice to: (1) advise the Receiving Party whether or not the Disclosing Party persists in such designation; and (2) if the Disclosing Party persists in the designation, to explain the reasons for the particular designation. The Receiving Party may then, after advising the Disclosing Party, move the Court for an order removing the particular designation and replacing it with a different designation or no designation. The designating party who asserts that the document or information is "CONFIDENTIAL" shall have the burden of proving that the designation is proper. Information designated "CONFIDENTIAL" by a Disclosing Party shall be treated as such by a Receiving Party unless otherwise agreed to by the parties or otherwise ordered by the Court or by any appellate court, should appellate review be sought.

The failure of a Receiving Party to expressly challenge a claim of confidentiality or the designation of any document or information as "CONFIDENTIAL" at the time of disclosure shall not constitute a waiver of the right to assert at any subsequent time that the same is not in fact confidential or not an appropriate designation for any reason.

#### 11. Access to CONFIDENTIAL INFORMATION: Access to CONFIDENTIAL

INFORMATION shall be limited to (a) the parties and witnesses and prospective witnesses of a Party who have a need to know the information to assist counsel in connection with the litigation; (b) outside counsel for the respective parties, including counsel's Support Staff and Outside Service Organizations; (c) in-house counsel for the respective parties, including inhouse counsel's Support Staff and Outside Service Organizations; (d) the parties' insurers, including the insurers' Support Staff and Service Organizations; (e) court reporters taking testimony and their support personnel; (f) deposition videographers recording testimony and their support personnel; (g) the Court and any authorized court personnel; (h) independent consultants or experts retained by counsel for assistance with respect to this litigation; (i) counsel for a potential Plaintiff who has executed a Participation Agreement in accordance with PTO #6 and Exhibit A attached hereto, together with each such person's Support Staff and Service Organizations; and (j) counsel for any Plaintiff, or any unrepresented Plaintiff, in a state court proceeding who has executed a Participation Agreement in accordance with Pretrial Order No. 6 and Exhibit A attached hereto, together with such person's Support Staff and Service Organizations. Prior to disclosure of Confidential Material to any consultant or experts, they shall be informed of the provisions of this Order, read this Order, and execute the Agreement attached hereto as Exhibit A. Furthermore, in the event that a Receiving Party intends to disclose CONFIDENTIAL INFORMATION to any employee, independent consultant, expert or any other agent who is currently employed by any entity that is or was in the last five years a competitor of any SPL or Baxter related entity in the manufacture, marketing, purchase or sale of heparin products, that party shall provide notice by facsimile to counsel for the Disclosing Party at least ten (10) business days prior to allowing the employee, independent consultant, expert, or any other agent access to confidential material subject to this Protective Order. Such written notice shall include the person's name, a copy of the person's curriculum vitae, information concerning the person's employment responsibilities and work with defendants' competitor or customer, identification of the type of information to which access is required, a brief statement as to why such access is necessary, and a signed copy of the agreement attached hereto as Exhibit A (if appropriate, modified as necessary to narrow the scope of access requested). The Disclosing Party shall have ten (10) days after mailing (via overnight delivery) the above-described information to object in writing to such disclosure. Pending resolution of any informal or formal petition for

disclosure, no disclosure shall be made to such person. If the Disclosing Party who so designated the documents refuses to give its consent, the disclosing and receiving parties shall confer to attempt to resolve the reasons for withholding consent. If an agreement cannot be reached, the Disclosing or Receiving Party desiring disclosure of the CONFIDENTIAL INFORMATION may petition the Court for an order granting or prohibiting disclosure. The Disclosing Party shall bear the burden of demonstrating that disclosure is inappropriate upon any such petition. Prior to disclosure of Confidential Material to any such person, they shall be informed of the provisions of this Order, read this Order, and execute the Agreement attached hereto as Exhibit A.

#### 12. Nothing herein is intended to prevent showing a document designated as

"CONFIDENTIAL" to a person who the document indicates is an author or authorized recipient of the document. No copies of such documents shall be given to such individuals for them to retain. Furthermore, if a document or testimony makes reference to the actual or alleged conduct or statements of a person who is a potential witness, the discussion by counsel of such conduct or statements with such witness (without revealing any portion of the document or testimony) shall not constitute a disclosure in violation of this Protective Order. Prior to disclosure of CONFIDENTIAL INFORMATION to any such witness who is not a current employee or officer of the Disclosing Party, the witness shall be informed of the provisions of this Order, read this Order, and execute the Agreement attached hereto as Exhibit A. Notwithstanding the foregoing, during deposition or trial testimony, counsel may disclose documents produced by a party to current employees or officers of the Disclosing Party.

13. Court Reporters and Videographers: Any court reporter or videographer who records testimony in this action at a deposition shall be provided with a copy of this Protective Order by the party noticing the deposition. That party shall advise the court reporter or videographer, before any testimony is taken, that all documents, information, or testimony designated "CONFIDENTIAL" is and shall remain confidential and shall not be disclosed except as provided in this Protective Order. The noticing party shall further advise the court reporter and videographer that copies of all transcripts, reporting notes and all other records of any such testimony must be treated in accordance with this Protective Order, delivered to attorneys of

record, or filed under seal with the Court.

14. Filing Under Seal: No party shall file with the Court any papers that contain or reference CONFIDENTIAL INFORMATION of any other party or non-party unless that party concurrently files a written application to seal those papers and a proposed order thereon. The parties shall cooperate with each other in taking steps to file CONFIDENTIAL INFORMATION under seal, including, when appropriate, joining in or consenting to motions to file under seal filed by another party. If a filing under seal is requested, a written application and a proposed order shall be presented to the judge along with the document submitted for filing under seal. The original and judge's copy of the document shall be sealed in separate envelopes with a copy of the title page attached to the front of each envelope. Conformed copies need not be placed in sealed envelopes.

**15.** Storage of Confidential Materials: The Receiving Party shall use due care with respect to the storage, custody, use and/or dissemination of CONFIDENTIAL

INFORMATION. CONFIDENTIAL INFORMATION shall not be stored at any business premises of the Receiving Party unless such information is stored in a reasonably secured area and accessible only to persons eligible to review such information.

16. Disclosure–Special Cases: If an attorney for any Receiving Party desires to give, show, make available or communicate any document or information designated "CONFIDENTIAL" to a person not authorized by paragraph 11 to receive such documents, the attorney must first provide written notice of that person's name, an identification of the type of information to which access is required, a brief statement as to why such access is necessary, and a signed copy of the agreement attached hereto as Exhibit A (if appropriate, modified as necessary to narrow the scope of access requested). The Disclosing Party shall have ten (10) days after mailing (via overnight delivery) the above-described information to object in writing to such disclosure. Pending resolution of any informal or formal petition for disclosure, no disclosure shall be made to such person. If the Disclosing Party who so designated the document refuses to give its consent, the disclosing and receiving parties shall confer to attempt to resolve the reasons for withholding consent. If an agreement cannot be reached, the Disclosing or

Receiving Party desiring disclosure of the CONFIDENTIAL INFORMATION may petition the Court for an order granting or prohibiting disclosure. The Disclosing Party shall bear the burden of demonstrating that disclosure is inappropriate upon any such petition.

17. Copies of Confidential Materials: Nothing herein shall restrict a qualified recipient from making working copies, abstracts, digests and analyses of such information for use in connection with this litigation, and such working copies, abstracts, digests and analyses shall be deemed to have the same level of protection under the terms of this Order. Further, nothing herein shall restrict a qualified recipient from converting or translating such information into machine-readable form for incorporation in a data retrieval system used in connection with this litigation, provided that access to such information, whatever form stored or reproduced, shall be limited to qualified recipients.

18. Custody of Confidential Materials: Documents or information designated "CONFIDENTIAL" shall be maintained in the custody of counsel for the parties except that: (a) any court reporter who transcribes testimony given in this action may maintain any such designated documents for the purpose of rendering his or her normal transcribing services; and (b) partial or complete copies of these documents may be retained by persons entitled to access of such documents under the terms of this Order to the extent necessary for their study, analysis and preparation of the case. A person with custody of documents designated

"CONFIDENTIAL" shall maintain them in a manner that limits access to those persons entitled under this Order to examine the documents so designated.

**19. Procedure in Event of Non-Permitted Disclosure:** Should any document or information designated as "CONFIDENTIAL" be disclosed, through inadvertence or otherwise, to any person or party not authorized under this Order, then the party responsible for the inadvertent disclosure shall use its best efforts to bind such person to the terms of this Order; and shall (a) promptly inform such person of all the provisions of this Order; (b) request such person to sign the agreement in the form attached hereto as Exhibit A; and (c) identify such person immediately to the Disclosing Party that designated the document as confidential. The executed agreement shall promptly be served upon the party that designated the document as

confidential.

**20. Limited Scope:** The purpose of this Order is to facilitate discovery in this litigation, and in no manner shall it affect the application of any state or federal law regarding confidentiality of information.

**21. Continuing Force and Effect:** The terms of this Order shall remain in force and effect after termination of this action unless modified, superseded, or terminated by the agreement of the parties or by order of the Court.

22. No Waiver of Privilege or Work Product: The terms of this Order shall in no way affect a Disclosing Party's right to (a) withhold information on grounds of immunity from discovery such as, for example, attorney-client privilege or the attorney work-product doctrine, or (b) reveal or disclose to anyone any documents or information designated by that party as "CONFIDENTIAL" and containing no information designated by another party or third party as "CONFIDENTIAL."

23. No Application to Public or Otherwise Available Information: The restrictions and obligations set forth herein relating to information designated "CONFIDENTIAL" shall not apply to any information which: (a) the parties agree, or the Court rules, is already public knowledge; (b) the parties agree, or the Court rules, has become public knowledge other than as a result of disclosure by a Receiving Party, its employees or agents in violation of this Protective Order; or (c) has come or shall come into a Receiving Party's legitimate possession independently of the Disclosing Party. Such restrictions and obligations shall not be deemed to prohibit discussions with any person of any information designated "CONFIDENTIAL" if that person already has or obtains legitimate possession thereof.

24. Conclusion of Litigation: Unless undersigned counsel agree otherwise in writing, within ninety (90) days of the final disposition of this action including any appeals, the attorneys for the parties shall return promptly to the Disclosing Party from whom they were obtained, all documents which have been designated "CONFIDENTIAL" or destroy same; and return or destroy all copies made thereof, including all documents, or copies provided by a Receiving Party to any other person. Notwithstanding the foregoing, counsel for the parties shall be permitted to retain a file copy of materials created by counsel, their Support Staff or Outside

Service Organizations, or by experts and consultants, in connection with the litigation, or made part of the record, or which have been filed under seal with the Clerk of the Court and a copy of all depositions, including exhibits, and deposition evaluations. Such file copies must be maintained under the conditions of materials designated "CONFIDENTIAL" as set out in paragraph 11. At the conclusion of the ninety (90) day period, counsel for each party shall represent in writing under penalty of perjury that to his or her knowledge and belief the party has either returned or destroyed all CONFIDENTIAL INFORMATION in accordance with this order.

**25. Subpoenas in Other Actions:** In the event any person or Receiving Party having possession, custody or control of any document or information produced in this action and designated "CONFIDENTIAL" by a Disclosing Party receives a subpoena or other process or order to produce such information, such subpoenaed person or entity shall notify by mail (via overnight delivery) the attorneys of record of the Disclosing Party claiming such confidential treatment of the document sought by such subpoena or other process or order, shall furnish those attorneys with a copy of said subpoena or other process or order, and shall cooperate with respect to any procedure sought to be pursued by the party whose interest may be affected. The Disclosing Party asserting the confidential treatment shall have the burden of defending against such subpoena, process or order. Subject to any reasonable procedure sought to be pursued by the party whose interest may be affected, the person or party receiving the subpoena or other process or order shall be entitled to comply with it except to the extent the Disclosing Party asserting the confidential treatment is successful in obtaining an order modifying or quashing it.

**26. Continuing Jurisdiction:** The Court retains jurisdiction even after termination of this action to enforce this Order and to make such amendments, modifications, deletions and additions to this Protective Order as the Court may from time to time deem appropriate. The disclosing parties reserve all rights to apply to the Court at any time, before or after termination of this action, for an order: (i) modifying this Protective Order, (ii) seeking further protection against discovery or use of CONFIDENTIAL INFORMATION, or other documents or information, or (iii) seeking further production, discovery, disclosure, or use of claimed

CONFIDENTIAL INFORMATION, or other documents or information.

**27. Headings:** The headings herein are provided only for the convenience of the parties, and are not intended to define or limit the scope of the express terms of this Protective Order.

Accordingly, IT IS HEREBY ORDERED, ADJUDGED AND DECREED.

This 23<sup>rd</sup> day of September, 2008.

/s/ James G. Carr Chief Judge James G. Carr

## UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO

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IN RE:

# HEPARIN PRODUCTS LIABILITY LITIGATION

MDL Docket No. 1953

CHIEF JUDGE JAMES G. CARR CASE NO. 1:08-60000

ALL CASES

## **EXHIBIT A TO PROTECTIVE ORDER**

# AGREEMENT CONCERNING INFORMATION COVERED BY PROTECTIVE ORDER ENTERED BY THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO

The undersigned hereby acknowledges that he/she has received and read First Amended Pretrial Order No. 7, Protective Order, entered by the United States District Court for the Northern District of Ohio, in connection with the above-captioned MDL proceeding, and understands its terms and agrees to be bound by each of those terms. Specifically, and without limitation upon such terms, the undersigned agrees not to use or disclose any confidential information made available to him/her other than in accordance with said Order. The undersigned further submits to jurisdiction of this Court for purposes of the Protective Order in this action.

DATED:

By:

(type or print name of individual)

(name of employer)