

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO**

<b>IN RE:</b>	)	<b>MDL Docket No. 1953</b>
	)	
<b>HEPARIN PRODUCTS</b>	)	<b>CHIEF JUDGE JAMES G. CARR</b>
<b>LIABILITY LITIGATION</b>	)	<b>CASE NO. 1:08-60000</b>
	)	
	)	<b>ALL CASES</b>

**Pretrial Order Number 8 – Discovery Plan**

The parties have met and conferred pursuant to Rule 26 of the Federal Rules of Civil Procedure (“F.R.C.P.”), and submit the following discovery plan.

**1. Initial Disclosures.**

Defendants will provide initial disclosures pursuant to F.R.C.P. 26(a) by October 30, 2008. The parties agree that the Plaintiffs’ Fact Sheets will provide the disclosures to Defendants necessary under Rule 26, and such disclosures will be provided within 60 days of a Court Order approving the form and substance of the Fact Sheets, in lieu of initial disclosures. The parties agree that Defendants are not required to serve updated disclosures each time a new case is filed in or transferred to the MDL.

**2. Plaintiffs’ Fact Sheets.**

Each Plaintiff whose case has already been transferred to this Court shall have 60 days from entry of the Court’s Order approving Plaintiffs’ Fact Sheet to complete and serve upon Defendants a Plaintiff Fact Sheet, in the form to be agreed upon by the parties’ counsel or to be determined by the Court.

Plaintiffs whose cases have not been transferred to this Court as of the date of this Order shall have 45 days from the entry of the Court's order approving Plaintiffs' Fact Sheet or 30 days from the date that the transferred case is assigned a case number in the MDL (whichever is longer) to complete and serve upon Defendants a Plaintiff Fact Sheet.

**3. Discovery Subjects.**

Plaintiffs intend to seek discovery from Baxter International Inc., Baxter Healthcare Corporation and any related entities or operating divisions ("Baxter" or "Baxter Defendants"), and from Scientific Protein Laboratories LLC, Changzhou SPL Co., Ltd., American Capital, Ltd. (ACAS), and any related entities or operating divisions ("SPL" or "SPL Defendants") in regard to the topics listed in Attachment A. Defendants reserve all rights to object to any discovery request and do not concede that the topics listed in Attachment A are appropriate, relevant to this litigation, or reasonable likely to lead to the discovery of admissible evidence. Further, Defendants do not concede that discovery is properly obtainable from all of the parties listed above.

Defendants intend to seek discovery from all Plaintiffs, Plaintiffs' Medical Providers and other third-party witnesses in regard to the topics listed in Attachment B. Plaintiffs reserve all rights to object to any discovery request and do not concede that the topics listed in Attachment B are appropriate, relevant to this litigation, or reasonable likely to lead to the discovery of admissible evidence. Both Plaintiffs and Defendants reserve the right to seek discovery related to topics not listed in either Attachment A or Attachment B.

Nothing in this section shall be construed to commence discovery or trigger any obligations on the part of the parties to produce or respond to the topics listed in Attachment A or Attachment B. Plaintiffs and Defendants shall still be required serve formal written discovery

requests pursuant to and in compliance with the F.R.C.P., and as set forth in this Order and any other subsequently issued order of the Court.

**4. Discovery Schedule.**

The parties are still in the process of evaluating the scope of discovery that will be conducted in this case. Accordingly, the parties agree to provide the Court with an update as to the agreed Discovery Schedule on or before October 15, 2008.

**5. Written Discovery.**

**(a). Document Requests.**

Plaintiffs shall serve upon Defendants a Master Set of Requests for Production of Documents at any time.

**(b). Interrogatories.**

Plaintiffs shall serve upon Defendants a Master Set of Interrogatories pursuant to F.R.C.P. 33(a), at any time.

**6. Production of Documents and Electronically Stored Information.**

**(a) Electronic Discovery.**

The parties agree that this case involves electronic discovery. The parties adopt the E-Discovery Guidelines of this Court (“Appendix K”) unless otherwise set forth herein. The parties shall exchange the information listed in Local E-Discovery Rule 2 subparts (a)-(d) on or before October 15, 2008. The parties agree to provide notice of problems reasonably anticipated to arise in connection with e-discovery as soon is practicable after such problems are identified. On or before October 22, 2008, the parties shall file with the Court statements of compliance with Local E-Discovery Rule 7. Defendants shall produce documents on a rolling basis and employ an electronic search to locate potentially relevant electronically stored information. Defendants shall search by means of search terms to be followed by an attorney review for

responsiveness and privilege. Agreement on the search methodology and terms shall be reached on or before October 1, 2008. Plaintiffs name Vestige Ltd. as their E-discovery coordinator. The Baxter Defendants name ACT Litigation Services as their E-Discovery coordinator. The SPL Defendants name FTI Consulting as their E-Discovery coordinator.

**(b) Production Format.**

All documents or electronically stored information that originally existed in either printed or native electronic form that are produced in these proceedings shall be produced as single-page Tagged-Image File Format (“TIFF” format) using Group 4 compression. For documents or electronically stored information that originally existed in electronic form, the parties will produce TIFF images along with cross-referenced, searchable text files. For documents that originally existed in printed form, the parties will provide TIFF images, as well as cross-referenced optical character recognition (“OCR”) text files. For documents that originally existed in printed form, the parties will also provide searchable text files, and objective coding as that term is defined in paragraph 6(g) to the extent that such searchable text files and objective coding are available. . The parties are under no obligation to convert documents that originally existed in printed form into searchable text files or create objective coding. . All images generated from printed documents shall be scanned at high resolution and reflect, without substantial visual degradation, the full and complete information contained on the original document. All images generated from native electronic documents or electronically stored information will reflect how the source document would have appeared if printed out to a printer attached to a computer viewing the file.

The parties shall produce an ASCII text “load file” in industry-standard Comma-Separated-Value (“CSV”) format to accompany the TIFF images, which will identify the beginning and end point of the document(s) to permit the produced images and load file to be

linked by means of a commercially-available, off-the-shelf (“COTS”) litigation support database system (e.g. Concordance). The parties shall meet and confer to the extent reasonably necessary to ensure that the produced images and load file can be electronically linked and searched by means of a COTS document management or litigation support software such as Concordance. The parties will specify any particular load requirements for the COTS document litigation support software application. The parties will promptly identify to each other documents that they have problems with accurately imaging or formatting, and the parties will meet and confer in an attempt to resolve such problems.

**(c) Document Unitization.**

Each page of a document shall be scanned or electronically saved into an image. If a document is more than one page, the unitization of the document and any attachments and/or affixed notes shall be maintained as it existed in the original when creating the image file.

**(d) Bates Numbering.**

Each page of a produced document by the parties shall have a legible, unique page identifier (“Bates Number”) electronically “burned” onto the image at a location that does not obliterate, conceal, or interfere with any information from the source document. No other legend or stamp will be placed on the document image without prior consent of the parties other than a confidentiality legend (where applicable), redactions (consistent with applicable law or Court order) and the Bates Number identified above. The confidentiality legend may be “burned” onto the document’s image at a location that does not obliterate or obscure any information from the source document.

**(e) File Naming Conventions.**

The TIFF image file for each page of each produced document shall be given a unique Bates Number, and in the case of single-page TIFFs, the image file naming convention will include a standard “.TIF” file extension (e.g., BAX123.TIF).

**(f) Production Media.**

The parties will produce documents and electronically stored information on one or more of the following media types: CD-ROM, DVD, external hard drive (with standard PC compatible interface formatted using NTFS with a firewire and/or USB 2.0 interface), at their discretion, or upon such other readily accessible computer or electronic media as the parties may hereafter agree upon (the “Production Media”). Each piece of Production Media shall identify the producing party, the case caption, the production date, and the bates range of documents on the Production Media.

**(g) Objective Coding.**

For production of documents or electronically stored information originally existing in electronic form, the parties will provide an appropriately delimited (e.g. CSV) data file in ACSII format, that provides the beginning Bates Number, ending Bates number, author, recipient, CCs, custodian, document title (or subject line if an email), attachment beginning Bates Number, attachment ending Bates number and date for the document or electronically stored information (the “objective coding”). Objective coding shall be labeled and produced on Production Media in accordance with the provisions of paragraph 4(g). The parties shall meet and confer to resolve problems, if any, in importing and using the Objective Coding with a COTS Concordance litigation support system. The parties’ production of Objective Coding shall not constitute any certification as to the reliability, accuracy or completeness of the coding, and shall not constitute any waiver of work product protection or the attorney-client privilege with respect to that coding.

**(h) Electronic Text Files.**

The parties will extract and produce all available text (“extracted text”) from any document or electronically stored information originally existing in electronic form. The extracted text shall be provided in ASCII text format and shall be labeled and produced on Production Media in accordance with the provisions of paragraph 4(g). The text files will be named with the unique Bates Number of the first page of the corresponding document followed by the extension “.txt”. The parties shall not be obligated to produce extracted text for documents that have been redacted in accordance with applicable law or Court order, however, the parties shall produce OCR text for such documents in accordance with paragraph 4(c). The parties agree to meet and confer to discuss whether embedded data or metadata is relevant and need be produced from electronically stored information.

**(i) Optical Character Recognition Text.** The parties shall produce Optical Character Recognition (OCR) text files for documents that exist natively in electronic format that have been redacted in accordance with applicable law or Court order. The OCR text shall be provided in ASCII text format and shall be labeled and produced on Production Media in accordance with the provisions of paragraph 6(f). The text files will be named in accordance with the provisions of paragraph 6(e).

**(j) Original and Color Documents.**

The parties shall, upon reasonable request, make originals of produced document available for inspection and copying. Upon reasonable request, the parties will make production of a color image of a document previously produced in non-color format. For electronically stored information, the parties agree that native format documents, including embedded data and metadata or other above-mentioned information, shall be provided to a party by the other upon request.

**(k) Privileged Materials.**

Any party that withholds the production of requested documents or materials, regardless of the manner in which they are kept or maintained, on the ground of any privilege or application of the work-product doctrine, must specify in writing, as to each document or thing not produced, the specific privilege(s) or doctrine(s) it is relying upon to withhold each document (“Privilege Log”). Each Privilege Log shall describe each document or thing to which a privilege or work product doctrine is asserted in enough detail for the requesting party to be able to determine the applicability of the privilege. Privilege Logs shall be produced within thirty (30) days of each production.

The Parties agree that the inadvertent production or disclosure of privileged or otherwise protected materials shall not be deemed per se a waiver or impairment of any claim of privilege or protection. If any document or electronically stored information which appears on its face to contain privileged information or attorney work product is produced during discovery, the receiving party shall, upon discovery, promptly notify the producing party. Upon confirmation by the producing party that the document or electronically stored information was inadvertently produced, the receiving party shall, within 3 business days, certify in writing that all printed and electronic copies, notes regarding, or summaries of the document or electronically stored information in question have been destroyed. If any producing party discovers that it has inadvertently produced privileged documents or electronically stored information, it must notify all receiving parties within 30 days of discovery of such. Within 3 business days of receiving a notice of inadvertent production, all receiving parties must certify in writing that all printed and electronic copies of the document or electronically stored information in question have been destroyed.



**(l). Translations:** To the extent that any documents exist in languages other than English, and counsel for the parties are aware that translations to English have been made of these documents, the original and English-translated documents will be produced.

**7. Depositions.**

**(a) Notice of Attendance at Depositions.**

In order for counsel to make arrangements for adequate deposition space, whenever feasible, counsel who intend to attend a deposition noticed by MDL-1953 should provide notice to Liaison Counsel no fewer than (7) days prior to the deposition, whenever feasible.

**(b) Avoidance of Duplicative Depositions.**

As a general rule, no witness should be deposed more than once in this litigation. If Plaintiffs or Defendants seek to take a second deposition of a witness, it shall provide the opposing party its basis for an exception to the rule along with a list of the new subject matters as to which interrogation is sought. Second depositions on new subject matter may be permitted by consent of the parties or upon order of this Court authorizing such deposition based upon a showing of good cause.

**(d) Postponements of Depositions.**

Once a deposition has been scheduled, it shall not be taken off calendar, postponed, rescheduled, or relocated less than five (5) calendar days in advance of the date it is scheduled to occur, except upon agreement of counsel or by leave of Court for good cause.

**(f) Examination by Counsel.**

Unless the Court orders otherwise, Plaintiffs and Defendants shall each designate no more than two attorneys for the MDL and one attorney for any coordinated state court proceeding to participate in the deposition and conduct non-duplicative questioning.

**(g) Disputes during Depositions.**

Disputes between the parties should be addressed to this Court rather than to the District Court in which the deposition is being conducted. Disputes arising during depositions that cannot be resolved by agreement and that, if not immediately resolved, will significantly disrupt the discovery schedule or require rescheduling of the deposition, or might result in the need to conduct a supplemental deposition, shall be presented to Judge Carr by telephone. In the event Judge Carr is not available, the deposition shall continue with full reservation of rights of the interrogation for a ruling at the earliest possible time. However, if the nature of the dispute would not stop the deposition from going forward, the parties may elect to continue on and present the matter to Judge Carr by telephone after the deposition.

**8. Federal Rules of Civil Procedure.**

Unless specifically modified herein, nothing in this order shall be construed to abrogate the Federal Rules of Civil Procedure.

Accordingly,

IT IS HEREBY ORDERED ADJUDGED AND DECREED,

This 15 day of September, 2008.

s/James G. Carr

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Chief Judge James G. Carr

## **ATTACHMENT A - PLAINTIFFS' DISCOVERY SUBJECTS**

- A. Corporate structure from January 2003 to date
- B. Organizational charts from January 2003 to date
- C. Liability insurance potentially available to compensate plaintiffs;
- D. Ownership, management and control of each corporate entity from January 2003 to date;
- E. Contracts, purchase order and business relationships between Baxter and SPL Defendants from January 2003 to date;
- F. Procurement of raw materials to produce Heparin;
- G. Manufacture of Heparin;
- H. Testing of Heparin;
- I. Identification of contaminants in Heparin;
- J. Adverse Event Reports, communications and analysis concerning Heparin;
- K. Supply issues regarding Heparin and/or raw materials for manufacture from January 2003 to date;
- L. Supervision, inspection, funding and oversight of manufacturing facilities for Heparin or its raw materials;
- M. Quality control, quality assurance, and failure investigations regarding Heparin manufacture;
- N. Cost analysis, sales, profits and other financial reports related to the production and sale of Heparin from January 2003 to date;
- O. Communications with the FDA or other regulatory entities concerning Heparin and/or manufacturing sites for Heparin;
- P. New Drug Application for Heparin and all amendments, supplements and additions thereto and/or INDs related to Heparin;
- Q. Studies, tests, protocols, reports and analysis concerning the safety or efficacy of Heparin;
- R. Internal communications concerning the production of Heparin, the sale of Heparin, the costs of production for Heparin, the contamination of Heparin, adverse events regarding Heparin, and regulatory relations concerning Heparin from January 2003 to date;

- S. Distribution information concerning lots or batches of Heparin and/or distribution of contaminated Heparin from January 2003 to date;
- T. Communications with medical professionals and/or regulatory authorities concerning Heparin from January 2003 to date;
- U. Disposition, testing, storage of all returned or recalled lots or batches of Heparin;
- V. Research, testing, patents, development of synthetic Heparin or its components, including but not limited to chondroitin sulfate;
- W. Communications with the CDC concerning Heparin from January 2003 to date;
- X. Specifications/formula for manufacture of Heparin, and any changes thereto;
- Y. Identification of raw materials suppliers, changes in suppliers, changes in specifications for raw materials, and changes in production of Heparin, its raw materials, or its components from January 2003 to date;
- Z. Public relations, publicity, damage control concerning contaminated Heparin;
- AA. Demands for indemnification, compensation or related claims between Baxter and SPL concerning contaminated Heparin, or between defendants and third parties, such as physicians, hospitals, pharmacists or suppliers of contaminated Heparin, or offers to provide same;
- BB. Joint defense agreements among or between Baxter, SPL or any related entities;
- CC. Computer database information from January 2003 to date;
- DD. Information, discussions and communications concerning the recall(s) of contaminated Heparin;
- EE. Information concerning sale of a misbranded or adulterated drug in regard to Heparin;
- FF. Information concerning notice to Baxter, SPL, their employees, officers or agents of contamination of Heparin and/or adverse reactions to Heparin;

## **ATTACHMENT B - DEFENDANTS' DISCOVERY SUBJECTS**

1. Medical history, treatment, and records of plaintiffs for the last 10 years;
2. Plaintiffs' employment history and status;
3. Any testing, evaluation, or analysis of heparin by plaintiffs or plaintiffs' testifying experts;
4. Plaintiffs' claimed damages;
5. The basis for plaintiffs' claims;
6. Any other litigation involving plaintiffs or claims asserted by plaintiffs against medical providers or medical product manufacturers; and
7. Communications, documents, or any other information related to plaintiffs' use of heparin, including but not limited to the alleged adverse events suffered by plaintiffs.