PRESENT:

Honorable Helen E. Freedman, J.S.C.

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

IN RE: NEW YORK RENU WITH MOISTURELOC PRODUCT LIABILITY LITIGATION	Index No.766,000/2007
THIS DOCUMENT APPLIES TO ALL CASES	**CASE MANAGEMENT ORDER NO. 7**

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PROTOCOL FOR ELECTRONIC EVIDENCE PRODUCTION

The following protocol will set forth the general protocol regarding the production of documents by Defendant, both in hard copy and in electronic format, and shall be followed for the production of all documents existing in hard-copy form and documents and/or data existing in native electronic format as to all derivations, marketed and unmarketed, of the contact lens solution known as ReNu with MoistureLoc including but not limited to products identified by Bausch & Lomb in 510 (K) applications as: K031646 – NRC03; K033854 – NRC07; and K051755 - ReNu with MoistureLoc. Plaintiffs reserve the right to seek to expand the scope of this CMO pending additional discovery.

This CMO shall apply only to Defendant. If such a protocol is found necessary as to Plaintiffs, an additional CMO will be considered.

This order was negotiated by the parties with the knowledge that Bausch & Lomb had already substantially began collecting and processing of documents prior to entry of this order.

A. Scope

1. To the extent possible, the litigation will be conducted as a "paperless" case and discovery shall be conducted so as to maximize efficient and quick access to document discovery

by litigants throughout the country and minimize document production and distribution costs. All documents that originally existed in either hard-copy or native electronic form that are not privileged or otherwise protected from production and are responsive to discovery requests or Court Order (or are otherwise produced in these proceedings) shall be produced, subject to objections and responses, in electronic image form in the manner provided herein.

2. Except as specifically limited herein, the procedures set forth below and protocols govern the production of discoverable electronic information (as defined below) by the parties during the pendency of the above-captioned litigation.

3. This protocol shall extend to all documents and/or electronic information originating nationally or internationally.

4. All documents shall be decrypted.

5. Reasonable efforts will be made to ensure that all documents are legible. If a copy is not legible, the original shall be made available for inspection and copying within twenty (20) days of request, or as mutually agreed upon.

6. Except as otherwise set forth herein, the procedures and protocols herein apply solely to documents and data subject to being reproduced in electronic form (in the broadest sense consistent with the laws of the State of New York).

7. The parties shall meet and confer regarding the options and burdens of the insertion of page numbers and/or breaks. Counsel for Bausch and Lomb will execute an affidavit certifying that they have not generated any produced, electronic documents for their own use with page breaks and page numbers that are not available to plaintiffs. If Bausch and Lomb's counsel creates a producible electronic document with inserted page numbers and/or breaks, Bausch and Lomb will provide such documents to plaintiffs.

8. The scope of the production with respect to the restoration, search, and production of backup and archival media, maintained by the Defendant, if needed, will be addressed in the future.

9. Definitions: The following definitions further clarify the scope of this protocol.

a. "Available": The Defendant will comply with its obligations under New York law to produce data responsive to all requests for Production of Documents and CMOs.

b. "Database" shall refer to electronic media of non-custodial structured data, including systems where notes, data and/or documents are depicted.

c. "Data Map" includes, to the extent available, the field names, table names, relationships, and notes on fields and tables where not apparent from the names alone to a person unfamiliar with the database.

d. "Defendant", shall mean the Defendant Bausch & Lomb Inc. and/or its predecessor(s).

e. "Document" or "Documents", are defined by the law of New York. wherever used throughout these requests, shall mean any written or graphic matter of any kind whatsoever, however produced or reproduced, any electronically or magnetically recorded matter of any kind or character, and any other matter constituting the recording of data or information upon any tangible thing by any means, including but not limited to,–the original and any non-identical. Any of the following (regardless of however or by whomever prepared, reproduced, maintained or stored): books, records, reports, articles, abstracts, posters, studies,

memoranda, notes, letters, correspondence, e-mail, instant messages, chats, chat postings, bulletin boards, electronic bulletin boards, posters, blogs, websites, voicemail, studies, trials, clinical data, reports, analysis, evaluations, assessments, speeches, telegrams, diaries, calendar entries, diary, journal, logs, schedules, maps, graphs, charts, contracts, releases, appraisals, valuations, estimates, opinions, studies, analyses, summaries, magazines, booklets, pamphlets, circulars, brochures, bulletins, instructions, minutes, photographs, purchase orders, bills, checks, drafts, certificates, tabulations, questionnaires, films, or tapes, surveys, messages, correspondence, letters, records (of meetings, conferences and telephone or other conversations or communications), tables, drawings, sketches, tax reports, working papers, financial statements, electronic databases, computer data (including information or programs stored in a computer or storage media, whether or not ever printed out or displayed) as well as any other tangible thing on which information is recorded in any writing, sound, electronic or magnetic impulse, or in any other manner, and including preliminary versions, drafts, revisions or amendments to or of any of the foregoing and any supporting, underlying or preparatory materials.

f. "Load file" refers to a delineated ASCII text file issued with each production providing a map to the images, extracted text/OCR files, and meta-data contained within the production.

g. "Meta-data" includes but is not limited to structured fields or information stored with or associated with a given file and shall include all hidden or embedded information that is not readily available to non-technically adept computer users.

h. The term "and/or" wherever used throughout these request, shall indicate that either or both of the items connected by it are involved.

B. Format Protocol for Specific Types of Discoverable Electronic Information

1. Documents in hard copy: All documents that only exist in hard copy form shall be produced in electronic image form (in the manner provided herein) and the document's image must convey the same information as if the subject document was produced in a hard copy form. All documents will be produced with the following fields contained in a separate load file: beginning bates number; ending bates number; date; type; and source. Documents that present imaging problems shall be promptly identified and thereafter the parties will attempt to mutually resolve the problem amongst themselves. If the parties are unable to mutually resolve the problem, the issue will be resolved by the Court on appropriate motion.

a. All documents shall be scanned as black and white images at 300 dpi resolution and shall be saved and produced in a Group IV compression single-page TIFF format file.

b. If an original document contains color, Defendant shall honor reasonable requests for either the production of an original document for inspection and copying, or production of a color image of the document within 20 days of the request, or as mutually agreed upon. Defendant will make best efforts to satisfy requests for expedited production.

c. Each page of a document shall be scanned into an image and 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. Additionally, reasonable efforts shall be used to scan the pages or images at 100% of their original size without reduction and scanned so that the print or image appears straight, not skewed, on the TIFF. Physically oversized originals, however, will appear reduced. For the purpose of displaying the bates numbers, the parties understand that to burn bates numbers without obliterating any text, as described below, the documents may need to be shrunk to no less than 90% whenever possible. Reasonable efforts will be made to ensure that all documents are legible. If a copy is not legible, the original shall be made available for inspection and copying within twenty (20) days of request, or as mutually agreed upon.

2. Electronic Documents: All documents existing in electronic format shall be produced in a Group IV TIFF compression single-page format file with extracted text files in ASCII text format, which shall represent the textual content of the electronic document with meta-data as defined herein. The objective coding will be contained in a separate load file, see herein.

a. Electronic mail ("email") containing discoverable electronic information, together with meta-data, as addressed below, associated with each such email, shall be produced. Any documents attached to the email will be

produced immediately after the parent email. All documents attached together shall be identified using a range of bates numbers for the complete set of attachments.

b. Word processing files, computer presentations (e.g., PowerPoint slides), stand alone databases (e.g., Access), spreadsheets (e.g., Excel), together with the meta-data associated with each such document, as addressed below in a separate load file shall be produced.

c. If an original document contains color, Defendant shall honor reasonable requests for either the production of an original document for inspection and copying, or production of a color image of the document within 20 days of the request, or as mutually agreed upon. Defendant will make best efforts to satisfy requests for expedited production.

3. Databases:

a. Identifying Databases: The Defendant shall produce a list identifying databases owned, under the control of Defendant, and/or maintained by or on behalf of Bausch & Lomb Inc. concerning the topics identified in Par. B(3)(e) as they relate to ReNu with MoistureLoc within twenty (20) days of the date of this Order together with a short description of the contents of each such database. The parties shall then meet and confer to discuss the details of databases that may contain potentially relevant information, available meta data associated with each database and potential methods of production. Plaintiffs shall thereafter serve a formal Notice of Discovery and Inspection for specific databases. Defendant is entitled to

all the procedures and protections of the New York Rules of Civil Procedure in responding to this request including the opportunity and obligation to supplement this response.

b. Production of Databases: In response to the Notice of Discovery and Inspection, to the extent possible, responsive data shall be produced in a format that allows for the data to be re-loaded into another database. Any such format is acceptable as long as a generally available database can be used to work with the data so that the database when loaded with data will be able to view all data as available to the Defendant. If a Defendant is not able to provide data as described above, the parties shall meet and confer.

c. To the extent available, Defendant shall provide a data map for each database production.

d. If size constraints or other technical considerations warrant database production in a delimited text file format, the producing party is <u>not</u> to use a "comma and double quote" format of delimited text, but rather use an alternate format such as "pipe and carat".

e. Defendant's databases should include, but will not be limited to:

1. adverse event databases
2. sales call tracking databases;
3. sales force databases;
4. clinical communications databases;
5. public communication databases;
6. patient communication databases;

7. medical communication databases;

8. regulatory databases;

9. regulatory contact databases;

10. clinical trial databases;

11. medical literature databases;

12. document management system databases;

13. clinical payments databases;

14. field force rosters;

15. marketing communications databases;

16. research & development communications databases; and

17. research & development databases.

4. Meta-data: The Defendant shall produce certain agreed upon meta-data for corresponding native electronic files. Specifically, all electronic documents, such as word processing documents, e-mails, spreadsheets and other similar type materials, should be produced as single-page TIFF images with the accompanying extracted text and meta-data (date, title, authors, recipient, subject, etc.).

a. Plaintiffs may request additional meta-data and/or production of the specific programs that were used to create the corresponding native electronic files if they are unable to access, search, or translate the meta-data as it is produced, or if they feel additional meta-data is discoverable after reviewing a production. Plaintiffs may also request a listing of available meta-data through discovery.

b. Load Files: For each electronic document produced, a load file shall be produced identifying the following pieces of information(meta-data):

1. Title;
2. Subject;
3. To, CC, BCC (for emails) Recipient(s) (for other types);
4. Last Date Modified;
5. Date Created;
6. Document Date (if different from Date Created);
7. Category/Subcategory (type of item);
8. Original document/file path;
9. Date;
10. Original file name;
11. Author;
12. Starting Bates;
13. Ending Bates;
14. Original person responsible for maintaining (custodian);
15. Revision history;
16. Application and software program used.

5. System-Level Meta-data: All copies of computer files for production shall be created in such a way as to preserve or record the original directory structure and system-level meta-data (file name and path, create, modify, and access date and time, and size).

6. Redaction Software: The Defendant shall describe to plaintiffs the procedures and software used to redact any documents or data existing in electronic form such that plaintiffs can identify how information was redacted and can obtain and or evaluate the software. Additionally, the original form of any redacted data shall be preserved by the Defendant so that it can potentially be reviewed if the propriety of a redaction is at issue.

C. Source Information

1. Electronic records and computerized information will be produced with sufficient information to permit identification of the source and path of the records or information custodian as described in Par. B(4)(b). Plaintiffs may not require these items until a later time; however, if it is more economical to produce these items at this time, Plaintiffs will accept same. This information shall include without limitation:

a. The name of the corporation or entity producing the information.

b. To the extent reasonably known and identified in the load file information described in Par. B(4)(b), the path and custodian from which the information was originally created and maintained during the regular course of business

D. Document/Data Identification Conventions for All Types of Discoverable Electronic Information

1. Production Media: All discoverable electronic information that is produced in this coordinated proceeding shall initially be produced in electronic image format with searchable text, in the manner provided herein, on a hard drive at no cost to the plaintiffs other than the cost of the hard drive itself. Supplemental productions, beyond the initial production, shall be produced on either CD-ROM, DVD or external hard drive.

2. Bates Numbering: Each individual piece of computer media produced must be clearly labeled with a unique media control or "Bates" number that is indelibly written on, or affixed to, both the media itself and any enclosure or case produced with the media.

a. Each page of the scanned document shall have a legible, unique document identifier electronically "burned" onto the image at a location that does not obliterate any information from the source document.

b. There shall be no other legend or stamp placed on the document image unless a document qualifies for designation as confidential (as addressed by another order). In such case the document image may also have burned in an appropriate legend regarding confidentiality at a location that does not obliterate any information from the source document. If a confidential document is later declassified, the party producing the document shall produce a new version of the document without the confidentiality legend. Any such confidentiality legend may not be placed in any area other than the bottom of the document. No watermarks that extend across the text of the documents are permitted.

c. Document identifiers should correspond and be consistent with the Bates number imprinted on the document. For example, if the Bates number "BL0000001" was imprinted, the document would bear the name "BL0000001.tif".

d. Bates numbers should allow for a range of up to 10 million documents or eight (8) numeric digits.

3. File Naming Conventions: Each document image file shall be named with the unique Bates Number of the first page of the corresponding TIFF image, followed by the extension "TIF". Each CD-ROM of documents, data or email produced by a party shall be

uniquely named with a sequential number that includes the producing party's unique alpha identifier (e.g., "BL001", BL002, etc.).

a. If any document production is substantial enough to require production on a hard drive, over ten (10) DVDs are to be produced at a single time, Plaintiffs will supply and/or pay for the hard drives.

b. Document image files (or files containing electronic production of data or email) shall be placed on a CD-ROM, DVD or hard drive in a subdirectory or subfolder bearing the same name as the particular media it is located on so that files are not in the root directory of that particular media. The name of each subdirectory shall be the name of the bates number of the first file in the subdirectory (e.g. "BL001\BL0001234" contains "BL0001234.TIF" as its first file).

c. There will be no more than 1,000 files in any given subdirectory and there must always be at least one subdirectory under the disk name subdirectory.

4. Privilege: The Defendant shall only withhold discoverable electronic information on the basis of privilege within the bounds of New York law, Orders of this Court or as required by Federal Regulatory Statutes. The Defendant shall be required to produce a privilege log in both searchable PDF and hard copy format within 45 days of the production. Defendant may contact Plaintiff's counsel to request an extension of the period to serve a privilege log.

5. Redaction: The Defendant shall only redact discoverable electronic information within the bounds of New York law, Orders of this Court, or as required by Federal Regulatory Statutes. The Defendant shall produce a redaction log simultaneously with the production which will identify the documents redacted and the basis of the redaction in searchable PDF

format. For documents that exist natively in electronic format that Defendant has redacted in accordance with applicable law or Court order, Defendant shall produce Optical Character Recognition (OCR) text files for such documents. The OCR text shall be provided in ASCII text format and shall be labeled and produced on an agreed upon Production Media with the corresponding images. 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 production of OCR text shall not constitute any certification as to the reliability, accuracy or completeness of the OCR text.

6. Delivery:

a. All computer media must be properly packaged to ensure safe shipping and handling.

b. If any piece of media produced is known to have any physical defect, electronic defect, or damaged data, or is infected with any virus or other harmful software of any kind, it should be clearly labeled so that appropriate care can be taken during its examination.

c. All computer media that is capable of write protection should be write-protected before production.

E. Resolution of Disputes Concerning Electronic Discovery

1. All disputes regarding discovery shall be addressed by the parties in a conference prior to the filing of any motion with the Court.

2. If the parties are unable to resolve the dispute, an appropriate motion may be made to the Court at that time.

3. Notwithstanding any provision set forth above, any party may apply to the Court for relief, but only after first meeting and conferring in good faith with the other party to resolve any dispute, and after giving sufficient notice to be heard.

4. Because of the potential for a large number of documents to be produced, it may not be possible to review the images immediately upon production. If any problems are encountered with imaged document(s), they shall be identified by the requesting party and thereafter the parties will attempt to mutually resolve the problem.

Dated: ~~May~~ June 6, 2007 ENTER:

New York, New York

Helen E. Freedman

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