UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: BENICAR (OLMESARTAN) PRODUCTS LIABILITY LITIGATION	HON. ROBERT B. KUGLER Civil no. 15-2606(RBK)(JS) **STIPULATION ESTABLISHING ELECTRONIC DISCOVERY PROTOCOL**

The parties, through their counsel, have stipulated and agreed to give effect to this Stipulation Establishing Electronic Discovery Protocol ("ESI Protocol") as set forth below to facilitate discovery. This ESI Protocol shall apply to all cases in this litigation.

WHEREAS certain documents and information have been and may be requested, sought, produced, or exhibited by, between and among the parties to the above-captioned actions that involve Benicar®, Benicar HCT®, Azor®, and Tribenzor®, and any future product liability cases in this consolidated litigation involving those medications; such records and data that constitute electronically stored information ("ESI") shall be produced by the Parties in accordance with the following protocol:

I. DEFINITIONS

A. **"Electronically stored information,"** or **"ESI,"** as used herein, means and refers to computer generated information or data of any kind, stored in or on any storage media as defined in this section. Non limiting examples of ESI include:

- Digital Communications (e.g., e-mail, voice mail, instant messaging, etc.);
- E-Mail Server Stores (e.g., Gmail, Lotus Domino .NSF or Microsoft Exchange .EDB);
- Word Processed Documents (e.g., Word or WordPerfect files and drafts);

- Spreadsheets and tables (e.g., Excel or Lotus 123 worksheets);
- Collaboration software tools (e.g., Microsoft SharePoint, Microsoft Lync, eRoom);
- Document Managements Systems (e.g., Documentum);
- Accounting Application Data (e.g., QuickBooks, Money, Peachtree data);
- Image and Facsimile Files (e.g., .PDF, .TIFF, .JPG, .GIF images);
- Sound Recordings (e.g., .WAV and .MP3 files);
- Video and Animation (e.g., .AVI and .MOV files);
- Databases (e.g., Access, Oracle, SQL Server data, SAP, other);
- Contact and Relationship Management Data (e.g., Outlook, ACT!);
- Calendar and Diary Application Data (e.g., Outlook PST, blog entries);
- Presentations (e.g., PowerPoint, Corel Presentations);
- Project Management Application Data;
- Task related data (e,g,, Task lists from Outlook PST)
- Computer Aided Design/Drawing Files;
- Backup and Archival Files (e.g., Veritas, Zip, .GHO); and
- Apps (data from smartphone applications used in the normal course of business).

This list does not represent that such ESI exists within the parties' data sources or that it will be produced. The parties agree to meet and confer regarding any disputes relating to relevancy, proportionality, or production issues before submission of any disputes to the court.

B. **"Native data format"** means and refers to the format of ESI in which it was generated and/or as used by the producing party in the usual course of its business and in its regularly conducted activities.

C. **"Metadata"** means and refers to information about information or data about data, and includes, without limitation: (1) information embedded in or associated with a native file that is not ordinarily viewable or printable from the application that generated, edited, or modified such native file which describes the characteristics, origins, usage and/or validity of the electronic file and/or (ii) information generated automatically by the operation of a computer or other information technology system when a native file is created, modified, transmitted, deleted or otherwise manipulated by a user of such system.

D. "**Documents**" includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data, data records or data compilations – stored in any medium (including cloud-based or cloud sourced media) from which information can be obtained.

E. "**Storage Media**" means an object or device, real or virtualized, including but not limited to a disc, tape, computer, mobile device, smartphone, iPad, Cloud (public, private or hybrid) or other device, or other similar means of communication, on which data is or was stored.

II. SEARCH TERMS FOR ELECTRONIC DOCUMENTS

The parties agree that they will cooperate in good faith regarding the disclosure and formulation of appropriate search methodology, search terms and protocols, and any TAR/predictive coding prior to using any such technology to narrow the pool of collected documents to a set to undergo review for possible production. The parties agree to meet and confer as early as possible, to discuss, *inter alia:*

- Search methodology(ies) to be utilized (including but not limited to Boolean searches and technology assisted review/predictive coding);

- Disclosure and selection of all search terms, including foreign language (e.g., Japanese) and search terms based upon actual terminology used in the producing party's documents;

- Search protocol; and

- Post-search error sampling and sampling/testing reports.

The parties will continue to meet and confer regarding any search process issues as necessary and appropriate. Nothing in this protocol, or the subsequent designation of any search terms, shall operate to limit a party's production obligations under applicable law, or limit the ability to

agree to meet and confer to modify the search terms, criteria, or methodologies as information is obtained and utilized in the course of the litigation.

This ESI protocol does not address or resolve any other objection to the scope of the parties' respective discovery requests.

III.   FORMAT OF PRODUCTION

A.   **General Production Formats.** ESI that can be readily converted to TIFF documents will be produced as TIFF documents pursuant to this order except as set forth below. Where agreed, ESI will be produced in native format with Metadata intact, except where this is not practicable. In this event, the producing party will promptly notify the requesting party of the issue, and the parties will attempt to agree upon an alternative format that is acceptable to the requesting party.

1.   Excel (or other spreadsheet formats) will be produced in native format. Native Excel files will be redacted by overwriting the data contained in a particular cell, row, column or tab with the word "REDACTED." These documents will be identified as redacted within the "REDACTED" field in the .DAT. If the producing party deems it necessary to produce redacted Excel (or other spreadsheet formats) in any format other than Native, the parties should meet and confer before such a production is made.

2.   PowerPoint (or other presentation formats) will be produced in native format. Native PowerPoint presentations that require redactions shall be produced as TIFF images, which shall include speaker notes and "hidden" slides as extracted by the software used to process the documents. Color PowerPoint presentations requiring redactions shall be converted to color images as set forth in Section D, and black and white PowerPoint presentations requiring redactions shall be converted to black and

white TIFF images, provided that proper grayscale printing is enabled to ensure that any dark colored text is not hidden by dark objects/drawings around the text. If the PowerPoint or slide program contains video or audio components, the video or audio will be produced as native files with the appropriate attachment relationships.

3. The receiving party may request a specific document or a specific category of documents produced as a TIFF document to be produced in native format upon good cause shown. The parties agree to meet and confer as to any dispute before the issue is submitted to the court.

4. If a document is converted from native format to any other format, the producing party shall extract and produce the agreed upon metadata, as described below in Section K, from the original Native file, and provide the hash value for the original file.

5. If the requesting party deems the alternate format to be insufficient, this will be brought to the attention of the producing party, and the parties will meet and confer within five (5) business days of being notified of the issue before submitting the issue to the Court.

B. Production Specifications.

1. Native Productions. All native productions shall be produced in such a way so as to identify and/or maintain the file structure of the data being produced. This shall be accomplished by providing a load file identifying the agreed upon metadata in Section K. Said load files shall be consistent with industry standard Concordance load files such as .DAT files and .OPT files. If documents that the parties have agreed to produce in native format per this protocol are to be used at depositions or attached to pleadings or

papers filed with the Court, the party offering the native document must identify the document as native format and provide the slip sheet provided by the producing party for each native file including Bates stamp, Protective Order designation, as appropriate, and agreed upon metadata fields for authentication purposes. A slipsheet shall be produced for all native files at the time of their production, including Bates stamp, Protective Order designation, and agreed upon metadata fields. The parties shall meet and confer regarding which metadata fields should be included on the slip sheet.

2. **Image Productions.**

(a) **Physical Documents.** Documents or records that either (i) were originally generated as ESI but now only exist in physical hard-copy format, or (ii) documents or records that were originally generated in hard-copy format, shall be produced as single page TIFF files along with an OCR acquired text file containing page break indications where available and the agreed upon metadata fields listed in Section K below. When subjecting physical documents to an OCR process, the settings of the OCR software shall maximize text quality over process speed. Any settings such as "auto-skewing", "auto-rotation" and the like should be turned on when documents are run through the process. In scanning paper documents, distinct documents shall not be merged into a single record, and single documents shall not be split into multiple records (i.e., paper documents should be logically unitized). Parent-child relationships (the association between attachments and their parent documents) shall be preserved. In the case of an organized compilation of separate documents -- for example, a binder containing several separate documents behind numbered tabs -- the document behind each tab should be scanned separately, but the relationship among the documents in the binder should be

reflected in proper coding of the beginning and ending document and attachment fields. Original document orientation shall be maintained (i.e., portrait to portrait and landscape to landscape). The parties agree to meet and confer as to any dispute before the issue is submitted to the court.

(b) ESI. For ESI produced as TIFF images, native format files shall be converted to single-page TIFF images. Accompanying the TIFF images shall be a multipage text (.TXT) file containing searchable text from the native file, and the metadata discussed in Section K below. Load files for the TIFF images should be created and produced together with their associated TIFF images to facilitate the use of the produced images by a document management or litigation support database system. The parties shall meet and confer to the extent reasonably necessary to determine how such production can be made reasonably usable for the requesting party, and to facilitate the import and use of the produced materials with commercially available document management or litigation support software.

C. Duplicates. The Parties are not required to produce exact duplicates of electronic documents stored in different locations. Defendants may globally de-duplicate identical ESI, which will be determined as follows:

(i) Electronic files will be de-duplicated based upon calculated MD5 Hash values for the entire file contents. File contents only will be used for MD5 Hash value calculation and will not include operating system metadata (e.g., filename, file dates) values.

(ii) Messaging files will be de-duplicated based upon MD5 Hash values for the message family, including parent object and attachments. The following fields will be used to create the unique value for each message: To; From; CC; BCC; eMail Subject; Internet

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Message ID; Body; and MD5 Hash values for all attachments, in attachment order. Messaging materials will be de-duplicated at a family level, including message and attachment(s).

(iii) If Defendants de-duplicate identical ESI, Defendants shall provide custodian associations in an overlay file, including fields BATES NUMBER, DUPLICATE CUSTODIANS, and DUPLICATE CUSTODIAN_SOURCEFILEPATHS as listed in Section K, with Concordance standard delimiters that include duplicate custodian name information. The overlay files shall be produced after every production and shall be regularly updated to account for rolling productions.

D.   Color. Documents or records containing color (for example, graphs, pictures, or color marketing materials) will be produced as color images for each such document or record, to the extent possible. This provision does not apply to hard copy documents or electronic records containing color logos, signatures, watermarks, or letterhead.

E.   System Files.   Electronic file collection will be "De-NISTed", removing commercially available operating system and application files contained on the National Institute of Standards and Technology ("NIST") file list. Identification of NIST list matches will be through MD5 Hash values.

F.   Time Zone.   When processing ESI, Coordinated Universal Time (UTC) should be selected as the time zone.

G.   Archive File Types.   Archive file types (e.g., .zip, .rar) shall be uncompressed for processing. Each file contained within an archive file shall be produced, and the reference to the parent archive file will be provided in the child file name.   If the archive file is itself an attachment, that parent/child relationship shall also be preserved.

H. **Bates Numbering and Other Unique Identifiers.** Documents produced in native format will be named with a Bates number, and the original file name will be identified in the load file. For image files (i.e. TIFF images), each page of a produced document shall have a legible, unique page identifier ("Bates Number") electronically stamped onto the TIFF image in such a manner that information from the source document is not obliterated, concealed, or interfered with. All files and documents that are replaced for any reason shall be identified with a "-R" designation appended to the original production number. There shall be no other legend or stamp placed on the document image unless a document qualifies for confidential treatment pursuant to the terms of a Protective Order entered by this Court in this litigation, or has been redacted in accordance with applicable law or Court order. In the case of confidential materials as defined in a Protective Order, or materials redacted in accordance with applicable law or Court order, a designation may be electronically stamped onto the document's image at a location that does not obliterate or obscure any information from the source document, other than material being redacted.

I. **Production Media.** Documents shall be produced on CD-ROM, DVD, external hard drive (with standard PC compatible interface), such other readily accessible computer or electronic media as the parties may hereafter agree upon, or electronically via secure file share/FTP (the "Production Media"). For any productions produced via FTP, those productions shall also be produced on hard drive. Each item of Production Media shall include: (1) the name of the producing party; (2) a legend identifying the production as being made for Olmesartan Cases; (3) the production date; (4) a unique production volume, starting with the same Bates prefix used on the documents being produced; and (5) where feasible, the Bates number range of the materials contained on such Production Media item, or other description of the items. Each

production shall be accompanied by a Production Letter setting forth the date and scope of production, and shall contain a Production Index, which shall be updated with each production, setting forth the date, Bates ranges, source of documents for each Bates range (e.g., custodian, database), document or discovery request responded to, and date of withdrawal of protected designation and replacement of document or image with no protected designation, where applicable.

J.   **Electronic Text Files**. For each document, a single text file shall be provided along with the native or image files and metadata. The text file name shall be the same as the Bates number of the first page of the document. File names shall not have any special characters or embedded spaces. Electronic text shall be extracted directly from the native electronic file unless the document was redacted, an image file, or a physical file. In these instances a text file created using OCR will be produced in lieu of extracted text. Where feasible, if the Producing Party has access to extracted text from electronic document files, the Receiving Party shall receive extracted text as well, instead of OCR text generated from an image file. If such conversion is unduly burdensome or renders the document unusable, the Producing Party may produce the document in any reasonably usable form as may be agreed upon by the respective parties. The parties shall meet and confer regarding any disputes relating to the availability of extracted text.

K.   **Metadata**. The following list identifies the metadata fields and manually generated fields that will be included in Load files, to the extent applicable:

- FIRSTBATES
- LASTBATES
- BEGATTACH

- ENDATTACH

- PARENT_BATES

- MAPI ATTACHMENT COUNT

- ATTACHMENTS

- CUSTODIAN

- DUPLICATE_CUSTODIANS

- DUPLICATE CUSTODIAN_SOURCEFILEPATHS (IN SEPARATE OVERLAY FILE)

- FROM

- TO

- CC

- BCC

- SUBJECT

- DATE_SENT (UTC TIME ZONE)

- DATE_RECEIVED (UTC TIME ZONE)

- FILENAME

- FILE_EXTEN

- AUTHOR

- DATE_CREATED

- DATE_MOD

- DATE_LASTACCESS

- LAST_PRINTED_DATE

- REDACTED

- FILE_SIZE

- FILETYPE

- RECORDTYPE

- FILEPATH

- INTMSGID

- HASH_VALUE

- TEXTLINK

- NATIVELINK

- PAGE_COUNT

- EMAIL IMPORTANCE (FLAG YES OR NO)

- REPLACEMENT (FLAG YES OR NO)

- PROD_VOLUME

- FOREIGN LANGUAGE (FLAG YES OR NO)

- SUBJECT TO PROTECTIVE ORDER (FLAG YES OR NO)

- REDACTED (FLAG YES OR NO)

- REDACTION TYPE (REASON FOR REDACTION)

- TITLE AND SUBJECT (E-DOCS)

- CONVERSATION INDEX

- EMAIL HEADER (FOR EMAILS)

- FOREIGN LANGUAGE (FLAG YES OR NO)

- APPLICATIONNAME

- CATEGORIES

- COMMENTS

- CONVERSATION

- DATELASTPRNT

- DELIVRECEIPT

- ERRORMSG

- FILEDESCRIPTION

- HASCOMMENTS

- HASTRACKCHANGES

- HIDDENTEXT

- KEYWORDS

- LANGUAGE

- LASTAUTHOR

- ORIGEXT

- READRECEIPT

- RECORDTYPE

- REVISION

- SENSITIVITY

- SUSPECTEXT

- SUSPECTOLE

- TEMPLATE

- TEXTXSTATUS

Such metadata fields will be produced to the extent available, except that they may be suppressed

or redacted if privileged or information protected by HIPAA or other information protected by

law. Parties agree to meet and confer if additional fields of metadata are needed.

L.   **Attachments.** Email attachments and embedded files will be mapped to their parent by attachment range within the Load file.

M.   **Structured data.** To the extent a response to a non-objectionable discovery request requires production of discoverable electronic information contained in a database, it shall be produced in its native format unless not practicable, in which case the producing party shall notify the requesting party and the parties shall promptly meet to attempt to resolve the issue. If the producing party asserts that production of a database in native is not practicable, the producing party may advise of a preference to (1) produce existing reports or reports readily able to be generated from the database that are reasonably responsive to the discovery requests, or (2) design queries in order to produce an extract from the database of relevant and responsive data in a reasonably usable and exportable electronic file (e.g., Excel, Access, CSV or Microsoft SQL server database format). Any production of a database not in its native format should be fully parsible. For enterprise database systems from which data will be produced, the parties will meet and confer as to the available data in the system, the data to be exported, and the format of production on a case by case basis. The producing party agrees to disclose the search parameters used to design the reports and/or queries prior to the production. Upon review of any such parameters and productions from structured databases, the requesting party may make reasonable requests for additional information to explain the database schema, fields, codes, abbreviations, and different report formats, and may object to this method of production.

N.   **Data Security.** The parties will ensure that third-party vendors hosting data produced in this litigation shall maintain the appropriate level of data security in an effort to prevent a security breach of protected or proprietary information, and pursuant to the Protective Order.

O.   Production of Medical Records. The Producing Party agrees to provide any medical records in either hard copy or in PDF format to comply with the reporting obligations associated with the FDA.

IV.   OBJECTIONS TO ESI PRODUCTION

A.   If any formatting requirements or other specifications agreed to in this protocol are later determined by the producing party to be not feasible, or unduly burdensome or unreasonably costly, the parties will promptly meet and confer in order to attempt to agree upon appropriate modifications to the protocol before presenting any such issue to the Court.

B.   Notwithstanding anything contained herein to the contrary, a producing party shall not produce ESI in a format not requested or agreed to by the requesting party. If an issue arises, the issue will only be submitted to the Court after reasonable efforts by the parties to reach agreement by the meet and confer process.

V.   PRIVILEGE AND WORK PRODUCT CLAIMS

The parties agree that, for documents redacted or withheld from production on the basis of attorney-client privilege or the work product doctrine and/or any other applicable privilege, the producing party will provide an updated summary log with each production of privileged material, in an electronically searchable format (e.g., Excel), containing, for each document claimed as privileged, and as required by applicable law, including Fed. R. Civ. P. 26(b)(5)(A), a description of "the nature of the documents, communications, or tangible things not produced or disclosed—and do so in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim," as well as an export of the metadata fields listed below (to the extent such information exists and has not been suppressed or redacted for privilege):

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- FIRSTBATES

- LASTBATES

- BEGATTACH

- ENDATTACH

- PARENT_BATES

- ATTACHMENTS

- CUSTODIAN

- DUPLICATE_CUSTODIANS

- FROM

- TO

- CC

- BCC

- SUBJECT

- DATE_SENT

- DATE_RECEIVED

- FILENAME

- AUTHOR

- DATE_CREATED

- FILETYPE

- PRIV_CLAIM

- STATUS OF PRIVILEGE DESIGNATION

If the requesting party requires further information, it shall explain in writing the need

for such information and identify, by Bates number or other unique identifier, each document

for which it seeks this information. Within thirty (30) days of such a request, the producing

party must either (i) provide the requested information or (ii) challenge the request. Either party

may seek to expedite this time period upon good cause shown. If a party challenges a request

for further information, the parties shall meet and confer to try to reach a mutually agreeable

solution. If they cannot agree, the parties must request a conference with the Court before any

motions may be filed. Withdrawal of privilege designations shall be noted on the summary log,

indicating the fact and date of withdrawal of the privilege designation.

The inadvertent production of privileged or protected documents or information shall be

governed by the Protective Order entered by the Court in this litigation.

VI.   AMENDMENTS TO THE ESI PROTOCOL

No modifications or amendments to the ESI Protocol shall be made except upon the

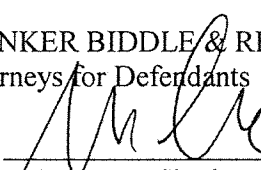filing of a formal motion and a showing of good cause.

Dated: July 14, 2015

AGREED TO BY:

MAZIE SLATER KATZ & FREEMAN, LLC
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By: _____
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          Michael C. Zogby, Esq.

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APPENDIX 1: FILE FORMATS

A. Image Load Files

- Every document referenced in a production image load file shall have all corresponding images, text, and data logically grouped together.
- The name of the image load file shall mirror the name of the delivery volume; and should have an .lfp, .opt or .dii extension (e.g., ABC001.lfp).
- The volume names shall be consecutive (i.e., ABC001, ABC002, et. seq.).
- The image load file shall contain one row per TIFF image.
- Every image in the delivery volume shall be contained in the image load file.
- The image key shall be named the same as the Bates number of the page.
- Load files shall not span across media (e.g., CDs, DVDs, Hard Drives, etc.), i.e., a separate volume shall be created for each piece of media delivered.

B. Metadata Load Files

- The metadata load file shall use the following delimiters:
  - o Column Delimiter: Pilcrow - ¶ (ASCII :020)
  - o Text Qualifier: Thorn - þ (ASCII :254)
  - o New line: Registered sign - ® (ASCII 174)
- The first record shall contain the field names in the order of the data set forth in Section K above.
- Metadata fields that are not applicable to a document shall be filled with two adjacent text delimiters.
- All date fields shall be produced in "mm/dd/yyyy hh:mm AM" format.
- A carriage-return line-feed shall be used to indicate the start of the next record.
- Load files shall not span across media (e.g., CDs, DVDs, Hard Drives, etc.); a separate volume shall be created for each piece of media delivered.
- The name of the metadata load file shall mirror the name of the delivery volume, and shall have a .dat, .csv or .txt extension (i.e., ABC001.dat).
- The volume names shall be consecutive (i.e., ABC001, ABC002, et. seq.).

- The .dat and .txt files shall be encoded in UTF-8 or UTF-16 coding as appropriate, preserving the integrity and full character set in use for any Japanese or other non-English text.