

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE: BENICAR (OLMESARTAN)	:	Master Docket No. 15-cv-2606 (RBK/JS)
PRODUCTS LIABILITY LITIGATION	:	
	:	
THIS DOCUMENT RELATES TO	:	STIPULATED DISCOVERY
ALL ACTIONS	:	PROTECTIVE ORDER

WHEREAS certain documents and information have been and will be requested, sought, produced, or exhibited by, between, and among the parties to the above-captioned action which involves the olmesartan products Benicar®, Benicar HCT®, Azor® and Tribenzor®, and any future cases consolidated in this MDL (hereinafter “Action”), which relate to the parties’ private proprietary information; trade secrets; proprietary scientific information; personal psychiatric, psychological, employment, and/or medical information, and/or other highly sensitive information, both business and personal; and,

WHEREAS, the Court finds that there is good cause for the entry of this Protective Order to protect “Protected Information” from use in any manner inconsistent with this Protective Order;

IT IS ON THIS 5th day of JUNE, 2015 ORDERED THAT:

SCOPE OF PROTECTIVE ORDER

1. This Protective Order applies to all hard copy and electronic materials and other products of discovery, all information contained therein and derived therefrom

and including, but not limited to, all copies, excerpts, summaries or compilations thereof, obtained by the Plaintiffs or Defendants pursuant to the requirements of any court order, any requirements of self-executing discovery, discovery requests under the Federal Rules of Civil Procedure; documents subpoenaed under the Federal Rules of Civil Procedure, affidavits, certifications, or otherwise, and transcripts of depositions and/or non-public or in camera hearings (hereinafter "Discovery Material"), produced by any party to this proceeding (the "Producing Party") to any other party (the "Receiving Party").

2. This Protective Order is binding upon the parties to the Action, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, agents, experts, consultants, representatives, officers, directors, joint venturers, and employees as set forth in this Order, or any party hereto or who shall become a party to this litigation, unless modified by the Court.

3. Third parties may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and therefore become a Producing Party and/or Receiving Party for purposes of this Protective Order.

4. Nothing herein shall be construed to affect or restrict in any manner the use or admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

5. This Protective Order is not intended to address or govern claims of privilege or work product that may otherwise be asserted by any of the parties, except to the extent provided in Paragraph 18 herein.

6. This Protective Order shall not be construed to protect from production or to permit the designation of any Discovery Material as "Protected Information" that: (a) the party has failed to make reasonable efforts to keep confidential, (b) has lawfully obtained by or from another source, without breach of law, regulation, court order, or privilege, or (c) is at the time of production or disclosure, or subsequently becomes, through no wrongful act of the Receiving Party, readily accessible to others on a non-confidential basis. In the event the receiving party identifies any document it reasonably believes falls under this paragraph, it shall continue to treat the document as "Protected Information" and follow the procedure set forth in Paragraph 17 of this Order.

7. Nothing in this Protective Order shall preclude any party or its representatives from inspecting, reviewing, using or disclosing its own "PROTECTED INFORMATION" in this litigation or in transactions or other matters unrelated to this case. To the extent the Designating Producing Party discloses any information previously designated as confidential, to another person or entity such that the information loses its confidential status, the Receiving Party is entitled to reasonably prompt notice that the information is no longer Protected Information as defined in this Protective Order. No penalty shall accrue as a result of an inadvertent failure to do so.

8. Nothing shall prevent disclosure of "PROTECTED INFORMATION" beyond that required by this Protective Order if the Producing Party consents in writing to such disclosure.

9. This Protective Order does not relieve any party of its obligations to respond to discovery in the Action and shall not restrict or limit the Defendants in any way from complying with regulatory obligations.

DEFINITION OF "PROTECTED INFORMATION"

10. The term "PROTECTED INFORMATION" as used in this Protective Order means all information produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is proprietary, trade secret and/or highly sensitive commercial information, and which is believed in good faith by the Producing Party to have the potential, if disclosed, for causing competitive harm to it or giving a competitive advantage to others, and/or as being entitled to protection under the Federal Rules of Civil Procedure and the Local Rules of the District of New Jersey, or other applicable case law, and/or as ordered by the Court. Plaintiffs shall be permitted to designate materials that contain personal information as "PROTECTED INFORMATION" pursuant to this Order. NOTE: It is anticipated that the volume of documents to be exchanged by the parties during pre-trial discovery will be substantial. Accordingly, nothing herein shall be construed to prevent a Producing Party from designating documents as "PROTECTED INFORMATION" in order to expedite the flow of discovery and to facilitate discovery in these consolidated actions. The Court is confident that all parties and their counsel shall act in good faith at all times in making designations. Nonetheless, should it be demonstrated to the Court that a Producing Party has abused the discretion contemplated by the language of this paragraph and has unduly burdened their adversary, the Court shall entertain a petition for sanctions.

11. The following shall not be designated as “PROTECTED INFORMATION”:

- a. Documents of public record which are “readily accessible” as defined by Federal Law, or otherwise publicly available;
- b. Documents filed as a public record with the clerk of any federal or state court, not including exhibits or depositions or discovery responses which, if filed, were to have been filed under seal and with clear marking on the envelopes in which they are enclosed that they are subject to this Protective Order or a Protective Order entered in another case; [NOTE: Any exhibits, deposition transcripts or discovery responses filed “under seal” shall remain PROTECTED INFORMATION.]
- c. Documents or articles published in trade magazines or other general circulation publications; or
- d. Documents previously provided to any individual or entity, or readily accessible to third-parties, on a non-confidential basis.

12. No items or information, including but not limited to summaries of items or information designated as “PROTECTED INFORMATION” shall be produced or disseminated orally, or by any other means, except as permitted by this Protective Order.

13. Any designation of “PROTECTED INFORMATION” under this Protective Order shall not be construed as an admission or an agreement by any party:

- a. That the designated disclosure constitutes or contains protected information; or
- b. That any document, material or information, or any portion thereof, constitutes competent, material, relevant, or admissible evidence in this case.

DESIGNATION OF "PROTECTED INFORMATION"

14. Subject to the admonition of the Court stated in Paragraph 10 hereinabove, the Producing Party shall designate "PROTECTED INFORMATION" by marking on the face of the document or material or, in the event that "PROTECTED INFORMATION" is produced electronically or natively, on the disc or CD, on a placeholder document, and/or by such other means, including consistent with the ESI Protocol, so that the designation is communicated to the party receiving the document:

"PROTECTED INFORMATION – SUBJECT TO PROTECTIVE ORDER"

Any Discovery Material for which it is impracticable or impossible to affix such a legend may be designated by written notice to that effect with a reasonable description of the material in question. Such stamping or marking shall take place prior to, or contemporaneously with, the production by the Producing Party, or subsequent to the selection by the Receiving Party for copying but prior to the actual copying if done expeditiously. The stamp shall be affixed in such a manner as not to obliterate or obscure any written matter. The stamp need not be affixed to every page of a multi-page document.

15. Inadvertent production of any document or information without a designation of "PROTECTED INFORMATION" will not be deemed to waive a later claim to its protected nature or preclude a party from designating said document or information as "PROTECTED INFORMATION" pursuant to this Order at a later date. Any party may designate as "PROTECTED INFORMATION" or withdraw "PROTECTED INFORMATION" designation from any material that it has produced, provided, however, that such re-designation shall be effective only as of the date of such re-designation. A party must treat such documents and things with the noticed level of protection from the date such notice is received. Such re-designation shall be accomplished by promptly notifying counsel for each party in writing of such re-designation and providing replacement images bearing the appropriate description. Upon receipt of any re-designation and replacement image that designates material as "PROTECTED INFORMATION," all Parties shall (1) treat such material in accordance with this Protective Order; (2) take reasonable steps to notify any persons known to have possession of any such material of such re-designation under this Protective Order; and (3) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under this Protective Order.

16. Prior to producing documents that contain the names of patients other than Plaintiffs and/or the physicians of such patients or consumers, the Producing Party may redact or delete the names, addresses, telephone numbers, social security numbers, and other information that would identify patients, research subjects and

physicians or others constituting voluntary reporters or any other person associated with an adverse event, and any other information required to be withheld from disclosure by 21 C.F.R. § 20.63, the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (“HIPAA”) and related regulations, applicable federal and state privacy laws, and other applicable laws and regulations. If the Producing Party produces copies of documents containing the names or other personal information of patients other than Plaintiffs or their physicians that is protected from disclosure pursuant to 21 C.F.R § 20.63, HIPAA, or other governmental statute, rule or regulation, neither the Parties nor their counsel shall disclose the names or other personal information or contact any such patient or physician identified through the production of documents. The prohibition does not apply, however, to information that was lawfully obtained through sources independent from the Producing Party’s discovery productions.

17. If a Receiving Party who receives documents or information designated as “CONFIDENTIAL INFORMATION” objects to such designation of any or all of such items, the following procedure shall apply:

(a) Counsel for the objecting party shall serve on the Producing Party or third party a written objection to such designation, which shall describe with particularity the documents or information in question and shall state the grounds for objection. Counsel for the Producing Party or third party shall respond in writing to such objection within fourteen (14) days of receiving the written objection, and shall state with particularity the grounds for asserting that

the document or information is CONFIDENTIAL or ATTORNEYS' EYES ONLY. If no timely written response is made to the objection, the challenged designation will be deemed to be void. If the Producing Party or third party makes a timely response to such objection asserting the propriety of the designation, counsel shall then confer in good faith within fourteen (14) days of the date when the Producing Party's written response is dated in an effort to resolve the dispute.

(b) If a dispute as to a "CONFIDENTIAL INFORMATION" designation of a document or item of information cannot be resolved by agreement, the proponent of the designation being challenged shall present the dispute to the Court initially by telephone or letter, in accordance with Local Civil Rule 37.1(a)(1), within twenty-one (21) days of the date when the Producing Party's written response is dated before filing a formal motion for an order regarding the challenged designation. Failure to request said conference, or to file the motion shall operate as a waiver of the disputed designation. The document or information that is the subject of the filing shall be treated as originally designated pending resolution of the dispute. These time frames may be modified for good cause for specific challenges on informal application to the Court.

18. Inadvertent production of documents or information (hereinafter "Inadvertently Produced Documents") subject to the attorney-client privilege, the work-product privilege or other legal privilege or doctrine protecting information from discovery shall not constitute a waiver of the privilege or doctrine, provided that the

Producing Party shall notify the Receiving Party in writing of such inadvertent production as soon as is practicable after discovery of the inadvertent production. In that event, such Inadvertently Produced Documents and all copies thereof shall be returned to the Producing Party or destroyed, upon request, and such returned or destroyed material shall be deleted from any litigation-support or other database, except as set forth below. No use shall be made of such documents during depositions or at any hearing or trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them. If the party receiving the Inadvertently Produced Documents disputes the claim of privilege, work product, or other statutory or court-ordered protection, it shall promptly notify the Producing Party. In the event the parties are unable to resolve the dispute, either Party may contact the Court for the scheduling of a telephone conference call with counsel to review whether the designated Documents are rightfully subject to a lawfully recognized privilege. In the event the Court resolves the dispute, either Party may petition the Court via formal Notice of Motion within ten (10) days from the date of the conference call; otherwise the Court's resolution of the issue shall stand. In the event the Court does not resolve the issue, the Producing Party may petition the Court to maintain the asserted privilege or protection, within ten (10) days from the date of the conference call; otherwise the claim of privilege or protection shall be deemed withdrawn. Counsel for the Receiving Party may retain one copy of the inadvertently produced document(s) for purposes of opposing the motion and may submit the document for in camera review by the Court in connection with the motion. If the claimed privilege or

protection is upheld or the challenge is waived, the document(s), along with any notes or other work product of the Receiving Party regarding the contents of such document(s), shall be destroyed or returned to the Producing Party.

LIMITATIONS ON DISCLOSURE OF "PROTECTED INFORMATION"

19. The parties agree that "PROTECTED INFORMATION" shall not be used by any person receiving such "PROTECTED INFORMATION" for any business or competitive purpose and shall be used solely for the purpose of the Action. All persons receiving or given access to "PROTECTED INFORMATION" in accordance with the terms of this Protective Order consent to the continuing jurisdiction of this Court for the purposes of enforcing this Protective Order and determining a remedy for a breach of the Protective Order.

20. "PROTECTED INFORMATION" shall not be disclosed to anyone other than the following categories of persons:

- a. The Court (and any appellate court), including court personnel and any court-appointed special master;
- b. Mediators, secretaries, paraprofessional assistants, and other employees of such mediators who are actively engaged in assisting the mediators in connection with this matter;
- c. Employees of counsel for Plaintiffs or Defendants who have responsibility for assisting in the preparation and trial of this action or any appeal herein.
- d. Employees of outside copying, document imaging, litigation and

trial support, and facsimile services;

- e. The persons who authored or contributed to the preparation of the “PROTECTED INFORMATION”;
- f. Disclosure may be made to consultants or experts (hereinafter, “consultants/experts”) employed by Plaintiffs or Defendants, or their counsel, to assist in the preparation and trial of this litigation. However, prior to disclosure to any consultant/expert (including undisclosed consulting experts), the consultants/experts must agree to be bound by the terms of this Protective Order by executing the acknowledgement annexed hereto as Exhibit “A”. A copy of each executed acknowledgement shall be maintained for Plaintiffs’ consultant/experts by Plaintiffs’ Counsel, and for Defendants’ consultants/experts by Counsel for Defendants during the course of the litigation. At the conclusion of the litigation, counsel for Receiving Party shall confirm in writing with counsel for Producing Party that it will seek to have any documents designated as “PROTECTED INFORMATION” that were provided to consultants/experts returned to counsel for the Receiving Party.
- g. In no event shall a Receiving Party make disclosure to consultants/experts who are employees, officers, or directors of any competitors of Defendants, or anyone who at the time of disclosure is anticipated to become an employee, officer, or director

of any competitor of Defendants, except pursuant to the terms of this provision. In the event a Receiving Party wishes to make disclosure to any such consultant/expert, or to anyone who at the time of disclosure, is anticipated to become such consultant/expert, irrespective of whether they are retained as a consultant/expert for Plaintiffs, the parties shall "meet and confer" to determine a method to address such proposed disclosure. If, after meeting and conferring, the Parties are unable to agree on a method to address such proposed disclosure, either Party may contact the Court for the scheduling of a telephone conference call for the Court to determine whether and under what circumstances such disclosure by the Receiving Party will be permitted. The Court may conduct an in camera review of the documents at issue, in its discretion. The Court's determination on these issues shall be binding on all Parties. Prior to a determination by the Court on these issues, the Receiving Party may not disclose any PROTECTED INFORMATION to the proposed consultant/expert.

A "competitor" shall be defined as any pharmaceutical manufacturer or other company that manufactures or markets Angiotensin Receptor Blockers.

- h. The Parties to the extent required for assisting in the preparation and trial of each individual case or any appeal herein. To the extent

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

- i. Deponents, Court reporters, videographers and their support personnel. Documents designated as "PROTECTED INFORMATION" may be shown to deponents during the deposition, but the deponent may not retain a copy of the document or have a copy of the transcript where the documents are discussed unless they have been informed of this Protective Order and has agreed in writing to be bound by it by executing Exhibit A to this Order.
- j. Any person who (i) wrote or received a copy of the document designated protected before it was furnished in this litigation, or (ii) was present or participated in a meeting or discussion of the protected information before it was furnished in this litigation.

21. All parties and their respective counsel, paralegals and employees and assistants of all counsel receiving Discovery Material shall take all steps reasonably necessary to prevent disclosure of "PROTECTED INFORMATION" other than in accordance with the terms of this Protective Order.

22. Disclosure of "PROTECTED INFORMATION" other than in accordance with the terms of this Protective Order may subject the disclosing person to such sanctions and remedies as this Court may deem appropriate.

23. No "PROTECTED INFORMATION" shall be made or delivered to any person other than those categories of persons referred to in Paragraph 20 above.

24. "PROTECTED INFORMATION" may only be disclosed to persons who are not included in those categories referred to in Paragraph 20, above, upon prior written consent of the Producing Party's counsel. If the Producing Party's Counsel refuses to give consent, the "PROTECTED INFORMATION" shall not be disclosed. The party requesting disclosure may apply to the Court via the procedure provided at Paragraph 17.

25. In the event that any question is asked at a deposition or non-public or in camera hearing, which a party asserts calls for "PROTECTED INFORMATION", or a document containing "PROTECTED INFORMATION" is identified as an exhibit in testimony given in this action, such question shall nevertheless be answered by the witness fully and completely to the extent required by law. In the case of deposition or other non-public or in camera hearing testimony, or any exhibit thereto, the transcript, video or exhibit, or portions thereof, as applicable, may be designated as "PROTECTED INFORMATION" in accordance with this Protective Order by notifying the other party: (1) on the record, at the time of the testimony; or (2) in writing within twenty (20) days after the transcript has been received by counsel making the designation, specifying the testimony being designated protected by page and line number(s). Until the expiration

of such 20-day period, the entire text of the deposition transcript, including all testimony therein, shall be treated as "PROTECTED INFORMATION" under this Protective Order. The court reporter shall mark the face of the transcript with the label set forth in Paragraph 14 of this Order. Any court reporter or transcriber who reports or transcribes testimony in this case shall be informed before the beginning of the deposition or non-public or in camera hearing about this Protective Order and shall be asked to take reasonable and appropriate steps to preserve "PROTECTED INFORMATION". It is the obligation of the Producing Party to make any application to the Court with respect to the provisions of this paragraph. Should there develop any conflict between the timing provisions set forth in this Paragraph and the timing provisions regarding motion procedures set forth in Paragraph 26, below, Paragraph 26 shall prevail.

26. If a party receiving "PROTECTED INFORMATION" in accordance with the terms of this Protective Order is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization which calls for the production of any "PROTECTED INFORMATION" produced by another party, the party to whom the subpoena or other process is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such documents or information until ten (10) business days after notifying counsel for the Producing Party in writing of the following: (a) the information and documents that are sought by the subpoena; (b) the date on which compliance with the subpoena is requested; (c) the location at which compliance with the subpoena is requested; (d) the identity of the

party serving the subpoena; (e) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena or other process has been issued. The party receiving the subpoena or other process shall cooperate with the Producing Party in any proceeding relating thereto.

COURT SUBMISSIONS CONTAINING "PROTECTED INFORMATION"

27. Any documents that a PROTECTED Party wishes to file with the Court during this Action which have previously been designated as "PROTECTED INFORMATION" (or which contain "CONFIDENTIAL INFORMATION"), and all pleadings and memoranda purporting to reproduce or paraphrase such "PROTECTED INFORMATION," shall be filed in a manner that preserves the confidentiality of such information. To the extent possible, parties shall attempt to avoid the need to file materials under seal by working with the Producing Party to create non-confidential, redacted or excerpted pages of materials containing "PROTECTED INFORMATION" to attach to filings. Where the filing party has not had an opportunity to confer with the Producing Party, in advance of a filing, the filing party shall not attach materials containing "PROTECTED INFORMATION" to its filing but shall instead designate by Bates number the materials containing "PROTECTED INFORMATION" that would have been attached or completely redact all "PROTECTED INFORMATION" from such materials. No otherwise timely filing shall be considered late or incomplete if the filing attaches Bates numbers or redacted documents in place of materials containing "PROTECTED INFORMATION." Within ten (10) business days of the filing, the filing

party and Producing Party shall confer to determine whether they can agree upon non-confidential redacted or excerpted pages of materials containing "PROTECTED INFORMATION" to attach to the filing in place of the Bates number designations or redacted materials. If the parties are unable to reach an agreement, then the designating party, the Producing Party, must file a motion to seal the materials containing "PROTECTED INFORMATION" pursuant to the requirements for doing so as set forth in Local Rule 5.3(c), and within thirty (30) days of the filing of the original motion, or else waive confidentiality as to the materials containing "PROTECTED INFORMATION" at issue. If the Producing Party waives confidentiality as to the materials at issue, the filing party may replace the Bates number designations or redacted materials with the full text of the documents at issue.

28. If "PROTECTED INFORMATION" is filed under seal pursuant to the procedure established by Paragraph 27, and is ordered by the Court to be maintained under seal, the "PROTECTED INFORMATION" and/or other papers shall be kept under seal until further order of the Court. However, said "PROTECTED INFORMATION" and other papers filed under seal shall only be available to the Court and counsel of record.

MISCELLANEOUS PROVISIONS

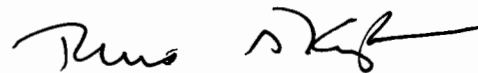
28. This Protective Order may be amended with leave of Court, or by the agreement of counsel for the parties in the form of a stipulation submitted to the Court for approval. If the parties cannot agree to an amendment, either Party may contact the Court for the scheduling of a telephone conference call with counsel to review whether

the requested amendment is appropriate. In the event said conference call does not resolve the question to both sides' satisfaction, either may petition the Court via formal Notice of Motion. This Protective Order is intended to regulate the handling of "PROTECTED INFORMATION" during this litigation, but shall remain in full force and effect until modified, superseded or terminated on the record by agreement of the parties thereto or by order of the Court.

29. Within thirty (30) days of the final termination of this case, whether by judgment, settlement or otherwise, (or such other time as the Producing Party may agree in writing), the parties shall return all "PROTECTED INFORMATION" to counsel for the Producing Party, and all copies thereof in his/her possession or subject to his/her control (including but not limited to materials furnished to consultants and/or experts), or shall certify to counsel for the Producing Party that all such Discovery Material has been destroyed. Outside counsel shall not, however, be required to return or destroy any pleadings, pretrial or trial records as are regularly maintained by that counsel in the ordinary course of business, which records will continue to be maintained as "PROTECTED INFORMATION" in conformity with this Protective Order.

30. All rights available at law are reserved for any violation of this agreement.

SO ORDERED, this 5 day of June, 2015



HON. ROBERT B. KUGLER

contained therein may be used only for the purposes authorized by this Protective Order.

I further agree and attest to my understanding that my obligation to honor the protected nature of such "PROTECTED INFORMATION" will continue even after this litigation concludes.

I further agree that if I fail to abide by the terms of this Protective Order, I will be subject to the jurisdiction of the United States District Court for the District of New Jersey for the purposes of any proceedings relating to enforcement of this Protective Order, and I specifically agree to subject myself to the jurisdiction of the United States District Court for the District of New Jersey for this purpose.

Date: _____

By: _____
(Signature)

(Printed)

(Street Address)

(City, State and Zip Code)

(Telephone)