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FILED

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	:	SUPERIOR COURT OF NEW JERSEY
	:	LAW DIVISION
	:	ATLANTIC COUNTY
IN RE ISOTRETINOIN LITIGATION	:	DOCKET NO. ATL-L-1321-09
APPLICABLE TO ALL CASES	:	CIVIL ACTION

SECOND AMENDED PROTECTIVE ORDER REGARDING DISCLOSURE OF CONFIDENTIAL DOCUMENTS BY GENERIC ISOTRETINOIN DEFENDANTS

THIS MATTER is before the Court pursuant to the Five Day Rule of R. 4:42-1(c) on the parties' request for entry of a Second Amended Protective Order Regarding Disclosure of Confidential Documents By Generic Isotretinoin Defendants ("Order"), to supersede the Amended Protective Order Regarding Disclosure of Confidential Documents by Generic Isotretinoin Defendants entered in this matter on December 4, 2008. This Order also incorporates the Supplemental Protective Order Regarding Disclosure of Certain Confidential Documents By Generic Isotretinoin Defendants entered in this matter on June 17, 2009.

This is a pharmaceutical products liability action. Claims for faulty design, marketing, testing, warning and manufacturing have been asserted and are likely to generate significant amounts of pretrial discovery documents. Given the sensitive nature of some of the discovery likely to be produced, a protective order is needed to expedite the flow of discovery documents, preserve the integrity of truly confidential information, trade secrets, and commercial and

proprietary information, promote the prompt resolution of disputes over confidentiality, and facilitate the preservation of documents worthy of protection. This Order strikes an appropriate balance between the parties' interests in prosecuting and defending this case, the judicial interest in the efficiency and integrity of the discovery process, and the public interest in access to information.

Accordingly, it is **ORDERED and ADJUDGED** as follows:

1. A party ("Producing Party") may designate as "Confidential" any documents, things and information (collectively referred to herein as "Documents") it produces in this litigation to a receiving party ("Receiving Party") if such Producing Party or counsel for such Producing Party believes in good faith that such Documents contains a trade secret or other confidential or proprietary research, development, or commercial information. In addition, this shall include, without limitation, information which, if disclosed, would invade physician-patient privileges and privacy interests or rights of persons not party to this action.

2. Absent a further order of this Court, Confidential Documents produced in this case shall not be used for any purpose other than the prosecution or defense of this captioned action, and shall not be shown, disseminated, or disclosed in any manner to anyone not authorized under this Order. Counsel for the Receiving Party ("Receiving Party Counsel"), however, may use the Confidential Documents consistent with the restrictions in paragraphs 3 and 4 of this Order.

3. This Order shall apply to all counsel, co-counsel who appear in the case, experts, persons noticed for depositions, actual or potential witnesses, and their respective counsel in this litigation, and associates, assistants, or employees. In addition, Receiving Party Counsel may disclose the Confidential Documents produced by any particular isotretinoin Defendant under

this Order (1) to other counsel of record having a filed case representing any plaintiffs against the same isotretinoin Defendant producing the documents designated as Confidential in which it is alleged that isotretinoin caused plaintiff's injuries or (2) to other counsel of record in cases filed against the branded manufacturer of isotretinoin (Accutane®) in which it is alleged that isotretinoin caused plaintiff's injuries (hereinafter collectively, "Other Counsel") if, and only if, such Other Counsel sign the certification attached to this Order certifying that they have read this Order and agree to be bound by it. Confidential Documents produced pursuant to this Order may be used by Receiving Party Counsel or Other Counsel in other filed cases pending in the Accutane Mass Tort proceeding in this Court, In re Accutane Litigation, No. 271, and/or in any other filed cases in which it is alleged that isotretinoin caused plaintiffs' injuries, subject to evidentiary and/or other objections. By executing this Order, Receiving Party Counsel and Other Counsel agree that they will be bound by this Order in such other cases. At the time of such disclosure of Confidential Documents by Receiving Party Counsel to Other Counsel, the Receiving Party Counsel shall also promptly provide notice of such disclosure in writing to the isotretinoin Defendant whose Confidential Documents are disclosed (identifying by name, address and telephone number such Other Counsel and/or experts receiving the Confidential Documents), so that the isotretinoin Defendant will have the ability to monitor the dissemination and disclosure of its Confidential Documents in such other cases.

4. Receiving Party Counsel or Other Counsel shall ensure that each of the attorneys and/or individuals associated with them by employment or otherwise in the handling of this case have read and are familiar with the terms of this Order. Receiving Party Counsel or Other Counsel and each of the attorneys and/or individuals associated with them by employment or otherwise in the handling of this case shall be deemed to be bound by the terms of this Order and subject to

the jurisdiction of the Court for appropriate proceedings in the event of any violation or alleged violation of this Order. Before showing or divulging the contents of any of the Confidential Documents produced in this case to any person identified in paragraph 3, other than counsel of record and employees of the law firm for counsel or record, Receiving Party Counsel or Other Counsel shall first obtain a signed statement from that person reciting that the person is familiar with the terms of this Order and has agreed to abide by those terms. The requirement of obtaining such a signed statement may be satisfied by affixing the name, affiliation and business address, as well as obtaining the signature of such person, on a copy of this Order. A copy of each such signed statement shall be retained by Receiving Party Counsel or Other Counsel for five (5) years after the conclusion of this case, including any appeal. A copy of the signed statement of any testifying expert, treating physician, or other witness to whom Confidential Documents have been provided under this Order, shall be provided to Producing Party Counsel upon either the date of said witness's deposition or the date of disclosure of such person as a testifying witness, whichever date is earlier. At the conclusion of this case, Receiving Party Counsel or Other Counsel shall retrieve all Confidential Documents from testifying experts, consulting experts, and any other person or entity to whom Confidential Documents have been disclosed pursuant to this Order and otherwise comply with paragraph 15 hereof.

5. Confidential Documents shall not be disclosed by Receiving Party Counsel or otherwise made public except in compliance with the terms of this Order. If any person or entity, other than those described in paragraph 3 or paragraph 4, seeks to obtain or compel the production of any Producing Party's Confidential Documents from a Receiving Party or any other person to whom Confidential Documents have been disclosed pursuant to this Order (collectively "Receiving Party"), by requests for documents, subpoena or other compulsory

process, the Receiving Party from which the Confidential Documents are requested and/or demanded shall immediately notify the Producing Party in writing of the demand in order to permit the assertion of all applicable rights and privileges with respect to the Confidential Documents, shall advise the person or entity seeking production of Confidential Documents of the existence of this Order, and shall cooperate fully to assert all applicable rights and privileges in any proceeding relating to any such request for documents, subpoena or other compulsory process. This provision, however, is not intended to restrict, abridge or impose any obligation upon Defendants in the exercise of their reporting responsibilities in conformance with the provisions of the Food, Drug & Cosmetics Act and/or its enabling regulations.

6. In addition, to protect against unauthorized disclosure of confidential personal information or invasion of the physician-patient privilege and/or individual privacy interests or rights, Defendants may redact from Confidential Documents names, addresses, and other identifying information pertaining to: research subjects or patients; reporters of adverse events or persons or entities identified in such reports; and other individuals or entities whose names and other identifying information are protected from disclosure by the FDA or Defendants by the regulations of the Food, Drug & Cosmetics Act, including, but not limited to, 21 C.F.R. 20.63, 21 C.F.R. 20.111, 21 C.F.R. 20.112, 21 C.F.R. 50.25, 21 C.F.R. 314.80 and 21 C.F.R. 803.9, or by the regulations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

7. If a Receiving Party, or any person or entity to whom Confidential Documents have been disclosed pursuant to this Order, believes in good faith that Confidential Documents produced in this case should be used for any purpose outside of this litigation, the party or witness shall first obtain the consent of the Producing Party for such disclosure. If consent is not forthcoming, the party shall make a good faith effort to resolve such dispute with counsel for the

Producing Party, explaining the reason(s) that the Confidential Documents should be used outside of this litigation. If the dispute cannot be resolved, either party or the witness may apply to the Court for a determination concerning the propriety of using the Confidential Documents outside of this litigation.

8. If a Receiving Part disputes the designation of a document as "Confidential," the Receiving Party Counsel shall inform counsel for the Producing Party in writing of the objection. Counsel for the Producing Party shall, within ten (10) business days after receipt of the objection, set forth in writing the basis for the designation. After the parties have conferred, if the dispute cannot be resolved, the Producing Party shall apply to the Court for a Protective Order. If the Producing Party does not re-designate the Document: (i) after the parties confer or (ii) if the Receiving Party does not withdraw its objection, then the Document will lose its Confidential designation unless the Producing Party files for a Protective Order within 20 days.

9. A party may designate a portion of a deposition transcript and/or videotape which refers to a document produced in this case as Confidential by, within ten (10) business days after the deposition transcript is delivered to the party, providing to all counsel written notice identifying those portions of the deposition transcript that counsel in good faith believes to contain Confidential Material. All deposition transcripts and videotapes shall be treated as Confidential until the expiration of the ten business day period. All parties shall label their copies of depositions accordingly.

10. Nothing in this Order shall be interpreted to prohibit or prevent the Producing Party from using or discussing its own Confidential Documents in the ordinary course of its business. Any such use or discussion of Confidential Documents by the Producing Party shall not be deemed a waiver of the terms of this Order.

11. Nothing in this Order shall be interpreted to require disclosure of documents that the Producing Party contends are protected from disclosure by the attorney-client privilege or the attorney work-product doctrine.

12. This Order only governs the conduct of the parties and their counsel. Nothing in this Order shall affect the Court's use of Confidential Documents once they are submitted to the Court.

13. The inadvertent or unintentional production of Documents containing, or otherwise disclosing, confidential, privileged, private, proprietary or trade secret information without being designated Confidential at the time of production or disclosure shall not be deemed a waiver in whole or in part of the claim of confidentiality privilege, either as to the specific information disclosed or as to any other information relating thereto on the same or related subject matter. The issue of waiver, to the extent contested by the parties, shall be determined by this Court. Any error in designation shall be corrected as soon as reasonably possible after the Producing Party becomes aware of the error.

14. The designation of Documents as Confidential, pursuant to this Order, shall not be construed as a concession by any Party that such information is relevant or material to any issue or is otherwise discoverable or admissible as evidence.

15. Within forty-five (45) days of the conclusion of all proceedings by settlement, adjudication, or otherwise, all Confidential Documents furnished pursuant to the terms of this Order, any copies thereof, and any materials recording and/or otherwise containing said information or documentation, and which are not in the custody of the Court, shall be destroyed, and an affidavit that all copies of these documents have been so destroyed shall be provided to the Producing Party. The parties may keep one copy of the records and documents produced in

their closed files under confidential seal for the exclusive purpose of maintaining an accurate record of the work done on this case for liability/malpractice concerns.

16. The disclosure of Confidential Documents produced in this case to any person not qualified to receive such information pursuant to this Order and subject to its terms, or without following the terms and conditions of this Order, may subject the person making such disclosure to a finding of contempt and the imposition of sanctions, fees, costs, or other penalties, as determined by the Court. Each person to whom disclosure of Confidential Documents is made pursuant to this Order shall subject himself to the jurisdiction of this Court for the purposes of contempt proceedings in the event of any violation of this Order.

This Order was submitted and entered pursuant to the Five Day Rule of R. 4:42-1(c).

Plaintiffs' counsel shall serve a copy of this Order on all parties of record within seven (7) days of receipt thereof.

SO ORDERED.

Hon. Carol Higbee, P.J. Cv.

Dated: Feb 19, 2010

CERTIFICATION OF COMPLIANCE

I, _____, do certify and state as follows:

1. My address is _____

_____ .

2. I have read the Protective Order entered in this case, a copy of which has been given to me.

3. I understand and agree to comply with and be bound by the provisions of the Protective Order, including that upon receipt of any confidential information, I will be personally subject to it, and to all of its requirements and procedures. Specifically, I acknowledge and agree that I hereby submit to the personal jurisdiction of the court as it relates to my ongoing compliance with the terms of the Protective Order entered in this matter on _____.

4. Further, pursuant to New Jersey Court Rule 1:4-4(b), I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Executed this ____ day of _____, 200_, at_____.

_____

Printed name: _____