

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:09-cv-00672-REB-BNB

PENNY M. HAGERMAN and
ALLEN HAGERMAN,

Plaintiffs,

v.

ELI LILLY AND COMPANY,
VALEANT PHARMACEUTICALS
INTERNATIONAL,
AMARIN CORPORATION PLC,
AMARIN PHARMACEUTICALS, INC.,
ÉLAN PHARMACEUTICALS, INC., and
ATHENA NEUROSCIENCES, INC.,

Defendants.

PROTECTIVE ORDER REGARDING DISCOVERY

THIS MATTER is before the Court on the Unopposed Motion for Protective Order Regarding Discovery requesting entry of this Protective Order Regarding Discovery (“Protective Order”).

Good cause exists in this products liability action to enter a protective order to expedite the flow of discovery, preserve the integrity of confidential information, trade secrets, and commercial and proprietary information produced in discovery, promote the prompt resolution of disputes over confidentiality, and facilitate the preservation of documents worthy of protection. This Protective Order strikes an appropriate balance between the parties’ interests in prosecuting and defending this lawsuit, the judicial interest in the efficiency and integrity of the discovery process, and the public’s interest in access to information.

Accordingly, for good cause shown, it is ORDERED and ADJUDGED as follows:

1. As used in this Protective Order:

- a. The term “**Confidential Discovery Material**” means documents and other information produced in the course of discovery in the above-captioned action that are designated “Confidential” pursuant to the terms of this Protective Order.
- b. The term “**document**” as used herein shall be interpreted broadly to encompass hard-copy and imaged documents as well as electronically stored information of any type. The term shall be interpreted broadly to include all documents and things contemplated by Federal Rules of Civil Procedure.
- c. The term “**party**” or “**parties**” means a person or persons subject to this Protective Order.
- d. The term “**producing party**” means the party who produces Confidential Discovery Material in the course of discovery.
- e. The term “**receiving party**” or “**recipient**” means a party who received Confidential Discovery Material in the course of discovery.

2. This Protective Order is applicable to all forms of discovery, including but not limited to deposition testimony, answers to interrogatories, documents produced in response to requests for production, responses to requests for admission, medical records, any documents recorded on electronic media, and other information disclosed pursuant to the disclosure or discovery duties created by the Federal Rules of Civil Procedure. This Order shall apply to all counsel, co-counsel who appear in this action, experts (whether testifying or consulting), persons noticed or subpoenaed for depositions, actual or potential witnesses and their respective counsel, and associates, assistants, and employees of counsel. Any party who receives any Confidential

Discovery Material in the course of discovery in this action shall not use such Confidential Discovery Material, or disclose it to anyone else, except as expressly permitted by this Protective Order.

3. Documents or other discovery material may be designated as “Confidential” (and therefore become Confidential Discovery Material) only to the extent that the producing party determines in good faith that they consist of or include trade secret or confidential research, development, competitive, proprietary or commercial information, including financial information, information relating to ownership or control of any non-public company; personal information concerning non-parties to this action; any information protected from disclosure by any privacy or other law or governmental regulation; as well as any other type of information given confidential status by the Court.

4. The producing party may designate a hard-copy or imaged document containing confidential information as described herein as Confidential Discovery Material by stamping or otherwise clearly marking the document “Confidential” in such a manner that will not interfere with legibility or audibility.

5. To the extent that Confidential Discovery Material stored or recorded in the form of electronic or magnetic media (including information, files, data bases or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes (“Electronic Discovery Material”)) is produced in such form, the producing party may designate it as confidential by cover letter referring generally to the Electronic Discovery Material, or by designation in the accompanying load file.

6. Whenever a deposition involves the disclosure of Confidential Discovery Material, the deposition or portions thereof shall be designated as such on the record during the

deposition whenever possible. With respect to deposition transcripts and exhibits, a party may designate information disclosed at depositions as Confidential Discovery Material by notifying the other party(ies) in writing within thirty (30) calendar days of receipt of the transcript of the specific pages and lines which are to be designated Confidential Discovery Material. During such thirty (30) day period, the entire transcript shall be treated as confidential. The parties may agree that entire deposition transcripts shall be treated as Confidential Discovery Material.

7. ~~Documents and information produced by a third person shall be treated as Confidential Discovery Material for thirty (30) calendar days after production, in order to allow the parties to review and assess the documents and information for confidentiality and designation.~~

8. The designation of documents or other information as Confidential Discovery Material pursuant to this Protective Order shall not be construed as a concession by any party that such document or information is relevant or material to any issue or is otherwise discoverable or admissible as evidence. The terms of this Protective Order shall in no way prevent a party from using or disclosing Confidential Discovery Material as necessary to meet reporting obligations to any governmental agency, including, but not limited to, the U.S. Food and Drug Administration.

9. Confidential information includes information that would identify patients and persons associated with adverse events involving human drugs (excluding Plaintiff), and research subjects. *See* 21 C.F.R. § 314.430 and 21 C.F.R. § 20.63. Defendants shall not be compelled to disclose this identifying information in discovery, and a defendant may redact this identifying information from discovery material before production, provided, however, that such

defendant shall maintain an un-redacted copy of the discovery material for any further review by the Court.

10. If at any time prior to the trial of this action a party realizes that previously undesignated documents or other information should be designated as Confidential Discovery Material, the party may so designate by advising all other parties in writing. The designated documents or material will thereafter be treated as Confidential Discovery Material pursuant to this Protective Order. Upon receipt of such designation in writing, each party shall take reasonable and appropriate action to notify any and all persons to whom the party has provided the discovery material of the protected status of the newly-designated Confidential Discovery Material, and to retrieve the newly-designated Confidential Discovery Material from any person to whom the party has provided it who is not permitted by this Protective Order to have Confidential Discovery Material.

11. Beginning September 1, 2009, and on a bi-monthly basis thereafter, the parties shall produce a (a) detailed privilege log identifying each document with such specificity that the inspecting party may evaluate the privilege to assess if the privilege has been waived or not and (b) a log that identifies any documents whose confidentiality designation has been changed from confidential to non-confidential or from non-confidential to confidential. The log shall be produced in a searchable electronic format that can be used with commercially available database software (e.g. Microsoft Access, Summation or Concordance) identifying the following information for each document produced in this action: the document's (a) beginning Bates numbers; (b) ending Bates numbers; (c) date; (d) title; and (e) confidentiality status (e.g., "Confidential" or "Non-Confidential"), and image load file showing file information and document breaks for commercially available database (e.g. DII, LOG or OPT).

12. Inadvertent production or other disclosure of documents subject to work-product immunity, the attorney-client privilege, or other legal privilege that protects information from discovery shall not constitute a waiver of the immunity, privilege, or other protection, provided that the producing party notifies the receiving party(ies) in writing when it becomes aware of such inadvertent production. Upon notification, the receiving party shall immediately, at the producing party's option, return or destroy the inadvertently-produced materials and all copies, and shall delete the material and all copies from any litigation support or other database. The receiving party shall destroy notes and work product reflecting the contents of such materials. The receiving party shall confirm in writing that it has returned or destroyed the inadvertently-produced materials, including all copies, and otherwise complied with the requirements of this paragraph. No further uses or disclosures shall be made of the inadvertently-produced materials, and the receiving party shall take all reasonable and appropriate steps to retrieve the materials, and all copies, from any person to whom the receiving party has provided them. Any party who receives such inadvertently-produced materials need not wait for notice from the producing party before complying with the above, and is expected to comply with the requirements of this paragraph as soon as it is known that the document and/or information produced is privileged and/or protected.

13. No person subject to this Protective Order other than the designating party shall disclose any Confidential Discovery Material to any other person, except as follows:

- a. Counsel for the parties in this action (including defendants' in-house counsel), and any paralegal, clerical, and other staff employed by counsel that works on this action;

- b. With respect to a specific document, the document's author, addressees, and any other person shown on the face of the document as having received a copy;
- c. Any witness who counsel for a party in good faith believes will be called to testify at trial or deposition in this action. Confidential Discovery Material shown to any potential witness shall not lose its Confidential status through such use, and counsel shall exercise their best efforts and take all steps reasonably required to protect its confidentiality during such use, including informing the prospective witness of the existence of this Protective Order as well as the confidential status of the Confidential Discovery Material, and requesting that the potential witness execute a non-disclosure agreement in the form attached to this protective Order. If the witness will not execute a non-disclosure agreement after a good faith request, counsel preparing the witness shall exercise discretion in disclosing Confidential Discovery Material to the witness. If, after a deposition is noticed or a hearing or trial is set, the producing party objects to Confidential Information being shown to that witness, the producing party shall attempt to confer with counsel to resolve the issue. If counsel are unable to resolve the issue themselves, counsel may seek an order from the Court prohibiting or limiting such use or for other relief;
- d. Any person retained by a party to serve as an expert consultant or witness or otherwise provide specialized advice to counsel in connection with this

action, provided such person has first executed a non-disclosure agreement in the form attached to this Protective Order;

- e. Insurers and indemnitors to the extent reasonably necessary to defend and evaluate the claims;
- f. Official court reporters and/or videographers present at trial, conferences, hearings, arguments or depositions held in this matter;
- g. The Court, mediators, and support personnel; and
- h. Any attorney of record for plaintiffs in other pending U.S. litigation alleging personal injury or economic loss arising from the alleged use, purchase, or payment of Permax and/or the generic pergolide mesylate for use in this or such other action, provided that (1) plaintiffs' counsel in the instant action is also counsel of record; and (2) the proposed recipient agrees to be bound by this order and/or signs a non-disclosure agreement in the form attached as Exhibit 1 to this Protective Order.

14. Prior to any disclosure of Confidential Discovery Material to any person referred to in subparagraphs (d) or (h) of paragraph 13 above, the person shall be provided by counsel with a copy of this Protective Order and shall sign a non-disclosure agreement in the form attached as Exhibit 1 hereto. The non-disclosure agreement will state that the person has read this Protective Order and agrees to be bound by its terms. All non-disclosure agreements will be maintained throughout this action by the attorneys obtaining them. At the conclusion of this action, upon a showing of good cause and necessity, any party may seek an order requiring production of non-disclosure agreements, but nothing in this Protective Order is intended to

modify or shift any burden of proof or privilege relating to the motion or authorize discovery of experts or their identities.

15. Any electronic materials produced or provided for in this Action shall be produced as follows:

- a. Documents which were originally native electronic files shall be produced as single-page Group IV TIFF images, imaged at 300 dpi. Each TIFF file will be given a unique name matching the Bates number labeled on the corresponding page, with a corresponding image (Opticon) load file defining the document boundaries. Every 1000 TIFF images will be grouped into a new folder; a separate folder will not be created for each document.
- b. For any electronic file not redacted, the following data will be produced where applicable in the form of a .DAT file: Bates begin, Bates end, attachment begin, attachment end, title (defined as the subject of an email or the filename of an attachment or stand-alone e-file), document date (creation date for e-files, sent date for e-mails), author, recipient, cc, bcc, and custodian. Extracted text will be produced from the image(s) associated with each document, with the text from each document stored in a separate .TXT file named for the beginning Bates number of the document, in the same directory as the image of the first page of the document. For redacted, electronic files, only TIFF images and the image load file referred to in 15.a. will be produced.

c. Paper documents will be produced in single-page Group IV TIFF files imaged at 300 dpi, with corresponding load files. Each TIFF file will be given a unique name matching the Bates number labeled on the corresponding page. For unredacted documents, OCR text will be produced from the image(s) associated with each document, with the text from each document stored in a separate .TXT file named for the beginning Bates number of the document, in the same directory as the image of the first page of the document. For unredacted documents, metadata for each document will be produced in the form of a .DAT file including the following fields: Bates begin, Bates end, attachment begin, attachment end, custodian. 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). The parties should re-unitize documents that have been improperly unitized. Parent-child relationships (the association between an attachment and its parent document) should be preserved. In the event that paper documents are produced in non-electronic form, productions shall be made at a reasonable time and location with sufficient facilities to allow outside vendors to image selected documents in a manner consistent with protecting the attorney work product privilege. All such productions shall be organized according to document requests or as maintained in the regular course of business.

- d. In the alternative, discovery materials may be produced as normally maintained in the ordinary course of business.

16. The following procedures will govern the filing of Confidential Discovery Material with the Court:

- a. Except in emergency situations, before a party files Confidential Discovery Material with the Court, the party shall meet and confer with the designating party to request agreement to file the Confidential Discovery Material in compliance with D.C.COLO.LCivR 7.1 (A).
- b. The parties shall file Confidential Discovery Material under seal in compliance with D.C.COLO.LCivR 7.2 and 7.3.

17. Any party objecting to the designation of confidentiality or trade secret, or requesting further limits on disclosure, may at any time prior to the close of discovery in this action serve upon counsel for interested parties a written notice stating with particularity the reasons for the objection or request. Only good-faith, ~~litigation-driven~~ objections to a confidential designation may be made. If the parties cannot resolve the objection within ten (10) business days after the time the notice is received, it shall be the obligation of the party designating the information as confidential to file an appropriate motion requesting that the Court determine whether the disputed information shall be treated as Confidential Discovery Material under the terms of this Protective Order. If such a motion is filed, the disputed information shall be treated as Confidential under the terms of this Protective Order until the Court rules on the motion. If the designating party fails to file such a motion, the disputed information shall lose its designation as Confidential Discovery Material and shall not thereafter be treated as Confidential Discovery Material in accordance with this Protective Order. In

connection with a motion filed under this provision, the party designating the information as Confidential Discovery Material shall bear the burden of establishing that good cause exists for the disputed information to be treated as Confidential Discovery Material.

18. The Court retains discretion to deny confidential treatment to any documents or discovery material submitted in connection with any motion, application, proceeding or paper that may result in an order or decision by the Court.

19. Each person who has access to Confidential Discovery Material shall take all due precautions to prevent the unauthorized or inadvertent disclosure of the material.

20. This Protective Order shall survive the termination of this action. Unless counsel agree otherwise in writing, within sixty (60) calendar days of the final disposition of this action, the attorneys for the parties and experts and consultants shall return promptly, to the producing party or witness from whom they were obtained, all documents, other than attorney work-product, that have been designated Confidential Discovery Material, or certify in writing that they have destroyed or deleted the same, including all documents or copies provided by a receiving party to any other person and all copies made thereof. Notwithstanding the foregoing, outside counsel for the parties shall be permitted to retain one copy of: (a) materials created during the course of the action, including attorney annotations and other work product; (b) work product of non-testifying consultants/experts; (c) materials made part of the Court record, or which have been filed under seal with the Clerk of the Court; (d) all depositions and Court transcripts, including exhibits; and (e) summaries of depositions. Such file copies must be maintained subject to the terms of this Protective Order.

21. The Court shall retain jurisdiction over all parties subject to this Protective Order to the extent necessary to modify this Protective Order, enforce its obligations, or to impose sanctions for any violation.

22. Nothing in this Protective Order shall prevent any party from seeking further or additional protection for, or removing protection from Confidential Discovery Material.

23. Additional parties may be added to this action as allowed under the Federal Rules of Civil Procedure. Before receiving Confidential Discovery Material, a new party to this action must agree to be bound by the terms of this Protective Order as if the party had stipulated to it at the time of entry, at which time the party shall be considered a “party” to this Protective Order. No newly-added party to this action shall have access to Confidential Discovery Material until the newly-added party to this action is subject to this Protective Order.

24. This Protective Order shall not apply to, or restrict, Confidential Discovery Material used during depositions, hearing, or at the time of trial as evidence. Protection of Confidential Discovery Material at trial may be addressed by the Court as a separate matter upon the motion of any party. The provisions of this Protective Order shall not prejudice the rights of the parties with respect to the use or protection of Confidential Discovery Material at trial.

25. Nothing in this Protective Order shall preclude a party from using or disclosing its own Confidential Discovery Material in any manner it sees fit, without the prior consent of any other party and without waiving its status as Confidential Discovery Material.

26. Any party served with a subpoena or other notice compelling production of Confidential Discovery Material shall immediately give written notice to counsel for the producing party. Upon receipt of such notice, the producing party bears the burden of opposing

the subpoena or other notice as it deems appropriate. The party receiving the subpoena or other notice shall cooperate with the producing party in any proceeding relating thereto.

27. A party who learns of an unauthorized disclosure of Confidential Discovery Material by it or by any person to whom the party has disclosed Confidential Discovery Material pursuant to this Protective Order shall immediately (a) issue written notice of the unauthorized disclosure to the designating party; (b) use best efforts to retrieve all copies of the Confidential Discovery Material subject to unauthorized disclosure; (c) inform all persons to whom unauthorized disclosure was made of the terms of this Protective Order; and (d) use best efforts to secure a non-disclosure agreement in the form attached as Exhibit 1 hereto from all persons to whom the unauthorized disclosure was made.

28. The disclosure of Confidential Discovery Material produced in this case to any person not qualified to receive such information pursuant to this Protective Order and subject to its terms, or without following the terms and conditions of this Protective 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 Protective Order shall subject himself to the jurisdiction of this Court for the purposes of contempt proceedings in the event of any violation of this Protective Order.

IT IS SO ORDERED.

Dated September 17, 2009.

BY THE COURT:

s/ Boyd N. Boland
United States Magistrate Judge

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FOR THE DISTRICT OF COLORADO

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PENNY M. HAGERMAN and ALLEN
HAGERMAN,

Plaintiffs,

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ELI LILLY AND COMPANY, VALEANT
PHARMACEUTICALS INTERNATIONAL,
AMARIN CORPORATION PLC, AMARIN
PHARMACEUTICALS, INC., ÉLAN
PHARMACEUTICALS, INC., and ATHENA
NEUROSCIENCES, INC.,

Defendants.

**CERTIFICATION CONCERNING CONFIDENTIAL DISCOVERY MATERIAL
COVERED BY PROTECTIVE ORDER**

UNDERTAKING OF _____

STATE OF _____)

)

COUNTY OF _____)

I, _____, being duly sworn, state that:

1. My present address is _____. My present
employer is _____ and the address of my present employer is
_____. My present occupation is
_____.

2. I have received a copy of the Protective Order in this action. I have carefully read and understand the provisions of the Protective Order.

3. I will comply with all of the provisions of the Protective Order. I will hold in confidence, will not disclose to anyone not qualified under the Protective Order, and will use only for purposes of this action, any Confidential Discovery Material, including the substance and any copy, summary, abstract, excerpt, index or description of such material, that is disclosed to me.

4. I will return all Confidential Discovery Material that comes into my possession, and all documents and things that I have prepared relating thereto, to trial or outside counsel for the party by whom I am employed or retained or from whom I received such material when requested to do so.

5. I understand that if I violate the provisions of the Protective Order, I may be subject to sanctions by the Court and that the parties may assert other remedies against me. I hereby submit to the jurisdiction of this Court for the purpose of enforcement of the Protective Order in this action.

Signature

Printed Name

Sworn and subscribed to before me this
____ day of _____, 2009.

Notary Public

My Commission expires: _____

