

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: FETZIMA

Civil Action No.

2:17-CV-10230-ES-SCM

ORDER

THIS MATTER having come before the Court by way of the parties' joint dispute letter (D.E. 59) regarding disputed language in the proposed discovery confidentiality order, and the Court having conducted a telephone conference on May 16, 2018, and having considered the parties' submissions, and for good cause shown;

IT IS on this Friday, May 18, 2018,

ORDERED, as follows:

1. Paragraph 13(b)--Access to Confidential Information; shall incorporate Plaintiffs' proposal with the revision "Or up to two (2) representatives employed by the party with responsibilities for managing this Proceeding, but only if a party does not have any in-house counsel with any responsibility over patent litigation (referred to hereinafter as "representatives")."
2. Paragraph 14(b), (c), and (i)--Access to Highly Confidential Information; shall incorporate Defendants' proposal, but with the modified language from ¶ 13(b). Accordingly, a party may only designate representatives if they do not have in-house counsel with responsibility over patent litigation.
3. Paragraph 15--Attendance at depositions; shall incorporate Defendant MSN's proposal.
4. Paragraph 16--Limitations on examination at a deposition, hearing, or trial; shall incorporate Plaintiffs' proposal with the revision "Confidential or Highly Confidential information that the witness authored, received, previously accessed, had access to, or knew, as demonstrated by the information itself or by foundation testimony during a deposition ~~hearing, or trial.~~"

5. Paragraph 38--Use of Confidential and Highly Confidential information in responses to common interrogatories, claim construction, expert reports, expert depositions, and at trial; shall incorporate Defendants' proposal.



Steven C. Mannion

Honorable Steve Mannion, U.S.M.J.
United States District Court,
for the District of New Jersey
phone: 973-645-3827

5/18/2018 3:26:58 PM

Original: Clerk of the Court
Hon. Esther Salas, U.S.D.J.
cc: All parties
File

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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C.A. No.: 2:17-CV-10230-ES-SCM

STIPULATED DISCOVERY CONFIDENTIALITY ORDER

WHEREAS Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.),¹ Forest Laboratories Holdings Limited, and Allergan USA, Inc., and Pierre Fabre Medicament S.A.S. (collectively, “Plaintiffs”), and Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Private Limited (together, “Amneal”), Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited (together, “Aurobindo”), MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. (together, “MSN”), Prinston Pharmaceutical Inc. and Solco Healthcare U.S., LLC (together, “Prinston”), Torrent Pharmaceuticals Limited and Torrent Pharma Inc. (together, “Torrent”), West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp. (together, “West-Ward”), and Zydus Pharmaceuticals (USA) Inc. (collectively, “Defendants”) are parties to the above-captioned case (the “Proceeding”); and

WHEREAS, the parties in this Proceeding may exchange discovery material, use or exhibit documents and things during discovery, and elicit testimony containing trade secrets,

¹Pursuant to an internal corporate restructuring, Allergan Sales, LLC is the successor in interest to Forest Laboratories, LLC. Effective January 1, 2018, Forest Laboratories, LLC merged with and into Allergan Sales, LLC, with Allergan Sales, LLC as the surviving entity.

confidential or proprietary research, development, technical, financial or marketing, strategic, customer, or commercial information, personal health information and personal data protected under state or federal privacy laws or other applicable personal data protection laws, as well as other kinds of commercially sensitive information within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G); and

WHEREAS third-parties may produce discovery material containing trade secrets, confidential or proprietary research, development, technical, financial or marketing, strategic, customer, or commercial information, personal health information and personal data protected under state or federal privacy laws or other applicable personal data protection laws in this Proceeding, as well as other kinds of commercially sensitive information within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G); and

WHEREAS the parties and this Court agree that disclosure of such commercially sensitive information poses a substantial risk of harm to the legitimate proprietary interests of the parties and third-parties; and

WHEREAS good cause exists to enter this Discovery Confidentiality Order to preserve the confidentiality of certain documents and information, outline procedures and reasonable restrictions on the disclosure of sensitive materials, and permit discovery to proceed without delay, *see* Fed. R. Civ. P. 26(c), *see also Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994); and

WHEREAS this Discovery Confidentiality Order provides reasonable restrictions on the disclosure of sensitive materials of a confidential nature; and

WHEREAS all parties agree to the terms of this Discovery Confidentiality Order to protect their confidential documents and information;

THEREFORE, in view of the foregoing and parties' stipulation to the entry of the following Discovery Confidentiality Order pursuant to Fed. R. Civ. P. 26(c) and Local Civil Rule 5.3(b), the Court determined that good cause exists to enter this Order,

IT IS HEREBY STIPULATED AND ORDERED THAT the following Discovery Confidentiality Order governs the disclosure, dissemination, and use of information in this Proceeding:

I. Designation of Confidential or Highly Confidential Information

1. Material designated "Confidential" by the producing party constitutes any trade secrets or other research, development, commercial, personnel, financial or marketing information that is non-public and confidential or proprietary, the value of which arises from its secrecy. This material also includes any information protected by the data privacy laws of the European Union or France, and any information relating to an identified or identifiable person residing in the European Economic Area ("EEA"). To the extent required by the data privacy laws of the European Union or France, a party or third-party may redact information that directly or indirectly identifies, or could be used to identify a person residing in the EEA, including but not limited to identification numbers, first and last names, titles, positions, salary and compensation, telephone and electronic records, employment history, contact information, personal life data, professional life data, business transaction data, physical data, physiological data, mental data, economic data, cultural data, and social identity data. Such designation is not an admission by either party that such documents are relevant or admissible in this Proceeding. Notwithstanding the foregoing, or anything else herein, the names of persons reasonably likely to have information related to matters at issue in this litigation will not be redacted.

2. Material designated "Highly Confidential" by the producing party constitutes: (1) material containing such sensitive and confidential information that its disclosure, whether

separately or in conjunction with other information being disclosed, is believed in good faith by the disclosing party to have the potential to cause competitive harm or confer a competitive advantage to others; and (2) any health information protected under state or federal privacy laws, including information that a party is required to maintain in confidence under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). Accordingly, access to such information will be more restricted. Highly Confidential material includes, but is not limited to, current or future financial documents (such as P&L statements), business strategy, projected future sales, pricing, customer/vendor agreements, revenue, cost, or profit information for the producing party’s products, documents concerning the research and development of the products in suit and any product not in suit, pending patent applications, new drug applications, abbreviated new drug applications, Drug Master Files, and information that could be used to identify an individual’s health information (“individual identifiers”). A party or third-party may redact individual identifiers before producing or disclosing the health information. Individual identifiers include names, initials, postal addresses, telephone numbers, fax numbers, electronic mail addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, dates of birth, vehicle identifiers or serial numbers, and full face photographic images or other comparable images or identifiers. Highly Confidential information that has been produced and not designated as such will, upon notice, be treated as Highly Confidential under this Discovery Confidentiality Order. Such designation is not an admission by either party that such documents are relevant or admissible in this Proceeding.

3. A party or third-party may designate as “Confidential” or “Highly Confidential,” all or part of any discovery, materials produced or served in this Proceeding, and Court filings (including without limitation, documents and things, pleadings, motions, interrogatory answers,

deposition testimony, and responses to requests for admission), containing sensitive proprietary, personal, business, financial, technical, or other confidential information or know-how protectable under Federal Rule of Civil Procedure 26(c)(1)(G), as set forth in paragraphs 1 and 2 above.

4. A party or third-party shall designate Confidential or Highly Confidential by marking it prominently with “CONFIDENTIAL,” “CONFIDENTIAL—SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER,” “HIGHLY CONFIDENTIAL,” or “HIGHLY CONFIDENTIAL—SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER.” Material that cannot be marked on its face shall be marked by placing the appropriate legend on the container or package of the thing produced or on a tag attached thereto. Each page of an entire multi-page document shall be marked Confidential or Highly Confidential to be treated as such. In addition, each page of every document or thing produced must bear a unique identifying number.

5. A party responding to written interrogatories or requests for admission, or any testimony adduced at a deposition upon written questions that discloses Confidential or Highly Confidential information shall mark the first page of that document near the caption with “CONFIDENTIAL INFORMATION SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER” and/or “HIGHLY CONFIDENTIAL INFORMATION SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER.”

6. Confidential or Highly Confidential information does not include information obtained independently of this Proceeding as to which no obligation of confidentiality applies. Accordingly, nothing in this Order prevents any person from using information designated Confidential or Highly Confidential if such information: (a) was in his or her lawful possession

before receiving the information or document under the provisions of this Order; or (b) was or becomes available to the public through no fault of a receiving party.

7. Nothing in this Order prevents a party or third-party from redacting otherwise discoverable documents or things that contain Confidential or Highly Confidential information irrelevant to this Proceeding or otherwise not discoverable pursuant Federal Rule of Civil Procedure 26(b).

8. Before production, a party or third-party may, to the extent required by the data privacy laws of the European Union or France, redact from all documents, electronic communications, business transaction data, personal electronic files, personally identifiable information described in paragraph 1 for persons residing in the EEA, and personal information.

9. Unless otherwise agreed upon by the parties, deposition transcripts in this Proceeding shall be temporarily designated and treated as Highly Confidential information for up to thirty (30) calendar days after both parties have received a final transcript of the deposition, to give the parties or third-parties an opportunity to properly designate any or all portions of the transcript as Confidential or Highly Confidential. Deposition transcripts or exhibits containing Confidential or Highly Confidential information shall be marked on each page, respectively, “CONFIDENTIAL —SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER” and “HIGHLY CONFIDENTIAL INFORMATION—SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER at page(s) ____.” Deponents may review their respective deposition transcripts at any time. Nothing in this paragraph prevents a party from showing depositions transcripts of its own witnesses to its own employees, officers, directors, or agents except that if those deposition transcripts contain Confidential or Highly Confidential

Information of another party, then such information may not be disclosed unless otherwise provided for under this Order.

10. Any material provided for inspection, as opposed to documents produced outright, shall be treated by the inspecting/receiving party as Highly Confidential information pending the copying and delivery of any copies of the same by the producing party. After copies are delivered to the inspecting/receiving party, the information in such documents or things will be treated consistent with any legend on each document or thing. Unless otherwise agreed upon or ordered by this Court, inspection of documents or things by a party shall be conducted only by Outside Counsel eligible under paragraph 14(a) below.

11. Material not designated Confidential or Highly Confidential shall not be subject to this Discovery Confidentiality Order, unless otherwise agreed upon by the parties or ordered by the Court.

II. Use of Confidential and Highly Confidential Information

12. Confidential and Highly Confidential information including all copies, summaries, abstracts, excerpts, indices, and descriptions of such material, shall be: (1) held in confidence by the receiving party; (2) used only by persons permitted access to the information under this Discovery Confidentiality Order; and (3) precluded from use outside of this Proceeding, appeal therefrom, and remands thereto. Nothing in this Order precludes a party from using its own Confidential or Highly Confidential information in any manner it sees fit, without prior consent of any party or the Court. Nothing in this Order restricts any party's counsel from rendering advice to its clients for this Proceeding using Confidential or Highly Confidential information, provided counsel does not disclose any other party's Confidential or Highly Confidential information other than in a manner provided for in this Order.

III. Access To Confidential Information

13. Confidential information may be disclosed only to the following:

a. Qualified Persons entitled to receive Highly Confidential information as identified and described in paragraph 14 below, and;

b. Up to two (2) in-house counsel employed by the party (or a subsidiary, parent, and/or affiliate of such party) with responsibilities for managing this Proceeding. Or up to two (2) representatives employed by the party with responsibilities for managing this Proceeding, but only if a party does not have in-house counsel with any responsibility over patent litigation (referred to hereinafter as “representatives”). If a party (or a subsidiary, parent, and/or affiliate of such party) employs in-house counsel or representatives residing in the U.S. with responsibilities for managing intellectual property litigation in the U.S., that party shall only identify such U.S.-based in-house counsel or representatives under this paragraph. In-house counsel or representatives residing outside of the U.S. shall only be identified if a party does not have any in-house counsel or representatives within the U.S. with responsibilities for managing intellectual property litigation in the U.S. The identity of in-house counsel or representatives may be exchanged herein or between Plaintiffs and Defendants. Before such in-house counsel or representatives receive any disclosure as permitted under this DCO of Confidential information, each in-house counsel or representative shall review and agree to be bound by the terms of this DCO by signing Exhibit A. To the extent Confidential Information is provided to in-house counsel or representatives at their offices, that information shall be maintained in a secure fashion and shall not be shared or disseminated. An in-house counsel or representative can be substituted upon written notification via email to all opposing parties along with a completed and signed agreement to be bound by the terms of this DCO (Exhibit A). Subject to the foregoing sentence, any party not now identifying in-house counsel or representatives can do so at a later

date upon written notification via email between Plaintiffs and Defendants pursuant to the provisions set forth in paragraph 17. Subject to the foregoing, the parties designate the following in-house counsel or representatives:

For Plaintiffs:

Forest and Allergan

(1) Ryan Coletti (in-house counsel for Forest Laboratories, LLC n/k/a Allergan Sales, LLC, Forest Laboratories Holdings Limited, and Allergan USA, Inc.)

(2) Shenade Walker (in-house counsel for Forest Laboratories, LLC n/k/a Allergan Sales, LLC, Forest Laboratories Holdings Limited, and Allergan USA, Inc.)

Pierre Fabre

(1) Pierick Rousseau (Intellectual Property Director for Pierre Fabre Medicament S.A.S.)

(2)

For Defendants:

Amneal

(1) TBD

(2) TBD

Aurobindo

(1) TBD

(2) TBD

MSN

(1) TBD

(2) TBD

Prinston

(1) TBD

(2) TBD

Torrent

(1) TBD

(2) TBD

West-Ward

(1) TBD

(2) TBD

Zydus

(1) TBD

(2) TBD

c. In-house counsel or representatives identified in paragraph 13(b) shall not have access to any physical or electronic database containing a party's Confidential or Highly Confidential information.

d. Secretarial and clerical employees of each party who work regularly with such in-house counsel or representatives. The number of in-house counsel or representatives permitted access to Confidential information may be increased by agreement of the parties without leave of the Court, or upon a showing, subject to the approval of the Court, by either party that such modification is necessary.

IV. Access To Highly Confidential Information

14. Highly Confidential information may be disclosed only to the following "Qualified Persons:"

a. Outside Counsel, defined as the attorneys representing a party in this Proceeding and staff who are from the law firms of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP; Walsh, Pizzi, O'Reilly & Falanga LLP, Rivkin Radler LLP; FisherBroyles, LLP; Richard G. Greco, P.C.; Budd Lerner, P.C.; Winston & Strawn LLP; Stone Conroy LLC; Maddox Edwards PLLC; Hill Wallack LLP; Buchanan Ingersoll & Rooney PC; Merchant & Gould PC, Saiber LLC; and Locke Lord LLP.

b. Up to two (2) in-house counsel employed by each party (or a subsidiary, parent, and/or affiliate of such party) with responsibilities for managing this Proceeding. Or up to two (2) representatives employed by the party with responsibilities for managing this Proceeding, but only if a party does not have in-house counsel with any responsibility over patent litigation (referred to hereinafter as "representatives"). The identity of in-house counsel or

representative may be herein or exchanged between plaintiffs and defendants. Before such in-house counsel or representative receive any disclosure as permitted under this DCO of Highly Confidential information, each in-house counsel or representative shall review and agree to be bound by the terms of this DCO by signing Exhibit A. An in-house counsel or representative can be substituted upon written notification via email to opposing parties along with a completed and signed agreement to be bound by the terms of this DCO (Exhibit A). Subject to the foregoing sentence, any party not now identifying in-house counsel or representatives can do so at a later date upon written notification via email between Plaintiffs and Defendants. Subject to the foregoing, the parties designate the following in-house counsel or representatives:

For Plaintiffs:

Forest and Allergan

- (1) Ryan Coletti (in-house counsel for Forest Laboratories, LLC n/k/a Allergan Sales, LLC, Forest Laboratories Holdings Limited, and Allergan USA, Inc.)
- (2) Shenade Walker (in-house counsel for Forest Laboratories, LLC n/k/a Allergan Sales, LLC, Forest Laboratories Holdings Limited, and Allergan USA, Inc.)

Pierre Fabre

- (1) Pierick Rousseau (Intellectual Property Director for Pierre Fabre Medicament S.A.S.)
- (2) TBD

For Defendants:

Amneal

- (1) TBD
- (2) TBD

Aurobindo

- (1) TBD
- (2) TBD

MSN

- (1) TBD
- (2) TBD

Princeton
(1) TBD
(2) TBD

Torrent
(1) TBD
(2) TBD

West-Ward
(1) TBD
(2) TBD

ZyduS
(1) TBD
(2) TBD

c. In-house counsel or representative (as defined and identified in Paragraph 14(b)) shall not have access to any physical or electronic database containing a party's Confidential or Highly Confidential information.

d. The individuals identified in paragraph 14(b), but only to Highly Confidential information that is: (1) incorporated in or attached as an exhibit to any discovery response (including any contentions required under the scheduling order and contention interrogatories); (2) used or disclosed in any deposition or attached to any deposition transcript; (3) incorporated in or attached as an exhibit to claim construction exchanges; (4) incorporated in or attached to any document or material filed with the Court; (5) incorporated in or attached to any document or material used in any Court proceeding; (6) incorporated in or attached to an expert report; or (7) documents attached to drafts of categories 1-6 above, consistent with such individuals' duties to review and advise outside counsel on draft work product.

e. Independent litigation support service personnel, including copy vendors, litigation consultants, outside exhibit or demonstrative preparation companies, or litigation study groups retained by a party for litigation support for this Proceeding, provided that such persons or entities: (1) agree to maintain the confidentiality of Confidential and Highly Confidential

information; and (2) are not engaged in the research, development, manufacture, marketing, or sale of pharmaceutical products;

f. Independent consultants or experts assisting Outside Counsel, provided that such consultants or experts: (1) are not current employees of any of the parties in the litigation; and (2) agree to comply with the requirements of this Discovery Confidentiality Order, and sign a copy of Exhibit A to this Discovery Confidentiality Order;

g. The Court and any members of its staff to whom it is necessary to disclose Confidential or Highly Confidential information for the purpose of assisting the Court in this Proceeding, as well as court reporters or typists for the sole purpose of recording, or transcribing testimony, documents, or information relating to this Proceeding;

h. Independent interpreters and translators for the sole purpose of recording, transcribing, or translating testimony or documents relating to this Proceeding.

i. As between Defendants in this case, any document designated “Confidential” may not be disclosed to another Defendant or its representatives and any document designated “Highly Confidential” may not be disclosed to another Defendant or its representatives (as defined in ¶ 14(b)) unless: (1) disclosure is otherwise agreed upon by the Defendants without leave of the Court; or (2) disclosure is necessary upon a showing by any Defendant, and subject to the approval of the Court. As between Plaintiffs and Defendants, any document designated “Confidential” or “Highly Confidential” by a Defendant may not be disclosed by Plaintiffs to the other, non-designating, Defendants unless otherwise agreed upon by the designating Defendant without leave of the Court, or upon Plaintiffs’ showing that such disclosure is necessary and subject to the approval of the Court.

j. Any mediators engaged by the parties, and their support staff.

k. Any person who has been designated as a Rule 30(b)(6) witness by the producing party may be shown the producing party's Highly Confidential information.

l. Any other person (i) agreed to by the parties, as long as such persons comply with the procedures herein and agree to be bound by Exhibit A, or (ii) permitted by the Court.

15. Only opposing outside counsel and opposing identified in-house counsel or representative(s), the deponent, and his or her attorney, shall be allowed to attend any portion of a deposition in which Confidential or Highly Confidential information is used or elicited from the deponent. Counsel for the designating party may request that all persons other than opposing outside counsel and opposing identified in-house counsel or representative(s), the witness, the court reporter, and counsel for the witness (if a third-party witness) leave the deposition room during any portion of a deposition which inquires into matters deemed Confidential or Highly Confidential by the designating party. Failure to leave the deposition room according to the preceding sentence constitutes adequate justification for the designating party's counsel to instruct the witness not to answer the question(s) posed concerning such matters.

16. Nothing in this Order limits a party's examination, at a deposition, hearing, or trial, of persons who are not authorized to receive Confidential or Highly Confidential information under the terms of this Order, so long as such examination concerns only Confidential or Highly Confidential information that the witness authored, received, previously accessed, had access to, or knew, as demonstrated by the information itself or by foundation testimony during a deposition. Nothing in this Order prevents counsel from examining a witness in a good-faith effort to determine whether the witness authored, received, previously accessed, or had knowledge of Confidential or Highly Confidential information.

17. Before disclosing another party's Confidential or Highly Confidential information to the opposing in-house counsel or representative(s) identified under paragraphs 13(b) and 14(b) that in-house counsel or representative(s) shall first provide to the producing party a completed and signed copy of the Certification found in Exhibit A of this Order. Once the producing party has received the requisite documents, the producing party may, within five (5) business days, provide a written objection to the proposed disclosure of its Confidential or Highly Confidential information, including the specific reason(s) for such objection. If a timely written objection is made: (a) the party seeking disclosure shall not disclose the Confidential or Highly Confidential information to the in-house counsel or representative(s), except by further order of the Court or upon agreement by the parties; (b) the parties agree to promptly meet and confer in good faith to resolve the objection; (c) if the parties cannot reach an agreement, the party opposing disclosure may raise the objection with the Court within seven (7) calendar days of the meet and confer. On any motion brought pursuant to this paragraph, the party opposing disclosure shall bear the burden of showing why disclosure of information to that in-house counsel or representative(s) should be precluded. Failure to timely object or file a motion with the Court will act as a waiver of the objection, and disclosure will be permitted to that in-house counsel or representative pursuant to the relevant provision(s) of this Order.

18. Before disclosing another party's Confidential or Highly Confidential information to an outside consultant or expert under paragraph 14(f), a party shall first obtain the signature of the company, firm, group, or person retained on the Certification attached hereto in Exhibit A. A single Certification signed by the company, firm, group, or person shall be sufficient to cover all employees of the company, firm, or group. However, any non-signing employee of the company, firm, or group must be made aware of their obligations under the DCO. Counsel

retaining the person(s) described in subparagraphs 14(f) shall retain the original of each such signed Certification, and exchange with opposing counsel copies of the executed certification within 3 days of its execution.

19. Before disclosing another party's Confidential or Highly Confidential information to any outside consultant or expert under paragraph 14(f), a party shall first provide to the producing party: (a) a completed and signed copy of the Certification found in Exhibit A of this Order; (b) a current resume (*curriculum vitae*) for the consultant or expert; and (c) a list of any other cases in which the consultant or expert has testified as an expert at trial or by deposition within the preceding four (4) years. Once the producing party has received the requisite documents, the producing party may, within five (5) business days, provide a written objection to the proposed disclosure of its Confidential or Highly Confidential information, including the specific reason(s) for such objection. If a timely written objection is made: (a) the party seeking disclosure shall not disclose the Confidential or Highly Confidential information to the consultant or expert, except by further order of the Court or upon agreement by the parties; (b) the parties agree to promptly meet and confer in good faith to resolve the objection; (c) if the parties cannot reach an agreement, the party opposing disclosure may file a motion within seven (7) calendar days of the meet and confer. On any motion brought pursuant to this paragraph, the party opposing disclosure shall bear the burden of showing why disclosure of information to that consultant/expert should be precluded. Failure to timely object or file a motion with the Court will act as a waiver of the objection, and the consultant or expert will be deemed a Qualified Person.

20. Absent consent of the producing parties and/or further order of this Court, any in-house counsel or representative receiving another party's Confidential or any in-house counsel or

representative (as defined in ¶ 14(b)) receiving another party's Highly Confidential information shall not participate in the prosecution of patent applications related to levomilnacipran or levomilnacipran hydrochloride or amend, draft, or otherwise substantively assist, directly or indirectly, in the drafting or amending of patent claims in any reexamination, post-grant review ("PGR") or inter partes review ("IPR") proceeding, claiming pharmaceutical compounds or compositions containing levomilnacipran², including but not limited to methods of using, manufacturing, or processing thereof, and will not participate in or aid in, directly or indirectly, any FDA Citizen Petition related to another party's pharmaceutical compounds or compositions containing levomilnacipran (this shall not preclude participation in responding to any FDA Citizen Petition related to pharmaceutical compounds or composition containing levomilnacipran submitted by another party or third party), for two (2) years after the later of (i) receipt of the Confidential Information or (ii) after a final decision in the suit. For the avoidance of doubt, this paragraph shall not preclude participation in patent opposition, *inter partes review*, post grant review or reexamination proceedings, including any such proceedings before the U.S. Patent and Trademark Office's Patent Trial and Appeal Board, or any foreign patent office, related to levomilnacipran or related products having the same active ingredient, provided that the participation does not include amending, drafting, or otherwise substantively assisting, directly or indirectly, in the drafting or amending of patent claims in any of these proceedings.

21. Without limiting the obligations otherwise imposed by this Order, and absent consent of the producing party, and/or further order of this Court, all Confidential Information and Highly Confidential Information disclosed by another party pursuant to this Order shall be used by a recipient thereof solely for the purposes of prosecuting or defending this litigation and

²When used herein, "levomilnacipran" means "levomilnacipran and/or levomilnacipran HCl."

not for any business, regulatory, commercial, or competitive purposes. This prohibition does not include legal decision-making responsibilities relating to management of this litigation, or resolution or settlement thereof, including without limitation responsibilities for negotiating or executing an agreement settling litigation, including responsibilities related to any financial terms of such an agreement and responsibilities related to advising on launch dates or providing legal advice regarding product launch.

V. Challenging or Changing the Designation of Confidential or Highly Confidential Information

22. A producing party may change a designation of Confidential or Highly Confidential (or withdraw a designation) by notifying counsel for each party in writing. Upon receipt of such notice, the non-producing party shall: (i) not make any further disclosure of the newly designated material except as provided in this Order; (ii) take reasonable steps to notify persons known to have possession of any material with the original designation (or lack of designation) and alert those persons of the effect of such a change in designation; and (iii) promptly retrieve or have destroyed all copies and transcriptions of such originally designated (or undesignated) material from persons known to have possession of such material and who are not Qualified Persons under paragraph 14. With respect to (iii) above, for documents originally lacking a Confidential designation, the copies and transcriptions of such documents should be destroyed or collected from persons or entities not qualified under paragraph 13. The producing party shall promptly and properly mark and provide documents, reflecting the new designation.

23. A party receiving documents or things is not required to challenge the propriety of a Confidential or Highly Confidential information designation (or re-designation) at the time the document or thing is produced, and failure to do so shall not preclude a subsequent challenge

thereto. If a receiving party objects to the producing party's designation, the following procedure shall take effect:

a. The receiving party shall provide the producing party with written notice identifying the documents, things, or information for which a change in designation is sought, and the reasons underlying the request. The producing party may then, within seven (7) calendar days after receipt of the written notice, object in writing to the change in designation sought and specify why the designation is appropriate under this Order.

b. If the producing party submits a timely objection, both parties shall meet and confer to attempt to resolve the dispute without involvement of the Court.

c. If the parties or third-parties cannot reach an agreement concerning the change in designation, the party seeking the change may then file and serve a motion with the Court.

d. The parties or third-parties shall continue to treat the document(s) or thing(s) at issue as Confidential or Highly Confidential information (according to the original designation(s)) until the dispute is resolved by Order of this Court, or by agreement of the parties and/or the third-party.

e. For motions arising out of the designation of any material as Confidential or Highly Confidential information under this Order, the producing party has the burden of justifying the designation.

VI. Inadvertent Production or Use of Confidential or Highly Confidential Information

24. Inadvertent production of any document, thing, or information not designated Confidential or Highly Confidential will not waive a later claim of confidentiality or preclude the producing party from designating the material inadvertently produced without the appropriate confidentiality designation as Confidential or Highly Confidential information at a later date.

25. If Confidential or Highly Confidential information is inadvertently used in contravention of this Order, the information shall not lose its confidential status. Counsel shall exercise best efforts and take reasonable measures to protect the confidentiality of the inadvertently used material. If Confidential or Highly Confidential information is inadvertently disclosed to a deposition witness, and the witness has testified concerning that information, the witness may be examined and cross-examined in connection with the document or information disclosed for the remainder of the deposition.

26. If Confidential or Highly Confidential information is disclosed in contravention of this Order, the party responsible for the disclosure shall immediately, but no later than three (3) business days of learning of such disclosure, inform the producing party of all pertinent facts related to such disclosure. The parties shall immediately thereafter use reasonable efforts to return any such Confidential or Highly Confidential information, and obtain a signed Certification (attached hereto as Exhibit A) from each unauthorized person or party receiving Confidential or Highly Confidential information. Nothing in this paragraph prevents the producing party from requesting that the party responsible for the inadvertent disclosure take additional remedial steps and/or applying to the Court for additional relief.

VII. Inadvertent Production Or Use of Privileged Information

27. Inadvertently produced information that is subject to a claim of attorney-client privilege, attorney work product immunity, or other legal privilege protecting information will not constitute a waiver (subject matter or otherwise) of any claim of privilege, work product immunity, or other ground for withholding production to which the producing party, third-party, or other person would otherwise be entitled. The protections afforded an inadvertent production include at least those provided in Fed. R. Civ. P. 26(b)(5)(B) and/or Fed. R. Evid. 502.

28. If a producing party makes a written claim of inadvertent production of privileged information to a receiving party, the receiving party shall:

a. upon receipt of the claim, immediately cease further copying, reproducing, or transcribing the inadvertently disclosed information or document; if the inadvertent disclosure is discovered during a deposition, a claim for inadvertent production may be made orally, and upon such oral claim all copies of the requested document must be immediately returned at the deposition; and

b. within five (5) days of receipt of the claim described in paragraph (a) above, destroy or return to the producing party every original, copy, reproduction, or transcription of all such inadvertently produced material in the receiving party's possession and persons to whom the receiving party may have disclosed such information.

29. A claim of inadvertent production based on privilege must be made within two (2) weeks after the material is used openly in the case, e.g., at a court hearing, in a deposition, as an exhibit to a motion, or is referenced in an expert report or pretrial order.

30. Nothing herein prevents a receiving party from challenging the propriety of the attorney-client privilege, work product immunity, or other privilege, or from presenting the information to the Court under seal for a determination of the privilege claim through a written challenge to the Court. If a party challenges the propriety of the attorney-client privilege, work product immunity, or other privilege, that party, notwithstanding the provisions in paragraph 28, may retain one copy of challenged material. The receiving party must preserve the confidentiality of the document or information until the claim is resolved.

VIII. Production or Disclosure of a Third-Party's Information

31. Any subpoena or other notice to a third-party requesting production of documents must include a copy of this Discovery Confidentiality Order.

32. Documents produced by a third-party pursuant to a subpoena or other request issued by one of the parties (or by Court order), which were not designated Confidential or Highly Confidential, are presumed to contain information requiring no designation under the Discovery Confidentiality Order. All parties to this Proceeding shall handle the third-party's documents and things according to the applicable designations under this Discovery Confidentiality Order. The party issuing the subpoena or other request for documents or things to the third-party shall provide the non-requesting party with copies of any documents produced in response to that subpoena or request.

33. A party in this Proceeding may temporarily withhold production of otherwise discoverable information sought in a discovery request (e.g., interrogatory, request for production, request for admission) if the party is under an obligation to a third-party to withhold such information (e.g., by prior agreement of confidentiality). In such an event (except for information subject to another protective order or confidentiality order by another court), the producing party shall:

- a. timely serve on the requesting party a written objection to the production of the requested information based on its obligation to a third-party to withhold such information;
- b. promptly provide the third-party whose confidentiality interests are implicated with (i) notice of the pending request to disclose the information (and shall copy the requesting party on such notice given to the third-party), and (ii) a copy of this Discovery Confidentiality Order; and
- c. if the third-party does not agree to disclose the information, the requesting party may (i) serve a subpoena on the third-party, provided that the requesting party has not

already done so, or (ii) file a motion to compel production of the requested documents from a party and/or third-party in the appropriate court.

34. A party receiving a subpoena or other request from a third-party seeking disclosure/production of Confidential or Highly Confidential information already disclosed in this Proceeding that the party did not itself produce, shall notify the original producing party of the subpoena or other request immediately, but not later than seven (7) calendar days after service of the subpoena or other request. If the original producing party opposes disclosure of documents sought in the subpoena or other request, the party served with the subpoena shall not disclose the pertinent information until a court has resolved the issue. Absent a court order, production or disclosure of another party's information to a third-party shall not be made until the original producing party has agreed to such production. The original producing party has the burden to oppose the subpoena or other request on the grounds of confidentiality. This paragraph does not apply to information disclosed pursuant to a third-party's subpoena or request for Confidential or Highly Confidential information, if the party receiving the subpoena or request has itself produced the documents or things sought in the subpoena or request, i.e., this paragraph shall not apply to the disclosure of a party's own documents or things.

IX. Use of Confidential or Highly Confidential Information in Filings and in Open Court

35. Nothing herein shall be construed to affect the admissibility at trial of any document, testimony, or other evidence.

36. The Clerk of the Court is directed to maintain under seal any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court in compliance with Local Rule 5.3, which has been designated,

in whole or in part, Confidential or Highly Confidential under this Discovery Confidentiality Order.

37. A party or third-party filing any document, material or information designated by another party as Confidential or Highly Confidential information shall move pursuant to Local Civil Rule 5.3(c) to seal such document, material, or information to prevent public disclosure. The party making such a motion shall also designate any document, material, or information which is the subject of the motion as “confidential materials” pursuant to Local Civil Rule 5.3(c)(3), and take appropriate action necessary to assure that such document, material or information shall remain sealed until the motion is decided.

Should a party fail to properly file documents or materials containing Confidential or Highly Confidential information in accordance with this Order, the Local Civil Rules, or the ECF Policies, any party who in good faith believes that filing under seal is required may file a motion with the Court to request an order sealing such documents or materials.

38. Plaintiffs may not use a Defendant’s produced Confidential or Highly Confidential information in responses to common interrogatories, common claim construction, common expert reports, or common expert depositions. All interrogatories, claim construction, expert reports, and expert depositions containing Confidential or Highly Confidential information unique to a particular Defendant shall be kept separate and not disclosed to another Defendant. To the extent a party contends that certain documents should be made available to another party in the case, the parties agree to make good faith efforts to address such situations on a case-by-case basis and resolve the issue, which may involve the production of redacted copies of the documents in question. Highly Confidential information shall not be used or disclosed in open court except according to Court order, such as an order of the Court sealing the

Court room. The Court will enter further orders as necessary to control the conduct of hearings and trial as it relates to the use of Confidential or Highly Confidential information.

39. Any health information protected under state or federal privacy laws that is disclosed in discovery by a party or third-party to this Proceeding shall not be used or disclosed in open court unless pursuant to Court order, such as an order of the Court sealing the courtroom. The Court will enter further orders as necessary to control the conduct of hearings and trial as it relates to the use of Confidential or Highly Confidential information.

X. Disposition of Confidential and Highly Confidential Materials After Conclusion of This Proceeding

40. Upon the final non-appealable termination of this Proceeding, all Confidential or Highly Confidential information received from an opposing or third-party (and all copies and transcriptions thereof), shall be destroyed or returned to the producing party within ninety (90) calendar days. Outside counsel, however, may retain (even if such documents or things contain Confidential or Highly Confidential information) all correspondence, pleadings and exhibits, deposition transcripts and exhibits, expert reports and exhibits, hearing and trial transcripts and exhibits, court-filed documents and exhibits, and all documents and things containing or reflecting attorney work product. Documents and work product retained by Outside Counsel remain subject to the terms of this Order. After ninety (90) calendar days following final non-appealable termination of this Proceeding, no person or entity other than Outside Counsel shall retain any Confidential or Highly Confidential information obtained from another party during the course of the Proceeding, including but not limited to Confidential or Highly Confidential information in the form of notes, recordings, memoranda, summaries or other written materials relating to or containing another party's Confidential or Highly Confidential information.

XI. Additional Provisions

41. This Order is binding upon the parties to this Proceeding and signatories to the Certification, including their successor(s) and assigns, and their respective attorneys, agents, representatives, officers, and employees.

42. This Order applies to all information and material produced in this Proceeding, including all information and material produced before the Court executed this Order.

43. The parties agree that the following documents are not discoverable: (a) drafts of expert reports, affidavits, or declarations; (b) counsel's communications with experts, affiants or declarants; and (c) experts', affiants', and declarants' notes and working papers regarding such documents.

44. If any party breaches, or threatens to commit a breach, of any of the provisions of this Order, each non-breaching party or third-party that produced information subject to this Order may seek remedies under law or in equity from the Court, including having the Order specifically enforced (without posting any bond) and/or entering a restraining order or injunction (preliminary or permanent) against the breaching party. It is agreed and acknowledged that, in the event of a breach or threatened breach, the breaching party is not entitled to a presumption that money damages or legal remedies are sufficient or adequate to remedy such a breach.

45. By written agreement of the parties, or upon motion and order of the Court, the terms of this Order may be amended or modified, provided that any stipulated modification concerning the use of Confidential or Highly Confidential information is presented to the Court.

46. This Order is enforceable until amended or superseded by express order of the Court. This Order survives this Proceeding, including any final judgment, appeal, or settlement with respect to Confidential or Highly Confidential information that has not otherwise been disclosed publicly.

47. Nothing in this Order prejudices the right of any party or third-party to oppose production of information for lack of relevance, privilege, or grounds other than confidentiality.

48. In the event a new party is added, substituted, or otherwise brought into this Proceeding, this Discovery Confidentiality Order will bind and inure to the benefit of the new party, subject to the new party's right to seek relief from or modification of this Discovery Confidentiality Order.

49. A legible photocopy of a document may be used as the "original" for all purposes in this Proceeding.

50. Each person or entity receiving any Confidential or Highly Confidential information is subject to the jurisdiction of this Court for proceedings related to the performance under, compliance with, or violation of this Discovery Confidentiality Order.

51. Other Proceedings. By entering this Discovery Confidentiality Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any party or third-party subject to this Discovery Confidentiality Order who becomes subject to a motion to disclose another party's information designated Confidential or Highly Confidential pursuant to this Discovery Confidentiality Order shall promptly notify the moving party so that party may have an opportunity to appear and be heard on whether that information may be disclosed.

52. In order to expedite the discovery process, until this Discovery Confidentiality Order has been entered by the Court, the parties agree that after counsel for the parties execute this Discovery Confidentiality Order, it will be treated as though it had been "So Ordered."

Respectfully submitted,

s/Liza M. Walsh

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IT IS SO ORDERED

Dated: 7/20/18, ~~2018~~



The Honorable Judge Mannion
UNITED STATES MAGISTRATE JUDGE

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

)	
)	
)	
IN RE: FETZIMA)	C.A. No. 2:17-CV-10230-ES-SCM
)	
)	
)	
)	AGREEMENT TO BE BOUND BY
)	DISCOVERY CONFIDENTIALITY
)	ORDER
)	
)	
)	

CERTIFICATION REGARDING DISCOVERY CONFIDENTIALITY ORDER

1. I, _____, have been asked by counsel for Plaintiffs / Defendants [circle one] in the above-captioned matter to review certain confidential or highly confidential documents, or other information subject to the Discovery Confidentiality Order, that has been or will be entered by the District Court for the District of New Jersey in the above-captioned case.

2. My present employer is _____ and the address of my present employer is _____. My present occupation or job title is _____. My present job description is _____.

3. I have received a copy of the Discovery Confidentiality Order in this Proceeding. I have carefully read and understand its provisions.

4. I will comply with all provisions of the Discovery Confidentiality Order, including but not limited to the following:

a) I will not disclose any information, documents, or things designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL to anyone other than those persons specifically authorized by the Discovery Confidentiality Order.

b) I will not use any Confidential or Highly Confidential information for any purpose other than the above-captioned case.

c) When requested to do so in accordance with the Discovery Confidentiality Order, I will return all materials containing Confidential or Highly Confidential information, and all documents and things that I have prepared relating thereto.

5. I will take reasonable steps to restrict access to any Confidential or Highly Confidential information to only those persons authorized by the Discovery Confidentiality Order to have such access. I will inform any of my employees or staff who encounter Confidential or Highly Confidential information of the terms of the Discovery Confidentiality Order.

6. I understand that my obligations regarding Confidential or Highly Confidential information under the Discovery Confidentiality Order apply equally to copies, summaries, excerpts, transcripts, indices, expert reports, or compilations of information *containing* Confidential or Highly Confidential information, as well as any knowledge or information *derived from* any such information I receive during this action.

7. I understand that if I violate the provisions of the Discovery Confidentiality Order, I will be subject to sanctions by the Court, and that the parties or third-parties that designated the information as Confidential or Highly Confidential may assert other remedies against me.

8. I voluntarily submit to the jurisdiction of the United States District Court for District of New Jersey with respect to the enforcement of the Discovery Confidentiality Order, or with respect to any other order issued by the Court governing the use of confidential information.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____

Signature: _____