

Case 6:06-md-01769-ACC-DAB Document 478 Filed 09/19/2007 Page 1 of 15

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION**

IN RE: Seroquel Products Liability Litigation

MDL DOCKET NO. 1769

This Document Relates to ALL CASES

PROTECTIVE ORDER

To expedite the flow of discovery material, facilitate the prompt resolution of disputes over confidentiality, adequately protect confidential material, and ensure that protection is afforded only to material so entitled, the Court enters this Protective Order pursuant to Federal Rule of Civil Procedure 26(c).

1. Discovery Materials: This Order governs the handling of confidential discovery materials, and applies to all products of discovery and all information derived therefrom, including, but not limited to, documents, objects and things, deposition testimony and interrogatory/request for admission responses, and any copies, excerpts or summaries, produced by any party informally or pursuant to any court order in the above-captioned matter ("Discovery Materials"). Plaintiffs and Defendants, as well as their officers, directors, employees, agents and legal counsel, are referred to as the "Parties."

2. Use of Discovery Materials: Confidential Discovery Materials (defined below) shall be used only for the litigation, including appeals, of this action, *In re: Seroquel Products Liab. Litig.*, MDL 1769 ("Litigation"), and any other Seroquel action alleging injuries or other damages. All persons given access to Confidential Discovery Materials shall (a) read and agree to be bound by this Order, (b) sign the Endorsement of Protective Order (Exhibit "A"), and (c) consent to this



Court's continuing jurisdiction for purposes of enforcing and remedying any violations of the Order. Confidential Discovery Materials shall not be disclosed except in accordance with paragraphs 3, 5 and 6, herein.

3. Procedure Prior to Disclosure of Confidential Discovery Materials: Prior to access to Confidential Discovery Materials, those within subparagraph 6(a) shall be (a) provided a copy of this Order by the party providing the Confidential Discovery Materials; (b) advised that Confidential Discovery Materials may not be divulged other than as specifically provided herein; (c) required to comply with the provisions of this Order, after reading and agreeing to be bound by it; and (d) required to sign the Endorsement of Protective Order (attached as Exhibit A). Anyone who reviews or examines any item produced under this Order shall not only agree to be bound by this Order and sign Exhibit A, but also shall take steps reasonably necessary to prevent the disclosure of confidential information. However, persons who come into contact with Confidential Discovery Materials or related information for clerical or administrative purposes, and who do not retain copies, are not required to sign the Endorsement of Protective Order.

4. Confidential Discovery Materials

(A) For purposes of this Order, "Confidential Discovery Materials" shall mean any discovery materials that the producing party, in good faith, designates as "confidential" pursuant to this Order based on the belief that such materials are entitled to protection under Federal Rule of Civil Procedure 26(c).

(B) In addition, discovery material in the possession of AstraZeneca AB, AstraZeneca plc, and AstraZeneca U.K. Ltd containing "personal data" as defined in E.U. Directive 95/46 and related

enactments in the countries of Sweden or the United Kingdom will be designated “Confidential Discovery Material.” In general terms, personal data consists of any and all data including information that may refer directly or indirectly to a natural person who is alive.

(C) If any Party believes that a document has been improperly designated “confidential” and is not entitled to protection under Federal Rule of Civil Procedure 26(c), that Party will notify the disclosing Party, and the Parties will make good faith efforts to resolve any dispute regarding the confidentiality of individual documents. If the dispute cannot be resolved informally, either Party may apply to the Court for a determination of whether the designation is appropriate. The burden rests on the Party asserting the “Confidential” designation to demonstrate that the designation is proper. Plaintiffs’ medical records are presumptively confidential and will be deemed confidential except as set forth in paragraph 6(d). By agreement of the Parties, Defendants may use information contained in Plaintiff Fact Sheets for required submissions to the Food and Drug Administration.

(D) The terms of this Order shall in no way affect the right of any person to withhold or redact information on grounds of immunity from discovery, such as attorney/client privilege, work product, or privacy grounds; or to withhold or redact information on grounds that such information is not relevant or reasonably calculated to lead to the discovery of admissible evidence, but upon request the reasons for such withholding or redaction shall be provided.

(E) Confidential Discovery Materials does not include information or documents produced or disclosed that are or become, without violating this Order, a matter of public record or publicly available by law or otherwise.

5. Designation of Confidential Discovery Materials

(A) The Party designating Discovery Material as “Confidential” will be referred to as the “Designating Party.”

(B) Any Discovery Material designated as “Confidential,” whether the information is provided orally or by a document, will be maintained as explained herein, and will not be disclosed to any person or entity, except as set forth herein.

(C) All Plaintiffs’ medical records and Fact Sheets will be deemed confidential. The parties will direct medical record collection service(s) used in this litigation to stamp as “Confidential” any medical records collected.

(D) All Discovery Material, whether or not filed with the Court, that contains Confidential information that the Designating Party seeks protection under this Order shall be designated as “Confidential” as follows:

(1) Documents or other tangible Discovery Material will, at the time of their production be designated by stamping or labeling “Confidential” on each page containing any confidential information. In the case of multi-page documents bound together, the word(s) “Confidential” need be stamped only on the first page of the document in order for the entire document to be treated as “Confidential.”

(2) Any non-party who is producing discovery materials in the Litigation may agree to and obtain the benefits of the terms and protections of this Order by designating as “Confidential” the discovery materials that the non-party is producing.

(3) Deposition testimony shall be designated “Confidential” (A) at the taking of the deposition by a statement on the record, by counsel at the time of such disclosure, or (B) by written notice sent to counsel of record for all Parties within twenty (20) days after receiving a copy

of the transcript by counsel making the designations or thirty (30) days if the deponent testified in a language other than English, identifying the specific pages designated as "Confidential" by page and line numbers. In both instances, counsel for the Designating Party will label "Confidential" the portions of the original and all copies of the transcript containing any confidential information. Counsel will not permit deposition transcripts to be distributed to persons beyond those specified in Paragraph 6, other than the deponent, until the relevant period for the designation has expired. Until the expiration of the relevant time period, the entire text of the deposition, including exhibits, shall be treated as confidential under this Order. If prior to the expiration of the twenty (20) day period a Party wishes to file any motion or pleading that will include reference to, or attach as exhibits, any portion of the deposition transcript or confidential exhibits thereto, the Party will give reasonable notice (not less than five business days prior to the filing of the motion or pleading) to the Parties and the deponent of the proposed filing date of the motion or pleading and of the pages and/or exhibits cited. Any Party or deponent who desires to designate or preserve any of the identified material as confidential will designate the material no less than two business days prior to the filing proposed date. If no Party or deponent designates any pages or exhibits from the deposition as confidential within the time frame provided, then the material will not be treated as Confidential Discovery Material.

(4) Non-documentary and non-testimonial material, such as oral statements of counsel on the record, will be designated orally at the time of disclosure and promptly confirmed in writing.

(E) Inadvertent failure to designate Discovery Material as "Confidential" does not constitute a waiver and may be corrected by supplemental written notice designating such Discovery Material as "Confidential." The Party receiving such supplemental written notice will then mark and treat materials as "Confidential" and those materials will be fully subject to this Order as if they had been initially designated. A person disclosing Discovery Material that is subsequently designated as "Confidential" will assist the Designating Party in retrieving such Discovery Material from all recipients not entitled to receive it under the terms of this Order and will act in good faith to prevent further disclosures except as authorized under the terms of this Order. This may include seeking appropriate relief regarding any such material that may have already been filed with a court.

After receipt of such notification, the parties will treat the designated materials as Confidential, subject to their right to dispute such designation in accordance with paragraph 12.

6. Permissible Disclosure of Discovery Materials

(A) Any Discovery Material designated as “Confidential,” and any information derived therefrom, may be disclosed only to the following persons: (I) the Parties (including their directors, officers, and employees); (ii) counsel to the Parties who have entered appearances in the Litigation, as well as their partners and associates, contract attorneys, paralegals, secretarial staff, clerical and other regular or temporary employees, and service vendors of such counsel (including outside copying and litigation support services, such as translators and interpreters); (iii) any persons associated with or employed by such attorneys or their firms, when working in connection with this litigation under the direct supervision of partners or associates of those firms; (iv) any outside experts who have been consulted for the purpose of being retained, or who have been retained by counsel to provide assistance, expert advice or technical consultation; provided that, prior to receiving Confidential Discovery Materials, outside experts or consultants will execute the Endorsement of Protective Order attached as Exhibit A; (v) the judges of the Court, Court staff, and any essential personnel retained or appointed by the Court (including Special Masters and their staffs); (vi) any other person only upon order of the Court or upon written agreement of the Designating Party; (vii) persons working in connection with this litigation under the direct supervision of persons described in section 6(a) (i-iii) above, but only to the extent necessary to perform their work in connection with this litigation; (viii) persons who authored the confidential discovery material or who received such confidential discovery material in the ordinary course of business; (ix) any attorney for claimants in other pending U.S. litigations alleging personal injury

or arising from the alleged use, purchase, or payment of Seroquel (or as attorneys for claimants in any other pending litigation as the parties may mutually agree or the Court directs) for use in this or such other action, provided the proposed recipient agrees to be bound by this Order and complies with the provisions of paragraph 3; (x) persons noticed for depositions or designated as trial witnesses and their attorneys, or those counsel of record who expect to testify at deposition or trial, to the extent reasonably necessary in preparing to testify; and (xi) such persons as counsel for the designating party shall consent to in writing before the proposed disclosure.

(B) Nothing in this Order prevents or restricts counsel from rendering advice to their clients and, in the course thereof, relying generally on examination of stamped confidential documents. Counsel will not disclose any Confidential item unless its disclosure is pursuant to the procedures of paragraph 3.

(C) All Parties, their respective counsel, and others bound by this Order will take all steps necessary to prevent the disclosure of Confidential Discovery Materials other than in accordance with the terms of this Order.

(D) Medical records for any plaintiff may be disclosed to that plaintiff's health care providers without first obtaining an Endorsement of Protective Order from those providers. This Court's Rules relating to electronic filing procedures shall govern the filing with the Court of depositions, pleadings, or other materials that reference the use of any atypical antipsychotic, including Seroquel; the reason for the use of any atypical antipsychotic, including Seroquel; and/or any condition that a plaintiff claims was caused by Seroquel usage.

7. Other Permissible Disclosure: Where produced by a defendant, Confidential Discovery Materials may be disclosed to plaintiff's attorneys in other filed actions alleging injuries or damages resulting from the use of the atypical antipsychotic medication(s) manufactured by the producing defendant(s), including their paralegal, clerical, secretarial and other staff employed or retained by such counsel; provided that such counsel have agreed to be governed by the terms of this Order and have signed the Endorsement of Protective Order.

8. Non-Party Designation of Discovery Material: Any non party to this Litigation may designate any Discovery Material taken from it, whether pursuant to subpoena or by agreement, as "Confidential" under the terms of this Order, so long as the non party has a written agreement to be subject to and governed by the requirements of this Order. A non-party will designate any Discovery Material as "Confidential" in a manner consistent with the procedures described in Paragraph 5.

9. Confidential Information in Depositions: Nothing shall prevent broader disclosures beyond those limited by this paragraph if the Designating Party consents in writing to such disclosure.

(A) A deponent may during the deposition be shown and examined about Confidential Discovery Materials if the provisions of paragraph 3 are complied with. Deponents will not retain or copy portions of the transcript of their depositions that contain confidential information not provided by them or the entities they represent unless they sign the form prescribed in paragraph 3. A deponent who is not a party, an employee or representative of a party or the attorney of said non-party, employee, or representative of a party, will be furnished with a copy of this Order before being examined about, or asked to produce potentially confidential documents.

(B) Any physician who treated a plaintiff, non-party fact witness or any other third party may be shown confidential information prior to and during his or her deposition if (I) there is a litigation need to show the information to the physician; and (ii) the physician complies with the terms of paragraph 3 herein.

(C) The parties will use their best efforts to make sure that every witness that will be shown Confidential Discovery Material signs the Endorsement of Protective Order. In the event that a deponent refuses to sign the endorsement, a party may not show a confidential document to the deponent unless the deponent affirms on the record in the deposition that they understand that the document and the information contained therein are confidential and understand that they are prohibited from sharing or discussing that document or the information contained therein with anyone outside the deposition.

(D) Except as set forth in this paragraph, Confidential Discovery Material may not be provided to current employees of any pharmaceutical company or other entity involved in the distribution, manufacturing or sale of pharmaceuticals. A copy of the signed Endorsement of Protective Order shall be provided to counsel for each defendant in this action at least five (5) business days before access to Confidential Discovery Material is allowed. Any defendant may object in writing at least one business day in advance of the date which access was to be allowed, stating the grounds and serving a copy of such objection on all Parties. The Parties will meet and confer to resolve the objection if possible. If the Parties cannot resolve the objection, plaintiffs may respond to the objection in writing and will provide the objection and their response to the Court which will then resolve the issue.

10. Filing of Confidential Discovery Materials with the Court: Filing of material under seal in this Court is governed by Local Rule 1.09.

11. Inadvertent Disclosures: The inadvertent production of any Discovery Materials that would be protected from disclosure pursuant to the attorney-client privilege, the work product doctrine or any other applicable privilege or doctrine will not constitute a waiver of the applicable privilege or doctrine. If any such Discovery Materials are inadvertently produced, the recipient of the Discovery Materials agrees that, upon discovery or notification of such a disclosure, it will promptly return the Discovery Materials and all copies of the Discovery Materials in its possession, delete any versions of the Discovery Materials on any database it maintains and make no use of the information contained in the Discovery Materials; provided, however, that the party returning such Discovery Materials shall have the right to apply for an order that such Discovery Materials are not protected from disclosure by any privilege or doctrine. The person returning such material may not, however, assert as a ground for such motion the fact or circumstances of the inadvertent production. The party to whom any inadvertently produced discovery materials were returned shall retain the returned materials until the end of the case, including any appeals.

12. Declassification

(A) Nothing shall prevent disclosure beyond that limited by this Order if the Designating Party consents in writing to such disclosure or upon order of the Court.

(B) If at any time a Party wishes for any reason to dispute a designation of Discovery Materials as confidential, such person shall notify the Designating Party of such dispute in writing,

specifying by exact Bates number(s), the Discovery Materials in dispute. The Designating Party shall respond in writing within 10 days of receiving this notification.

(C) If the Parties are unable to amicably resolve the dispute, the proponent of confidentiality may request by motion a ruling that Discovery Materials designated as confidential are entitled to such status and protection under the Federal Rules and this Order. Such motion shall be made within thirty (30) days of receipt by the Designating Party of the notification of the recipient's challenge to the designation, or such other time period as the Parties may agree to in writing. The Designating Party shall have the burden of proof on such motion to establish the propriety of its confidential designation.

(D) If the time for filing a motion has expired without the filing of any such motion, or ten (10) business days (or such longer time as ordered by this Court) have elapsed after the appeal period for an order that the Discovery Material shall not be entitled to confidential status, the Confidential Discovery Material shall lose its designation.

13. Confidential Discovery Materials Offered as Evidence at Trial: The manner in which Confidential Discovery Material will be handled at trial shall be determined by the court conducting the trial.

14. Subpoena by Other Courts or Agencies: If another court or an administrative agency subpoenas or otherwise orders production of Confidential Discovery Materials (or confidential information) which any Party or other person has obtained under the terms of this Order, the Party or other person to whom the subpoena or other process is directed will immediately notify the Designating Party in writing of all of the following: (a) the discovery materials that are requested

for production in the subpoena; (b) the date which compliance with the subpoena is requested; (c) the location at which compliance with the subpoena is requested; (d) the identity of the party serving the subpoena; and (e) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or other designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena or other process has been issued. Confidential Discovery Materials shall not be produced prior to the receipt of written notice by the Designating Party and after a reasonable opportunity to object has been offered. Further, the Party or person receiving the subpoena or other process will cooperate with the Designating Party in any proceeding related thereto. The Designating Party will bear the burden and all costs of opposing the subpoena on grounds of confidentiality.

15. Return or Certified Destruction of Confidential Materials: The provisions of this Order will not terminate at the conclusion of this Litigation. Within ninety (90) days after conclusion of any attorneys' last case in this or any other proceedings involving Seroquel in which the attorney may be permitted to use confidential information under the terms of a Protective Order, including any appeals related thereto, or such other time as the Designated Party may agree in writing, counsel will, at their option, return or destroy Confidential Discovery Materials and documents or things containing confidential information and all copies. If counsel elects to destroy Confidential Discovery Materials, they will consult with counsel for the Designating Party on the manner of destruction and obtain such Party's consent as to the method and means of destruction. Outside counsel, however, will not be required to return or destroy any pretrial or trial records that are regularly maintained by that counsel in the ordinary course of business; which records will continue to be maintained as Confidential Discovery Materials in conformity with this Order. However, counsel may retain the privileged communications, work product, signed copies of the

Endorsement of Stipulation and Protective Order pursuant to paragraph 3, and all court filed documents even though they contained Confidential Discovery Materials, but such documents will remain confidential subject to the terms of this Protective Order.

16. Modification Permitted: Nothing herein shall prevent any Party or other person from seeking modification of this Order, or objecting to discovery it believes to be improper.

17. Responsibility of Attorneys as to Copies: The attorneys of record are responsible for employing reasonable measures to control and track access to and distribution of Confidential Discovery Materials, including abstracts and summaries.

18. No Waiver of Rights or Implication of Discoverability

(A) No disclosure pursuant to any provision of this Order will waive any rights or privileges of any Party or person granted by this Order.

(B) This Order will not enlarge or affect the proper scope of discovery in this or any other litigation; nor will it imply that Confidential Discovery Materials are properly discoverable, relevant, or admissible in this or any other litigation. Each Party reserves the right to object to any disclosure of information or production of any documents that the Designating Party designates as Confidential Discovery Materials on any other ground it deems appropriate.

(C) The entry of this Order shall be without prejudice to the rights of the Parties, or any non-party to assert or apply for additional or different protection. Nothing herein prevents any Party from seeking an appropriate protective order to further govern the use of Confidential Discovery Materials at trial.

(D) Nothing will prevent disclosure beyond that required under this Order if the producing party consents in writing to such disclosure, or if the Court, after notice to all affected parties, orders such disclosures, subject to any review as authorized under the Federal Rules of Civil Procedure or the Local Rules of this Court.

19. Miscellaneous: Nothing in this Order prevents a producing Party from any use of its own documents and information.

20. Improper Disclosure of Confidential Discovery Material: Disclosure of Confidential Discovery Materials other than in accordance with this Order may subject the disclosing Party or person to sanctions and remedies as the Court may deem appropriate.

SO ORDERED this 19th day of September, 2007.

David A. Baker

DAVID A. BAKER

UNITED STATES MAGISTRATE JUDGE

ENDORSEMENT OF PROTECTIVE ORDER

I hereby attest to my understanding that information or documents designated as Confidential Discovery Materials or confidential information are provided to me subject to the Protective Order (“Order”) dated September 18, 2007 (the “Protective Order”), in the above-captioned litigation (“Litigation”); that I have been given a copy of and have read the Order; and, that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Protective Order, indicating my agreement to be bound by the Order, is a prerequisite to my review of any information or documents designated as Confidential Discovery Material or confidential information pursuant to the Order.

I further agree that I shall not disclose to others, except in accord with the Order, any Confidential Discovery Materials or Confidential Information, in any form whatsoever, and that such Confidential Discovery Materials and Confidential Information may be used only for the purposes authorized by the Order.

I further agree to return all copies of any Confidential Discovery Materials or any document or thing containing Confidential Information I have received to counsel who provided them to me, or to destroy such materials, upon completion of the purpose for which they were provided and no later than the conclusion of this Litigation.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such Confidential Discovery Material and Confidential Information will continue even after this Litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court, Middle District of Florida, Orlando Division, for the purposes of any proceedings relating to enforcement of the Order. I further agree to be bound by and to comply with the terms of the Order as soon as I sign this Agreement, regardless of whether the Order has been entered by the Court.

Date: _____

By: _____