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WESTERN DISTRICT OF LOUISIANA
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE-PRODUCTS LIABILITY LITIGATION This Document Applies to All Actions	6-11-md-2299 JUDGE DOHERTY MAGISTRATE JUDGE HANNA

FIRST AMENDED CASE MANAGEMENT ORDER:
Protecting the Confidentiality of Discovery Materials[1]

For good cause shown, the Court issues the following Protective Order:

1. Discovery Material.

(a) This Order applies to all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise (collectively "discovery material"), by any party to this proceeding (the "Producing Party") to any other party (the "Receiving Party").

(b) At the time this Order is entered in the *In re Actos (Pioglitazone) Products Liability Litigation* (W.D. La., MDL No. 2299), it becomes binding upon all parties presently involved, or who are later named, in these proceedings including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, experts, consultants, representatives, directors, officers, employees, and others as set forth in this Order.

[1] This amendment effects only one change to the original order: it substitutes a new Exhibit A ("Endorsement"), one which eliminates the need for a notarial act in favor of allowing individuals to execute a declaration that comports with 28 U.S.C. § 1746.

(c) If additional parties are added other than parents, subsidiaries or affiliates of current parties to this litigation, their ability to receive Confidential Information as set forth in this Order will be subject to their being bound, by agreement or Court Order, to this Order.

(d). The entry of this Protective Order does not prevent any party from seeking a further order of this Court regarding Discovery Materials.

(e) Nothing herein shall be construed to affect in any manner the admissibility at trial or hearings before this Court of any document, testimony, or other evidence.

2. Confidential Discovery Material. "Confidential Discovery Material," as used herein, means information of any type, kind or character that the Producing Party believes in good faith constitutes, reflects, discloses, or contains information subject to protection under Rule 26(c)(1)(G), whether it is a document, information contained in a document, information revealed during a deposition or other testimony, information revealed in an interrogatory response, or information otherwise revealed. Discovery material containing trade secrets, or other confidential or proprietary research, development, manufacturing or commercial or business information may be designated by the Producing Party as "Confidential." Without prejudice to the right of a Producing Party to object to the production of the following information or of a party to seek production and/or de-designation, examples of the information that may be alleged to be subject to such designation include but are not limited to the Producing Party's:

a. Customer names and compilations of information related to opinion leaders and other consultants;

b. Proprietary licensing, distribution, marketing, design, development, research and manufacturing information regarding products and medicines, whether previously or currently marketed or under development (not to include disseminated marketing materials or materials that, on its face, was published to the general public);

c. Unpublished clinical studies, scientific literature, and related documents;

d. Information concerning competitors;

e. Production information;

f. Personnel records and information;

g. Financial information not publicly filed with any federal or state regulatory authorities or not contained within any publicly available quarterly or annual reports;

h. Private medical information that identifies a person unless such identifying information is redacted; and

i. Information submitted to any governmental or regulatory agency, which information is exempt from public disclosure.

3. Discovery Material and Foreign Law. Any entity organized under the laws of a country other than the United States, including but not limited to Japan, France, Germany, and the United Kingdom, that produces information in this litigation may designate as confidential those documents in any form (including electronic or paper

form) containing "Protected Data" within the meaning of the applicable data protection or privacy laws, if any.[2]

4. Use of Confidential Discovery Material.

(a) Any discovery material that is designated as "Confidential" in accordance with Paragraph 2 above, along with any copies, abstracts, summaries, excerpts, compilations thereof, or information derived from such discovery material, and any notes or other records regarding the contents of such discovery material (collectively "confidential discovery material"), shall not be used for any business or competitive purpose, except by the Producing Party, or for any other purposes whatsoever, other than the litigation of cases in this MDL, including post-MDL proceedings in transferor courts (hereinafter referred to collectively as "this litigation"), and for any other action brought by or on behalf of a former pioglitazone user alleging injuries or other damages therefrom ("Other Actos Lawsuits"), so long as all parties are bound by and subject to this Order or another judicially approved order that is identical to or the substantial equivalent to this Order. Confidential discovery material will not be disclosed except in accordance with paragraphs 4(b), 7, 10, and 11.

(b) Prior to being given access to confidential discovery material, any person falling within subparagraphs 7(a)(vi) or 7(a)(vii) shall be provided with a copy of

[2] "Protected Data" shall refer to any information that a party believes in good faith to be subject to foreign data protection laws. Protected Data constitutes highly sensitive materials requiring special protection. Examples of such data protection laws include but are not limited to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L281/31) (European Union personal information); Data Protection Act 1998 (c. 29) (United Kingdom personal information); the German Federal Data Protection Act (Germany personal information); French Data Protection Act. Law No. 78-17 of January, 6, 1978, J.C.P. 1978, III, No. 44692; and The Personal Information Protection Act (Law No. 57 of 2003) (Japan personal information).

this Order and shall execute a copy of the Endorsement of Protective Order, attached as Exhibit A. Counsel providing such access to confidential discovery material shall retain copies of the Endorsement(s) of Protective Order and shall provide them to counsel producing confidential discovery materials as provided below. For testifying experts, a copy of the Endorsement of Protective Order executed by the testifying expert shall be furnished to counsel for the party who produced the confidential discovery material to which the expert has access.

5. Designation of Confidential Discovery Material.

(a) Confidential discovery material, if in writing, shall have the following language stamped on the face of the writing, or shall otherwise have such language clearly marked in the margins:

"CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER"

Such stamping or marking will take place prior to production by the Producing Party, or subsequent to selection by the Receiving Party for copying but prior to the actual copying if done expeditiously. The stamp shall be affixed in such manner in the margins as not to obliterate or obscure any written matter.

(b) To the extent that confidential discovery material is stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) ("Computerized Material") is produced by any party in such form, the Producing Party may designate such matters as confidential by a designation of "**CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER**" on the media. Whenever any Receiving Party reduces such material to

hardcopy form, that party shall mark the hardcopy form with the corresponding "**CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER**" designation.

(c) In the case of deposition testimony relating to documents designated as confidential, the portion of the transcript in which confidential writings are offered, identified or discussed shall also be designated as confidential. Any additional confidentiality designations shall be made within thirty (30) calendar days after the transcript has been received by counsel making the designation, and shall specify the testimony being designated confidential by page and line number(s). Until the expiration of such thirty (30) day period, the entire text of the deposition, including exhibits, shall be treated as confidential under this Order.

(d) In the event that the Producing Party inadvertently fails to designate discovery material as confidential in this or any other litigation, it may make such a designation subsequently by notifying all parties to whom such discovery material was produced, in writing as soon as practicable. After receipt of such notification, the Receiving Party shall treat the designated discovery material as confidential, subject to that party's right to dispute such designation in accordance with Paragraph 8.

6. Consent to Jurisdiction. All persons receiving or given access to confidential discovery material in accordance with the terms of this Order consent to the continuing jurisdiction of the Court for the purposes of enforcing this Order and remedying any violations thereof.

7. Disclosure of Confidential Discovery Material.

(a) Confidential discovery material shall not be disclosed to anyone other than the following categories of persons:

i. The Court (and any appellate court), including court personnel, Special Masters and members of their staffs, jurors, and alternate jurors only in the manner provided in paragraph 10 below.

ii. If produced by Plaintiffs, Defendants' in-house counsel, paralegals and clerical support staff, and outside counsel, including any attorneys employed by or retained by Defendants' outside counsel who are assisting in connection within this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by such outside counsel or retained by the attorneys employed by or retained by Defendants' outside counsel. To the extent a Defendant does not have in-house counsel, it may designate two individuals employed by each Defendant (in addition to outside counsel) to receive Confidential Discovery Materials produced by Plaintiffs.

iii. If produced by any Defendant, a Plaintiff in this litigation, Plaintiff's attorneys in this litigation, including the paralegal, clerical, secretarial and other staff employed or retained by such counsel. Additionally, confidential discovery material produced by any defendant in this MDL may be disclosed to the named plaintiff(s) in Other Actos Lawsuits, and their counsel, including paralegal, clerical, secretarial and other staff employed or retained by such other plaintiffs' counsel if: (a) the lawsuit alleges or involves injuries or damages resulting from the use of pioglitazone; and (b) an order identical to or the substantial equivalent to this Order has been entered in such lawsuit or all counsel for plaintiff who receive the documents agree to be governed by the terms of this Order and shall sign an Endorsement of Protective Order, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms. Further, confidential discovery material produced

by any defendant in this MDL may be disclosed to counsel representing an Actos claimant with an unfiled claim, if: (a) the claim alleges or involves injuries or damages resulting from the use of pioglitazone; and (b) all counsel for claimant who receive the documents agree to be governed by the terms of this Order and shall sign an Endorsement of Protective Order, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms.

iv. If produced by any Defendant, clients of Plaintiff's attorneys in this litigation, including those with unfiled claims, if those clients agree to be governed by the terms of this Order and shall sign a Confidentiality Agreement, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms.

v. If produced by any Defendant, outside counsel for any other Defendant, including any attorneys employed by or retained by any other Defendant's outside counsel who are assisting in connection with this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by such outside counsel.

vi. Any Defendant's insurer or counsel for its insurer provided that prior to receiving confidential discovery materials a person with sufficient authority to bind each insurer and its counsel executes the Endorsement of Protective Order and provides a copy to the Producing Party on behalf of the insurer or law firm. Any materials provided to an insurer or its counsel shall not be used for any purpose other than evaluation of the claims asserted in this litigation and shall not be used outside the claims asserted in this litigation.

vii. Court reporters (including persons operating video recording equipment at depositions) and persons preparing transcripts of testimony to the extent necessary to prepare such transcripts.

viii. Retained experts, advisors and consultants, including persons directly employed by such experts, advisors and consultants (collectively "Experts"), but only to the extent necessary to perform their work in connection with this litigation or Other Actos Lawsuits in which an order that is identical to or the substantial equivalent of this Order has been entered.

ix. The persons who authored the confidential discovery material, were a source of the confidential discovery material, are in good faith believed to be referenced in the confidential discovery material and already familiar with the subject-matter of the confidential discovery material or who received such confidential discovery material.

(b) All parties and their respective counsel, paralegals and the employees and assistants of all counsel receiving discovery material shall take all steps reasonably necessary to prevent the disclosure of confidential discovery material other than in accordance with the terms of this Order.

(c) A plaintiff's current or former healthcare provider who has agreed on the record at deposition to maintain the confidentiality of any document intended to be used at the deposition may be shown or questioned about Confidential Discovery Material at the deposition, provided that no copies of the Confidential Discovery Material shall be left in the possession of the healthcare provider witness and copies of that Confidential Discovery Material shall not be attached to or included with any original or

copy of the transcript of that deposition provided to the healthcare provider; however, copies of the Confidential Discovery Material shall be attached to the deposition transcript and made available for the use of the deponent in the event he or she testifies at trial. Counsel present at the deposition should make a good faith effort to obtain the healthcare provider's agreement on the record to maintaining confidentiality and no counsel shall make efforts to dissuade the healthcare provider from refusing to agree on the record to maintaining the confidentiality of any such documents. Regardless of whether any deponent signs the Endorsement of Protective Order attached as Exhibit A, this Order will apply to any deponent who is shown or examined about Confidential Discovery Material and the deponent cannot take any exhibits with them nor can he/she reveal any information learned from the confidential materials shown to them. This paragraph is not intended to prevent any deponent from seeking other relief from this Court.

(d) Except for plaintiff's current or former healthcare provider (who are subject to the foregoing sub-section) and current employees and consultants of the defendants or the producing party, each person who is permitted to see confidential documents shall first be shown a copy of this Order and shall further be advised of the obligation to honor the confidentiality designation.

(e) Disclosure of confidential discovery material other than in accordance with the terms of this Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate, including without limitation, contempt, injunctive relief and damages.

8. **Disputes concerning designation of Confidential Discovery Material.**

a) If at any time a Receiving Party wishes in good faith to dispute a designation of discovery material as confidential hereunder, such party shall notify the designating party of such dispute in writing (Dispute Notice), specifying by exact document numbers the discovery material in dispute and providing a brief explanation of the basis of the dispute with regard to each such document or other discovery material. No more than 50 documents shall be challenged in a single Dispute Notice, and only one Dispute Notice may be sent within a three-week period. If no change in designation is offered by the Producing Party, the Producing Party must provide within fourteen (14) calendar days a written explanation of the good faith basis for the designation(s) at issue.

If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, the Receiving Party shall, in writing (Challenge Notice), notify the Producing Party that a resolution cannot be reached regarding the confidentiality designation of a document or, the Receiving Party may elect to file and serve a motion that identifies the challenged material and sets forth the basis for the challenge to the confidentiality designation. Any such motion shall be accompanied by a Motion for Leave to File Under Seal ("Sealing Motion"), in accordance with this Court's order concerning Sealing Motions. On such motion, the Producing Party shall have the burden of proving that the material is entitled to protection, as if this Order has not been entered, pursuant to Rule 26(c)(1)(G). On such a motion by the Receiving Party, the Producing Party shall have no less than fifteen (15) calendar days to file and serve an Opposition, and the Receiving Party shall waive its right to file a reply brief.[3] The Opposition shall be accompanied by a Sealing Motion.

[3] If the number of pending challenges becomes burdensome, the parties agree to alter the schedule to provide sufficient time for an Opposition.

If the Receiving Party elects to serve a Challenge Notice rather than move, the Producing Party shall, within twenty-one (21) calendar days of receiving such notice from the Receiving Party, file and serve a motion that identifies the challenged material and sets forth in detail the basis for the confidentiality designation. Any such motion shall be accompanied by Sealing Motion. The Producing Party shall have the burden of proof on such motion to establish the propriety of its confidentiality designation. The time allotted under this paragraph for a Producing Party to respond in writing to a Challenge Notice or to file and serve a motion setting forth the basis of a challenged confidentiality designation shall not be shortened except upon a showing of good cause.

(b) All discovery material designated as confidential under this Order, whether or not such designation is in dispute pursuant to subparagraph 8(a) above, shall retain that designation and be treated as confidential in accordance with the terms hereof unless and until:

i. the Producing Party agrees in writing that the material is no longer confidential and subject to the terms of this Order; or

ii. fourteen (14) calendar days after the expiration of the appeal period of an Order of this Court that the matter shall not be entitled to confidential status (or such longer time as ordered by this Court) if the Order on appeal is not subject to a stay; or

iii. the Producing Party does not respond as set forth above within fourteen (14) calendar days of service of the Dispute Notice; or

iv. the Producing Party does not serve a motion within twenty-one (21) days of receiving a Challenge Notice.

9. **Designation by Non-Parties.** Any non-party who is producing discovery materials in this litigation may subscribe to and obtain the benefits of the terms and protections of this Order by designating pursuant to the terms of this Order as "Confidential" the discovery materials that the non-party is producing. Such subscription shall be through a Notice filed with this Court and such Notice shall indicate that the Non Party agrees to this Order in its entirety.

10. **Filing with the Court.** The parties will use the following procedure for submitting to the Court papers consisting of, relating to, containing, incorporating, reflecting, describing, or attaching Confidential Information: Other than motion practice relating to disputes concerning designation of Confidential Discovery Material which shall be filed, together with a Sealing Motion, pursuant to paragraph 8 of this order. All papers consisting of, relating to, containing, incorporating, reflecting, describing, or attaching Confidential Information shall be timely served upon opposing counsel pursuant to Court Ordered deadlines or agreements by the parties. A courtesy copy of such papers shall simultaneously be provided to the Deputy Special Master. Following service of Reply papers upon opposing counsel, the parties shall meet and confer in good faith for up to twenty-one (21) days to resolve objections of the use of any confidential information or confidential documents in the briefs (Confidential Document Review Period or CDRP). During the CDRP, any party objecting to the use of any information or documents in the briefs must contact the filing party and both sides must attempt in good faith to resolve the objection(s). If no resolution is achieved within the CDRP and the objecting party is not waiving its objection, then the objecting party must file a Sealing Motion no later than the last day of the CDRP. The objecting party shall refrain from

filing any papers that are the subject of the objection until either Sealing Motion is resolved or, if no Sealing Motion has been filed with the Court, the expiration of the CDRP.

11. Use of Confidential Discovery Material at Hearings or Trial. This Order does not restrict or limit the use of confidential discovery material at any trial. However, prior to any hearing that is held other than a trial at which the use of confidential discovery material is anticipated, the parties shall meet and confer regarding the use of the confidential discovery material. If the parties cannot agree, the parties shall request the Court to rule on such procedures.

12. Responses to Subpoenas or Other Process. If a Receiving Party or its counsel or expert is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization which calls for production of any confidential discovery material produced by another party, the party to whom the subpoena or other process is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such document or information until fourteen (14) calendar days after notifying counsel for the producing party in writing of all of the following: (1) the information and documentation which is requested for production in the subpoena; (2) the date on which compliance with the subpoena is requested; (3) the location at which compliance with the subpoena is requested; (4) the identity of the party serving the subpoena; and (5) 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 has been issued. The party, counsel or expert receiving the subpoena or other process shall cooperate, to

the extent reasonably possible, with the Producing Party in any proceeding relating thereto.

13. Return or Destruction of Confidential Discovery Materials. Within thirty (30) calendar days of the conclusion of any attorney's last case in this proceeding, including any appeals related thereto, at the written request and opinion of the Producing Party, such attorney and any persons to whom he or she disclosed confidential discovery material under this Order shall return and surrender or destroy any such material or copies thereof to the Producing Party at the Producing Party's expense. Such persons shall return or surrender any discovery materials produced by the Producing Party and any and all copies (electronic or otherwise), summaries, notes, compilations, and memoranda related thereto; provided, however, that counsel may retain their privileged communications, work product, Endorsements of Protective Order, materials required to be retained by applicable law, and all court-filed documents even though they contain discovery materials produced by the Producing Party, but such retained privileged communications and work product shall remain subject to the terms of this Order. At the written request of the Producing Party, any person or entity having custody or control of recordings, notes, memoranda, summaries or other written materials, and all copies thereof, relating to or containing discovery materials produced by the Producing Party shall deliver to the Producing Party an affidavit certifying that reasonable efforts have been made to assure that all such discovery materials produced by the Producing Party and any copies thereof, any and all records, notes, memoranda, summaries, or other written material regarding the discovery materials produced by the Producing Party (except for privileged communications, work product and court-filed documents as stated

above) have been delivered to the Producing Party in accordance with the terms of this Order or destroyed. In lieu of returning the materials, the Producing Party may direct that the materials be destroyed in a manner that will protect the confidential discovery materials and the destroying party shall certify that it has done so.

14. Reservation of Rights.

(a) Except as provided for herein, nothing in this Order shall prevent or restrict counsel for any party in any way from inspecting, reviewing, using or disclosing any discovery material produced or provided by that party, including discovery materials designated as confidential.

(b) Nothing shall 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 disclosure and that Order is not subject to an appellate stay within twenty-one (21) calendar days after it is issued.

(c) No disclosure pursuant to this Paragraph shall waive any rights or privileges of any party granted by this Order.

15. No Effect on Other Obligations. This Order shall not enlarge or affect the proper scope of discovery in this or any other litigation, nor shall this Order imply that confidential discovery material is 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 Producing Party designates as confidential discovery material on any other ground it may deem appropriate. The actions of the parties and their counsel in designating (or de-designating) discovery

material as confidential pursuant to this Order shall not constitute evidence that is admissible to a jury at trial.

16. Obligation of Good Faith. All parties and counsel for such parties in this litigation shall make a good faith effort to ensure that their experts, employees, and agents comply with this Order. In the event of a change in counsel, retiring counsel shall fully instruct new counsel of their responsibilities under this Order.

17. Modifications/Continuing Effect. By written agreement of the parties, or upon motion and order of the Court, the terms of this Order may be amended or modified. This Order shall continue in force until amended or superseded by express order of the Court, and shall survive any final judgment or settlement in this litigation.

SO ORDERED, this 23 day of April, 2013

REBECCA F. DOHERTY
UNITED STATES DISTRICT JUDGE

AGREED TO BY COUNSEL OF RECORD