

JUL 10 2012

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY  
LITIGATION

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This Document Relates to All Cases  
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MDL Docket No.

6:11-MD-2299

**CASE MANAGEMENT ORDER:**

**Assertions of Attorney-Client Privilege and Work Product Doctrine**

**I. Scope of Order**

This Order is entered to provide general principles and specific guidelines that shall apply to assertions of attorney-client and/or work-product privilege, the protocols that shall be followed with regard to privilege logs, and the method of determining any disputes relating to the assertion of the attorney-client privilege or work product doctrine by any party. This Order applies to claims brought by any U.S. citizen or resident based on alleged ingestion of Actos®, ACTOplus Met®, ACTOplus Met XR®, Duetact®, or pioglitazone (“Actos”) that (i) currently are pending in MDL No. 2299, (ii) currently are pending in the Western District of Louisiana and are related to MDL No. 2299, or (iii) will be filed in, removed to, or transferred to this Court within the noted proceeding(s) (collectively, “the MDL Proceedings”).

**II. Grounds for Asserting Privilege**

In order to avoid any future dispute about what substantive law might apply to a claim of attorney-client privilege, the parties have agreed that federal common law governing privilege applies, including the general and specific principles set forth in *In re Vioxx Prod. Liab. Litig.*, 501 F. Supp. 2d 789 (E.D. La. 2007), as summarized in part below. The parties have also agreed

the work product doctrine shall be governed by the law of the U.S. Court of Appeals, Fifth Court, as described in part below.

**A. General Principles**

1. The attorney-client privilege applies only if:
  - (a) the asserted holder of the privilege is or sought to become a client;
  - (b) the person to whom the communication was made;
    - (i.) is a member of the bar of a court, or his or her subordinate;  
and
    - (ii.) in connection with this communication is acting as a lawyer;
  - (c) the communication relates to a fact of which the attorney was informed;
    - (i.) by his or her client;
    - (ii.) without the presence of strangers;
    - (iii.) for the purpose of securing primarily either;
      - (a) an opinion on law or;
      - (b) legal services or;
      - (c) assistance in some legal proceeding;
    - (iv.) and not for the purpose of committing a crime or tort; and
  - (d) the privilege has been claimed and not waived by the client.<sup>1</sup>
2. The attorney-client privilege applies where counsel was participating in the

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<sup>1</sup> *In re Vioxx Products Liab. Litig.*, 501 F. Supp. 2d 789, 795 (E.D. La. 2007). This definition was adopted by the Fifth Circuit Court of Appeals in 1975 in *In re Grand Jury Proceedings*, 517 F.2d 666, 670 (5th Cir.1975).

communications primarily for the purpose of rendering legal advice or assistance.<sup>2</sup> Therefore, merely because a legal issue can be identified that relates to on-going communications does not justify shielding those communications from discovery. The lawyer's role as a lawyer must be primary to his or her participation in the communications.<sup>3</sup> The burden of persuasion on all elements of claimed privileges is exclusively the proponent's.<sup>4</sup>

3. The work product doctrine only applies to documents or data compilations that are created in anticipation of litigation. Fed. R. Civ. P. 26(b)(3). Thus, to assert work product privilege, the document or data compilation must be prepared by or for the party or its representative (including the party's attorney, consultant, surety, indemnitor, insurer, or agent) for prospective litigation, meaning that the primary motivating purpose behind the creation of the document was to aid in pending or threatened litigation.

## **B. Specific Guidelines**

1. The attorney-client privilege protects documents and communications addressed solely to an attorney with apparently limited circulation with an identifiable legal question raised by the author (whether or not it was answered by the attorney). The attorney's response (if any) is also privileged if its primary purpose is to provide legal advice.<sup>5</sup>

2. When an e-mail message is addressed to both lawyers and non-lawyers for review, comment, and approval ("mixed-purpose" communication), the message is protected by

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<sup>2</sup> *Vioxx*, 501 F. Supp. 2d at 798.

<sup>3</sup> *See id.* at 798.

<sup>4</sup> *See id.* at 798-99.

<sup>5</sup> *See id.* at 795-796. The Court in *Vioxx* discussed two exceptions to this general rule: (1) when the attorney had conveyed information to the client that the attorney had acquired from third parties (e.g., previously published articles and discussions with third parties like a U.S. attorney), and (2) when in-house lawyers were electronically rendering their advice (in the form of line edits) on a non-privileged attachment to non-privileged client communications and the non-privileged attachment was claimed as privileged because of the advice its lawyers chose to place on it. As to the latter situation, the lawyer's comments and changes may be redacted.

the attorney-client privilege if the proponent can satisfy the burden of proving that the non-lawyers are included on the communication to apprise them of the legal services sought. Absent this exception, neither the message nor attachments to it are protected by the attorney-client privilege.<sup>6</sup>

3. For a mixed-purpose communication, any portion of such a communication that specifically requests legal advice may be redacted. The attorney's response to such a communication is similarly privileged to the extent it provides legal advice. If the attorney provides comments or changes on an attachment to the communication (in the form of line edits or other comments embedded in the document), those comments and changes may be redacted subject to the provisions below:

- (a) If the document on which attorney comments and changes were being proposed was not a typical legal instrument and the response had changes and commentary that were extensive or related purely to technical, scientific, promotional, management, or marketing matters that do not appear to be related to legal assistance, then the proponent may not redact the comments and changes of the attorney unless the proponent can satisfy the burden of proving that the primary purpose of the responses was providing legal advice;
- (b) If the document on which attorney comments and changes were being proposed related to identifiable legal instruments like a proposed contract, the comments and changes are privileged, even with extensive editorial and grammatical revisions, because they

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<sup>6</sup> *See id.* at 809 (“A corporation’s choices of means and format in the communications between their lawyers and employees cannot limit their adversaries’ right to discovery of what otherwise is non-privileged and discoverable.”).

are the type of instruments that one reasonably expects more extensive input and guidance from reviewing attorneys.<sup>7</sup>

4. The attorney-client privilege protects what independently is not privileged only if it is attached to, or incorporated in, a communication that is protected by the privilege.<sup>8</sup> For instance, if a memorandum was written only to an attorney within the corporation's legal department, with an attachment for examination, review, comment, and approval, the e-mail and attachment are sent primarily for the purpose of obtaining legal advice and, therefore, are protected by the attorney-client privilege. The attorney-client privilege does not, however, protect a document sent from one corporate officer to another simply because a copy is sent to counsel. The document is protected if the proponent can satisfy the burden of proving that the primary purpose of the document was a request for or the provision of legal advice.

5. The attorney-client privilege protects the additional dissemination of a privileged e-mail when the conveyance was by a non-lawyer recipient only if it is clear that legal advice previously obtained was being circulated to those within the corporate structure who needed the advice in order to fulfill their corporate responsibilities.<sup>9</sup> The attorney-client privilege does *not* protect e-mails that were either to or from an attorney but did not reveal the substance of what either the client was communicating (for example attaching a study, report, article, etc.) or the attorney was advising (because the comments appeared on the attachment), regardless of whether the attachments are privileged.<sup>10</sup>

6. The attorney-client privilege protects communications among non-attorneys if the purpose of the communication is to gather information necessary for the obtaining of legal

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<sup>7</sup> *Id.* at 811.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at 812.

advice or to convey such legal advice. Absent extraordinary circumstances, the burden to demonstrate a privileged purpose of the communication will not be met when an attorney is not the sender or a recipient of a communication.<sup>11</sup>

7. Where an attorney was involved in the process of drafting an otherwise non-privileged document, drafts of the document are privileged to the extent they reveal the attorney's legal advice and are not otherwise privileged.<sup>12</sup>

8. The attorney work-product doctrine, in part, shelters the mental processes of an attorney. The work-product doctrine also protects materials assembled and brought into being by the party or its representative at the direction of counsel in anticipation of litigation. Excluded from the scope of work-product are materials assembled in the ordinary course of business or pursuant to public requirements unrelated to litigation.<sup>13</sup>

9. Materials are not protected as attorney work-product merely because they were prepared by the party or its representative at the direction of counsel at a time when litigation was ongoing or imminent. The test is whether the primary motivating purpose behind the creation of the document was to aid in existing or possible future litigation.<sup>14</sup>

### **III. Privilege Log Protocol**

#### **A. General Principles**

The party asserting a privilege shall provide sufficient information in its privilege logs to enable the opposing party to assess the applicability of the privilege.<sup>15</sup> Additionally, the burden

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<sup>11</sup> See *Smithkline Beecham Corp. v. Apotex Corp.*, 232 F.R.D. 467, 477 (E.D. Pa. 2005)

<sup>12</sup> See *Vioxx*, 501 F. Supp. 2d at 802-804. See also *Smithkline Beecham Corp.*, 232 F.R.D. at 477-78 (“In general, attorney-client privilege does not shield documents merely because they were transferred to or routed through an attorney.”) (internal citations omitted).

<sup>13</sup> See *U.S. v. El Paso Co.*, 682 F.2d 530 (5th Cir.1982).

<sup>14</sup> See *U.S. v. El Paso Co.*, 682 F.2d 530 (5th Cir.1982).

<sup>15</sup> Fed. R. Civ. P. 26(b)(5).

of demonstrating the applicability of a privilege rests on the party asserting same.<sup>16</sup> A party asserting privilege is required to provide specific, rather than generic, information about the withheld information.<sup>17</sup>

**B. Specific Privilege Log Protocols**

1. Privilege logs provided in lieu of producing documents requested shall comply with Rule 26(b)(5), which requires a party to:

- (a) Expressly identify the privilege asserted; and
- (b) Describe the nature of the documents, communications, or tangible things not produced or disclosed—and do so *in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim.*<sup>18</sup>

2. Privilege logs provided in lieu of producing documents requested shall substantially follow the form set forth in Exhibit 1.

3. Such privilege logs, if any – specifically identifying every withheld or redacted document by Bates number – shall be produced no more than 30 days after the date upon which the documents *are required to be produced or were partially produced.*

4. A separate entry in the privilege log – specifically identifying every withheld or redacted document by Bates number – shall be made for each document as to which any party asserts a privilege, with each entry identifying all parties asserting the privilege. E-mail threads may be treated as a single document with a single entry in the privilege log where the same claim of privilege or attorney work product extends to the entire thread. Large e-mail threads that are

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<sup>16</sup> *Hodges, Grant & Kaufmann v. United States*, 768 F.2d 719, 720 (5th Cir. 1985).

<sup>17</sup> *In re Pabst Licensing, GmbH Patent Litig.*, No. CIV. A. MDL 1298, 2001 WL 1135268, \*2-3 (E.D. La. Sept. 19, 2001).

<sup>18</sup> Fed. R. Civ. P. 26(b)(5).

not included in the same privilege claim shall be assigned separate Bates numbers and identified by separate entries in the privilege log if they are being withheld for a variety of privilege claims to allow separate descriptions of each privilege portion. Large e-mail threads that precede direct or limited exchanges with attorneys shall be assigned separate Bates numbers and identified by separate entries in the privilege log if they are being withheld pursuant to these guidelines.<sup>19</sup>

5. No entry on the privilege log asserting attorney-client privilege will be sufficient unless it provides a clear description showing that the attorney was acting in his or her professional legal capacity.<sup>20</sup>

6. Unacceptable descriptions are those that include only vague characterizations such as “documents regarding requests for legal advice,” “regulatory issues,” “study issues,” or “public relations documents” absent additional explanation clarifying the basis for the claim of privilege or work product protection.

7. No entry on the privilege log asserting work product privilege will be sufficient unless it provides a clear description that the subject document or communication directly relates to pending or threatened litigation.

8. It shall be insufficient to give only generic descriptions that simply incant the code words of the privilege, for example, “regarding litigation issues” or “preparatory measures taken in anticipation of litigation.”

9. It shall be inadequate to provide entries that do not identify authors or recipients contending instead that such information is “N/A” or “Distribution.”<sup>21</sup> In this circumstance,

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<sup>19</sup> *In re Vioxx Products Liab. Litig.*, 501 F. Supp. 2d 789, 812 (E.D. La. 2007). Simply because technology has made it possible to physically link these separate communications (which in the past would have been separate memoranda) does not justify treating them as one communication and denying the demanding party a fair opportunity to evaluate privilege claims raised by the producing party.

<sup>20</sup> *Id.* at 797.

<sup>21</sup> See *Freeport-McMoran Sulphur L.L.C. v. Mullen Energy Equipment Resources*, No. Civ.A. 03-1496, {L0210064.3}

identify is “to disclose the title and employer.” For each specific author or recipient listed, it shall be inadequate to provide entries that do not disclose the title and employer of those individuals who sent, who received, or who were copied on, allegedly privileged communications.

10. It shall be inadequate to provide entries containing only cryptic descriptions such as “list,” “presentation,” and “correspondence,” “attorney report,” “client inquiry,” “payment” and “attorney communication.”

11. It shall be inadequate to provide entries describing documents only as “labeling” or “regulatory” stemming from FDA regulation or perhaps in anticipation of FDA communications or inquiry.

12. It shall be inadequate to provide entries that do not identify the Bates numbers found on each and every withheld or redacted page.

#### **IV. Redaction of Confidential, Irrelevant, and Privileged Information.**

1. To protect against inappropriate disclosure of information subject to the attorney-client or other privilege and confidential information as defined in this Order, and to comply with all applicable state and federal laws and regulations, the Defendants or Plaintiffs may redact from produced documents, materials or other things, or portions thereof, the following items, or any other item(s) agreed upon by the parties or ordered by the Court:

- (a) The names, addresses, Social Security numbers, tax identification numbers, e-mail addresses, telephone numbers, and other personal identifying information of patients (including plaintiffs), health

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2004 WL 1299042, \* 11 (E.D. La. 2004), reconsideration denied, 2004 WL 1488665 (June 30, 2004) (“there is no way for the Court to know who prepared the draft insert, for whom it was prepared, and whether it was prepared for the purpose of seeking or rendering legal advice. Freeport has failed to establish that a privilege applies here . . .”).

care providers, and individuals enrolled as subjects in clinical studies or adverse event reports. Other general identifying information, however, such as patient or health care provider numbers, shall not be redacted unless required by state or federal law;

- (b) Materials that contain information protected from disclosure by the attorney-client privilege, the work product doctrine or any other recognized privilege;
- (c) Those portions of documents that contain information relating to Defendants' non-pioglitazone-containing medicines;
- (d) The street addresses, Social Security numbers, tax identification numbers, dates of birth, home telephone numbers, and cellular telephone numbers of employees in any records; and
- (e) The names, addresses, Social Security numbers, tax identification numbers, e-mail addresses, telephone numbers, and other personal identifying information of any clinical investigator in any records.

2. Defendants shall redact only those portions of a document that are within the scope of the permitted subject-matter set forth above, and not the entire document or page unless the entire document or page is within such scope.

3. Defendants shall indicate on each redaction a brief, but specific, identifier stating the basis for the redaction, *e.g.* "other product," "employee privacy," "attorney-client privilege." When a redacted document is produced, this identifier will be listed in a "reason for redaction" field included with the objective coding which accompanies the load file for the document production. Where a redaction is subsequently lifted by order of the Court or by agreement of

the parties (*e.g.*, subject to a privilege challenge), Defendants shall produce replacement media for that document, including the unredacted TIFF, text or OCR files, and objective coding, with appropriate load files.

4. Documents withheld from production based on a claim of privilege of any kind shall be identified, by Bates number and proper description, on a privilege log created in accordance with the stipulated protocol for discovery of electronically stored information.

5. Privilege logs shall promptly be supplemented under Fed. R. Civ. P. 26 (e)(1) as to any document which becomes producible thereafter.

6. Any failure to redact information described above does not waive any right to claims of privilege or privacy, or any objection, including relevancy, as to the specific document or any other document that is or will be produced.

#### **V. Inadvertent Production of Documents.**

Inadvertent production of documents (hereinafter “Inadvertently Produced Documents”) subject to work-product immunity, the attorney-client privilege, or other legal privilege protecting information from discovery shall not constitute a waiver of the immunity or privilege, provided that the Producing Party shall notify the Receiving Party in writing within 10 days from the discovery of the inadvertent production.

Upon receiving such a notification, the Inadvertently Produced Documents and all copies thereof shall, upon request, be returned to the Producing Party, all notes or other work product of the receiving party reflecting the contents of such materials shall be destroyed, and such returned or destroyed material shall be deleted from any litigation-support or other database.<sup>22</sup> Alternatively, the Receiving Party may elect to file a motion as described below. In the event that such a motion is filed, the Receiving Party, subject to the requirements below, may retain

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<sup>22</sup> Fed. R. Civ. P. 26(b)(5)(B).

possession of the Inadvertently Produced Documents as well as any notes or other work product of the receiving party reflecting the contents of such materials pending the resolution by the Court of the motion described below, but must not use or disclose the information until the motion is resolved.<sup>23</sup> Specifically, no use shall be made of such Inadvertently Produced Documents during depositions or at trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them. If the Receiving Party's motion is denied and the time to appeal has expired without an appeal being filed, the Receiving Party shall promptly comply with the provisions of this paragraph concerning the return of Inadvertently Produced Documents to the Producing Party.

A party receiving Inadvertently Produced Documents may, after receipt of a Producing Party's notice of inadvertent production, file a motion with the Court to dispute the claim of privilege or immunity. 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 a motion, 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. The Opposition shall be accompanied by a Sealing Motion.

## **VI. Privilege Dispute Procedure**

1. If at any time a Receiving Party wishes in good faith to dispute a privilege designation, such party shall notify the Producing 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.

2. 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.

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<sup>23</sup> *Id.*

3. 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 privilege designation(s) at issue.

4. If a Receiving Party elects to press a challenge to a privilege 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 privilege 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 privilege designation. Any such motion shall be accompanied by a Sealing Motion. On such motion, the Producing Party shall have the burden of proving that the materials 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, nor more than twenty-one (21) calendar days, to file and serve an Opposition, and the Receiving Party shall waive its right to file a reply brief.<sup>24</sup> The Opposition shall be accompanied by a Sealing Motion. 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. The Motion shall be accompanied by a Sealing Motion.

5. The Producing Party shall have the burden of proof on such motion to establish the propriety of its privilege or work product 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 designation shall not be shortened except upon a

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<sup>24</sup> If the number of pending challenges becomes burdensome, the parties agree to alter the schedule to provide sufficient time for an Opposition.

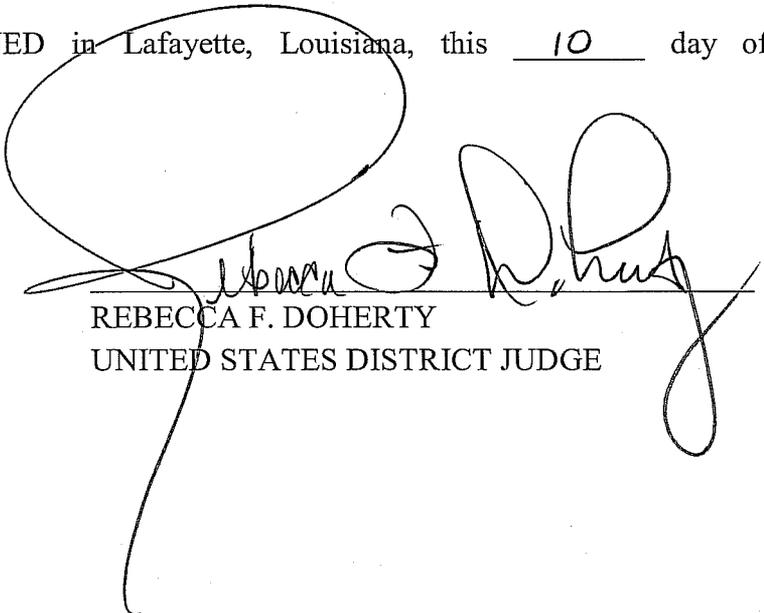
showing of good cause.

6. All discovery material designated as privileged under this Order, whether or not such designation is in dispute, shall retain that designation and be treated as privileged in accordance with the terms hereof unless and until:

- (a) the Producing Party agrees in writing that the material is no longer privileged and subject to the terms of this Order; or
- (b) fourteen (14) calendar days after the expiration of all appeal(s) period(s) of an Order(s) 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
- (c) the Producing Party does not respond as set forth above within fourteen (14) calendar days of service of the Dispute Notice; or
- (d) the Producing Party does not serve a motion within twenty-one (21) days of receiving a Challenge Notice.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 10 day of

July, 2012.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE