SUPERIOR COURT OF NEW JERSEY LAW DIVISION - MIDDLESEX COUNTY

CASE TYPE: MCL NO. 628

MASTER DOCKET NO. MID-L-4998-18-CM

FILED AUG 07 2019

Judge James F. Hytend

CIVIL ACTION
IN RE TAXOTERE LITIGATION

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PROTECTIVE ORDER

WHEREAS New Jersey Court Rule 4:10-3 authorizes the entry of an Order to limit disclosure of certain confidential information; and

WHEREAS the parties anticipate that discovery will include documents and information that are sensitive, confidential and proprietary in nature, and that contain confidential, proprietary and trade secrets essential to the continued business and privacy interests of the parties, the improper disclosure of which could cause substantial damage to the legitimate business interests and/or privacy interests of one or more parties; and

WHEREAS the parties, through their counsel, have stipulated and agreed to give effect to this Protective Order as set forth below to protect the designated information from use in any manner inconsistent with this Protective Order, and that any interpretation of the Protective Order to the contrary is rejected by these parties;

WHEREAS, the Court finds that there is good cause for the entry of this Order within the meaning of New Jersey Court <u>Rule</u> 4:10-3;

IT IS ON THIS ______, 2019, AGREED, STIPULATED AND ORDERED THAT:

- 1. This Protective Order applies to all documents and other products of discovery, all information derived therefrom and including, but not limited to, all copies, excerpts or summaries thereof, obtained by the Plaintiffs or Defendants pursuant to the requirements of any court order, any requirements of self-executing discovery, discovery requests under New Jersey Court Rules 4:17 (interrogatories), 4:18 (document requests) or 4:22 (requests for admissions); documents subpoenaed under New Jersey Court Rule 1:9-1, affidavits, certifications, memoranda, briefs, and transcripts of depositions and/or non-public or *in camera* hearings (hereinafter "Discovery Material").
- 2. <u>Scope</u>. All materials produced or adduced in the course of discovery, including responses to discovery requests, deposition testimony and exhibits, pleadings and motions, and information derived directly therefrom (hereinafter collectively "documents"), shall be subject to this Order concerning Confidential Information as defined below. This Order is subject to the New Jersey Court Rules on matters of procedure and calculation of time periods.
- 2. Confidential Information. As used in this Order, "Confidential Information" means unredacted information designated as "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER" by the Producing Party that falls within one or more of the following categories as designated in good faith by the party producing the material in accordance with the terms of this Protective Order (the "Producing Party") as being entitled to protection under New Jersey Court Rule 4:10-3 or other applicable case law, or as ordered by the Court: (a) information prohibited from disclosure by law; (b) information that reveals trade secrets; (c) research, technical, commercial or financial information that the party has maintained as confidential; (d) medical and

protected health information ("PHI") concerning any individual; (e) personal identifying information ("PII"); (f) income tax returns (including attached schedules and forms), W-2 forms and 1099 forms; and/or (g) personnel or employment records of a person who is not a party to the case.

4. Designation.

Procedure. A party may designate only the portion of a document that is entitled to be designated pursuant to R. 4:10-3, and shall designate as Confidential Information for protection under this Order by placing or affixing the words "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER" on the document, or page or pages, as applicable, and on all copies in a manner that will not interfere with the legibility of the document.

As used in this Order, the term "copies" includes electronic images, duplicates, extracts, summaries or descriptions that contain the Confidential Information. Except as otherwise set forth in paragraph 3.b, the marking "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER" shall be applied prior to or at the time that the documents are produced or disclosed. Applying the marking "CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER" to a document does not mean that the document has any status or protection by statute or otherwise except to the extent and for the purposes of this Order. Any copies made of any documents marked "CONFIDENTIAL -SUBJECT TO PROTECTIVE ORDER" shall also be so marked, except that indices, electronic databases or lists of documents that do not contain substantial portions or images of the text of Confidential Information and do not otherwise disclose the substance of the Confidential Information are not required to be marked. The parties shall make their best efforts to ensure that the stamp is affixed in such a manner as not to obliterate or obscure any written matter.

- a. <u>Electronic Discovery Material</u>. To the extent that Confidential Information stored or recorded in the form of electronic or magnetic media produced in native format (including information, files, databases or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes ("Electronic Discovery Material") is produced in such form, a party producing such Electronic Discovery Material may designate it as confidential by cover letter referring generally to the Electronic Discovery Material, or by designation in the accompanying load file.
- b. Inadvertent Failure to Designate. An inadvertent failure to designate a document, testimony, or other information as Confidential Information does not, standing alone, waive the right to subsequently so designate the information. A party may designate a document or ESI as Confidential Information following production, provided that such new designation is made promptly after discovery of inadvertent failure to designate. Upon such designation, the Receiving Party shall: treat such document or information as designated pursuant to the terms of this Order; take reasonable steps to return or destroy all previously-received copies of the information and provide certification of same; notify any persons known to have possession of such material of such new designation under this Order; and promptly endeavor to procure all copies of such materials from persons known to have possession of such material who are not entitled to receipt of it pursuant to this Order. No party shall be found to have violated this Order for failing to maintain the confidentiality of material during a time when that material has not been designated Confidential Information. Should any motion be filed concerning information designated as Confidential Information after production, the Receiving Party shall not assert in support of its position the fact or circumstances of the inadvertent disclosure of the Confidential Information.

c. Inadvertent Disclosure.

- (i) Pursuant to N.J.R.E. 520, the inadvertent production of documents subject to a claim of attorney-client privilege, the work-product privilege or other legal privilege or doctrine protecting information from discovery shall not constitute a waiver of the privilege or doctrine, provided that the Producing Party shall notify the Receiving Party in writing of such inadvertent production as soon as is practicable after discovery of the inadvertent production. Upon delivery of the request, such inadvertently produced documents and all copies thereof shall be returned to the Producing Party or destroyed, upon request, and such returned or destroyed material shall be deleted from any litigation-support or other database within five (5) days and may not be used for any purpose. No use shall be made of such documents during depositions or at any hearing or trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them. Moreover, any notes or summaries referring or relating to any such inadvertently produced documents shall be destroyed, except to the extent they are contained in work product created by counsel for the Requesting Party prior to the written request for return or destruction.
- lawyer who receives a document or electronic information and has reasonable cause to believe that the document or information was inadvertently sent shall not read the document or information or, if he or she has begun to do so, shall stop reading it. The lawyer shall (1) promptly notify the sender (2) return the document to the sender and, if in electronic form, delete it and take reasonable measures to assure that the information is inaccessible.
- (iii) Within fourteen (14) days of the Producing Party's request for return or destruction of the inadvertently produced information, the Producing Party shall provide a

privilege log corresponding to the information or material identified in the written notice sufficient to enable the Receiving Party to assess the claim. If the party receiving the inadvertently produced information wants to challenge the claim of privilege, work product, or other statutory or court-ordered confidentiality, Liaison Counsel for the Receiving Party may move before the Court for an order compelling production of the material relying on the information presented in the privilege log. Such motion shall not assert as a ground for entering such an order the fact or circumstances of the inadvertent production in this action, and shall not disclose the substance of the inadvertently produced material, except to the extent that an in camera inspection of the materials may be requested. The pendency of any such motion or dispute regarding the legitimacy of the claim of privilege or work product shall not entitle the moving party to retain or use the information. If the motion is denied, the document(s), along with any notes or other work product of the Receiving Party regarding the contents of such document(s), shall be destroyed or returned to the Producing Party.

- (iv) If a party subsequently re-produces in redacted form a document that had previously been inadvertently produced and then was returned or destroyed in its entirety based on a request under this Paragraph, the subsequently reproduced, redacted version of the document shall bear the same Bates number as the originally-produced document, along with an "-R" suffix.
- d. <u>Inspection of Materials Prior to Production.</u> In the event that documents, materials or other information are made subject to inspection prior to their production, no marking of those materials need be made by the Producing Party at the time of that inspection. For purposes of such an inspection, all materials made available for the inspection shall be considered Confidential Information and subject to this Order at the time of the inspection. Thereafter, if any materials subject

to that inspection are produced and the Producing Party wishes those materials to be considered Confidential Information under this Order, the Producing Party shall so designate them in accordance with the procedures set forth in this Order.

- e. <u>Certification by Counsel or Party</u>. The designation of materials as Confidential Information is made pursuant to New Jersey <u>Rule</u> 4:10-3.¹
- f. <u>Materials Designated in Other Litigation</u>. The parties agree to abide by the confidentiality designations under which documents, discovery material, or other information, including depositions, have been designated in cases in other jurisdictions involving Taxotere/Docetaxel, provided that these designations may be challenged pursuant to this Order, including the procedure described in Paragraph 13 herein.
- 5. <u>Depositions</u>. Deposition testimony and exhibits are protected by this Order if the testimony or exhibit, or portions thereof, as applicable, is designated as confidential when the deposition is taken or within thirty (30) business days. In the event that any question is asked at a deposition or non-public or *in camera* hearing, which a party asserts calls for Confidential Information, or a document containing Confidential Information is identified as an exhibit in testimony given in this action, such question shall nevertheless be answered by the witness fully and completely to the extent required by law. Such designation shall be specific as to the portions that contain Confidential Information. Until the expiration of the 30-day period, the deposition testimony, transcript, and all exhibits are protected by this Order if the testimony or exhibit is designated. The failure to serve a timely Notice of Designation waives any designation of deposition testimony as Confidential Information that was made on the record of the deposition, unless otherwise ordered by the Court. It is the obligation of the Producing Party to make any application to the

¹ By designating documents as confidential pursuant to this Order, counsel submits to the jurisdiction and authority of this Court concerning such designations and the enforcement of this Order.

Court with respect to the provisions of this paragraph and to bear all expenses that are necessitated thereby. Should there develop a conflict between the timing provisions set forth in this Paragraph and the timing provisions regarding motion procedures set forth in Paragraph 13, below, Paragraph 13 shall prevail.

6. Protection of Confidential Material.

- a. <u>General Protections.</u> Confidential Information shall not be used or disclosed by the parties, counsel for the parties or any other persons identified in subparagraph (b) for any purpose whatsoever other than in this litigation, which includes any appeal thereof.
- b. <u>Limited Third-Party Disclosures.</u> The parties and counsel for the parties shall not disclose or permit the disclosure of any Confidential Information to any third person or entity except as set forth below. Subject to these requirements, the following categories of persons may be allowed to review Confidential Information: (1) Counsel for the parties and employees of counsel who have responsibility for the action; (2) individual parties and officers, directors, employees, agents or representatives of a party but only to the extent counsel determines in good faith that the employee's assistance is reasonably necessary to the conduct of the litigation in which the information is disclosed; (3) the Court and its personnel; (4) court reporters and recorders engaged for depositions and/or hearings; (5) those persons specifically engaged for the limited purpose of making copies of documents or organizing or processing documents, including outside vendors hired to process electronically stored documents; (6) consultants, investigators, or experts employed by the parties or counsel for the parties to assist in the preparation and trial of this action but only after such persons have completed the certification contained in Attachment A ("Acknowledgment of Understanding and Agreement to Be Bound by Protective Order"); (7) during their depositions, or in preparation for their trial or deposition testimony, witnesses in this action to whom disclosure is reasonably necessary.

While a deponent is being examined about any Confidential Information, persons to whom disclosure is not authorized under this Order shall be excluded from the deposition. Witnesses may receive copies of exhibits in connection with review of the transcripts, but shall not retain a copy of documents containing Confidential Information. Pages of transcribed deposition testimony or exhibits to depositions that are designated as Confidential Information pursuant to the process set out in this Order must be separately bound by the court reporter and may not be disclosed to anyone except as permitted under this Order. (8) The author or recipient of the document in the regular course of business (not including a person who received the document in the course of litigation); and (9) other persons only by written consent of the Producing Party or upon order of the Court and on such conditions as may be agreed upon or ordered. The parties agree that this provision does not preclude the Producing Party from objecting to or moving to preclude disclosure to any person or to seek amendment of this provision in the future, if it believes it has a good faith basis for such objection or motion.

- c. <u>Non-Disclosure to Competitors.</u> Notwithstanding the foregoing, without express written consent or Court Order, a Receiving Party shall not disclose a defendant's Confidential Information to any current employee of any other manufacturer of, or manufacturer involved in the sale or distribution of, any taxane, irrespective of whether such person is retained as an expert in this action. If a party seeks to disclose confidential information to such person, the party seeking disclosure shall follow the notice provisions set forth in paragraph 15 below.
- 7. Prior to producing documents that contain the names of patients other than Plaintiffs and/or the physicians of such patients or consumers, the Producing Party may redact or delete the names, addresses, telephone numbers, social security numbers, and other information that would identify patients, research subjects and physicians or others constituting voluntary reporters or any other person associated with an adverse event, and any other information required

to be withheld from disclosure by 21 C.F.R. § 20.63, the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA") and related regulations, applicable federal and state privacy laws, and other applicable laws and regulations. Alternatively, the Producing Party may allow inspection of such documents but redact or delete the names of patients or physicians prior to allowing counsel for other parties to photocopy or otherwise record the contents of such documents. If the Producing Party produces copies of documents containing the names or other personal information of patients other than Plaintiffs or their physicians that is protected from disclosure pursuant to 21 C.F.R § 20.63, HIPAA or other governmental statute, rule or regulation, neither Plaintiffs nor their counsel shall disclose the names or other personal information or contact any such patient or physician identified to Plaintiffs or their counsel through the production of documents. The prohibition does not apply, however, to information that was obtained through sources independent from the Producing Party's discovery productions.

- 8. <u>Control of Documents.</u> Counsel for the parties shall make reasonable efforts to prevent unauthorized or inadvertent disclosure of Confidential Information. Counsel shall maintain the originals of the forms signed by persons acknowledging their obligations under this Order for a period of three (3) years after the termination of the case.
- 9. <u>Storage and Transmission of Documents.</u> To avoid security risks, a Receiving Party agrees to abide by existing HIPAA data protection provisions (e.g., Business Association Agreements) when handling Confidential Information and other ESI protected by federal or state law.
- 10. No Greater Protection of Specific Documents. Except on grounds of privilege not addressed by this Order or other orders of the Court, no party may withhold information from discovery on the ground that it requires protection greater than that afforded by this Order or other

orders of the Court unless the party moves for an order providing such special protection.

- 11. Challenges by a Party to Designation as Confidential Information. At any time during this case, the designation of any material or document as Confidential Information is subject to challenge by any party. The following procedure shall apply to any such challenge.
- a. <u>Meet and Confer.</u> At any time during the case, any party may challenge the designation of Confidential Information as confidential by written notice to the Producing Party's counsel specifying by exact document numbers the materials in dispute and a brief explanation of the basis for contesting the Confidential Information designation (the "Notice"). If the same document in the Notice appears in the production at other Bates numbers or locations, the Notice shall be deemed to be sufficient for all such documents and information. The Notice shall be sufficient if it identifies documents being challenged and states the basis for the challenge. Within seven (7) business days of receipt of the Notice, the Producing Party shall respond in writing, setting forth the reasons that the materials should continue to be treated as Confidential Information.
- b. <u>Judicial Intervention.</u> If the parties are unable to resolve the dispute, the Producing Party may apply by motion to the Court for a ruling as to whether the designated Discovery Material may properly continue to be treated as confidential, provided that such motion is made within fourteen (14) days from the date on which the written notice challenging the designation of material as "confidential" was received and either party has deemed the meet and confer process complete. The Producing Party shall have the burden of proof on such a motion to establish good cause pursuant to <u>Rule</u> 4:10-3 for the confidential designation and treatment. If no motion is filed within fourteen (14) days, the designated Confidential Information at issue shall no longer be treated a confidential or subject to this Protective Order.

- c. The Court may raise the issue of designation of Confidential Information without a request from any party.
- 12. **Action by the Court.** Applications to the Court for an order relating to materials or documents designated Confidential Information shall be by motion. Nothing in this Order or any action or agreement of a party under this Order shall limit the Court's authority to make orders concerning the disclosure of documents produced in discovery or at trial.
- 13. **Filings 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 a document that has been designated under this Protective Order as Confidential Information.
- a. For discovery-related motions, only the notice of motion will be filed with the clerk of the court. All other papers will be served upon the specific counsel of record in the specific case in the in the specific matter to which the motion applies, but not filed with the Court. Courtesy copies of all other motion papers will be provided to the Court for *in camera* use. Following its disposition of the motion, the Court will destroy the papers or return them to the filing party.
- b. For non-discovery motions, only the notice of motion initially will be filed with the clerk of the court. All other papers will be served in the specific matter to which the motion applies, but not filed with the Court. Courtesy copies of all other motion papers will be provided to the Court for *in camera* use. The parties shall set a schedule during a conference with the Court that is sufficient to allow ten (10) days after the completion of briefing by all parties for any party to file a motion to seal all or part of the papers. The parties shall exchange their respective moving, opposition and reply papers in accordance with the schedule set by the Court, but shall

not file these papers until ten (10) days after the service of the moving party's reply papers and then only if no party has filed a motion to seal any of the papers in support or in opposition to the motion. In the event that a party moves to seal any of the motion papers, it shall file a notice of motion to seal directly with the Honorable James F. Hyland, J.S.C. The parties shall also submit to the Honorable James F. Hyland at that time, for *in camera* use, their respective papers, including a version of the dispositive motion papers or exhibits with appropriate redactions consistent with the party's position on the motion to seal. After the Court disposes of the motion to seal, the Clerk will file the papers on both motions in accordance with the Court's order.

- c. When submitting a document that has been designated as Confidential Information to the Court pursuant to these procedures, the submitting party shall make an effort to submit only those portions of the document or transcript or other information that is cited, referred to, or relied upon by the submitting party. The party making a motion to seal pursuant to these procedures shall make an effort to redact and/or seek protection only over those portions of the papers or documents that require protection.
- d. Any and all documents to be filed under seal shall be placed in an envelope with a description of the contents sufficient for the Court Clerk to enter a brief description into the Court System.
- e. If Confidential Information is filed under seal pursuant to the procedure established herein, and is ordered by the Court to be maintained under seal, the Confidential Information and/or other papers shall be kept under seal until further order of the Court. However, said Confidential Information and other papers filed under seal shall be available to the Court and counsel of record, and to all other persons entitled to receive the Confidential Information contained therein under the terms of this Protective Order.

14. <u>Use of Confidential Documents or Information at Trial.</u> Nothing in this Order shall be construed to affect the use of any document, testimony, or information at any trial or hearing. A party who intends to present or who anticipates that another party may present Confidential Information at a hearing or trial, following a meet and confer, shall bring that issue to the Court's and parties' attention by motion or in a pretrial memorandum without disclosing the substance of the Confidential Information. The Court may thereafter make such orders as are necessary to govern the use of such documents or information at trial.

15. Confidential Information Subpoenaed or Ordered Produced in Other Litigation.

- a. If a Receiving Party is served with a request, subpoena, or order issued by another court, administrative agency, legislative body, or any other person or organization that directs disclosure of any material or document designated in this action as Confidential Information, the Receiving Party must so notify the Producing Party, in writing, immediately and in no event more than three (3) court days after receiving the request, subpoena, or order. Such notification must include a copy of the request, subpoena or court order. The recipient of the request, subpoena, or order shall not disclose any Confidential Information pursuant to the same prior to the date specified for production in the request, subpoena, or order.
- b. The Receiving Party also must immediately inform, in writing, the person or entity that issued the request, subpoena, or order that some or all of the material covered by the request, subpoena, or order is the subject of this Order. In addition, the Receiving Party must deliver a copy of this Order promptly to the party, person, or other entity that issued the request, subpoena or order.
- c. The purpose of imposing these duties is to alert the issuing person or entity to the existence of this Order and to afford the Producing Party in this case an opportunity to make attempts to protect its Confidential Information in the court from which the subpoena or order issued.

The Producing Party shall bear the burden and the expense of seeking protection of its Confidential Information, and nothing in these provisions should be construed as authorizing or encouraging a Receiving Party in this action to disobey a lawful directive from another court or authority. The obligations set forth in this paragraph remain in effect while the party has in its possession, custody or control Confidential Information by the other party to this case.

16. Obligations upon Conclusion of Litigation.

- a. Order Continues in Force. Unless otherwise agreed upon or ordered, this

 Order shall remain in force after dismissal or entry of final judgment not subject to further appeal.
- Obligations upon Conclusion of Litigation. Within sixty (60) days after dismissal or entry of final judgment not subject to further appeal, the Producing Party may make demand upon the Receiving Party for return or destruction of all materials considered Confidential Information under this Order, including "copies" as defined above. No party shall have any obligation to return or destroy Confidential Information if such a demand is not timely made. Where the demand for return or destruction is timely made, the subject documents shall be returned to the Producing Party that are within his/her possession or subject to his/her control unless: (1) the document has been offered into evidence or filed without restriction as to disclosure; (2) the parties agree to destruction to the extent practicable in lieu of return; or summations, or other mental impressions of the Receiving Party (i.e., attorney work product), that party elects to destroy the documents and certifies to the Producing Party that it has done so; or (4) to the extent retention is required by other laws, rules or regulations, including those of the New Jersey State Bar Association and New Jersey Supreme Court. The parties may choose to agree that the Receiving Party shall destroy documents containing Confidential Information and certify the fact of destruction, and that the Receiving Party shall not be required to locate, isolate and return e-mails

(including attachments to e-mails) that may include Confidential Information or Confidential Information contained in deposition transcripts or drafts or final expert reports.

- Notwithstanding the above requirements to return or destroy documents, counsel may retain: (1) attorney work product, including an index that refers or relates to designated Confidential Information, so long as that work product does not duplicate verbatim substantial portions of Confidential Information, and (2) one complete set of all documents filed with the Court including those filed under seal. Any retained Confidential Information shall continue to be protected under this Order. An attorney may use his or her own work product in subsequent litigation, provided that its use does not disclose or use Confidential Information or otherwise violate this Order.
- Order Subject to Modification. This Order shall be subject to modification by the Court on its own initiative, on motion of a party or any other person with standing concerning the subject matter, or by the agreement of counsel for the parties in the form of a stipulation submitted to the Court for approval. If the parties cannot agree to an amendment, either party may contact the Court for the scheduling of a telephone conference call with counsel to review whether the requested Amendment is necessary. In the event said conference call does not resolve the question to both sides' satisfaction, either may petition the Court via formal Notice of Motion.
- 18. No Prior Judicial Determination. This Order is entered based on the representations and agreements of the parties and for the purpose of facilitating discovery. Nothing herein shall be construed or presented as a judicial determination that any document or material designated Confidential Information by counsel or the parties is entitled to protection under Rule 4:10-3 or otherwise until such time as the Court may rule on a specific document or issue.

- 19. <u>Persons Bound</u>. This Order shall take effect when entered and shall be binding upon all counsel of record and their law firms, the parties, and persons made subject to this Order by its terms.
- 20. This Protective Order applies to all proceedings in these cases, including any appeals, and upon final termination of this case, whether by judgment, settlement or otherwise, including all appeals, the clerk of the court shall return to the Producing Parties all documents designated as Confidential Information that have been filed under seal and have not been the subject of an order of the Court ruling on the non-confidentiality of the materials.

Dated: 07/19

Hon. James F. Hyland, J.S.C.

SUPERIOR COURT OF NEW JERSEY LAW DIVISION - MIDDLESEX COUNTY

CASE TYPE: MCL NO. 628

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Signature:

AGREEMENT TO MAINTAIN CONFIDENTIALITY & ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND

The undersigned hereby acknowledges that he/she has read the Protective Order dated
in the above-captioned action and attached hereto, understands the terms thereof and agrees to be bound
by those terms. The undersigned submits to the jurisdiction of the Superior Court of New Jersey,
Middlesex County in matters relating to the aforementioned and attached Protective Order and
understands that the terms of the Order obligate him/her to use materials designated as Confidentia
Information in accordance with the Order solely for the purposes of the above-captioned action, and no
to disclose any such Confidential Information to any other person, firm or concern. The undersigned
acknowledges that violation of the Protective Order may result in penalties for contempt of court.
Name (printed):
Job Title:
Employer:
Business Address:
Date: