

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION



ORIGINAL

_____)
In the Matter of)
)
Impax Laboratories, Inc.,)
a corporation.)
)
)
_____)

DOCKET NO. 9373

**UNOPPOSED MOTION OF NON-PARTY PURDUE PHARMA, L.P.
FOR *IN CAMERA* TREATMENT OF DESIGNATED TRIAL EXHIBITS**

Pursuant to Rule 3.45 of the Federal Trade Commission’s Rules of Practice, 16 C.F.R. § 3.45(b), non-party Purdue Pharma, L.P. (“Purdue”) respectfully moves this Court for *in camera* treatment of competitively sensitive documents from Purdue’s files that Impax intends to offer into evidence in this matter (together, the “Confidential Documents”). Purdue produced these documents, among others, in response to the third-party subpoena duces tecum issued by the Federal Trade Commission (“FTC”) on June 23, 2017 (attached as Exhibit A) that *inter alia* required Purdue to submit the “final version of each annual brand or strategic plan for the product OxyContin® from the year 2006 to 2014.” Exhibit A at 3.

I. Introduction

The Confidential Documents for which Purdue seeks *in camera* treatment contain highly confidential, competitively sensitive proprietary information that Purdue guards carefully. The documents include any number of trade secrets important for Purdue’s business, including such matters as sales and marketing initiatives, discounting tactics, training plans for providing prescribers and patients appropriate information, goals for negotiations with third-party payors,

and internal training and compliance information. This information is financially and competitively valuable to Purdue, is subject to confidentiality protections, and is carefully maintained by Purdue in a manner that protects its secrecy.

The disclosure of the competitively sensitive information contained in the Confidential Documents would harm Purdue's competitive ability in the marketplace, harm competition between and among companies that are marketing and selling opioids or planning to do so, and harm consumers and third-party payors by diminishing price and non-price competitive conduct for certain categories of prescription pharmaceuticals. For these reasons, more fully described below, Purdue requests that this Court provide *in camera* treatment for these documents indefinitely. In support of this motion, Purdue relies on the Declaration of Mr. Edward B. Mahony, Executive Vice President, attached as Exhibit B.

II. Information for Which *In Camera* Treatment is Sought

Purdue requests *in camera* treatment for each of the following Confidential Documents, attached as Exhibit C.

EXHIBIT NO.	BATES BEGIN	BATES END	DESCRIPTION
RX-444	Purdue Pharma 02_000095	Purdue Pharma 02_000127	Purdue Presentation, OxyContin [®] Tablets 2009 Marketing Plan
RX-445	Purdue Pharma 02_000128	Purdue Pharma 02_000157	2010 Purdue Presentation, OxyContin [®] Tablets Budget Presentation (Nov. 2009)
RX-446	Purdue Pharma 02_000158	Purdue Pharma 02_000241	Purdue Presentation, 2011 OxyContin [®] Tablets Budget Submission (Nov. 2010)
RX-447	Purdue Pharma 02_000242	Purdue Pharma 02_000319	Purdue Presentation, 2012 Budget Presentations Marketing Overview (2012)
RX-448	Purdue Pharma 02_000320	Purdue Pharma 02_000366	Purdue Presentation, Sales & Marketing, Opioid Market Overview
RX-449	Purdue Pharma 02_000367	Purdue Pharma 02_000400	2013 OxyContin [®] (oxycodone HCL controlled-release) Tablets Annual Marketing Plan (Oct. 6, 2013)

III. Standard for *In Camera* Treatment

In camera treatment of material is appropriate when its “public disclosure will likely result in a clearly defined, serious injury to the person, partnership, or corporation requesting” such treatment. 16 C.F.R. § 3.45(b). A movant demonstrates serious competitive injury by showing that the documents are secret and that they are material to the business. *In re General Foods Corp.*, 95 FTC 352, 355 (1980); *In re Dura Labe Corp.*, 1999 FTC LEXIS 255, *5 (1999). In this context, courts generally attempt “to protect confidential business information from unnecessary airing.” *H.P. Hood & Sons, Inc.*, 58 FTC 1184, 1188 (1961).

In considering both secrecy and materiality, the Court may consider: (1) the extent to which the information is known outside of the business; (2) the extent to which it is known by employees and others involved in the business; (3) the extent of measures taken to guard the secrecy of the information; (4) the value of the information to the business and its competitors; (5) the amount of effort or money expended in developing the information; and (6) the ease or difficulty with which the information could be acquired or duplicated by others. *In re Bristol-Myers Co.*, 90 FTC 455, 456-457 (1977). An applicant for *in camera* treatment can establish such serious injury by showing that the information at issue is “sufficiently secret and sufficiently material to the applicant’s business that disclosure would result in serious competitive injury.” *In re General Foods Corp.*, 95 FTC 352, 355 (1980). Furthermore, a showing of injury may consist of extrinsic evidence or, in certain instances, may be inferred from the nature of the documents themselves. *In re E.I. Dupont de Nemours & Co.*, 97 FTC 116 (1981).

While FTC Rule 3.45(b)(3) provides that indefinite *in camera* treatment is only warranted “in unusual circumstances,” the FTC has recognized that “in some unusual cases the competitive sensitivity or the proprietary value of the information for which *in camera* treatment

is requested will not necessarily diminish, and may actually increase, with the passage of time.”

In re Coca-Cola Co., 1990 FTC LEXIS 364, at *7 (Oct. 17, 1990) (internal citations omitted);

In re Jerk, LLC, 2015 FTC LEXIS 39 (Feb. 23, 2015).

Finally, Purdue’s status as a third party is relevant to the treatment of the Confidential Documents. The FTC has held that “[t]here can be no question that the confidential records of businesses involved in Commission proceedings should be protected insofar as possible.” *H.P. Hood & Sons*, 58 FTC at 1186. Indeed, third parties warrant “special solicitude” in requests for in camera treatment of confidential business information. See *In re Kaiser Aluminum & Chem. Corp.*, 103 FTC 500, 500 (1984) (“As a policy matter, extensions of confidential or *in camera* treatment in appropriate cases involving third party bystanders encourages cooperation with future adjudicative discovery requests.”). Purdue’s third-party status therefore weighs in favor of granting *in camera* status to the Confidential Documents.

IV. Purdue’s Documents are Secret and Material such that Disclosure Would Result in Serious Injury to Purdue and Harm to Competition in the Marketplace

The Confidential Documents are both secret and material to Purdue’s business operations. They detail such competitive secrets as launch strategies, marketing goals and tactics, and decisions regarding development projects, and they provide specific information about Purdue’s overall competitive strategies and implementation plans for those strategies. This information could readily be used by competitors to undermine Purdue’s competitiveness in the market, providing a literal roadmap to Purdue’s upcoming strategies in both the near term and over the long run, and to harm competition generally in the marketplace.

A. Purdue Expends Significant Resources and Effort to Develop the Information Contained in the Confidential Documents

The Confidential Documents describe the most important aspects of Purdue's market strategy for OxyContin[®]. Purdue gathers its best intelligence company-wide to analyze such competitive elements as product research, development opportunities and unmet patient needs; marketing and sales trends; Purdue's and competitor products' performance in the marketplace; and practitioners' prescribing patterns. Together, these elements are then used to develop forward-looking goals and opportunities and to set specific objectives for each upcoming year. The Confidential Documents represent the culmination of all of Purdue's efforts and resources devoted to each product over the years subject to the subpoena duces tecum. For example, the Confidential Documents summarize Purdue's plans regarding the manner and timing of Purdue's Saving Card Program and other price reduction plans as well as promotion strategies for OxyContin[®], they describe Purdue's analysis of the efficacy of these plans and intended recalibration of these strategies, and they adjust the plans for the upcoming year based upon those analyses. Perhaps most importantly, the documents describe product launch and marketing repositioning plans and the timing for these plans. Together, these plans provide a literal roadmap for its competition in the marketplace.

B. Purdue Takes Great Care to Ensure Neither Its Competitors Nor Individuals Outside of Purdue Have Access to the Information In the Confidential Documents

Purdue takes significant efforts to guard the confidentiality of the Confidential Documents and to provide appropriate instruction throughout the company. Each employee must sign a confidentiality agreement that describes what is confidential and how to protect confidential information, and Purdue's internal compliance department trains employees on protecting confidentiality to ensure everyone knows and understands the importance of keeping confidential

information secret. Purdue's Employee Manual makes clear that failure to protect confidential information may result in disciplinary action up to and including termination of employment. The handling of confidential information is addressed in Purdue's Code of Business Ethics, which includes specific provisions calling for the protection of confidential and proprietary information. The Confidential Documents for which Purdue seeks *in camera* treatment are included in those the company trains its employees to protect, and the systematic approach that Purdue has employed with regard to the Confidential Documents has, to the best of Purdue's knowledge, resulted in their confidentiality up to this point in time.

Purdue's efforts to ensure confidentiality of its competitively sensitive information is of material importance to its own business. Purdue has internalized the axiom that the public disclosure of Purdue's strategic decision-making documents and information will destroy their value to Purdue and inure to the significant benefit of its competitors. Other companies would readily be able to use the information to compete unfairly against Purdue. Indeed, Purdue instituted the internal processes to protect confidential information, as described above, exactly because Purdue has long recognized that this information in the wrong hands could harm Purdue and be used by its competitors to gain an unfair advantage in the market.

C. The Information in the Confidential Documents Would Be Valuable to Competitors Seeking an Unfair Advantage in the Marketplace, Who Could Not Otherwise Develop the Information

The Confidential Documents would be competitively valuable to Purdue's competitors. Other companies could use the trade secret, proprietary, and confidential information to emulate or undermine Purdue's competitive efforts. Much of this information could only be developed by individuals with inside knowledge of Purdue. Because the information could not be developed independently by competitors, it would be very valuable to them.

A competitor with this knowledge could use it to gauge its own competition efforts to just meet and barely better the Purdue strategy rather than facing Purdue's market strategy with its own aggressive competition. Even Purdue's relatively older documents, such as the 2009 Marketing Plan (marked as RX-444), have significant competitive importance, precisely because they provide strategically valuable competitive insights, such as this document's discussion of whether, when and how to launch new dosage strengths of OxyContin[®] and the evolution of Purdue's Savings Card Program strategies. In short, competitors overall would be able to cease competing as vigorously against Purdue because they would understand ahead of time critical elements of their competitive target—Purdue's pricing and marketing strategies. Such an outcome would harm Purdue and inhibit competition. The disclosure of this information would allow Purdue's competitors to determine Purdue's possible future strategic moves in managing its products and would provide those companies an unfair advantage in competing against Purdue, but Purdue would have no access to its competitors' information. Purdue would therefore be weakened competitively. The current competitive uncertainty among Purdue and other companies inures to customers' benefits keeping prices for drugs at competitive prices lower than they might be if Purdue's documents are made public and, similarly, encouraging product innovation among all competitors.

D. The Confidential Documents Include Confidential and Proprietary Information About Butrans[®], Which Was Not Responsive to the Subpoena Duces Tecum But Was Included Pursuant to Its Instructions Prohibiting Redaction

The Confidential Documents also include information and marketing plans that relate to a product other than OxyContin[®]. The FTC's subpoena duces tecum requested that Purdue provide certain documents related to OxyContin[®] but instructed also that no documents could be redacted

prior to submission. As a result, the Confidential Documents include some pages devoted entirely to another Purdue product, Butrans[®]. This information was not responsive to the subpoena and thus presumably therefore is not relevant to this litigation. Nevertheless the disclosure of these nonresponsive materials exposes Purdue to injury, and has the same harmful potential impact on the opioid market as the disclosure of Purdue's highly confidential business strategy for OxyContin[®] that is described above. Thus, Purdue requests that the Confidential Documents be redacted to remove also that information related to plans for other Purdue products.

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It is with this understanding of continued confidentiality protections, including *in camera* treatment, that Purdue complied with this Court's subpoena in an expeditious and cooperative manner. The promise of confidentiality was crucial to Purdue's decision to submit its materials without contesting the fact that the subpoena requested some of Purdue's most carefully guarded documents that provide direction for the Company's most significant product, OxyContin[®].

Because of the highly confidential nature of the information, its materiality to Purdue's business, and the potential adverse harm to competition, *in camera* treatment is appropriate for the Confidential Documents.

V. Conclusion

Purdue, in seeking to remain competitive in the pharmaceutical industry, maintains certain highly sensitive documents. The disclosure of these documents would result in serious injury to Purdue's ability to compete and competitive harm to the opioid marketplace as well. For the

reasons provided in this motion and in the Declaration of Mr. Edward Mahony, Purdue respectfully requests that this Court grant the six Confidential Documents *in camera* treatment.

Respectfully submitted,

A handwritten signature in blue ink that reads "Claudia R. Higgins". The signature is written in a cursive style with a horizontal line underneath the name.

Claudia R. Higgins
Shawna Bray
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Avenue, NW
Washington, D.C. 20001
(202) 942-5000

Counsel for Purdue Pharma L.P.

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of Impax Laboratories, Inc., a corporation.))))))))))	DOCKET NO. 9373
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**[PROPOSED] ORDER GRANTING UNOPPOSED MOTION OF NON-PARTY
PURDUE PHARMA, L.P. FOR *IN CAMERA* TREATMENT
OF DESIGNATED TRIAL EXHIBITS**

Upon consideration of Non-Party Purdue Pharma, L.P.’s (“Purdue’s”) Motion for *In Camera* Treatment of Designated Trial Exhibits, it is HEREBY ORDERED that the following documents are to be provided permanent *in camera* treatment from the date of this Order in their entirety.

ORDERED:

D. Michael Chappell
Chief Administrative Law Judge

Date: _____

EXHIBIT A



SUBPOENA DUCES TECUM

Provided by the Secretary of the Federal Trade Commission, and
Issued Pursuant to Commission Rule 3.34(b), 16 C.F.R. § 3.34(b)(2010)

1. TO Purdue Pharma L.P. c/o Claudia R. Higgins, Esq. Arnold & Porter Kaye Scholer LLP 601 Massachusetts Ave., NW Washington, DC 20001	2. FROM <p style="text-align: center;">UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION</p>
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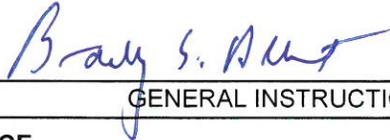
This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things, at the date and time specified in Item 5, and at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION Federal Trade Commission c/o Eric M. Sprague, Esq. 400 7th Street, SW Washington, DC 20024	4. MATERIAL WILL BE PRODUCED TO Eric M. Sprague, Esq. <hr/> 5. DATE AND TIME OF PRODUCTION June 23, 2017 at 9:00am
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6. SUBJECT OF PROCEEDING In the Matter of Impax Laboratories, Inc., Docket No. 9373
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7. MATERIAL TO BE PRODUCED Documents & materials responsive to the attached Subpoena Duces Tecum Requests for Production

8. ADMINISTRATIVE LAW JUDGE The Honorable D. Michael Chappell Federal Trade Commission Washington, D.C. 20580	9. COUNSEL AND PARTY ISSUING SUBPOENA Charles A. Loughlin, or designee Federal Trade Commission 400 7th Street, SW Washington, DC 20024 (202) 326-2114
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DATE SIGNED <i>5/24/17</i>	SIGNATURE OF COUNSEL ISSUING SUBPOENA 
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GENERAL INSTRUCTIONS

APPEARANCE

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply.

MOTION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any motion to limit or quash this subpoena must comply with Commission Rule 3.34(c), 16 C.F.R. § 3.34(c), and in particular must be filed within the earlier of 10 days after service or the time for compliance. The original and ten copies of the petition must be filed before the Administrative Law Judge and with the Secretary of the Commission, accompanied by an affidavit of service of the document upon counsel listed in Item 9, and upon all other parties prescribed by the Rules of Practice.

TRAVEL EXPENSES

The Commission's Rules of Practice require that fees and mileage be paid by the party that requested your appearance. You should present your claim to counsel listed in Item 9 for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from counsel listed in Item 9.

A copy of the Commission's Rules of Practice is available online at <http://bit.ly/FTCRulesofPractice>. Paper copies are available upon request.

This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

RETURN OF SERVICE

I hereby certify that a duplicate original of the within subpoena was duly served: (check the method used)

- in person.*
- by registered mail.*
- by leaving copy at principal office or place of business, to wit:*

via FedEx

on the person named herein on:

May 24, 2017

(Month, day, and year)

Eric M. Sprague

(Name of person making service)

Attorney

(Official title)

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of

Impax Laboratories, Inc.,
a corporation.

Docket No. 9373

COMPLAINT COUNSEL'S SUBPOENA *DUCES TECUM* ATTACHMENT
TO PURDUE PHARMA L.P.

Pursuant to the Federal Trade Commission's Rule of Practice, 16 C.F.R. § 3.34, and the Definitions and Instructions set forth below, Complaint Counsel hereby requests that the Company produce all documents, electronically stored information, and other things in its possession, custody, or control responsive to the following requests:

1. All agreements submitted by Purdue to the Federal Trade Commission pursuant to Section 1112(a) of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 relating to the drug product OxyContin.
2. The final version of each annual brand or strategic plan for the drug product OxyContin from the year 2006 to 2014.

For the purpose of this Subpoena, the following definitions and instructions apply without regard to whether the defined terms used herein are capitalized or lowercase and without regard to whether they are used in the plural or singular forms:

DEFINITIONS

1. The terms "Purdue," "Company," "You," or "Your" mean Purdue Pharma L.P., the Purdue Frederick Company Inc., the P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., their directors, officers, trustees, employees, attorneys, agents, accountants, consultants, and representatives, its domestic and foreign parents, predecessors, divisions, subsidiaries, affiliates, partnerships and joint ventures, and the directors, officers, trustees, employees, attorneys, agents, consultants, and representatives of its domestic and foreign parents, predecessors, divisions, subsidiaries, affiliates, and partnerships and joint ventures.

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2. The term “agreement” means any oral or written contract, arrangement, or understanding, whether formal or informal, between two or more persons, together with all modifications or amendments thereto.
3. The terms “and” and “or” have both conjunctive and disjunctive meanings.
4. The term “Computer Files” includes information stored in, or accessible through, computer or other information retrieval systems. Thus, the Company should produce Documents that exist in machine-readable form, including Documents stored in personal computers, portable computers, workstations, minicomputers, mainframes, servers, backup disks and tapes, archive disks and tapes, and other forms of offline storage, whether on or off company premises. If the Company believes that the required search of backup disks and tapes and archive disks and tapes can be narrowed in any way that is consistent with Complaint Counsel’s need for Documents and information, you are encouraged to discuss a possible modification to this instruction with the Complaint Counsel identified on the last page of this request. Complaint Counsel will consider modifying this instruction to:
 - a. exclude the search and production of files from backup disks and tapes and archive disks and tapes unless it appears that files are missing from files that exist in personal computers, portable computers, workstations, minicomputers, mainframes, and servers searched by the Company;
 - b. limit the portion of backup disks and tapes and archive disks and tapes that needs to be searched and produced to certain key individuals, or certain time periods or certain specifications identified by Complaint Counsel; or
 - c. include other proposals consistent with Commission policy and the facts of the case.
5. The term “Containing” means containing, describing, or interpreting in whole or in part.
6. The terms “Discuss” or “Discussing” mean in whole or in part constituting, Containing, describing, analyzing, explaining, or addressing the designated subject matter, regardless of the length of the treatment or detail of analysis of the subject matter, but not merely referring to the designated subject matter without elaboration. A document that “Discusses” another document includes the other document itself.
7. The term “Documents” means all Computer Files and written, recorded, and graphic materials of every kind in the possession, custody, or control of the Company. The term “Documents” includes, without limitation: electronic mail messages; electronic correspondence and drafts of documents; metadata and other bibliographic or historical data describing or Relating to documents created, revised, or distributed on computer systems; copies of documents that are not identical duplicates of the originals in that Person’s files; and copies of documents the originals of which are not in the possession, custody, or control of the Company.

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Unless otherwise specified, the term “Documents” excludes (a) bills of lading, invoices, purchase orders, customs declarations, and other similar documents of a purely transactional nature; (b) architectural Plans and engineering blueprints; and (c) documents solely Relating to environmental, tax, human resources, OSHA, or ERISA issues.

8. The terms “each,” “any,” and “all” mean “each and every.”
9. The term “NDA” means New Drug Application, as defined in Title I of the Drug Price Competition and Patent Term Restoration Act of 1984.
10. The term “OxyContin” means all dosage strengths of the drug product covered by NDA No. 022272 or NDA No. 20-553.
11. The term “Person” includes the Company, and means any natural person, corporate entity, partnership, association, joint venture, governmental entity, trust, or any other organization or entity engaged in commerce.
12. The terms “Plan” or “Plans” mean proposals, strategies, recommendations, analyses, reports, or considerations, whether or not tentative, preliminary, precisely formulated, finalized, authorized, or adopted.
13. The terms “Relate” or “Relating to” mean in whole or in part Discussing, constituting, commenting, Containing, concerning, embodying, summarizing, reflecting, explaining, describing, analyzing, identifying, stating, referring to, dealing with, or in any way pertaining to.

INSTRUCTIONS

1. This request for documents shall be deemed continuing in nature so as to require production of all documents responsive to any specification included in this request produced or obtained by the Company up to forty-five (45) calendar days prior to the date of the Company’s full compliance with this request.
2. Except for privileged material, the Company will produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they directly relate to the specified subject matter. The Company should submit any appendix, table, or other attachment by either attaching it to the responsive document or clearly marking it to indicate the responsive document to which it corresponds. Except for privileged material, the Company will not redact, mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.
3. Unless modified by agreement with Complaint Counsel, this subpoena requires a search of all documents in the possession, custody, or control of the Company including, without limitation, those documents held by any of the Company’s officers, directors, employees, agents, representatives, or legal counsel, whether or not such documents are on the premises of the Company. If any person is unwilling to have his or her files searched, or is unwilling to produce responsive documents, the Company must provide the Complaint

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Counsel with the following information as to each such person: his or her name, address, telephone number, and relationship to the Company. In addition to hard copy documents, the search must include all of the Company's Electronically Stored Information.

4. Form of Production. The Company shall submit all documents as instructed below absent written consent signed by Complaint Counsel.
 - a. Documents stored in electronic or hard copy formats in the ordinary course of business shall be submitted in the following electronic format provided that such copies are true, correct, and complete copies of the original documents:
 - i. Submit Microsoft Excel, Access, and PowerPoint files in native format with extracted text and applicable metadata and information as described in subparts (a)(iii) and (a)(iv).
 - ii. Submit emails in image format with extracted text and the following metadata and information:

Metadata/Document Information	Description
Beginning Bates number	The beginning bates number of the document.
Ending Bates number	The last bates number of the document.
Custodian	The name of the custodian of the file.
To	Recipient(s) of the email.
From	The person who authored the email.
CC	Person(s) copied on the email.
BCC	Person(s) blind copied on the email.
Subject	Subject line of the email.
Date Sent	Date the email was sent.
Time Sent	Time the email was sent.
Date Received	Date the email was received.
Time Received	Time the email was received.
Attachments	The Document ID of attachment(s).
Mail Folder Path	Location of email in personal folders, subfolders, deleted items or sent items.

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Message ID	Microsoft Outlook Message ID or similar value in other message systems.
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- iii. Submit email attachments in image format, or native format if the file is one of the types identified in subpart (a)(i), with extracted text and the following metadata and information:

Metadata/Document Information	Description
Beginning Bates number	The beginning bates number of the document.
Ending Bates number	The last bates number of the document.
Custodian	The name of the custodian of the file.
Parent Email	The Document ID of the parent email.
Modified Date	The date the file was last changed and saved.
Modified Time	The time the file was last changed and saved.
Filename with extension	The name of the file including the extension denoting the application in which the file was created.
Production Link	Relative file path to production media of submitted native files. Example: FTC-001\NATIVE\001\FTC-00003090.xls.
Hash	The Secure Hash Algorithm (SHA) value for the original native file.

- iv. Submit all other electronic documents in image format, or native format if the file is one of the types identified in subpart (a)(i), accompanied by extracted text and the following metadata and information:

Metadata/Document Information	Description
Beginning Bates number	The beginning bates number of the document.
Ending Bates number	The last bates number of the document.
Custodian	The name of the custodian of the file.

Modified Date	The date the file was last changed and saved.
Modified Time	The time the file was last changed and saved.
Filename with extension	The name of the file including the extension denoting the application in which the file was created.
Originating Path	File path of the file as it resided in its original environment.
Production Link	Relative file path to production media of submitted native files. Example: FTC-001\NATIVE\001\FTC-00003090.xls.
Hash	The Secure Hash Algorithm (SHA) value for the original native file.

- v. Submit documents stored in hard copy in image format accompanied by OCR with the following information:

Metadata/Document Information	Description
Beginning Bates number	The beginning bates number of the document.
Ending Bates number	The last bates number of the document.
Custodian	The name of the custodian of the file.

- vi. Submit redacted documents in PDF format accompanied by OCR with the metadata and information required by relevant document type in subparts (a)(i) through (a)(v) above. For example, if the redacted file was originally an attachment to an email, provide the metadata and information specified in subpart (a)(iii) above. Additionally, please provide a basis for each privilege claim as detailed in Instruction 6.
- b. Submit data compilations in electronic format, specifically Microsoft Excel spreadsheets or delimited text formats such as CSV files, with all underlying data un-redacted and all underlying formulas and algorithms intact.
- c. If the Company intends to utilize any electronic search terms, de-duplication or email threading software or services when collecting or reviewing information that is stored in the Company's computer systems or electronic storage media, or if the Company's computer systems contain or utilize such software, the Company must contact the Commission to determine, with the assistance of the

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appropriate Commission representative, whether and in what manner the Company may use such software or services when producing materials in response to this Subpoena.

- d. Produce electronic file and image submissions as follows:
 - i. For productions over 10 gigabytes, use IDE, EIDE, and SATA hard disk drives, formatted in Microsoft Windows-compatible, uncompressed data in a USB 2.0 external enclosure;
 - ii. For productions under 10 gigabytes, CD-R CD-ROM optical disks formatted to ISO 9660 specifications, DVD-ROM optical disks for Windows-compatible personal computers, and USB 2.0 Flash Drives are acceptable storage formats; and
 - iii. All documents produced in electronic format shall be scanned for and free of viruses prior to submission. The Commission will return any infected media for replacement, which may affect the timing of the Company's compliance with this Subpoena.
 - iv. Encryption of productions using NIST FIPS-compliant cryptographic hardware or software modules, with passwords sent under separate cover, is strongly encouraged.¹
 - e. Each production shall be submitted with a transmittal letter that includes the FTC matter number; production volume name; encryption method/software used; passwords for any password protected files; list of custodians and document identification number range for each; total number of documents; and a list of load file fields in the order in which they are organized in the load file.
5. All documents responsive to these requests:
- a. Shall be produced in complete form, unredacted unless privileged, and in the order in which they appear in the Company's files;
 - b. Shall be marked on each page with corporate identification and consecutive document control numbers when produced in image format;
 - c. Shall be produced in color where necessary to interpret the document (if the coloring of any document communicates any substantive information, or if black and white photocopying or conversion to TIFF format of any document (e.g., a

¹ The National Institute of Standards and Technology (NIST) issued Federal Information Processing Standard (FIPS) Publications 140-1 and 140-2, which detail certified cryptographic modules for use by the U.S. Federal government and other regulated industries that collect, store, transfer, share, and disseminate sensitive but unclassified information. More information about FIPS 140-1 and 140-2 can be found at <http://csrc.nist.gov/publications/PubsFIPS.html>.

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chart or graph) makes any substantive information contained in the document unintelligible, the Company must submit the original document, a like-color photocopy, or a JPEG format image);

- d. Shall be accompanied by an affidavit of an officer of the Company stating that the copies are true, correct, and complete copies of the original documents; and
 - e. Shall be accompanied by an index that identifies (i) the name of each person from whom responsive documents are submitted; and (ii) the corresponding consecutive document control number(s) used to identify that person's documents. The Commission representative will provide a sample index upon request.
6. If any documents are withheld from production based on a claim of privilege, the Company shall provide, pursuant to 16 C.F.R. § 3.38A, a schedule which describes the nature of documents, communications, or tangible things not produced or disclosed, in a manner that will enable Complaint Counsel to assess the claim of privilege.
 7. If documents responsive to a particular specification no longer exist for reasons other than the ordinary course of business or the implementation of the Company's document retention policy but the Company has reason to believe have been in existence, state the circumstances under which they were lost or destroyed, describe the documents to the fullest extent possible, state the specification(s) to which they are responsive, and identify Persons having knowledge of the content of such documents.
 8. The Company must provide the Commission with a statement identifying the procedures used to collect and search for electronically stored documents and documents stored in paper format. The Company must also provide a statement identifying any electronic production tools or software packages utilized by the company in responding to this subpoena for: keyword searching, Technology Assisted Review, email threading, de-duplication, global de-duplication or near-de-duplication, and
 - a. if the company utilized keyword search terms to identify documents and information responsive to this subpoena, provide a list of the search terms used for each custodian;
 - b. if the company utilized Technology Assisted Review software;
 - i. describe the collection methodology, including: how the software was utilized to identify responsive documents; the process the company utilized to identify and validate the seed set documents subject to manual review; the total number of documents reviewed manually; the total number of documents determined nonresponsive without manual review; the process the company used to determine and validate the accuracy of the automatic determinations of responsiveness and nonresponsiveness; how

- the company handled exceptions (“uncategorized documents”); and if the company’s documents include foreign language documents, whether reviewed manually or by some technology-assisted method; and
- ii. provide all statistical analyses utilized or generated by the company or its agents related to the precision, recall, accuracy, validation, or quality of its document production in response to this subpoena; and identify the person(s) able to testify on behalf of the company about information known or reasonably available to the organization, relating to its response to this specification.
 - c. if the Company intends to utilize any de-duplication or email threading software or services when collecting or reviewing information that is stored in the Company’s computer systems or electronic storage media in response to this subpoena, or if the Company’s computer systems contain or utilize such software, the Company must contact a Commission representative to determine, with the assistance of the appropriate government technical officials, whether and in what manner the Company may use such software or services when producing materials in response to this subpoena

Any questions you have relating to the scope or meaning of anything in this request or suggestions for possible modifications thereto should be directed to Eric M. Sprague at (202) 326-2101. The response to the request shall be addressed to the attention of Eric M. Sprague, Federal Trade Commission, 400 7th Street SW, Washington, D.C. 20024, and delivered between 8:30 a.m. and 5:00 p.m. on any business day to the Federal Trade Commission.

CERTIFICATION

Pursuant to 28 U.S.C. § 1746, I hereby certify under penalty of perjury that this response to the Subpoena *Duces Tecum* is complete and correct to the best of my knowledge and belief.

(Signature of Official)

(Title/Company)

(Typed Name of Above Official)

(Office Telephone)

CERTIFICATE OF SERVICE

I hereby certify that I delivered via FedEx and electronic mail a copy of the foregoing document to:

Claudia R. Higgins
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave., NW
Washington, DC 20001

Counsel for Purdue Pharma L.P.

I hereby certify that I delivered via electronic mail a copy of the foregoing document to:

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Counsel for Respondent Impax Laboratories, Inc.

May 24, 2017

By: /s/ Eric M. Sprague
Eric M. Sprague
Federal Trade Commission
Bureau of Competition
400 7th Street SW
Washington, DC 20024
esprague@ftc.gov
Telephone: (202) 326-2101

Counsel Supporting the Complaint

EXHIBIT B

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

_____)
In the Matter of)
)
Impax Laboratories, Inc.,) DOCKET NO. 9373
a corporation.)
)
)
_____)

I, Edward Mahony, declare as follows:

1. I am over 18 years of age and have personal knowledge of the facts set forth in this declaration.

2. I am currently Executive Vice President of Purdue Pharma L.P. ("Purdue"), which is a third party that received a subpoena from the U.S. Federal Trade Commission ("FTC") in connection with this matter. I was hired by Purdue in 1993 into the position of Vice President of Finance, and was promoted in 1999 to the position of Executive Vice President and Chief Financial Officer.

3. I have been advised that Respondent Impax Laboratories, Inc. ("Impax") has provided notice to Purdue that it intends to introduce into evidence certain of the documents Purdue submitted in response to the FTC subpoena mentioned above. I understand that, if these documents are admitted into the record without *in camera* treatment having been granted that they will become part of the FTC's public record in this case.

4. I have familiarized myself with the documents that Impax designated as trial exhibits.

5. The documents designated by Impax include Purdue's trade secrets, such as strategic business and marketing plans and compilations of information that provide the basis for

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Purdue's overall product launch and marketing strategies. These documents include the most sensitive of Purdue's competitive decision-making documents that provide the company's overall plans for supporting its products through each year from 2009 through 2014, profit and loss information and allocation of marketing and sales resources throughout the country.

6. The trade secret, proprietary, and confidential information described above is financially and competitively valuable to Purdue and/or is subject to confidentiality protections, and is the subject of substantial efforts to maintain its secrecy.

7. Purdue takes significant efforts to maintain the confidentiality of the documents designated by Impax, and I am aware of these efforts through the course of my employment at Purdue and have further familiarized myself with these efforts during the course of Purdue's review of the documents. Purdue's efforts to maintain the documents' confidentiality include the following:

- (a) When an employee joins Purdue, he or she must sign a confidentiality agreement that describes confidential information and how it must be protected.
- (b) Purdue also provides new employees with an Employee Manual that includes a section on "Data Privacy and Protection of Personal and Confidential Information." That manual makes clear that failure to comply with Purdue's policies relating to personal and confidential information may result in disciplinary action up to and including termination of employment.
- (c) Purdue maintains a Code of Business Ethics, which includes provisions calling for the protection of confidential and proprietary information.

Purdue's Compliance department deploys annual training modules on the Code of Business Ethics, including the provisions regarding confidentiality, that employees are required to complete.

- (d) The Compliance department also deploys targeted reminders on confidential and proprietary information to certain employees (i) prior to their attending industry conferences, (ii) that handle restricted data sets, and (iii) for certain aspects of sales training.
- (e) In addition, Purdue's regular practice is to require confidentiality agreements before sharing any confidential information with an external entity, such as a vendor, and its commercial contracting practices also call for the use of confidentiality provisions.

8. Purdue has enacted these confidentiality measures because disclosure of information described in this declaration would both harm Purdue and help its competitors. For example, the public disclosure of Purdue's marketing plans and sales data would destroy their value by revealing Purdue's confidential business strategies and relationships, including to Purdue's competitors, who would be able to use the information to compete unfairly with Purdue.

I hereby declare that the above statement is true to the best of my knowledge and belief, and that I understand it is made for use as evidence in court and is subject to penalty for perjury.

Dated: 10/9/17

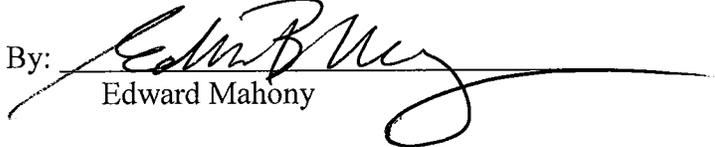
By: 
Edward Mahony

EXHIBIT C

(filed *in camera*)

Notice of Electronic Service

I hereby certify that on October 10, 2017, I filed an electronic copy of the foregoing Unopposed Motion of Non-Party Purdue Pharma, L.P. For In Camera Treatment of Designated Trial Exhibits, with:

D. Michael Chappell
Chief Administrative Law Judge
600 Pennsylvania Ave., NW
Suite 110
Washington, DC, 20580

Donald Clark
600 Pennsylvania Ave., NW
Suite 172
Washington, DC, 20580

I hereby certify that on October 10, 2017, I served via E-Service an electronic copy of the foregoing Unopposed Motion of Non-Party Purdue Pharma, L.P. For In Camera Treatment of Designated Trial Exhibits, upon:

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Complaint

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