5. a continuation or renewal of a pre-existing agreement between an NDA Holder and a Generic Filer but only if: (i) the pre-existing agreement was entered into at least 90 days before the relevant Brand/Generic Settlement Agreement, (ii) the terms of the renewal or continuation, including the duration and the financial terms, are substantially similar to those in the pre-existing agreement, and (iii) entering into the continuation or renewal is not expressly contingent on agreement to a Brand/Generic Settlement.

X. "Subject Drug Product" means the Drug Product for which one or more Patent Infringement Claims are settled under a given Brand/Generic Settlement. For purposes of this Order, the Drug Product of the NDA Holder and the Generic Filer to the same Brand/Generic Settlement shall be considered to be the same Subject Drug Product.

Y. "U.S. Patent" means any patent issued by the United States Patent and Trademark Office, including all divisions, reissues, continuations, continuations-in-part, modifications, or extensions thereof.

II. Prohibited Agreements

IT IS FURTHER ORDERED that:

A. Respondent is prohibited from entering into any Brand/Generic Settlement that includes:

1. (i) a No-AG Commitment and (ii) an agreement by the Generic Filer not to research, develop, manufacture, distribute, Market, or sell the Subject Drug Product for any period of time; or

2. (i) any Payment by the NDA Holder to the Generic Filer and (ii) an agreement by the Generic Filer not to research, develop, manufacture, distribute, Market, or sell the Subject Drug Product for any period of time.

B. Respondent shall not enter any agreement with another Oxymorphone ER Manufacturer or Applicant that prevents or restricts competition between Oxymorphone ER Products.

III. Compliance Program

IT IS FURTHER ORDERED that Respondent shall design, maintain, and operate an Antitrust Compliance Program that sets forth the policies and procedures Respondent has implemented to comply with this Order and with the antitrust laws. The Antitrust Compliance Program shall include:

A. Designation and retention of an antitrust compliance officer or director to supervise the design, maintenance, and operation of the program;

B. Training regarding Respondent's obligations under this Order and the antitrust laws for Executive and General Counsel Staff within 30 days after this Order becomes final and at least annually thereafter;

C. Certification by each Executive and General Counsel Staff member that she or he has

received the training required in Paragraph III.B;

D. Policies and procedures for employees and representatives of Respondents to ask questions about, and report violations of, this Order and the antitrust laws confidentially and without fear of retaliation of any kind;

E. Policies and procedures for disciplining employees and representatives of Respondents for failure to comply with this Order and the antitrust laws; and

F. The retention of documents and records sufficient to record Respondents' compliance with its obligations under this Paragraph III of this Order, including but not limited to records showing that employees and representatives of Respondents have received all trainings required under this Order during the preceding two years.

IV. Reporting Requirements

IT IS FURTHER ORDERED that

A. Respondent shall file a verified written report to the Commission ("compliance report"):

1. 90 days after the date this Order is issued; and
2. One year after the date this Order is issued, and annually for the next 19 years on the anniversary of that date, and
3. At such other times as the Commission may require.

B. In each compliance report, Respondent shall describe the manner and form in which Respondent intends to comply, is complying, and has complied with this Order, including by submitting:

1. a copy of any additional agreement with a party to a Brand/Generic Settlement to which Respondent is a signatory if (i) the relevant Brand/Generic Settlement Agreement includes an agreement by the Generic Filer not to research, develop, manufacture, Market or sell the Subject Drug Product for any period of time, and (ii) the relevant additional agreement is entered within a year of executing the Brand/Generic Settlement Agreement;
2. copies of all documents that contain or describe an agreement that relates to one or more Oxymorphone ER Products and is an agreement between Respondent and (i) any holder of an NDA, ANDA or 505(b)(2) for any Drug Product, or (ii) any Oxymorphone ER Manufacturer or Applicant; and
3. Copies of the certifications required by Paragraph III.C and the policies and procedures required by Paragraphs III.D and III.E.

provided that, Respondent does not need to submit any agreements, correspondence or other documents that Respondent submitted to the Commission with a prior verified written report required by this provision.

C. Each compliance report submitted pursuant to this Paragraph shall be verified by a notarized signature or sworn statement of the Chief Executive Officer or other officer or employee of the Respondent specifically authorized to perform this function, or self-

verified in the manner set forth in 28 U.S.C. § 1746. Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), requires that the Commission receive an original and two copies of each compliance report. A paper original of each compliance report shall be filed with the Secretary of the Commission and electronic copies shall be transmitted to the Secretary at ElectronicFilings@ftc.gov, and the Compliance Division at bccompliance@ftc.gov.

D. This Order does not alter the reporting requirements of Respondent pursuant to Section 1112 of the Medicare Prescriptions Drug, Improvement, and Modernization Act of 2003.

V. Change of Corporate Control

IT IS FURTHER ORDERED that

A. Respondent shall notify the Commission at least 30 days prior to:

1. Any proposed dissolution of Impax Laboratories LLC;

2. Any proposed acquisition of, or merger or consolidation involving Impax Laboratories LLC; or

3. Any other change in Respondent, including assignment or the creation, sale, or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order.

B. Respondent shall submit any notice required under this paragraph electronically to the Secretary of the Commission at ElectronicFilings@ftc.gov and the Compliance Division at bccompliance@ftc.gov.

VI. Access Provisions

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, upon written request and five days' notice to the relevant Respondent, made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters office, the notified Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and electronically stored information as defined in Section 2.7(a)(1) and (2) of the Commission's Rules, 16 C.F.R. § 2.7(a)(1) (2), in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative of the Commission and at the expense of the Respondent; and

B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII. Termination

IT IS FURTHER ORDERED that this Order shall terminate March 28, 2039.

By the Commission.

SEAL:

ISSUED: March 28, 2019

April J. Tabor
Acting Secretary

From: Freer, Daniel R. [mailto:dfreer@ftc.gov]
Sent: Wednesday, April 10, 2019 09:14
To: Hassi, Ted; Loughlin, Chuck; Weinstein, Rebecca; Michael E. Antalics; bhendricks@omm.com; smcintyre@omm.com; Meier, Markus H.; Albert, Bradley Scott; Butrymowicz, Daniel W.; Davis, Alpa D.
Cc: Tabor, April; Freer, Daniel R.; Mack, Julie; Swenson, Robert; Christie, Joel
Subject: Service Date For the Commission Opinion and Final Order Package in In the Matter of Impax Laboratories, D9373

Good Morning Everyone,

Our records indicate that service of the official paper copies of the Commission Opinion and Final Order package in this matter -- containing the Opinion of the Commission, and the Final Order -- was completed on Monday, April 8, 2019. Pursuant to Commission Rule 3.55, at the following URL:

https://www.ecfr.gov/cgi-bin/text-idx?SID=ccc36d0914dfb31b24ab32b987312386&mc=true&node=se16.1.3_155&rgn=div8

and Commission Rule 3.56(d), at the following URL:

https://www.ecfr.gov/cgi-bin/text-idx?SID=fda6eb1e78722b9183926a31f503e86f&mc=true&node=se16.1.3_156&rgn=div8

the fourteen-calendar-day period within which a Petition for Reconsideration must be filed -- and the thirty-calendar-day period within which an Application for Stay must be filed -- therefore both began yesterday, Tuesday, April 9, 2019, and will respectively end on Monday, April 22, 2019 and Wednesday, May 8, 2019. Please let me know if you need any additional information.

Best regards,

Daniel R. Freer
General Attorney
Office of the Secretary

Federal Trade Commission
202-326-2663

CERTIFICATE OF SERVICE

Endo Pharmaceuticals, Inc. was permitted to intervene in proceedings before the administrative law judge for the limited purpose of responding to Complaint Counsel's Post-Trial Brief and Proposed Order and opposing certain factual findings and remedies. I hereby certify that, on June 6, 2016, I caused a copy of this petition to be served on the foregoing by email and by First Class mail:

George G. Gordon
DECHERT LLP
2929 Arch Street
Philadelphia, PA 19104
(215) 994-2000

Counsel for Non-Party Endo Pharmaceuticals, Inc.

Dated: New York, New York
June 6, 2019

Respectfully submitted,

/s/ Jay P. Lefkowitz
Jay P. Lefkowitz

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE,
Suite 115
NEW ORLEANS, LA 70130

June 07, 2019

Mr. Joseph J. Simons
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Mr. Alden F. Abbott
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room 568
Washington, DC 20580

Mr. Donald S. Clark
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room 172
Washington, DC 20580

Ms. Heather Hippsley
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Room 582
Washington, DC 20580

No. 19-60394 Impax Laboratories, Incorporat v. FTC
Agency No. 9373

Dear Mr. Simons, Mr. Abbott, Mr. Clark, and Ms. Hippsley,

You are served with the following document(s) under FED. R. APP. P. 15:

Petition for Review.

Special Guidance for Filing the Administrative Record: Pursuant to 5th Cir. R. 25.2, Electronic Case Filing (ECF) is mandatory for all counsel. Agencies responsible for filing the administrative record with this court are requested to electronically file the record via CM/ECF using one or more of the following events as appropriate:

Electronic Administrative Record Filed;
Supplemental Electronic Administrative Record Filed;
Sealed Electronic Administrative Record Filed; or
Sealed Supplemental Electronic Administrative Record Filed.

Electronic records must meet the requirements listed below. Records that do not comply with these requirements will be rejected.

- Max file size 20 megabytes per upload.
- Where multiple uploads are needed, describe subsequent files as "Volume 2", "Volume 3", etc.
- Individual documents should remain intact within the same file/upload, when possible.
- Supplemental records must contain the supplemental documents only. No documents contained within the original record should be duplicated.

Electronic records are automatically paginated for the benefit of counsel and the court and provide an accurate means of citing to the record in briefs. A copy of the paginated electronic record is provided to all counsel at the time of filing via a Notice of Docket Activity (NDA). Upon receipt, counsel should save a copy of the paginated record to their local computer.

Agencies unable to provide the administrative record via docketing in CM/ECF may instead provide a copy of the record on a flash drive or CD which we will use to upload and paginate the record.

If the agency intends to file a certified list in lieu of the administrative record, it is *required* to be filed electronically. Paper filings will not be accepted. See FED. R. APP. P. 16 and 17 as to the composition and time for the filing of the record.

ATTENTION ATTORNEYS: Attorneys are required to be a member of the Fifth Circuit Bar and to register for Electronic Case Filing. The "Application and Oath for Admission" form can be printed or downloaded from the Fifth Circuit's website, www.ca5.uscourts.gov. Information on Electronic Case Filing is available at www.ca5.uscourts.gov/cmecf/.

We recommend that you visit the Fifth Circuit's website, www.ca5.uscourts.gov and review material that will assist you during the appeal process. We especially call to your attention the Practitioner's Guide and the 5th Circuit Appeal Flow Chart, located in the Forms, Fees, and Guides tab.

Counsel who desire to appear in this case must electronically file a "Form for Appearance of Counsel" within 14 days from this date. You must name each party you represent, see FED. R. APP. P. and 5TH CIR. R. 12. The form is available from the Fifth Circuit's website, www.ca5.uscourts.gov. If you fail to electronically file the form, we will remove your name from our docket.

Sealing Documents on Appeal: Our court has a strong presumption of public access to our court's records, and the court scrutinizes any request by a party to seal pleadings, record excerpts, or other documents on our court docket. Counsel moving to seal matters