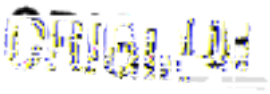
~~PUBLIC~~

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

08 09 2018
591817

COMMISSIONERS: Joseph J. Simons, Chairman
Maureen K. Ohlhausen
Noah Joshua Phillips
Rohit Chopra
Rebecca Kelly Slaughter



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

COMPLAINT COUNSEL S NOTICE OF REVISED PROPOSED ORDER

Complaint Counsel submits this notice to provide a copy of the correct Proposed Order that Complaint Counsel asks the Commission to enter in this case (attached as Appendix 1). Complaint Counsel had inadvertently attached an incorrect version of this Proposed Order as Appendix A to its July 2 appeal brief.

Complaint Counsel respectfully requests that the Commission consider only the proposed order attached herein and disregard the erroneous version attached to its appeal brief.

Respectfully submitted,

Dated: August 9, 2018

/s/ Bradley S. Albert
Bradley S. Albert
Federal Trade Commission
Bureau of Competition
600 Pennsylvania Ave., NW
Washington, DC 20580
Telephone: (202) 326-3670
Facsimile: (202) 326-3384
Email: balbert@ftc.gov
Counsel Supporting the Complaint

CERTIFICATE OF SERVICE

I hereby certify that on August 9, 2018, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

Donald S. Clark
Secretary

August 9, 2018

By: /s/ *Rebecca E. Weinstein*
Rebecca E. Weinstein

Counsel Supporting the Complaint

CERTIFICATE FOR ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

August 9, 2018 By: /s/ *Rebecca E. Weinstein*
Rebecca E. Weinstein

APPENDIX 1

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS:	**Joseph J. Simons, Chairman**
	Maureen K. Ohlhausen
	Noah Joshua Phillips
	Rohit Chopra
	Rebecca Kelly Slaughter

In the Matter of

)

G. "Brand/Generic Settlement Agreement" means a written agreement that settles a Patent Infringement Claim in or affecting Commerce in the United States.

H. "Branded Subject Drug Product" means a Subject Drug Product marketed, sold, or distributed in the United States under the proprietary name identified in the NDA for the Subject Drug Product.

I. "Commerce" has the same definition as it has in 15 U.S.C. § 44.

J. "Contract Settlement Agreement" means the Contract Settlement Agreement, including all exhibits thereto, entered as of August 5, 2017, between Impax and Endo Pharmaceuticals Inc. (CX3275).

K. "Control" or "Controlled" means the holding of more than 50% of the common voting stock or ordinary shares in, or the right to appoint more than 50% of the directors of, or any other arrangement resulting in the right to direct the management of, the said corporation, company, partnership, joint venture, or entity.

L. "Drug Product" means a finished dosage form (e.g., tablet, capsule, solution, or patch), as defined in 21 C.F.R. § 314.3(b), approved under a single NDA, ANDA or 505(b)(2) Application, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

M. "Executive and General Counsel Staff" means the Respondent's Executive Team, including the Chief Executive Officer, the Chief Financial Officer, the General Counsel, the Chief Compliance Officer, Presidents of divisions within Respondent, including the Generics Division and Specialty Pharm Division, and all attorneys in the Respondent's office of General Counsel.

N. "Generic Entry Date" means the date in a Brand/Generic Settlement Agreement, whether certain or contingent, on or after which a Generic Filer is authorized by the NDA Holder to begin manufacturing, using, importing, or Marketing the Generic Subject Drug Product.

O. "Generic Filer" means a party to a Brand/Generic Settlement who controls an ANDA or 505(b)(2) Application for the Subject Drug Product or has the exclusive right under such ANDA or 505(b)(2) Application to di

S. "NDA Holder" means a party to a Brand/Generic Settlement that controls the NDA for the Subject Drug Product or has the exclusive right to distribute the Branded subject Drug Product in the United States.

T. "No-AG Commitment" means any agreement with, or commitment or license to, the Generic Filer that prohibits, prevents, restricts, requires a delay of, disincentivizes, or imposes a condition precedent upon the research, development, manufacture, regulatory approval, or Marketing of an Authorized Generic.

U. "Oxymorphone ER Product" means any extended-release tablet containing oxymorphone that is the subject of an NDA, ANDA, or 505(b)(2) Application.

V. "Patent Infringement Claim" means any allegation threatened in writing or included in a complaint filed with a court of law that a Generic Product may infringe one or more U.S. Patents held by, or licensed to, an NDA Holder.

W. "Payment by the NDA Holder to the Generic Filer" means a transfer of value by the NDA Holder to the Generic Filer (including, but not limited to, a No-AG Commitment, money, goods, or services), regardless of whether the Generic Filer purportedly transfers value in return, where such transfer is either (i) expressly contingent on entering a Brand/Generic Settlement Agreement, or (ii) agreed to during the 90 days period starting 45 days before executing a Brand/Generic Settlement Agreement and ending 45 days after executing a Brand/Generic Settlement Agreement. The following, however, are not Payment by the NDA Holder to the Generic Filer:

1. compensation for the NDA Holder's saved future litigation expenses, but only if the total compensation the NDA Holder agrees to provide to the Generic Filer during the 90 day period starting 45 days before and ending 45 days after executing the Brand/Generic Settlement Agreement does not exceed a maximum limit, which is initially set at $7,000,000 and shall be increased (or decreased) as of January 1 of each year by an amount equal to the percentage increase (or decrease) from the previous year in the annual average Producer Price Index for Legal Services (Series Id. PCU5411—5411--) published by the Bureau of Labor Statistics of the United States Department of Labor or its successor;

2. the right to Market, as of an agreed upon Generic Entry Date, Generic Product(s) in the United States under an ANDA or 505(b)(2) Application (i) that is controlled by the Generic Filer and was not transferred to the Generic Filer by the NDA Holder or (ii) to which the Generic Filer has a license from a party other than the NDA Holder;

3. provisions to facilitate, by means other than the transfer of goods or money, the Generic Filer's ability to secure or maintain final regulatory approval, or commence or continue the Marketing, of a Generic Product, by, inter alia, providing covenants, waivers, permissions, releases, dismissals of claims, and/or authorizations; and

4. waiver or a limitation of a claim for damages based on prior Marketing of the

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 and each that she or he has received the training required in Paragraph III.C;

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 any holder of an NDA, ANDA or 505(b)(2) for any Drug Product;

3. a summary of Respondent's efforts to cease being a party to an agreement that violates Paragraph II.B and copies of all correspondence (including, but not limited to, electronic mail and letters) sent or received by Respondent as part of such efforts;

4. a summary of Respondents efforts to comply with Paragraph II.C and copies of all correspondence (including, but not limited to, electronic mail and letters) sent or received by Respondent as part of such efforts; and

5. 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

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 20 years from the date it is issued.

ORDERED:

_____

By the Commission
Donald S. Clark
Secretary

Date: _____, 2018

Notice of Electronic Service

I hereby certify that on August 09, 2018, I filed an electronic copy of the foregoing Complaint Counsel's Notice of Revised Proposed Order, 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 August 09, 2018, I served via E-Service an electronic copy of the foregoing Complaint Counsel's Notice of Revised Proposed Order, upon:

Bradley Albert
Attorney
Federal Trade Commission
balbert@ftc.gov
Complaint

Daniel Butrymowicz
Attorney
Federal Trade Commission
dbutrymowicz@ftc.gov
Complaint

Nicholas Leefer
Attorney
Federal Trade Commission
nleefer@ftc.gov
Complaint

Synda Mark
Attorney
Federal Trade Commission
smark@ftc.gov
Complaint

Maren Schmidt
Attorney
Federal Trade Commission
mschmidt@ftc.gov
Complaint

Eric Sprague
Attorney
Federal Trade Commission
esprague@ftc.gov
Complaint

Jamie Towey
Attorney
Federal Trade Commission
jtowey@ftc.gov

rweinstein@ftc.gov
Complaint

Garth Huston
Attorney
Federal Trade Commission
ghuston@ftc.gov
Complaint

I hereby certify that on August 09, 2018, I served via other means, as provided in 4.4(b) of the foregoing Complaint Counsel's Notice of Revised Proposed Order, upon:

Markus Meier
Attorney
Federal Trade Commission
mmeier@ftc.gov
Complaint

Edward D. Hassi
Attorney
Debevoise & Plimpton LLP
thassi@debevoise.com
Respondent

Rebecca Weinstein
Attorney