

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



ORIGINAL

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

Docket No. 9373

**Stipulation and [Proposed] Order Regarding Treatment
of Certain Documents From Endo Pharmaceuticals, Inc.**

Complaint Counsel, Impax Laboratories, Inc. (“Impax”), and Endo Pharmaceuticals Inc. (“Endo”) hereby stipulate and jointly request entry of an order providing as follows:

1. The FTC conducted an investigation under File No. 141-0004 (the “FTC Investigation”) relating to two separate Hatch-Waxman patent litigation settlements to which Endo was a party, referred to herein respectively as the “Lidoderm Settlement” and the “Opana ER Settlement.” In connection with the FTC Investigation, Endo produced documents and data (the “Endo Documents”) to the FTC pursuant to two Civil Investigative Demands. The FTC also conducted investigational hearings of a number of Endo’s then-current and former employees (the “IHs”). The present proceeding relates only to the Opana ER Settlement, and Endo is not a party to the proceeding. Impax has submitted a document request to Complaint Counsel seeking, among other things, all documents relating to the FTC’s Opana ER investigation, “as designated by FTC File No. 141-0004.” In response to Impax’s document request, Complaint Counsel now seeks to produce the Endo

- Documents and transcripts of the IHs (the “Endo IH Transcripts”) to Impax in this proceeding.
2. Complaint Counsel may produce the Endo Documents to counsel of record appearing for Impax in this proceeding (the “Impax Counsel”) subject to the following terms and conditions:
 - a. Endo shall produce to Complaint Counsel and Impax Counsel a list (organized by beginning production number) of the Endo Documents and exhibits to the Endo IH Transcripts that it has identified as relating to the Opana ER Settlement, including where applicable family members of such documents (the “Opana ER Documents”).
 - b. The Endo Documents and all exhibits to the Endo IH Transcripts shall be treated by Complaint Counsel and by Impax Counsel as “confidential materials” under the Protective Order Governing Confidential Material previously entered in this matter on January 24, 2017 (the “January 24 Protective Order”).
 - c. In addition, any and all of the Endo Documents and exhibits to Endo IH Transcripts that are not Opana ER Documents (the “Non-Opana Documents”) shall be designated as and treated by Complaint Counsel and Impax Counsel on a “Restricted Basis.” Except as otherwise provided herein, documents treated on a Restricted Basis shall not be disclosed or shown, including but not limited to by providing access to or copies or summaries, by either Complaint Counsel or Impax Counsel to fact witnesses or to present or former employees of Impax, including but not limited to in-house counsel for Impax, absent

express written consent by Endo, provided, however, that such documents may be disclosed or shown to (i) this tribunal and its staff but shall not be placed on the public record prior to the administrative hearing and shall not be placed on the public record during or after the administrative hearing without an opportunity for Endo to seek an *in camera* order, which Complaint Counsel and Impax Counsel shall not oppose, (ii) current or former Endo employees who would have seen or received such documents in the course of their employment, and (iii) testifying and non-testifying expert consultants employed by or acting as agents of Impax Counsel or Complaint Counsel.

- d. In the event that Complaint Counsel or Impax Counsel believes that any of the Non-Opana Documents should be made available for use and re-designated as Opana ER Documents for purposes of this proceeding, they shall give Endo's undersigned counsel notice in writing, specifying the documents in question by their beginning production numbers and the reason for their request to re-designate such documents.
 - i. If the request includes 50 or fewer documents (including family members), Endo shall have three (3) business days (counted starting on the first business day following the day notice is provided) within which to either consent or object to the requested re-designation. If the request includes more than 50 documents (including family members), Endo shall have five (5) business days (counted as above) within which to either object or consent to the requested re-designation.

- ii. If Endo objects on the basis that the document(s) does/do not pertain to the issues of this proceeding, it shall have an additional four (4) business days within which to move for entry of a protective order. Until such motion is resolved, the document(s) in question shall continue to be treated on a Restricted Basis as described in Paragraph 2.c.
 - e. Any Non-Opana Documents that are re-designated as Opana ER Documents, whether by agreement or by order of this tribunal, shall be maintained as “confidential materials” under the January 24 Protective Order. Endo’s agreement, or any order of the tribunal, to re-designate any Non-Opana Documents shall apply to this proceeding only and shall not be binding on or deemed an admission by Endo in any other proceeding or litigation.
- 3. The FTC may also produce the Endo IH Transcripts to Impax Counsel subject to the following terms and conditions:
 - a. By April 5, 2017, Endo shall produce to Complaint Counsel and Impax Counsel copies of the Endo IH Transcripts that have been redacted to exclude testimony that Endo believes does not relate to this proceeding (the “Non-Opana Testimony”).
 - b. The Endo IH Transcripts shall be treated by the FTC and by Impax as “confidential materials” under the January 24 Protective Order, provided however that any Non-Opana Testimony shall be treated on a Restricted Basis (as defined herein).

- c. In the event that Complaint Counsel or Impax Counsel believes that any Endo IH testimony designated by Endo counsel as “Non-Opana Testimony” should be designated as Opana Testimony for purposes of this proceeding, they shall give Endo’s undersigned counsel notice in writing, specifying the testimony in question and the reason for their request to re-designate such testimony. Endo shall thereafter have five (5) business days within which to either object or consent to the requested re-designation. If Endo objects, it shall have an additional four (4) business days within which to move for entry of a protective order. Until such motion is resolved, the testimony in question shall continue to be treated as provided in Paragraph 3.b.
 - d. Any Non-Opana Testimony that is re-designated as Opana Testimony, whether by agreement or by order of this tribunal, shall be maintained as “confidential materials” under the January 24 Protective Order. Endo’s agreement, or any order of this tribunal, to re-designate any Endo IH Testimony shall apply to this proceeding only and shall not be binding on or deemed an admission by Endo in any other proceeding or litigation.
 - e. Any and all exhibits to the Endo IH Transcripts shall be treated in the manner provided in Paragraph 2.
4. The terms of this Stipulation and [Proposed] Order shall remain in effect following the termination of this proceeding.

Respectfully submitted, April 5, 2017:

/s/ Bradley S. Albert

Bradley S. Albert
FEDERAL TRADE COMMISSION
Bureau of Competition
400 7th Street, SW
Washington, DC 20024
balbert@ftc.gov
Telephone: (202) 326-3670

Counsel Supporting the Complaint

/s/ Steven G. Reade

Steven G. Reade
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave., NW
Washington, D.C. 20001
steven.reade@apks.com
Telephone: (202) 942-5678

George G. Gordon
DECHERT LLP
Cira Centre, 2929 Arch Street
Philadelphia, PA 19104
george.gordon@dechert.com
Telephone: (215) 994-14000

Counsel for Endo Pharmaceuticals, Inc.

/s/ Edward D. Hassi

Edward D. Hassi
O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, D.C. 20006
ehassi@omm.com
Telephone: (202)383-5300

Counsel for Impax Laboratories, Inc.

SO ORDERED this ___ day of _____, 2017.

The Honorable D. Michael Chappell
Chief Administrative Law Judge

CERTIFICATE OF SERVICE

I hereby certify that on April 5, 2017, 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
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

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

Edward D. Hassi
O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, D.C. 20006
ehassi@omm.com

Counsel for Respondent Impax

Steven Reade
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave., NW
Washington, D.C. 20001
steven.reade@apks.com

George G. Gordon
DECHERT LLP
Cira Centre, 2929 Arch Street
Philadelphia, PA 19104
george.gordon@dechert.com

Counsel for Endo Pharmaceuticals, Inc.

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.

April 5, 2017

By: /s/ Maren J. Schmidt

Maren J. Schmidt

Rebecca E. Weinstein

FEDERAL TRADE COMMISSION

Bureau of Competition

Washington, D.C. 20024

mschmidt@ftc.gov

rweinstein@ftc.gov

Counsel Supporting the Complaint