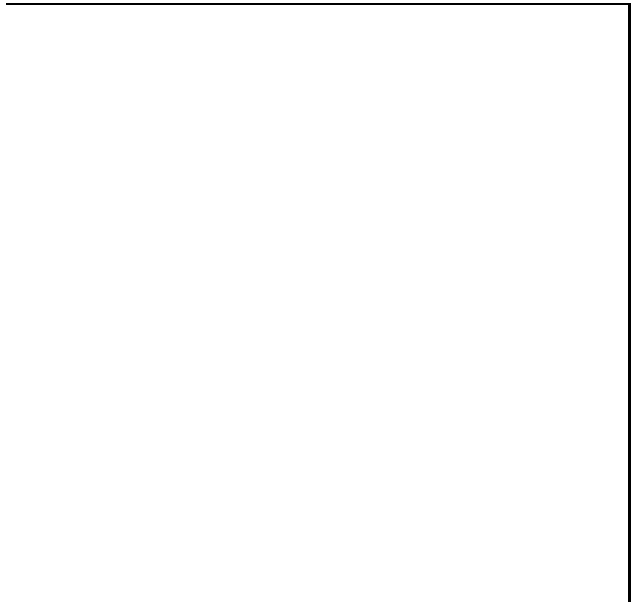


1 Bradley S. Albert, Md. Bar
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1 Commission jointly seek entry of the attached proposed Stipulated Order by the Court, thereby
2 bringing all of the litigation between the Commission and Endo to an end, including the
3 following "Covered Actions": (a) this action; (b) Endo's claims against the Commission under
4 the Declaratory Judgment Act in *Endo Pharmaceuticals Inc., et al. v. Federal Trade*
5 *Commission, Civ. Action No. 16-cv-5599 (E.D. Pa.)* and *Endo Pharmaceuticals Inc., et al. v.*
6 *Federal Trade Commission, Civ. Action No. 16-cv-5600 (E.D. Pa.)*; and (c) the Commission's
7 claims against *Par Pharmaceuticals Companies* and *Paddock Laboratories, Inc.* now known
8 as *Paddock Holdings, LLC* in *Federal Trade Commission v. Actavis, Civ. Action No. 09-*
9 *cv-955 (N.D. Ga.)*.

10 Proposed Stipulated Order

11 6. The proposed Stipulated Order prohibits Endo from entering into patent
12 infringement settlement agreements containing certain types of provisions for a period of ten
13 years. Paragraph II of the proposed Stipulated Order prohibits Endo from entering into any
14 settlement agreement containing: (1) terms providing for either (a) a Payment by the NDA
15 Holder to the Generic Filer or (b) a "No-AG Commitment," in which the brand company agrees
16 to restrictions on its ability to compete through the sale of an authorized generic of a drug product
17 for some period of time; and (2) an agreement by the generic company to refrain from
18 researching, developing, manufacturing, marketing, or selling the drug product at issue in the
19 patent infringement litigation (the "Subject Drug Product") for some period of time. The term
20 "Payment by the NDA Holder to the Generic Filer" defined to include any transfer of value
21 (including money, goods, or services) where such transfer is either

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1 b. provisions, including the right to market a generic product on the Generic
2 Entry Date, that allow the generic company to begin or continue selling the Subject Drug
3 Product;

4 c. under certain circumstances, a waiver of damages based on the generic
5 company's prior marketing of the Subject Drug Product; and

6 d. under certain circumstances, the continuation or renewal of a pre-existing
7 agreement.

8 8. The proposed Stipulated Order also exempts from the prohibition in Paragraph II
9 certain supply agreements relating to supply of Generic Subject Drug Product or materials
10 used to make that product and certain agreements for which the Defendants seek prior approval
11 from the Commission.

12 9. Paragraph VIII of the proposed Stipulated Order includes certain provisions
13 relating to Endo's obligations

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Conclusion

For the reasons set forth above, the FTC and Dechert jointly request that the Court enter the proposed Stipulated Order that accompanies this motion.

Respectfully submitted,

/s/ Bradley S. Albert
Bradley S. Albert
FEDERAL TRADE COMMISSION
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/s/ Daniel B. Asimow
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January 23, 2017

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1 and stipulate to entry of this Stipulated Order for Permanent Injunction (“Order”) to resolve all
2 matters in dispute in this action.

3 FINDINGS

- 4 1. This Court has jurisdiction over the parties and the subject matter of this action.
5 Defendants have stipulated that, for purposes of this Order alone, the Court has
6 jurisdiction over Endo Pharmaceuticals, Inc. and Endo International plc.
- 7 2. Venue for these matters is proper in this Court under 15 U.S.C. § 22 and 28 U.S.C. §
8 1391(b) and (c), and under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b).
- 9 3. The Complaint alleges that Defendants engaged in anticompetitive acts that constitute an
10 unfair method of competition in violation of Sections 5(a) and 13(b) of the FTC Act, 15
11 U.S.C. §§ 45(a) and 53(b), and an acquisition violation of Sec 15
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1 8. Entry of this Order is in the public interest. The Commission and Defendants have
2 agreed to stipulate to entry of this Order to finally resolve the claims and litigations
3 between them in the FTC Litigation and the Federal Court Actions.

4 STIPULATIONS

5 1. Defendants stipulate that venue for this matter is proper in this Court under 15 U.S.C. §
6 22 and 28 U.S.C. § 1391(b) and (c), and under Section 13(b) of the FTC Act, 15 U.S.C. §
7 53(b).

8 2. Defendants waive all rights to appeal or otherwise challenge or contest the validity of this
9 Order.

10 3 to appeal or otherw

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1 9. The Commission stipulates that, within ~~one~~ of the entry of this Order, the
2 Commission will file a motion for voluntary ~~dismissal~~ with prejudice of its claims against
3 Defendants, including but not limited to ~~Par~~ Pharmaceutical Companies, Inc., as well as
4 Paddock Holdings, LLC and Paddock Laboratories, Inc. ~~Federal Trade Commission v.~~
5 Actavis, Inc. Civ. Action No. 09-cv-955 (N.D. Ga.), ~~in~~ the form provided in Exhibit 2 to
6 this Order.

7 I.

8 IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- 9 A. "Commission" means the United States Federal Trade Commission.
- 10 B. "Endo Pharmaceuticals" means Endo Pharmace~~utic~~al Inc., any joint venture, subsidiary,
11 division, group, or affiliate ~~Control~~led currently or in the future by Endo Pharmaceuticals Inc.,
12 their successors and assigns, and the respective ~~officers~~ officers, employees, agents, and
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1 I. "Brand/Generic Settlement" means any agreement or understanding that settles a Patent
2 Infringement Claim in or affecting Commerce in the United States.

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

5 K. "Branded Subject Drug Product" means a SubDrug Product Marketed in the United
6 States under the proprietary name identified in the NDA for the Subject Drug Product.

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

8 M. "Control" or "Controlled" means the holding of more than fifty percent (50%) of the
9 common voting stock or ordinary shares in, or the right to appoint more than fifty percent (50%)
10 of the directors of, or any other arrangement giving in the right to direct the management of,
11 the said corporation, company, partnership, joint venture, or entity.

12 N. "Contingent Supply Agreement" means a Supply Agreement that: (i) is contingent on the
13 Generic Filer's inability to market the Generic Subject Drug Product on or after the Generic
14 Entry Date because (x) the FDA has not granted final approval of the Generic Filer's ANDA or

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1 commence or continue the Marketing, of a Generic Product, by, inter alia,
2 providing covenants, waivers, permissions, releases, dismissals of claims, and/or
3 authorizations;

- 4 4. waiver or limitation of a claim for damages or other monetary relief based on
5 prior Marketing of the Generic Subject Drug Product, but only if the NDA Holder
6 and the Generic Filer do not agree, and have not agreed, to another Brand/Generic
7 Settlement for a different Drug Product during the sixty (60) day period starting
8 thirty (30) days before and ending thirty (30) days after the execution of the
9 Brand/Generic Settlement Agreement; or
- 10 5. a continuation or renewal of a pre-existing agreement between an NDA Holder
11 and a Generic Filer, but only if: (i) the pre-existing agreement was entered into at
12 least 90 days before the relevant Brand/Generic Settlement Agreement, (ii) the
13 terms of the renewal or continuation, including the duration and the financial
14 terms, are substantially similar to those in the pre-existing agreement, and (iii)
15 entering into the continuation or renewal was not expressly contingent on agreeing
16 to a Brand/Generic Settlement.

17 R. "Exempted Agreement" means a Materials Agreement or Supply Agreement that meets
18 all of the following conditions:

- 19 1. the price is above the Fully Allocated Manufacturing Cost, meaning:
- 20 a. if the Agreement is a Materials Agreement, the Materials Price charged by the
21 NDA Holder for Materials provided through the Materials Agreement is at or
22 above the Fully Allocated Manufacturing Cost incurred by the NDA Holder
23 per unit of the relevant Materials, or
- 24 b. if the Agreement is a Supply Agreement, the Supply Price charged by the
25 NDA Holder for the Authorized Generic of the Subject Drug Product is at or
26 above the Fully Allocated Manufacturing Cost incurred by the NDA Holder
27 per unit of the Authorized Generic of the Subject Drug Product provided
28 under the agreement;

- 1 2. the Brand/Generic Settlement Agreement containing or incorporating the
2 Materials Agreement or Supply Agreement is the only Brand/Generic Settlement
3 Agreement that the NDA Holder and the Generic Filer have entered, or agreed to
4 enter, during the sixty (60) day period ending thirty (30) days before and ending
5 thirty (30) days after the execution of the Brand/Generic Settlement Agreement;
- 6 3. within fourteen (14) days after signing the Brand/Generic Settlement Agreement
7 containing or incorporating the Materials Agreement or Supply Agreement,
8 Defendants Submitted to the Monitor a full and complete copy of the
9 Brand/Generic Settlement Agreement, including any Materials Agreement and/or
10 Supply Agreement;
- 11 4. within fourteen (14) days after the NDA Holder provides to the Generic Filer the
12 Materials Price or Supply Price, as applicable, Defendants Submitted to the
13 Monitor notification of the relevant Materials Price or Supply Price;
- 14 5. within thirty (30) days after beginning supply under the relevant Materials
15 Agreement or Supply Agreement, the NDA Holder Submitted to the Monitor:

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determine the relevant Fully Allocated Manufacturing Cost, including without limitation and subject to any demonstrably legally recognized privilege, providing the Monitor reasonable access to personnel, books, documents, and records kept in the ordinary course of business;

provided that notwithstanding subparagraph I.S.(5) or subparagraph I.S.(6), a Materials Agreement or Supply Agreement in which a Defendant is the Generic Filer shall also be considered an Exempted Agreement if it complies with subparagraphs I.S.(1) to (4):

- a. if a Materials Agreement, Defendants Submit to the Monitor within thirty (30) days of beginning to receive the Materials, a verified written statement containing (i) Defendants' best estimate of what would be the Fully Allocated Manufacturing Cost per unit for the Materials if manufactured or sourced by the Generic Filer, including a separate estimate of each cost component on a per-unit basis, and (ii) a description of the terms and conditions of any agreement(s), offer(s), purchase order(s), or price quote(s) a Defendant has entered into or received for supply of the Materials in connection with manufacture of the Subject Drug Product and other facts and circumstances, if any, that Defendants deem relevant to understanding such terms and conditions; and
- b. if a Supply Agreement, it is a Contingent Supply Agreement and Defendants Submit to the Monitor within thirty (30) days of beginning to receive the Authorized Generic, a verified written statement containing (i) Defendants' best estimate of what would be the Fully Allocated Manufacturing Cost per unit for the Subject Drug Product if manufactured by Generic Filer and (ii) a detailed calculation of the estimated Fully Allocated Manufacturing Cost, including an estimate of each cost component on a per-unit basis.

S. "Federal Court Actions" means Declaratory Judgment Actions, Federal Trade Commission v. Endo Pharmaceuticals, Inc., Civ. Action No. 16-cv-1440 (E.D. Pa.), which was dismissed without prejudice by the Commission on October 25, 2016; and Federal Trade Commission v. Actavis, Inc., Civ. Action No. 09-cv-955 (N.D. Ga.).

1 T. "FTC Investigation" means the pre-complaint investigation conducted by FTC staff under
2 File No. 141-0004.

3 U. "FTC Litigation" means any legal proceeding brought by the Commission that alleges the
4 Lidoderm Settlement Agreement and/or the Op Settlement Agreement violates the law(s)
5 enforced by the Commission.

6 V. "Fully Allocated Manufacturing Cost" means: (1) direct costs incurred to produce or, if
7 applicable, to acquire, the Subject Drug Product or Materials, determined in accordance with
8 GAAP, as consistently applied in accordance with past practices in the ordinary course of
9 business, including, but not limited to (x) acquisition costs or (y) if applicable, materials, labor,
10 manufacturing costs, packaging, testing, quality control, storage, insurance, and product
11 maintenance; (2) the cost to ship the Subject Drug Product or Materials to the Generic Filer, and
12 (3) administrative and overhead expenses associated with production or if applicable, the
13 acquisition of the Subject Drug Product or Materials, including, but not limited to, administrative expenses of ought b

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- 1 Y. "Generic Product" means a Drug Product manufactured and/or sold under an ANDA or
2 pursuant to 505(b)(2) Application.
- 3 Z. "Generic Subject Drug Product" means the Generic Product that is the subject of the
4 Patent Infringement Claim being resolved by the Brand/Generic Settlement.
- 5 AA. "Lidoderm Settlement Agreement" means the Settlement and License Agreement
6 between Endo Pharmaceuticals, Inc. and Watson Laboratories, Inc. resolving the ANDA patent
7 litigation involving the brand-name drug Lidoderm that is the subject of the Complaint in this
8 action.
- 9 BB. "Market," "Marketed," or "Marketing" means the promotion, offering for sale, sale, or
10 distribution of a Drug Product.
- 11 CC. "Materials" means components or ingredients used in the manufacturing of a Subject
12 Drug Product, including, but not limited to, hard-to-source APIs, hard-to-source active
13 pharmaceutical ingredients, hard-to-source packaging, devices, or kits for injectables.
- 14 DD. "Materials Agreement" means provisions or incorporated in, a Brand/Generic
15 Settlement Agreement providing for the supply of Materials to the Generic Filer by the NDA
16 Holder for securing and/or maintaining regulatory approval, or manufacturing and Marketing by
17 the Generic Filer of the Subject Drug Product, including the terms and conditions of any such
18 supply.
- 19 EE. "Materials Price" means the total actual per-unit price charged by the NDA Holder for
20 Materials provided through a Materials Agreement, including any transfer fee and royalty to be
21 paid by the Generic Filer, net of any discounts, allowances, rebates, or other reductions.
- 22 FF. "Monitor" means an individual appointed pursuant to the terms of Section IV below.
- 23 GG. "NDA" means a New Drug Application file with the United States Food and Drug
24 Administration pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21
25 U.S.C. § 355(b), including all changes or supplements thereto that do not result in the submission
26 of a new NDA.
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1 included in the Original Action or which arise from or are related to allegations, claims, or
2 remedies included in the Original Action.

3 NN. "Submit to the Commission" or "Submitted to the Commission" means to file with the
4 Office of the Secretary of the Commission and an electronic copy to the Compliance
5 Division of the Commission at compliance@ftc.gov

6 OO. "Submit to the Monitor" or "Submitted to the Monitor" means to deliver to the Monitor
7 appointed pursuant to the Order, or if no Monitor is appointed under this Order, to Submit to the
8 Commission.

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

13 QQ. "Supply Agreement" means provisions incorporated into, a Brand/ Generic
14 Settlement Agreement providing for the supply of the Subject Drug Product to the Generic Filer
15 by the NDA Holder for the Marketing by the Generic Filer of an Authorized Generic on or after
16 the Generic Entry Date, including the terms and conditions of any such supply.

17 RR. "Supply Price" means the total actual net price charged by the NDA Holder for
18 supply provided through a Supply Agreement, including transfer price and royalty to be paid
19 by the Generic Filer for the right to sell an Authorized Generic of the Subject Drug Product, net
20 of any discounts, allowances, rebates, or other reductions.

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

24 II.

25 IT IS FURTHER ORDERED that, in connection with any actions in or affecting
26 Commerce,

1 A. Defendants shall cease and desist from, either

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- 1 3. the Monitor shall have authority to employ, at the expense of Defendants, such
2 consultants, accountants, attorneys, and other representatives and assistants as are
3 reasonably necessary to carry out the Monitor's duties and responsibilities;
- 4 4. the Monitor shall evaluate reports submitted to the Monitor pursuant to the
5 requirements of Paragraph V and within thirty (30) days from the date the
6 Monitor receives a report, report writing to the Commission concerning
7 whether any Materials Agreement or Supply Agreement that Defendants assert is
8 an Exempted Agreement meets the requirements of Paragraph I.S of this Order.

9 D. Defendants shall grant and transfer to the Monitor, and such Monitor shall have, all
10 rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities
11 under this Order, including but not limited to, the following:

- 12 1. Defendants shall cooperate with any reasonable request of the Monitor and shall
13 take no action to interfere with or impede the Monitor's ability to perform his/her
14 duties as provided in this Paragraph;
- 15 2. subject to any demonstrated legally recognized privilege, Defendants shall
16 provide the Monitor full and complete access to personnel, books, documents,
17 records kept in the ordinary course of business, facilities and technical
18 information, and such other relevant information as the Monitor may reasonably
19 request to perform his/her duties under this Paragraph;
- 20 3. Defendants shall indemnify the Monitor and hold the Monitor harmless against
21 any losses, claims, damages, liabilities, expenses arising out of, or in
22 connection with, the performance of the Monitor's duties, including all reasonable
23 fees of counsel, and other reasonable expenses incurred in connection with the
24 preparations for, or defense of, any claim, whether or not resulting in any liability,
25 except to the extent that such losses, claims, damages, liabilities, or expenses
26 result from gross negligence, willful or wanton acts, or bad faith by Monitor; and
- 27 4. Defendants may require the Monitor and each of the Monitor's consultants,
28 accountants, attorneys, and other representatives and assistants to sign an

1 Submit to the Monitor a copy of the report. Among other things and without limitation,
2 Defendants shall include in each report:

- 3 1. a copy of each agreement a Defendant has entered with any party to a
4 Brand/Generic Settlement signed by Defendant if: (i) the Brand/Generic
5 Settlement Agreement includes an agreement by the Generic Filer not to research,
6 develop, manufacture, or Market the Subject Drug Product for any period of time;
7 and (ii) the agreement was entered within (6) months of executing the
8 Brand/Generic Settlement Agreement; provided that Defendants do not need to
9 submit any agreement that was submitted with a prior verified written report; and
- 10 2. if, during the period covered by the report, an NDA Holder has supplied
11 Authorized Generic to Defendant pursuant to a Contingent Supply Agreement
12 that Defendants assert is an Exemption Agreement, identify the Contingent Supply
13 Agreement; if Defendants have not obtained FDA approval for the Generic
14 Subject Drug Product, provide a statement describing the status of their efforts
15 and planned actions to obtain approval; and if Defendants are not able to
16 manufacture commercial quantities of the Generic Subject Drug Product, provide
17 a statement describing the status of their efforts and what steps they are taking to
18 develop commercial manufacturing capability.

19 B.

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XI.

IT IS FURTHER ORDERED that this Order shall terminate ten (10) years from the date on which the Order is issued.

1 STIPULATED AND AGREED

2
3
4 Bradley Scott Albert
5 Deputy Assistant Director
6 Health Care Division
7 Bureau of Competition
8 Federal Trade Commission
9 FOR PLAINTIFF FEDERAL TRADE COMMISSION

Date: _____

10 Paul V. Campanelli
11 President and Chief Executive Officer of Endo Pharmaceuticals Inc.
12 FOR ENDO PHARMACEUTICALS INC.

Date: _____

13
14 Jonathan L. Stern
15 Dechert LLP
16 Steven G. ...
17 Arnold & Porter Kaye Scholer LLP

18 Michael F. Brockmeyer
19 Former, Lawrence & Haug LLP
20 COUNSEL FOR ENDO PHARMACEUTICALS INC.

Date: _____

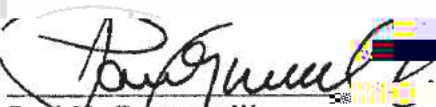
21
22 Paul V. Campanelli
23 President and Chief Executive Officer of Endo International
24 ENDO INTERNATIONAL PLC

Date: _____

25
26 George G. Gordon
27 Dechert LLP

1 SO STIPULATED AND AGREED.

2
3
4 Bradley Scott Albert
5 Deputy Assistant Director
6 Health Care Division
7 Bureau of Competition
8 Federal Trade Commission

9 

Date: 1-10-17

10 Paul V. Campanelli
11 President
12 FOP ENDO PHARMACEUTICALS INC.

13 

14 George G. Gordon
15 Dechert LLP

16 Jonathan L. Stern
17 Stern
18 Arnold & Porter Kaye LLP

19 Michael F. Brockmeier
20 Frommer, Lawrence & Haug LLP
21 COUNSEL FOR ENDO PHARMACEUTICALS INC.

22 

Date: 1/10/2017

23 Paul V. Campanelli
24 President and Chief Executive Officer
25 FOP ENDO INTERNATIONAL PLC

26 

27 George G. Gordon
28 Dechert LLP

Exhibit 1

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ENDO PHARMACEUTICALS INC., et. al.,

Plaintiffs,

v.

FEDERAL TRADE COMMISSION,

Defendant.

Case No: 16-cv-5599

NOTICE OF VOLUNTARY DISMISSAL WITH PREJUDICE

Pursuant to Federal Rule of Civil Procedure 41(a)(1), Plaintiffs Endo Pharmaceuticals Inc. and Endo International hereby give notice that their claims against Defendant in the above-captioned action are voluntarily dismissed with prejudice. The Defendant has not filed an answer or motion for summary judgment in this case.

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ENDO PHARMACEUTICALS INC., et. al.,

Plaintiffs,

v.

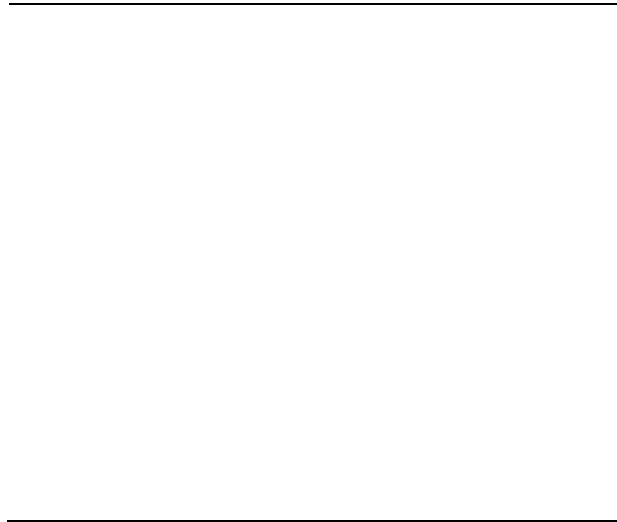
FEDERAL TRADE COMMISSION,

Defendant.

Case No: 16-cv-5600

NOTICE OF VOLUNTARY DISMISSAL WITH PREJUDICE

Pursuant to Federal Rule of Civil Procedure 41(a)(1)(A), Plaintiffs Endo Pharmaceuticals Inc. and Endo International hereby give notice that their claims against Defendant in the above-captioned action are voluntarily dismissed with prejudice. The Defendant has not filed an answer or motion for summary judgment in this case.



Cal.). A copy of the Stipulated Order for Permanent Injunction (“Permanent Injunction”) is attached as Exhibit A.

2. As of September 28, 2015, Par is a wholly owned indirect subsidiary of Endo International plc. (“Endo”).

3. Under the Permanent Injunction, Endo and its subsidiaries (including Par) are prohibited from entering into agreements similar to those challenged in this case. (Permanent Injunction at § II.) The scope of this prohibition is consistent with the relief the FTC seeks in this case. See

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

FEDERAL TRADE
COMMISSION,

Plaintiff,

vs.

ACTAVIS, INC., et al.,

Defendants.

Case Number: 1:09-cv-955-TWT

[Proposed] Order of Dismissal with Prejudice

Before this Court is Plaintiff Federal Trade Commission's Unopposed

ENTERED and ORDERED this ____ day of _____, 2017.

Honorable Thomas W. Thrash, Jr.