SETTLEMENT AGREEMENT AND STIPULATED ORDER FOR PERMANENT INJUNCTION AND MONETARY RELIEF

This Settlement Agreement and Stipulated Order ("ASO") is made and entered into this day of May, 2019 ("Effective Date"), by the Attorney General of the State of California ("California" or "Attorney General"), on the one hand, and Endo Pharmaceuticals Inc. and Endo International plc (collectively "Endo"), on the other (California and Endo, collectively, the "Parties").

WHEREAS, Endo Pharmaceuticals is or was engaged in the manufacturing, marketing, and/or selling certain pharmaceuticals, including but not limited to Lidoderm®, throughout the United States;

WHEREAS, the State of California alleges that it has reason to believe that Endo
Pharmaceuticals entered into an agreement that foreclosed competition from generic equivalents
of the brand-name drug Lidoderm® for a period of time in violation of federal antitrust and state
antitrust and consumer protection laws;

WHEREAS, California initiated an investigation of Endo with respect to the above alleged actions;

WHEREAS, California has filed an enforcement Complaint ("Complaint") against Endo in this Court alleging such violations of federal and state laws;

WHEREAS, Endo denies that it engaged in any wrongful or unlawful conduct and asserts that it has, at all times, operated within the law and within industry standard practices; and

WHEREAS, nothing in this ASO will be construed as a finding or admission of any violation of law on the part of Endo.

The Parties have agreed to resolve California's concerns identified through the investigation and the allegations in the Complaint by entering into this ASO, as follows:

FINDINGS

- 1. This Court has jurisdiction over the Parties and the subject matter of this action. Endo has stipulated that, for purposes of this ASO alone, the Court has jurisdiction over Endo Pharmaceuticals Inc. and Endo International plc.
- 2. Venue for these matters is proper in this Court under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c).
- 3. The Complaint alleges that Endo engaged in violations of federal antitrust and state antitrust and consumer protection laws by entering an agreement that foreclosed competition from generic equivalents of the brand-name drug Lidoderm® and later reduced competition between sellers of generic lidocaine patches.
- 4. Endo admits the facts necessary to establish the personal and subject matter jurisdiction of this Court in this matter only.
- 5. Endo denies the charges in the Complaint and disputes that California is entitled to obtain relief.
- 6. This Order does not constitute any evidence against Endo, or an admission of liability or wrongdoing by Endo, in this case or in any other litigation. This ASO shall not be used in any way, as evidence or otherwise, in any other litigation or proceeding; *provided*, *however*, that this provision shall not prevent California or Endo from using this ASO in any proceeding regarding enforcement or modification of this ASO or as otherwise required by law.
 - 7. Entry of this ASO is in the public interest. California and Endo have agreed to

stipulate to entry of this ASO to finally resolve the claims and litigation between them.

STIPULATIONS

- 1. California stipulates that it will not file litigation or any other proceedings against Endo asserting, or seeking remedies based on, Released Claims, other than any legal proceeding regarding enforcement or modification of this ASO.
- 2. Upon entry of this ASO by the Court, the Complaint shall be deemed dismissed with prejudice.

I. **DEFINITIONS**

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

- A. "505(b)(2) Application" means an application filed with the United States Food and Drug Administration pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, U.S.C. § 355(b)(2).
- B. "ANDA" means an Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j).
- C. "Authorized Generic" means a Drug Product that is manufactured pursuant to an NDA and Marketed in the United States under a name other than the proprietary name identified in the NDA.
- D. "Brand/Generic Settlement" means any agreement or understanding that settles a

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

Patent Infringement Claim in or affecting Commerce in the United States.

- F. "Branded Subject Drug Product" means a Subject Drug Product Marketed in the United States under the proprietary name identified in the NDA for the Subject Drug Product.
 - G. "Commerce" has the same definition as it has in 15 U.S.C. § 44.
- H. "Control" or "Controlled" means the holding of more than fifty percent (50%) of the common voting stock or ordinary shares in, or the right to appoint more than fifty percent (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.
- I. "Contingent Supply Agreement" means a Supply Agreement that: (i) is contingent on the Generic Filer's inability to market the Generic Subject Drug Product on or after the Generic Entry Date because (x) the FDA has not granted final approval of the Generic Filer's ANDA or 505(b)(2) Application for the Generic Subject Drug Product and/or (y) the Generic Filer cannot manufacture commercial quantities of the Generic Subject Drug Product; and (ii) terminates within thirty (30) days after the Generic Filer has final FDA approval and can manufacture commercial quantities of the Generic Subject Drug Product using good faith, commercially reasonable efforts, *provided, however*, the Generic Filer may take delivery of, Market, and sell quantities of Authorized Generic ordered prior to termination of the Supply Agreement *so long as* the total quantity of Authorized Generic delivered to the Generic Filer following termination of the Supply Agreement: (i) does not exceed the total quantity needed by the Generic Filer (as reflected in forecasts provided to the NDA Holder prior to termination of the Supply Agreement) during the eight (8) months following (x) termination of the Supply Agreement, if termination occurs after the Generic Entry Date, or (y) the Generic Entry Date, if

termination occurs before the Generic Entry Date; and (ii) is delivered within eight (8) months of termination of the Supply Agreement.

- J. "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.
- K. "Endo Pharmaceuticals" means Endo Pharmaceuticals Inc., any joint venture, subsidiary, division, group, or affiliate Controlled currently or in the future by Endo Pharmaceuticals Inc., their successors and assigns, and the respective directors, officers, employees, agents, and representatives acting on behalf of each.
- L. "Endo International" means Endo International plc, any joint venture, subsidiary, division, group, or affiliate Controlled currently or in the future by Endo International plc, their successors and assigns, and the respective directors, officers, employees, agents, and representatives acting on behalf of each.
 - M. "Endo" means Endo Pharmaceuticals and Endo International.
 - N. "Exception" means the following in a Brand/Generic Settlement:
 - 1. compensation for saved future litigation expenses, *but only if* the total compensation the NDA Holder agrees to provide to the Generic Filer during the sixty (60) day period starting thirty (30) days before and ending thirty (30) days after executing the Brand/Generic Settlement Agreement does not exceed a maximum limit, which is initially set at seven million, two hundred sixty-two thousand, eight hundred seventy-nine dollars

(\$7,262,879)¹ and shall be increased (or decreased) as of January 1 of each year following entry of this ASO 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: (i) Generic Product(s) in the United States under an ANDA or 505(b)(2) Application (x) that is controlled by the Generic Filer and was not transferred to the Generic Filer by the NDA Holder, or (y) to which the Generic Filer has a license from a party other than the NDA Holder; or (ii) an Authorized Generic of the Subject Drug Product; provided that this Exception shall apply regardless of whether or not the Generic Filer must pay for the right to Market and, if so, the terms and conditions governing such payment;
- 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;
- 4. waiver or limitation of a claim for damages or other monetary relief based on prior Marketing of the Generic Subject Drug Product, *but only if* the NDA Holder and the Generic Filer do not agree, and have not agreed, to another Brand/Generic Settlement for a different Drug Product during the sixty (60) day period starting thirty (30) days

For avoidance of doubt, this amount is intended to be equivalent to the maximum limit in the definition of Exception in the FTC Order, but is adjusted herein to reflect to the subsequent annual changes in the Producer Price Index as provided for in the FTC Order.

before and ending thirty (30) days after the execution of the Brand/Generic Settlement Agreement; or

- 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 agreeing to a Brand/Generic Settlement.
- O. "Exempted Agreement" means a Materials Agreement or Supply Agreement that meets all of the following conditions:
 - 1. the price is above the Fully Allocated Manufacturing Cost, meaning:
 - a. if the Agreement is a Materials Agreement, the Materials Price charged by the NDA Holder for Materials provided through the Materials Agreement is at or above the Fully Allocated Manufacturing Cost incurred by the NDA Holder per unit of the relevant Materials, or
 - b. if the Agreement is a Supply Agreement, the Supply Price charged by the NDA Holder for the Authorized Generic of the Subject Drug Product is at or above the Fully Allocated Manufacturing Cost incurred by the NDA Holder per unit of the Authorized Generic of the Subject Drug Product provided under the agreement;

- 2. the Brand/Generic Settlement Agreement containing or incorporating the Materials Agreement or Supply Agreement is the only Brand/Generic Settlement Agreement that the NDA Holder and the Generic Filer have entered, or agreed to enter, during the sixty (60) day period starting thirty (30) days before and ending thirty (30) days after the execution of the Brand/Generic Settlement Agreement;
- 3. within fourteen (14) days after signing the Brand/Generic Settlement
 Agreement containing or incorporating the Materials Agreement or Supply Agreement,
 Endo Submitted to the Monitor a full and complete copy of the Brand/Generic Settlement
 Agreement, including any Materials Agreement and/or Supply Agreement;
- 4. within fourteen (14) days after the NDA Holder provides to the Generic Filer the Materials Price or Supply Price, as applicable, Endo Submitted to the Monitor notification of the relevant Materials Price or Supply Price;
- 5. within thirty (30) days after beginning supply under the relevant Materials Agreement or Supply Agreement, the NDA Holder Submitted to the Monitor:
 - a. if a Materials Agreement, a verified written statement containing (i) the Fully Allocated Manufacturing Cost per unit for the Materials and (ii) a detailed calculation of the Fully Allocated Manufacturing Cost for the Materials, stated separately by cost component and on a per-unit basis; and
 - b. if a Supply Agreement, a verified written statement containing (i) the Fully Allocated Manufacturing Cost per unit for the relevant Authorized Generic of the Subject Drug Product and (ii) a detailed calculation of the Fully Allocated Manufacturing Cost for the Authorized Generic of the Subject Drug Product,

stated separately by cost component and on a per-unit basis; and

- 6. if the NDA Holder is not Endo, the Materials Agreement or Supply Agreement, as applicable, requires the NDA Holder to (i) provide the notification required by subparagraphs I.O.5. and (ii) cooperate with any reasonable request by the Monitor or staff of the FTC for documents and information to determine the relevant Fully Allocated Manufacturing Cost, including without limitation and subject to any demonstrated legally recognized privilege, providing the Monitor reasonable access to personnel, books, documents, and records kept in the ordinary course of business;
- 7. notwithstanding subparagraph I.O.5. and subparagraph I.O.6., a Materials Agreement or Supply Agreement in which Endo is the Generic Filer shall also be considered an Exempted Agreement if it complies with subparagraphs I.O.1. to 4. and:
 - a. if a Materials Agreement, Endo Submits to the Monitor within thirty (30) days of beginning to receive the Materials, a verified written statement containing (i) Endo's 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) Endo 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 Endo deems relevant to

understanding such terms and conditions; and

- b. if a Supply Agreement, it is a Contingent Supply Agreement and Endo Submits to the Monitor within thirty (30) days of beginning to receive the Authorized Generic, a verified written statement containing (i) Endo's best estimate of what would be the Fully Allocated Manufacturing Cost per unit for the Subject Drug Product if manufactured by the 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.
- P. "FTC" means the United States Federal Trade Commission.
- Q. "FTC Order" means the Stipulated Order for Permanent Injunction entered in the United States District Court for the Northern District of California, in *Federal Trade Commission* v. *Endo Pharmaceuticals Inc.*, Civ. Action No. 17-cv-00312 (Document 25, February 2, 2017).
- R. "Fully Allocated Manufacturing Cost" means: (1) direct costs incurred to produce or, if applicable, to acquire, the Subject Drug Product or Materials, determined in accordance with GAAP, as consistently applied in accordance with past practice and in the ordinary course of business, including, but not limited to (x) acquisition costs or (y) if applicable, materials, labor, manufacturing costs, packaging, labeling, testing, quality control, storage, insurance, and product maintenance; (2) the cost to ship the Subject Drug Product or Materials to the Generic Filer, and (3) administrative and overhead expenses associated with production or, if applicable, the acquisition of the Subject Drug Product or Materials, including, but not limited to, administrative labor costs, maintenance, information technology, quality assurance, insurance, depreciation of the equipment, and depreciation of the facility, allocated in accordance with past practice and in

the ordinary course of business. To the extent the NDA Holder does not allocate administrative and overhead expenses associated with the Subject Drug Product to the Subject Drug Product, for purposes of this ASO such administrative and overhead expenses shall be calculated as a proportion of the NDA Holder's COGS of the Subject Drug Product to the NDA Holder's total COGS (for purposes of this definition, COGS means the NDA Holder's cost of goods sold, determined in accordance with GAAP, as consistently applied in accordance with past practice and in the ordinary course of business).

- S. "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.
- T. "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 distribute the Subject Drug Product.
- U. "Generic Product" means a Drug Product manufactured and/or sold under an ANDA or pursuant to 505(b)(2) Application.
- V. "Generic Subject Drug Product" means the Generic Product that is the subject of the Patent Infringement Claim being resolved by the Brand/Generic Settlement.
- W. "Lidoderm Settlement Agreement" means the Settlement and License Agreement between Endo Pharmaceuticals Inc. and Watson Laboratories, Inc. resolving the ANDA patent litigation involving the brand-name drug Lidoderm that is the subject of the Complaint in this action.

- X. "Market," "Marketed," or "Marketing" means the promotion, offering for sale, sale, or distribution of a Drug Product.
- Y. "Materials" means components or ingredients used in the manufacturing of a Subject Drug Product, including, but not limited to, hard-to-source excipients, hard-to-source active pharmaceutical ingredients, hard-to-source packaging, devices, or kits for injectables.
- Z. "Materials Agreement" means provisions in, or incorporated into, a Brand/Generic Settlement Agreement providing for the supply of Materials to the Generic Filer by the NDA Holder for securing and/or maintaining regulatory approval, or manufacturing and Marketing by the Generic Filer of the Subject Drug Product, including the terms and conditions of any such supply.
- AA. "Materials Price" means the total actual per-unit price charged by the NDA Holder for Materials provided through a Materials Agreement, including any transfer price and royalty to be paid by the Generic Filer, net of any discounts, allowances, rebates, or other reductions.
- BB. "Monitor" means an individual appointed pursuant to Paragraph IV of the FTC Order.
- CC. "Multistate Agreement" means a similar single settlement agreement with multiple states related to the Covered Conduct (as defined in II.A below) containing similar enforcement, notification and reporting provisions as this ASO.
- DD. "NDA" means a New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), including all changes or supplements thereto that do not result in the submission

of a new NDA.

- EE. "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.
- FF. "No-AG Commitment" means any agreement with, or commitment or license to, the Generic Filer that prohibits, prevents, restricts, requires a delay of, or imposes a condition precedent upon the research, development, manufacture, regulatory approval, or Marketing of an Authorized Generic, *provided, however*, that agreement by the Generic Filer to pay royalties to the NDA Holder for the right to Market the Generic Subject Drug Product or an Authorized Generic of the Subject Drug Product, including agreement on the terms and conditions governing payment of such royalties, shall not be considered a No-AG Commitment.
- GG. "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.
- HH. "Payment by the NDA Holder to the Generic Filer" means a transfer of value, other than a No-AG Commitment, by the NDA Holder to the Generic Filer (including, but not limited to, 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 sixty (60) day period starting thirty (30) days before and ending thirty (30) days after executing a Brand/Generic Settlement Agreement.
 - II. "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 ASO, 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.

- JJ. "Supply Agreement" means provisions in, or incorporated into, a Brand/Generic Settlement Agreement providing for the supply of the Subject Drug Product to the Generic Filer by the NDA Holder for the Marketing by the Generic Filer of an Authorized Generic on or after the Generic Entry Date, including the terms and conditions of any such supply.
- KK. "Supply Price" means the total actual per-unit price charged by the NDA Holder for supply provided through a Supply Agreement, including any transfer price and royalty to be paid by the Generic Filer for the right to sell an Authorized Generic of the Subject Drug Product, net of any discounts, allowances, rebates, or other reductions.
- LL. "U.S. Patent" means any patent issued by the United States Patent and Trademark Office, including all renewals, derivations, divisions, reissues, continuations, continuations-in part, modifications, or extensions thereof.
- MM. "Verified Written Report" means a report that must be submitted to the FTC pursuant to Paragraph V of the FTC Order.
- NN. "Effective Date" means the date on which California receives the Settlement Payment described in Section III below.

II. RELEASED CLAIMS

IT IS FURTHER ORDERED that:

A. Release. In consideration of the injunctive provisions and Settlement Amount contained herein, the State of California will be deemed, upon the Effective Date, to have fully,

finally, and forever released Endo and affiliated entities and their current and former officers, directors, employees, agents, other associated persons and attorneys (collectively "Releasees") from any and all manner of claims, counterclaims, set-offs, demands, actions, rights, liabilities, costs, debts, expenses, attorneys' fees, and causes of action of any type, whether or not accrued in whole or in part, known or unknown, under federal or state law, arising from the Lidoderm Settlement Agreement and from the facts, matters, transactions, events, occurrences, acts, disclosures, statements, omissions, or failures to act arising from said agreement ("Covered Conduct") that were asserted or alleged, or could have been asserted or alleged, in the Complaint by its Attorney General in his sovereign capacity as the chief law enforcement officer of the State of California. The State of California is otherwise deemed to have stipulated and agreed that, in light of the terms of this settlement agreement and the class settlement reached on behalf of California natural persons in In re Lidoderm Antitrust Litigation, No. 14-md-02521-WHO (N.D. Cal.), which includes a waiver of Section 1542 of the California Civil Code, neither it nor its Attorney General will assert any claim in any capacity or any claim on behalf of its departments, commissions, divisions, districts and other agencies, and the predecessors, successors, administrators and assigns of any of the foregoing against Endo arising from the Covered Conduct that were asserted or alleged, or could have been asserted or alleged, in its Complaint. This agreement does not relate to or release the Excluded Claims defined below. In addition, in connection with the release provided above, the Parties expressly waive, release, and forever discharge any and all provisions, rights, and benefits conferred by § 1542 of the California Civil Code, which reads:

Section 1542. General Release; extent. A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor;

or by any law of any state or territory of the United States or other jurisdiction, or principle of common law, which is similar, comparable or equivalent to § 1542 of the California Civil Code. A Party may hereafter discover facts other than or different from those which he, she, or it knows or believes to be true with respect to the Released Claims, but each Party hereby expressly waives and fully, finally, and forever settles, releases, and discharges, upon this ASO becoming final, any known or unknown, suspected or unsuspected, asserted or unasserted, contingent or non-contingent claim that would otherwise fall within the definition of Released Claims, whether or not concealed or hidden, without regard to the subsequent discovery or existence of such different or additional facts. This provision shall not in any way expand the scope of the Released Claims and shall not convert what is a limited release into a general release.

- B. Excluded Claims. The release provided herein shall not have an effect on the following Excluded Claims and such Excluded Claims shall not be included within the Released Claims:
 - (1) claims for alleged violations of state revenue codes;
 - (2) claims based on alleged breach of expressed or implied warranty claims or other liability for defective or deficient products and services provided by Endo;
 - (3) claims based on alleged failure to deliver goods or services due; or
 - (4) any claim for liability under common law, any statute, regulation, or rule lawfully promulgated under California's administrative code or other enabling legislation for any conduct other than the Covered Conduct, including but not limited to:
 - claims regarding Medicare or Medicaid fraud, false claims, unlawful kickbacks, off-label marketing, unfair or deceptive representations,

false advertising or product liability;

- ii. claims for criminal liability; or
- iii. claims for breach of this ASO.
- C. Res Judicata. The ASO shall be deemed to have rendered any Released Claim as res judicata.

III. SETTLEMENT PAYMENT

IT IS FURTHER ORDERED that:

A. Endo Pharmaceuticals Inc. shall make a payment to California in the amount of U.S. \$760,000 ("Settlement Amount") within the later of thirty (30) calendar days after the Effective Date or thirty (30) calendar days after receiving written payment processing instructions and any related documentation reasonably requested by Endo. In accordance with Section 162(f) of the Internal Revenue Code, the Settlement Amount is an amount paid to come into compliance with the antitrust, consumer protection and other laws of California as cited in the Complaint. No portion of that Settlement Amount represents reimbursement to California or any other person or entity for the costs of any investigation or litigation. In addition, the Parties understand and agree that no portion of the Settlement Amount represents or can be characterized as the payment of fines, penalties, or other punitive assessments. Each Party agrees to perform such further acts and to execute and to deliver such further documents as may reasonably be necessary to carry out this Agreement.

Notwithstanding the foregoing regarding what the Settlement Amount represents, upon receipt of the Settlement Amount, California shall have sole discretion as to its use and the

allocation of settlement, and Endo shall have no responsibility for or influence with respect to such use(s) or allocation(s). California shall provide Endo Pharmaceuticals Inc. with written payment processing instructions for payment of the Settlement Amount by electronic transfer.

The payment may be used by the California Attorney General for any one or more of the following purposes, as the Attorney General, in his sole discretion, sees fit: (i) antitrust or consumer protection law enforcement; (ii) for deposit of monies received under the Cartwright Act into a state antitrust or consumer protection account for use in accordance with the state laws governing that account; (iii) for deposit into a fund exclusively dedicated to assisting the California Attorney General enforce the antitrust laws; or (iv) for such other purpose as the California Attorney General deems appropriate, consistent with state law.

B. Endo warrants that, as of the date of this Settlement Agreement, it is not insolvent, nor will its Settlement Payment render it insolvent within the meaning of and/or for the purposes of the United States Bankruptcy Code. If (i) a case is commenced with respect to Endo under Title 11 of the United States Code (Bankruptcy), or a trustee, receiver or conservator is appointed under any similar law, and (ii) a court of competent jurisdiction enters a final order determining the Settlement Payment, or any portion thereof, by or on behalf of Endo Pharmaceuticals Inc., to be a preference, voidable transfer, fraudulent transfer or similar transaction, and (iii) pursuant to an order of a court of competent jurisdiction monies paid by Endo Pharmaceuticals Inc. pursuant to this Settlement Agreement are either not delivered or are returned to Endo Pharmaceuticals Inc. or the trustee, receiver, or conservator appointed by a court in any bankruptcy proceeding with respect to Endo Pharmaceuticals Inc., the releases given and judgment entered in favor of Endo pursuant to this Settlement Agreement shall be null and void.

IV. PERMANENT INJUNCTION

IT IS FURTHER ORDERED that:

- A. In connection with any actions in or affecting Commerce, Endo shall cease and desist from, either directly or indirectly, or through any corporate or other device, individually or collectively entering into a Brand/Generic Settlement that includes:
 - (i) a No-AG Commitment and (ii) an agreement by the Generic Filer not to research, develop, manufacture, or Market the Subject Drug Product for any period of time; or
 - (i) any Payment by the NDA Holder to the Generic Filer that is not an
 Exception or an Exempted Agreement and (ii) an agreement by the
 Generic Filer not to research, develop, manufacture, or Market the Subject
 Drug Product for any period of time,

Provided, however, that any agreement entered into by an entity prior to that entity becoming part of Endo is not subject to the terms of this ASO.

- B. In the event of a material change in the law governing the antitrust implications of Brand/Generic Settlements, California will consider, in good faith, modifications to this ASO proposed by Endo.
- C. Nothing in this ASO shall prohibit Endo from entering a written agreement, including a Brand/Generic Settlement, for which Endo has submitted to California a request for prior approval of the agreement, which shall include any information provided to the FTC pursuant to Paragraph III of the FTC Order, *so long as* (1) within thirty (30) days of California's

receipt of the request for prior approval under this provision, California has not notified Endo in writing that, after considering the request in good faith, it believes the relevant agreement raises substantial questions regarding violation of state or federal antitrust law or any other applicable law that its Attorney General has authority to enforce and of the reasons for such a belief, or (2) Endo has received California's prior approval.

D. Nothing in this Section IV shall prohibit Endo from executing a written agreement so long as such agreement contains a provision or provisions expressly stating: (1) Endo will submit to California a request for prior approval of the agreement, and (2) the agreement is not effective, and shall not become effective, until and unless (i) thirty (30) days have passed since the request for prior approval was submitted to California and California has not notified Endo in writing that it believes the agreement raises substantial questions regarding violation of state or federal antitrust law or any other applicable law that its Attorney General has authority to enforce, or (ii) California has approved of the agreement.

V. ENFORCEMENT AUTHORITY

IT IS FURTHER ORDERED that:

- A. The Attorney General of the State of California shall have exclusive responsibility for enforcing this ASO running in favor of California.
- B. If California believes that Endo is not in compliance with the terms of this ASO, it shall give Endo written notice of such alleged non-compliance and the reasons why it believes that Endo is not complying with this ASO. Endo shall have twenty (20) business days from the date of receipt of such notice to respond in writing unless otherwise agreed by the Parties. If California is not satisfied with Endo's response, it shall so notify Endo in writing, and Endo shall

have seventy-five (75) calendar days from the date of receipt of such notice to cure such alleged non-compliance.

- C. In the event that California believes that Endo remains in non-compliance with any of the provisions of this ASO other than those in Section IV (Permanent Injunction) following the notice and cure period provided in Section V.B., above, California may seek to enforce such provisions of this ASO by filing a motion in this Court, seeking such relief as is available under applicable laws, including, if so available, fees and costs thereof, and civil penalties. Such civil enforcement proceedings shall be governed by a preponderance of the evidence standard, absent an applicable statutory provision or other binding legal authority to the contrary
- D. In the event that California believes that Endo remains in non-compliance with any of the provisions of Section IV (Permanent Injunction) of this ASO following the notice and cure period provided in Section V.B., above, California shall request that the FTC review Endo's compliance with the corresponding provisions of Paragraph II of the FTC Order and consider pursuing coordinated enforcement proceedings under this ASO and the FTC Order. In the event that the FTC declines or fails to agree after forty-five (45) days from such a request by California to take action to enforce Paragraph II of the FTC Order, California may then seek to enforce Section IV of this ASO by filing a motion in this Court, seeking such relief as is available under applicable laws, including, if so available, fees and costs thereof, and civil penalties. Such civil enforcement proceedings shall be governed by a preponderance of the evidence standard, absent an applicable statutory provision or other binding legal authority to the contrary. California shall provide written notice to Endo within three (3) business days of any request(s) to the FTC provided herein.

E. Nothing in this Section V, however, prohibits California from pursuing immediate enforcement for alleged non-compliance with this ASO upon a showing that delay would cause irreparable harm or would prevent California from seeking adequate enforcement of the ASO.

VI. REPORTING AND MONITORING OBLIGATIONS

IT IS FURTHER ORDERED that:

- A. Each Verified Written Report that Endo is required to submit to the FTC shall also be submitted to California within five (5) business days of submission to the FTC.
- B. Each Branded/Generic Settlement Agreement submitted to the FTC pursuant to Section 1112(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 shall also be submitted to California within five (5) business days of submission to the FTC.
- C. Endo shall consent to the FTC providing California with a copy of each written report that the Monitor is required to submit to the FTC under the FTC Order within five (5) business days of submission to the FTC.
- D. Endo shall consent to the FTC providing California with copies of any and all of its submissions to the FTC under the FTC Order made between February 2, 2017 and the entry of this ASO, provided that: (a) Endo shall have five (5) business days after the entry of this ASO to notify the necessary third parties of the pending disclosure; (b) such third parties shall have twenty (20) business days from the entry of this ASO to assert an objection to this Court; and (c) Endo's consent shall not be effective until, either: (i) twenty-six (26) business days from the entry of this ASO have passed without a third party having asserted an objection to this Court; or

- (ii) if a third party has asserted an objection, this Court has issued a ruling permitting such disclosure over any such objection(s).
- E. Except as provided in Section VI.F. below, any agreements, information, or documents submitted by Endo to California pursuant to this ASO ("Endo Materials") shall be kept confidential pursuant to California Government Code sections 11180 *et seq.* and may be divulged or disclosed by California only to a person or entity who is California's authorized representative or retained consultant or expert, who is engaged in matters pertaining to the implementation or enforcement of this ASO, and who has agreed to be bound by the provisions of this Section VI.D. To the extent California retains private counsel to investigate or assert potential claims against Endo in matters that are not related to the implementation or enforcement of this ASO, then no Endo Materials may be disclosed or divulged to those private counsel.
 - F. Notwithstanding the foregoing Section VI.D,
 - 1. Endo Materials may be disclosed in the course of a legal proceeding between Parties to this ASO to enforce or modify this ASO, provided all parties to such a proceeding take reasonable steps to prevent disclosure of such Endo Materials to persons or entities who are not Parties to this ASO and Endo is given at least ten (10) business days' advance written notice and a reasonable opportunity to preserve the confidentiality of Endo Materials sought to be disclosed;
 - 2. California may disclose Endo Materials in response to a discovery request or other legal process in a legal proceeding to which it is a party, or as otherwise

required by law (other than a grand jury proceeding), provided California shall reasonably attempt to preserve the confidentiality of such Endo Materials by proceeding under any applicable protective order and/or utilizing sealing procedures provided by law or court rule and by providing Endo with at least ten (10) business days' advance written notice and a reasonable opportunity to preserve the confidentiality of Endo Materials sought to be disclosed before disclosing such Endo Materials to a third party; and

- 3. Endo Materials may be disclosed to the FTC or the United States

 Department of Justice, provided Endo is given at least ten (10) business days'

 advance written notice of such disclosure.
- 4. Endo Materials may be disclosed to another state that has reached a similar settlement agreement with Endo with respect to Lidoderm, provided that (i) such state agrees to be bound by the confidentiality protections set forth at California Government Code sections 11180, et seq, (ii) Endo is given at least ten (10) business days written notice of such disclosure, and (iii) such disclosure shall not be made until the time period regarding notice to third parties and the opportunity to object provided for in Section VI.D. above has passed.
- F. California acknowledges and agrees that (i) the production of Endo Materials to California is compelled by the terms of this ASO; (ii) Endo may mark any such Endo Materials, where appropriate, as trade secrets or otherwise exempt from public disclosure ("Confidential Endo Materials"); (iii) Endo does not waive any claimed exemption from public disclosure under any law with respect to Confidential Endo Materials, and (iv) nothing in this ASO shall prevent

Endo from seeking appropriate relief under California law concerning public disclosures. In the event of a request for production of any Endo Materials pursuant to any law regarding public disclosure of documents in California's possession (a "Records Request Notice"), the Attorney General staff, to the extent not prohibited by law, shall (a) promptly provide Endo with notice and a copy of the Records Request Notice, (b) designate any Confidential Endo Materials as falling within any trade secret or similar exemptions from disclosure under California laws, and (c) notify Endo in advance of any disclosure of any Endo Materials in order to afford Endo the ability to seek appropriate relief under California law with respect to the disclosure of such Endo Materials.

- G. Said documents and reports to be produced to California as specified in the preceding paragraphs shall be addressed to its Attorney General, with an electronic copy provided to the Senior Assistant Attorney General of the Antitrust Law Section at Kathleen.Foote@doj.ca.gov.
- H. An enforcement action in this Court pursuant to this ASO shall be the exclusive remedy for violation of this ASO. Neither the terms of this ASO nor any reports or notices provided by Endo under this ASO shall operate as a waiver of any future claims by any third party. Further, any such reports or notices provided by Endo to California under this ASO shall not be deemed to constitute actual or constructive notice of any claims as to any third party. No provision in this ASO may be used as evidence by the Parties in a proceeding other than an enforcement action pursuant to this ASO.

VII. PROPOSED CHANGE OF CORPORATE CONTROL

IT IS FURTHER ORDERED that:

- A. Endo shall notify California at least thirty (30) days prior to:
 - 1. Any proposed dissolution of Endo; or
 - 2. Any proposed acquisition, merger, or consolidation of Endo; or
 - 3. Any other change in Endo, including, but not limited to, assignment and the creation, sale or dissolution of subsidiaries, if such change might affect the compliance obligations arising out of this ASO.
- B. Endo shall notify California within ten (10) days after any filing by Endo of a petition in bankruptcy.
- C. Endo shall submit any notice required under this paragraph to California, addressed to its Attorney General, with an electronic copy provided to the Senior Assistant Attorney General of the Antitrust Law Section at Kathleen.Foote@doj.ca.gov.

VIII. ACCESS TO INFORMATION

IT IS FURTHER ORDERED that:

- A. For the purpose of determining or securing compliance with this ASO, subject to and without limiting any legally recognized privilege, and upon written request with reasonable advance notice, Endo shall:
 - 1. timely respond to and cooperate with California's reasonable request for production of documents or information related to compliance, including permitting any duly authorized representative of California to access, during office hours and in the presence of counsel, all facilities and access to inspect and copy all non-privileged business records and

documentary material (which may be redacted for privilege) related to compliance with this ASO, including without limitation, electronically stored information as defined in Rule 2.7(a)(1) and (2), 16 C.F.R. §2.7(a)(1), and books, ledgers, accounts, correspondence, memoranda, written justifications, economic models, and other records and documents (in whatever form such records and documents are kept) in the possession or under the control of Endo, which copying services shall be provided by Endo in a timely manner at California's request;

- permit any duly authorized representative of California to interview officers, directors, or employees of Endo, who may have counsel present, regarding any such matters; and
 agree to accept service of process of any motion filed with the Court hereunder and, subject to any objections Endo may assert, cooperate with any subpoenas issued by
 California in connection with any motion to enforce this ASO.
- B. California shall to the fullest extent possible coordinate any requests for information under this Section with the FTC, Department of Justice, and any other state that has reached a similar settlement agreement with Endo with respect to Lidoderm, if involved.

IX. EFFECT OF SUBSEQUENT SETTLEMENTS WITH OTHER STATES

A. If following the filing or entry of this ASO, Endo enters into a Multistate Agreement, California will join the enforcement and reporting provisions in the Multistate Agreement. The Parties will submit an amended ASO reflecting that California's enforcement authority and each of Endo's notification and reporting obligations, including but not limited to the provisions reflected in paragraphs IV.B, IV.C, and V through VIII (with the exception of VI.F regarding confidentiality) above, have been replaced by the corresponding provisions in the Multistate Agreement.

B. If following the filing or entry of this ASO, Endo enters into a similar settlement agreement with another state, or a series of similar agreements with individual states, but has not entered into a Multistate Agreement, California shall coordinate its enforcement actions, and Endo's reporting obligations with such other state(s). The Parties will use their best efforts to negotiate an agreement among and between Endo, California and the other settling states to coordinate enforcement authority and Endo's notification and reporting obligations under the respective settlement agreement(s) with Endo and will submit any such agreement to this Court as an amendment to this ASO.

X. JURISDICTION

IT IS FURTHER ORDERED that this Court shall retain jurisdiction over these matters for purposes of construction, modification, and enforcement of this ASO.

XI. TERMINATION

IT IS FURTHER ORDERED that this ASO shall terminate on February 2, 2027.

XI. **DISMISSAL WITH PREJUDICE**

IT IS FURTHER ORDERED that within five (5) days of the Effective Date, California shall file a notice of voluntary dismissal with prejudice of its Complaint against Endo. Each party to bear its own costs aside from the Settlement Amount paid to California.

SO ORDERED this 6th day of June, 2019.

The Honorable William H. Orrick

Date:

SO STIPULATED AND AGREED:

FOR THE STATE OF CALIFORNIA:

XAVIER BECERRA

Attorney General of California

Cheryl Lee Johnson

Deputy Attorney General

California Department of Justice

Office of the Attorney General

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FOR ENDO PHARMACEUTICALS INC.:

Name:

By:

Paul Campanelli

Title:

Chief Executive Officer

FOR ENDO INTERNATIONAL PLC:

Name:

Title:

Paul Campanelli

Chief Executive Officer

 $\mathbf{R}\mathbf{v}$

George G. Gordon

Dechert LLP

COUNSEL FOR ENDO PHARMACEUTICALS INC. AND

ENDO INTERNATIONAL PLC

5/8/19