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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

STATE OF CALIFORNIA **STATE OF ALABAMA** **STATE OF ARKANSAS** **STATE OF DELAWARE** **DISTRICT OF COLUMBIA** **STATE OF FLORIDA** **STATE OF HAWAII** **STATE OF IDAHO** **STATE OF ILLINOIS** **STATE OF INDIANA**	Case No. 18-cv-675 **SETTLEMENT AGREEMENT AND STIPULATED ORDER FOR ENTRY OF INJUNCTION**

STATE OF IOWA
COMMONWEALTH OF KENTUCKY
STATE OF LOUISIANA
STATE OF MARYLAND
STATE OF MINNESOTA
STATE OF MISSISSIPPI
STATE OF NORTH DAKOTA
STATE OF OKLAHOMA
STATE OF OHIO
STATE OF RHODE ISLAND
STATE OF WASHINGTON
STATE OF WISCONSIN
COMMONWEALTH OF VIRGINIA

Plaintiffs,

v.

TEIKOKU SEIYAKU CO., LTD. and TEIKOKU PHARMA USA, INC.

Defendants.

This Settlement Agreement and Stipulated Order for Entry of Injunction (ASO) is made and entered into this 31st day of January, 2018, by and between the States of States of California, Alabama, Arkansas, Delaware, Hawaii, Florida, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maryland, Minnesota, Mississippi, North Dakota, Oklahoma, Ohio, Rhode Island, Virginia, Washington, and Wisconsin, and the District of Columbia through their respective Attorneys General acting in their law enforcement and sovereign capacities (the "States"), on the one hand, and Teikoku Pharma USA, Inc. (TPU) and Teikoku Seiyaku Co., Ltd. (TSC)

(hereinafter together "Teikoku"), on the other (collectively "Parties"). Any State electing to join the ASO shall do so by executing a signature page that shall be annexed to this ASO.

WHEREAS, TSC manufactures a five-percent lidocaine patch product sold under the brand name Lidoderm® in Japan, which it sells to its wholly owned subsidiary TPU;

WHEREAS, TPU is the owner of the New Drug Approval for Lidoderm® and TPU sells Lidoderm® in the United States to Endo Pharmaceuticals;

WHEREAS, on May 28, 2012, Teikoku entered into a Settlement and License Agreement with Endo Pharmaceuticals, Inc. and Watson Laboratories, Inc., which agreement settled litigation captioned *Endo Pharmaceuticals Inc., et al. v. Watson Laboratories, Inc.,* Civil Action No. 1:10-cv-l38-GMS and *Endo Pharmaceuticals Inc. v. Watson Laboratories, Inc.,* Civil Action No. ll-cv-S75-GMS (the "Lidoderm Settlement and License Agreement");

WHEREAS, the States contend that the Lidoderm Settlement and License Agreement delayed and foreclosed competition from generic equivalents of Lidoderm® for a period of time in violation of federal and state antitrust and consumer protection laws;

WHEREAS, the States initiated an investigation of Teikoku with respect to the above alleged actions;

WHEREAS, Teikoku deny that they have engaged in any wrongful or unlawful conduct and contend that they have, at all times, operated within the law and within industry standard practices;

WHEREAS, the Parties have agreed to resolve any claims arising from the States' investigation through this ASO;

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

WHEREAS, Teikoku have consented to this ASO and will comply with the provisions of this ASO pending entry by the Court of the Stipulated Order for Entry of Injunction per the terms of this ASO; and

WHEREAS, the States contend that the entry of this ASO is in the public interest;

THEREFORE, IT IS on this 31st day of January, 2018 AGREED, as follows:

I. DEFINITIONS

For purposes of this ASO, the following definitions apply:

1. "States" means the Attorneys General of the states of States of California, Alabama, Arkansas, Delaware, Hawaii, Florida, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maryland, Minnesota, Mississippi, North Dakota, Oklahoma, Ohio, Rhode Island, Virginia, Washington, and Wisconsin, and the District of Columbia.

2. "Teikoku" means Teikoku Pharma USA, Inc. and Teikoku Seiyaku Co., Ltd. collectively, and their respective predecessors, affiliates, parent, and assigns, any joint venture, subsidiary, division, group, or affiliate controlled directly or indirectly, currently or in the future, by Teikoku, their successors and assigns, including successors in interest through bankruptcy, merger, acquisition or otherwise, and the respective directors, officers, employees, agents, and representatives acting on behalf of each.

3. "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, 21 U.S.C.§ 355(b)(2).

4. "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).

5. "Authorized Generic" or "AG" means a Drug Product that is manufactured pursuant to an NDA and marketed, sold, or distributed in the United States under a name other than the proprietary name identified in the NDA, or by the NDA Holder or a party at the direction or consent of the NDA Holder.

6. "Brand/Generic Settlement" means any agreement or understanding that resolves, settles or results in termination of a Patent Claim that has been threatened or made by or against an NDA Holder with respect to any Patent alleged to cover any Drug Product, whether said Claim has

been filed in a court or in the Patent & Trademark Office or before the Patent Trademark & Appeals Board.

7. "Brand/Generic Settlement Agreement" means a written agreement that resolves, settles, precedes or follows by up to 30 days the termination of a Patent Claim.

8. "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.

9. "Commerce" has the same definition as it has in 15 U.S.C. § § 12, 44.

10. "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.

11. "Drug Product" means a finished dosage form (e.g., tablet, capsule, solution, or patch), as defined in 21 C.F.R. § 3l4.3(b), that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

12. "Investigation" means the investigation conducted by the States.

13. "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.

14. "Generic Product" means a Drug Product manufactured and/or sold under an ANDA or pursuant to a 505(b)(2) Application.

15. "Lidoderm Settlement and License Agreement" means the Settlement and License Agreement entered into on or about May 28, 2012, by and between Endo Pharmaceuticals Inc., Teikoku, and Watson Laboratories, Inc. relating to Lidoderm®.

16. "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.

17. "NDA Holder" means a party 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.

18. "No-AG Commitment" means any agreement with, or commitment or license to, a Generic Filer that restricts, delays, transfers, imposes a condition precedent upon, or otherwise interferes with the research, development, manufacture, regulatory approval, marketing or sale of an Authorized Generic.

19. "Patent Claim" means any allegation threatened or included in a petition or complaint filed with a court of law or with the United States Patent & Trademark Office or Patent Trial & Appeal Board, that a Generic Product or other Drug Product may infringe any U.S. Patent held by, or licensed to, an NDA Holder, or that any U.S. Patent held by the NDA Holder is invalid, unenforceable or not infringed, or that any U.S. Patent held by a Generic Filer is invalid, unenforceable or not infringed.

20. "Payment by the NDA Holder to the Generic Filer" means a transfer of any form of value or consideration by the NDA Holder to the Generic Filer (including, but not limited to: a No-AG Commitment; money; contracts for distribution, manufacturing, co-promotion, stand-by manufacturing, co-development[1]; agreements about the dates of launch of the Subject Drug Products or other drug products outside the United States; settlements of pre-existing lawsuits; or other contracts for goods, or services) regardless of whether the Generic Filer purportedly transfers value in return, where such transfer is either (i) implicitly or expressly contingent on entering into a Brand/Generic Settlement Agreement, or (ii) agreed to or formulated in whole or in part, during the 60 day period starting 30 days before executing a Brand/Generic Settlement Agreement and ending 30 days after executing a Brand/Generic Settlement Agreement. The following, however, are not Payments by the NDA Holder to the Generic Filer:

[1] Contracts for distribution, manufacturing, co-promotion, stand-by manufacturing, co-development will not be considered Payments under this definition if they were contemplated, executed and documented at least in part more than 30 days prior to the commencement of discussion of the resolution of a Patent Claim or more than 30 days after the resolution of a Patent Claim and are the result of an arms length transaction that is not implicitly or expressly contingent on entering into a Brand/Generic Settlement Agreement.

a. compensation for saved future litigation expenses of the Brand or Generic Filer that Teikoku can prove was budgeted and forecast in writing in good faith at least four months prior to the subject Brand/Generic Settlement Agreement, not to exceed a maximum limit which is initially set at seven million dollars ($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 ld. PCU541 1--541 1--) published by the Bureau of Labor Statistics of the United States Department of Labor, or its successor;

b. provisions in a Brand/Generic Settlement Agreement that provide only a date after which a Generic Filer can begin selling, offering for sale, or distributing the Subject Drug Product on the condition that Teikoku enters into no other agreements otherwise providing Payments to a Generic Filer less than 30 days before or greater than 30 days after the resolution of the Patent Claim;

c. continuation or renewal of a pre-existing agreement provided: (i) the preexisting agreement was entered at least thirty (30) 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 preexisting agreement; and (iii) entering the continuation or renewal is not implicitly or expressly contingent on agreeing to a Brand/Generic Settlement or termination of a Patent Claim.

d. provisions in a Brand/Generic Settlement Agreement that permit a Generic Filer to begin selling, offering for sale, or distributing the Subject Drug Product once another drug company begins selling, offering for sale, or distributing the Subject Drug Product.

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

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

23. "States Enforcement Council" means counsel for the States of California, Minnesota, Mississippi and any other State whose status as States Enforcement Council has been established per this Agreement.

II. PROHIBITED AGREEMENTS

A. From the date Teikoku signs this ASO, Teikoku individually and collectively, are prohibited from entering into any Brand/Generic Settlement that includes both: (1) Payment by the NDA Holder to the Generic Filer; and (2) an agreement by the Generic Filer not to research, develop, manufacture, market, or sell the Subject Drug Product or any other drug product for any period of time.

B. Nothing in this ASO shall preclude any State from challenging a future Brand/Generic Agreement under otherwise applicable law if such future Brand/Generic Agreement falls outside the scope of this ASO. Nothing in this ASO shall or can be utilized in any litigation or manner outside of any enforcement action brought under this ASO.

III. ENFORCEMENT AUTHORITY

A. The States Enforcement Council shall consist initially of the Attorney General of the State of California, the Attorney General of Louisiana, the Attorney General of Minnesota, the Attorney General of Mississippi (the original States Enforcement Council). Any other State that has provided Teikoku 30 days' notice of its desire to serve as a member of the States Enforcement Council shall become active members of the States Enforcement Council upon the expiration of the 30-day notice period. The States that are party to this ASO shall have exclusive authority to enforce this ASO as set forth herein, but only active members of the States Enforcement Council shall have authority to implement the Reporting Requirements set forth under Section IV of this ASO or the right to demand and receive Reports from Teikoku under this ASO.

B. The States Enforcement Council shall have the exclusive authority to implement the terms of this ASO by filing a complaint and request to enter the Stipulated Order for Injunctive

Relief described herein. The exclusive forum to file such a complaint and request or in which to file any complaint, petition or other action to enforce the terms of this ASO shall be the United States District Court for the Northern District of California (the "Court"). The States Enforcement Council shall also have the exclusive authority to seek such orders as are necessary from the Court to enforce this Stipulated Order, provided, however, that the States Enforcement Council will provide notice of an alleged violation and an opportunity to cure alleged violations to Teikoku as set forth below. Notwithstanding the foregoing, any action by the Teikoku to cure any such violation shall not be a defense to enforcement with respect to any knowing, willful or systematic violations of this ASO.

C. If any of the States Enforcement Council or any party State believes that a Teikoku entity is not in compliance with the terms of this ASO, the States Enforcement Council shall give Teikoku written notice of such alleged non-compliance. Teikoku shall have fifteen (15) working days from the date of receipt to respond in writing to such notice unless the parties agree to a longer period of time. If the States Enforcement Council is not satisfied with Teikoku's response, it shall notify Teikoku in writing, and Teikoku shall have thirty (30) calendar days from the date of receipt of the States' response to cure such non-compliance. If after such time, the States Enforcement Council alleges that a Teikoku entity is still not in compliance, the States Enforcement Council may seek enforcement, fees and costs thereof, and civil penalties as granted by applicable state law. Nothing in this clause prohibits the States Enforcement Council from pursuing immediate enforcement for potential noncompliance if delay would cause irreparable harm or prevent the States Enforcement Council from adequately enforcing the ASO.

D. The Parties agree that the exclusive venue for enforcing this ASO or any disputes that arise out of the interpretation of this ASO or the entry of the Stipulated Order for Injunctive Relief shall be the United States District Court for the Northern District of California (the "Court") and that no such action shall be brought in any other forum. The Parties agree to submit to the jurisdiction of the Court to resolve such disputes and that the Court has the subject matter to resolve them. The Parties further agree that venue to bring such action properly lies in the Court.

E. To the extent the States Enforcement Council commences legal action to challenge a Brand/Generic Settlement, any party State wishing to proceed as a member of the States Enforcement Council as to that challenge must provide Teikoku with notice of its intention to do so within 90 days of the commencement of such proceeding.

IV. REPORTING REQUIREMENTS

A. To determine and enforce compliance with this ASO, Teikoku shall submit to the States Enforcement Council:

1) Copies of all agreements submitted to the Federal Trade Commission Bureau of Competition and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice pursuant to Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the 2003 Act).

2) Copies of the written reports and additional documents required to be submitted to the FTC under Section II of the FTC SO.

3) Along with each verified written report required under this section, Teikoku shall also provide the States Enforcement Council a copy of any additional agreement with a party to a Brand/Generic Settlement to which Teikoku is also 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. For clarity, Teikoku need not submit such additional agreement to the extent such agreement was submitted with a prior verified written report to the States Enforcement Council pursuant to this ASO; this provision is intended to mirror the requirement set forth in the FTC SO.

B. Any reports or notices required under this ASO shall be submitted to each active member of the States Enforcement Council. Specific address information for Teikoku and for each current member of the States Enforcement Council and all States that are party to this ASO

is attached hereto as Exhibit A. Teikoku may, at its option, provide notice to any State that is a party to this ASO.

C. No agreements, information or documents produced by Teikoku pursuant to this ASO shall be divulged by any party State to any person not an authorized representative or retained consultant or expert of any party State as set forth above, with the following exceptions:

1) in the course of a legal proceeding regarding enforcement or modification of this ASO provided all parties to such a proceeding take reasonable steps to protect the confidentiality of documents or information that they may reasonably understand Teikoku considers confidential;

2) as otherwise required by law for the purpose of securing compliance with this ASO provided Teikoku is given notice and a reasonable opportunity to preserve the confidentiality of documents that might otherwise be disclosed;

3) in a legal proceeding to which a party State is a party, or as otherwise required by law (other than a grand jury proceeding), provided the party State shall reasonably attempt to preserve such confidentiality by proceeding under any applicable protective order and utilizing sealing procedures provided by law or court rule and by providing reasonable advance notice to Teikoku (a minimum ten business days) before disclosing Teikoku's confidential documents to a third person.

4) to the Federal Trade Commission or the Department of Justice.

D. Neither the terms of this ASO nor any reports or notices provided by Teikoku under this ASO shall operate as a waiver of any future claims by any party. Further, any such reports or notices provided by Teikoku to active members of the States Enforcement Council or to other States that are parties to this ASO shall not be deemed to constitute actual or constructive notice of any claims as to other states that have not received such reports or notices.

V. CHANGE OF CORPORATE CONTROL

A. Teikoku shall notify the States Enforcement Council within thirty (30) days of

1) Dissolution of Teikoku;

2) Any final acquisition, merger, or consolidation of Teikoku; or

3) Any other substantial change in Teikoku, including, but not limited to,

assignment of a substantial portion of Teikoku's assets, or the creation or dissolution of subsidiaries, if such changes might affect Teikoku's compliance with the obligations arising out of this ASO.

B. Teikoku shall submit any notice required under this paragraph to the States Enforcement Council or, at its option, to any party States as set forth above.

VI. ACCESS TO INFORMATION

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 notice, Teikoku shall:

1) Timely respond to and cooperate with the States Enforcement Council's reasonable request for production of documents or information related to compliance to include unredacted (except for privilege) internal written justifications and economic modeling;

2) Agree to accept service of process of any complaint filed hereunder provided it is filed in the United States District Court for the Northern District of California and cooperation with any subpoenas issued by the States Enforcement Council, and

3) Allow the States Enforcement Council to informally interview a reasonable number of officers, directors, or employees of Teikoku who may have counsel present regarding such matters.

B. The States Enforcement Council will seek to coordinate any requests for information under this Section with the FTC and Department of Justice, if involved, to the fullest extent possible. The States Enforcement Council agrees to coordinate any and all requests and designate one State to forward such requests from the States Enforcement Council.

VII. COOPERATION

A. At the request of States Enforcement Council, Teikoku shall cooperate with the party States in the Investigation as follows:

(1) To the extent practical, Teikoku shall make its employees available in the United States in person, by video conference, or by such other means as the Parties may agree to, for such interviews and affidavits as reasonably required by the party States;

(2) Upon request, Teikoku shall provide the last-known contact information for any former employees;

(3) Teikoku shall produce at trial in person, by deposition, or by affidavit, whichever is legally necessary, witnesses to testify as to the amount of their respective relevant sales and to testify as to the genuineness, status as business records, and authenticity of documents;

(4) Teikoku will provide non-privileged evidence supporting the assertions made in the July 30, 2015 presentation to the Federal Trade Commission Staff, which presentation was also made to the States representatives on May 27, 2016.

(5) Notwithstanding anything in the foregoing, Teikoku will have no obligation to disclose evidence provided to Teikoku pursuant to a joint defense agreement with Endo Pharmaceuticals, Inc. and Actavis plc to the extent doing so would violate the terms of such agreement.

VIII. MONETARY RELIEF

The parties recognize that there is ongoing litigation between Teikoku and private class and individual parties (the "Private Parties") pending in the Northern District of California before Judge Orrick concerning the claims that are the subject of this ASO. In the event that Teikoku and the Private Parties ultimately agree to mediation or engage in settlement negotiations, the States reserve the right to participate in said proceedings. The Parties agree, however, that a recovery the States may receive from participating in such proceedings and the injunction contemplated herein shall be the States' exclusive remedy for any alleged violation by Teikoku arising from the Lidoderm Settlement and License Agreement and that Teikoku does not guarantee and shall have no obligation to ensure that the States Enforcement Council or the States will be permitted to participate in such proceedings or that they will receive any monetary recovery as any resolution between Teikoku and the Private Parties ("Private Resolution").

IX. RELEASED CLAIMS

In consideration of the injunctive provisions and the other commitments made by Teikoku contained in this ASO, each State will be deemed to have fully, finally, and forever released Teikoku and their officers, directors, employees, and attorneys (collectively "Releasees") from antitrust and consumer protection claims that were asserted or could have been asserted, by the

State Attorneys General in his or her sovereign capacity as chief law enforcement officer of his or her respective state, arising from the Lidoderm Settlement and License Agreement. This agreement does not relate to or release criminal actions or any non-competition or non-consumer protection claims regarding Lidoderm, including but not limited to those regarding Medicare or Medicaid fraud, irregularities or false claims, off-label marketing, false advertising or product or product liability claims.

X. EXPIRATION

This ASO will expire on the date that is the earlier of 20 years from the date Teikoku signs this ASO or the expiration of the FTC SO.

XI. OTHER

A. The terms of this ASO shall be binding on, and shall inure to the benefit of the Parties and their successors.

B. If any clause, provision, or section of this ASO shall, for any reason, be held illegal, invalid, or unenforceable, such illegality, invalidity, or unenforceability shall not affect any other clause, provision, or section of this ASO, and this ASO shall be construed and enforced as if such illegal, invalid, or unenforceable clause, section, or other provision had not been contained herein.

XII. DISMISSAL AND COSTS

This action shall be dismissed with prejudice. Each party shall bear its own costs.

SO ORDERED this 12th day of February, 2018.

The Honorable William H. Orrick