FILED
JAN 30 2017
Clerk, U.S. District & Bankruptcy
Courts for the District of Columbia

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, the States of ALASKA, MARYLAND, NEW YORK, TEXAS, and WASHINGTON,

Plaintiffs,

v.

MALLINCKRODT ARD INC., formerly known as QUESTCOR PHARMACEUTICALS, INC., a California corporation, and MALLINCKRODT PLC, an Irish public limited company,

Defendants.

Case Number: 1:17-cv-120 EGS

~~[PROPOSED]~~ STIPULATED ORDER FOR PERMANENT INJUNCTION AND EQUITABLE MONETARY RELIEF

Plaintiffs, the Federal Trade Commission ("Plaintiff Commission"), and the states of Alaska, Maryland, New York, Texas and Washington (collectively, the "Plaintiff States"), by their designated attorneys, filed their Complaint seeking permanent injunctive and other equitable relief against Defendants Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc., and Mallinckrodt plc. The Plaintiffs and Defendants have reached an agreement to resolve this case through settlement and without trial or final adjudication of any issue of fact or law, and stipulate to entry of this Stipulated Order for Permanent Injunction and Equitable Monetary Relief ("Order") to resolve all matters in dispute in this action.

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

1. "Application(s)" means any and all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the applications for a Synthetic ACTH Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 *et seq*., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. "Application" also includes an "Investigational New Drug Application" ("IND") filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.

2. "Clinical Trial(s)" means a controlled study in humans of the safety, efficacy or bioequivalence of a Synthetic ACTH Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of the FDA in connection with any Application and any other human study used in the research and Development of a Synthetic ACTH Product.

3. "Closing Date" means the date on which the Defendants (or a Licensing Trustee appointed pursuant to Paragraph V of this Order) consummate a transaction to grant the Synacthen Sublicense as required by this Order.

4. "Commercialize" means to market, promote, distribute, import, offer to sell, and/or sell a Synthetic ACTH Product.

5. "Defendant(s)" means Questcor and Mallinckrodt plc, individually and collectively.

6. "Development" means all preclinical and clinical drug development activities, including test method development and stability testing; toxicology; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from the FDA necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Synthetic ACTH Product (including any government price or reimbursement approvals); Synthetic ACTH Product approval and registration; and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

7. "Designated State Representatives" means the following: Chief Assistant Attorney General, Consumer Protection Unit, Alaska Department of Law, 1031 W. 4th Ave. #200, Anchorage, AK 99501; Chief, Antitrust Division, Maryland Office of the Attorney General, 200 St. Paul Place, 19th Floor, Baltimore, MD 21202-2021; Chief, Antitrust Bureau, Office of the New York State Attorney General, 120 Broadway, New York, NY 10271; Chief, Antitrust Section, Consumer Protection Division, Texas Office of the Attorney General, P.O. Box 12548, Austin, TX 78711-2548; and Antitrust Division Chief, Office of the Attorney General of Washington State, 800 5th Ave, Ste. 2000, Seattle, WA 98104.

8. "Drug Substance" means the active pharmaceutical ingredient tetracosactide acetate (a synthetic ACTH analogue) contained in Synacthen having the structure set forth in Confidential Appendix A, and all other salt forms of such tetracosactide.

9. "FDA" means the United States Food and Drug Administration.

10. "Global Medical Information" means the following information related to Synacthen and/or the Drug Substance that Defendants obtained from Novartis pursuant to the Synacthen License Agreement: medical or clinical information, adverse event reports, and safety information, including, but not limited to, clinical study reports, pre-clinical data and toxicity data.

11. "Global Regulatory Approval Information" means documents and information related to Synacthen and/or the Drug Substance that Defendants obtained from Novartis pursuant to the Synacthen License Agreement that were submitted to any Governmental Entity to support obtaining or maintaining an approval to market or sell Synacthen.

12. "Governmental Entity" means any Federal, state, local, or non-U.S. government; any court, legislature, government agency, or government commission; or any judicial or regulatory authority of any government.

13. "Licensed IP" means the Licensed IP as defined in Synacthen License Agreement.

14. "Mallinckrodt plc" means Mallinckrodt plc, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Mallinckrodt plc (including, but not limited to, Questcor), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

15. "Manufacturing Technology" means all technology, trade secrets, know-how and proprietary information in each case to the extent necessary for the manufacture, validation, packaging, release testing, stability and/or shelf life of Synacthen and/or the Drug Substance, including the Synacthen drug product formulations and/or other records

related to the manufacturing process, and that are in existence and owned or controlled by Defendants on the date that this Order is entered.

16. "Marathon" means Marathon Pharmaceuticals, LLC, a Delaware limited liability company with its principal place of business at 1033 Skokie Blvd., Northbrook, IL 60062.

17. "Novartis" means Novartis AG, a corporation organized, existing, and doing business under and by virtue of the laws of the Swiss Confederation, with its principal executive offices located at Lichstrasse 35 4056, Basel, Switzerland; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Novartis AG (including, but not limited to Novartis Pharma AG), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

18. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Governmental Entity, and any subsidiaries, divisions, groups, or affiliates thereof.

19. "Plaintiff Commission" means the United States Federal Trade Commission.

20. "Questcor" means Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc., a corporation acquired by Mallinckrodt plc on August 14, 2014, and now its wholly-owned subsidiary; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Mallinckrodt ARD Inc. (including Akasia Limited), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

21. "Sublicense Field" means all uses in humans for infantile spasms and all types of nephrotic syndrome, including without limitation, idiopathic membranous nephropathy.

22. "Synacthen" means the following, individually and collectively:

    a. SYNACTHEN® i.m. 0.25 mg.ml solution for injection (or other dosage strength and/or form) that includes the Drug Substance as the sole active ingredient; and

    b. SYNACTHEN DEPOT® i.m. 1 mg/mL suspension for injection (or other dosage strength and/or form) that includes the Drug Substance as the sole active ingredient.

23. "Synacthen License Agreement" means the *License Agreement* between Novartis Pharma AG, Novartis AG, Questcor Pharmaceuticals, Inc., and Akasia Limited, dated as of June 11, 2013, attached as a Confidential Appendix A, and incorporated herein.

24. "Synthetic ACTH Product" means any drug product containing the active pharmaceutical ingredient tetracosactide or tetracosactide acetate (which is a synthetic peptide comprising the first 24 amino acids of adrenocorticotropic hormone), either alone or in combination with other active pharmaceutical ingredients.

25. "Synacthen Sublicense" means a license on terms and conditions that grants the following:

    a. a perpetual, irrevocable, fully paid-up, royalty-free, sublicensable, assignable, exclusive (even as to the Defendants) license to Commercialize Synacthen in the Sublicense Field and in the Territory;

    b. a perpetual, irrevocable, fully paid-up, royalty-free, sublicensable, assignable, exclusive (even as to the Defendants) license to the Trademark in the Territory;

c. a perpetual, irrevocable, fully paid-up, royalty-free, sublicensable, assignable, non-exclusive license in the Sublicense Field and in the Territory to all rights not included elsewhere in this Definition No 25:

i. that Novartis granted to Defendants pursuant to the Synacthen License Agreement,

ii. to all improvements and innovations to the Licensed IP and Manufacturing Technology developed prior to the Closing Date that arise from Defendants' activities under the Synacthen License Agreement, and

iii. to any data created prior to the Closing Date that relates to any Development arising from Defendants' activities under the Synacthen License Agreement other than data related exclusively to the treatment of Duchenne Muscular Dystrophy;

d. a perpetual, irrevocable, fully paid-up, royalty-free, sublicensable, assignable, non-exclusive license in the Territory to all rights to Global Medical Information and Global Regulatory Approval Information, *provided that* the scope of the license may be limited to use for Synthetic ACTH Products in the Territory and, at the sole option of the Synacthen Sublicensee, may be further limited to the Sublicense Field; and

e. all other rights and benefits required to be provided to the Synacthen Sublicensee by the Defendants pursuant to this Order.

26. "Synacthen Sublicensee" means Marathon or another Person approved by Plaintiff Commission in its sole discretion to be the grantee of the Synacthen Sublicense.

27. "Territory" means the United States of America.

28. "Third Party" means any Person other than the Defendants or the Synacthen Sublicensee.

29. "Trademark" means the proprietary name SYNACTHEN, including all registrations and applications for registration of SYNACTHEN (including without limitation Serial Number 85495963 with filing date December 15, 2011, and all renewals, modifications, and extensions thereof), and all common law rights and goodwill associated therewith.

FINDINGS

1. This Court has jurisdiction over the subject matter of, and each of the parties to, this action pursuant to Sections 5 and 13(b) of the FTC Act, 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345, and with respect to the non-federal claims, pursuant to 28 U.S.C. § 1367(a) and the principles of pendent jurisdiction. Defendants admit all facts necessary to establish the personal jurisdiction and subject matter jurisdiction of this Court in this action only. This Order does not constitute evidence against the Defendants or any admission of liability or wrongdoing by Defendants. This Order shall not be used as evidence in any proceedings other than a proceeding by Plaintiffs or the Synacthen Sublicensee regarding enforcement or modification of this Order.

2. Venue for this matter is proper in this Court under Section 13(b)(2) of the FTC Act, 15 U.S.C. § 53(b), 15 U.S.C. § 22, and 28 U.S.C. § 1391(b), (c), and (d).

3. In the Complaint, Plaintiff Commission charges that Defendants engaged in anticompetitive acts and practices that constitute an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). Plaintiff States charge that Defendants engaged in monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, violations of Alaska's Restraint of Trade Act, Alaska Stat. §§ 45.50.562 *et*

seq., Alaska's Unfair Trade Practices and Consumer Protection Act, Alaska Stat. §§ 45.50.471 *et seq.*, and the common law of Alaska; the Maryland Antitrust Act, Md. Code Ann., Com. Law §§ 11-201 *et seq.*; New York's antitrust law, the Donnelly Act, New York Gen. Bus. Law §340 *et seq.*, and New York Executive Law 63(12); Texas's Free Enterprise and Antitrust Act, Tex. Bus. & Com. Code Ann. §§ 15.01 *et seq.*; and Washington's Consumer Protection Act, Wash. Rev. Code §§ 19.86 *et seq.*, as proscribed by § 19.86.040. Plaintiffs and, without admitting any violation of any law, Defendants, have agreed to stipulate to the entry of this Order.

4. Defendants waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agree to bear their own costs and attorney fees in this action.

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

6. Entry of this Order fully satisfies the requests for relief made by the Plaintiffs in their Complaint and is in the public interest.

STIPULATIONS

1. Defendants and Plaintiff Commission, by and through their counsel, have agreed that entry of this Order fully and finally resolves all issues between them arising from the specific events giving rise to the allegations described in the Complaint and precludes further litigation between Plaintiff Commission and Defendants on the resolved issues except for purposes of enforcing or modifying this Order.

2. Defendants and Plaintiff States, by and through their counsel, have agreed that entry of this Order fully and finally resolves all antitrust, unfair competition or trade practices,

and consumer protection issues between them arising from the specific events giving rise to the allegations described in the Complaint and precludes further litigation between Plaintiff States and Defendants on the resolved issues except for purposes of enforcing or modifying this Order.

3. Defendants stipulate their consent to this Court's exercise of personal jurisdiction over them for purposes of this action only, and waive any objection to venue for purposes of this Order only.

4. Defendants stipulate that their Taxpayer Identification Numbers (Employer Identification Numbers), which Defendants must submit to Plaintiff Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

5. Defendants stipulate that they shall comply with the provisions of this Order pending its entry by the Court.

6. Defendants stipulate that they will bear their own costs in this matter and shall not make any claims against Plaintiffs for attorneys' fees or costs.

ORDER

I. LICENSE

IT IS HEREBY ORDERED that:

A. Not later than one hundred twenty (120) days after the date this Order is entered, Defendants shall grant the Synacthen Sublicense, absolutely and in good faith, at no minimum price, to a Synacthen Sublicensee approved by Plaintiff Commission in its sole discretion and in a manner and on terms and conditions approved by Plaintiff Commission in its sole discretion.

B. Defendants shall

1. ensure that all rights granted to Defendants pursuant to the Synacthen License Agreement that Defendants grant to the Synacthen Sublicensee pursuant to this Order will remain in full force and effect;

2. not take any action or fail to take any required action under the Synacthen License Agreement that would invalidate, diminish or impair any rights granted to the Synacthen Sublicensee pursuant to this Order; and

3. make all payments that are or become payable to Novartis under the Synacthen License Agreement.

C. Not later than sixty (60) days after the Closing Date, Defendants shall provide the Synacthen Sublicensee with a full and complete copy of all tangible documentation and records embodying the Licensed IP and Manufacturing Technology in the Defendants' possession or control, which if in electronic form shall be readily useable with off-the-shelf commercially available software and equipment. Defendants shall deliver all such documentation and records to the Synacthen Sublicensee in good faith, in a timely manner (*i.e.*, as soon as practicable, avoiding any delays in transmission of the respective documents and records), and in an organized and comprehensive manner that ensures completeness and accuracy and that fully preserves the usefulness of such documents and records. Pending complete delivery of all such documents and records to the Synacthen Sublicensee, Defendants shall provide the Synacthen Sublicensee and the Monitor (if any has been appointed) with access to all such documents and records and employees of the Defendants who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Licensed IP and Manufacturing Technology and facilitating the delivery in a manner consistent with this Order.

D. Defendants shall indemnify and hold the Synacthen Sublicensee and its respective officers, directors, agents and employees harmless from and against any and all costs, charges, claims, damages or expenses (including attorney's fees and expenses) to the extent arising or resulting from any action by Novartis against the Synacthen Sublicensee for any non-payment of fees or other payments due or owing under the Synacthen License Agreement or any breach of the Synacthen License Agreement by the Defendants.

E. In the event that the Defendants receive (1) FDA approval to label any Synthetic ACTH Product for any indication within the Sublicense Field prior to the Synacthen Sublicensee receiving FDA approval to label a Synthetic ACTH Product for such indication within the Sublicense Field, and (2) orphan exclusivity rights in that indication, then Defendants shall grant to the Synacthen Sublicensee a perpetual, irrevocable, fully paid-up, royalty-free, sublicensable, and assignable license to Defendants' Synthetic ACTH Product, which license shall be exclusive (even as to the Defendants) in the Territory for such indication(s). Defendants shall grant such license to the Synacthen Sublicensee and make it effective not later than ten (10) days after the receipt by the Defendants of such FDA Approval and Designation.

F. Defendants shall not communicate orally or in writing with a physician, hospital, or clinical research organization regarding Clinical Trials conducted by or on behalf of the Synacthen Sublicensee that are related to a Synthetic ACTH Product and are within the Sublicense Field; *provided, however*, it shall not be a violation of this paragraph to (1) make public statements to investors whether such statements are made directly, in securities filings or through the media; (2) communicate with a physician, hospital, or clinical research organization about the Defendants' own products or clinical trials (and not those of the Synacthen Sublicensee) or, in the course of developing and conducting clinical trials, determine whether a

patient, physician, hospital or clinical research organization is participating in other Clinical Trials, or (3) make communications in connection with a legal or administrative action or investigation.

G. Upon the Synacthen Sublicensee's request, Defendants shall provide access to the Synacthen Sublicensee to any manufacturing site (whether or not owned or controlled by the Defendants; *provided, however*, that, for any manufacturing site not owned or controlled by Defendants, Defendants are only required to provide access to the extent that Defendants have access and as permitted under any agreement(s) with the manufacturing site) that Defendants use to manufacture Synacthen and make such arrangements with any Third Party necessary to permit that access for the purposes of evaluating and learning the manufacturing process of Synacthen and discussing the process with Persons involved in the manufacturing process (including, without limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, methods to ensure batch consistency), pharmaceutical development, and validation of the manufacturing of Synacthen at that facility.

H. For a period of eighteen (18) months following the Closing Date, Defendants shall provide reasonable access to Defendants' personnel to provide instructions and answer questions regarding the application of the Licensed IP and Manufacturing Technology (to the extent known by Defendants).

I. Defendants shall not join, file, prosecute, or maintain any suit, in law or equity, against the Synacthen Sublicensee for violation of intellectual property rights in existence as of the Closing Date for the world-wide research, Development, manufacture of any Synthetic ACTH Product in the Sublicense Field, or the sale of any Synthetic ACTH Product in the Sublicense Field in the Territory; it being understood that intellectual property rights include

rights to the following: patents, know-how, trade secrets, techniques, data, inventions, practices, methods, and other confidential and proprietary information (including without limitation technical, business, research and Development information).

J. Defendants shall not exercise any right to restrict any Third Party from entering into any contract with the Synacthen Sublicensee:

1. to manufacture or provide components (including, without limitation, the active pharmaceutical ingredient(s)), or provide any part of the manufacturing process (including, without limitation, finish, fill, and/or packaging) for a Synthetic ACTH Product for use in the Sublicense Field in the Territory; or

2. to Commercialize a Synthetic ACTH Product for use in the Sublicense Field in the Territory.

K. The purpose of this Paragraph I is to ensure the continued research, Development and commercialization of Synthetic ACTH Products containing synthetic adrenocorticotropic hormones for the treatment of diseases in humans and to remedy the lessening of competition as alleged in the Complaint in a timely and sufficient manner.

II. PRIOR NOTIFICATION

IT IS FURTHER ORDERED that

A. Defendants shall not acquire, directly or indirectly, through subsidiaries or otherwise (1) any Person, or any rights in whole or in part in any Person, engaged in the research, Development, manufacture, marketing, distribution, or sale of a Synthetic ACTH Product containing any form of synthetic or natural adrenocorticotropic hormone (other than any product owned by Defendants as of the date they agree to entry of this stipulated Order), or (2)

any exclusive rights to market or distribute any Synthetic ACTH Product containing any form of synthetic or natural adrenocorticotropic hormone (other than any product owned by Defendants as of the date they agree to entry of this stipulated Order) within the United States of America, without providing prior written notification to Plaintiff Commission and each of the Designated State Representatives.

B. The prior notification required by this Paragraph II shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as the "Notification"), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification; Notification shall be filed with the Secretary of Plaintiff Commission and copies delivered to each of the Designated State Representatives; Notification need not be made to the Department of Justice; and Notification is required only of the Defendants and not of any other party to the transaction. Defendants shall provide two (2) complete copies (with all attachments and exhibits) of the Notification to Plaintiff Commission and a complete copy (with all attachments and exhibits) to each of the Designated State Representatives at least thirty (30) days prior to consummating any such transaction (hereafter referred to as the "first waiting period"). If, within the first waiting period, representatives of Plaintiff Commission makes a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 802.20), Defendants shall not consummate the transaction until thirty (30) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested by Defendants and, where appropriate, granted by a letter from Plaintiff Commission's Bureau of Competition; *provided, however*, that prior notification shall not be required by this Paragraph for a transaction for which

notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

III. EQUITABLE MONETARY RELIEF

IT IS FURTHER ORDERED that:

A. Judgment in the amount of one hundred million dollars ($100,000,000) is entered in favor of Plaintiff Commission against Defendants, jointly and severally.

B. Defendants are ordered to pay Plaintiff Commission one hundred million dollars ($100,000,000) as follows:

1. within ten (10) business days of entry of this Order, Defendants shall pay ninety million dollars ($90,000,000) to Plaintiff Commission by electronic fund transfer in accordance with instructions previously provided by a representative of Plaintiff Commission;

2. within ninety (90) days of entry of this Order, Defendants shall pay ten million dollars ($10,000,000) in accordance with instructions provided by a representative of Plaintiff Commission,

provided that, Plaintiff Commission shall subrogate its right to this monetary recovery of ten million ($10,000,000) and provide instructions to Defendants to pay such monies to the Plaintiff States (in accordance with instructions previously provided by a representative of the Plaintiff States to Defendants) if the Plaintiff States (i) use such funds in accordance with their state laws for equitable relief reasonably related to the Plaintiff States' independent causes of action against Defendants; (ii) consult with a representative of Plaintiff

Commission regarding the use of the monies; (iii) do not place any such monies in the general funds of any Plaintiff State or use such monies for general antitrust or consumer protection enforcement or education, *provided, however*, the money may, if allowable under relevant state law, be used for payment into a state Medicaid fund; (iv) do not pay such monies to for-profit organizations, including non-profit or charitable entities within such organizations; and (v) do not use the monies for attorneys' fees or costs.

C. All money paid to Plaintiff Commission pursuant to this Order may be deposited into a fund administered by Plaintiff Commission or its designee to be used for equitable relief, including consumer redress and other equitable relief Plaintiff Commission determines to be reasonably related to the Defendants' alleged violative practices and injury, and any attendant expenses for the administration of such fund. Any money not used for such equitable relief is to be deposited to the U.S. Treasury as disgorgement. Any interest earned on amounts deposited into the fund will remain in the fund and become a part of the fund.

D. Within ten (10) business days of entry of the Order, Defendants shall submit their Taxpayer Identification Numbers (Employer Identification Numbers) to Plaintiff Commission.

E. Defendants shall have no right to challenge any actions Plaintiff Commission or its representatives, or the Plaintiff States, may take pursuant to this Paragraph III of the Order.

F. The payments provided for herein are provided for purposes of settlement only, are remedial and neither a penalty nor a fine.

G. Defendants are further ordered to pay to the Plaintiff States two million dollars ($2,000,000) for reimbursement of their attorneys' fees and costs, which fees and costs were

incurred on behalf of the Plaintiff States and do not constitute an antecedent debt with respect to this litigation. Once payment under this Paragraph III.G. is made, Defendants shall retain no domination, control, or title the monies transferred. Such payment must be made within ten (10) business days of entry of this Order in accordance with instructions previously provided by a representative of the Plaintiff States. Disbursement of the attorneys' fees and costs paid pursuant to this paragraph shall be in accordance with the Attorneys' Fees Disbursement Protocol, attached as Appendix C to this Order.

IV. MONITOR

IT IS FURTHER ORDERED that:

A. At any time after this Order is entered, Plaintiff Commission may appoint, or request that the Court appoint, a Person to act as a monitor ("Monitor") to assure that the Defendants expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order. Plaintiff Commission shall select the Monitor, subject to the consent of Defendants, which consent shall not be unreasonably withheld. If Defendants have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within five (5) days after notice by the staff of Plaintiff Commission to Defendants of the identity of any proposed Monitor, Defendants shall be deemed to have consented to the selection of the proposed Monitor.

B. Not later than one (1) day after appointment of the Monitor, Defendants shall execute an agreement that, subject to the prior approval of Plaintiff Commission, in its sole discretion, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Defendants' compliance with all of their obligations and responsibilities under this Order ("Monitor Agreement").

C. The Monitor shall serve until (i) the grant of the Synacthen Sublicense to a Synacthen Sublicensee has been completed, (ii) the transfer and delivery of the Licensed IP and Manufacturing Technology (including a full and complete copy of all tangible documentation and records embodying the Licensed IP and Manufacturing Technology) to the Synacthen Sublicensee has been completed, in a manner that fully satisfies the requirements of this Order, and (iii) Plaintiff Commission determines the services of the Monitor are no longer necessary to ensure achievement of the purposes of this Order, but in any event not longer than two (2) years after the Closing Date, unless the term is extended by further Order of this Court.

D. Defendants shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:

1. the Monitor shall have the power and authority to monitor Defendants' compliance with the terms of this Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with this Order. The Monitor shall, in consultation with Plaintiff Commission, assure that the Defendants expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order;

2. the Monitor shall act in a fiduciary capacity for the benefit of Plaintiff Commission;

3. subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Defendants' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Defendants' compliance with their obligations under this Order. Defendants shall cooperate with any

reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Defendants' compliance with this Order;

4. the Monitor shall serve, without bond or other security, at the expense of Defendants on such reasonable and customary terms and conditions as Plaintiff Commission may set. The Monitor shall have authority to employ, at the expense of Defendants, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of Plaintiff Commission;

5. Defendants shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, malfeasance, willful or wanton acts, or bad faith by the Monitor;

6. the Monitor Agreement shall provide that, within one (1) month from the date the Monitor is appointed pursuant to this paragraph, and every sixty (60) days thereafter, the Monitor shall report in writing to Plaintiff Commission and each of the Designated States concerning performance by Defendants of their obligations under the Order; and

7. Defendants may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a

customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to Plaintiff Commission and the Plaintiff States.

E. Plaintiff Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement relating to Plaintiff Commission's materials and information received in connection with the performance of the Monitor's duties.

F. If Plaintiff Commission determines that the Monitor has ceased or failed to act diligently, Plaintiff Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.

G. Plaintiff Commission may, on its own initiative or at the request of the Monitor, request that the Court issue such additional orders or directions, as may be necessary or appropriate to accomplish the grant of the Synacthen Sublicense as required by this Order.

V. APPOINTMENT OF TRUSTEE TO EFFECTUATE LICENSE

IT IS FURTHER ORDERED that:

A. If the Defendants have not granted a Synacthen Sublicense acceptable to Plaintiff Commission to a Synacthen Sublicensee approved by Plaintiff Commission within the time period specified in Paragraph I.A. of this Order, Plaintiff Commission may appoint, or request that the Court appoint, a Person selected by Plaintiff Commission to grant and otherwise effectuate the Synacthen Sublicense in a manner consistent with this Order ("Licensing Trustee").

B. Plaintiff Commission shall appoint, or request that the Court appoint, a Licensing Trustee pursuant to procedures similar to those outlined in Appendix B, "Licensing Trustee Appointment," for the appointment of a Licensing Trustee in the event one is required. Neither the appointment of a Licensing Trustee nor a decision not to appoint a Licensing Trustee under this Paragraph shall preclude Plaintiff Commission, or the Court, from seeking or ordering additional relief that may be available for any failure by the Defendants to comply with this Order.

VI. REPORTING REQUIREMENTS

IT IS FURTHER ORDERED that:

A. Defendants shall submit to Plaintiff Commission and each of the Designated State Representatives a verified written report setting forth in detail the manner and form in which Defendants intend to comply, have complied, and are complying with this Order:

1. within sixty (60) days after the date of entry of this Order, and every sixty (60) days thereafter until Defendants have (i) completed their obligations to grant the Synacthen Sublicense to the Synacthen Sublicensee, and (ii) fully provided the Licensed IP and Manufacturing Technology to the Synacthen Sublicensee. Defendants shall submit at the same time a copy of these reports of compliance with this Order to the Monitor, if any Monitor has been appointed. Defendants shall include in these reports, among other things that are required from time to time, a full description of all efforts being made to comply with the Order, including: (i) a detailed description of all substantive contacts, negotiations, or recommendations related to any potential grantee of the Synacthen Sublicense, and the grant of the Synacthen Sublicense, and (ii) provision of the Licensed IP and Manufacturing Technology to the Synacthen Sublicensee; and

2. on the first anniversary of the date of entry of this Order, and annually thereafter for nine (9) years on the anniversary of the date of entry of this Order, and at other times as Plaintiff Commission may require. Defendants shall also include in these annual reports of compliance with the Order a list containing (i) all of Defendants' products that contain adrenocorticotropic hormone (whether synthetic or otherwise) and (ii) total sales in units and dollars in the United States of each of these products for either the one-year period immediately preceding the report or the full calendar or fiscal year that immediately precedes the report.

B. Defendants shall submit each report required under this paragraph to the Secretary of Plaintiff Commission and each of the Designated State Representatives and shall send an electronic copy of each report to the Compliance Division of the Bureau of Competition of Plaintiff Commission at bccompliance@ftc.gov.

VII. CHANGE OF CORPORATE CONTROL

IT IS FURTHER ORDERED that Defendants shall notify Plaintiff Commission and each of the Designated State Representatives at least thirty (30) days prior to:

A. any proposed dissolution of Mallinckrodt ARD Inc. or Mallinckrodt plc;

B. any proposed acquisition, merger, or consolidation of Mallinckrodt ARD Inc. or Mallinckrodt plc; or

C. any other change in a Defendant, 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 Order.

D. Defendants shall submit any notice required under this paragraph to the Secretary of Plaintiff Commission and each Designated State Representative, and shall send an electronic copy of the notification to the Compliance Division of the Bureau of Competition of Plaintiff Commission at bccompliance@ftc.gov.

VIII. ACCESS TO INFORMATION

IT IS FURTHER ORDERED that:

A. For the purpose of determining or securing compliance with this Order, subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to a Defendant made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, each Defendant shall, without restraint or interference, permit any duly authorized representative of Plaintiff Commission or of a Designated State Representative:

1. access, during business office hours of that Defendant and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Defendant related to compliance with this Order, which copying services shall be provided by that Defendant at the request of the requesting authorized representative(s) and at the expense of that Defendant; and

2. to interview officers, directors, or employees of that Defendant, who may have counsel present, regarding such matters.

IX. RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

X. EXPIRATION OF ORDER

IT IS FURTHER ORDERED that this Order shall expire ten (10) years after the date it is entered.

XI. DISMISSAL AND COSTS

This action shall be dismissed with prejudice.

SO ORDERED this 30th day of JAN, 2017.

The Honorable Emmet G. Sullivan

SO STIPULATED AND AGREED:

Date: 1/17/2017

Michael R. Moiseyev
Assistant Director
Mergers 1 Division
Bureau of Competition
Federal Trade Commission
FOR PLAINTIFF FEDERAL TRADE COMMISSION

SO STIPULATED AND AGREED:

Date: 1-17-17

Clyde E. Sniffen Jr.
Chief Assistant Attorney General
Alaska Department of Law
FOR PLAINTIFF THE STATE OF ALASKA

SO STIPULATED AND AGREED:

Ellen S. Cooper Date: 1/17/17

Ellen S. Cooper
Assistant Antitrust Attorney General
Chief, Antitrust Division
Office of the Attorney General, State of Maryland
FOR PLAINTIFF THE STATE OF MARYLAND

SO STIPULATED AND AGREED:

Date: JAN 17, 2017

Beau Buffier Chief, Antitrust Bureau
New York State Office of the Attorney General
FOR PLAINTIFF THE STATE OF NEW YORK

SO STIPULATED AND AGREED:

Date: 1/30/17

William J. Shieber
Assistant Attorney General
Office of the Attorney General of Texas
FOR PLAINITIFF THE STATE OF TEXAS

SO STIPULATED AND AGREED:

Luminita Nodit Date: 01/17/2017

Luminita Nodit
Assistant Attorney General
Washington State Office of the Attorney General
FOR PLAINITIFF THE STATE OF WASHINGTON

_____ Date: _____
Kathleen A. Schaefer
President of Mallinckrodt ARD Inc.
FOR DEFENDANT MALLINCKRODT ARD INC.

_____ Date: _____

COUNSEL FOR DEFENDANT MALLINCKRODT ARD INC.

_____ Date: _____
Mark Trudeau
President and CEO of Mallinckrodt plc
FOR DEFENDANT MALLINCKRODT PLC

_____ Date: _____

COUNSEL FOR DEFENDANT MALLINCKRODT PLC

SO STIPULATED AND AGREED:

_____ Date: _____

Kathleen A. Schaefer
President of Mallinckrodt ARD Inc.
FOR DEFENDANT MALLINCKRODT ARD INC.

George S Cary Date: 1/17/17

George S. Cary
Cleary Gottlieb Steen & Hamilton LLP
COUNSEL FOR DEFENDANT MALLINCKRODT ARD INC.

_____ Date: _____

Mark Trudeau
President and CEO of Mallinckrodt plc
FOR DEFENDANT MALLINCKRODT PLC

George S. Cary Date: 1/17/17

George S. Cary
Cleary Gottlieb Steen & Hamilton LLP
COUNSEL FOR DEFENDANT MALLINCKRODT PLC

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Confidential Appendix A

Synacthen License Agreement

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Appendix B

Licensing Trustee Appointment

Appendix B to Stipulated Order for Permanent Injunction and Equitable Monetary Relief

LICENSING TRUSTEE APPOINTMENT

A. In the event Plaintiff Commission, or the Court, determines to appoint a Licensing Trustee pursuant to Paragraph V of this Order to grant and otherwise effectuate the Synacthen Sublicense in a manner consistent with this Order, Plaintiff Commission shall select the Licensing Trustee, subject to the consent of the Defendants, which consent shall not be unreasonably withheld. The Licensing Trustee shall be an attorney licensed to practice before the United States Patent and Trademark Office with expertise in licensing pharmaceutical intellectual property or other Person that possesses equivalent expertise, credentials, skills, and experience. If the Defendants have not opposed, in writing, including the reasons for opposing, the selection of any proposed Licensing Trustee within ten (10) days after notice by the staff of Plaintiff Commission to the Defendants of the identity of any proposed Licensing Trustee, then the Defendants shall be deemed to have consented to the selection of the proposed Licensing Trustee.

B. No later than ten (10) days after the appointment of a Licensing Trustee, the Defendants shall execute an agreement that, subject to the prior approval of Plaintiff Commission, in its sole discretion, transfers to the Licensing Trustee all rights and powers necessary to permit the Licensing Trustee to grant and otherwise effectuate the Synacthen Sublicense required by this Order.

C. If a Licensing Trustee is appointed by Plaintiff Commission, or the Court, pursuant to Paragraph V of the Order, the Defendants shall consent to the following terms and conditions regarding the Licensing Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of Plaintiff Commission, in its sole discretion, the Licensing Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets and/or rights that are required to be licensed, assigned, granted, divested, transferred, delivered or otherwise conveyed by the Synacthen Sublicense pursuant to this Order;

2. The Licensing Trustee shall have twelve (12) months from the date Plaintiff Commission approves the agreement described herein to accomplish the sublicense grant and related transactions, which shall be subject to the prior approval of the Commission, in its sole discretion. If, however, at the end of the twelve-month period, the Licensing Trustee has submitted a plan to grant the sublicense or believes that such grant can be achieved within a reasonable time, this period may be extended by Plaintiff Commission, or, in the case of a court-appointed Licensing Trustee, by the Court; *provided, however,* Plaintiff Commission may extend the period only two (2) times;

3. Subject to any demonstrated legally recognized privilege, the Licensing Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets and/or rights that are required to be licensed, assigned, granted, divested, delivered or otherwise conveyed by the Order, or to any other relevant information, as the Licensing Trustee may request. Defendants shall develop such financial or other information as the Licensing Trustee may request and shall cooperate with the Licensing Trustee. Defendants shall take no action to interfere with or impede the Licensing Trustee's accomplishment of the sublicense grant or related transactions. Any delays caused by Defendants shall extend the Licensing Trustee's time for granting

the sublicense under this Paragraph in an amount equal to the delay, as determined by Plaintiff Commission or, for a court-appointed Licensing Trustee, by the Court;

4. The Licensing Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in the sublicense agreement that is submitted to Plaintiff Commission, subject to the Defendants' absolute and unconditional obligation to grant the Synacthen Sublicense expeditiously and at no minimum price. The Synacthen Sublicense shall be made in the manner and to a grantee as required by this Order; *provided, however,* if the Licensing Trustee receives bona fide offers from more than one potential grantee, and if Plaintiff Commission determines to approve more than one such Person, the Licensing Trustee shall grant the Synacthen Sublicense to the grantee selected by the Defendants from among those approved by Plaintiff Commission; provided further that the Defendants shall select such entity within five (5) days after receiving notification of Plaintiff Commission's approval;

5. The Licensing Trustee shall serve, without bond or other security, at the cost and expense of the Defendants, on such reasonable and customary terms and conditions as Plaintiff Commission or the Court may set. The Licensing Trustee shall have the authority to employ, at the cost and expense of Defendants, such consultants, accountants, attorneys, investment bankers, business brokers, appraiser, and other representatives and assistants as are necessary to carry out the Licensing Trustee's duties and responsibilities. The Licensing Trustee shall account for all monies derived from the sublicense grant and all expenses incurred. After approval by Plaintiff Commission and, in the case of a court-appointed Licensing Trustee, by the Court, of the account of the Licensing Trustee, including fees for the Licensing Trustee's services, all remaining

monies shall be paid at the direction of the Defendants, and the Licensing Trustee's power shall be terminated. The compensation of the Licensing Trustee shall be based at least in significant part on a commission arrangement contingent on the successful grant of the Synacthen Sublicense required by this Order;

6. Defendants shall indemnify the Licensing Trustee and hold the Licensing Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Licensing Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Licensing Trustee;

7. The Licensing Trustee shall have no obligation or authority to operate or maintain the relevant assets and/or rights required to be licensed, assigned, granted, divested, transferred delivered or otherwise conveyed by this Order; *provided, however,* that the Licensing Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order;

8. The Licensing Trustee shall report in writing to the Defendants and to Plaintiff Commission every sixty (60) days concerning the Licensing Trustee's efforts to accomplish the grant of the Synacthen Sublicense; and

9. Defendants may require the Licensing Trustee and each of the Licensing Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* such agreement shall not restrict the Licensing Trustee from providing any information to Plaintiff Commission.

D. Plaintiff Commission may, among other things, require the Licensing Trustee and each of the Licensing Trustee's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Plaintiff Commission's materials and information received in connection with the performance of the Licensing Trustee's duties.

E. If Plaintiff Commission, or in the case of a court-appointed Licensing Trustee, the Court, determines that the Licensing Trustee has ceased to act or failed to act diligently, Plaintiff Commission or the Court may appoint a substitute Licensing Trustee in the same manner as provided in this Paragraph.

F. Plaintiff Commission may, on its own initiative or at the request of the Licensing Trustee, request that the Court issue such additional orders or directions, as may be necessary or appropriate to accomplish the grant of the Synacthen Sublicense as required by this Order.

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Appendix C

Attorneys' Fees Disbursement Protocol

ATTORNEYS' FEES DISBURSEMENT PROTOCOL

A. The attorneys' fees and costs awarded to Plaintiff States pursuant to Paragraph III.G of this Order shall be apportioned among the Plaintiff States of Alaska, Maryland, Texas and Washington at their sole discretion. Each Plaintiff States may use its share of the payment, at its exclusive option and as otherwise consistent with its state law, for any of the following purposes:

1. as reimbursement of attorneys' fees and investigation, litigation and settlement administration costs incurred by such state;

2. for antitrust or consumer protection enforcement by the Attorney General of such state;

3. for deposit into a state antitrust or consumer protection account (e.g., revolving account, trust account) for use in accordance with the state laws governing that account;

4. for deposit into a fund exclusively dedicated to assisting the State Attorney General to defray the cost of experts, economists, and consultants in multistate antitrust investigations and litigations;

5. as reimbursement for Plaintiff States' consultation or expert fees, including reimbursement of any grants paid to expert witnesses by either the National Association of Attorneys' General Milk Fund or the State Center; or

6. for any other lawful purpose as otherwise required or provided for by applicable state law.