

**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:

**JOINT MOTION FOR ENTRY OF STIPULATED ORDER FOR
PERMANENT INJUNCTION AND EQUITABLE MONETARY RELIEF**

Plaintiffs, the Federal Trade Commission (“FTC”) and the States of Alaska, Maryland, New York, Texas, and Washington (collectively, the “Plaintiff States”), and Defendants Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc. (“Questcor”), and Mallinckrodt plc (“Mallinckrodt”), by their respective attorneys, respectfully move this Court to enter the accompanying proposed Stipulated Order for Permanent Injunction and Equitable Monetary Relief (“Stipulated Order”). Entry of the Stipulated Order will end the litigation between Plaintiffs and Defendants. A copy of the proposed Stipulated Order is attached as Exhibit 1. As grounds for this request, the parties state as follows:

Introduction

1. On January 18, 2017, Plaintiffs filed their Complaint against Defendants pursuant to Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C. § 26, and various state laws. The Complaint alleges that Defendants have exercised, and continue to exercise, monopoly power in the United States with H.P. Acthar Gel (“Acthar”), the only therapeutic adrenocorticotrophic hormone (“ACTH”) product currently sold in the United States. The Complaint alleges that Questcor violated Section 5 of the FTC Act, 15 U.S.C. § 45, Section 2 of the Sherman Act, 15 U.S.C. § 2, and various state laws by acquiring the U.S. rights to Synacthen Depot (“Synacthen”), a synthetic ACTH drug, from Novartis AG (“Novartis”) in June 2013. The Complaint alleges that by acquiring Synacthen, Questcor eliminated a nascent competitive threat to Acthar.

2. In their Complaint, Plaintiffs seek a permanent injunction to prevent Defendants from engaging in similar and related conduct to that alleged in the Complaint in the future; a divestiture and any further actions needed to restore competition lost due to Defendants’ alleged violations; other equitable relief as the Court finds necessary, to redress and prevent recurrence of Defendants’ alleged violations; civil penalties pursuant to various state statutes; and an award to the Plaintiff States for the costs of this action, including reasonable attorneys’ fees and costs.

3. Defendants have reached a settlement with Plaintiffs. In doing so, Defendants admit only the facts necessary to establish the personal and subject matter jurisdiction of this Court in this matter. Defendants deny that they engaged in any conduct violating Section 5 of the FTC Act, Section 2 of the Sherman Act, or any of the state laws referenced in the Complaint. The settlement provides that it does not constitute evidence against the Defendants or any admission of liability or wrongdoing by the Defendants and shall not be used as evidence in any

proceedings (other than to enforce or modify the settlement).

4. On January 17, 2017, Defendants executed the Stipulated Order in settlement of all claims against them in the above-captioned case. On January 18, 2017, the Commission voted 3-0 to approve the proposed Stipulated Order. Plaintiffs and Defendants jointly seek entry of the attached proposed Stipulated Order by the Court, thereby bringing the litigation between the parties to an end.

Proposed Stipulated Order

5. Paragraph I.A. of the Stipulated Order requires Defendants to grant a limited sublicense to Synacthen in the United States in two indications, Infantile Spasms (“IS”) and Nephrotic Syndrome (“NS”) along with certain other rights (the “Synacthen Sublicense”) to Marathon Pharmaceuticals, LLC, or another sublicensee approved by the FTC in its sole discretion (“Synacthen Sublicensee”). Defendants will retain the rights to Synacthen for all other indications, including the rights to continue to develop the drug for Duchenne Muscular Dystrophy. The “Synacthen Sublicense” is defined as (1) an exclusive license to commercialize Synacthen in the United States for the IS and NS indications; (2) an exclusive license to the Synacthen trademark in the United States for all indications; (3) a non-exclusive license in the United States for the IS and NS indications to certain other rights—including clinical data (but excluding data exclusively related to Duchenne Muscular Dystrophy) and know-how and information related to the formulation and manufacturing process; and (4) the right to use certain safety and clinical data obtained from Novartis and information obtained from Novartis contained in certain foreign regulatory submissions in the United States for any indication.

6. Paragraph I.B of the proposed Stipulated Order requires Defendants to ensure that all of the rights that Defendants grant to the Synacthen Sublicensee pursuant to the order will

remain in full force and effect.

7. Paragraph I.D of the proposed Stipulated Order requires Defendants to indemnify the Synacthen Sublicensee against any action brought by Novartis for non-payment or any other breach by Defendants of the license agreement between Novartis and Defendants.

8. Paragraph I.E of the proposed Stipulated Order requires that, if the Defendants were to receive approval for a Synthetic ACTH Product from the United States Food and Drug Administration ("FDA") in an IS or NS indication and receive orphan exclusivity rights, Defendants grant to the Synacthen Sublicensee an exclusive license to that Synthetic ACTH Product for the United States for the IS or NS indication.

9. Paragraph I.F of the proposed Stipulated Order prohibits Defendants from communicating with physicians, hospitals, or clinical research organizations about the Synacthen Sublicensee's clinical trial(s) involving any Synthetic ACTH Product for the IS or NS indications.

10. Section II of the proposed Stipulated Order prohibits Defendants from acquiring the rights to any natural or synthetic ACTH product without providing prior written notification.

11. Section III of the proposed Stipulated Order requires Defendants to pay one hundred million dollars (\$100,000,000) in equitable monetary relief.

12. Paragraph III.B.1 provides that Defendants shall pay ninety million dollars (\$90,000,000) to the FTC within ten (10) business days of entry of the proposed Stipulated Order. Paragraph III.B.2 provides that Defendants shall pay ten million dollars (\$10,000,000) to the FTC within ninety (90) days of entry of the proposed Stipulated Order and that the FTC shall subrogate its right to ten million (\$10,000,000) to the Plaintiff States use such funds under certain specified conditions.

13. Paragraph III.C of the proposed Stipulated Order provides that all money paid to the FTC pursuant to this proposed Stipulated Order may be deposited into a fund administered by the FTC or its designee to be used for equitable relief, including consumer redress and other equitable relief the FTC determines to be reasonably related to Defendants' alleged illegal practices and consumer injury, and any attendant expenses for the administration of such fund. Paragraph III.C of the proposed Stipulated Order further provides that any money not used for such equitable relief is to be deposited to the U.S. Treasury.

14. Paragraph III.G of the proposed Stipulated Order provides that Defendants shall pay the Plaintiff States two million dollars (\$2,000,000) as payment for attorneys' fees and costs within ten (10) business days of entry of this proposed Stipulated Order.

15. The remaining paragraphs of the proposed Stipulated Order contain reporting and other standard requirements designed to assist the FTC and the Plaintiff States in either administering or monitoring compliance with the proposed Stipulated Order.

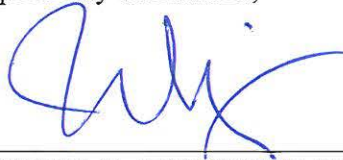
16. Section X provides that the proposed Stipulated Order will expire in ten (10) years.

Conclusion

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

Dated: January 18, 2017

Respectfully Submitted,



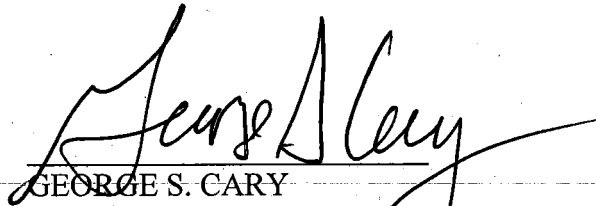
MICHAEL R. MOISEYEV (D.C. Bar No. 431722)
DANIEL K. ZACH (N.Y. Bar No. 4332698)
DAVID J. GONEN (D.C. Bar No. 500094)
DYLAN G. BROWN (D.C. Bar No. 984628)
JAMIE E. FRANCE (D.C. Bar No. 1010887)
STEPHEN W. RODGER (D.C. Bar No. 485518)
JASMINE Y. ROSNER (D.C. Bar No. 989416)
JAMES E. SOUTHWORTH (Pa. Bar No. 77497)
Attorneys for Plaintiff
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
Tel: (202) 326-3106
email: mmoiseyev@ftc.gov

DEBORAH L. FEINSTEIN (D.C. Bar No. 442470)
Director
Bureau of Competition
Federal Trade Commission

MARKUS H. MEIER (D.C. Bar No. 459715)
Acting Deputy Director
Bureau of Competition
Federal Trade Commission

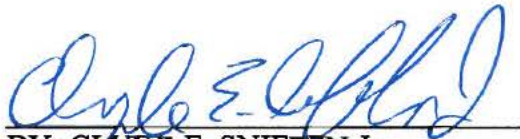
CHARLES A. LOUGHLIN (D.C. Bar No. 448219)
Chief Trial Counsel
Bureau of Competition
Federal Trade Commission

DAVID C. SHONKA (D.C. Bar No. 224576)
Acting General Counsel
Federal Trade Commission

A handwritten signature in black ink, appearing to read "George S. Cary". The signature is written in a cursive style with a large, sweeping flourish at the end.

GEORGE S. CARY
Attorney for Defendants
Mallinckrodt ARD Inc.
Mallinckrodt plc
Cleary Gottlieb Steen & Hamilton LLP
2000 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
Tel: (202) 974-1920
email: gcary@cgsh.com

The State of Alaska
Attorney General JAHNA LINDEMUTH

A handwritten signature in blue ink, appearing to read "Clyde E. Sniffen Jr.", is written over a horizontal line.

BY: CLYDE E. SNIFFEN Jr.

Chief Assistant Attorney General

Alaska Department of Law

1031 West 4th Ave. #200

Anchorage, AK 99501

Tel: (907) 269-5100

Fax: (907) 375-8282

Email: Ed.sniffen@alaska.gov

The State of Maryland
Attorney General BRIAN E. FROSH



BY: ELLEN S. COOPER
Assistant Attorney General
Chief, Antitrust Division
Office of the Attorney General, State of Maryland
200 St. Paul Place, 19th Floor
Baltimore, MD 21202
Tel: (410) 576-6470
Fax: (410) 576-7830
Email: ecooper@oag.state.md.us

The State of New York
Attorney General ERIC T. SCHNEIDERMAN

A handwritten signature in black ink, appearing to read "Beau Buffier", is written over a horizontal line.

BY: BEAU BUFFIER

Chief, Antitrust Bureau

ELINOR R. HOFFMAN

Deputy Chief, Antitrust Bureau

SAAMI ZAIN

Assistant Attorney General

MANISHA M. SHETH

Executive Deputy Attorney General for
Economic Justice

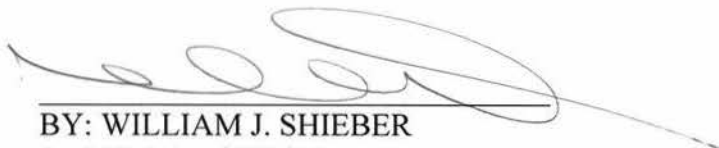
120 Broadway, 26th Floor

New York, New York 10271-0332

Tel: (212) 416-8267

Fax: (212) 416-6015

The State of Texas
Attorney General KEN PAXTON
First Assistant Attorney General JEFFREY C. MATEER
Deputy Attorney General for Civil Litigation JAMES E. DAVIS
Chief, Consumer Protection Division, DAVID A. TALBOT
Chief, Antitrust Section KIM VAN WINKLE



BY: WILLIAM J. SHIEBER
DAVID M. ASHTON
Assistant Attorneys General
The State of Texas
Office of the Attorney General of Texas
300 W. 15th Street, 7th Floor
Austin, Texas 78701
Tel: (512) 463-1710
Fax: (512) 320-0975
Email: william.shieber@oag.texas.gov
Email: david.ashton@oag.texas.gov

The State of Washington
Attorney General ROBERT W. FERGUSON
Senior Assistant Attorney General JONATHAN A. MARK

Lumin Nodit

BY: LUMINITA NODIT
ERICA KOSCHER
Assistant Attorneys General
Attorney General's Office
800 Fifth Ave., Suite 2000
Seattle, WA 98104-3188
Tel: (206) 464-7744
Fax: (206) 464-6338
Email: Luminitan@atg.wa.gov
Email: EricaK@atg.wa.gov