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:

COMPLAINT FOR INJUNCTIVE AND OTHER EQUITABLE RELIEF

Plaintiffs, the Federal Trade Commission ("FTC") and the states of Alaska, Maryland, New York, Texas, and Washington (collectively, the "Plaintiff States"), by their designated attorneys, petition this Court, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C. § 26, and the relevant state laws—Alaska Stat. §§ 45.50.501, 45.50.577 and 45.50.580, Md. Code Ann. Com. Law § 11-209, NY Gen. Bus. Law § 340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080—for permanent injunctive and other equitable relief against Defendants Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc. ("Questcor"), and Mallinckrodt plc ("Mallinckrodt") to undo and prevent their unfair methods of competition in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), and acts of monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and various state laws as identified in Count III, and state for their complaint as follows:

I. Nature of the Case

1. Through its anticompetitive conduct, Questcor has extinguished a nascent competitive threat to its monopoly. Questcor's H.P. Acthar Gel ("Acthar") is the only therapeutic adrenocorticotropic hormone ("ACTH") product sold in the United States. ACTH is the standard of care for infantile spasms ("IS"), a rare but extremely serious disorder involving seizures within the first two years of life. It is also used to treat nephrotic syndrome ("NS")—a kidney disorder whose largest single cause is idiopathic membranous nephropathy ("IMN")—as well as other disorders.

2. Questcor acquired Acthar from Aventis Pharmaceuticals, Inc. in 2001 for $100,000 plus modest royalties. At that time, the price of Acthar was $40 per vial. Questcor has since raised Acthar's price to over $34,000 per vial—an 85,000% increase.

3. A course of Acthar treatment for IS requires multiple vials and can cost well over $100,000.

4. For other indications, as the CEO of Mallinckrodt has admitted, Acthar is in many cases "the only alternative for patients that have tried and failed on many other therapies."

5. Questcor's Acthar price increases have persisted and proved very profitable. Acthar's U.S. revenues in 2015 exceeded $1 billion.

6. In Europe, Canada, and other parts of the world, doctors treat patients suffering from these same conditions with Synacthen Depot ("Synacthen"), a synthetic ACTH drug. Although Acthar is a natural ACTH drug derived from the pituitary glands of pigs, Acthar and Synacthen have very similar biological activities and pharmacological effects. As the Canadian product monograph for Synacthen reads, "SYNACTHEN . . . exhibits the same activity as natural ACTH with regard to all its biological activities." Questcor considers the drugs so

similar that it submitted Synacthen information to support its application to the U.S. Food and Drug Administration ("FDA") to expand the label indications for Acthar and cited Synacthen studies in its Acthar marketing materials.

7. Until June 2013, Novartis AG ("Novartis") marketed and sold Synacthen abroad.

8. In 2011, Novartis decided to sell the rights to market Synacthen in the United States. For years, Questcor had viewed Synacthen as a significant potential competitive threat to Acthar. In June 2013, Questcor outbid other companies to acquire the U.S. rights to Synacthen. Questcor's participation in the bidding process was a defensive move designed to protect its monopoly over ACTH drugs in the United States. By acquiring Synacthen, Questcor harmed competition by preventing another bidder from trying to develop the drug and launch it in the United States to challenge Questcor's monopoly over ACTH drugs.

II. The Parties

9. Plaintiff FTC is an administrative agency of the United States, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 et seq., with its principal offices at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC is vested with the authority and responsibility for enforcing, inter alia, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to seek injunctive relief to prevent or remedy violations of any law the FTC enforces and to seek equitable remedies.

10. The Attorneys General of the Plaintiff States are the chief legal officers for their respective states. They are granted authority under federal antitrust law to bring actions for injunctive relief and under the laws of their respective states to bring actions to ensure compliance with their state laws and to enjoin violations of state law.

11. Defendant Mallinckrodt is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.

12. Mallinckrodt acquired Questcor on August 14, 2014, for approximately $5.9 billion. At that time, Acthar was the only drug product sold by Questcor. With Mallinckrodt's acquisition, Questcor became a wholly owned subsidiary of Mallinckrodt and subsequently changed its corporate name from Questcor Pharmaceuticals, Inc. to Mallinckrodt ARD Inc.

13. Defendant Mallinckrodt ARD Inc. is a biopharmaceutical company incorporated in California and headquartered in Anaheim, California. The company manufactures and sells Acthar in the United States.

III. Jurisdiction and Venue

14. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.

15. This Court has personal jurisdiction over Defendants pursuant to 15 U.S.C. § 53(b) because each Defendant has the requisite constitutional contacts with the United States of America.

16. In conjunction with the Commission, the Plaintiff States also bring this action for civil penalties and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, Alaska Stat. §§ 45.50.501, 45.50.551, 45.50.577 and 45.50.580, Md. Code Ann. Com. Law § 11-209, NY Gen. Bus. Law § 340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080. All claims under federal and state law are based upon a common nucleus of operative fact, and the entire action commenced by this Complaint constitutes a single case that would ordinarily be tried in one judicial proceeding. This Court has jurisdiction over the non-federal claims under 28 U.S.C. § 1367(a), as well as

under principles of pendent jurisdiction.

17. Venue in this district is proper 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). Each Defendant resides, transacts business, or is found in this district.

18. Questcor and Mallinckrodt are, and at all relevant times have been, engaged in commerce or in activities affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12. Defendants also are, and at all relevant times have been, engaged in commerce in each of the Plaintiff States.

19. Questcor and Mallinckrodt are, and at all times relevant have been, a "corporation," as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

IV. Questcor Possesses Monopoly Power With Acthar

20. Questcor has exercised, and continues to exercise, monopoly power in the United States with Acthar. The supracompetitive prices that Questcor charges for Acthar and its restriction of Acthar's output are direct evidence of this monopoly power. Questcor's monopoly power is also established by indirect evidence, which shows that Acthar holds a dominant share of the relevant market for ACTH drugs in the United States. That market is and has been characterized by substantial barriers to entry.

A. Direct Evidence of Acthar's Monopoly Power

21. Questcor has repeatedly and profitably raised Acthar's price substantially over the last decade. On August 27, 2007, Questcor increased the price of Acthar more than 1,300% overnight, from $1,650 to $23,269 per vial, causing its revenues to increase dramatically and its profits to soar. Additionally, Questcor has taken significant and profitable increases on eight occasions since 2011, pushing the price up another 46% to its current $34,034 per vial. Acthar

net sales grew from $218 million in 2011 to more than $1 billion in 2015.

22. Each alternative bidder expected to profitably sell Synacthen at a price well below Acthar's price, demonstrating that Acthar is currently priced at a supracompetitive level. The lower prices that would prevail in a duopoly market containing Acthar and Synacthen show that Acthar is currently extracting substantial monopoly rents.

23. Questcor restricts the output of Acthar by charging an extraordinarily high price, forcing third-party payers (e.g., health insurers) to limit Acthar's usage to the narrowest possible group of patients—those for whom no effective therapeutic alternatives exist. When Questcor implemented its 1,300% price increase in 2007, payers implemented formulary restrictions on Acthar. Most payers continue to impose stringent restrictions on Acthar. By setting a supracompetitive price and restricting the output of Acthar, Questcor has reduced market-wide output below competitive levels.

B. Indirect Evidence of Acthar's Monopoly Power

24. The relevant product market is ACTH drugs.

25. Questcor has encountered no competitive constraint on its ability to repeatedly and profitably increase Acthar's price and earn extremely high margins. Questcor does not set the price of Acthar in reference to the price of any of the other drugs that are prescribed to treat the same indications that Acthar treats. Acthar is priced significantly higher than non-ACTH drugs used to treat the same indications.

26. Acthar is indicated for the treatment of IS. Pediatric neurologists consider ACTH the gold standard treatment for IS. Other market participants—including doctors, third-party payers, and pharmaceutical companies (including Questcor)—agree. Treating an infant with IS using Acthar can cost more than $100,000. The only other treatment that is FDA-approved for

IS is Sabril, which has a completely different molecular structure and mechanism of action than Acthar and is used primarily in a discrete subset of IS patients. At approximately $25,000 per course of treatment, Sabril costs substantially less than Acthar. Although some doctors prescribe other treatments for a minority of IS patients, those treatments work differently than Acthar and are not substitutes for Acthar. Neither the price of Sabril nor the prices of other IS treatments have affected Acthar's pricing, and none of these other treatments constrains the price of Acthar.

27. Acthar is indicated for the treatment of IMN. Because of its high price, Acthar typically is prescribed only as a last-line therapy to treat IMN. A course of Acthar treatment for IMN can cost hundreds of thousands of dollars. Nephrologists prescribe low-cost, generic oncology agents or immunosuppressants as first and second-line therapies to treat most IMN patients. If those therapies fail or cannot be tolerated, some doctors may prescribe the drug Rituxan, whose costs can range from approximately $13,000 to $40,000 for a course of treatment. Because Acthar functions differently than any of these other therapies, doctors and payers do not consider these therapies substitutes for Acthar, and the price of Acthar is not constrained by any of these treatments.

28. Acthar is indicated for the treatment of other indications, including MS flare-ups and rheumatology conditions. For these indications, the price of Acthar is unconstrained by other drugs used to treat those conditions.

29. Even if Synacthen were approved by the FDA for only one of Acthar's indications, Synacthen would compete directly with Acthar and would be properly included in the relevant market. Synacthen is pharmacologically very similar to Acthar, as the active ingredient in both drugs is an ACTH molecule. Many doctors would prescribe Synacthen as a substitute for Acthar, and many payers would require its use in place of Acthar. Each alternative

purchaser of the Synacthen assets expected to compete head-to-head with Acthar and to take a substantial amount of Acthar's business with both on- and off-label sales.

30. The relevant geographic market is the United States. FDA approval is required to market pharmaceuticals to U.S. consumers. As a result, drugs sold outside of the United States are not viable competitive alternatives for U.S. consumers, even in the event of a significant price increase for ACTH drugs available in the United States.

31. Acthar has a 100% share of the market for ACTH drugs in the United States. No other ACTH drug is FDA-approved for therapeutic use.

32. The U.S. ACTH market is characterized by high barriers to entry. Developing a long-acting, depot-injection formulation of a drug product containing ACTH (natural or synthetic) that is stable, safe, and effective would require significant time, cost, and effort, with no guarantee of success. The requirements for entry include sourcing the active pharmaceutical ingredient, formulating a sustained-release depot-injection formulation, scaling production to clinical scale, and successfully conducting clinical trials necessary for FDA approval. Mallinckrodt's CEO has assured investors that Acthar "has significant durability in the marketplace" because "it will be very difficult for this product to be replicated in any way [by] a generic."

V. Questcor Engaged in Anticompetitive Conduct By Acquiring Synacthen

33. Synacthen posed a threat to Questcor's ACTH drug monopoly, so Questcor intervened when other firms attempted to acquire the U.S. rights to Synacthen from Novartis. Questcor submitted a bid that included substantially more guaranteed money than the other bidders had offered, effectively ending the bidding process. By acquiring Synacthen, Questcor eliminated the possibility that another firm would develop it and compete against Acthar.

A. Synacthen Posed a Nascent Competitive Threat to Acthar

34. Synacthen constituted a nascent competitive threat to Questcor's ACTH drug monopoly, notwithstanding the significant uncertainty that Synacthen, a preclinical drug, would be approved by the FDA.

35. For years, Questcor viewed Synacthen as a significant potential competitive threat to its monopoly.

36. In 2006, when Questcor decided to pursue an "orphan" (i.e., high) pricing model for Acthar, it recognized the potential threat Synacthen posed to Acthar's revenue growth.

37. In 2009, Questcor approached Novartis about acquiring Synacthen. At that time, Questcor continued to view Synacthen as a possible future competitor. Unsuccessful in that attempt, Questcor continued to monitor the competitive threat from Synacthen.

38. In 2012, Questcor again concluded that Synacthen posed a threat to Acthar should it be approved for sale in the United States.

39. In 2013, Questcor feared that if another company were to acquire Synacthen and obtain FDA approval, it could decimate its business.

40. But as long as Questcor believed no other firm was seeking to bring Synacthen to the United States, Questcor did not make further attempts to acquire it. Just months before Questcor began pursuing the acquisition of Synacthen, top Questcor officials questioned whether Synacthen would provide any affirmative value to Questcor.

B. Other Bidders Planned to Use Synacthen to Challenge Acthar's Monopoly

41. Unbeknownst to Questcor at the time, Novartis decided in late 2011 to divest exclusive rights to seek FDA approval for Synacthen and commercialize it in the United States, along with the marketing rights for Synacthen in over thirty-five other countries where the drug

was already approved and sold. Dozens of companies contacted Novartis and expressed interest in acquiring Synacthen. Three firms proceeded through several rounds of negotiations with Novartis, submitted formal offers, and drafted near-final agreements.

42. Each of the three firms planned to develop Synacthen for IS and/or IMN and use Synacthen to compete directly with Acthar. With approval for one or both of these indications, each firm expected to capture a significant share of the U.S. ACTH market from Questcor by pricing Synacthen well below Acthar. Having the requisite pharmaceutical expertise and financing, the three firms independently conducted due diligence, crafted business plans and regulatory approval strategies, and took other affirmative steps in furtherance of developing Synacthen for the U.S. market.

C. The Value of the Synacthen Assets

43. The Synacthen assets and related rights provide a proven formulation for a long-acting, depot-injection drug containing synthetic ACTH. The drug product manufactured using the Synacthen formulation has been safely and effectively used to treat patients suffering from IS and other conditions worldwide for decades. The Synacthen assets would therefore facilitate commercializing a synthetic ACTH therapy in the United States.

44. The asset package sold by Novartis included valuable trade secrets, including technical documentation detailing both the precise formulation for the Synacthen drug product and the manufacturing process.

45. In possession of the Synacthen assets, a buyer would not need to create a synthetic ACTH drug formulation de novo, nor would it need to develop from scratch the manufacturing and testing protocols necessary for production of the drug product.

D. Questcor Disrupted the Synacthen Bidding Process

46. In October 2012, Questcor learned that at least one unidentified firm was attempting to acquire Synacthen from Novartis and develop it for the United States. Questcor immediately attempted to reach Novartis and shortly thereafter signed a confidentiality agreement with Novartis and submitted an offer for Synacthen.

47. Novartis negotiated with the three alternative bidders in parallel with Questcor. By the spring of 2013, all three of the alternative bidders had submitted offers for Synacthen, with plans to develop and launch Synacthen in the United States in direct competition with Acthar. At the point where those negotiations left off, each company had exchanged deal terms with Novartis and had submitted a formal offer. The offers by the three alternative bidders were comparable in value and structured similarly, and included an upfront payment, milestone payments upon FDA approval, and significant royalties on U.S. Synacthen sales.

48. Unlike the three alternative bidders, Questcor had only inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer to Novartis.

49. On June 11, 2013, Questcor and Novartis entered into a Licensing Agreement, Asset Purchase Agreement, and Supply Agreement (collectively, "the Agreements"), pursuant to which Questcor gained the exclusive rights to develop, market, and sell Synacthen in the United States and over thirty-five other countries. Under the Agreements, Questcor is obligated to pay a minimum of $135 million, and likely will pay $300 million to Novartis for Synacthen.

E. Questcor's Acquisition of Synacthen Harmed Competition

50. Questcor's strategy to protect its monopoly position with Acthar was successful. But for Questcor's acquisition of Synacthen, one of the three alternative bidders would have acquired Synacthen and pursued its plan to develop Synacthen for IS and/or IMN to compete

directly with Acthar at a lower price. With the acquisition of Synacthen, Questcor thwarted a nascent challenge to its Acthar monopoly and thereby harmed competition.

51. Questcor claimed that it acquired Synacthen to develop it for new, non-Acthar indications, but given the drugs' similarities, any therapeutic indication that Questcor pursues with Synacthen could have been pursued with Acthar.

52. Fourteen months after acquiring Synacthen, Mallinckrodt acquired Questcor for $5.9 billion. The vast majority of Questcor's value was attributable to Acthar.

COUNT I – Monopolization in Violation of the FTC Act

53. Plaintiff the FTC re-alleges and incorporates by reference all of the allegations in the above paragraphs.

54. Defendants have, and at all relevant times had, monopoly power in the market for the sale of ACTH drugs in the United States.

55. Disrupting the bidding process for Synacthen and executing a license to the U.S. rights to Synacthen from Novartis eliminated the nascent competitive threat posed by an independently owned Synacthen and is conduct reasonably capable of contributing significantly to Questcor's maintenance of monopoly power.

56. Defendants' acts and practices are anticompetitive in nature and tendency and constitute unfair methods of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

COUNT II – Monopolization in Violation of the Sherman Act

57. Plaintiff States re-allege and incorporate by reference all of the allegations in the above paragraphs.

58. Defendants have, and at all relevant times had, monopoly power in the market for

the sale of ACTH drugs in the United States.

59. Disrupting the bidding process for Synacthen and executing a license to the U.S. rights to Synacthen from Novartis eliminated the nascent competitive threat posed by an independently owned Synacthen and is conduct reasonably capable of contributing significantly to Questcor's maintenance of monopoly power.

60. Defendants' acts and practices constitute monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT III – Supplemental State Law Claims

61. Plaintiff States re-allege and incorporate by reference all of the allegations in the above paragraphs.

62. The aforementioned practices by Defendants were and are in violation 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.

63. The aforementioned practices by Defendants were and are in violation of the Maryland Antitrust Act, Md. Code Ann., Com. Law §§ 11-201 et seq.

64. The aforementioned practices by Defendants were and are in violation of New York's antitrust law, the Donnelly Act, New York Gen. Bus. Law §340 et seq., and is proscribed by New York Executive Law 63(12), in that the aforementioned practices constitute illegality and/or illegal acts in the carrying on, conducting, or transacting of business.

65. The aforementioned practices by Defendants were and are in violation of Texas's Free Enterprise and Antitrust Act, Tex. Bus. & Com. Code Ann. §§ 15.01 et seq.

66. The aforementioned practices by Defendants were and are in violation of Washington's Consumer Protection Act, Wash. Rev. Code §§ 19.86 et seq., as proscribed by §

19.86.040, in that the aforementioned practices are unlawful in any part of trade or commerce.

Prayer for Relief

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C. § 26, Alaska Stat. §§ 45.50.501 and 45.50.580, Md. Code Ann. Com. Law § 11-209, New York Gen. Bus. Law §340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080 empower this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by Defendants' violations; therefore, Plaintiffs request that this Court enter final judgment against Defendants Mallinckrodt and Questcor:

1. Adjudging that Defendants' conduct constitutes monopolization in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a),

2. Adjudging that Defendants' conduct constitutes monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;

3. Adjudging that Defendants have committed violations of each of the state laws enumerated in Count III;

4. Ordering that Defendants are permanently enjoined from engaging in similar and related conduct in the future;

5. Ordering divestiture and any further actions needed to restore competition lost due to the Defendants' violations;

6. Granting such other equitable relief as the Court finds necessary, including equitable monetary relief, to redress and prevent recurrence of Defendants' violations of Section 5(a) of the FTC Act, Section 2 of the Sherman Act, and the state laws enumerated in Count III,

as alleged herein;

7. Ordering Defendants to pay civil penalties pursuant to Alaska Stat. §§ 45.50.551(b) and 45.50.578(b)(2), Md. Code Ann., Com. Law § 11-209(a)(4), New York Gen. Bus. Law §342-a, Tex. Bus. & Com. Code Ann. §15.20(a), and Rev. Code of Wash. Ann. § 19.86.140; and

8. Awarding the Plaintiff States the costs of this action, including reasonable attorneys' fees and costs, as provided for in the Clayton Act and applicable state law.

Dated: January 18, 2017

Respectfully Submitted,

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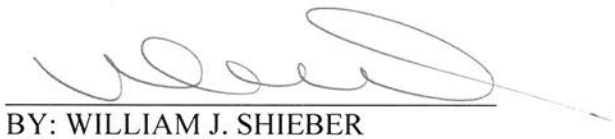

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