UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GENERIC PHARMACEUTICALS PRICING ANTITRUST LITIGATION	MDL 2724 16-MD-2724
IN RE: DIGOXIN CASES THIS DOCUMENT RELATES TO: *ALL DIGOXIN DIRECT PURCHASER ACTIONS*	HON. CYNTHIA M. RUFE LEAD CASE: 16-DG-27240 DIRECT CASE: 16-DG-27241 JURY TRIAL DEMANDED
AHOLD USA, INC.; CÉSAR CASTILLO, INC.; FWK HOLDINGS, L.L.C.; KPH HEALTHCARE SERVICES, INC., a/k/a KINNEY DRUGS, INC.; and ROCHESTER DRUG CO-OPERATIVE, INC.; on behalf of themselves and all others similarly situated, Plaintiffs, v. IMPAX LABORATORIES, INC.; LANNETT COMPANY, INC.; MYLAN INC.; MYLAN PHARMACEUTICALS INC.; PAR PHARMACEUTICAL, INC.; and WEST-WARD PHARMACEUTICALS CORP., Defendants.	

CONSOLIDATED DIRECT PURCHASER CLASS ACTION COMPLAINT

REDACTED PUBLIC VERSION
CONTAINS INFORMATION REDACTED PURSUANT
TO MDL 2724 PROTECTIVE ORDER

TABLE OF CONTENTS

I. INTRODUCTION

1. Plaintiffs Ahold USA, Inc., César Castillo, Inc., FWK Holdings, L.L.C., KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc., and Rochester Drug Co-Operative, Inc., on behalf of themselves and all others similarly situated, bring this Class Action Complaint on behalf of a Class (defined below) of direct purchasers who purchased generic digoxin 0.125 or 0.25 mg tablets ("Digoxin"), directly from Defendants Impax Laboratories, Inc., Lannett Company, Inc., Mylan Inc., Mylan Pharmaceuticals Inc., Par Pharmaceutical, Inc., or West-Ward Pharmaceuticals Corp.

2. In the pharmaceutical industry, the entry of generic versions of branded drugs usually results in aggressive price competition, which in turn reduces prices for drug wholesalers, retail pharmacies, consumers, and third party payors. Defendants here, however, conspired to thwart the economic benefits of generic competition.

3. This is a civil action seeking treble damages arising out of the Defendants' unlawful scheme to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation of Digoxin. As set forth below, Defendants' scheme violates Section 1 of the Sherman Act, 15 U.S.C. § 1. Defendants were not alone in subverting the operation of a competitive marketplace for generic pharmaceuticals. Defendants' anticompetitive conduct in the Digoxin market is part of a larger conspiracy or series of conspiracies involving many generic pharmaceutical manufacturers and more than a dozen generic pharmaceuticals.

4. Plaintiffs' allegations are based on personal knowledge of these matters relating to themselves and upon information and belief as to all other matters. Parts of Plaintiffs' allegations are based on information made public during ongoing government investigations of Defendants and other generic pharmaceutical companies for alleged unlawful price-fixing and other conduct in the generic pharmaceutical industry.

5. Digoxin is a purified cardiac glycoside derived from *digitalis lanata*, or the foxglove plant used to treat heart failure and atrial fibrillation. Digoxin has been designated an essential medicine by the World Health Organization.[1]

6. Digoxin was first described in the medical literature in 1785 and it has been available in the United States for well over a decade. The market for Digoxin is mature and Defendants dominate the market for Digoxin.

7. Beginning in approximately October 2013 and continuing today (the "Class Period"), Defendants and co-conspirators engaged in an overarching anticompetitive scheme in the market for Digoxin to artificially inflate prices through unlawful agreements. Defendants caused the price of these products to dramatically and inexplicably increase as much as [redacted] higher than September 2013 prices, as alleged in Section V(B)(3) herein. The United States Government Accountability Office ("GAO") singled out Digoxin as an example of a generic pharmaceutical that "experienced an extraordinary price increase."[2] This increase was the consequence of an agreement among Defendants to increase pricing and restrain competition for the sale of Digoxin in the United States. Defendants orchestrated their conspiracy through secret communications and meetings, both in private and at public events, such as industry events and trade association meetings held by the Generic Pharmaceutical Association ("GPhA") (now

[1] According to the World Health Organization: "Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford." World Health Organization Website, Essential medicines, *available at* http://www.who.int/topics/essential_medicines/en/.

[2] GAO Report to Congressional Requesters, *Generic Drugs Under Medicare* (Aug. 2016), *available at* http://www.gao.gov/assets/680/679055.pdf.

called the Association for Accessible Medicines),[3] the Healthcare Distribution Management Association ("HDMA") (now called the Healthcare Distribution Alliance), the Minnesota Multistate Contracting Alliance for Pharmacy ("MMCAP"), the National Association of Chain Drug Stores ("NACDS"), Efficient Collaborative Retail Marketing ("ECRM"), and the National Pharmacy Forum ("NPF"),[4] among others.

8. Defendants' and other generic pharmaceutical manufacturers' conduct has resulted in extensive scrutiny by federal and state regulators, including by the Antitrust Division of the United States Department of Justice ("DOJ"), the United States Senate, the United States House of Representatives, and at least 45 attorneys general from 44 states and the District of Columbia (the "State AGs"). The DOJ empaneled a federal grand jury in this District, which has issued subpoenas relating to price-fixing and other anticompetitive conduct in the generic pharmaceutical industry, including to at least Impax, Lannett, and Par.

9. The DOJ's and State AGs' investigations followed a congressional hearing and investigation prompted by the National Community Pharmacists Association's ("NCPA") January 2014 correspondence to the United States Senate Health Education Labor and Pensions ("HELP") Committee and the United States House Energy and Commerce Committee requesting hearings on significant spikes in generic pharmaceutical pricing.[5] The NCPA's news release reported price hikes on essential generic pharmaceuticals exceeding 1,000% in some instances,

---

[3] *See* Russell Redman, *New name for Generic Pharmaceutical Association*, CHAIN DRUG REVIEW (Feb. 14, 2017), *available at* http://www.chaindrugreview.com/new-name-for-generic-pharmaceutical-association/.

[4] The NPF is an annual industry event co-hosted by the Healthcare Supply Chain Association and the Healthcare Industry Supply Chain Institute.

[5] News Release, *Generic Drug Price Spikes Demand Congressional Hearing, Pharmacists Say* (Jan. 8, 2014), *available at* http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say.

according to its survey of over a thousand community pharmacists, resulting in some patients being forced to leave their prescriptions at the pharmacy counter due to increased copays, and forcing more seniors into Medicare's coverage gap (or "donut hole") where they must pay far higher out-of-pocket costs.

10. On December 12 and 13, 2016, the DOJ filed its first criminal charges against Defendants Glazer and Malek in their capacities as former executives of Defendant Heritage. *See United States of America v. Jeffrey A. Glazer*, No. 2:16-cr-00506-RBS (E.D. Pa.); *United States of America v. Jason T. Malek*, No. 2:16-cr-00508-RBS (E.D. Pa.). The DOJ alleged that both Glazer and Malek conspired with others "to allocate customers, rig bids, and fix and maintain prices" of generic glyburide and doxycycline sold in the United States. Each was charged with two felony counts under the Sherman Act, 15 U.S.C. § 1. On January 9, 2017, both Glazer and Malek pleaded guilty to the charges. They continue to cooperate with the DOJ's ongoing investigation as they await sentencing.

11. The DOJ has publicly acknowledged that its investigation overlaps with MDL 2724. For example, the DOJ filed a motion for a stay of discovery in MDL 2724 noting that:

> Evidence uncovered during the criminal investigation implicates other companies and individuals (including a significant number of the Defendants here) in collusion with respect to doxycycline hyclate, glyburide, and other drugs (including a significant number of the drugs at issue here).[6]

12. Soon after the DOJ filed criminal charges, 20 state attorneys general led by the State of Connecticut also sued generic manufacturers Aurobindo, Citron, Heritage, and Teva, as well as Mayne and Mylan for bid rigging, price-fixing and market and customer allocation in

[6] *See* Intervenor United States' Motion to Stay Discovery, *In re: Generic Pharm. Pricing Antitrust Litigation*, MDL No. 2724, ECF 279 (E.D. Pa. May 1, 2017).

connection with their sale of generic glyburide and doxycycline in the United States. On March 1, 2017, the complaint in the State AGs' action was amended to, *inter alia*, add claims of an additional 20 state attorneys general, bringing the total number of state AGs prosecuting the action to 40. Glazer and Malek entered into settlement agreements with the attorneys general on March 16, 2017.[7] Commenting on the scope of its current antitrust investigation, the Connecticut Attorney General ("CTAG") George Jepsen stated that "[t]he issues we're investigating go *way beyond* the two drugs and six companies. *Way beyond…We're learning new things every day*."[8] On July 17, 2017, 5 additional attorneys general joined the action by filing a nearly identical complaint and a notice of related case.[9]

13. As noted above, the State AGs' and DOJ's investigations are ongoing. Just last week, Pfizer Inc. reported in an SEC filing dated August 10, 2017 that:

> As of July 2017, the U.S. Department of Justice's Antitrust Division is investigating our Greenstone generics business. We believe this is related to an ongoing antitrust investigation of the generic pharmaceutical industry. The government has been obtaining information from Greenstone.

14. As a result of Defendants' scheme to fix, maintain, and stabilize the prices, rig bids, and engage in market and customer allocation of Digoxin, direct purchasers paid, and continue to pay, supracompetitive prices for Digoxin.

---

[7] John Kennedy, *Ex-Heritage Execs to Help States Probe Drug Price-Fixing*, LAW360 (May 24, 2017), *available at* https://www.law360.com/competition/articles/927899/ex-heritage-execs-to-help-states-probe-drug-price-fixing?nl_pk=eb0b62b3-08e3-46ed-ac8a-7ab5fa616c07&utm_source=newsletter&utm_medium=email&utm_campaign=competition.

[8] Liz Szabo, et al., *How Martinis, Steaks, and a Golf Round Raised Your Prescription Drug Prices*, THE DAILY BEAST (Dec. 21, 2016), *available at* http://thebea.st/2haV9xg (emphasis added).

[9] *Arkansas v. Aurobindo Pharma USA, Inc.*, No. 17-cv-1180 (D. Conn.).

15. Plaintiffs, on behalf of themselves and members of a direct purchaser class, seek damages caused by Defendants' and co-conspirators' violations of Section 1 of the Sherman Act, 15 U.S.C. § 1.

II. JURISDICTION AND VENUE

16. This Court has jurisdiction over the subject matter of this action as it arises under Section 1 of the Sherman Act, 15 U.S.C. § 1, and Section 4 of the Clayton Act, 15 U.S.C. § 15. Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).

17. Venue is proper in this District pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391(b), (c), and (d), because during the Class Period Defendants transacted business throughout the United States, including in this District, Defendants resided, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District.

18. During the Class Period, Defendants sold and distributed generic pharmaceuticals in a continuous and uninterrupted flow of interstate commerce, which included sales of Digoxin in the United States, including in this District. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

19. This Court has personal jurisdiction over each Defendant because, *inter alia*, each Defendant: (a) transacted business throughout the United States, including in this District; (b) participated in the selling and distribution of Digoxin throughout the United States, including in this District; (c) had and maintained substantial contacts within the United States, including in this District; and/or (d) was engaged in an unlawful conspiracy to inflate the prices for Digoxin that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

III. PARTIES

A. Plaintiffs

20. Plaintiff Ahold USA, Inc. ("Ahold") is a Maryland corporation with its principal places of business in Quincy, Massachusetts and Carlisle, Pennsylvania. During the Class Period, Ahold purchased Digoxin directly from one or more Defendants. As a result of Defendants' antitrust conspiracy, Ahold paid supracompetitive prices for its Digoxin purchases and was injured by the illegal conduct alleged herein.

21. Plaintiff César Castillo, Inc. ("CCI") is a Puerto Rico corporation with its principal place of business in Rio Piedras, Puerto Rico. During the Class Period, CCI purchased Digoxin directly from one or more Defendants. As a result of Defendants' antitrust conspiracy, CCI paid supracompetitive prices for its Digoxin purchases and was injured by the illegal conduct alleged herein.

22. Plaintiff FWK Holdings, LLC ("FWK") is an Illinois corporation with its principal place of business in Glen Ellyn, Illinois. FWK is the assignee of antitrust claims possessed by Frank W. Kerr Company ("Kerr") and brings this action as successor-in-interest to Kerr's claims arising from its purchase of Digoxin directly from one or more of the Defendants during the Class Period. As a result of Defendants' antitrust conspiracy, FWK, through assignor Kerr, paid supracompetitive prices for its Digoxin purchases and was injured by the illegal conduct alleged herein.

23. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("KPH") is a New York corporation with its principal place of business in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. During the Class Period, KPH directly purchased Digoxin from one or more of the Defendants.

As a result of Defendants' antitrust conspiracy, KPH paid supracompetitive prices for its Digoxin purchases, and KPH was injured by the illegal conduct alleged herein.

24. Plaintiff Rochester Drug Co-Operative, Inc. ("RDC") is a New York corporation with its principal place of business in Rochester, New York. During the Class Period, RDC purchased Digoxin directly from one or more of the Defendants at artificially and unlawfully inflated prices. As a result of Defendants' antitrust conspiracy, RDC paid supracompetitive prices for its Digoxin purchases, and RDC was injured by the illegal conduct alleged herein.

B. Defendants

25. Defendant Impax Laboratories, Inc. ("Impax") is a Delaware corporation with its principal place of business in Hayward, California. In 1999, Global Pharmaceutical Corporation merged with Impax Pharmaceuticals, Inc. to become Impax. Impax continues to sell generic products, including Digoxin, through its Global Pharmaceutical division. During the Class Period, Impax marketed and sold Digoxin to purchasers in this District and throughout the United States. Impax sells Digoxin pursuant to Abbreviated New Drug Applications ("ANDAs") that were approved by the United States Food and Drug Administration ("FDA") in July 2009.

26. Defendant Lannett Company, Inc. ("Lannett") is a Delaware corporation with its principal place of business in Philadelphia, Pennsylvania. During the Class Period, Lannett sold Digoxin to purchasers in this District and throughout the United States. Lannett sells Digoxin pursuant to ANDAs that were approved by the FDA in July 2002.[10]

[10] The ANDAs were submitted by Jerome Stevens Pharmaceutical, Inc. In May 2004, Lannett announced that it had entered a contract with Jerome Stevens Pharmaceutical, Inc. for the exclusive right to distribute digoxin, among other products, in the United States.

27. Defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business in Canonsburg, Pennsylvania.

28. Defendant Mylan Pharmaceuticals Inc. is a West Virginia corporation with its principal place of business in Morgantown, West Virginia.

29. Mylan Inc. and Mylan Pharmaceuticals Inc. are wholly-owned subsidiaries of Mylan N.V., a Dutch pharmaceutical company. In this complaint, Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. are together referred to as "Mylan." During the Class Period, Mylan sold Digoxin to purchasers in this District and throughout the United States.

30. Defendant Par Pharmaceutical Inc. ("Par") is a subsidiary of Endo International plc ("Endo"), an Irish pharmaceutical company. In September 2015, Endo completed an acquisition of Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par, from a private investment firm for about $8 billion in cash and stock. At that time Endo created a combined U.S. Generics segment that included Par, and Endo's subsidiary Qualitest, naming the segment Par Pharmaceutical, Inc. During the Class Period, Par sold Digoxin to purchasers in this District and throughout the United States. Par sells Digoxin through an exclusive contract to distribute the authorized generic version of the drug.

31. Defendant West-Ward Pharmaceuticals Corporation ("West-Ward") is a Delaware corporation with its principal place of business in Eatontown, New Jersey. During the Class Period, West-Ward sold Digoxin to purchasers in this District and throughout the United States. West-Ward sells Digoxin pursuant to ANDAs that were submitted by its parent Hikma International Pharmaceuticals LLC ("Hikma") and approved by the FDA in October 2007.

32. Defendants and their officers, agents, employees, or representatives have engaged in the conduct alleged in this Complaint while actively involved in the management of Defendants' business and affairs.

C. Co-Conspirators

33. Various other persons, firms, entities, and corporations, not named as Defendants in this Complaint, have participated as co-conspirators with Defendants in the violations alleged herein, and have aided, abetted, and performed acts and made statements in furtherance of the conspiracy.

34. The true names and capacities of additional co-conspirators, whether individual, corporate, associate, or representative, are presently unknown to Plaintiffs. Plaintiffs may amend this Complaint to allege the true names and capacities of additional co-conspirators as they are discovered.

35. At all relevant times, other persons, firms, and corporations, referred to herein as "co-conspirators," the identities of which are presently unknown, have willingly conspired with Defendants in their unlawful scheme as described herein.

36. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

37. The wrongful acts alleged to have been done by any one Defendant or co-conspirator were authorized, ordered, or done by its directors, officers, managers, agents, employees, or representatives while actively engaged in the management, direction, or control of such Defendant's or co-conspirator's affairs.

IV. INTERSTATE TRADE AND COMMERCE

38. Defendants are the leading manufacturers and suppliers of Digoxin sold in the United States.

39. Digoxin is produced by or on behalf of Defendants or their affiliates in the United States or overseas.

40. During the Class Period, Defendants, directly or through one or more of their affiliates, sold Digoxin throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

41. The activities of Defendants and their co-conspirators were within the flow of, intended to, and had a substantial effect on interstate commerce in the United States.

42. Defendants' and their co-conspirators' conduct, including the marketing and sale of Digoxin, took place within, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.

43. The conspiracy alleged in this Complaint has directly and substantially affected interstate commerce in that Defendants deprived Plaintiffs of the benefits of free and open competition in the purchase of Digoxin within the United States.

44. Defendants' agreement to fix, maintain, and stabilize the prices, rig bids, and engage in market and customer allocation of Digoxin, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing Digoxin prices, were intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States.

V. FACTUAL ALLEGATIONS

A. The Generic Drug Market Is a Commodities Market, Where Competition Historically Has Been Keen.

1. Generic drugs should lead to lower prices.

45. Generic drugs provide a lower-cost but bioequivalent alternative to brand drugs. Before any generic drug can be marketed, the FDA requires rigorous testing to ensure it has the same strength, quality, safety, and performance as the brand. By law, generics must have the same amount of active ingredient and must be "therapeutically equivalent" to the brand, meaning they must meet exacting bioequivalence testing specifications so patients can expect "equal effect and no difference when [generics are] substituted for the brand name product."[11]

46. To encourage the production and sale of generic drugs, the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") simplified the regulatory hurdles that generic pharmaceutical manufacturers have to clear prior to marketing and selling generic pharmaceuticals. Instead of filing a lengthy and costly New Drug Application, the Hatch-Waxman Act allows generic pharmaceutical manufacturers to obtain FDA approval in an expedited fashion.

47. To obtain marketing approval for a generic pharmaceutical, an ANDA must be filed with the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs; "abbreviated" because so long as the ANDA includes data showing bioequivalence to the brand, the ANDA sponsor can reference efficacy data supporting approval of the brand (described in the regulations as the "Reference Listed Drug" or "RLD" for short) instead of repeating all the same clinical trials. Upon the FDA's determination that bioequivalence to the brand has been

[11] FDA, *Drugs@FDA Glossary of Terms*, *available at* http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G.

established, the ANDA will be approved and may be marketed in the United States as substitutable with the RLD.

48. Although equivalent from a safety and efficacy standpoint, generic versions of brand name drugs are priced significantly below their brand counterparts, and because of this, they rapidly gain market share from the brand beginning immediately following launch. Indeed, in every state, pharmacists are permitted (and in many states required) to substitute a generic product for a brand product barring a note from a doctor that the brand product must be dispensed as written.

49. It is well established in economic literature that competition by generic products results in lower prices for drug purchasers. In the period before generic entry, a brand drug commands 100% of the market share for that drug and the brand manufacturer can set the price free from competitive market forces. But once the first lower-priced generic enters, a brand drug rapidly loses sales due to automatic pharmacy counter substitution, and generics capture as much as 80% of the market or more within months of launch. And as more generics become available, generic prices only decline further due to competition among generics. These cost reductions to drug purchasers were the very legislative purpose behind the abbreviated regulatory pathway for generic approval under the Hatch Waxman Act.

50. Generic competition, under lawful and competitive circumstances, reduces drug costs by driving down the prices of both generic versions of the brand drug and often the brand drug itself, and every year generic drugs result in hundreds of billions of dollars in savings to consumers, insurers, and other drug purchasers.

51. A Federal Trade Commission study found that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[12] A mature generic market, such as the market for Digoxin, has several generic competitors. Because each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers.[13] Over time, generics' pricing nears the generic manufacturers' marginal costs.

52. Generic competition usually enables purchasers to purchase generic versions of the brand drug at a substantially lower price than the brand drug. Generic competition to a single blockbuster brand drug can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and federal governments, and others. Indeed, one study found that the use of generic drugs saved the United States healthcare system $1.68 trillion between 2005 and 2014.[14]

---

[12] Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, at 8 (Jan. 2010), *available at* https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff.

[13] *See, e.g.*, Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at 17 (Aug. 2011) ("[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price."), *available at* https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission; U.S. Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Proceed and Returns in the Pharmaceutical Industry* (July 1998), *available at* https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

[14] GPhA, GENERIC DRUG SAVINGS IN THE U.S. (7th ed. 2015) at 1, *available at* http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

2. Prescription drug prices in the United States are governed by institutional safeguards, which are intended to keep drug prices competitive.

53. Ordinarily, the price for a consumer product is set by the retailer based on the amount the typical consumer is willing to pay. But because of the unique features of the prescription drug marketplace, prescription drug pricing for most consumers is not determined between the retailer and the consumer. Rather, because most consumers' prescription drug purchases are reimbursed by public or private health plans, consumer pricing for prescription drugs is determined by reimbursement agreements between these prescription drug payers, *i.e.*, health plans and their prescription benefit managers, and the pharmacies that dispense drugs to the payers' insured customers.

54. Generic manufacturers typically report a Wholesale Acquisition Cost ("WAC") for their drugs. WAC prices represent the manufacturer's benchmark or reported list price. The WAC typically functions as the manufacturer's list or benchmark price in sales to wholesalers or other direct purchasers and typically does not include discounts that may be provided, *e.g.*, for volume sales. Manufacturers generally provide their WACs to purchasers or report them to publishers that compile that information for the market.[15]

55. Generic drug manufacturers may charge different amounts for an equally interchangeable, *i.e.*, therapeutically equivalent, multisource drug. But manufacturers are usually constrained in their ability to price generic drugs by the Maximum Allowable Cost ("MAC"). [16]

---

[15] At one time, payors relied on cost-based pricing metrics to reimburse pharmacies that dispensed drugs to their insured customers, paying the dispensing pharmacies an amount based on the manufacturer's list price for the drug, plus a small mark-up or dispensing fee. Over time, however, it was learned that the list price for most generic drugs published by their manufacturers was substantially higher than the actual cost incurred by pharmacies to acquire the drugs.

[16] To define therapeutic categories, MAC pricing typically relies on the FDA's Orange Book, which lists approved prescription drugs and their therapeutic equivalents. An "A"-rated

MAC is a contractually based payment model that, in the private sector, is commonly established by a pharmacy benefits manager ("PBM"), who manages an insurance plan, and that is paid to the pharmacies within the plan's network.[17] A MAC price sets the upper limit that a pharmacy will be paid by the PBM for procuring and dispensing a particular generic medication.

56. While PBMs usually do not disclose publicly which drugs they subject to MAC pricing, what the MAC price is, or what factors they apply to set MAC prices, it is believed that PBMs rely on a wide-variety of market-wide pricing information or plan-specific data.[18] In recent years, 79% of employer prescription drug plans and 45 state Medicaid programs have been using MAC prices to control the cost of generic drugs.[19] MAC prices give pharmacies an incentive to procure and dispense the lowest-priced drug product available for a particular multisource drug. If a generic drug is subject to MAC pricing, a pharmacy purchasing a higher-priced generic product will make less profit or potentially even lose money when it dispenses a higher-priced product.[20]

57. MAC pricing is neither uniform, nor transparent and may be subject to frequent changes. So whether a generic manufacturer's products are even subject to MAC pricing or how

---

drug is one that the FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products. *See* U.S. FDA Website, Orange Book Preface, *available at* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#tecode.

[17] Academy of Managed Care Pharmacy, *Where We Stand, Maximum Allowable Cost (MAC) Pricing* (Dec. 2013), *available at* www.amcp.org/Sec.aspx?id=9287. For the purposes of this complaint, MAC prices refer solely to prices that limit a pharmacy's reimbursement for generic drugs, not the amounts PBMs charge to the insurance plans, which may also be referred to as a MAC price. *See* National Community Pharmacists Association, *The Need for Legislation Regarding "Maximum Allowable Cost" (MAC) Reimbursement*, *available at* http://www.ncpa.co/pdf/leg/mac-one-pager.pdf.

[18] *Id.*

[19] Express Scripts, *MAC Pricing lncents More Affordable Rx* (Feb. 24, 2016), *available at* http://lab.express-scripts.com/lab/insights/drug-options/mac-pricing-incents-more-affordable-rx.

[20] *See supra* Academy of Managed Care Pharmacy article.

that MAC pricing is set for any particular generic drug is not easy for the manufacturers to decipher. PBMs typically exercise control over the selection of generic medications that will be subjected to MAC pricing, and they fiercely guard the secrecy of their MAC price lists.[21] Industry groups, like the Academy of Managed Care Pharmacy, actively oppose government regulation of MAC pricing and any efforts to disclose MAC prices or the method of calculating them.[22]

58. By setting a ceiling for reimbursement of any particular generic drug at the pharmacy level, MAC prices indirectly affect the price at which generic drug manufacturers may sell their products to direct purchasers. Because many generic drugs are subject to MAC pricing, generic drug manufacturers have an incentive to price their generic drug products competitively to maintain demand by pharmacies.

59. MAC pricing can penalize the generic drug manufacturer that raises price on its own when its competitors do not. A unilateral price increase in a competitive generic drug market that is subject to MAC pricing is likely to send buyers to a lower-price alternative. MAC pricing has little effect if generic drug manufacturers collectively increase their prices for a multi-source drug. First, PBMs generally permit pharmacies—who may be contractually obligated to dispense an unprofitable prescription—to challenge MAC prices under a MAC appeals process.[23] If the price of a generic drug has been increased by the majority of generic drug manufacturers, then these MAC appeals may be successful in getting the PBM to increase the MAC price allowed. Second, PBMs typically have a policy of revising MAC prices under

[21] *See supra* National Community Pharmacists Association article.

[22] *See supra* Academy of Managed Care Pharmacy article.

[23] *Id.*

certain contingencies.[24] One large PBM, Express Scripts, for example, states that its MAC price list is frequently updated to reflect "the current market dynamics."[25]

60. MAC pricing provides yet another reason that Defendants' stark increases in the price of Digoxin are indicative of coordinated pricing activity. Knowing that they hold an overwhelming majority share of the market for Digoxin, Defendants had the capacity to dictate the market price and to influence the MAC prices set by PBMs, but only if they acted collectively. Absent collusion, individual Defendants could not have increased their prices at the high levels they did (or maintain high prices in the face of a significantly lower competitor price) without incurring the loss of a significant volume of sales.

B. Defendants' Conspired to, Among Other Things, Raise Digoxin Prices.

1. Defendants' dominance over Digoxin sales permitted them to fix prices, and their abrupt price increases are otherwise inexplicable.

61. The market for Digoxin is mature, as generic versions have been on the market for years. In 2014 alone, Defendants' total revenue from direct sales of these products were approximately [redacted][26] This compares to just [redacted] in 2012, the year before the price fixing conspiracy.

---

[24] *Id.*

[25] *See supra* Express Scripts article.

[26] Revenue, unit sales, and effective prices are obtained from QuintilesIMS Inc. ("IMS Health"). IMS Health is the largest vendor of physicians' prescribing data in the United States and is widely relied upon in the pharmaceutical industry and elsewhere. As used in this complaint, "effective prices" represent actual transaction prices, as reported by IMS Health. Plaintiffs calculate Defendants' effective prices based on IMS Health's National Sales Perspectives ("NSP") data, which "captures 100% of the total U.S. pharmaceutical market, measuring sales at actual transaction prices[.]" IMS Institute for Healthcare Informatics, HSRN Data Brief: National Sales Perspectives, at 1, *available at* https://www.imshealth.com/files/web/IMSH%20Institute/NSP_Data_Brief-.pdf.

Effective prices are calculated to multiple decimals. For ease of reference, prices in this complaint are rounded to the nearest cent. However, percentage increases are calculated based on the more precisely calculated price.

62. A mature generic market, such as the market for Digoxin, has several generic competitors. As noted above, because each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers. In a market free from collusive activity, over time, generics' pricing would naturally near (and stay near) the generic manufacturers' marginal costs.

63. At all times relevant for this lawsuit, there have been multiple manufacturers of Digoxin on the market. Under accepted economic principles of competition, when there are multiple generics on the market, prices should remain at highly competitive, historic levels, and should not increase starkly as they did here absent anticompetitive conduct. Drastic increases in Digoxin prices are themselves suggestive of Defendants' collective market dominance: if they did not already dominate the market, Defendants' pricing excesses would be disciplined because they would lose market share to non-colluding competitors.

2. Defendants' collective market dominance permitted them to collude.

64. During the Class Period, the Defendants dominated the market with about a [redacted] share.[27] Likewise, before the Class Period, from May 2010 through September 2013, their sales made up about [redacted] of all United States direct purchases of Digoxin.

65. In terms of revenue, in 2014, Defendant Impax's sales to direct purchasers were roughly [redacted], Defendant Lannett's were about [redacted], Par's were about [redacted], and West Ward's were about [redacted].

[27] Market share is calculated in this complaint by reference to IMS unit sales data.

3. Defendants' effective prices were remarkably stable before skyrocketing in the Class Period.

66. Before the Class Period, the effective prices of Defendants' Digoxin remained stable for years, as is typical in a mature market. From May 2010 through September 2013, *i.e.*, for over three years leading up to the price-fixing conspiracy, the standard deviation percentage of mean prices for Defendants Impax, Lannett, and West Ward was no more than [redacted]

67. As illustrated below, Defendants' effective prices inexplicably increased sharply beginning in October 2013:

68.

[redacted]

[redacted]

69. **Impax**: For over three years before the Class Period began, the average effective price per unit of its products was [redacted]

70. [redacted]

Product	Price Sept. 2013	Hike Date	Hike Price	Percentage Increase
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

71. [redacted]

Product	Price Date	Peak Price	Percentage Increase
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

72. [redacted]

Product	Price Sept. 2013	Price Apr. 2016	Percentage Increase
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

73. **Lannett**: For over two years before the Class Period began, the average effective price per unit of its products was [redacted]

74. [redacted]

Product	Price Sept. 2013	Hike Date	Hike Price	Percentage Increase
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

75. [redacted]

Product	Price Date	Peak Price	Percentage Increase
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

76. [redacted]

Product	Price Sept. 2013	Price Apr. 2016	Percentage Increase
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

77. **Par**: [redacted]

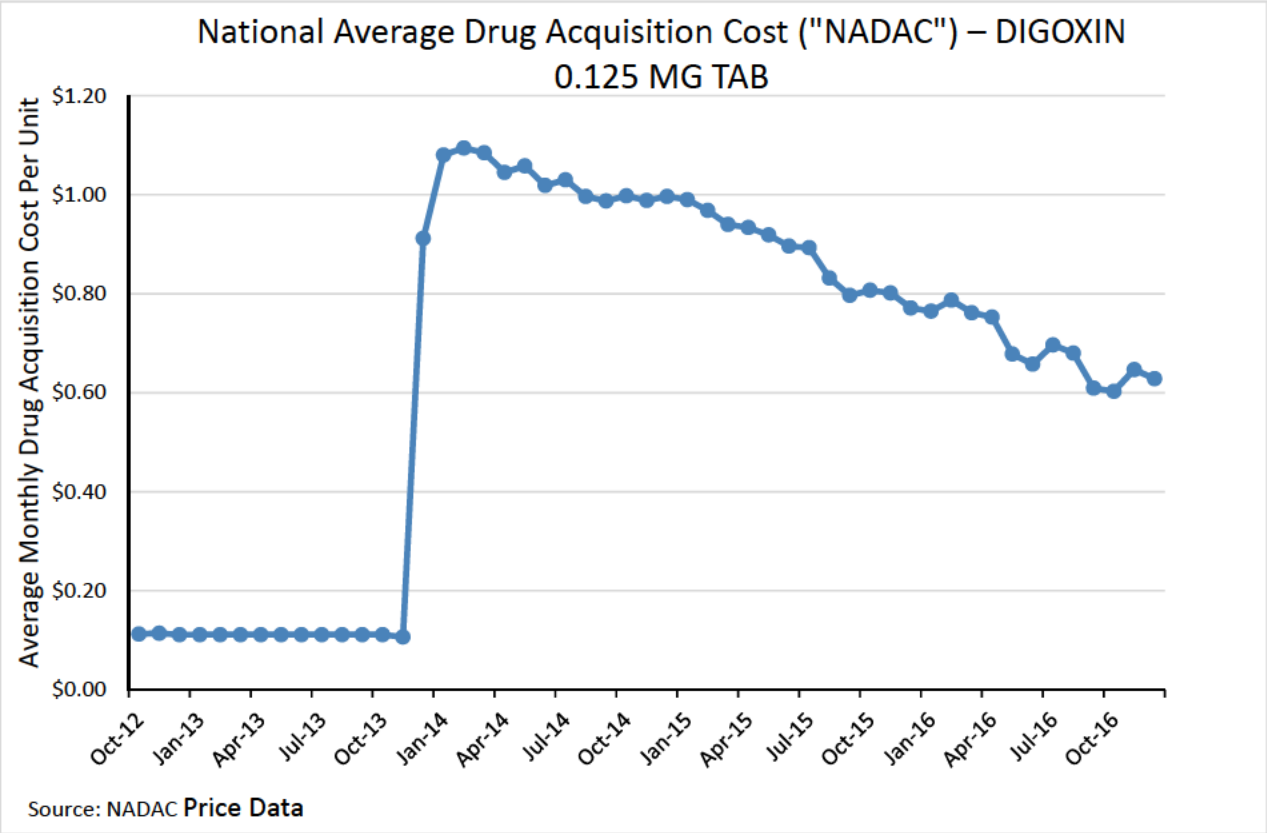
78. **West Ward**: From May 2010 through the end of 2012, before West-Ward temporarily exited the market, the average effective price per unit of its products was [redacted]

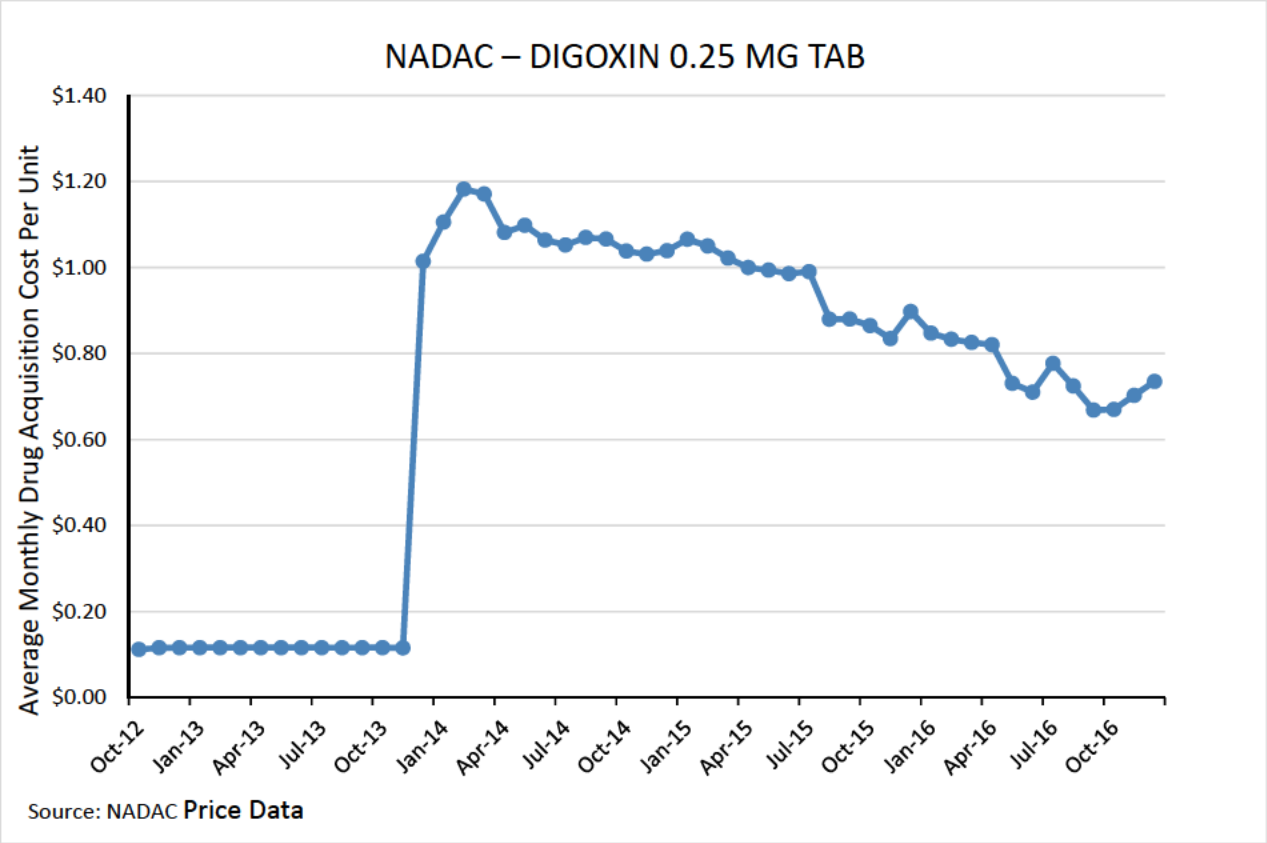
79. [redacted]

80. **Mylan**: Mylan withdrew from the market long before the Class Period began. When it returned to the market, instead of competing on price, it entered the market at

supracompetitive prices, comparable to the other Defendants. Likewise, even today its prices are far above Defendants' pre-conspiracy prices.

81. Defendants' price increases coincide with increases reported by the Centers for Medicare & Medicaid Services:





4. As part of the conspiracy, some Defendants increased their WAC benchmarks in lockstep.

82. Although MAC pricing was implemented to discourage unilateral price increases of generic drugs by setting an upper limit, an individual manufacturer's WAC increase influences the actual prices paid by direct purchasers. This is the case here, where Defendants dominate the Digoxin market. In October 2013, Lannett and Impax reported identical WACs—even though that meant a several fold increase from their previous benchmarks. Instead of competing on price, Par, West-Ward, and Mylan reported the same WAC benchmarks as Lannett and Impax, as they entered the market:[28]

[28] For ease of reference, WAC prices are rounded to the nearest cent, but the percentage increases are calculated on the actual reported WACs.

Product	Defendant	NDC	Old WAC	New WAC	Date of Increase	Percentage increase
0.125 mg, 100 ct.	Lannett	00527-1324-01	$0.14	$1.19	16-Oct-13	734%
0.125 mg, 100 ct.	Impax	00115-9811-01	$0.14	$1.19	22-Oct-13	734%
0.125 mg, 100 ct.	Par	49884-0514-01	*	$1.19	17-Jan-14	*
0.125 mg, 100 ct.	West-Ward	00143-1240-01	$0.16	$1.19	14-Apr-14	638%
0.125 mg, 100 ct.	Mylan	00378-6155-01	*	$1.19	17-Nov-14	*

Product	Defendant	NDC	Old WAC	New WAC	Date of Increase	Percentage increase
0.125 mg, 1,000 ct.	Lannett	00527-1324-10	$0.12	$0.99	16-Oct-13	738%
0.125 mg, 1,000 ct.	Impax	00115-9811-03	$0.12	$0.99	22-Oct-13	738%
0.125 mg, 1,000 ct.	Par	49884-0514-10	*	$0.99	17-Jan-14	*
0.125 mg, 1,000 ct.	West-Ward	00143-1240-10	$0.13	$0.99	14-Apr-14	687%
0.125 mg, 1,000 ct.	Mylan	00378-6155-10	*	$0.99	17-Nov-14	*

Product	Defendant	NDC	Old WAC	New WAC	Date of Increase	Percentage increase
0.25 mg, 100 ct.	Lannett	00527-1325-01	$0.14	$1.19	16-Oct-13	734%
0.25 mg, 100 ct.	Impax	00115-9822-01	$0.14	$1.19	22-Oct-13	734%
0.25 mg, 100 ct.	Par	49884-0494-01	*	$1.19	17-Jan-14	*
0.25 mg, 100 ct.	West-Ward	00143-1241-01	$0.16	$1.19	14-Apr-14	638%

Product	Defendant	NDC	Old WAC	New WAC	Date of Increase	Percentage increase
0.25 mg, 100 ct.	Mylan	00378-6156-01	*	$1.19	17-Nov-14	*

Product	Defendant	NDC	Old WAC	New WAC	Date of Increase	Percentage increase
0.25 mg, 1,000 ct.	Lannett	00527-1325-10	$0.12	$0.99	16-Oct-13	738%
0.25 mg, 1,000 ct.	Impax	00115-9822-03	$0.12	$0.99	22-Oct-13	738%
0.25 mg, 1,000 ct.	Par	49884-0494-10	*	$0.99	17-Jan-14	*
0.25 mg, 1,000 ct.	West-Ward	00143-1241-10	$0.13	$0.99	14-Apr-14	687%
0.25 mg, 1,000 ct.	Mylan	00378-6156-10	*	$0.99	17-Nov-14	*

5. There are no shortages or other market changes that would justify Defendants' price increases.

83. During the Class Period, there was no significant increase in the costs of making Digoxin, no significant decrease in supply, and no significant increase in demand. Nonetheless, there were extraordinary increases by each of the Defendants in the prices they charged their customers for Digoxin. Such price increases in a commodity product for which there were no significant increases in costs or demand and no significant decrease in supply would not have been in each Defendant's unilateral self-interest absent the existence of a cartel.

84. Federal law requires that drug manufacturers report drug shortages.[29] Digoxin is not listed on the FDA's list of Current and Resolved Drug Shortages and Discontinuations

[29] FDA Safety and Innovation Act of 2012, Pub. L. No. 112-144, §§ 1001-1008, 126 STAT. 995, 1099-1108.

Reported to FDA. Digoxin also does not appear on any archived lists of the American Society of Health-System Pharmacists ("ASHP") Current Shortage Bulletins from July 3, 2012, through today, nor does it appear on the current list of ASHP Resolved Shortage Bulletins (which includes drug shortages dating back to August 2010). None of the Defendants reported any drug shortages or supply disruptions to the FDA in explanation for the supracompetitive pricing of Digoxin.

85. Nor does any change in the marketplace explain the rising prices—before the Class Period, from May 2010 through September 2013, Defendants accounted for around [redacted] of the direct sales of Digoxin tablets. During the Class Period, Defendants also maintained roughly 99% of the Digoxin tablets market.

86. The presence or absence of competitors in the marketplace also does not explain the price of Digoxin. As the preceding charts show, the price of Digoxin remained steady for about three years before the price hikes. From at least October 2012 until the fall of 2013, many months after West-Ward temporarily exited the market, the price for Digoxin as reported in the NADAC data was consistently around $0.11 for the 0.125 mg tablets and between $0.11 and $0.12 for the 0.25 mg tablets. Following the astronomical price increases in the fall of 2013, West-Ward reentered, and Par entered in early 2014, later followed by Mylan in 2015. Prices did not fall to 2013 levels *despite the new competitors*. Pricing has remained inflated to this day.

87. Defendants' sudden and massive price increases represented a sharp departure from the previous years of stable prices with catastrophic effect on consumers. According to a December 2013 report:

> Bill Drilling, an owner of a pharmacy in Sioux City, Iowa, apologizes as he rings up a customer's three-month supply of the heart medicine Digoxin. The total is $113.12—almost 10 times the cost for the same prescription in August. Digoxin isn't a new miracle

> drug. . . . "I've been doing this since 1985, and the only direction that generics-drug prices have gone is down," Drilling says.
>
> "This is starting to create hardship," he says. Many of his customers fall into what is known as the Medicare "doughnut hole," a coverage gap in which patients pay 47.5 percent of branded-drug costs and 79 percent of a generic's price. Russ Clifford, a retired music teacher, learned Digoxin's cost had jumped more than fourfold when he picked up his 30-day supply in mid-November. Clifford and his wife have had to dip into savings to pay their rising pharmaceutical bills. [30]

88. On July 8, 2014, *The New York Times* reported that with respect to rapid price increases of generic pharmaceuticals, "[d]igoxin provides a telling case study." But

> [o]nly one of the companies, Lannett, responded to calls and emails for comment and would not discuss the specific case of Digoxin, saying only in an emailed statement, "On occasion and for a variety of reasons generic drug makers can and do raise prices." Those factors, it said, included problems acquiring raw material, increased costs of complying with Food and Drug Administration requirements and manufacturers exiting the market.[31]

89. These factors do not apply to Digoxin. As noted by *The New York Times*:

> There was no drug shortage, according to the Food and Drug Administration that might explain the increase. There was no new patent or new formulation. Digoxin is not hard to make. What had changed most were the financial rewards of selling an ancient, lifesaving drug and company strategies intended to reap the benefits.[32]

90. A report in Generics and Biosimilars Initiative, echoed the same conclusion and noted that the price of Digoxin began to climb around the time that Par entered the market. "It is

---

[30] Alan Katz, *Surprise! Generic Drug Prices Spike*, BLOOMBERG (Dec. 12, 2013), *available at* https://www.bloomberg.com/news/articles/2013-12-12/generic-drug-prices-spike-in-pharmaceutical-market-surprise.

[31] Elisabeth Rosenthal, *Rapid Price Increases for Some Generic Drugs Catch Users by Surprise*, N.Y. TIMES (July 8, 2014), *available at* http://www.nytimes.com/2014/07/09/health/some-generic-drug-prices-are-soaring.html?emc=eta1&_r=0.

[32] *Id*.

not clear which company started this, however, the price doubled in six months. . . . The companies have not yet provided an explanation for the price rise."[33]

C. Defendants Orchestrated Their Conspiracy Through In-Person Meetings at Trade Association Meetings, Industry Meetings, and Other Events.[34]

91. During the Class Period, Defendants conspired, combined, and contracted to fix, raise, maintain, and stabilize prices, rig bids and engage in market and customer allocation for Digoxin, which had the intended and actual effect of causing Plaintiffs and the other members of the proposed Class to pay artificially inflated prices above prices that would exist if a competitive market had determined prices for Digoxin.

92. Beginning in [redacted] Defendants collectively caused the price of Digoxin to increase dramatically. Defendants' conduct cannot be explained by normal competitive forces. It was the result of an agreement among Defendants to increase pricing and restrain competition for the sale of Digoxin in the United States. The agreement was furthered by discussions held at meetings and industry events hosted by the GPhA, HDMA, MMCAP, NACDS, NPF, and ECRM as well as other meetings and communications.

93. In formulating and effectuating their conspiracy, Defendants engaged in numerous anticompetitive activities, including, among other things:

(a) Participating, directing, authorizing, or consenting to the participation of subordinate employees in meetings, conversations, and communications with co-conspirators to discuss the sale and pricing of Digoxin in the United States;

(b) Participating, directing, authorizing, or consenting to the participation of subordinate employees in meetings, conversations, and communications with co-conspirators to engage in customer and market allocation or bid rigging for

[33] Generics and Biosimilars Initiative, *Lawyers Look at New Price Hike for Old Drug* (Aug. 29, 2014), *available at* http://www.gabionline.net/layout/set/print/content/view/full/3437.

[34] The allegations included in this section pertaining to the HDMA, MMCAP, NACDS, and ECRM are based in part upon documents produced to plaintiffs pursuant to subpoenas *duces tecum* issued in *In re: Propranolol Antitrust Litigation*, No. 16-cv-9901 (S.D.N.Y.).

Digoxin sold in the United States;

(c) Agreeing during those meetings, conversations, and communications to engage in customer and market allocation or bid rigging for Digoxin sold in the United States;

(d) Agreeing during those meetings, conversations, and communications not to compete against each other for certain customers for Digoxin sold in the United States;

(e) Submitting bids, withholding bids, and issuing price proposals in accordance with the agreements reached;

(f) Selling Digoxin in the United States at collusive and noncompetitive prices; and

(g) Accepting payment for Digoxin sold in the United States at collusive and noncompetitive prices.

94. To sustain a conspiracy, conspirators often communicate to ensure that all are adhering to the collective scheme. Here, such communications occurred primarily through (1) trade association meetings and conferences, (2) private meetings, dinners, and outings among smaller groups of employees of various generic drug manufacturers, and (3) individual private communications between and among Defendants' employees through use of the phone, electronic messaging and similar means.

95. These secret, conspiratorial meetings, discussions, and communications helped to ensure that all Defendants agreed to participate in, implement, and maintain an unlawful bid-rigging, price-fixing, and market and customer allocation scheme.

96. The industry intelligence-gathering reporting firm *Policy and Regulatory Report* has reportedly obtained information regarding the investigation of generic drug companies by the DOJ, and has indicated that the DOJ is investigating the extent to which trade associations and industry conferences have been used as forums for collusion among competing generic drug

companies.[35] The State AGs have similarly noted the centrality of trade associations and industry conferences in their investigation stating that they have uncovered evidence that certain generic drug companies "routinely coordinated their schemes through direct interaction with their competitors at industry trade shows, customer conferences, and other events, as well as through direct email, phone, and text message communications."[36]

97. Defendants were members of numerous trade associations, which they used to facilitate their conspiratorial communications and implement their anticompetitive scheme to raise, maintain, and stabilize the prices, rig bids, and allocate market and customers for Digoxin, including, but not limited to, GPhA, the NACDS, and HDMA. In addition, Defendants regularly attended industry events hosted by the MMCAP, NPF, and the ECRM.

98. The GPhA (now called the Association for Accessible Medicines) is the "nation's leading trade association for manufacturers and distributors of generic prescription drugs . . . ."[37] GPhA was formed in 2000 from the merger of three industry trade associations: the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

99. GPhA's website touts, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry" and lists its "valuable membership services, such as business networking opportunities, educational forums, access to lawmakers

---

[35] Eric Palmer, *Actavis gets subpoena as DOJ probe of generic pricing moves up food chain*, FIERCEPHARMA (Aug. 7, 2015), *available at* http://www.fiercepharma.com/story/actavis-gets-subpoena-doj-probe-generic-pricing-moves-food-chain/2015-08-07.

[36] CTAG Website, Press Release, *40 State Attorneys General Now Plaintiffs in Federal Generic Drug Antitrust Lawsuit* (Mar. 1, 2017), *available at* http://www.ct.gov/ag/cwp/view.asp?Q=588538&A=2341.

[37] GPhA, *Membership*, http://web.archive.org/web/20150413013008/http:/www.gphaonline.org:80/about/membership.

and regulators, and peer-to-peer connections."[38] GPhA's "member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year."

100. Defendants Impax, Mylan, Par, and West-Ward were regular members of the GPhA during the Class Period. Regular members "are corporations, partnerships or other legal entities whose primary United States business derives the majority of its revenues from sales of (1) finished dose drugs approved via ANDAs; (2) products sold as authorized generic drugs; (3) biosimilar/biogeneric products; or (4) DESI products."[39]

101. Several of Defendants' high-ranking corporate officers have served on GPhA's Board of Directors before and during the Class Period:

a. **2012 Board of Directors**: Tony Mauro, President of Mylan Inc.; and Carol Ben-Maimon, President, Impax Global Pharmaceuticals;

b. **2013 Board of Directors**: Tony Mauro, President of Mylan Inc.; and Carol Ben-Maimon, President, Impax Global Pharmaceuticals;

c. **2014 Board of Directors**: Carol Ben-Maimon, President, Impax Global Pharmaceuticals; and Tony Mauro, President of Mylan Inc.;

d. **2015 Board of Directors**: Marcy McDonald, VP Regulatory Affairs of Impax; Marcie McClintic Coates, VP & Head of Global Regulatory Affairs for Mylan; and Tony Pera, Chief Commercial Officer of Par;

e. **2016 Board of Directors**: Marcy McDonald, VP Regulatory Affairs of Impax; Heather Bresch, CEO of Mylan; Tony Pera, President of Par; and Jim Kedrowski.

[38] *Id.*

[39] *Id.*

102. In addition, former Heritage CEO, Jeffrey Glazer, who pleaded guilty to federal criminal charges relating to the price fixing and other anticompetitive activity concerning generic drugs, also served on GPhA's board of directors.

103. The NACDS is a national trade association representing chain community pharmacies. Its members include generic drug manufacturers, wholesalers, and retail chain pharmacies. NACDS holds regular industry events, including annual and regional conferences, which Defendants and other generic drug manufacturers attended, including the annual Total Store Expo.

104. The HDMA (now called HDA) is a national trade association that represents "primary pharmaceutical distributors" which links the nation's drug manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, and clinics.[40] HDMA holds regular conferences where its members, including generic drug manufacturers, meet to discuss various issues affecting the pharmaceutical industry. HDMA members during the Class Period have included Defendants Impax, Lannett, Mylan, Par, and West-Ward.

105. According to its website, MMCAP is a "free, voluntary group purchasing organization for government facilities that provide healthcare services. MMCAP has been delivering pharmacy and healthcare value to members since 1985. MMCAP's membership extends across nearly every state in the nation, delivering volume buying power. Members receive access to a full range of pharmaceuticals and other healthcare products and services; such as, medical supplies, influenza vaccine, dental supplies, drug testing, wholesaler invoice auditing and returned goods processing."

[40] HDA, About, *available at* https://www.healthcaredistribution.org/about.

106. MMCAP's Charter provides that "[i]n 1989, the Minnesota Department of Administration, an agency of the State of Minnesota, began a cooperative purchasing venture program to procure pharmaceutical products at the best price possible for the benefit of any other state interested in participating in the program . . . In 1996, the cooperative purchasing venture was named Minnesota Multistate Contracting Alliance for Pharmacy . . . and currently provide healthcare-related contracting to state and local government members located across the United State of America. Total purchasers by MMCAP member facilities for all MMCAP programs exceed $1 billion annually . . . ."

107. According to its website, ECRM conducts Efficient Program Planning Sessions that are made up of one-on-one strategic meetings that connect decision makers in an effort to maximize time, grow sales, and uncover industry trends.

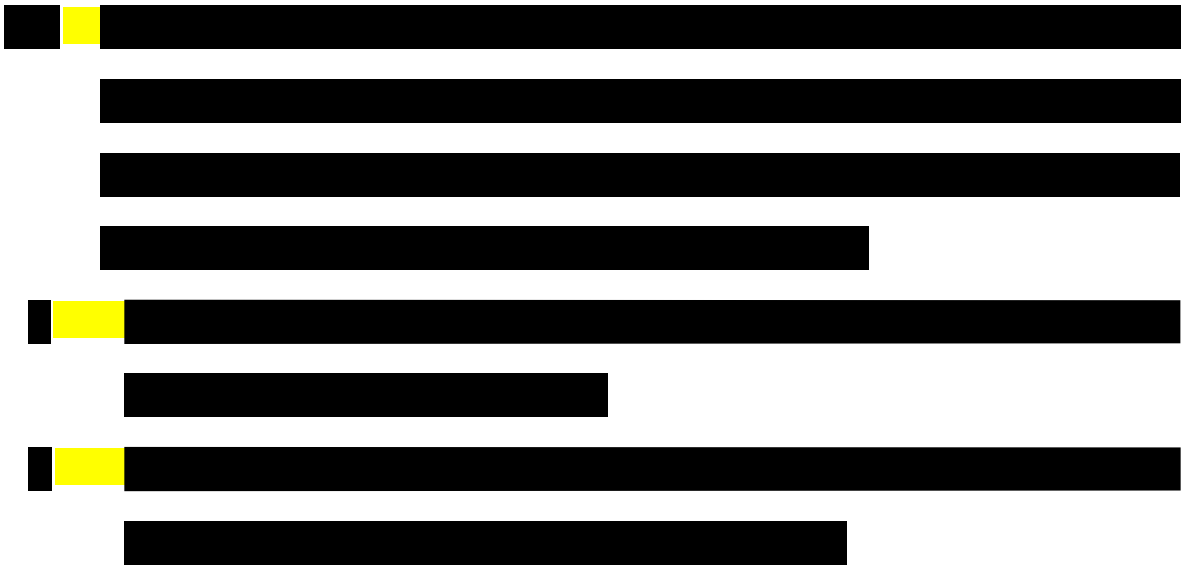
108. At annual meetings organized by ECRM, generic drug manufacturers have scheduled meetings with generic drug buyers at chain drug stores, supermarkets, mass merchants, wholesalers, distributors, and buy groups for independents.

[redacted]

110. As set forth below, meetings and events hosted by the GPhA, HDMA, NACDS, MMCAP, and ECRM were frequently held during the Class Period and attended by high-level representatives from each Defendant, including employees with price-setting authority.

111. For example, on October 1-3, 2012, GPhA held in Bethesda, Maryland that was attended by representatives from Defendants Impax, Lannett, Mylan, and Par.

112. On February 20-22, 2013, GPhA held a meeting in Orlando, Florida that was attended by representatives from Defendants Impax, Mylan, and Par.



114. On April 20-23, 2013 NACDS held its 2013 Annual Meeting at The Breakers in Palm Beach, Florida. NACDS's 2013 Annual Meeting was attended by at least the following representatives from Defendants, who were key executives for generic drug sales and pricing:

a. **Mylan**: Joe Duda, President, Mylan Pharmaceuticals; Robert Potter, SVP N.A. National Accounts and Channel Development; Tony Mauro, President of Mylan Inc. Jim Nesta, VP, Sales; and

b. **Par**: Jon Holden, VP Sales; Paul Campanelli, President; Michael Altamuro, VP Marketing & Business Analytics.

115. On June 2-5, 2013, HDMA held its 2013 Business Leadership Conference ("BLC") in Orlando, Florida. HDMA's June 2013 BLC was attended by the following representatives from all six Defendants, including at least the following key executives for generic drug sales and pricing:

a. **Impax:** Gary Skalski, Director of Sales; William Ball, Senior National Account Manager; Danny Darnell, Senior National Account Manager; Todd Engle, Senior Director, Sales Operations;

b. **Lannett:** Kevin Smith, VP, Sales & Marketing; Grace Wilks, Director, Sales & Marketing; Tracy Sullivan, Director of National Accounts;

c. **Mylan**: Janet Bell, National Accounts Director; Joseph Duda, President, Mylan Pharmaceuticals; Edgar Escoto, National Accounts Director; Kevin McElfresh, Executive Director, National Accounts; James Nesta, Executive Director, National Accounts; Robert O'Neill, VP; Sean Reilly, Key Account Manager; John Shane, Director National Trade Accounts; Gary Tighe, National Accounts Director; Lance Wyatt, National Accounts Director;

d. **Par**: Jon Holden, VP Sales; Sandra Bayer, National Accounts Manager; Peter Garguilo, Director, National Accounts; Christopher Neurohr, Director, National Accounts; and

e. **West-Ward**: Mark Boudreau, Executive Director of National Sales; Paul Kersten, VP, Sales & Marketing; Neal Gervais, National Account Director; John Kline, National Account Director; and Joseph Ruhmel, National Account Director.

116. On June 4-5, 2013, GPhA held a meeting in Bethesda, Maryland that was attended by representatives from at least Defendants Impax, Lannett, Mylan, and Par.

117. On August 10-13, 2013, NACDS held its 2013 Total Store Expo at the Sands Expo Convention Center in Las Vegas, Nevada. NACDS's August 2013 Total Store Expo was attended by representatives from all six Defendants, including at least the following key executives for generic drug sales and pricing:

a. **Impax**: Chris Gerber, Director of Pricing and Contracts; Italo Pennella, Account Manager; Dan Rozmiarek, Account Manager;

b. **Lannett**: Kevin Smith, VP, Sales & Marketing; Arthur Bedrosian, President & CEO; William Schreck, COO;

a. **Mylan**: Jim Nesta, VP, Sales; Mike Aigner, Director, National Accounts; Joe Duda, President, Mylan Pharmaceuticals; Kevin McElfresh, Executive Director, National Accounts; Robert O'Neill, Head of Sales, Generic NA; Robert Potter, SVP, National Accounts & Channel Development; Lance Wyatt, Director, National Accounts; Matt Cestra, Sr. Director Marketing; Rodney Emerson, Director, Pricing & Contracts; Edgar Escoto, Director National Accounts; Stephen Krinke, National Accounts Manager; Sean Reilly, National Accounts Manager;

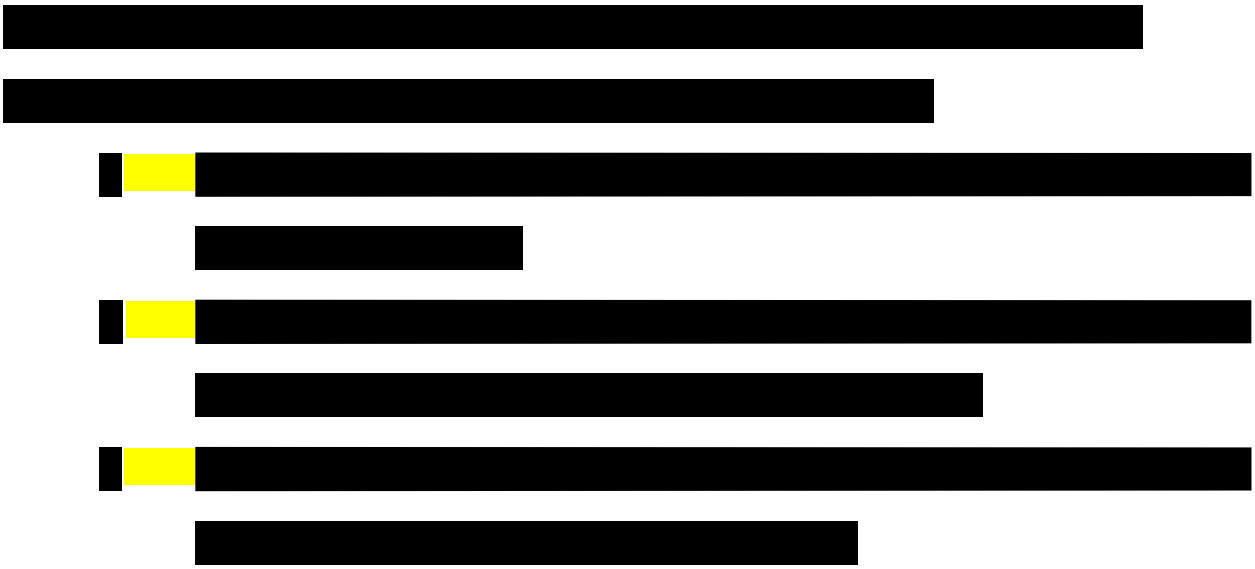
b. **Par**: Jon Holden, Vice President of Sales; Renee Kenney, Senior Advisor Generic Sales; Karen O'Connor, Vice President National Accounts; Michael Altamuro, VP Marketing and Business Analytics; Rick Guillory, VP National Account; Gerald Burton, VP, National Account; and

c. **West-Ward:** Spiro Gavaris, VP Sales & Marketing; Sam Goodman, Marketing Manager; Tareq Darwazeh, National Accounts Sr. Manager; Paul Markowitz, Director, National Accounts.

118. On October 28-30, 2013, GPhA held a meeting in Bethesda, Maryland that was attended by representatives from Defendants Impax, Mylan, Lannett, and Par.

119. On February 19-21, 2014, GPhA held its Annual Meeting in Orlando, Florida that was attended by representatives from Defendants Impax, Mylan, and Par.

[redacted]



121. On April 26-29, 2014, NACDS held its 2014 Annual Meeting in Scottsdale, Arizona. NACDS's 2014 Annual Meeting was attended by at least the following representatives from Defendants, who were key executives for generic drug sales and pricing:

a. **Mylan**: Joe Duda, President; Tony Mauro, President of Mylan Inc.; Robert Potter, Senior Vice President North America National Accounts and Channel Development; Rob O'Neill, Head of Sales; and

b. **Par**: Jon Holden, Vice President of Sales; Paul Campanelli, President; Renee Kenney, Senior Advisor Generic Sales.

122. On May 12-15, 2014, MMCAP held its National Member Conference in Bloomington, Minnesota. At MMCAP's 2014 National Member Conference, topics included "RFPs under consideration for Pharmacy," "contract evaluation," and "pharmaceutical price increases." At the MMCAP conference, a Heritage employee met in person and discussed price increase strategies with a number of different competitors and was able to personally confirm agreement to raise prices of at least one drug (Glyburide).

123. On May 12-15, 2014, MMCAP held its National Member Conference in Bloomington, Minnesota. At MMCAP's 2014 National Member Conference, topics included "RFPs under consideration for Pharmacy," "contract evaluation," and "pharmaceutical price increases."

124. MMCAP's May 12-15, 2014 National Member Conference was attended by the following representatives from Defendants, who were key executives for generic drug sales and pricing:

a. **Lannett:** Tracy Sullivan, Director National Accounts; and

b. **Mylan**: Jan Bell, National Accounts Director.

125. On June 1-4, 2014, the HDMA held a BLC at the JW Marriott Desert Ridge in Phoenix, Arizona. The June 1-4, 2014 BLC was attended by the following representatives from all six Defendants, including at least the following key executives for generic drug sales and pricing:

a. **Impax:** Gary Skalski, Senior Director of Sales; Danny Darnell, Senior National Accounts Manager; William Ball, Senior National Accounts Manager;

b. **Lannett:** Kevin Smith, SVP, Sales and Marketing; Grace Wilks, Director, Sales and Marketing; Tracy Sullivan, Director of National Accounts;

c. **Mylan**: Richard Issac, Senior Manager, Strategic Accounts; Lance Wyatt, Director, National Accounts; Joseph Duda, President, Mylan Pharmaceutical; Edgar Escoto, Director, National Account; James Nesta, VP, Sales;

d. **Par**: Peter Gargiulo, Director, National Accounts; Sandra Bayer, Senior National Account Executive; Karen O'Connor, VP National Accounts; and

e. **West-Ward:** Mark Boudreau, Executive Director of National Sales; John Kline, National Account Director; Joseph Ruhmel, National Account Director; and Steven Snyder, National Account Director.

126. On June 3-4, 2014, GPhA held a meeting in Bethesda, Maryland that was attended by representatives from Defendants Impax, Lannett, Mylan, and Par.

127. On August 23-26, 2014, NACDS held its 2014 Total Store Expo at the Boston Convention Center in Boston, Massachusetts. NACDS's August 2014 Total Store Expo was attended by the following representatives from all six Defendants, who were key executives for generic drug sales and pricing:

a. **Impax:** Chris Gerber, Director of Pricing and Contracts;

b. **Lannett:** Kevin Smith, VP Sales & Marketing; Tracy Sullivan, National Accounts Manager; Justin McManus, Director, National Accounts;

c. **Mylan**: Joe Duda, President, Mylan Pharmaceuticals; Robert Potter, Senior Vice President North America National Accounts; Mike Aigner, Director, National Accounts; Tony Mauro, President of Mylan Inc.; Kevin McElfresh, Executive Director, National Accounts; Gary Tighe, Director, National Accounts; Lance Wyatt, Director, National Accounts;

d. **Par**: Jon Holden, Vice President of Sales; Renee Kenney, Senior Advisor Generic Sales; Lori Minnihan, Manager, Pricing & Analytics; Warren Pefley, Director, National Accounts; Charles "Trey" Propst, Vice President, National Accounts; Michael Reiney, Vice President, Sales; Jeremy Tatum, Demand Manager; and

e. **West-Ward:** Spiro Gavaris, VP, Sales and Marketing; Sami Goodman, Marketing Manager; Joel Rosenstack, Senior Director, Marketing; Doug Statler, Sr. Director, Head of Sales.

128. On October 27-29, 2014, GPhA held a meeting in Bethesda, Maryland that was attended by representatives from each of the Defendants.

129. On February 9-11, 2015, the GPhA held its Annual Meeting in Miami Beach, Florida, which was attended by representatives from Defendants Impax, Mylan, Par, and West-Ward.

130. On February 16-18, 2015 the NPF took place at the Marriott Waterside Hotel & Marina in Tampa Florida.

131. At the February 2015 NPF, speaker topics included: "current pricing and spending trends"; "a critique of the rationale for high prices offered by manufacturers"; and "the U.S. pharmaceutical market and the ongoing changes within the pharmaceutical world," including "market trends."

132. The National Pharmacy Forum was attended by the following representatives from Defendants, who were key executives for generic drug sales and pricing:

a. **Mylan**: Lee Rosencrance, District Manager; Martin Wingerter, Director of National Accounts; Jan Bell, Director of National Accounts; Mark Pittenger: Sr. Director of National Accounts; and

b. **Westward**: Neal Gervais, National Account Director; Joseph Schrick, Director, National Accounts; and Mark Zampella. Director, National Accounts.

[redacted]

[redacted]

134. On April 25-28, 2015, NACDS held its 2015 annual meeting at The Breakers, Palm Beach, Florida. NACDS's 2015 annual meeting was attended by at least the following representatives from Defendants, who were key executives for generic drug sales and pricing:

a. **Mylan**: Jim Nesta, VP, Sales; Robert Potter, Senior Vice President North America National Accounts; Rob O'Neill, Head of Sales Generics, NA; Tony Mauro, President of Mylan Inc.;

b. **Par**: Michael Altamuro, Vice President Marketing and Business Analytics; Jon Holden, Vice President of Sales; Antonio Pera, Chief Commercial Officer; and

c. **West-Ward:** Spiro Gavaris, VP Sales and Marketing; Doug Statler, Senior Director/Head of Sales; Joel Rosenstack, Senior Director of Marketing.

135. Later in 2015, and 2016, Defendants continued to regularly attend trade association meetings, conferences and events, including: (i) the June 7-10, 2015 HDMA BLC in San Antonio, Texas; (ii) the June 9-10, 2015 GPhA meeting in Bethesda, Maryland; (iii) the August 22-25, 2015 NACDS Total Store Expo in Denver, Colorado; (iv) the November 2-4, 2015 GPhA meeting in Bethesda, Maryland; (v) the February 8-10, 2016 NPF meeting in Scottsdale, Arizona; (vi) the April 12, 2016 HDMA Eighth Annual CEO Roundtable Fundraiser in New York; (vii) the April 16-19, 2016, NACDS 2016 Annual Meeting in Palm Beach, Florida; (viii) the June 12-16, 2016 HDMA BLC in Colorado Springs, Colorado; and (ix) the August 6-9, 2016, NACDS 2016 Total Store Expo in Boston, Massachusetts.

136. As uncovered in the State AGs' ongoing investigation, at these various conferences and trade shows, representatives from Defendants, as well as other generic drug manufacturers, discussed their respective businesses and customers. These discussions would occur at social events, including lunches, cocktail parties, dinners, and golf outings, that usually accompanied these conferences and trade shows. Defendants' employees used these opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers.[41]

137. In conjunction with meetings at conferences and trade shows, representatives of generic drug manufacturers get together separately, in more limited groups, allowing them to further meet face-to-face with their competitors and discuss their business. In fact, high-level

[41] *See, e.g.*, Amended Complaint (Public Version), *Connecticut v. Aurobindo Pharma USA, Inc.*, No. 16-cv-2056, ECF 168 (D. Conn.), at ¶¶ 50-52, *available at* http://www.ct.gov/ag/lib/ag/press_releases/2016/20161215_gdms_complain.pdf.

executives of many generic drug manufacturers get together periodically for what at least some of them refer to as "industry dinners."[42]

138. A large number of generic drug manufacturers, including Defendants Impax, Lannett, Par, Mylan, and West-Ward, are headquartered or have major offices in close proximity to one another in New Jersey and eastern Pennsylvania, giving them easier and more frequent opportunities to meet and collude. For example, in January 2014, at a time when the prices of a number of generic drugs were reportedly soaring, at least thirteen high-ranking male executives, including CEOs, Presidents, and Senior Vice Presidents of various generic drug manufacturers, met at a steakhouse in Bridgewater, New Jersey.

139. Generic drug manufacturer employees also get together regularly for what is referred to as a "Girls' Night Out" ("GNO"), or alternatively "Women in the Industry" meetings and dinners. During these GNOs, meetings and dinners, these employees meet with their competitors and discuss competitively sensitive information. For example, several different GNOs were held in 2015, including: (1) in Baltimore, Maryland in May, and (2) at the NACDS conference in August.

140. Through these various interactions, Defendants' employees are often acutely aware of their competition and, more importantly, each other's current and future business plans. This familiarity and opportunity often leads to agreements among competitors to fix prices or to allocate a given market so as to avoid competing with one another on price.

141. Defendants also routinely communicate and share information with each other about bids and pricing strategy. This can include forwarding bid packages received from a customer (*e.g.*, a Request for Proposal or "RFP") to a competitor, either on their own initiative,

[42] *Id.* at ¶¶ 53-60.

at the request of a competitor, or by contacting a competitor to request that the competitor share that type of information.

142. Additionally, Defendants share information regarding the terms of their contracts with customers, including various terms relating to pricing, price protection, and rebates. Defendants use this information from their competitors to negotiate potentially better prices or terms with their customers, which could be to the ultimate detriment of consumers.

1. Investor communications demonstrate Defendants' intent to fix and maintain supracompetitive prices.

143. Defendants' public statements and admissions in their investor communications show that Defendants realized record revenues during the Class Period and emphasize a commitment to increasing generic pharmaceutical prices as well as maintaining them at supracompetitive levels.

144. **Lannett:** According to Lannett's 2014 annual report, Digoxin accounted for 20% of Lannett's fiscal 2014 net sales and 8% of Lannett's 2013 fiscal net sales.

145. On September 10, 2013, Lannett's CEO, Arthur P. Bedrosian, stated in an earnings call that:

> We're not a price follower. We tend to be a price leader on price increasing and the credit goes to my sales vice president. He takes an aggressive stance towards raising prices. He understands one of his goals, his objectives as a sales vice president is to increase profit margins for the company. And he's the first step in that process. I can reduce costs and manufacturing efficiencies, but it has to be combined with sales increase, a profit increase, as I should say, by the salespeople. And he's done a good job there. With 1 or 2 exceptions, we've tended to lead in the way of price increases. We believe that these prices are important. We need to try raising them. Sometimes, it doesn't stick and we have to go back and reduce our price, and other times it does. I am finding a climate out there has changed dramatically and I see more price increases coming from our competing – competitors than I've seen in the past. And we're going to continue to lead. We have more price increases planned

> for this year within our budget. And hopefully, our competitors follow suit. If they don't, that's their issue. But our plan is to raise prices on any product that we think we can or we haven't raised a price.

146. During the same call, Bedrosian further described his expectation that other generics would also raise prices. After citing costs applicable to all generic firms, he stated that "I would expect that all the companies are not going to behave like they have in the past. And I suspect you're going to see more price increases in the generic marketplace or certainly less price erosion in the marketplace because of that."

147. In addition Bedrosian noted, "I'm always grateful to see responsible generic drug companies realize that our cost of doing business is going up as well . . . [s]o whenever people start acting responsibly and raise prices as opposed to the typical spiral down of generic drug prices, I'm grateful. Because Lannett tends to be active in raising prices. We believe we have to sell our products for a price that we can make profit. . . . So I'm grateful to see price increases."

148. In a subsequent earnings call, Bedrosian reported that Lannett's chief competitor had indeed heeded its price increase signal. On November 7, 2013 – after the initial generic Digoxin price increases – Bedrosian noted, referring to Impax, that "[w]e've had a recent price increase on the [generic Digoxin] product as well because we are now only 1 of 2 people in the market. And as a result, I expect that product to do very well."

149. In the same earnings call, Bedrosian was confident enough that its price increases would hold to increase Lannett's next quarter guidance stating, "[t]he primary drivers for our outstanding first quarter performance was a combination of strong sales of existing products, a favorable product mix and price increases on key products. I'm pleased to report that we believe these positive trends will continue throughout fiscal 2014. Accordingly, we have raised our guidance for fiscal 2014."

150. Bedrosian also reiterated Lannett's "[i]ncrease in the guidance, probably a significant portion is the price increases that we've talked about previously that have now really hit us in a beneficial way." Bedrosian indicated that he believed Lannett's growth margin was sustainable, notwithstanding the fact that they are in a commodity market, reflecting confidence that his competitors were committed to the conspiracy and would hold to their higher prices, "I would believe they are sustainable because we're not expecting any changes that we anticipate at this point. But we're in the commodity business, so it's always hard to determine point when you're going to get additional competition or when prices will erode as they generally do." Bedrosian also indicated that the price increases were industry-wide and that he believed all generic companies would continue to adhere to higher prices: "So these price increases that are going on in the industry, I think they're going to stick for all the companies."

151. In a February 6, 2014 earnings call, Bedrosian reported that he was not troubled by Par's pricing in after Par launched generic Digoxin and that he viewed Par to be "one of our rational competitors in the marketplace." Lannett's sales reported in February 2014 were the best in the company's history, and Lannett was able to increase its profit guidance on the strength of the price increases. As predicted in November 2013, Bedrosian reported that these record sales were driven by "price increases on key products, strong sales of existing products and a favorable product mix." Lannett's stellar performance is not reflective of a company that took price increases that were forced by rising costs, but instead is reflective of a company that was enjoying the fruits of supracompetitive prices and stifling of competition. On the same call, Lannett's CFO Martin P. Galvan also mentioned that prices were increasing across many different generic products: "But . . . I must say that we have been able to increase prices on more

than just those two products and it's the portfolio of products and their price increases which is driving that gross margin you see."

152. On the same February 6, 2014 earnings call, with respect to Digoxin, Bedrosian alerted the other generic suppliers that Lannett stood ready to increase prices again because there was a potential for a market disruption that "certainly could equate to a price increase for us. So I would just say stay tuned. But we're also looking to capture more market share on the Digoxin. This is an important product for us." Bedrosian then immediately offered a warning to other generic manufacturers that they would be prepared to discipline them, "We don't want to sit by and just let our competition take away our market share." As to the recent entrant, Par, whom he had noted was "a rational competitor", he did not fear it would discount to Lannett's pricing: "Well, discounting to our price, no. We've seen their prices discounted to the brand, of course, but we're not troubled by their pricing in the marketplace. Not at all."

153. In a quarterly earnings call held on November 3, 2014, Bedrosian again expressed confidence that Lannett would not have to engage in price competition generally for it generics. He said Lannett and its competitors were "less concerned about grabbing market share. We're all interested in making a profit, not how many units we sell." Bedrosian went on to discuss, *inter alia*, Par and Impax, saying that "the companies we're looking at here are not irrational players. I don't see them just going out and trying to grab market share." He also noted that Mylan was expected to enter the market, "but Mylan is one of those rational competitors, so we're not really expecting anything crazy from them." He predicted that price increases would continue.

154. Bedrosian stated in a February 4, 2015 earnings call, in response to a question regarding the sustainability of pricing, that,

> So I'm expecting these pricings to really sustain themselves to continue. I see people raising prices further, because the generic prices were so low, when you're 10% of the brand, that's not because the brand overpriced the product by 90%. It's because the generic marketplace has so much competition sometimes, people get desperate just to unload their inventory that they cut the prices.
>
> We don't see that kind of behavior sustainable, and we don't see it going further into the future. I think you're going to find more capital pricing, more – I'll say less competition, in a sense. You won't have price wars. You are still going to have competition, because there's a lot of generic companies in the market.
>
> I just don't see the prices eroding like they did in the past. It's really unfortunate, but what they see some significant pricing, cost increases, I should say, that are driving this.

155. A May 2015 presentation by Bedrosian and Lannett's CFO noted that one of Lannett's strengths was a "track record of selecting products with high profit potential and manageable competition."[43]

156. Lannett reported rising revenues in its United States generics business during the Class Period.

157. **Impax:** On November 4, 2013, the then-President of Impax, Carole Ben-Maimon, acknowledged in an earnings call that Impax had increased the price of Digoxin after Lannett had increased its price, after noting its medical necessity to patients. In response to a question concerning Impax's "huge price increase on digoxin following Lannett's pricing action," Ben-Maimon stated: "The price increase on dig[oxin] speaks for itself, but clearly, as a medically necessary drug, our focus there is really just to make sure that a high quality product is available to the customer." Ben-Maimon's comments make clear that Impax had no intention of competing for market share for Digoxin by offering lower prices; it simply would ensure there was sufficient supply, at its newly increased pricing for its customers. During the same call,

[43] Lannett PowerPoint Presentation, at 7 (May 2015).

Impax's CFO Bryan Reasons stated that Impax "did take some nice pricing moves" on generic products and Ben-Maimon stated that it was important generally to "recogniz[e] the potential for price."

158. Ben-Maimon demonstrated Impax's continued acceptance of Lannett's invitation to increase prices and noted Impax's commitment to maintaining price increases during a February 20, 2014 earnings call with analysts. Ben-Maimon stated regarding Digoxin, "the market has been pretty stable . . . [w]e're pretty comfortable that what we have done is rational and will result in ongoing profitability for that product." Ben-Maimon also stated:

> Obviously, we can't really talk about, for competitive reasons, about specific products with specific prices. But as you've seen across the industry, pricing has improved and the ability to take some price increases has clearly been available. Obviously, we're really careful and we want to make sure that we do that in a very rational way so that we make sure that the price -- that what we're doing sticks and that we actually do make more money in the long run. But we're pretty confident that what we did through towards the end -- throughout the end of last year and the beginning of this year will result in more profitability from many other products that we have been able to take some price on.

159. On a May 2, 2014 Impax earnings call, Reasons noted that a "strong quarter in the generic division" was driven in part by "some pricing initiatives."

160. On an August 6, 2014 Impax earnings call, Ben-Maimon again spoke about pricing:

> Yes. So of course, we look at any opportunity to raise price when it's appropriate. I can't say that -- we didn't talk specifically about specific products here, but we look at our portfolio regularly, if not every single day and look for opportunities in the marketplace to take advantage of services or increased share or price.

Later during the same call, Ben-Maimon mentioned that: "So on pricing, obviously, we don't comment on specific products or what's going on in the market. There are opportunities and we continue to evaluate our portfolio and take advantage where we can."

161. On a November 4, 2014 Impax earnings call, Impax's CEO Frederick Wilkinson, continued to echo Lannett's message on increasing prices:

> [L]et me address pricing. We really don't talk much about pricing publicly, and whether we're going for competitive reasons but surprising to say we've done what most of the other generic competitors have done, we look at opportunities, we look at how competition shifts, we look at where there may be some market movement that will allow us to take advantages on price increases and we've implemented those and we'll continue to evaluate our line product-by-product probably a week and monthly basis to see if there are some opportunities to participate in that practice.

Wilkinson also acknowledged the federal investigation of pricing in the pharmaceutical industry during that earnings call.

162. Impax reported rising revenues in its United States generics business during the Class Period.

163. **Mylan**: On October 25, 2012, Mylan's CEO Heather Bresch stated in an earnings call: "You've heard me quarter after quarter coming and saying we weren't going to chase the bottom, that there's been irrational behavior and that we would continue to hold steady and control what we can control."

164. On February 27, 2013, Mylan's CFO, John Sheehan, stated in an earnings call:

> 2013 will yet be another strong year for Mylan. In the U.S., we are anticipating a high volume of new product launches, and we expect to once again be agile enough to quickly seize new supply opportunities when they become available. In addition, favorable changes to the regulatory environment, including increased resources to expedite product reviews and greater oversight with respect to manufacturing, as well as an anticipated more stable pricing environment resulting in part from continued consolidation

> within the industry, are just two of the favorable macroeconomic factors that we see in 2013.

165. On May 2, 2013, Bresch stated in an earnings call: "From my perspective, we see the generic industry alive and well. We still see a lot of runway room here in the United States."

166. On May 1, 2014, Bresch stated in an earnings call: "We continue to see stability really across our entire generic line on pricing."

167. On August 7, 2014, Bresch stated in an earnings call:

> As far as pricing, look, I think that, that stability in our North American – that core business is certainly why we're able to deliver the results we have today, which, like I said, despite those product delays, we see growth year-over-year. We've seen North America continue to maximize opportunities.

168. On October 30, 2015, Sheehan stated in an earnings call:

> With respect to gross margin, I guess I would start by pointing out that since 2010 our gross margins have increased from 45% up to the high end of the guidance range that we indicated we would be at this year of 55%. So the gross margins have been sustained. They have steadily increased over the last five, six years. . . . It also has been driven by the positive pricing environment that we've seen, especially over the last couple of years in North America.

169. During the same call, Bresch stated: "Look, I would say as far as price increases, we've had a very consistent approach. We have absolutely had opportunities around generic pricing."

170. On February 10, 2016, Bresch stated in an earnings call her belief that Mylan had been "a very responsible generic player with hundreds of products into the market and have shown very responsibly price erosion."

171. Mylan reported rising revenues in its United States generics business during the Class Period.

172. **Par:** During Endo's May 1, 2014 earnings call, Endo CEO Rajiv De Silva stated that Endo's generics business (Par) was performing strongly in part because "we have been able to take advantage of some pricing opportunities."

173. On July 31, 2014, Endo's CEO Rajiv De Silva stated in an earnings call that in the generics business "there are certain specific situations and market opportunities which we take advantage of, as do our competitors."

174. On March 2, 2015, Silva stated in an earnings call that "pricing actions give us some gross margin benefit."

175. In a May 18, 2015 presentation by Endo International plc concerning its acquisition of Par, Endo noted that "consolidation and maturation of competitors have stabilized the pricing environment" for generic pharmaceuticals in the U.S.

176. On an August 8, 2016 earnings call, Par's President Paul Campanelli stated in response to a question about the generics environment: "And typically you want to just be very careful about trying to go after too much share. You just have got to take a balanced approach."

177. Par reported rising revenues in its United States generics business during the Class Period.

178. **West-Ward:** In 2013, Hikma, parent company to West-Ward, reported "[s]trong cash flow."[44]

179. On March 12, 2014, Hikma announced strong revenue growth and forecasted continued growth in 2014. Said Darwazah, Hikma's CEO was "confident about the prospects for

[44] Hikma Pharmaceuticals Preliminary Results (2013).

2014," and noted that in 2013, "[o]ur Generics business delivered very strong revenue . . . and generated significant cash flow."[45]

180. In Hikma's Q2 2014 earnings call, Hikma's CFO stated: "I don't know how many of you have covered U.S. generic companies. But when I look at competitors, I look at the -- most companies that are either U.S. based or have a strong position in the U.S. are doing very well the last few years. So the market forces are changing, I believe, in the market."

181. In December 2013, Darwazah told Bloomberg Business that some of West-Ward's huge increases prices were justified because it was "'forced' to raise prices because its competitors raised theirs."[46] This assertion only confirms Bedrosian's statement that his generic drug competitors were no longer interested in competing on price.

182. West-Ward reported rising revenues in its United States generics business during the Class Period.

1. Industry commentary indicates defendants' collusion is a plausible explanation for the increase in Digoxin price

183. Comments from industry analysts suggest that collusion is a plausible explanation for the increase in Digoxin, and other generic pharmaceutical, prices. For instance, Richard Evans at Sector & Sovereign Research wrote:

> A plausible explanation [for price increases] is that generic manufacturers, having fallen to near historic low levels of financial performance are cooperating to raise the prices of products whose

[45] Press Release, Hikma Pharmaceuticals plc, *Hikma anticipated potentially reduced doxycycline revenue in the U.S. market in 2014 due to increased competition* (Mar. 12, 2014).

[46] Alan Katz, *Surprise! Generic Drug Prices Spike*, Bloomberg (Dec. 12, 2013), *available at* https://www.bloomberg.com/news/articles/2013-12-12/generic-drug-prices-spike-in-pharmaceutical-market-surprise.

> characteristics – low sales due to either very low prices or very low volumes – accommodate price inflation.[47]

184. According to one study, since 2013 approximately one in 19 generic drugs sold in the United States have undergone major price hikes that may be consistent with collusion:

> Fideres Partners LLP, a London-based consultancy that works with law firms to bring litigation against companies, reported "anomalous pricing patterns" in scores of generic drugs sold in the U.S. from 2013 to 2016. It identified 90 medicines whose prices rose at least 250 percent over the three-year period and were increased by at least two drug companies around the same time, even though there was no obvious market reason for the increases. The average price jump among the 90 drugs was 1,350 percent, Fideres found.
>
> "I don't think the public or even the politicians in the U.S. have any idea just how widespread and extreme the phenomenon is," said Alberto Thomas, one of Fideres's founders.[48]

185. Another study concluded that in 2014: "292 generic medication listings went up by 10% or more, 109 at least doubled in price and 14 went up by ten or more times in price that year."[49] The GAO Report also noted similar "extraordinary price increases" across many generic drugs in recent years that could not be linked to any particular cause.

186. Pennsylvania physicians through the Pennsylvania Medical Society called on state and federal governments to investigate surging generic prices, believing anticompetitive conduct was to blame:

---

[47] *See* Ed Silverman, *Generic Drug Prices Keep Rising, but is a Slowdown Coming?*, WALL STREET JOURNAL (Apr. 22, 2015), *available at* http://blogs.wsj.com/pharmalot/2015/04/22/generic-drug-prices-keep-rising-but-is-a-slowdown-coming/.

[48] Liam Vaughan and Jered S. Hopkins, *Mylan, Teva Led Peers in "Anomalous" Price Moves, Study Says*, BLOOMBERG (Dec. 22, 2016) *available at* https://www.bloomberg.com/news/articles/2016-12-22/widespread-drug-price-increases-point-to-collusion-study-finds.

[49] David Belk, MD, *Generic Medication Prices, available at* http://truecostofhealthcare.net/generic_medication_prices/.

> According to Robert Campbell MD, chair of Physicians Against Drug Shortages and immediate past president of the Pennsylvania Society of Anesthesiologists, surging prices have hit hundreds of mainstay generics, including anesthetics, chemotherapeutic agents, antibiotics, and nutritional intravenous solutions. He believes the surging prices are a result of anti-competitive behavior.[50]

D. Defendants' Conduct in Generic Drug Pricing Is Under Investigation by the United States Congress, the DOJ, and the State Attorneys General.

1. Congress launched an investigation in response to news reports of a dramatic rise in price of certain generic drugs.

187. As noted above, in January 2014 the NCPA sent correspondence to the United States Senate HELP Committee and the United States House Energy and Commerce Committee requesting hearings on significant spikes in generic pharmaceutical pricing.

188. On October 2, 2014, Senator Bernie Sanders (I-VT), Chair of the Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, and Representative Elijah E. Cummings (D-MD), the Ranking Member of the House Committee on Oversight and Government Reform, sent letters to 14 drug manufacturers requesting information about the escalating prices of generic drugs used to treat everything from common medical conditions to life-threatening illnesses.[51]

189. Senator Sanders and Representative Cummings issued a joint press release, advising "[w]e are conducting an investigation into the recent staggering price increases for generic drugs used to treat everything from common medical conditions to life-threatening

---

[50] Pennsylvania Medical Society, Press Release, *Rising Generic Drug Costs Have Physicians Raising Red Flags* (Feb. 5, 2016), *available at* http://www.prnewswire.com/news-releases/rising-generic-drug-costs-have-physicians-raising-red-flags-300216006.html.

[51] U.S. Senator Bernie Sanders Website, Press Release, *Congress Investigating Why Generic Drug Prices Are Skyrocketing* (Oct. 2, 2014), *available at* https://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.

illnesses." They noted the "huge upswings in generic drug prices that are hurting patients" are having a "'very significant'" impact threatening pharmacists' ability to remain in business.[52]

190. The October Letter to Lannett, for example, states,

> We are writing to your company to request information about the escalating prices it has been charging for two drugs: Digoxin and Doxycycline Hyclate, which are used to treat certain types of irregular heartbeats and heart failure, and to treat a variety of infections, respectively. . . . [a]ccording to data provided by the [Healthcare Supply Chain Association], the average price charged for Digoxin has increased by as much as 884 percent from October 2012 to June 2014.[53]

191. In Lannett's October Letter [or appropriate defendant], Senator Sanders and Representative Cummings requested the following information and documents from January 1, 2012, to the present:

(1) Total gross revenues from the company's sales of these drugs;

(2) The dates, quantities, purchasers, and prices paid for all sales of these drugs;

(3) Total expenses relating to the sales of these drugs, as well as the specific amounts for manufacturing, marketing and advertising, and purchases of active pharmaceutical ingredients, if applicable;

(4) Sales contracts or purchase agreements for active pharmaceutical ingredients for these drugs, including any agreements relating to exclusivity, if applicable;

(5) A description and valuation of the specific financial and non-financial factors that contributed to your company's decisions to increase the prices of these drugs;

(6) Any cost estimates, profit projections, or other analyses relating to the company's current and future sales of these drugs;

(7) Prices of these drugs in all foreign countries or markets, including price information for the countries paying the highest and lowest prices; and

---

[52] *Id.*

[53] *See* Letter from Bernie Sanders, United States Senator, and Elijah Cummings, United States Representative, to Arthur Bedrosian, President and CEO of Lannett, *available at* https://www.sanders.senate.gov/download/letter-to-mr-bedrosian-president-and-ceo-lannett-company-inc?inline=file.

(8) The identity of company official(s) responsible for setting the prices of these drugs over the above time period.

192. Lannett's letter provided that the requested information and documents be turned in to congressional offices by October 23, 2014.

193. On February 24, 2015, Senator Sanders and Representative Cummings sent a letter requesting that the Office of the Inspector General ("OIG") of the Department of Health and Human Services "examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and Medicaid programs."[54] The OIG responded to the request on April 13, 2015, advising it would examine pricing for the top 200 generic drugs to "determine the extent to which the quarterly [Average Manufacturer Pricing] exceeded the specified inflation factor."[55]

194. In August 2016, the United States GAO issued its report finding "extraordinary price increases" on many generic pharmaceuticals including Digoxin.[56]

2. The DOJ launched a broad criminal investigation into anticompetitive conduct by generic drug manufacturers.

195. The DOJ opened a criminal investigation into collusion in the generic pharmaceutical industry on or around November 3, 2014. The DOJ also empaneled a grand jury in this District at about the same time.

---

[54] Letter from Sen. Bernard Sanders & Rep. Elijah E. Cummings, U.S. Cong., to Inspector Gen. Daniel R. Levinson, Dep't of Health & Human Servs. (Feb. 24, 2015), *available at* http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file.

[55] Letter from Inspector Gen. Daniel R. Levinson, Dep't of Health & Human Servs., to Sen. Bernard Sanders (Apr. 13, 2015), *available at* http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file.

[56] GAO Report to Congressional Requesters, *Generic Drugs Under Medicare* (Aug. 2016), *available at* http://www.gao.gov/assets/680/ 679055.pdf.

196. Initial reports suggest that, at the beginning, the DOJ's probe was focused on two generic drugs: Digoxin and doxycycline. However, news reports, court filings, and other public statements have confirmed the sweeping nature of the DOJ's investigation. Reportedly, the DOJ believes price-fixing between makers of generic pharmaceuticals is widespread, and its investigation could become the next auto parts investigation, which is the DOJ's largest prosecution to date.[57] According to sources cited by Bloomberg, the DOJ investigation already "spans more than a dozen companies and about two dozen drugs."[58]

197. **Impax**: In its July 15, 2014 SEC filing, Impax disclosed that it received a subpoena from the CTAG concerning Impax's sales of Digoxin and whether it agreed with others to fix prices or allocate customers or territories.[59] In November 2014, Impax further disclosed that one of its sale representatives received a federal grand jury subpoena, requesting testimony and documents about "any communication or correspondence with any competitor (or an employee of any employer) about the sale of generic drugs."[60] The scope of the subpoenas was not limited to a particular drug or a particular timeframe.

198. Impax later disclosed that on March 13, 2015, "the Company received a grand jury subpoena from the Justice Department requesting the production of information and documents regarding the sales, marketing, and pricing of certain generic prescription medications. In particular, the Justice Department's investigation currently focuses on four

---

[57] Joshua Sisco, *DoJ believes collusion over generic drug prices widespread—source*, POLICY AND REGULATORY REPORT (June 26, 2015), available at http://www.mergermarket.com/pdf/DoJ-Collusion-Generic-Drug-Prices-2015.pdf.

[58] David McLaughlin and Caroline Chen, *U.S. Charges in Generic Drug Probe to be Filed by Year-End*, BLOOMBERG (Nov. 3, 2016), *available at* https://www.bloomberg.com/news/articles/2016-11-03/u-s-charges-in-generic-drug-probe-said-to-be-filed-by-year-end.

[59] Impax SEC Form 8-K (July 15, 2014).

[60] Impax SEC Form 8-K (Nov. 6, 2014).

generic medications: Digoxin, terbutaline sulfate tablets, prilocaine/lidocaine cream, and calcipotriene topical solution."[61]

199. **Lannett**: Lannett issued a press release on July 16, 2014, that it received a subpoena from the CTAG in connection with its investigation into whether "anyone engaged in a contract, combination or conspiracy in restraint of trade or commerce which has the effect of (i) fixing, maintaining or controlling prices of Digoxin or (ii) allocating and dividing customers or territories relating to the sale of Digoxin in violation of Connecticut antitrust law."[62] In a quarterly report Lannett disclosed that on November 3, 2014, its "Senior Vice President of Sales and Marketing of the Company was served with a grand jury subpoena relating to a federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act."[63] Lannett reported: "The subpoena requests corporate documents of the Company relating to communications or correspondence with competitors regarding the sale of generic prescription medications, but is not specifically directed to any particular product and is not limited to any particular time period."[64]

200. **Mylan**: Mylan disclosed in a 2016 filing with the United States Securities and Exchange Commission (SEC) that it received a DOJ subpoena "seeking information relating to the marketing, pricing, and sale of our generic Doxycycline products and any communications with competitors about such products."[65] Mylan received a similar subpoena from the CTAG, seeking "information relating to the marketing, pricing and sale of certain of the Company's

---

[61] Impax, SEC 2015 Form 10-K (Feb. 22, 2016), at F-53.

[62] Lannett Website, Press Release, *Lannett Receives Inquiry from Connecticut Attorney General* (July 16, 2014), *available at* http://lannett.investorroom.com/2014-07-16-Lannett-Receives-Inquiry-From-Connecticut-Attorney-General.

[63] Lannett, SEC Form 10-Q (Nov. 6, 2014) at 16.

[64] *Id.*

[65] Mylan, SEC 2015 Form 10-K (Feb. 16, 2016), at 160.

generic products (including Doxycycline) and communications with competitors about such products."[66]

201. Subsequently, on November 9, 2016, Mylan disclosed in its quarterly report that both it and "certain employees and senior management, received subpoenas from the DOJ seeking additional information relating to the marketing, pricing and sale of our generic Cidofovir, Glipizide-metformin, Propranolol and Verapamil products and any communications with competitors about such products."[67] Significantly, Mylan disclosed that "[r]elated search warrants also were executed" in connection with DOJ's investigation.[68]

202. **Par**: Par disclosed in an SEC Form 10-K for 2014 that it received a subpoena from the CTAG on August 6, 2014, requesting documents related to Digoxin and that it had completed its response on October 28, 2014.[69] Par subsequently received a DOJ subpoena on December 5, 2014, "requesting documents related to communications with competitors regarding [its] authorized generic version of Covis's Lanoxin® (Digoxin) oral tablets and [its] generic doxycycline products."[70] In December 2015, Endo Pharmaceuticals Inc. (Par's parent company) disclosed that it "received Interrogatories and Subpoena Duces Tecum from the [CTAG] requesting information regarding pricing of certain of its generic products, including doxycycline hyclate, amitriptyline hydrochloride, doxazosin mesylate, methotrexate sodium and oxybutynin chloride."

---

[66] *Id.*

[67] Mylan SEC Form 10-Q (Nov. 9, 2016), at 58.

[68] *Id.*

[69] Par Pharmaceuticals Companies, Inc., SEC 2014 Form 10-K (Mar. 12, 2015).

[70] *Id.*

203. Defendants are not alone. Numerous other generic manufacturers have likewise received subpoenas in connection with the DOJ and the State AG's broad investigations into anticompetitive conduct in the generic drug industry. Additionally, some of these generic manufacturers have disclosed that search warrants have been executed or that certain employees have been separately subpoenaed as part of these ongoing probes.

204. The fact that these companies received subpoenas from a federal grand jury is significant, as is reflected in Chapter 3 of the 2014 edition of the DOJ's Antitrust Division Manual. Section F.1 of that chapter notes that when deciding whether to request the initiation of a grand jury investigation "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution."[71] The staff request needs to be approved by the relevant field chief and is then sent to the Antitrust Criminal Enforcement Division.[72] "The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation."[73] "The investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred."[74]

---

[71] DOJ, ANTITRUST DIVISION MANUAL (5th ed. 2015) at III-82.

[72] *Id.*

[73] *Id.* at III-83.

[74] *Id.*

205. Receipt of federal grand jury subpoenas is an indication that antitrust offenses have occurred.

206. That a target has reportedly applied for leniency is also significant.[75] As the DOJ notes on its web site (http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program):

> **5. Does a leniency applicant have to admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter?**
>
> Yes. The Division's leniency policies were established for corporations and individuals "reporting their illegal antitrust activity," and the policies protect leniency recipients from criminal conviction. Thus, the applicant must admit its participation in a criminal antitrust violation involving price fixing, bid rigging, capacity restriction, or allocation of markets, customers, or sales or production volumes, before it will receive a conditional leniency letter. Applicants that have not engaged in criminal violations of the antitrust laws have no need to receive leniency protection from a criminal violation and will not qualify for leniency through the Leniency Program.

The DOJ further provides that the leniency applicant must also satisfy the following condition, among others, to avail itself of the government's leniency: "[t]he confession of wrongdoing is truly a corporate act, as opposed to isolated confessions of individual executives or officials." *Id*.

207. The DOJ's first charges were made on December 12, 2016, against two generic industry executives (Glazer and Malek) with criminal counts related to price collusion for generic doxycycline hyclate and glyburide. *See United States of America v. Jeffrey A. Glazer*,

[75] Leah Nylen and Josh Sisco, *Generic drug investigation started small before ballooning to dozen companies*, MLEX (Nov. 4, 2016) ("While the Justice Department didn't have a whistleblower at the beginning of the investigation, it is understood that [in the summer of 2016] a company applied for leniency, which grants full immunity to the first company to come forward and admit to cartel violations."), *available at* http://www.mlex.com/GlobalAntitrust/DetailView.aspx?cid=841053&siteid=191&rdir=1.

No. 2:16-cr-00506-RBS (E.D. Pa.); *United States of America v. Jason T. Malek*, No. 2:16-cr-00508-RBS (E.D. Pa.).

208. These cases allege that these former senior executives of generic drug maker Heritage Pharmaceuticals Inc. violated Section 1 of the Sherman Act by participating in conspiracies to fix prices, rig bids and engage in market and customer allocation for generic glyburide and doxycycline. On January 9, 2017, both Glazer and Malek pleaded guilty to the charges. The DOJ charges mention that Glazer and Malek's co-conspirators included "individuals that [Glazer] supervised at his company and those he reported to at his company's parent[.]"[76] Sentencing for both Glazer and Malek was originally set for April 2017 but was later rescheduled to September 2017 as they continue to cooperate with the DOJ. Evidence reportedly unearthed in the State AGs' action shows that Malek compiled a large list of generic drugs and instructed employees to contact competitors to reach agreement to increase prices and engage in market and customer allocation, and that some competitors were willing to reach such agreement.

209. The DOJ has intervened in MDL 2724 as well as numerous civil antitrust actions alleging price-fixing, bid rigging, and market and customer allocation of generic pharmaceuticals stating that these cases overlap with the DOJ's ongoing criminal investigation. For example, in a civil antitrust action related to the generic pharmaceutical propranolol, the DOJ intervened and requested a stay, stating that "the reason for the request for the stay is the government's ongoing criminal investigation and overlap of that investigation and this case," and that "the government's ongoing investigation is much broader than the [Glazer and Malek] informations

[76] Transcript of Jan. 9, 2017 Plea Hearing, *United States of America v. Jeffrey A. Glazer*, No. 2:16-cr-00506-RBS, ECF 24 at 19 (E.D. Pa.). A similar statement appears in the transcript from Malek's plea hearing.

that were unsealed."[77] The DOJ filed a brief with the United States Judicial Panel on Multidistrict Litigation noting that, "The complaints in those civil cases – which typically allege that a group of generic pharmaceutical companies violated Section 1 of the Sherman Act by conspiring to fix prices and allocate customers for a particular drug – overlap significantly with aspects of the ongoing criminal investigation."[78] As noted above, the DOJ also filed a motion for a stay of discovery in MDL 2724 stating that: "Evidence uncovered during the criminal investigation implicates other companies and individuals (including a significant number of the Defendants here) in collusion with respect to doxycycline hyclate, glyburide, and other drugs (including a significant number of the drugs at issue here)."[79]

210. The DOJ's Spring 2017 Division Update notes that:

> Millions of Americans purchase generic prescription drugs every year and rely on generic pharmaceuticals as a more affordable alternative to brand name medicines. The Division's investigation into the generics market, however, has revealed that some executives have sought to collude on prices and enrich themselves at the expense of American consumers.[80]

3. Led by the State of Connecticut, 45 state attorneys general launched their own investigation of antitrust violations in the generic drug industry.

211. The State AGs' action was filed just days after the DOJ filed its first criminal charges against two former executives of Heritage Pharmaceuticals. According to the State

---

[77] *See* Transcript of Hearing, *FWK Holdings, LLC v. Actavis Elizabeth, LLC*, No. 16-cv-9901, ECF 112 (S.D.N.Y. Feb. 21, 2017).

[78] *See* Memorandum of Amicus Curiae United States of America Concerning Consolidation, *In re: Generic Digoxin and Doxycycline Antitrust Litig.*, MDL No. 2724, ECF 284 (J.P.M.L. Mar. 10, 2017).

[79] *See* Intervenor United States' Motion to Stay Discovery, *In re: Generic Pharm. Pricing Antitrust Litig.*, MDL No. 2724, ECF 279 (E.D. Pa. May 1, 2017).

[80] DOJ Website, Division Update Spring 2017 (Mar. 28, 2017), *available at* https://www.justice.gov/atr/division-operations/division-update-spring-2017/division-secures-individual-and-corporate-guilty-pleas-collusion-industries-where-products.

AGs' complaint, the information developed through its investigation (which is still ongoing) uncovered evidence of a broad, well-coordinated, and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States. Although the State AGs' action currently focuses on doxycycline hyclate and glyburide, it alleges that the Plaintiff States have uncovered a wide-ranging series of conspiracies implicating numerous different generic pharmaceuticals and competitors. As reported by *The Connecticut Mirror*, the State AGs "suspected fraud on a broader, nearly unimaginable scale" and "new subpoenas are going out, and the investigation is growing beyond the companies named in the suit."[81] CTAG George Jepsen has called evidence that has so far been obtained in the State AGs' investigation "mind-boggling."[82]

212. CTAG George Jepsen confirmed the scope of the State AGs' action in the following press release:

> My office has dedicated significant resources to this investigation for more than two years and has developed compelling evidence of collusion and anticompetitive conduct across many companies that manufacture and market generic drugs in the United States. . . . While the principal architect of the conspiracies addressed in this lawsuit was Heritage Pharmaceuticals, we have evidence of widespread participation in illegal conspiracies across the generic drug industry. Ultimately, it was consumers – and, indeed, our healthcare system as a whole – who paid for these actions through artificially high prices for generic drugs. We intend to pursue this and other enforcement actions aggressively, and look forward to

[81] Mark Pazniokas, *How a small-state AG's office plays in the big leagues*, The Connecticut Mirror (Jan. 27, 2017), *available at* https://ctmirror.org/2017/01/27/how-a-small-state-ags-office-plays-in-the-big-leagues/. *The Connecticut Mirror* further reported that the DOJ grand jury was convened in this District shortly after the CTAG issued its first subpoena. *Id.*

[82] *Id.*

> working with our colleagues across the country to restore competition and integrity to this important market.[83]

213. In filings with the United States Judicial Panel on Multidistrict Litigation on May 16, 2017 and June 13, 2017, the State AGs reiterated that their ongoing investigation is broad in scope and goes beyond doxycycline hyclate DR and glyburide.[84] The State AGs further stated that their doxycycline hyclate DR and glyburide action "encompass[es] illegal agreements – including with regard to Doxy DR – where prices remained constant (or remained higher than they would have been in a competitive market) as a result of customer or market allocation agreements designed specifically to avoid price erosion[.]" The State AGs also disclosed that they have entered into settlements with Glazer and Malek and that these settlements require Glazer and Malek's cooperation with the State AGs.

214. During a conference call on July 27, 2017, W. Joseph Nielsen, an assistant AG for the State of Connecticut, said "he expects future actions by the group of states investigating price-fixing and market allocation in the generic drug industry" including "more lawsuits against additional generic manufacturers for additional drugs [and] lawsuits against high-level executives for their roles in the collusion."[85] Nielsen also stated that the States AGs realized very quickly that the generic drug industry is "set up structurally in a way that fosters and

---

[83] CTAG Website, Press Release, *Connecticut Leads 20 State Coalition Filing Federal Antitrust Lawsuit against Heritage Pharmaceuticals, other Generic Drug Companies* (Dec. 15, 2016), *available at* http://www.ct.gov/ag/cwp/view.asp?Q=588538&A=2341.

[84] *See* Brief and Reply in Support of Plaintiff States' Motion to Vacate Conditional Transfer Order (CTO-3), *In re: Generic Pharm. Pricing Antitrust Litig.*, MDL No. 2724, ECF 321 & 334 (J.P.M.L. May 16, 2017 & June 13, 2017).

[85] Can Calik, *Future actions by state enforcers expected over generic drug collusion, Connecticut official says*, MLEX (July 27, 2017), *available at* http://www.mlex.com/GlobalAntitrust/DetailView.aspx?cid=908454&siteid=191&rdir=1.

promotes collusion among generic competitors" and that the State AGs' investigation "has expanded greatly to the point where we are now looking at numerous drugs."

215. New York AG Eric T. Schneiderman also reported that the State AGs' action "uncovered evidence of a broad, well-coordinated and long running series of conspiracies to fix prices and allocate markets for certain generic pharmaceuticals in the United States."[86]

216. The DOJ's and State AGs' investigations of alleged price-fixing and other unlawful conduct in the generic pharmaceutical industry are ongoing.

VI. THE DIGOXIN MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION

217. Because Defendants' anticompetitive conduct constitutes a conspiracy to fix prices and engage in market and customer allocation, which is a *per se* violation of Section 1 of the Sherman Antitrust Act, Plaintiffs need not define a relevant market. However, there are features of the market relevant to this case that show both (i) that the market is susceptible to collusion and (ii) that the price increases were in fact the result of collusion and not the result of conscious parallelism.

218. Factors showing that a market is susceptible to collusion include in this case:

(1) **High Level of Industry Concentration** – A small number of competitors (Defendants) control virtually all market share for Digoxin, as detailed above. In October 2013, at the outset of the Class Period the Defendants together accounted for roughly [redacted] of the market for these products.

(2) **Sufficient Numbers to Drive Competition** – While the market for Digoxin had a small enough number of competitors to foster collusion, the number of sellers was large enough that – given decades of experience with

[86] New York AG Website, Press Release, *A.G. Schneiderman Files Federal Antitrust Lawsuit With 19 Other States Against Heritage Pharmaceuticals And Other Generic Drug Companies* (Dec. 15, 2016), *available at* https://ag.ny.gov/press-release/ag-schneiderman-files-federal-antitrust-lawsuit-19-other-states-against-heritage.

competitive generic pricing, and accepted models of how generic companies vigorously compete on price – one would have expected prices to remain at their historical, near marginal cost levels. With the number of generic competitors such as there were here, historical fact and accepted economics teaches that – absent collusion – prices would have remained at competitive levels.

(3) **High Barriers to Entry** –The high costs of manufacture, intellectual property, development and testing requirements, and lengthy time delay related to regulatory approval and oversight are among the barriers to entry in the generic drug market. For example, the six Defendants that control virtually all of the Digoxin market each sell Digoxin pursuant to FDA approvals granted years before the price soared in 2013. Any potential new entrant would have to go through the lengthy ANDA-approval process before coming to market. The FDA has not approved any ANDA for the sale and marketing of Digoxin during the Class Period, there are no other holders of approved ANDAs that have not yet entered the market, and it may take years for the FDA to approve any new ANDA if filed. By insulating against new entrants, these barriers to entry and others increase the market's susceptibility to a coordinated effort among the dominant players to maintain supracompetitive prices.

(4) **High Inelasticity of Demand and Lack of Substitutes** – For the majority of patients who rely on it, Digoxin is a necessity that must be purchased regardless of price hikes. While there are other drugs on the market for the treatment of heart conditions, there are significant barriers to changing treatments, and both patients and physicians are likely to prioritize medical considerations over price. This makes demand for Digoxin highly inelastic.

(5) **Commoditized Market** – Defendants' Digoxin products are fully interchangeable because they are bioequivalent to one another by FDA standards. Thus, all manufactured versions of Digoxin are therapeutically equivalent to each other and pharmacists may substitute one for another interchangeably.

(6) **Absence of Non-Conspiring Competitors** – Defendants control virtually all of the market share for Digoxin and have maintained supracompetitive pricing throughout the Class Period. Thus, Defendants have market power in the

market for Digoxin, which enables them to increase prices without loss of market share to non-conspirators.

(7) **Opportunities for Contact and Communication Among Competitors** – Defendants participate in the committees and events of the GPhA, HDMA, MMCAP, NACDS, ECRM, NPF, and other industry groups, which provide and promote opportunities to communicate. The grand jury subpoenas to Defendants targeting inter-Defendant communications, further supports the existence of communication lines between competitors with respect to, among other things, generic pricing.

(8) **Size of Price Increases** – The magnitude of the price increases involved in this case further differentiates them from parallel price increases. At the time of their October 2013 price increases, Lannett and Impax were aware that there were other ANDA holders that could (and eventually did) enter the market. Absent collusion, Lannett and Impax thus should have been concerned that drastic hikes would have led these potential competitors to enter at lower prices leading to severe market share loss. But here the increases are not cautious 5% or even 10% jumps – the increases are of far greater magnitude. A rational company would not implement such large increases unless certain that its ostensible competitors would follow.

(9) **Reimbursement of Generic Drugs** – This market, as with many generic markets, has institutional features that would inhibit non-collusive parallel price increases. The reimbursement for generic pharmaceuticals to retail pharmacies is limited by MAC pricing, which is based on the lowest acquisition cost for each generic pharmaceutical paid by retail pharmacies purchasing from a wholesaler for each of a pharmaceutical's generic equivalent versions. As a result, the usual inhibition of an oligopolist to unilaterally raise prices is embedded in the generic reimbursement system.

219. Through their market dominance, Defendants have been able to substantially foreclose the market to rival competition, thereby maintaining and enhancing market power and enabling Defendants to charge Plaintiffs and the proposed Class members inflated prices above competitive levels for Digoxin through unlawful price collusion.

VII. CLASS ACTION ALLEGATIONS

220. Pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), Plaintiffs bring this action on behalf of a Class defined as:

> All persons or entities that directly purchased Digoxin (generic digoxin 0.125 or 0.25 mg tablets) from one or more of the Defendants in the United States and its territories and possessions at any time during the period from October 2013 through the present (the "Class Period").
>
> Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, judicial officers and their personnel, and all governmental entities.

221. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe that there are dozens of Class members, geographically dispersed throughout the United States, such that joinder of all Class members is impracticable. Further, the Class members are readily identifiable from information and records maintained by Defendants.

222. Plaintiffs' claims are typical of, and not antagonistic to, the claims of the other Class members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants.

223. Plaintiffs will fairly and adequately protect and represent the interests of the Class and Plaintiffs' interests are coincident with, and not antagonistic to, those of the Class.

224. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation.

225. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class. Thus, determining damages with respect to the Class as a whole is appropriate. The common applicability of the relevant facts to claims of

Plaintiffs and the proposed class is inherent in Defendants' wrongful conduct, because the overcharge injuries incurred by Plaintiffs and each member of the proposed class arose from the same collusive conduct alleged herein.

226. The common legal and factual questions do not vary among Class members and may be determined without reference to individual circumstances, and include, but are not limited to, the following:

(a) Whether Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate competition and thereby increase the prices of Digoxin in the United States;

(b) The duration and extent of the alleged contract, combination, or conspiracy between and among Defendants and their co-conspirators;

(c) Whether Defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;

(d) The effect of the contract, combination, or conspiracy on the prices of Digoxin in the United States during the Class Period;

(e) Whether Defendants' conduct caused supracompetitive prices for Digoxin;

(f) Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiffs and other members of the Class; and

(g) Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

227. Treatment as a class action is the superior method for the fair and efficient adjudication of this controversy, as it will permit numerous similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, avoiding unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding as a class action, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.

228. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VIII. ANTITRUST INJURY

229. During the Class Period, Plaintiffs and Class members directly purchased Digoxin from Defendants. Because of the Defendants' anticompetitive conduct, Plaintiffs and Class members were forced to pay more for Digoxin than they otherwise would have, and thus have suffered substantial overcharge damages at the hands of Defendants. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

230. Defendants' unlawful conduct has successfully eliminated competition in the market, and Plaintiffs and Class members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such overcharge damages will be calculated after discovery and upon proof at trial.

231. Defendants, through their unlawful conduct alleged herein, reduced competition in the Digoxin market, increased prices, reduced choice for purchasers, and caused antitrust injury to purchasers in the form of overcharges.

232. Because Defendants' anticompetitive conduct is ongoing, Plaintiffs and the Class continue to pay supracompetitive prices for Digoxin through the present.

IX. CLAIM FOR RELIEF – VIOLATION OF SECTION 1 OF THE SHERMAN ACT

233. Plaintiffs repeat and re-allege the foregoing as though fully set forth herein.

234. In violation of Section 1 of the Sherman Antitrust Act, Defendants entered agreements with one another concerning the pricing of Digoxin in the United States. This conspiracy was *per se* unlawful price-fixing.

235. Each of the Defendants has committed at least one overt act to further the conspiracy alleged in this Complaint. Defendants' anticompetitive acts were intentional, were

directed at the sales of Digoxin in the United States, and had a substantial and foreseeable effect on interstate commerce by raising and fixing Digoxin prices throughout the United States.

236. The conspiracy had its intended effect, because Defendants have benefited—and continue to benefit—from their collusion and the elimination of competition, both of which artificially inflated the prices of Digoxin.

237. The contract, combination, or conspiracy had the following direct, substantial, and reasonably foreseeable effects upon commerce in the United States:

a. Prices charged to and paid by Plaintiffs for Digoxin were artificially raised, fixed, maintained, or stabilized at supracompetitive levels;

b. Plaintiffs were deprived of the benefits of free, open, and unrestricted competition in the sale of Digoxin in the United States market; and

c. Competition in establishing the prices paid for Digoxin was unlawfully restrained, suppressed, or eliminated.

238. As a direct and proximate result of Defendants' unlawful conduct, Plaintiffs and Class members have been injured in their business and property in that they have paid more for Digoxin than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown and will be determined after discovery and upon proof at trial.

239. Defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

240. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

241. Defendants' unlawful conduct as alleged herein poses a significant and continuing threat of antitrust injury.

X. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and Class members pray for relief from this Court and request:

A. Certification as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiffs as Class Representatives and their counsel of record as Class Counsel;

B. Adjudication that the acts alleged herein constitute unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;

C. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiffs and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

D. An award to Plaintiffs and Class members of pre-judgment and post-judgment interest at the highest legal rate provided by law from and after the date of service of the first-filed Complaint in this action;

E. An award to Plaintiffs and Class members of the costs of this suit, including reasonable attorney fees; and

F. An award of any further relief as the Court deems just and proper.

XI. JURY TRIAL DEMANDED

Plaintiffs hereby request a jury trial on all claims so triable.

Dated August 15, 2017

NASTLAW LLC

By: _____
Dianne M. Nast

Dianne M. Nast (PA Bar No. 24424)
Erin C. Burns (PA Bar No. 89742)
1101 Market Street
Suite 2801
Philadelphia, Pennsylvania 19107
215-923-9300
215-923-9302 (fax)
dnast@nastlaw.com
eburns@nastlaw.com

LEAD AND LIAISON COUNSEL

BERGER & MONTAGUE P.C.
David F. Sorensen
Zachary D. Caplan
1622 Locust Street
Philadelphia, Pennsylvania 19103
(215) 875-3000
dsorensen@bm.net
zcaplan@bm.net

KAPLAN FOX & KILSHEIMER LLP
Robert N. Kaplan
Elana Katcher
850 Third Avenue
New York, New York 10022
(212) 687-1980
rkaplan@kaplanfox.com
ekatcher@kaplanfox.com

ROBERTS LAW FIRM P.A.
Michael L. Roberts
Jana K. Law
20 Rahling Circle
Little Rock, Arkansas 72223
(501) 821-5575
mikeroberts@robertslawfirm.us
janalaw@robertslawfirm.us

HAGENS BERMAN SOBOL SHAPIRO LLP
Thomas M. Sobol
David S. Nalven
55 Cambridge Parkway, Suite 301
Cambridge, Massachusetts 02142
617-482-3700
tom@hbsslaw.com
davidn@hbsslaw.com

Barbara A. Mahoney
1918 8th Avenue, Suite 3300
Seattle, Washington 98101
(206) 623-7292
bmahoney@hbsslaw.com

NUSSBAUM LAW GROUP P.C.
Linda P. Nussbaum
Bradley J. Demuth
1211 Avenue of the Americas, 40th Floor
New York, New York 10036
(917) 438-9102
lnussbaum@nusspaumpc.com
bdemuth@nussbaumpc.com

DIRECT PURCHASER PLAINTIFFS' STEERING COMMITTEE

COHEN MILSTEIN SELLERS & TOLL PLLC
Sharon K. Robertson
Donna M. Evans
88 Pine Street, 14th Floor
New York, New York 10005
(212) 838-7797
srobertson@cohenmilstein.com
devans@cohenmilstein.com

FARUQI & FARUQI LLP
Peter Kohn
Joseph T. Lukens
101 Greenwood Avenue, Suite 600
Jenkintown, Pennsylvania 19046
(215) 277-5770
pkohn@faruqilaw.com
jlukens@faruqilaw.com

GUSTAFSON GLUEK PLLC
Daniel E. Gustafson
Daniel C. Hedlund
Canadian Pacific Plaza
120 South 6th Street, Suite 2600
Minneapolis, Minnesota 55402
(612) 333-8844
dgustafson@gustafsongluek.com
dhedlund@gustafsongluek.com

RADICE LAW FIRM
John D. Radice
April D. Lambert
34 Sunset Blvd
Long Beach, New Jersey 08008
(646) 245-8502
jradice@radicelawfirm.com
alambert@radiclawfirm.com

SALTZ MONGELUZZI BARRETT & BENDESKY P.C.
Simon B. Paris
Patrick Howard
One Liberty Place, 52nd Floor
Philadelphia, Pennsylvania 19103
(215) 496-8282
sparis@smbb.com
phoward@smbb.com

TAUS, CEBULASH & LANDAU LLP
Barry S. Taus
Kevin Landau
80 Maiden Lane, Suite 1204
New York, New York 10038
(212) 931-0704
btaus@tcllaw.com
klandau@tcllaw.com

VANEK, VICKERS & MASINI P.C.
Joseph M. Vanek
David P. Germaine
55 West Monroe, Suite 3500
Chicago, Illinois 60603
(312) 224-1500
jvanek@vaneklaw.com
dgermaine@vaneklaw.com

WEXLER WALLACE LLP
Kenneth A. Wexler
Bethany R. Turke
55 West Monroe Street, Suite 3300
Chicago, Illinois 60603
(312) 346-2222
kaw@wexlerwallace.com
brt@wexlerwallace.com

ZIMMERMAN REED LLP
Charles S. Zimmerman
David M. Cialkowski
1100 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402
(612) 341-0400
charles.zimmerman@zimmreed.com
david.cialkowski@zimmreed.com

ADDITIONAL COUNSEL TO DIRECT PURCHASER PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2017, a copy of the Consolidated Direct Purchaser Class Action Complaint was manually filed under seal with the Clerk of the Court and served upon counsel of record via electronic mail.

Dianne M. Nast