

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

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FRATERNAL ORDER OF POLICE, MIAMI	)	CASE NO.
LODGE 20, INSURANCE TRUST FUND	)	
on behalf of itself and all others similarly situated,	)	
	)	
<i>Plaintiff,</i>	)	<u>CLASS ACTION COMPLAINT</u>
v.	)	
	)	
LANNETT COMPANY, INC., ALLERGAN PLC,	)	
IMPAX LABORATORIES, INC., MYLAN INC.,	)	
PAR PHARMACEUTICALS, INC.	)	
SUN PHARMACEUTICAL INDUSTRIES	)	<u>JURY TRIAL DEMANDED</u>
CO., and WEST-WARD PHARMACEUTICAL	)	
CORP.,	)	
	)	
<i>Defendants.</i>	)	
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INTRODUCTION

1. Plaintiff Fraternal Order of Police, Miami Lodge 20, Insurance Trust Fund (“FOP Miami” or “Plaintiff”), on behalf of itself and all others similarly situated, brings this class action for claims under federal and state antitrust and consumer protection laws and the common law of unjust enrichment to recover damages and to obtain injunctive and equitable relief for the injuries it and others similarly situated have sustained against Defendants Lannett Company, Inc., (“Lannett”) Allergan plc (“Allergan”), Mylan Inc. (“Mylan”), Par Pharmaceuticals, Inc. (“Par”), Sun Pharmaceutical Industries Co. (“Sun”), and West-Ward Pharmaceutical Corp. (“West”), arising from their conspiracy to fix, raise, maintain and stabilize the prices of certain doxycycline products and digoxin tablets, 0.125 mg and 0.25 mg (“digoxin”), in the United States during the period of October 1, 2012, through the present or the date on which the anticompetitive effects subside (the “Class Period”), in the states and districts identified below, and to allocate markets and customers for those products during the same time period. All allegations herein are based on

information and belief, except for those relating to Plaintiff, which are made on Plaintiff's personal knowledge.

2. Doxycycline and digoxin are common medications, both of which are listed as "essential medicines" by the World Health Organization.¹ Doxycycline is an antibiotic used to treat various bacterial infections, including pneumonia, acne, chlamydia, Lyme disease, cholera and syphilis. It was developed synthetically in the mid-20th century and has been commercially available since the 1960s. Digoxin, is a heart medication derived from the digitalis plant used to treat atrial fibrillation and other cardiac issues. Forms of it have been used for treatment since the 1700s. Neither is patent-protected.

3. Generic versions of each drug have been marketed for at least 20 years and have generally been very inexpensive, costing patients mere pennies per unit. This is a direct result of competition spurred by the presence of various generic drugs, which benefits consumers and third-party payors through lower prices.

4. Within the past four years, however, both doxycycline and digoxin have seen unprecedented and astounding price increases. Since October 2012, the price of doxycycline has soared to **more than 8,000%** of its prior prices. Since October 2013, the price of digoxin has jumped **more than 800%**.

5. These price increases did not stem from competitive behavior caused by, for instance, supply shortages or changed product demand. Rather, they were the scion of Defendants' broad and wide-ranging conspiracy to fix, raise, maintain and stabilize the prices of these products, and to allocate customers and markets for them. Defendants effectuated their conspiracy by direct

¹ World Health Org., WHO Model List of Essential Medicines (Apr. 2015), at 8, 6, 17, 27, 29, http://www.who.int/selection_medicines/committees/expert/20/EML_2015_FINAL_amended_AUG2015.pdf?ua=1.

business-to-business contacts among generic drug manufacturers, secret communications and meetings, and/or joint participation taken under the guise of trade associations like the Generic Pharmaceutical Association (“GPHA”).

6. Defendants’ conspiracy has further benefited from oligopolistic market conditions, caused by the low number of competitors and barriers to entry in the doxycycline and digoxin markets. Such conditions have allowed Defendants to sustain anticompetitive behaviors such as their increased pricing as of the filing of this Complaint.

7. These price increases, along with similar ones for other generic drugs Defendants manufacture, have garnered scrutiny from federal and state governments alike. The Department of Justice (“DOJ”) and the Connecticut Attorney General’s Office (“CTAG”) have both issued subpoenas for Defendants Lannett, Impax and Par seeking documents and testimony concerning prices of digoxin. The same departments have issued subpoenas for Defendants Lannett, Allergan, Mylan and Par concerning prices of doxycycline. The DOJ’s subpoenas arose from a grand jury proceeding in the Eastern District of Pennsylvania.

8. The DOJ’s investigation in particular is expected to include generic pharmaceutical products other than digoxin and doxycycline but will likely reveal additional information about these two drugs. Plaintiff reserves the right to add more parties and/or claims and to otherwise supplement the facts and other information alleged in this Complaint on the basis of additional investigation by the DOJ or otherwise.

9. Along with these investigations, Congress has taken notice of the price increases as well. Rep. Elijah Cummings, Ranking Member of the House Committee on Oversight and Government Reform, and Sen. Bernie Sanders, Chairman of the Subcommittee on Primary Health and Aging of the Senate Committee on Health, Education, Labor and Pensions, have each written

letters to Defendants to request information concerning their sales of doxycycline and digoxin, as well as other generic drugs that have experienced similar increases. Such drugs include albuterol sulfate, glycopyrrolate, divalproex sodium ER, pravastatin sodium, neostigmine methylsulfate, and benazepril/hydrochlorothiazide.

10. Rep. Cummings and Sen. Sanders launched their investigations on the basis of drug price information that they compiled after the increases were recorded.² This information shows the stunning rise in generic prices during the relevant time period:

Drug	Use	Average Market Price Oct. 2013	Average Market Price April 2014	Average Percentage Increase
Doxycycline Hyclate (bottle of 500, 100 mg tablets)	antibiotic used to treat a variety of infections	\$20	\$1,849	8,281%
Albuterol Sulfate (bottle of 100, 2 mg tablets)	used to treat asthma and other lung conditions	\$11	\$434	4,014%
Glycopyrrolate (box of 10 0.2 mg/mL, 20 mL vials)	used to prevent irregular heartbeats during surgery	\$65	\$1,277	2,728%
Divalproex Sodium ER (bottle of 80, 500 mg tablets ER 24H)	used to prevent migraines and treat certain types of seizures	\$31	\$234	736%
Pravastatin Sodium (bottle of 500, 10 mg tablets)	used to treat high cholesterol and to prevent heart disease	\$27	\$196	573%
Neostigmine Methylsulfate (box of 10 1:1000 vials)	used in anesthesia to reverse the effects of some muscle relaxants	\$25	\$121	522%
Benazepril/Hydrochlorothiazide (bottle of 100, 20-25 mg tablets)	used to treat high blood pressure	\$34	\$149	420%
Drug	Use	Average Market Price Nov. 2012	Average Market Price Sept. 2014	Average Percentage Increase
Isuprel (box of 25, 0.2 mg/mL vials)	used to treat heart attacks and irregular heartbeat	\$916	\$4,489	390%
Nitropress (50 mg vial)	used to treat congestive heart failure and reduce blood pressure	\$44	\$215	388%
Drug	Use	Average Market Price Oct. 2012	Average Market Price June 2014	Average Percentage Increase
Digoxin (single tablet, 250 mcg)	used to treat irregular heartbeats and heart failure	\$0.11	\$1.10	884%

² <http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file>

11. Defendants' conspiracy to fix, raise, maintain and stabilize the prices of doxycycline and digoxin has caused and continues to cause consumers and third-party payors to pay supracompetitive prices for doxycycline and digoxin tablets.

12. Plaintiff seeks to certify two classes. The first class (the "Injunctive Class") is a national injunctive class of persons or entities in the United States and its territories who purchased, paid and/or provided reimbursement for some or all of the purchase price of generic digoxin or doxycycline products manufactured by Defendants during the Class Period.

13. The second class (the "Damages Class") includes all persons or entities who purchased, paid and/or provided reimbursement for some or all of the purchase price of generic digoxin or doxycycline products manufactured by Defendants during the Class Period in the states identified herein and the District of Columbia.

JURISDICTION AND VENUE

14. Plaintiff brings this action under Section 16 of the Clayton Act (15 U.S.C. § 26), for injunctive relief and costs of suit, including reasonable attorneys' fees, against Defendants for the injuries sustained by Plaintiff and the Class Members by reason of the violations of Sections 1 and 3 of the Sherman Act (15 U.S.C. § 1, 3).

15. This action is also instituted under the antitrust, consumer protection, and common laws of various states for damages and equitable relief, as described in the Claims for Relief below.

16. Pursuant to 28 U.S.C. §§ 1331 and 1337, Section 16 of the Clayton Act (15 U.S.C. §26), and 28 U.S.C. § 1367, jurisdiction is conferred upon this Court.

17. Pursuant to 15 U.S.C. §§ 15(a) and 22 and 28 U.S.C § 1391(b), (c) and (d), venue is proper in this judicial district because during the Class Period, Defendants resided, transacted

business, were found, or had agents in this District, and a substantial portion of the affected interstate trade and commerce described below has been carried out in this District, where Lannett and Mylan are headquartered and where Impax's generics division is located. Therefore, it is likely that acts in furtherance of the alleged conspiracy took place here. Venue is also proper in this District because the federal grand jury investigating the pricing of generic drugs is empaneled here.

18. 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) sold both doxycycline and digoxin throughout the United States, including in this District; (c) had substantial contacts with the United States, including in this District; and/or (d) was engaged in an illegal scheme and price-fixing conspiracy 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.

PARTIES

19. Plaintiff FOP Miami is a governmental plan established and funded through contributions from the City of Miami and the plan's members, who are current and retired sworn officers from the City of Miami Police Department and their dependents. FOP Miami was established pursuant to a duly executed Trust Agreement for the purpose of providing medical, surgical and hospital care or benefits, including prescription drug benefits, to its members. FOP Miami maintains its principal place of business at 400 NW 2nd Avenue, Miami, Florida, and is a citizen of Florida. During the Class Period, FOP Miami purchased and paid for some or all of the purchase price for one or more doxycycline in Florida, South Carolina, Tennessee, Virginia, Georgia and North Carolina, thereby suffering injury to its business and property. During the Class Period, FOP Miami purchased and paid for some or all of the purchase price for one or more

digoxin in Florida, North Carolina, Georgia and Alabama, thereby suffering injury to its business and property. FOP Miami paid and reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets and customers.

20. Defendant Lannett Company, Inc. ("Lannett") is a Delaware corporation that has its principal place of business in Philadelphia, Pennsylvania. Lannett is a distributor of generic digoxin and generic doxycycline. During the Class Period, Lannett sold generic digoxin and generic doxycycline to customers in this District and other locations in the United States.

21. Defendant Allergan plc ("Allergan") is an Irish corporation that has its global headquarters in Dublin, Ireland and its administrative headquarters in Parsippany-Troy Hills, New Jersey. During the Class Period, Allergan sold generic digoxin and generic doxycycline to customers in this District and other locations in the United States.

22. Defendant Impax Laboratories, Inc. ("Impax") is a Delaware corporation that has its principal place of business in Hayward, California. As noted above, Impax's generics division, called Global Pharmaceuticals ("Global"), is located within this District, in Chalfont, Pennsylvania. Global manufactures and distributes generic digoxin. During the Class Period, Global sold generic digoxin to customers in this District and other locations in the United States.

23. Defendant Mylan Inc. ("Mylan") is a Delaware corporation with its principal place of business in Canonsburg, Pennsylvania. During the Class Period, Mylan sold generic digoxin and generic doxycycline to customers in this District and other locations in the United States.

24. Defendant Par Pharmaceuticals Inc. ("Par") is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. In January of 2014, Par announced that it had entered into an exclusive United States supply and distribution agreement with Covis

Pharma S.à.r.l. (“Covis”) to distribute the authorized generic version of Covis’ Lanoxin (digoxin) tablets. At that time, Par began selling and shipping 0.125 mg and 0.250 mg strengths of digoxin tablets in this country. Par also manufactures generic doxycycline. During the Class Period, Par sold generic digoxin and doxycycline to customers in this District and other locations in the United States.

25. Defendant Sun Pharmaceutical Industries Ltd. (“Sun”) is an Indian corporation with U.S. offices located at 270 Prospect Plains Road, Cranbury, New Jersey, 08512. The term “Sun” includes its subsidiaries, Caraco Pharmaceutical Laboratories Ltd. (“Caraco”), which became a wholly-owned subsidiary in 2010, and URL Pharma (“URL”), which became a subsidiary of Caraco in 2013. Sun manufactures, markets, and sells branded and generic pharmaceutical products in the United States. During the Class Period, Sun manufactured and sold generic digoxin and doxycycline in the United States.

26. Defendant West-Ward Pharmaceuticals Corp. (“West-Ward”) is a Delaware corporation with its principal place of business in Eatontown, New Jersey. West-Ward is the United States agent and subsidiary of Hikma Pharmaceuticals PLC (“Hikma”), a London-based global pharmaceutical company and is a manufacturer and distributor of generic digoxin. During the Class Period, West-Ward sold generic digoxin and generic doxycycline to customers in this District and other locations in the United States.

27. Whenever in this Complaint reference is made to any act, deed or transaction of any corporation, the allegation means that the corporation engaged in the act, deed or transaction by or through its officers, directors, agents, employees or representatives while they were actively engaged in the management, direction, control or transaction of the corporation’s business or affairs.

28. All acts alleged in this Complaint to have been done by Defendants were performed by their officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of Defendants' business affairs.

CO-CONSPIRATORS

29. Various other persons, firms, corporations and entities have participated as unnamed co-conspirators with Defendants in the violations and conspiracy alleged herein. In order to engage in the offenses charged and violations alleged herein, these co-conspirators have performed acts and made statements in furtherance of the antitrust violations and conspiracies alleged herein.

30. At all relevant times, each Defendant was an agent of each of the remaining Defendants, and in doing the acts alleged herein, was acting within the course and scope of such agency. Each Defendant ratified and/or authorized the wrongful acts of each of the Defendants. Defendants, and each of them, are individually sued as participants and as aiders and abettors in the improper acts and transactions that are the subject of this action.

INTERSTATE AND INTRASTATE TRADE AND COMMERCE

31. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.

32. During the Class Period, Defendants sold substantial quantities of generic digoxin and/or doxycycline in a continuous and uninterrupted flow of interstate commerce to customers throughout the United States.

33. Defendants' anticompetitive conduct has substantial intrastate effects in that, *inter alia*, generic digoxin and doxycycline have been and are offered at higher prices to end-payors inside each respective state than they would have been or would be but for Defendants' conduct.

The complete lack of availability of competitive priced generic digoxin and doxycycline directly impacts and disrupts commerce for end-payors within each state.

34. Defendants' conduct had and continues to have a direct, substantial and reasonably foreseeable effect on both interstate commerce and on intrastate commerce in each Class state, including commerce in this District and state, and it will continue to do so if not constrained by the Court.

FACTUAL ALLEGATIONS

Generic Drugs and the Pharmaceutical Industry

35. Defendants manufacture and sell, *inter alia*, generic versions of branded drugs once any applicable patent on the branded drugs expires.

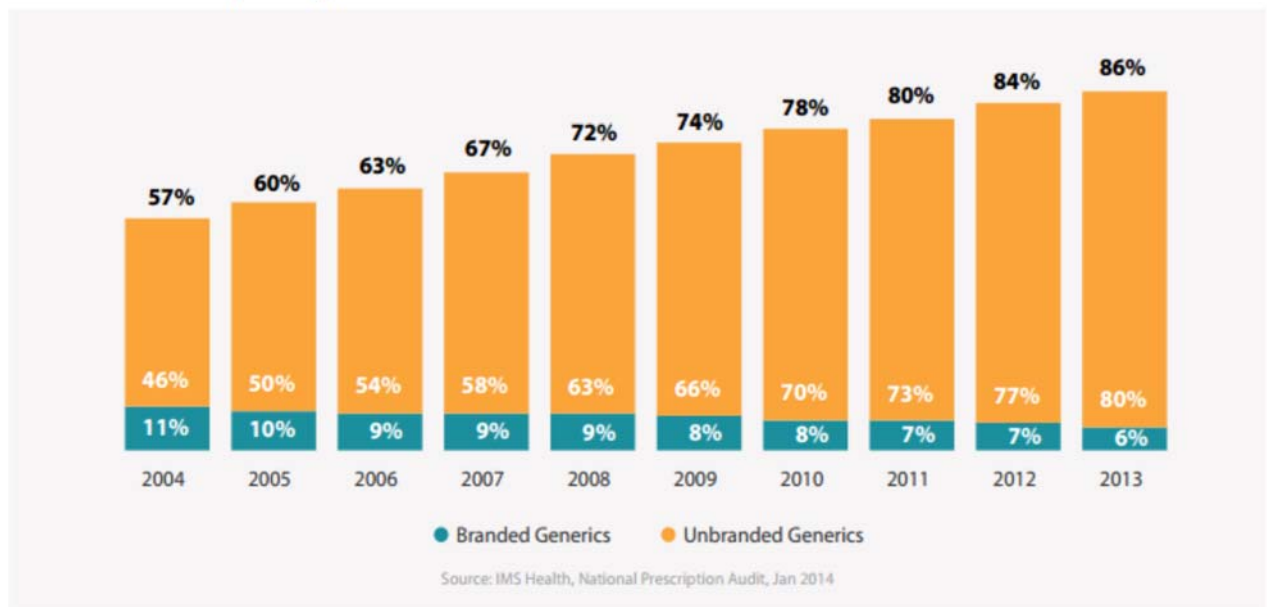
36. Generic drugs are "the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use."³ If the FDA approves a generic drug as "therapeutically equivalent" to a brand drug, the generic version "can be expected to have equal effect and no difference when substituted for the brand name product." *Id.* Generics in mature markets often cost as little as 10-15% of the branded drug's price.⁴

37. Studies have shown that generic drugs' entrance onto the market can quickly erode a branded drug's market share – often 90% of the branded drug's sales. Per IMS Health data, generic drugs as of 2013 account for 86% of all drugs dispensed in the United States.⁵

³ <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G>.

⁴ FTC Staff Study, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010), *available at* <http://emmanuelcombe.org/delay.pdf>.

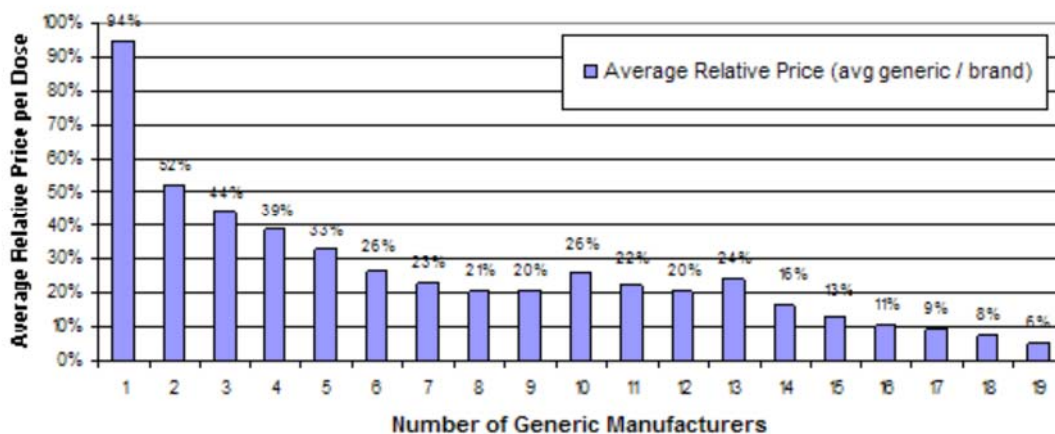
⁵ IMS Institute for Healthcare Informatics, Medicine use and shifting costs of healthcare: A review of the use of medicines in the United States in 2013 (Apr. 2014), at 51, http://www.plannedparenthoodadvocate.org/2014/IIHI_US_Use_of_Meds_for_2013.pdf.

Percent share of prescriptions

38. The more generic versions of a drug available on the market, the lower the prices that consumers and third-party payors have to pay. Each successive generic product in a competitive market lowers the price because each entry increases competition for sales and market share. In a competitive market, both the branded manufacturer and the older generic manufacturers lower prices in response to the new competitor, as the following FDA chart shows⁶:

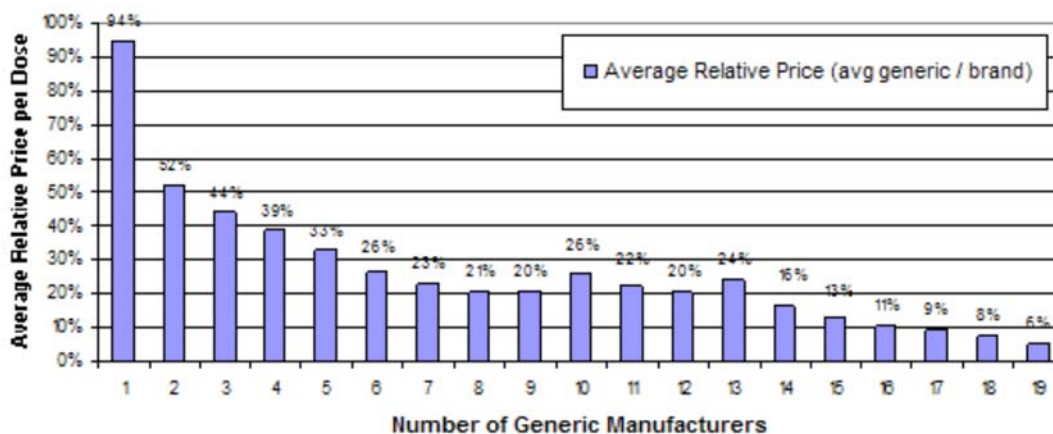
⁶ FDA, Generic Competition and Drug Prices, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

Generic Competition and Drug Prices



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

Generic Competition and Drug Prices



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

39. Accordingly, generic competition to a branded drug can provide billions of dollars in savings to consumers, pharmacies, other purchasers, private health insurers, health and welfare funds and state Medicaid programs, which reimburse drug purchases for their insureds. A GPHA study found that generic drugs saved the U.S. healthcare system \$1.68 trillion between 2005 and 2014, including \$254 billion in 2014 alone.⁷

⁷ Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.*, at 1 (2015), http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

40. Due to the price differentials between branded and generic drugs, as well as other institutional features of the pharmaceutical industry, pharmacists liberally (and sometimes are legally required to) substitute a generic drug when consumers fill prescriptions for a branded drug. Since passage of the Hatch-Waxman Act (Pub. L. No. 98-417), every state has adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for branded drug prescriptions (unless the prescribing physician specifically orders otherwise by writing “dispense as written” or similar language on the prescription).

Market for Generic Digoxin

41. The market for generic digoxin is mature. Defendants must compete on price in order to gain market share.

42. Lanoxin is a branded version of digoxin. Formerly owned by GlaxoSmithKline (“GSK”), Covis purchased commercial rights to Lanoxin from GSK in December 2011. Currently, DSM Pharmaceuticals, Inc., manufactures Lanoxin, and Covis distributes it. As noted above, in January 2014, Par agreed to obtain distribution rights for an authorized generic version of Lanoxin in the United States from Covis.

43. According to the 2015 edition of the FDA’s Orange Book, the .250 mg strength of Lanoxin is a reference listed drug (“RLD”). An RLD is an “approved drug product to which new generic versions are compared to show that they are bioequivalent ... [The generic drug] performs in the same manner as the Reference Listed Drug.”⁸ A drug company seeking approval to market a generic equivalent files an Abbreviated New Drug Application (“ANDA”), which must refer to the RLD. *Id.* Once the FDA determines that a generic drug company’s ANDA contains sufficient scientific evidence to warrant the bioequivalence of the product to the RLD, the generic drugmaker

⁸ FDA’s Glossary, available at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#RLD>.

may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to U.S. consumers. *Id.*

44. The FDA also generally assigns a Therapeutic Equivalence Code (“TE Code”) of AB to those products it finds to be bioequivalent.⁹ This coding system signals information to consumers about the drug product in question.¹⁰ For example, “[p]roducts generally will be coded AB if a study is submitted demonstrating bioequivalence. Even though drug products of distributors and/or repackagers are not included in the List, they are considered therapeutically equivalent to the application holder’s drug product if the application holder’s drug product is rated AB.”¹¹

45. Lanoxin tablets have a TE Code of “AB.” Current generic equivalents to Lanoxin – that is, digoxin product which share the code AB – are those distributed by Lannett; Global, the Impax subsidiary; West-Ward; Par; Mylan; and Caraco, the Sun subsidiary. As set forth herein, on February 12, 2012, the FDA sent a warning letter to West-Ward over quality assurance issues that caused its generic digoxin tablets to fail to be in compliance with current good manufacturing practices as defined in 21 C.F.R. Parts 210-11.¹² West-Ward closed its New Jersey facility in November of 2012 after FDA inspectors found other problems and reopened it in July of 2013 after Hikma spent \$39 million on remediation.

⁹ <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071713.htm>.

¹⁰ <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#TEC>.

¹¹ <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071713.htm>.

¹² <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm291643.htm>

46. According to its Form 10-K filed with the United States Securities & Exchange Commission (“SEC”) on August 27, 2015,¹³ Lannett has distributed generic digoxin since at least March 2004. At that time, Lannett made a supply agreement with Jerome Stevens Pharmaceuticals (“JSP”) for the exclusive distribution rights in the United States to generic digoxin. As reflected in the aforementioned Form 10-K, JSP acquired four million shares of Lannett’s common stock in exchange. Lannett and JSP later amended the original agreement to extend the initial contract through March 2019. As further reflected in the aforementioned Form 10-K, Lannett issued 1.5 million more shares of Lannett common stock to JSP, valued at approximately \$20.1 million. The contract between Lannett and JSP is thus still valid and subsisting, and the companies together produce, market, distribute and sell generic digoxin for sale in the United States.

47. Lannett distributes two generic digoxin strengths: .125 mg and .250 mg. Each has a TE Code of AB, meaning each is a generic equivalent to the corresponding respective strengths of Lanoxin. As reflected in SEC Form 10-Ks from 2007-14, Lannett’s sales of generic digoxin totaled \$12.4 million in 2011; \$10.9 million in 2012; \$11.7 million in 2013; and \$54.7 million in 2014. Lannett’s net sales of digoxin in fiscal year 2015 were \$49 million, 12% of the company’s overall net sales.¹⁴ By October 2013, the generic digoxin market was entirely controlled by Lannett and Impax. Defendant West-Ward was also a competitor, but as discussed above it had to suspend operations in November 2012 due to production problems at its manufacturing facility. It resumed participation in the generic digoxin market in July 2013, after \$39 million in repair costs.

¹³ http://www.sec.gov/Archives/edgar/data/57725/000110465915062047/a15-13005_110k.htm.

¹⁴ http://www.sec.gov/Archives/edgar/data/57725/000110465915062047/a15-13005_110k.htm, at 6, 19.

The Market for Generic Doxycycline

48. The market for generic doxycycline is mature and the Defendants in that market can only gain market share by competing on price.

49. The primary actors in that market are Lannett, Allergan, Par, West-Ward and Mylan, who collectively control a commanding market share. As with generic digoxin, generic doxycycline hyclate in capsule form almost universally has a TE Code of AB. The RLD in this market is Vibramycin, sold by Pfizer Inc. Doxycycline monohydrate in capsule or tablet form also almost universally has a TE Code and its RLD is listed as a generic form of the drug.

50. Total United States retail sales of doxycycline in 2013 were estimated to be over \$972 million.¹⁵

Defendants' Price Increases for Generic Digoxin

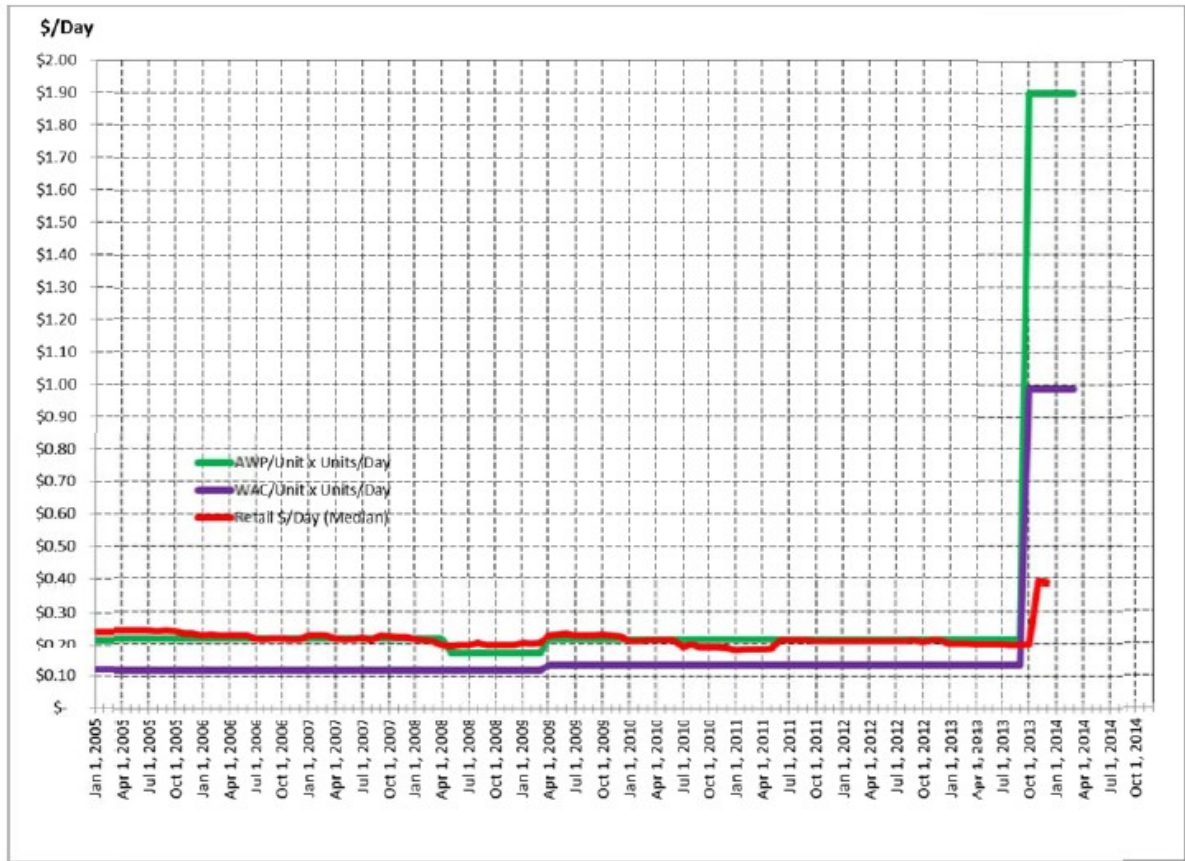
51. From at least January 2005 through October 2013, generic digoxin prices were very stable, before a huge and sudden uptick reflected in the following charts:^{16 17}

¹⁵ <http://www.drugs.com/stats/doxycycline>.

¹⁶ Testimony from Dr. Stephen Schondelmeyer ("Schondelmeyer"), Director of the PRIME Institute at the College of Pharmacy for the University of Minnesota, at a Senate hearing in front of Sen. Sanders' committee on Nov. 20, 2014, eliciting testimony on increasing generic drug prices. The testimony can be found at <http://www.help.senate.gov/imo/media/doc/Schondelmeyer.pdf>. The term "AWP" refers to "Average Wholesale Price." The term "WAC" refers to "Wholesale Acquisition Cost." Schondelmeyer used both terms as benchmark prices in his analysis.

¹⁷ This chart appeared in the letters Rep. Cummings and Sen. Sanders sent to Defendants in October 2014.

**Figure 12. Digoxin 0.25 mg Tablet (Lannett) Price per Day of Therapy:
(January 1, 2005 to December 31, 2013)**

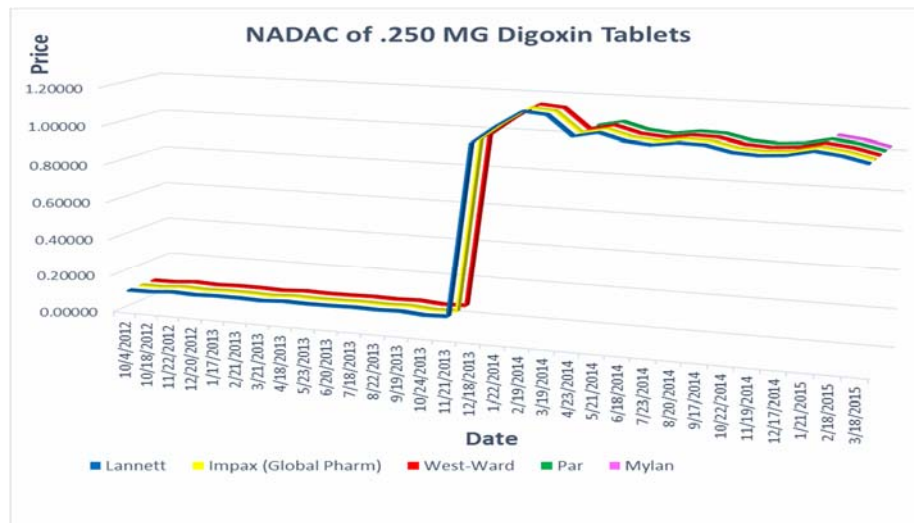
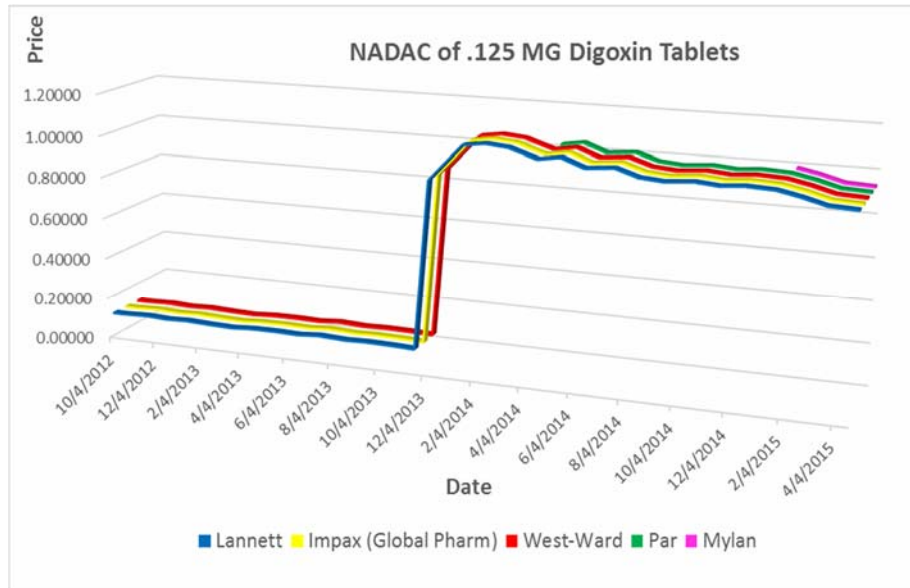


Drug	SKU	Average Market Price, October 2012	Average Market Price, June 2014	Cost Increase	Average Percentage Increase
Digoxin	125mcg tablet	\$.11	\$1.06	\$0.95	839%
Digoxin	250mcg tablet	\$.11	\$1.10	\$0.99	884%

52. Defendants Lannett, West-Ward and Impax caused these sharp increases.

Defendants Par and Mylan entered the generic digoxin market in 2014 and 2015, respectively, and followed the same pricing structure. As shown by the chart above, prices for .125 mg and .250 mg digoxin tablets rose more than 750% in September 2013 through November 2013 alone. By January 2014, prices for this essential daily medication were nearly ten times what they were just a few months prior.

53. The federal government tracks the National Average Drug Acquisition Cost (“NADAC”) to keep drug pricing benchmarks as part of the overall U.S. healthcare system. Defendants’ NADAC data shows that they all acted in concert, each recording nearly identical price changes for generic digoxin for both .125 mg and .250 mg tablets, regardless of when each Defendant joined the market for generic digoxin:



54. Defendants have never proffered a competitive or even reasonable justification for this joint shift in pricing. Though federal law requires drug manufactures to report drug shortages to the FDA along with information about the reasons and duration of any shortage or expected

shortage,¹⁸ Defendants never reported any such supply disruption for digoxin any time around fall 2013.

55. Further, a trade publication for the generic pharmaceuticals industry, the Generics and Biosimilars Initiative (“GABI”), reported on the Connecticut Attorney General’s investigation into Lannett, Impax and Covis on August 29, 2014.¹⁹ GABI wrote, *inter alia*, that “[a]t the time of the price increases, the US Food and Drug Administration had reported no drug shortages, there was no new patent or new formulation and digoxin is not difficult to make. The companies have not yet provided an explanation for the price rise.” *Id.* GABI’s report also indicated that one consumer encountered a price rise from \$1.15 for a three-month supply of digoxin to \$30 for a mere month’s supply. *Id.*

56. Nor did Defendants offer any kind of explanation to the Senate hearing in front of Sen. Sanders in 2014. Executives from Lannett, Impax and Par refused to testify.

57. The number of competitors in the generic digoxin market does not justify such significant price increases, either. For instance, the NADAC increased in late 2013, after West-Ward returned to the market in July 2013 following its quality assurance issues that required shutting down its New Jersey facility temporarily. In other words, digoxin prices went up at the same time that competition should have increased. The same effect repeated itself again later, when Par and Mylan both entered the digoxin market in late 2014 into 2015. Prices again stayed stable at anticompetitively high levels despite the change from two competitors to five. It remains so today.

¹⁸ See <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm#q>.

¹⁹ <http://www.gabionline.net/Generics/General/Lawyers-look-at-new-price-hike-for-old-drug>

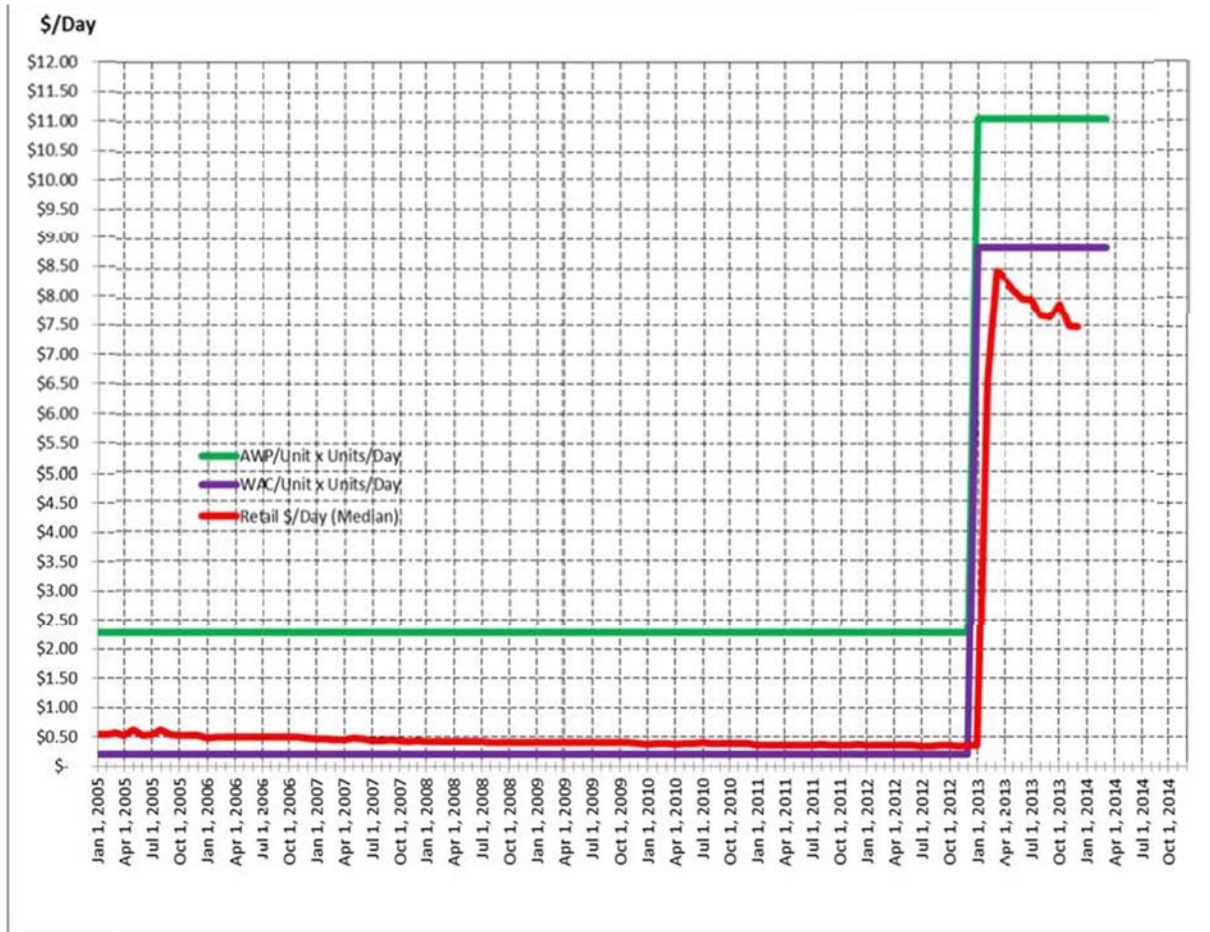
Defendants' Price Increases for Generic Doxycycline

58. Generic doxycycline prices began to rise in fall 2012, a year earlier than those of generic digoxin but according to similar patterns.

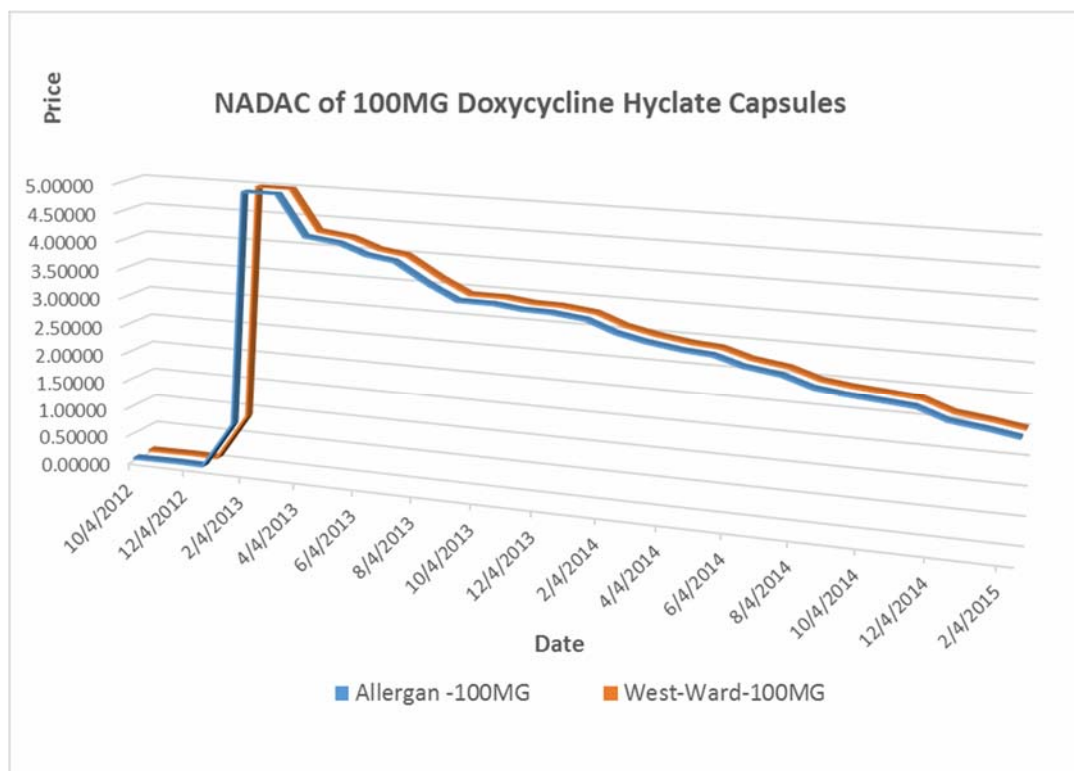
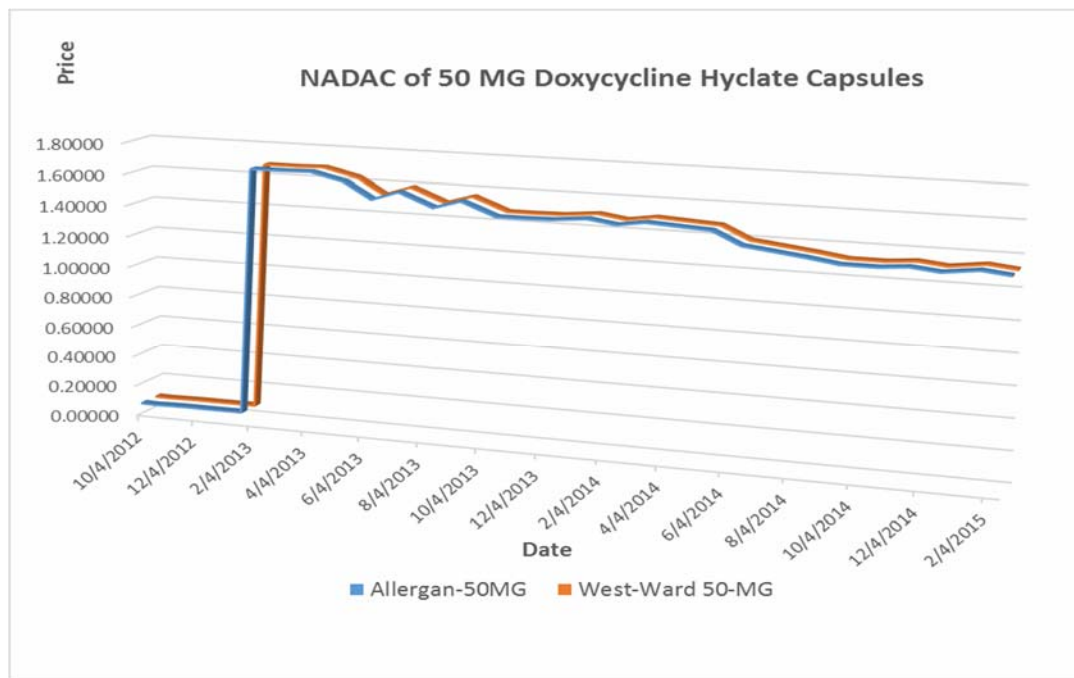
59. Rep. Cummings and Sen. Sanders memorialized stunning increases in prices for generic doxycycline:

Drug	SKU	Average Market Price October 2013	Average Market Price April 2014	Cost Increase	Average Percentage Increase
Doxycycline Hyclate	bottle of 50, 100mg capsules	\$4	\$191	\$187	5,025%
Doxycycline Hyclate	bottle of 50, 100mg tablets	\$3	\$191	\$187	4,986%
Doxycycline Hyclate	bottle of 50, 50mg capsules	\$3	\$70	\$67	2,191%
Doxycycline Hyclate	bottle of 500, 100mg capsules	\$27	\$1,849	\$1,822	7,105%
Doxycycline Hyclate	bottle of 500, 100mg tablets	\$20	\$1,849	\$1,829	8,281%

60. Likewise, Schondelmeyer, in his Senate testimony, recorded similarly sudden and extraordinarily high price increases around late 2012 in what had previously been a very stable market:



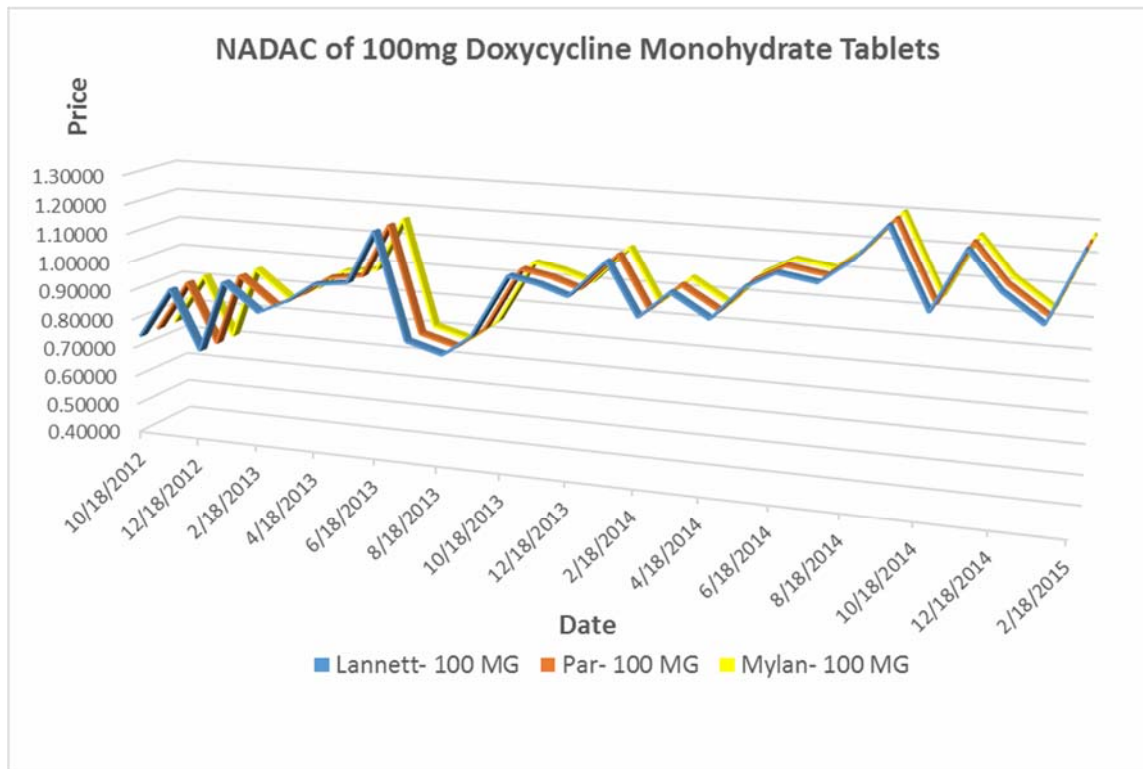
61. NADAC data for 50 mg and 100 mg of generic doxycycline hyclate capsules and tablets, manufactured by Defendants Allergan and West-Ward, also reflects the pricing activity:



62. For these Defendants in all respective strengths and forms, doxycycline prices spiked in late 2012 or early 2013. While prices have receded somewhat in the time since, they are

still significantly higher than they were prior the price increases, and the prices of each respective competitor have remained strikingly similar through the entire recorded time period.

63. NADAC data for 100 mg doxycycline monohydrate tablets manufactured by Lannett, Par and Mylan also displays both price increases as well as concerted pricing behavior by multiple competitors, as shown below:



64. As a result of Defendants' pricing behavior, consumers faced serious hardships in purchasing and maintaining stocks of a medication used for a wide variety of acute ailments in both humans and animals. Local news reports from Nashville, Tennessee, in March 2013 indicate that Vanderbilt University hospital's pharmacy had to pay \$250 for a 50-count bottle of 100 mg doxycycline tablets that had shortly prior cost only \$10. Around the same time, a local veterinarian

“wrote a prescription for doxycycline that cost \$77. This week, the price increased to nearly \$3,000.”²⁰

Industry Executives’ Statements on Competition in the Generic Drug Industry

65. Defendants’ pricing conduct smacks of collusion, as multiple competitors at multiple times for multiple products have engaged in mirror-image price raises to untenable and anticompetitive levels, to the great detriment of the purchasing public.

66. As illustrated in the charts above, prices for these generic drugs had been both stable and low for years prior to Defendants’ huge increases.

67. In an investor call on September 10, 2013, Lannett CEO Arthur Bedrosian (“Bedrosian”) indicated publicly Lannett’s strategy to raise prices and his belief that Lannett’s competitors would do the same thing:

I am finding a climate out there has been 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.

68. On a November 7, 2013, investor call, Bedrosian confirmed that Impax, Lannett’s only competitor in the generic digoxin market at the time, had indeed followed through on price increases: “[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.”

69. By the time of the next investor call, on February 6, 2014, Par had entered the market. But price increases continued, and Bedrosian expressed confidence that prices would remain high despite the new competition: “[W]e see Par as one of our rational competitors in the marketplace...we’re not troubled by their pricing in the marketplace. Not at all.”

²⁰ <http://www.wsmv.com/story/21616095/sudden-increase-in-cost-of-common-drug-concerns-many>.

70. On a November 3, 2014, investor call, Bedrosian repeated his assurances that prices would remain high, stating, incredibly, that Lannett did not care how much digoxin it sold so long as it made a profit: “We’re all interested in making a profit, not how many units we sell. ... [T]he companies we’re looking at here are not irrational players. I don’t see them just going out and trying to grab market share.” Even though Mylan was preparing to enter the market around that time, “Mylan is one of those rational competitors, so we’re not really expecting anything crazy from them.” Bedrosian remained confident that price increases would continue in what would soon be a five-firm market, up from two just a year and a half prior.

71. Finally, on a February 4, 2015, investor call, Bedrosian explicitly stated that competition in the generic digoxin market would go down even though the number of competitors had gone up: “I think you’re going to find more capital pricing [for generic drugs], more – I’ll say less competition, in a sense. You won’t have price wars. ... I just don’t see the prices eroding like they did in the past.”

72. Impax CEO Frederick Wilson spoke of a similar confidence on price during his company’s investor call in 2014: “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....”²¹

73. Defendants benefited greatly from their scheme. On the February 4, 2015, investor call, Bedrosian stated that Lannett “recorded the highest net sales and net income in our company’s history.” Gross profits in the first six months of the 2015 fiscal year were \$158.8 million or 76% of net sales, compared with \$42.3 million or 37% of net sales during the previous

²¹ <http://www.nasdaq.com/symbol/ipxl/call-transcripts>.

fiscal year. Generic digoxin pricing played a big role in its success. Generic digoxin accounted for 23% of Lannett's 2015 revenues. Lannett is highly dependent on price increases for revenue growth. Along the same lines, Impax recorded a 17% increase in year-over-year revenues from 2013 to 2014, when the company's revenues totaled \$596 million. Impax explicitly stated that "higher sales of our Digoxin" was a key factor in the rising revenues.²²

Government Responses and Defendants' Corporate Filings

74. Due to the huge increase in Defendants' reported profits, Congress and state governments each began inquiries into Defendants' actions. The pricing data and other evidence resulted from these investigations.

75. After Sen. Sanders' Senate hearing, on February 24, 2015, Rep. Cummings and Sen. Sanders wrote to the U.S. Department of Health & Human Services' Office of the Inspector General ("OIG"). They asked OIG to investigate how Defendants' price increases, including on generic digoxin, affected spending in the Medicare and Medicaid programming.²³ OIG accordingly began to review quarterly average manufacturer prices for the top 200 generic drugs from 2005 to 2014.²⁴

76. On the state level, Connecticut attorney general George Jepsen issued subpoenas to Defendants in July 2014, on the basis that there was reason to believe that Defendants engaged in a conspiracy which "has the effect of, (a) fixing, controlling or maintaining prices, rates, quotations, or fees; or (b) allocating or dividing customers or territories..."²⁵

²² Impax Laboratories Inc., Q3 2014 Earnings Call (Nov. 4, 2014), <http://seekingalpha.com/article/2638955-impax-laboratories-ipxl-ceo-frederick-wilkinson-on-q3-2014-results-earnings-call-transcript?part=single>.

²³ <http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file>.

²⁴ <http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file>

²⁵ Impax Laboratories (IPXL) Receives Subpoena from Connecticut AG,

77. Next, in November 2014, DOJ issued grand jury subpoenas to Lannett, Impax, Par, Allergan and Mylan, as well as some of their employees, to investigate possible Sherman Act violations in the generic pharmaceutical industry.²⁶ Lannett received a second grand jury subpoena on December 5, 2014.

78. Lannett reported some of the contents of this subpoena in its SEC Form 10-Q, dated February 6, 2015. Lannett turned over corporate, financial and employee information, communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale and pricing of products including digoxin and doxycycline. Trade publications and subsequent SEC filings report similar information.^{27 28}

79. Lannett issued another SEC form 10-K on August 27, 2015, further discussing the DOJ explanation as follows: “In fiscal year 2015, the Company and certain affiliated individuals each were served with a grand jury subpoena relating to a federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act. The subpoenas request corporate documents of the Company relating to corporate, financial, and employee information, communications or correspondence with competitors regarding the sale of generic prescription medications, and the marketing, sale, or pricing of certain products, generally for the period of 2005 through the dates of the subpoenas.”²⁹

[http://www.streetinsider.com/Corporate+News/Impax+Laboratories+\(IPXL\)+Receives+Subpoena+from+Connecticut+AG/9662945.html](http://www.streetinsider.com/Corporate+News/Impax+Laboratories+(IPXL)+Receives+Subpoena+from+Connecticut+AG/9662945.html)

²⁶ As West-Ward’s parent Hikma is a foreign entity and does not make disclosures to the SEC, it is unknown whether West-Ward also received a subpoena.

²⁷ <http://www.pharmacytimes.com/publications/issue/2014/December2014/Senate-Hearing- Investigates- Generic-Drug-Prices>.

²⁸ http://www.sec.gov/Archives/edgar/data/57725/000110465916094983/a15-24119_110q.htm.

²⁹ http://www.sec.gov/Archives/edgar/data/57725/000110465915062047/a15-13005_110k.htm.

80. Par's corporate filings reflect similar treatment as of March 12, 2015. Par stated that "[o]n December 5, 2014, we received a subpoena from the Antitrust Division of the DOJ requesting documents related to communications with competitors regarding our authorized generic version of Covis's Lanoxin® (digoxin) oral tablets."³⁰ Par's parent company, Endo International plc, stated in separate SEC filings that the grand jury subpoena "requests documents and information focused primarily on product and pricing information relating to Par's authorized generic version of Lanoxin (digoxin) oral tablets and Par's generic doxycycline products, and on communications with competitors and others regarding those products."³¹

81. Impax filed a Form 10-K for 2015, as well as a Form 10-Q on May 11, 2015, with similar statements. Impax indicated, *inter alia*, that "[o]n December 5, 2014, we received a subpoena from the Antitrust Division of the DOJ requesting documents related to communications with competitors regarding our authorized generic version of Covis's Lanoxin® (digoxin) oral tablets and our generic doxycycline products."³²

82. Allergan filed a Form 10-Q with similar statements as well: "[o]n June 25, 2015, the Company received a subpoena from the DOJ Antitrust Division seeking information relating to the marketing and pricing of certain of the Company's generic products and communications with competitors about such products."³³

83. Mylan's parent, Mylan N.V., filed a form 8-K on December 4, 2015, also with similar statements: "[o]n December 3, 2015, a subsidiary of Mylan N.V. ... received a subpoena

³⁰ <https://www.sec.gov/Archives/edgar/data/878088/000087808815000002/prx-20141231x10k.htm>

³¹ See, e.g., <http://www.sec.gov/Archives/edgar/data/1593034/000159303416000051/endorp-12312015x10k.htm>, at F-61.

³² http://www.sec.gov/Archives/edgar/data/1003642/000143774915009723/ipxl20150331_10q.htm, at 46.

³³ http://www.sec.gov/Archives/edgar/data/1578845/000156459015009844/agn-10q_20150930.htm, at 72.

from the Antitrust Division of the U.S. Department of Justice ... seeking information relating to the marketing, pricing and sale of our generic Doxycycline products and any communications with competitors about such products.”³⁴

84. Mylan N.V. further reported, in a Form 10-K filed on February 16, 2016, that “[o]n December 21, 2015, the Company received a subpoena and interrogatories from the Connecticut Office of the Attorney General seeking information relating to the marketing, pricing and sale of certain of the Company’s generic products (including Doxycycline) and communications with competitors about such products.”³⁵

85. The results of the federal grand jury investigation are as yet unknown, but DOJ policy is only to issue grand jury subpoenas in matters where illegal acts are confirmed. For instance, the DOJ’s *Antitrust Division Manual* sets forth “the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution.”³⁶ Since Defendants Lannett, Impax, Allergan, Mylan and Par, or their employees, have received federal grand jury subpoenas, this suggests that the grand jury found enough evidence to merit following through with subpoenas.

Collusion in the Generic Drug Market

86. The United States generic digoxin and doxycycline markets display various qualities that place them at risk of collusion and other anticompetitive behavior. Such qualities include: (1) high concentration; (2) high barriers to entry; (3) inelasticity of demand; (4) lack of available product substitutes; and (5) opportunities to conspire.

³⁴ <http://www.sec.gov/Archives/edgar/data/1623613/000119312515394875/d225442d8k.htm>, at Item 8.01.

³⁵ http://www.sec.gov/Archives/edgar/data/1623613/000162361316000046/myl10k_20151231xdoc.htm, at 160.

³⁶ <http://www.justice.gov/atr/public/divisionmanual/chapter3.pdf>, at Section F.1, III-82.

87. **Concentration in the Market.** Concentration in a market for goods creates susceptibility for collusion and other anticompetitive conduct. The markets for doxycycline and digoxin are both highly concentrated. Defendants each possess large market shares in their respective markets. Only a handful of competitors exist in each market.

88. Between October 2013 and January 2014, only Lannett, Impax and West-Ward manufactured generic digoxin tablets. Between January 2014 and the filing of this Complaint, even after the addition of multiple competitors, the only manufacturers of generic digoxin tablets remained as Lannett, Impax, Mylan, Par and West-Ward.

89. Meanwhile, the number of generic doxycycline producers declined over the past 20 years, heavily concentrating the doxycycline market. By October 2012, six manufacturers dominated: Lannett, Allergan, Mylan, Par, Sun and West-Ward. Only five of those produce doxycycline monohydrate: Lannett, Allergan, Mylan, Par and Sun. Only four produce doxycycline hyclate: Allergan, Mylan, Sun and West-Ward.

90. Statements such as Bedrosian's, discussed *supra*, showed that Lannett saw the market as only having three serious competitors: Impax, Par and Mylan.

91. The limited number of manufacturers in these markets facilitated Defendants' ability to coordinate prices of their generic drugs.

92. **High Barriers to Entry.** Typically, markets for goods that have high prices attract new competitors who can undercut competition by offering lower prices to the consuming public, thus mitigating effects of collusion. However, when a market has high barriers to entry, new competitors are less likely to enter the market. Accordingly, high barriers to entry facilitate collusive behavior.

93. The markets for generic digoxin tablets and doxycycline have high barriers to entry, including regulatory, intellectual property and financial hurdles.

94. All generic drug manufacturers must receive FDA approval prior to marketing and selling products. FDA approval requires, *inter alia*, the preparation and filing of an ANDA, which typically costs at least \$1 million.³⁷

95. Further, both state and federal law govern the operation of drug manufacturing facilities. The temporary closing of West-Ward's New Jersey plant stanching West-Ward's digoxin production capability, and it forced the company to spend \$39 million in remediation so that the plant could be used again. Such costs of doing business are another regulatory barrier to entry for potential competitors.

96. Intellectual property costs can include acquisition of and litigation over patent rights, either through the investigation of whether a drug compound is protected by a valid patent or for establishment of preferred generic treatment under the Hatch-Waxman Act. Transactional costs such as licensing deals can add further layers of costs; Lannett's contract with JSP, discussed above, provides an example of a trade of stock for supply of materials.

97. Finally, generic drugmakers also incur large research and development costs, high labor costs to retain employees with specialized skills and knowledge as well as professional certifications suitable for the work required, significant capital outlay for sufficient real estate and equipment, and other corporate financial requirements inherent to the pharmaceuticals industry.

98. The small number of competitors in the generic digoxin and doxycycline reflects these high barriers to entry. But new competitors entered in recent years, such as Par and Mylan.

³⁷ Testimony of Dr. Scott Gottlieb, Hearing on "Why Are Some Generic Drugs Skyrocketing in Price?" (Nov. 20, 2014), available at <https://www.aei.org/wp-content/uploads/2014/11/Gottlieb-Generic-Drug-Testimony-112014.pdf>, at 7

However, the price of generic digoxin and doxycycline has not responded in kind to the new entrants. Instead, prices have continued to rise or at least stabilize at supracompetitive levels. Further, public statements from industry leaders such as Lannett CEO Bedrosian have inferred cooperation among competitors to retain higher profits, such as his proclamation on investor calls that new competitor Par would be a “rational” competitor whose presence on the market would not put a dent in Lannett’s profits.

99. **Inelastic Demand.** In economics, elasticity of demand is the sensitivity of demand for a good to changes in other economic variables. Price elasticity is defined as the measure of how much the quantity demanded will change if price, a separate factor, changes. When price elasticity of demand is inelastic, prices increase because there will only be a small decrease in demand relative to the price increase, such that the increases make up for the decreases. Accordingly, total revenues rise in a market with price inelasticity of demand, even if raw sales figures go down.

100. Perfectly inelastic demand occurs when consumers would pay anything for a good, such as food or water, that is necessary for survival. Colluding entities can profit handsomely from goods that have nearly perfectly inelastic demand because they can charge whatever they wish knowing, first, that consumers will pay whatever price is charged, and second, that the collusion blocks any kind of competition that should serve to lower prices in that market.

101. As discussed above, both generic digoxin and doxycycline are considered “essential medicines” by the WHO. Generic digoxin is crucial to patients with cardiovascular issues. It must be taken daily, and its benefits quickly wear off if patients stop using it. Patients will accordingly pay whatever is charged for generic digoxin because its use is quite literally life or death for those who require it. Similarly, doxycycline is ubiquitous because it is effective in

treating a wide variety of conditions affecting both humans and animals, and because it was inexpensive prior to Defendants' anticompetitive conduct.

102. Accordingly, Defendants have been able to reap materially significant profits as a result of attacking the integrity of the markets for generic digoxin and doxycycline, as the market for both drugs displays a price inelasticity of demand.

103. **Lack of Available Product Substitutes.** Many patients require the use of digoxin or doxycycline, whose conditions are not treated effectively by the use of alternative products. Further, because very few suppliers of the raw materials used to manufacture these drugs exist, Defendants end up using many of the same suppliers. Thus, a high proportion of the available raw materials used to treat applicable medical conditions end up in Defendants' products, leaving consumers with a lack of available substitutes for anticompetitively priced digoxin and doxycycline.

104. **Opportunities to Conspire.** Defendants' collusive scheme works because each Defendant has constant and continuous opportunities to meet rather than to compete. All Defendants participate in some capacity in GPHA, a leading trade association for generic drug manufacturers and distributors. Current "Regular Members" of GPHA include Impax, Mylan, Par, Sun and West-Ward. "Regular Members" are "corporations, partnerships or other legal entities whose primary U.S. 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."³⁸ Several executive officers serve on GPHA's Board of Directors, including Mylan's Heather Bresch (who is currently Chairperson of GPHA), Impax's Marcy MacDonald, Par's Tony Pera and Sun's Jim Kedrowski. Representatives

³⁸ GPHA, Membership, <http://www.gphaonline.org/about/membership>.

from Defendants attended GPHA conferences in Florida and Maryland from at least 2012 through 2014.

105. Further, Lannett's Bedrosian has stated publicly that Defendants are comfortable with the level of competition for these products, and that each will act "rationally" not to compete on price. Such statements are improbable without communication and agreement between competitors.

106. Moreover, the DOJ's grand jury subpoenas also indicate that communication between Defendants was prevalent. The DOJ has stated that "prosecutors are taking a close look at trade associations as part of their investigation as having been one potential avenue for facilitating the collusion between salespeople at different generic producers."³⁹

ANTITRUST EFFECTS AND VIOLATIONS

107. During the Class Period, Plaintiff and Damages Class Members purchased substantial amounts of doxycycline and digoxin tablets indirectly from Defendants. Because of Defendants' illegal conduct set forth herein, the indirect purchasers have paid, and are still paying, artificially and substantially inflated prices for doxycycline and digoxin tablets.

108. Plaintiff and Damages Class Members have sustained substantial losses and resultant damage to their business and property in the form of overcharges. These losses and damage will continue to accrue until the anticompetitive conduct set forth herein ceases. The full amount of such damages will be determined at trial.

109. These losses are caused directly by Defendants' anticompetitive conduct, which had at least the following effects:

³⁹ <http://www.mergermarket.com/pdf/DoJ-Collusion-Generic-Drug-Prices-2015.pdf>.

- a. Price competition in the market for generic digoxin and doxycycline has been artificially restrained, suppressed or eliminated in the United States;
- b. Prices for generic digoxin and/or doxycycline sold by Defendants have been raised, fixed, maintained, or stabilized at artificially high and supracompetitive levels; and
- c. Purchasers of generic digoxin and/or doxycycline from Defendants have been deprived of the benefit of free and open competition in the market for generic digoxin and doxycycline.

110. At all relevant times, Defendants sold generic digoxin and doxycycline within the continuous and uninterrupted flow of interstate commerce. Defendants transmitted invoices, contract, funds and other forms of business communication throughout this time.

111. The pricing and regulation in the generic drugs industry means that overcharges at higher levels of the distribution chain get passed down to end-payors such as Plaintiff and Damages Class Members. Wholesalers and retailers who incurred higher charges for digoxin and doxycycline due to Defendants' behavior simply passed on those charges to the indirect purchasers.

112. During the Class Period, Defendants engaged in a continuing agreement, understanding, and conspiracy in restraint of trade to artificially raise, fix, maintain or stabilize the prices of generic drugs in the United States.

113. In forming, effectuating and operating the contract, combination or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially raise, fix, maintain, and/or stabilize the price of generic digoxin and/or doxycycline sold in the United States. These activities included the following:

- a. Defendants met in person or telephonically to discuss the price of generic digoxin and/or doxycycline in the United States;
- b. Defendants agreed during those meetings and conversations to charge set prices and otherwise to increase or maintain prices of generic digoxin and/or doxycycline sold in the United States;
- c. Defendants agreed during those meetings and conversations to fix the price of generic digoxin and/or doxycycline;
- d. Defendants issued price announcements in accordance with their agreements; and
- e. Defendants actually set prices in accordance with their agreements.

114. Defendants' anticompetitive behavior allowed them to charge the purchasing public prices higher than what they would have been able to charge otherwise.

115. Inflated prices for consumers purchasing doxycycline and digoxin were a direct, traceable and foreseeable result of Defendants' conspiracy.

116. Plaintiff and Damages Class Members purchased generic doxycycline and digoxin from Defendants or their affiliates or co-conspirators at inflated, supracompetitive prices during the period of the conspiracy.

117. Defendants' contract, combination or conspiracy constitutes an unreasonable restraint of interstate trade and commerce in violation of Sections 1 and 3 of the Sherman Act, 15 U.S.C. §§ 1, 3, and the laws of various states.

118. But for Defendants' anticompetitive conduct, Plaintiff and Damages Class Members would not have paid these inflated prices. Accordingly, Plaintiff and Damages Class Members have been injured in their business and property in that they paid more for generic doxycycline and/or digoxin than they would have paid in a competitive market.

CLASS ALLEGATIONS

119. Plaintiff brings this action on behalf of itself and as a class action under Rules 23(a) and 23(b)(2) of the Federal Rules of Civil Procedure, seeking equitable and injunctive relief on behalf of the following class (the “Nationwide Class”):

All persons and entities in the United States and its territories who purchased, paid and/or provided reimbursement for some or all of the purchase price for Defendants’ generic digoxin or generic doxycycline products during the Class Period, which runs from October 1, 2012, through the present or the date on which the anticompetitive effects subside.

This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, or municipalities with self-funded prescription drug plans; (c) all persons or entities who purchased Defendants’ generic digoxin or doxycycline products for purposes of resale or directly from Defendants; (d) fully insured health plans (*i.e.*, health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) any “flat co-pay” consumers whose purchases of Defendants’ generic digoxin or doxycycline products were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price; and (f) any judges or justices involved in this action and any members of their immediate families.

120. Plaintiff also brings this action on behalf of itself and as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages pursuant to the common law of unjust enrichment and the state antitrust, unfair competition and consumer protection laws of the states listed below (the “Indirect Purchaser States”)⁴⁰ on behalf of the following class (the “Damages Class”):

All persons and entities in the Indirect Purchaser States who purchased, paid and/or provided reimbursement for some or all of

⁴⁰ The “Indirect Purchaser States” are Alabama, Arizona, California, District of Columbia, Florida, Hawaii, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Missouri, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia and Wisconsin.

the purchase price for Defendants' generic digoxin or generic doxycycline products during the Class Period, which runs from October 1, 2012, through the present or the date on which the anticompetitive effects subside.

This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, or municipalities with self-funded prescription drug plans; (c) all persons or entities who purchased Defendants' generic digoxin or doxycycline products for purposes of resale or directly from Defendants; (d) fully insured health plans (i.e., health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) any "flat co-pay" consumers whose purchases of Defendants' generic digoxin or doxycycline products were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price; and (f) any judges or justices involved in this action and any members of their immediate families.

121. The Nationwide Class and the Damages Class are herein referred to as the "Classes." Members of each Class may be referred to as "Class Members."

122. The Classes are each individually sufficiently numerous. Plaintiff believes there are hundreds of thousands, if not millions, of members in each Class, in an amount to be determined in discovery and at trial. The identities of Class Members will be readily ascertainable through Defendants' business records kept in regular order.

123. Common questions of law and fact exist as to all Class Members. The effects of Defendants' conspiracy were generally applicable to all Class Members, thereby making relief appropriate with respect to the Classes as a whole. Such questions of law and fact common to the Classes include but are not limited to:

- a. Whether Defendants and their co-conspirators engaged in a combination and conspiracy among themselves to fix, raise, maintain and/or stabilize prices of generic digoxin and/or doxycycline;
- b. Whether Defendants and their co-conspirators allocated markets or customers for generic digoxin and/or doxycycline sold in the United States;

- c. Whether Defendants' conduct harmed competition in the markets for generic digoxin and/or doxycycline;
- d. Whether Defendants' conduct has substantially affected interstate and intrastate commerce;
- e. Whether, and to what extent, Defendants' conduct caused and/or is causing antitrust injury to the business or property of Plaintiff and Damages Class Members in the nature of overcharges;
- f. The quantum of overcharges paid by Plaintiff and Damages Class Members;
- g. The participants in the alleged conspiracy;
- h. The duration of the alleged conspiracy;
- i. The acts carried out by Defendants and their co-conspirators in furtherance of the conspiracy;
- j. Whether the alleged conspiracy violated the Sherman Act, as alleged in the First Claim for Relief;
- k. Whether the alleged conspiracy violated state antitrust and unfair competition laws, and/or state consumer protection laws, as alleged in the Second Claim for Relief;
- l. Whether the Defendants unjustly enriched themselves to the detriment of the Plaintiff and the Class Members, thereby entitling Plaintiff and the Class Members to disgorgement of all benefits derived by Defendants, as alleged in the Third Claim for Relief;
- m. Whether the conduct of the Defendants and their co-conspirators, as alleged in this Complaint, caused injury to the business or property of Plaintiff and the Class Members;
- n. The effect of the alleged conspiracy on the prices of generic digoxin and doxycycline sold in the United States during the Class Period;
- o. The appropriate injunctive and related equitable relief for the Nationwide Class; and
- p. The appropriate class-wide measure of damages for the Damages Class.

124. Plaintiff's claims are typical of the claims of the Class Members. Plaintiff will fairly and adequately protect the interests of the Classes. Plaintiff and all Class Members are all affected

by Defendants' wrongful conduct in the same way, in that they paid artificially inflated prices for generic digoxin and doxycycline purchased indirectly from the Defendants and/or their co-conspirators.

125. Plaintiff's claims arise out of the same common course of conduct giving rise to the claims of the other Class Members. Plaintiff's interests coincide with, and are not antagonistic to, those of the other Class Members. Plaintiff is represented by counsel who are competent and experienced in the prosecution of antitrust and class action litigation.

126. The questions of law and fact common to Class Members predominate over any questions affecting only individual members, including legal and factual issues relating to liability and damages.

127. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons or entities located throughout the United States to prosecute common claims in a single forum simultaneously, efficiently and without the unnecessary duplication of evidence, effort and expense that numerous individual actions would require. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining relief for claims that could not practicably be pursued individually, substantially outweigh any difficulties that may arise in management of this class action.

128. The prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for Defendants.

FIRST CLAIM FOR RELIEF
Violation of Sections 1 and 3 of the Sherman Act
(on behalf of Plaintiff and the Nationwide Class)

129. Plaintiff repeats the allegations set forth above as if fully set forth herein.

130. Defendants and unnamed conspirators entered into and engaged in a contract, combination, or conspiracy in unreasonable restraint of trade, in violation of Section 1 and Section 3 of the Sherman Act (15 U.S.C. §§ 1, 3).

131. The acts done by each Defendant as part of, and in furtherance of, their contract, combination, or conspiracy were authorized, ordered, or done by their officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

132. During the Class Period, Defendants and their co-conspirators entered into a continuing agreement, understanding and conspiracy in restraint of trade to establish a price floor and artificially fix, raise, stabilize, and control prices for generic digoxin and doxycycline, thereby creating anticompetitive effects in the markets therefor.

133. Defendants' acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for generic digoxin and doxycycline.

134. As a result of Defendants' unlawful conduct, Plaintiff and other similarly situated indirect purchasers in the Nationwide Class who purchased generic digoxin and doxycycline have been harmed by being forced to pay inflated, supracompetitive prices for generic digoxin and doxycycline.

135. In formulating and carrying out the alleged agreement, understanding, contract, combination and conspiracy, Defendants and their co-conspirators did those things that they combined and conspired to do, including but not limited to the acts, practices and course of conduct set forth herein.

136. Defendants' conspiracy had the following effects, among others:

- a. Price competition in the market for generic digoxin and doxycycline has been artificially restrained, suppressed or eliminated in the United States;
- b. Defendants' prices for generic digoxin and doxycycline have been raised, fixed, maintained, or stabilized at artificially high and supracompetitive levels; and
- c. Purchasers of generic digoxin and/or doxycycline from Defendants have been deprived of the benefit of free and open competition in the market for generic digoxin and doxycycline.

137. Plaintiff and members of the Nationwide Class have been and will continue to be injured in their business and property by paying more for generic digoxin and doxycycline purchased indirectly from Defendants and the co-conspirators than they would have paid and will pay in the absence of the conspiracy.

138. The alleged contract, combination or conspiracy violates the federal antitrust laws, including the Sherman Act.

139. Plaintiff and members of the Nationwide Class are entitled to injunctive relief, preventing and restraining Defendants from committing the violations alleged herein.

SECOND CLAIM FOR RELIEF
Violation of State Antitrust Statutes
(on behalf of Plaintiff and the Damages Class)

140. Plaintiff repeats the allegations set forth above as if fully set forth herein.

141. During the Class Period, Defendants and their co-conspirators engaged in a continuing contract, combination or conspiracy with respect to the sale of generic digoxin and doxycycline in unreasonable restraint of trade and commerce, in violation of the various state antitrust and consumer protection statutes set forth below.

142. The contract, combination, or conspiracy consisted of an agreement among the Defendants and their co-conspirators to fix, raise, inflate, stabilize, and/or maintain at artificially

supracompetitive prices for generic digoxin and doxycycline and to allocate customers for generic digoxin and doxycycline in the United States.

143. In formulating and effectuating this conspiracy, Defendants and their co-conspirators performed acts in furtherance of the combination and conspiracy, including: (a) participating in meetings and conversations among themselves in the United States during which they agreed to price generic digoxin and doxycycline at specified levels, and otherwise to fix, increase, maintain, or stabilize effective prices paid by Plaintiff and members of the Damages Class with respect to generic digoxin and doxycycline provided in the United States; and (b) participating in meetings and conversations among themselves in the United States to implement, adhere to, and enforce their unlawful agreements.

144. Defendants and their co-conspirators engaged in the actions described above for the purpose of carrying out their unlawful agreements to fix, increase, maintain, or stabilize prices of generic digoxin and doxycycline.

145. Defendants' knowingly and willfully carried out the anticompetitive acts described above. There was and is no legitimate, non-pretextual, procompetitive business justification for Defendants' contract, conspiracy or combination that outweighs its harmful effects. Accordingly, these acts constitute violations or flagrant violations of the antitrust laws of various states.

146. Alternatively, during at least the Class Period, there has been a gross disparity between the price that Plaintiff and Damages Class Members paid for generic digoxin and doxycycline compared to what they would have paid under competitive market conditions, which should and would have been present but for Defendants' unlawful and inequitable conduct.

147. Said disparity was a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, from which Plaintiff and Damages

Class Members were deprived of the opportunity to purchase competitively priced generic digoxin and doxycycline from Defendants and were forced to pay higher prices for generic digoxin and doxycycline than they otherwise would have paid.

148. Accordingly, Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state consumer protection statutes.

149. By engaging the foregoing conduct, Defendants have threatened the business or property of Plaintiff and thus violated the antitrust laws of various states, and/or they have participated in unfair competition or unfair or deceptive acts or practices in violation of state unfair and deceptive trade practices and consumer protection statutes of various states, both of which are listed herein:

- a. Ala. Code §§ 8-10-1 and 6-5-60(a), with respect to purchases in Alabama by Damages Class Members;
- b. Ariz. Rev. Stat. 44-1401, *et seq.*, with respect to purchases in Arizona Damages Class Members;
- c. Cal. Bus. & Prof. Code § 16700 *et seq.*, with respect to purchases in California by Damages Class Members;
- d. D.C. Code § 28-4501 *et seq.*, with respect to purchases in the District of Columbia by Damages Class Members;
- e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by Damages Class Members;
- f. Haw. Rev. Stat. § 480 *et seq.*, with respect to purchases in Hawaii by Damages Class Members;
- g. Iowa Code § 553 *et seq.*, with respect to purchases in Iowa Damages Class Members;
- h. Kan. Stat. Ann. § 50-101 *et seq.*, with respect to purchases in Kansas by Damages Class Members;
- i. Me. Rev. Stat. Ann. Tit. 10, § 1101 *et seq.*, with respect to purchases in Maine by Damages Class Members;

- j. Mich. Comp. Laws § 445.772 *et seq.*, with respect to purchases in Michigan by Damages Class Members;
- k. Minn. Stat. § 325D.49 *et seq.*, with respect to purchases in Minnesota by Damages Class Members;
- l. Miss. Code Ann. § 75-21-1(a) *et seq.*, with respect to purchases in Mississippi by Damages Class Members;
- m. Mo. Rev. Stat. § 407.020, *et seq.*, with respect to purchases in Missouri by Damages Class Members;
- n. Neb. Rev. Stat. § 59-801 *et seq.*, with respect to purchases in Nebraska by Damages Class Members;
- o. Nev. Rev. Stat. Ann. § 598A *et seq.*, with respect to purchases in Nevada by Damages Class Members, in that at least thousands of sales of Defendants' PSPs took place in Nevada, purchased by Nevada consumers at supracompetitive prices caused by Defendants' conduct;
- p. N.H. Rev. Stat. Ann. § 356:1 *et seq.*, with respect to purchases in New Hampshire by Damages Class Members;
- q. N.M. Stat. Ann. § 57-1-1 *et seq.*, with respect to purchases in New Mexico by members of the Class;
- r. N.Y. Gen. Bus. Law § 340 *et seq.*, with respect to purchases in New York by Damages Class Members;
- s. N.D. Cent. Code § 51-08.1-01 *et seq.* with respect to purchases in North Dakota by Damages Class Members;
- t. Or. Rev. Stat. § 646.705 *et seq.*, with respect to purchases in Oregon by Damages Class Members;
- u. 73 P.S. 201-1, *et seq.*, with respect to purchases in Pennsylvania by Damages Class Members;
- v. R.I. Gen. Laws § 6-36-11(a), with respect to purchases in Rhode Island by Damages Class Members;
- w. S.D. Codified Laws § 37-1 *et seq.*, with respect to purchases in South Dakota by Damages Class Members;

- x. Utah Code Ann. § 76-10-3101 *et seq.*, with respect to purchases in Utah by Damages Class Members who are either Utah residents or Utah citizens;
- y. Vt. Stat. Ann. Tit. 9, § 2453, *et seq.*, with respect to purchases in Vermont by Damages Class Members; and
- z. Wis. Stat. § 133.01 *et seq.*, with respect to purchases in Wisconsin by Damages Class Members, in that the actions alleged herein substantially affected the people of Wisconsin, with at least thousands of consumers in Wisconsin paying substantially higher prices for generic digoxin and/or doxycycline in Wisconsin.

THIRD CLAIM FOR RELIEF

Unjust Enrichment

(on behalf of Plaintiff and the Damages Class)

150. Plaintiff repeats the allegations set forth above as if fully set forth herein.

151. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

152. As a result of their unlawful conduct described above, Defendants have and will continue to be unjustly enriched. Defendants have been unjustly enriched by the receipt of, at a minimum, unlawfully inflated prices and unlawful profits on generic digoxin and generic doxycycline.

153. Defendants' financial benefits are traceable to Plaintiff's and Damages Class Members' overpayments for generic digoxin and doxycycline.

154. Plaintiff and Damages Class Members have conferred and continue to confer an economic benefit upon Defendants in the nature of profits resulting from the unlawful overcharges described herein, to the economic detriment of Plaintiff and Damages Class Members.

155. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments

made by Plaintiff and the members of the Damages Class for generic digoxin and generic doxycycline manufactured by Defendants during the Class Period.

156. It would be futile for Plaintiff and Damages Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased generic digoxin and doxycycline, as those intermediaries are not liable and would not compensate Plaintiff and Damages Class Members for Defendants' unlawful conduct.

157. The economic benefit Defendants derived from overcharging Plaintiff and Damages Class Members for generic digoxin and doxycycline is a direct and proximate result of Defendants' unlawful and anticompetitive practices.

158. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to Plaintiff and Damages Class Members, who paid and continue to pay artificially inflated prices that inured to Defendants' benefit.

159. It would be inequitable under unjust enrichment principles under the laws of each state in the United States as well as the District of Columbia for Defendants to retain any of the overcharges Plaintiff and Damages Class Members paid for generic digoxin and doxycycline that were derived from Defendants' unfair, anticompetitive and unlawful methods, acts and trade practices.

160. Defendants are aware of and appreciate the benefits that Plaintiff and the Damages Class Members have bestowed upon them.

161. Defendants should be ordered to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and Damages Class Members, who collectively have no adequate remedy at law.

162. Plaintiff and Damages Class Members are entitled to the amount of Defendants' ill-gotten gains resulting from their unlawful, unjust, and inequitable conduct, and to the establishment of a constructive trust consisting of such amount, from which Plaintiff and Damages Class Members may make claims on a *pro rata* basis.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the proposed Classes demands judgment that:

A. The Court determine that this action may be maintained as a class action under Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Civil Procedure, be given to each and every member of the Class;

B. That the unlawful conduct, contract, conspiracy, or combination alleged herein be adjudged and decreed: (a) an unreasonable restraint of trade or commerce in violation of Sections 1 and 3 of the Sherman Act; (b) a *per se* violation of Sections 1 and 3 of the Sherman Act; (c) an unlawful combination, trust, agreement, understanding and/or concert of action in violation of the state antitrust and unfair competition and consumer protection laws as set forth herein; and (d) acts of unjust enrichment by Defendants as set forth herein;

C. Plaintiff and Damages Class Members recover damages, to the maximum extent allowed under such laws, and that joint and several liability be found to accrue against Defendants in an amount to be trebled to the extent such laws permit;

D. Plaintiff and Damages Class Members recover damages, to the maximum extent allowed by such laws, in the form of restitution and/or disgorgement of profits unlawfully gained from them;

E. Defendants, their affiliates, successors, transferees, assignees and other officers, directors, partners, agents and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be permanently enjoined and restrained from in any manner continuing, maintaining or renewing the conduct, contract, conspiracy, or combination alleged herein, or from entering into any other contract, conspiracy, or combination having a similar purpose or effect;

F. Plaintiff and Damages Class Members be awarded restitution, including disgorgement and restitution of profits Defendants obtained as a result of their acts of unfair competition and acts of unjust enrichment, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

G. Plaintiff and the Class Members be awarded pre- and post- judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of this Complaint;

H. Plaintiff and the Class Members recover their costs of suit, including reasonable attorneys' fees, as provided by law; and

I. Plaintiff and the Class Members have such other and further relief as the case may require and the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all issues so triable, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure.

Dated: April 26, 2016

Respectfully submitted,

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