

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

<p>IN RE: GENERIC PHARMACEUTICALS PRICING ANTITRUST LITIGATION</p>	<p>MDL 2724 16-MD-2724</p>
<p>LIDOCAINE/PRILOCAINE</p> <p>THIS DOCUMENT RELATES TO:</p> <p><i>DIRECT PURCHASER ACTIONS</i></p>	<p>HON. CYNTHIA M. RUFÉ</p>
<p>ROCHESTER DRUG CO-OPERATIVE, INC. and FWK HOLDINGS, L.L.C., on behalf of themselves and all others similarly situated,</p> <p style="text-align: center;">Plaintiffs,</p> <p>v.</p> <p>AKORN, INC; FOUGERA PHARMACEUTICALS INC.; HI-TECH PHARMACAL; IMPAX LABORATORIES, INC.; and SANDOZ, INC.,</p> <p style="text-align: center;">Defendants.</p>	<p>Civil Action No.</p> <p>JURY TRIAL DEMANDED</p>

**DIRECT PURCHASER CLASS ACTION COMPLAINT**

**TABLE OF CONTENTS**

	<b><u>Page</u></b>
I. INTRODUCTION .....	1
II. JURISDICTION AND VENUE .....	3
III. PARTIES .....	4
A. Plaintiffs .....	4
B. Defendants .....	4
C. Agents and Co-Conspirators .....	5
IV. INTERSTATE TRADE AND COMMERCE .....	6
V. FACTUAL ALLEGATIONS .....	7
A. The Generic Drug Market Is a Commodities Market, Where Competition Is Expected to be Keen. ....	7
1. Generic drugs should lead to lower prices.....	7
2. The prescription drug prices are governed in the U.S. by institutional safeguards, which are intended to keep drug prices competitive.....	10
B. Consolidation Has Reduced the Number of Competitors in the Generic Pharmaceutical Industry.....	12
C. Defendants’ Dominance in the Generic Lidocaine/Prilocaine Cream Market Permitted Them to Fix Prices, and Their Abrupt Price Increases Are Otherwise Inexplicable. ....	12
1. Defendants’ collective market dominance permitted them to collude.....	13
2. Defendants’ effective prices were remarkably stable before skyrocketing in the Class Period.....	14
3. There are no shortages or other market changes that would justify the capsule price increases. ....	16
D. Defendants’ Anticompetitive Activities .....	17

1.	Defendants have ample opportunities to communicate through trade organizations, and have availed themselves of those opportunities to collude.....	18
2.	Industry Commentary .....	19
E.	Government Investigation.....	20
VI.	THE LIDOCAINE/PRILOCAINE CREAM MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION.....	27
VII.	CLASS ACTION ALLEGATIONS .....	31
VIII.	ANTITRUST INJURY .....	33
IX.	CLAIM FOR RELIEF – VIOLATION OF SECTION 1 OF THE SHERMAN ACT.....	34
	PRAYER FOR RELIEF .....	35
	JURY TRIAL DEMANDED .....	36

## I. INTRODUCTION

1. Plaintiffs Rochester Drug Co-Operative, Inc. and FWK Holdings, L.L.C., 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 lidocaine/prilocaine cream directly from Defendants.

2. This is a civil action seeking treble damages arising out of the Defendants' unlawful scheme to fix, maintain, and stabilize the prices, rig bids, and allocate customers for generic lidocaine/prilocaine cream. As set forth below, Defendants' scheme violates Section 1 of the Sherman Act, 15 U.S.C. § 1.

3. Lidocaine/prilocaine cream is a local anesthetic commonly used before minor procedures.

4. Generic versions of lidocaine/prilocaine cream have been available in the United States for years. Defendants dominate the market for lidocaine/prilocaine cream.

5. Beginning on approximately March 1, 2014, and continuing today (the "Class Period"), Defendants and co-conspirators engaged in an overarching anticompetitive scheme in the market for generic lidocaine/prilocaine cream to artificially inflate prices through unlawful agreements between and among would-be competitors. Defendants caused the price of lidocaine/prilocaine cream 30 mg to dramatically increase as much as [REDACTED] higher than February 2014 prices, as alleged in paragraphs 58-69. These increases were the result of an agreement among Defendants to increase pricing and restrain competition for the sale of lidocaine/prilocaine cream in the United States. As alleged in paragraphs 74-78 below, the agreement was furthered by discussions held at trade association meetings and events.

6. Plaintiffs' allegations are based on personal knowledge of these matters relating to themselves and upon information and belief as to all other matters. Part of Plaintiffs'

allegations are based on information made public during government investigations of Defendants for alleged unlawful conduct in the generic drug industry.

7. Defendants' dramatic and unexplained price increases have resulted in extensive and ongoing 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 40 states' Attorneys General, as alleged in paragraphs 82-98.

8. The DOJ's 2014 investigation followed a congressional hearing and investigation prompted by the National Community Pharmacists Association's ("NCPA") January 2014 correspondence to the U.S. Senate Health Education Labor and Pensions ("HELP") Committee and the U.S. House Energy and Commerce Committee requesting hearings on the significant spike in generic drug pricing.<sup>1</sup> The NCPA's news release reports price hikes on essential generic drugs exceeding 1,000% in some instances, according to its survey of over a thousand community pharmacists, resulting in 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.

9. The direct, foreseeable, and intended consequence of Defendants' anticompetitive scheme was to cause Plaintiffs and Class Members to pay more for generic lidocaine/prilocaine cream than they otherwise would have paid in the absence of Defendants' unlawful conduct. Were it not for Defendants' collusion to restrain or eliminate competition by engaging in a conspiracy to foreclose competition in the United States market for generic lidocaine/prilocaine

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<sup>1</sup> 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>.

cream, Plaintiffs and Class Members would not have paid supracompetitive prices for generic lidocaine/prilocaine cream.

10. Plaintiffs seek damages incurred due to Defendants' and co-conspirators' violations of Section 1 of the Sherman Act, 15 U.S.C. § 1.

## II. JURISDICTION AND VENUE

11. 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).

12. Venue is proper in this District pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391(b) and (c), because during the Class Period the Defendants transacted business throughout the United States, including in this District.

13. During the Class Period, Defendants sold and distributed generic drugs in a continuous and uninterrupted flow of interstate commerce, which included sales of generic lidocaine/prilocaine cream 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.

14. 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 generic lidocaine/prilocaine cream 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 generic lidocaine/prilocaine cream 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

15. Plaintiff FWK Holdings, L.L.C. (“FWK”) is an Illinois limited liability company located in Glen Ellyn, Illinois. Plaintiff 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 direct purchases of lidocaine/prilocaine cream during the Class Period from one or more of the Defendants at artificially and unlawfully inflated prices. As a result of Defendants’ antitrust conspiracy, FWK/Kerr paid supracompetitive prices for lidocaine/prilocaine cream and was injured by the illegal conduct alleged herein.

16. Plaintiff Rochester Drug Co-Operative, Inc. (“RDC”) is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business in Rochester, New York. During the Class Period RDC purchased lidocaine/prilocaine cream directly from one or more of the Defendants during the Class Period at artificially and unlawfully inflated prices. As a result of Defendants’ antitrust conspiracy, RDC paid supracompetitive prices for lidocaine/prilocaine cream and was injured by the illegal conduct alleged herein.

#### B. Defendants

17. Defendant Akorn, Inc. is a Louisiana corporation with its principal place of business in Lake Forest, Illinois. Akorn marketed and sold lidocaine/prilocaine cream to customers in this District and in other locations in the United States.

18. Defendant Hi-Tech Pharmacal Co., Inc. is a Delaware corporation with its principal place of business in Amityville, New York. Akorn acquired Hi-Tech in August 2013, in part to broaden its product line into topical creams and ointments. Hi-Tech marketed and sold

lidocaine/prilocaine cream to customers in this District and in other locations in the United States.

19. Defendant Impax Laboratories, Inc. is a Delaware corporation with its principal place of business in Hayward, California. Impax manufactures and distributes lidocaine/prilocaine cream through its Global Pharmaceuticals division. During the Class Period, Impax marketed and sold lidocaine/prilocaine cream to customers in this District and in other locations in the United States.

20. Defendant Sandoz Inc. is a Colorado corporation with its principal place of business in Princeton, New Jersey. Sandoz develops, manufactures, and markets prescription drugs, including lidocaine/prilocaine cream, throughout the United States.

21. Defendant Fougera Pharmaceuticals Inc. is a New York corporation with its principal place of business in Melville, New York. Fougera is a specialty dermatology generic pharmaceutical company and a wholly owned subsidiary of Defendant Sandoz, Inc. In this Complaint, Fougera and Sandoz will be referred to collectively as “Sandoz.” Sandoz marketed and sold lidocaine/prilocaine cream to customers in this District and in other locations in the United States.

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

**C. Agents and Co-Conspirators**

23. Each Defendant acted as the principal of, or agent for, all other Defendants with respect to the acts, violations, and common course of conduct described in this Complaint.

24. 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.

25. 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.

26. 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 monopolization as described herein.

27. 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.

28. 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**

29. Defendants are the leading manufacturers and suppliers of lidocaine/prilocaine cream sold in the United States.

30. Lidocaine/prilocaine cream is produced by or on behalf of Defendants or their affiliates in the United States or overseas.

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

32. 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.

33. Defendants' and their co-conspirators' conduct, including the marketing and sale of lidocaine/prilocaine cream, 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.

34. 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 lidocaine/prilocaine cream within the United States.

35. Defendants' agreement to inflate, fix, raise, maintain, or artificially stabilize prices and allocate customers for lidocaine/prilocaine cream, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing lidocaine/prilocaine cream prices and customer allocation, 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.

36. Generic drugs provide a lower-cost but bioequivalent alternative to brand drugs. Before any generic drug can be marketed, the Food and Drug Administration ("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.”<sup>2</sup>

37. To obtain marketing approval for a generic drug, an Abbreviated New Drug Application (“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 itself. Upon the FDA’s determination that bioequivalence to the brand has been established, the ANDA will be approved and may be marketed in the U.S. as substitutable with the RLD.

38. Although equivalent from a safety and efficacy standpoint, generic versions of brand drugs are priced significantly below their brand counterparts, and because of this 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.

39. 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

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<sup>2</sup> FDA, *Drugs@FDA Glossary of Terms*, available at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G>.

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, and the brand drug's share of the overall market erodes even faster. These cost reductions to drug purchasers were the very legislative purpose behind the abbreviated regulatory pathway for generic approval.<sup>3</sup>

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

41. A Federal Trade Commission ("FTC") study found that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices." A mature generic market, such as the market for lidocaine/prilocaine cream, 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.<sup>4</sup> Over time, generics' pricing nears the generic manufacturers' marginal costs.

42. 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

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<sup>3</sup> H.R. Rep. No. 98-857, pt. 1, at 1 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

<sup>4</sup> *See, e.g.,* FTC, *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."); 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>.

that the use of generic drugs saved the United States healthcare system \$1.68 trillion between 2005 and 2014.<sup>5</sup>

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

43. 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, the pricing for prescription drugs is determined by reimbursement agreements between these prescription drug payors, *i.e.*, health plans and their prescription benefit managers, and the pharmacies that dispense drugs to the payors' insured customers.

44. 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 do not include discounts that may be provided, *e.g.*, for volume sales.

45. 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 and/or dispensing fee. Over time, however, it was learned that the list price for most generic drugs published by their

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<sup>5</sup> GENERIC PHARM. ASS'N, *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](http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf).

manufacturers was substantially higher than the actual cost incurred by pharmacies to acquire the drugs.

46. To reduce the cost of prescription drugs to the public, prescription drug payors developed Maximum Allowable Cost prices (“MACs”) to determine the amount that pharmacies would be reimbursed for dispensing generic pharmaceuticals. The MAC price refers to the maximum amount that a payor will reimburse a pharmacy for a given strength and dosage of a generic drug or brand drug that has a generic version available. A MAC price thus represents the upper limit that a prescription drug payor will pay a pharmacy for a generic drug.

47. Payors set the MAC pricing of a drug based on a variety of factors, including, most significantly, the lowest acquisition cost for each generic drug paid by retail pharmacies purchasing from a wholesaler for each of a drug’s generic versions.

48. MAC pricing is designed to incentivize pharmacies to purchase the least costly version of a generic drug available on the market, without regard to the manufacturer’s list price. Because the reimbursement amount to a pharmacy is limited by the MAC price for a generic drug and each of its equivalents regardless of the pharmacy’s acquisition cost, a pharmacy’s profit will be reduced, or lost altogether, if it purchases other than the lowest cost generic product. Alternatively, if a retail pharmacy purchases the lowest priced generic version of the drug, it will maximize its profit.

49. MAC pricing also incentivizes an individual generic manufacturer to refrain from unilaterally increasing its prices. Because MAC pricing bases reimbursement on the generic drug’s lowest acquisition cost, a generic manufacturer that increases its price for a drug will lose sales to a competing generic manufacturer whose price remains constant.

50. Consequently, in the absence of coordinated pricing activity among generic manufacturers, an individual generic manufacturer cannot significantly increase its price without incurring the loss of a significant volume of sales.

**B. Consolidation Has Reduced the Number of Competitors in the Generic Pharmaceutical Industry.**

51. Since 2005, consolidation has generally reduced the number of competitors in generic pharmaceutical markets. Consolidation reduces the number of potential competitors, rendering the market ripe for collusion.

52. Generic pharmaceutical industry leader Teva, for example, acquired Ivax Corporation in 2006, Barr Laboratories in 2008, Ratiopharm—Germany’s second largest generic drug producer—in 2010, and Allergan’s generics business (including Actavis generics) in 2016. Other major transactions that occurred during the same period include Watson Pharmaceuticals’ acquisition of Andrx Corporation in 2006; Daiichi Sankyo’s purchase of a majority stake in Ranbaxy in 2008; Endo’s 2010 acquisition of Qualitest; Perrigo’s acquisition of Paddock Laboratories, Inc. in 2011; and Sandoz’s acquisition of Fougera in 2012.

**C. Defendants’ Dominance in the Generic Lidocaine/Prilocaine Cream Market Permitted Them to Fix Prices, and Their Abrupt Price Increases Are Otherwise Inexplicable.**

53. The market for generic lidocaine/prilocaine cream is mature, as generic versions have been on the market for decades. In 2015 alone, total revenue from direct purchases of lidocaine/prilocaine cream 30 mg was nearly [REDACTED]<sup>6</sup>

54. A mature generic market, such as the market for lidocaine/prilocaine cream, has several generic competitors. Because each generic is readily substitutable for another generic of

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<sup>6</sup> Revenue, unit sales, and effective prices are obtained from QuintilesIMS Inc. (“IMS Health”). IMS Health is the largest vendor of physician prescribing data in the United States and is widely relied upon in the pharmaceutical industry and elsewhere. “Effective prices” represent actual transaction prices, as reported by IMS Health.

the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers.<sup>7</sup> Over time, generics' pricing nears the generic manufacturers' marginal costs.

55. At all times relevant for this lawsuit, there have been at least three manufacturers of generic lidocaine/prilocaine cream 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 would not increase as they did here absent anticompetitive conduct. Drastic increases in lidocaine/prilocaine cream prices are themselves suggestive of Defendants' collective market dominance: if they did not already dominate the market, pricing excesses would be disciplined by losing market share to non-colluding competitors.

**1. Defendants' collective market dominance permitted them to collude.**

56. During the Class Period, the Defendants dominated the lidocaine/prilocaine cream market. [REDACTED]

[REDACTED]

57. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>7</sup> See, e.g., FTC, *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.”); 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>.



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

58. Before the Class Period, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

59. [REDACTED]

[REDACTED] Defendants Hi-Tech, Impax, and Sandoz/Fougera attended a three-day generic pharmaceutical manufacturers conference in late February in Orlando, Florida.

[REDACTED]

60. **Sandoz:** [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

61. [REDACTED]

[REDACTED]

62. [REDACTED]

[REDACTED]  
[REDACTED]

63. **Impax:** [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

64. [REDACTED]

[REDACTED]

65. **Akorn:** [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

66. [REDACTED]

[REDACTED]

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8 [REDACTED]

67. [REDACTED]

68. **Hi-Tech:** [REDACTED]

69. [REDACTED]

**3. There are no shortages or other market changes that would justify the price increases.**

70. There are no potential drug shortages or supply disruptions, or any other lawful market phenomena, to explain the price increases. Federal law requires mandatory drug shortage reporting for drug manufacturers.<sup>9</sup>

71. Lidocaine/prilocaine cream is not listed on the FDA's list of Current and Resolved Drug Shortages and Discontinuations Reported to FDA. Lidocaine/prilocaine cream also does not appear on any archived lists of the American Society of Health-System Pharmacists ("ASHP") Current Shortage Bulletins from 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 lidocaine/prilocaine cream.

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<sup>9</sup> Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. No. 112-144, §§ 1001-1008, 126 STAT. 995, 1099-1108.

72.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**D. Defendants' Anticompetitive Activities**

73. During the Class Period, Defendants conspired, combined, and contracted to fix, raise, maintain, and stabilize prices at which generic lidocaine/prilocaine cream 30 mg would be sold, 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 generic lidocaine/prilocaine cream.

**1. Defendants have ample opportunities to communicate through trade organizations, and have availed themselves of those opportunities to collude.**

74. 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 organizations have been used as forums for collusion between sales personnel among competing generic drug companies.<sup>10</sup>

75. For example, the Generic Pharmaceutical Association (“GPhA”) is the “leading trade association for generic drug manufacturers.”<sup>11</sup> 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.

76. 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

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<sup>10</sup> 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>.

<sup>11</sup> Ass’n for Accessible Medicines, *The Association*, available at <http://www.gphaonline.org/about/the-gpha-association>. While MDL 2724 has been pending, the GPhA changed its name to the Association for Accessible Medicines. 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/>.

and regulators, and peer-to-peer connections.”<sup>12</sup> GPhA’s “member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year.”

77. Several of Defendants’ high-ranking corporate officers have served on GPhA’s Board of Directors, including Impax’s Carol Ben-Maimon and Marcy Macdonald, Sandoz’s Peter Goldschmidt and Don DeGolyer, and Fougera’s David Klaum. Jeff Glazer, who has pleaded guilty to federal criminal charges relating to the price fixing and other anticompetitive activity concerning generic pharmaceuticals, of Heritage Pharmaceuticals, also served on GPhA’s Board of Directors during the same time period.

78. Defendants each attended the GPhA meetings shortly before and during the Class Period, including the Fall Technical Conference in Bethesda, Maryland, from October 28-30, 2013, and the annual meeting in Orlando, Florida, on February 19-21, 2014.

## **2. Industry Commentary**

79. Comments from industry analysts suggest manufacturers’ alternative explanations for the price hikes (*e.g.*, supply disruptions) are mere pretext, intended to shroud the Defendants’ conspiratorial conduct and ends. For instance, Richard Evans at Sector & Sovereign Research recently 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 characteristics – low sales due to either very low prices or very low volumes – accommodate price inflation.”<sup>13</sup>

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<sup>12</sup> Ass’n for Accessible Medicines, *Membership*, available at <http://www.gphaonline.org/about/membership>.

<sup>13</sup> 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/>; Sector & Sovereign Research Note (Apr. 21, 2015), available at <http://www.sector-sovereign.com/abccahmck-us-generic-inflation-continues-in-1q15/>.

80. In 2015 the *Financial Times* reported on Defendant Mylan's planned merger with Teva and quoted Mylan as cautioning that it could be blocked by regulators concerned "about pricing power and potential for drug shortages."<sup>14</sup>

81. One 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."<sup>15</sup> A U.S. Government Accountability Office Report also noted similar "extraordinary price increases" across many generic drugs in recent years that could not be linked to any particular cause.<sup>16</sup>

#### **E. Government Investigations**

82. Defendants' conduct in generic drug pricing is under investigation by the federal government, including the U.S. Senate and DOJ, as well as state governments.

83. Following the DOJ opening its criminal investigation into Defendants' conduct on or about November 3, 2014, grand jury subpoenas have been issued to at least 14 generic drug companies. Recently, generic drug manufacturer Perrigo Company plc disclosed in a press release that "search warrants were executed at the Company's corporate offices associated with an ongoing investigation by the U.S. Department of Justice Antitrust Division related to drug pricing in the pharmaceutical industry."<sup>17</sup> The press release also noted that, "As has been

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<sup>14</sup> David Crow, *Teva bids for Mylan amid pressure on copycat drugmakers*, THE FINANCIAL TIMES (May 12, 2015), available at <https://www.ft.com/content/8ff2fc5a-f513-11e4-8a42-00144feab7de>.

<sup>15</sup> David Belk, MD, *Generic Medication Prices*, TRUE COST OF HEALTH-CARE available at [http://truecostofhealthcare.net/generic\\_medication\\_prices/](http://truecostofhealthcare.net/generic_medication_prices/).

<sup>16</sup> U.S. Government Accountability Office Report to Congressional Requesters, *Generic Drugs Under Medicare* (Aug. 2016), available at <http://www.gao.gov/assets/680/679055.pdf>.

<sup>17</sup> Perrigo Website, Press Release, *Perrigo Discloses Investigation* (May 2, 2017), available at <http://perrigo.investorroom.com/2017-05-02-Perrigo-Discloses-Investigation>.

previously disclosed by a number of companies, the Antitrust Division has been looking at industry-wide pricing practices.”

84. Impax's 2015 annual report dated February 22, 2016 disclosed that one of its sales representatives received a grand jury subpoena from the DOJ and that the company had also received a grand jury subpoena from DOJ for documents concerning sales, marketing, and pricing of certain generic prescription medications concerning digoxin tablets and other pharmaceuticals.

85. According to *Bloomberg*, Sandoz received a Justice Department subpoena in March 2016. The company reported that it relates to the industry-wide investigation into generic drug pricing in the United States.<sup>18</sup>

86. The fact that these companies or their employees 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 “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.”<sup>19</sup> The staff request needs to be approved by the relevant field chief and is then sent to the Antitrust Criminal Enforcement Division.<sup>20</sup> “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

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<sup>18</sup>Ari Altstedter, *NYPD Union Goes After Drug Prices Amid DOJ Pharma Probe*, BLOOMBERG (Nov. 17, 2016), available at <https://www.bloomberg.com/news/articles/2016-11-17/nypd-union-goes-after-drug-prices-amid-doj-pharma-investigation>.

<sup>19</sup> U.S. Dep't of Justice, ANTITRUST DIVISION MANUAL (5th ed. 2015) at III-82.

<sup>20</sup> *Id.*



investigation.”<sup>21</sup> “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.”<sup>22</sup> Thus, Defendants’ and their representatives’ receipt of federal grand jury subpoenas is an indication that antitrust offenses have occurred.

87. That a target has reportedly applied for leniency is also significant. 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 receive no benefit from 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.*

88. On December 12, 2016, the DOJ filed the first two criminal charges stemming from this investigation. 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.).

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<sup>21</sup> *Id.* at III-83.

<sup>22</sup> *Id.*

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 allocate customers for generic glyburide and doxycycline. On January 9, 2017, both Mr. Glazer and Mr. Malek pleaded guilty to the charges. Sentencing for both Mr. Glazer and Mr. 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 a related case shows that Mr. Malek compiled a large list of generic drugs and instructed employees to contact competitors to reach agreement to increase prices and allocate customers, and that some of its competitors were willing to reach such agreement.

89. The DOJ has intervened in numerous civil antitrust actions alleging price fixing, bid rigging, and market allocation of generic pharmaceuticals due to the fact 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 [Malek and Glazer] informations that were unsealed."<sup>23</sup> The DOJ has 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

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<sup>23</sup> See Transcript of Hearing, *FWK Holdings, LLC v. Actavis Elizabeth, LLC*, No. 16-cv-9901, ECF 112 (S.D.N.Y. Feb. 21, 2017).

ongoing criminal investigation.”<sup>24</sup> The DOJ also recently filed a motion for a stay of discovery in *In re Generic Pharmaceuticals Pricing Antitrust Litigation*, 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).”<sup>25</sup>

90. The steep climb of generic drug prices of late is an issue of national importance. In addition to the DOJ subpoenas, Congress has taken a keen interest in the matter. For instance, in October 2014, Senator Bernie Sanders (I-VT) and Representative Elijah E. Cummings (D-MD) launched an investigation into the inexplicably soaring generic drug prices.

91. Sen. Sanders and Rep. Cummings issued a joint press release at the start of the investigation indicating that they had issued letters to 14 pharmaceutical companies, 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 illnesses.” The bicameral duo 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. The legislators made this issue a priority because, for some of their constituents, “the outrageous price hikes are preventing patients from getting the drugs they need.”<sup>26</sup>

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<sup>24</sup> See Memorandum of Amicus Curiae United States of America Concerning Consolidation, *In re Generic Digoxin and Doxycycline Antitrust Litig.*, MDL 2724, ECF 284 (J.P.M.L. Mar. 10, 2017).

<sup>25</sup> See Intervenor United States’ Motion to Stay Discovery, *In re Generic Pharmaceuticals Pricing Antitrust Litigation*, MDL 2724, ECF 279 (E.D. Pa. May 1, 2017).

<sup>26</sup> Press Release, *Congress Investigating Why Generic Drug Prices Are Skyrocketing* (Oct. 2, 2014), available at <http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing>.

92. The U.S. Senate HELP Committee conducted a hearing on November 20, 2014, “Why Are Some Generic Drugs Skyrocketing in Price?”<sup>27</sup> The committee heard testimony from one pharmacist, who explained “it was extremely concerning when about a year ago, pharmacies began noticing a rash of dramatic price increases for many common, previously low-cost generic drugs.”<sup>28</sup> Using generic digoxin and doxycycline as examples of two of the generic drugs with price spikes, the pharmacist explained:

A recent example from my own experience is the price of Digoxin—a drug used to treat heart failure. The price of this medication jumped from about \$15 for 90 days’ supply, to about \$120 for 90 days’ supply. That’s an increase of 800%. One of my patients had to pay for this drug when he was in the Medicare Part D coverage gap in 2014. Last year, when in the coverage gap he paid the old price. This year he paid the new price. Needless to say, the patient was astounded, and thought I was overcharging him. The patient called all around to try to get the medicine at the old, lower price, but to no avail. This caused him lots of stress and time, and caused us lots of stress and time in explaining the situation, reversing, and rebilling the claim. This example is typical of how these price spikes put consumers and pharmacists in a bad position, often grasping at straws for explanations. And all the while, everyone pays more, including the patient, the pharmacy, and the insurer (often the federal government).<sup>29</sup>

93. Additional congressional hearings concerning the dramatic rise of generic drug prices were held in December 2015 and February 2016. At the U.S. Senate Special Committee on Aging’s December 9, 2015 hearing, the Director of the Drug Information Service of the University of Utah noted the deleterious effect these drug prices have had on patient access and

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<sup>27</sup> Press Release, *Drugmakers Mum on Huge Price Hikes* (Nov. 20, 2014), available at <http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes>.

<sup>28</sup> *Why are Some Generic Drugs Skyrocketing in Price?: Hearing Before the Subcomm. on Primary Health & Aging of the S. Comm. on Health, Educ., Labor & Pensions, 113th Cong. (2014)* (testimony of Rob Frankil, Independent Pharmacist & Member of the Nat’l Community Pharmacists Ass’n (“NCPA”), available at <http://www.help.senate.gov/imo/media/doc/Frankil.pdf>.

<sup>29</sup> *Id.*

healthcare: “[w]hen medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage.”

94. On February 24, 2015, Senator Sanders and Congressman 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.”<sup>30</sup> The OIG responded to the request on April 13, 2015, advising 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.”<sup>31</sup>

95. According to a November 3, 2016 *Bloomberg* report: “U.S. prosecutors are bearing down on generic pharmaceutical companies in a sweeping criminal investigation into suspected price collusion” and that, according to the DOJ, “the first charges could emerge by the end of the year.” As predicted, on December 12, 2016, the DOJ charged two generic industry executives with criminal counts related to price collusion for generic doxycycline hyclate and glyburide.

96. On December 15, 2016, several states’ attorneys general, led by the State of Connecticut Office of Attorney General, filed a civil action in the U.S. District Court for the District of Connecticut for violation of the Sherman Act against Heritage Pharmaceuticals, Inc. and other sellers of generic doxycycline hyclate and glyburide. The action filed by the attorneys

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<sup>30</sup> 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>.

<sup>31</sup> 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>.

general is styled *The State of Connecticut, et al. v. Aurobindo Pharma USA, Inc., Citron Pharms, LLC, Mylan Pharmaceuticals USA, Inc. and Teva Pharmaceuticals USA, Inc., Heritage Pharmaceuticals, Inc. and Mylan Pharmaceuticals, Inc.* (“State AG Action”).

97. According to the State AG Action, 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 AG Action focuses on doxycycline hyclate and glyburide, it alleges that the Plaintiff States have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors.

98. The DOJ and State AG investigations of Defendants’ alleged price-fixing conduct in the generic pharmaceutical industry are ongoing. 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.<sup>32</sup>

## **VI. THE LIDOCAINE/PRILOCAINE CREAM MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION**

99. Because Defendants’ anticompetitive conduct constitutes a conspiracy to fix prices, which is a *per se* violation of Section 1 of the Sherman Antitrust Act, Plaintiffs do not need to define a relevant market. However, there are features of the market relevant to this case

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<sup>32</sup> 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>.

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.

100. The factors necessary to show that a market is susceptible to collusion are present in this case:

- (1) **High Level of Industry Concentration** – A small number of competitors (Defendants) control a significant market share for generic lidocaine/prilocaine cream, as detailed above. At the outset of the Class Period the three Defendants together accounted for [REDACTED] of the market for lidocaine/prilocaine cream 30 gm.
- (2) **Sufficient Numbers to Drive Competition** – While the market for lidocaine/prilocaine cream had a small enough number of competitors to foster collusion, the number of makers was large enough that – given decades of experience with 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 direct cost levels. With the number of generic competitors such as there were here, historical fact and accepted economics teaches that – absent collusion – prices would remain at competitive levels.
- (3) **High Barriers to Entry** – The high costs of manufacture, intellectual property, and expenses related to regulatory approval and oversight are among the barriers to entry in the generic drug market. 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** – For the hundreds of thousands of generic lidocaine/prilocaine cream prescriptions written annually, it is a necessity that must be purchased regardless of price hikes. This makes demand for lidocaine/prilocaine cream highly inelastic. Defendants can significantly raise lidocaine/prilocaine cream prices with minimal effect on quantity thus increasing overall revenue.
- (5) **Lack of Substitutes** – While there are other local anesthetics, there are significant barriers to change treatments.

- (6) **Commoditized Market** – Defendants’ generic lidocaine/prilocaine cream products are fully interchangeable because they are bioequivalent to one another by FDA standards. Thus, all manufactured versions of lidocaine/prilocaine cream are therapeutically equivalent to each other and pharmacists may substitute one for another interchangeably.
- (7) **Absence of Departures from the Market** – There were no departures from the market that could explain the price increases.
- (8) **Absence of Non-Conspiring Competitors** – Defendants have maintained supracompetitive pricing for generic lidocaine/prilocaine cream 30 gm throughout the Class Period. Thus, Defendants have oligopolistic market power in the generic lidocaine/prilocaine cream market, which enables them to increase prices without loss of market share to non-conspirators.
- (9) **Opportunities for Contact and Communication Among Competitors** – Defendants participate in the committees and events of the GPhA, which provides and promotes 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.
- (10) **Size of Price Increases** – The magnitude of the price increases involved in this case further differentiates them from parallel price increases. Oligopolists seeking to test market increases need to take measured approaches. [REDACTED]  
[REDACTED]  
[REDACTED] A rational oligopolist, when unaided with the certainty that its ostensible competitors would follow, would not do so.
- (11) **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.

101. Though it is not necessary to allege a relevant market, at all relevant times, Defendants had substantial market power (*i.e.*, monopoly power) with respect to generic lidocaine/prilocaine cream because they had the power to maintain the price of the drug at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

102. A small but significant, non-transitory price increase above the competitive level for lidocaine/prilocaine cream by Defendants would not have caused a loss of sales sufficient to make the price increase unprofitable.

103. Defendants sold lidocaine/prilocaine cream at prices well in excess of marginal costs, and in excess of competitive price, and enjoyed high profit margins.

104. Defendants, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to regulatory protections and high costs of entry and expansion.

105. To the extent that Plaintiffs are legally required to prove substantial market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant market is generic lidocaine/prilocaine cream or narrower markets contained therein. During the relevant time, Defendants were able to profitably maintain the price of lidocaine/prilocaine cream substantially above competitive levels.

106. The relevant geographic market is the United States and its territories.

107. From the outset of the Class Period, Defendants held ██████████ of the relevant market, implying a substantial amount of market power.

108. 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 generic lidocaine/prilocaine cream through unlawful price collusion.

## VII. CLASS ACTION ALLEGATIONS

109. 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 generic lidocaine/prilocaine cream from one or more of Defendants in the United States and its territories and possessions at any time during the period from March 1, 2014, 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

110. 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 is readily identifiable from information and records maintained by Defendants.

111. 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. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

112. 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.

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

114. 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.

115. 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 generic lidocaine/prilocaine cream 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 generic lidocaine/prilocaine cream in the United States during the Class Period;
- (e) Whether Defendants' conduct caused supracompetitive prices for generic lidocaine/prilocaine cream;
- (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.

116. 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.

117. 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**

118. During the Class Period, Plaintiffs and Class Members directly purchased generic lidocaine/prilocaine cream from Defendants. Because of the Defendants' anticompetitive conduct, Plaintiffs and Class Members were forced to pay more for generic lidocaine/prilocaine cream 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.

119. 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.

120. Defendants, through their unlawful conduct alleged herein, reduced competition in the lidocaine/prilocaine cream market, increased prices, reduced choice for purchasers, and caused antitrust injury to purchasers in the form of overcharges.

121. Because Defendants' anticompetitive conduct is ongoing, Plaintiffs and the Class continue to pay supracompetitive prices for lidocaine/prilocaine cream 30 gm through the present.

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

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

123. In violation of Section 1 of the Sherman Antitrust Act, Defendants entered agreements with one another concerning the pricing of generic lidocaine/prilocaine cream in the United States. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

124. 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 lidocaine/prilocaine cream in the United States, and had a substantial and foreseeable effect on interstate commerce by raising and fixing lidocaine/prilocaine cream prices throughout the United States.

125. 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 lidocaine/prilocaine cream.

126. 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 lidocaine/prilocaine cream 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 lidocaine/prilocaine cream in the United States market; and
- c. Competition in establishing the prices paid for lidocaine/prilocaine cream was unlawfully restrained, suppressed, or eliminated.

127. 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 lidocaine/prilocaine cream 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, but is believed to be in the hundreds of millions of dollars classwide.

128. 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.

129. There is no legitimate, non-pretexual, 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.

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

#### **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 this Complaint;

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.

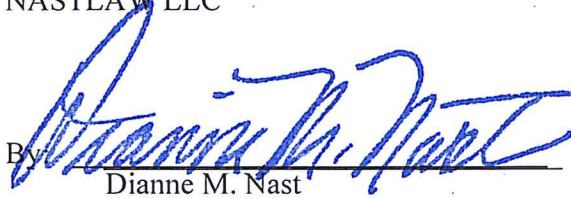
**JURY TRIAL DEMANDED**

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

Dated May 9, 2017

Respectfully submitted,

NASTLAW LLC

  
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Class*

JS 44 (Rev. 07/16)

**CIVIL COVER SHEET**

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

<p><b>I. (a) PLAINTIFFS</b>                  ROCHESTER DRUG CO-OPERATIVE, INC. and FWK HOLDINGS, L.L.C., on behalf of themselves and all others similarly situated</p> <p><b>(b)</b> County of Residence of First Listed Plaintiff <u>Monroe County, NY</u>                  (EXCEPT IN U.S. PLAINTIFF CASES)</p> <p><b>(c)</b> Attorneys (Firm Name, Address, and Telephone Number)                  Dianne M. Nast, 1101 Market Street, Suite 2801, Philadelphia, PA 19107 (215) 923-9300</p>	<p><b>DEFENDANTS</b>                  AKORN, INC; FOUGERA PHARMACEUTICALS INC.; HI-TECH PHARMACAL; IMPAX LABORATORIES, INC.; and SANDOZ, INC.</p> <p>County of Residence of First Listed Defendant <u>Lake County, IL</u>                  (IN U.S. PLAINTIFF CASES ONLY)</p> <p>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.</p> <p>Attorneys (If Known)</p>
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<p><b>II. BASIS OF JURISDICTION</b> (Place an "X" in One Box Only)</p> <p><input type="checkbox"/> 1 U.S. Government Plaintiff</p> <p><input checked="" type="checkbox"/> 3 Federal Question (U.S. Government Not a Party)</p> <p><input type="checkbox"/> 2 U.S. Government Defendant</p> <p><input type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)</p>	<p><b>III. CITIZENSHIP OF PRINCIPAL PARTIES</b> (Place an "X" in One Box for Plaintiff and One Box for Defendant)</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td></td> <td style="text-align: center;">PTF</td> <td style="text-align: center;">DEF</td> <td></td> <td style="text-align: center;">PTF</td> <td style="text-align: center;">DEF</td> </tr> <tr> <td>Citizen of This State</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> </tr> </table>		PTF	DEF		PTF	DEF	Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
	PTF	DEF		PTF	DEF																				
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Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6																				

**IV. NATURE OF SUIT** (Place an "X" in One Box Only)

<b>CONTRACT</b>	<b>TORTS</b>	<b>FORFEITURE/PENALTY</b>	<b>BANKRUPTCY</b>	<b>OTHER STATUTES</b>	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<p><b>PERSONAL INJURY</b></p> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <p><b>PERSONAL PROPERTY</b></p> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other <p><b>LABOR</b></p> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act <p><b>IMMIGRATION</b></p> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <p><b>PROPERTY RIGHTS</b></p> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <p><b>SOCIAL SECURITY</b></p> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <p><b>FEDERAL TAX SUITS</b></p> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input checked="" type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b>	<b>CIVIL RIGHTS</b>	<b>PRISONER PETITIONS</b>			
<input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	<p>Habeas Corpus:</p> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <p>Other:</p> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

**V. ORIGIN** (Place an "X" in One Box Only)

1 Original Proceeding   
 2 Removed from State Court   
 3 Remanded from Appellate Court   
 4 Reinstated or Reopened   
 5 Transferred from Another District (specify)   
 6 Multidistrict Litigation - Transfer   
 8 Multidistrict Litigation - Direct File

**VI. CAUSE OF ACTION**

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):  
15 U.S.C. § 1, 15(a)

Brief description of cause:  
Violation of Sherman Act and Clayton Act

**VII. REQUESTED IN COMPLAINT:**

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.C.P.    DEMAND \$ \_\_\_\_\_    CHECK YES only if demanded in complaint:  
 JURY DEMAND:  Yes     No

**VIII. RELATED CASE(S) IF ANY** (See instructions):

JUDGE Hon. Cynthia M. Fuje    DOCKET NUMBER 16-md-2724 (Lidocaine Prilocaine)

DATE 05/09/2017    SIGNATURE OF ATTORNEY OF RECORD 

FOR OFFICE USE ONLY

RECEIPT # \_\_\_\_\_ AMOUNT \_\_\_\_\_ APPLYING IFP \_\_\_\_\_ JUDGE \_\_\_\_\_ MAG. JUDGE \_\_\_\_\_

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: Rochester Drug Co-Operative, Inc., 50 Jet View Drive, Rochester, New York, 14624

Address of Defendant: Akorn, Inc, 1925 W. Field Ct., Ste 300, Lake Forest, IL 60045

Place of Accident, Incident or Transaction: United States (Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock? (Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes [ ] No [X]

Does this case involve multidistrict litigation possibilities? Yes [X] No [ ]

RELATED CASE, IF ANY:

Case Number: 16-md-2724 (Lidocaine Prilocaine) Judge Hon. Cynthia M. Rufe Date Terminated: Pending

Civil cases are deemed related when yes is answered to any of the following questions:

- 1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes [ ] No [X]
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes [X] No [ ]
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes [ ] No [X]
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes [ ] No [X]

CIVIL: (Place [X] in ONE CATEGORY ONLY)

A. Federal Question Cases:

- 1. [ ] Indemnity Contract, Marine Contract, and All Other Contracts
2. [ ] FELA
3. [ ] Jones Act-Personal Injury
4. [X] Antitrust
5. [ ] Patent
6. [ ] Labor-Management Relations
7. [ ] Civil Rights
8. [ ] Habeas Corpus
9. [ ] Securities Act(s) Cases
10. [ ] Social Security Review Cases
11. [ ] All other Federal Question Cases (Please specify)

B. Diversity Jurisdiction Cases:

- 1. [ ] Insurance Contract and Other Contracts
2. [ ] Airplane Personal Injury
3. [ ] Assault, Defamation
4. [ ] Marine Personal Injury
5. [ ] Motor Vehicle Personal Injury
6. [ ] Other Personal Injury (Please specify)
7. [ ] Products Liability
8. [ ] Products Liability — Asbestos
9. [ ] All other Diversity Cases (Please specify)

ARBITRATION CERTIFICATION

(Check Appropriate Category)

I, Dianne M. Nast, counsel of record do hereby certify:
[ ] Pursuant to Local Civil Rule 53.2, Section 3(c)(2) that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs;
[ ] Relief other than monetary damages is sought.

DATE: May 9, 2017

[Handwritten signature of Dianne M. Nast]

Attorney-at-Law

P.A. I.D. 24424
Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: Attorney-at-Law Attorney I.D.#

**CMR**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA  
CASE MANAGEMENT TRACK DESIGNATION FORM**

ROCHESTER DRUG CO-OPERATIVE, INC. :  
and FWK HOLDINGS, L.L.C., on behalf of :  
themselves and all others similarly situated :  
v. :  
AKORN, INC, et al. :

CIVIL ACTION

**17 2136**

NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

**SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:**

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)
- (f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

		ROCHESTER DRUG CO-OPERATIVE, INC. and FWK HOLDINGS, L.L.C.
May 9, 2017	Dianne M. Nast	
<b>Date</b>	<b>Attorney-at-law</b>	<b>Attorney for</b>
(215) 923-9300	(215) 923-9302	dnast@nastlaw.com
<b>Telephone</b>	<b>FAX Number</b>	<b>E-Mail Address</b>

MAY - 9 2017.

# ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [Four New Suits Filed in MDL Over Alleged Pharma Price-Fixing Scheme](#)

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