

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

IN RE: GENERIC PHARMACEUTICALS
PRICING ANTITRUST LITIGATION

MDL 2724
16-MD-2724
HON. CYNTHIA M. RUFÉ

IN RE: CLOBETASOL CASES

16-CB-27240

THIS DOCUMENT RELATES TO:

ALL DIRECT PURCHASER ACTIONS

16-CB-27241

KPH HEALTHCARE SERVICES, INC.,
a/k/a KINNEY DRUGS, INC., individually
and on behalf of all others similarly situated

Civil Action No.

Plaintiffs,

v.

FOUGERA PHARMACEUTICALS, INC.;
SANDOZ, INC.; NOVARTIS AG; AKORN,
INC.; HI-TECH PHARMACAL CO., INC.;
PERRIGO COMPANY PLC; TARO
PHARMACEUTICAL INDUSTRIES, LTD.;
TARO PHARMACEUTICALS USA, INC.;
WOCKHARDT LTD.; and MORTON
GROVE PHARMACEUTICALS, INC.,

Jury Trial Demanded

Defendants.

I. INTRODUCTION

1. Plaintiff KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. (“Plaintiff”), brings this Class Action Complaint on behalf of itself and on behalf of a Class of direct purchasers (hereinafter referred to as “Class Members”) who purchased the following generic Clobetasol Propionate products: topical ointment 0.05%, topical solution 0.05%, topical gel

0.05%, topical cream 0.05%, and emollient 0.05% (collectively referred to as “Clobetasol”), from Defendants Fougera Pharmaceuticals Inc., Sandoz, Inc., Novartis AG, Akorn, Inc., Hi-Tech Pharmacal Co., Inc., Perrigo Company PLC, Taro Pharmaceutical Industries Ltd. (“Taro Israel”), Taro Pharmaceuticals USA, Inc. (“Taro U.S.A.”), Wockhardt Ltd., and Morton Grove Pharmaceuticals, Inc., during the period from July 1, 2014 to the present (hereinafter referred to as “Class Period”).

2. Plaintiff seeks to recover damages incurred by itself and the Class due to Defendants’ and co-conspirators’ violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an overarching scheme to eliminate competition in the market for generic Clobetasol and to artificially inflate the prices through unlawful agreements.

3. As a result of Defendants’ anticompetitive scheme, Plaintiff and Class Members paid more for generic Clobetasol than they otherwise would have paid in the absence of Defendants’ unlawful conduct. As set forth below, Defendants’ scheme violates the federal antitrust laws and, in particular, Section 1 of the Sherman Act, 15 U.S.C. § 1 (“Sherman Act”).

4. Plaintiff makes the allegations herein based on personal knowledge and investigation of these matters relating to itself and upon information and belief as to all other matters.

II. NATURE OF THE CASE

5. Defendants have collectively and unlawfully colluded to restrain and/or eliminate competition by engaging in an anticompetitive conspiracy designed to foreclose competition in the market for generic Clobetasol in the United States, in violation of Section 1 of the Sherman Act. This misconduct enabled each and every Defendant to overcharge direct purchasers for generic Clobetasol.

6. Plaintiff, on behalf of itself and the proposed Class, seeks redress for the overcharge damages sustained as a result of Defendants' unlawful conspiracy and other anticompetitive conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. But for Defendants' illegal conduct, Plaintiff and Class Members would not have paid supracompetitive prices for generic Clobetasol.

7. Plaintiff's allegations made on behalf of itself and Class Members are based on information made public during government investigations of Defendants for alleged unlawful conduct in the generic drug market. In 2014, the U.S. Department of Justice, Antitrust Division ("DOJ") began an in-depth investigation of alleged criminal conduct in the generic drug industry. As a result of the DOJ's investigation, grand jury subpoenas were issued to Defendants Taro USA and Sandoz.

8. Generic Clobetasol is not the only drug at issue in the DOJ's investigation.

9. 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.¹ The NCPA's news release states,

Pharmacy acquisition prices for many essential generic drugs have risen by as much as 600%, 1,000% or more, according to a survey of more than 1,000 community pharmacists conducted by NCPA. The same survey found that patients are declining their medication due to increased co-pays (or total costs for the uninsured) and that the trend has forced more seniors into Medicare's dreaded coverage gap (or "donut hole") where they must pay far higher out-of-pocket costs.

¹ News release available at <http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say>.

“Over the last six months I have heard from so many of our members across the U.S. who have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate,” NCPA CEO B. Douglas Hoey, RPh, MBA wrote in a letter to the panels’ respective leaders, Chairman Tom Harkin (D-Iowa) and Ranking Member Lamar Alexander (R-Tenn.) and Chairman Fred Upton (R-Mich.) and Ranking Member Henry Waxman (D-Calif.).

10. NCPA’s survey of community pharmacists found the following:
 - 77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug’s acquisition price.
 - 86% of pharmacists said it took the pharmacy benefit manager (PBM) or other third-party payer between two and six months to update its reimbursement rate (but not retroactively).
 - Patients may be referred to other pharmacies because the community pharmacy could not absorb losses of \$40, \$60, \$100 or more per prescription filled, due to inadequate and/or outdated reimbursement rates.
 - 84% of pharmacists said the unsustainable losses per prescription are having a “very significant” impact on their ability to remain in business to continue serving patients.

11. In December 2016, the DOJ filed the first criminal indictments to result from the ongoing investigation of the generic drug industry.² On December 12 and December 13, 2016, the DOJ filed separate two-count felony indictments in the U.S. District Court for the Eastern District of Pennsylvania against two former executives of Heritage Pharmaceuticals, Inc. for conspiring to allocate customers and fix the prices of two other generic drugs, doxycycline hyclate and glyburide.

12. State Attorneys General are also conducting ongoing investigations of the generic drug industry. On December 15, 2016, Connecticut Attorney General George Jepsen, along with the Attorney Generals of nineteen other states, filed suit in the U.S. District Court for the District

² See *U.S. v. Glazer*, 2:16-cr-00506-RBS (E.D. Pa.) and *U.S. v. Malek*, 2:16-cr-00508-RBS (E.D. Pa.).

of Connecticut against Aurobindo Pharma USA, Inc., Citron Pharma, LLC, Heritage Pharmaceuticals, Inc., Mayne Pharma (USA), Inc., Mylan Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc., for price-fixing of doxycycline hyclate delayed release and glyburide (“the AG Complaint”).³ The AG Complaint states claims under Section 1 of the Sherman Act, 15 U.S. C. § 1, and notes that, “the Plaintiff States have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the appropriate time.” Twenty additional states have since joined.

13. Plaintiff reserves the right to amend its complaint to include additional parties and claims related to the pricing of other generic drugs as new information from the government investigations becomes public.

III. JURISDICTION AND VENUE

14. 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 Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26. Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).

15. 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 in the United States, including in this District.

16. During the Class Period, Defendants sold and shipped generic drugs in a continuous and uninterrupted flow of interstate commerce, which included sales of generic Clobetasol 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.

³ See *Connecticut et al. v. Aurobindo Pharma USA, Inc. et al*, 3:16-cv-02056-VLB (D. Conn.).

17. 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 Clobetasol throughout the United States, including in this District; (c) had and maintained substantial contacts with the United States, including in this District; and/or (d) was engaged in an unlawful conspiracy to inflate the prices for generic Clobetasol 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.

IV. THE PARTIES

A. PLAINTIFF

18. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. (“KPH”) is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH directly purchased generic Clobetasol from Defendants during the Class Period. For example, KPH’s purchases from Defendants during the Class Period include Clobetasol Propionate topical cream .05% from Defendant Sandoz. As a result of Defendants’ antitrust conspiracy, KPH paid supracompetitive prices for its generic Clobetasol purchases and KPH was injured by the illegal conduct alleged herein.

B. DEFENDANTS

19. Defendant Fougera Pharmaceuticals Inc. (“Fougera”) is a New York corporation with its principal place of business at Melville, New York. Fougera is a specialty dermatology generic pharmaceutical company and is a wholly owned subsidiary of Defendant Sandoz, Inc.

During the Class Period, Fougera sold generic Clobetasol to purchasers in this District and throughout the United States.

20. Defendant Sandoz, Inc. (“Sandoz”) is a Colorado corporation with its principal place of business in Princeton, New Jersey. Sandoz manufactures, markets, and sells generic drug products and is a subsidiary of Defendant Novartis AG. Sandoz acquired Fougera in July 2012 for \$1.5 billion, making Sandoz the top generic dermatology medicines company in the U.S. and the world. During the Class Period, Sandoz sold generic Clobetasol to purchasers in this District and throughout the United States.

21. Defendant Novartis AG (“Novartis”) is a Swiss multinational pharmaceutical company based in Basel, Switzerland. Novartis, through its subsidiaries Fougera and Sandoz, manufactures its dermatology products at locations in Hicksville and Melville, New York. During the Class Period, Novartis, through its subsidiaries Fougera and Sandoz, sold generic Clobetasol to purchasers in this District and throughout the United States.

22. Defendant Hi-Tech Pharmacal Co., Inc. (“Hi-Tech Pharmacal”) is a Delaware corporation with its principal place of business in Amityville, New York. Hi-Tech Pharmacal markets and sells Clobetasol throughout the United States. Hi-Tech Pharmacal acquired five Abbreviated New Drug Applications (“ANDA”) for clobetasol propionate 0.05% (ointment, solution, cream, emollient cream, and gel) from DFB Pharmaceuticals, Inc., in or around 2009. In August of 2013, Akorn, Inc. acquired Hi-Tech Pharmacal for \$640 million. During the Class Period, Hi-Tech Pharmacal sold generic Clobetasol to purchasers in this District and throughout the United States.

23. Defendant Akorn, Inc. (“Akorn”) is a Louisiana corporation with its principal place of business in Chicago, Illinois. Akorn acquired Hi-Tech Pharmacal in August 2013, and

the acquisition broadened Akorn's product line of topical creams and ointments. During the Class Period, Akorn sold generic Clobetasol to purchasers in this District and throughout the United States.

24. Defendant Perrigo Company plc ("Perrigo plc") is incorporated under the laws of Ireland with its principal place of business in Dublin, Ireland. Perrigo's North American base of operations is located at 515 Eastern Avenue, Allegan, Michigan 49010, where Perrigo's domestic subsidiaries (Perrigo Company, a holding company; Perrigo Pharmaceuticals Co. and L. Perrigo Co., which are pharmaceuticals manufacturers; and Perrigo Sales Corp., a sales company), all Michigan corporations, are located. Perrigo's prescription drug business focuses primarily on the manufacture and sale of extended topical prescription pharmaceuticals, such as Clobetasol. During the Class Period, Perrigo plc sold generic Clobetasol through its U.S. subsidiaries to purchasers in this District and throughout the United States.

25. Perrigo New York, Inc. ("Perrigo New York"), a Delaware corporation, manufactures Perrigo's cream and ointment tubes, producing more than 50 million tubes annually. The officers and directors of Perrigo and these domestic Perrigo subsidiaries have been the same or have substantially overlapped during the Class Period.

26. Defendant Taro Pharmaceutical Industries, Ltd. ("Taro Israel") has its principal place of business in Haifa, Israel. Voting power in Taro Israel is 79.3% controlled by Sun Pharmaceutical Company, Ltd. ("Sun"). During the Class Period, Taro Israel sold generic Clobetasol through its U.S. subsidiary, Taro USA, to purchasers in this District and throughout the United States.

27. Defendant Taro Pharmaceuticals USA, Inc. ("Taro USA") is a New York corporation with its principal place of business in Hawthorne, New York. Taro USA is a wholly-

owned subsidiary of Defendant Taro Pharmaceutical Industries, Ltd. During the Class Period, Taro USA sold generic Clobetasol to purchasers in this District and throughout the United States.

28. Defendant Wockhardt Ltd. (“Wockhardt”) is an international pharmaceutical and biotechnology company headquartered in Mumbai, India. Wockhardt manufactures, markets and sells generic drugs, including Clobetasol, throughout the United States. Wockhardt maintains manufacturing plants and substantial operations in the United States, including its wholly-owned subsidiary Morton Grove Pharmaceuticals, Inc. During the Class Period, Wockhardt, through its subsidiary Defendant Morton Grove Pharmaceuticals, Inc., sold generic Clobetasol to purchasers in this District and throughout the United States.

29. Defendant Morton Grove Pharmaceuticals Inc. (“Morton Grove Pharma”) is a Delaware corporation headquartered in Morton Grove, Illinois. As noted above, Morton Grove Pharma is a wholly-owned subsidiary of Defendant Wockhardt. During the Class Period, Morton Grove Pharma sold generic Clobetasol to purchasers in this District and throughout the United States.

30. 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.

V. UNIDENTIFIED CO-CONSPIRATORS

31. 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.

32. The true names and capacities, whether individual, corporate, associate, or representative, is unknown to Plaintiff at this time. Plaintiff may amend this Complaint, as necessary, to allege the true names and capacities of additional co-conspirators as their identities become known through discovery.

33. 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.

34. 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.

VI. FACTUAL ALLEGATIONS

A. Overview of Generic Drug Market

35. Generic drugs typically provide consumers with a lower-cost alternative to brand name drugs while providing the same treatment. Specifically,

A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or “therapeutic equivalence,” of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as “therapeutically equivalent” can be expected to have equal effect and no difference when substituted for the brand name product.⁴

⁴ <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G>

36. Further, “[d]rug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.”⁵

37. Generic versions of brand name drugs are priced significantly below the brand name versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand name counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand name product unless the doctor has indicated that the prescription for the brand name product must be dispensed as written. States adopted substitution laws following the federal government’s 1984 enactment of the Hatch-Waxman Act (Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282)).

38. Economic literature in the healthcare market has demonstrated that competition by generic products results in lower prices for consumers. In the period before generic entry, a brand name drug commands 100% of the market share for that drug and the brand name manufacturer can set the price without the impact of competitive market forces. Once the first generic enters the market, however, a brand name drug rapidly loses sales, as much as 80% or more by the end of the first year. As more generic manufacturers enter the market, prices for generic versions of a drug predictably will continue to decrease because of competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generic accelerates as more generic options are available to purchasers.⁶ Generic

⁵ *Id.*

⁶ See, e.g., Ernst R. Berndt, et al., *Authorized Generic Drugs, Price Competition, And Consumers’ Welfare*, Health Affairs 26, no. 3 (2007):790-799.

drugs that are substitutable for a brand name drug become like any other commodity, because the products are interchangeable, competition between the manufacturers is based on price.

39. Generic competition usually enables purchasers to (a) purchase generic versions of the brand name drug at a substantially lower price than the brand name drug, and/or (b) purchase the brand name drug at a reduced price. Generic competition to a single branded drug product can result in billions of dollars in savings to consumers, insurers, and other drug purchasers.

40. Drug companies that want to introduce a generic drug to the market file an Abbreviated New Drug Application (“ANDA”) with the FDA’s Center for Drug Evaluation and Research, Office of Generic Drugs. The filing is called “abbreviated” because the ANDA sponsor references data submitted in the approval of the Reference Listed Drug (“RLD”) (the brand name drug). “By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart.”⁷ An ANDA sponsor is generally not required to include clinical trial data to establish the safety and efficacy of the drug. Instead, a generic drug company must show that its generic product is “bioequivalent” to the name brand drug,⁸ i.e., the generic product and the brand RLD have the same (i) active ingredient, (ii) maximum amount of drug in the blood at a given time, (iii) total amount of drug in the blood over time, (iv) strength, dosage, dosage form, (v) expected safety and efficacy, and (vi) FDA approval of manufacturing facilities. Upon the FDA’s determination that

⁷ <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#RLD>.

⁸ <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#A>.

bioequivalence has been established, the ANDA applicant may manufacture and market its generic drug in the U.S. as interchangeable with the RLD.

41. Generic drugs that are bioequivalent to an RLD are assigned a Therapeutic Equivalence Code (“TE Code”).⁹ An oral generic drug product will be coded “AB” if bioequivalence is demonstrated. The purpose of this coding is to allow users to determine whether the FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products and to provide information on the basis of the FDA’s evaluations.¹⁰

B. Consolidation in the Generic Drug Industry

42. Since 2005, consolidations in the generic drug industry have affected control of product supply and pricing for consumers.

43. For example, Teva Pharmaceutical Industries Ltd. acquired Ivax Corporation for \$7.4 billion in 2006; Barr Laboratories for \$7.4 billion in 2008; Ratiopharm, Germany’s second largest generic drug producer, for \$5 billion in 2010, and agreed to acquire Allergan Generics in 2015 for \$40.5 billion. Watson Pharmaceuticals acquired Andrx Corporation in 2006 for \$1.9 billion; Daiichi Sankyo acquired a majority stake in Ranbaxy in 2008; and Endo Pharmaceuticals acquired Qualitest for \$1.2 billion in 2010.

44. In the market for generic Clobetasol, generic manufacturers Glenmark Pharmaceuticals and Teva Pharmaceutical Industries left the market in the years leading up to the Defendants’ price increases. Fewer manufacturers then had nearly complete control over the Clobetasol market.

⁹ <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#T>.

¹⁰ <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm>.

45. Consolidation in the generic drug industry has led to higher prices for consumers and the combining or discontinuation of generic product lines, which contributed to reducing price competition. Mergers within the generic drug industry were a reaction, in part, to the consolidation of distributors. Generic manufacturers then had leverage to charge higher prices if distributors were unable to negotiate lower prices with other generic manufacturers offering therapeutically equivalent drugs.

C. Opportunities for Collusion

46. The DOJ is reportedly examining trade associations where Defendants allegedly have opportunities to communicate and collude, such as the Generic Pharmaceutical Association's ("GPhA"). According to an intelligence report from the *Policy and Regulatory Report* ("PaRR"), a source that was given inside information by someone with knowledge of the government's generic pricing investigation, the DOJ is looking closely "at trade associations as part of their investigation as having been one potential avenue for facilitating the collusion between salespeople at different generic producers."¹¹

47. The GPhA is the "leading trade association for generic drug manufacturers and distributors, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry." GPhA was formed in 2000 from the merger of three industry trade associations: GPhA, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.¹²

¹¹ <http://www.fiercepharma.com/story/actavis-gets-subpoena-doj-probe-generic-pricing-moves-food-chain/2015-08-07>.

¹² In February 2017, the GPhA changed its name to the Association for Accessible Medicines ("AAM"). 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/>.

48. Defendants Sandoz and Perrigo have representatives on GPhA's 2016 Board of Directors.

49. According to GPhA's website, "GPhA member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year." GPhA states that, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry and help secure the future of this vital pharmaceutical market segment. In addition, GPhA provides valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections."¹³

50. Generic drug manufacturers attend meetings and industry trade shows throughout the year, including those hosted by the GPhA, National Association of Chain Drug Stores, Healthcare Distribution Management Association (now the Healthcare Distribution Alliance), and Efficient Collaborative Retail Marketing.¹⁴

51. At these meetings and trade shows, generic drug manufacturers have opportunities to discuss and share competitively sensitive information, such as pricing, upcoming bids, and customer contracts.¹⁵

52. Many of these conferences and trade shows also include organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities that provide further opportunity to meet with competitors.

53. High-level executives of generic drug manufacturers meet periodically at industry dinners. For example, in January 2014, when certain generic drug prices were increasing

¹³ <http://www.gphaonline.org/about/membership>.

¹⁴ See AG Complaint at ¶ 50.

¹⁵ *Id.* at ¶ 51.

exponentially, at least thirteen (13) high-ranking male executives of various generic drug manufacturers met at a steakhouse in Bridgewater, New Jersey.¹⁶

54. Female sales representatives for generic drug manufacturers regularly hold meetings and dinners for “Girls Night Out” (“GNO”) and Women in the Industry events, where competitively sensitive information is discussed.¹⁷ For example, GNOs were held at the ECRM conference in February 2015, in Baltimore in May 2015, and at the NACDS conference in August 2015.¹⁸

55. Many generic drug manufacturers, including most of the Defendants, have offices in close proximity to one another in New Jersey, New York, or Illinois, providing them with more opportunities to meet and collude.

D. Generic Clobetasol Market and Pricing Information

56. Generic Clobetasol Propionate, a highly potent corticosteroid of the glucocorticoid class, is one of the most prescribed dermatological drugs in the country for the treatment of skin conditions, including eczema and psoriasis. Clobetasol is also prescribed to treat some autoimmune diseases, such as alopecia areata, vitiligo, lichen sclerosus and lichen planus. Generic versions of Clobetasol have been available on the market since 1994.

57. In the market for generic Clobetasol, generic manufacturers Glenmark Pharmaceuticals and Teva Pharmaceuticals Industries exited the market, which left Defendants with almost complete control of the supply. In 2009, there were approximately ten manufacturers of generic Clobetasol, but by 2014, only about half of the generic manufacturers

¹⁶ *Id.* at ¶ 55.

¹⁷ *Id.* at ¶ 57.

¹⁸ *Id.* at ¶ 60.

remained for Clobetasol topical ointment .05%, topical solution .05%, topical gel .05%, and topical cream .05%.

58. On February 19-21, 2014, Defendants Akorn/Hi-Tech, Fougera/Sandoz, Taro, and Wockhardt/Morton Grove attended the GPhA annual meeting in Orlando, Florida. On June 3-4, 2014, Defendants met again at a GPhA workshop in North Bethesda, Maryland.

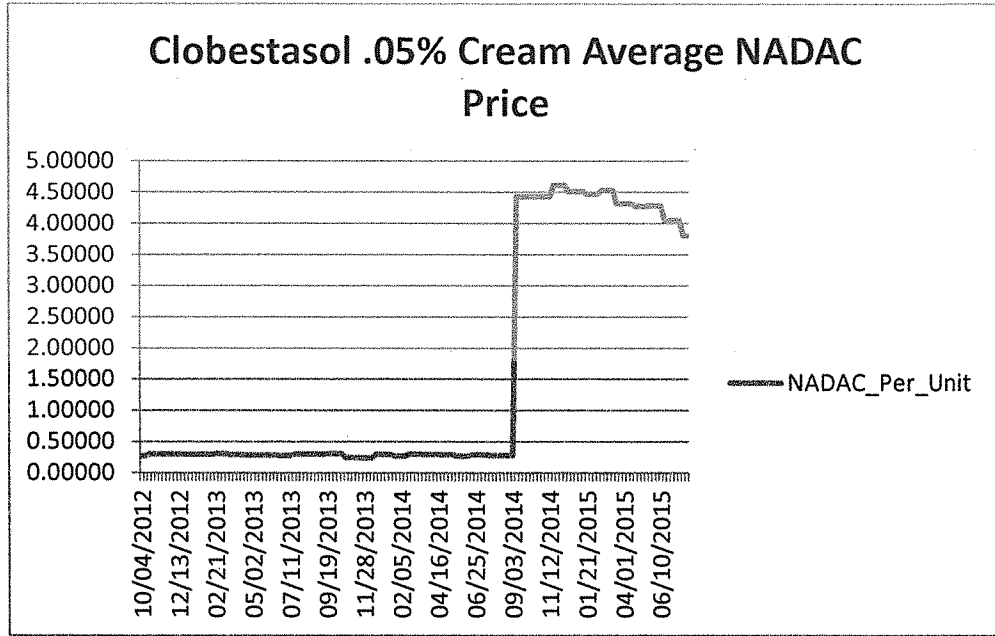
59. Defendants had an opportunity to collude at the GPhA meetings. Following the June GPhA workshop, the price of prescription products containing Clobetasol increased sharply and without justification, because the Defendants entered an anticompetitive agreement to restrain competition in the market for Clobetasol and caused an exponential price increase over the next three months.

60. Defendants Fougera, Hi-Tech Pharmacal, Perrigo, Sandoz, Taro U.S.A., and Wockhardt have dominated the market for generic Clobetasol since June 2014.

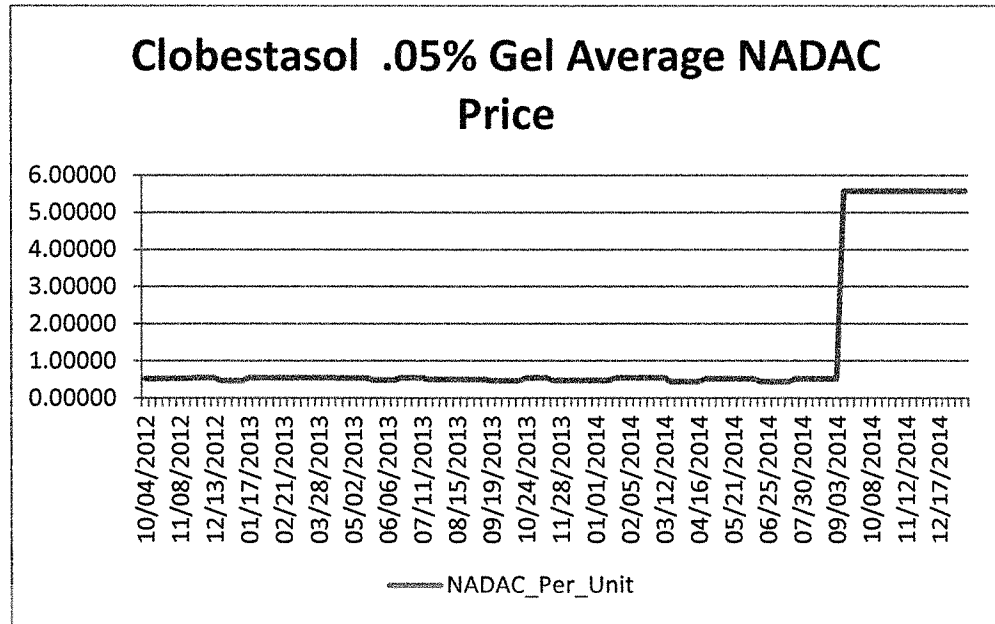
61. Shortly after the June 2014 GPhA workshop, National Average Drug Acquisition Cost ("NADAC") data shows a significant price increase for all formulations of generic Clobetasol, whereas previously, the average price paid in the U.S. for Clobetasol was stable. NADAC is the National Association of State Medicaid Directors method of measuring the cost of drugs in order to set a single national pricing benchmark based on average drug acquisition costs.

62. Soon after the GPhA June 2014 workshop, NADAC data shows the following average price increases for Clobetasol products:

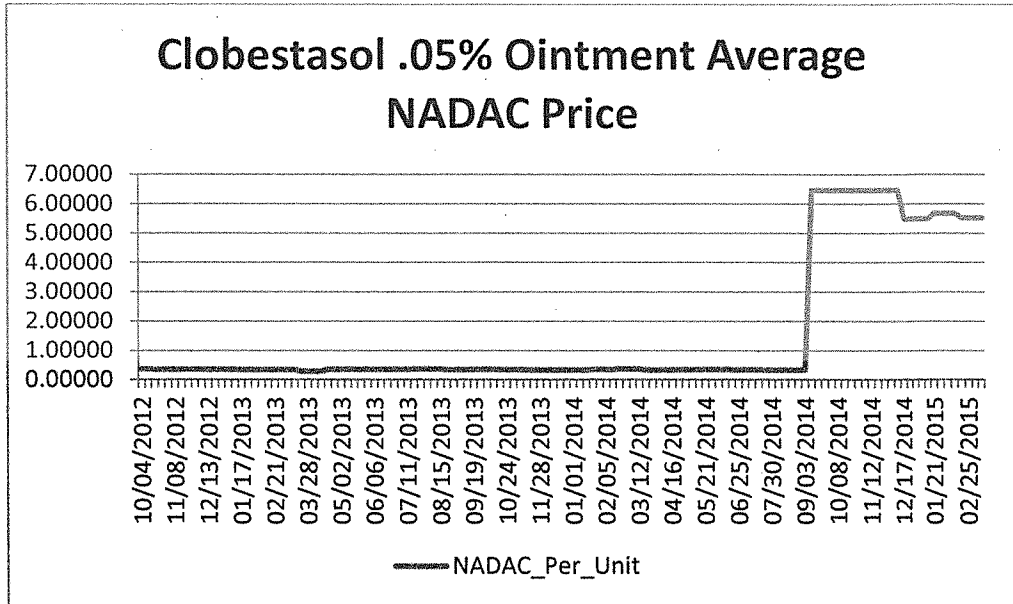
- a. **Clobetasol 0.05% cream:** As demonstrated by the below chart, the average price for Clobetasol 0.05% cream increased by 1488% in September 2014.



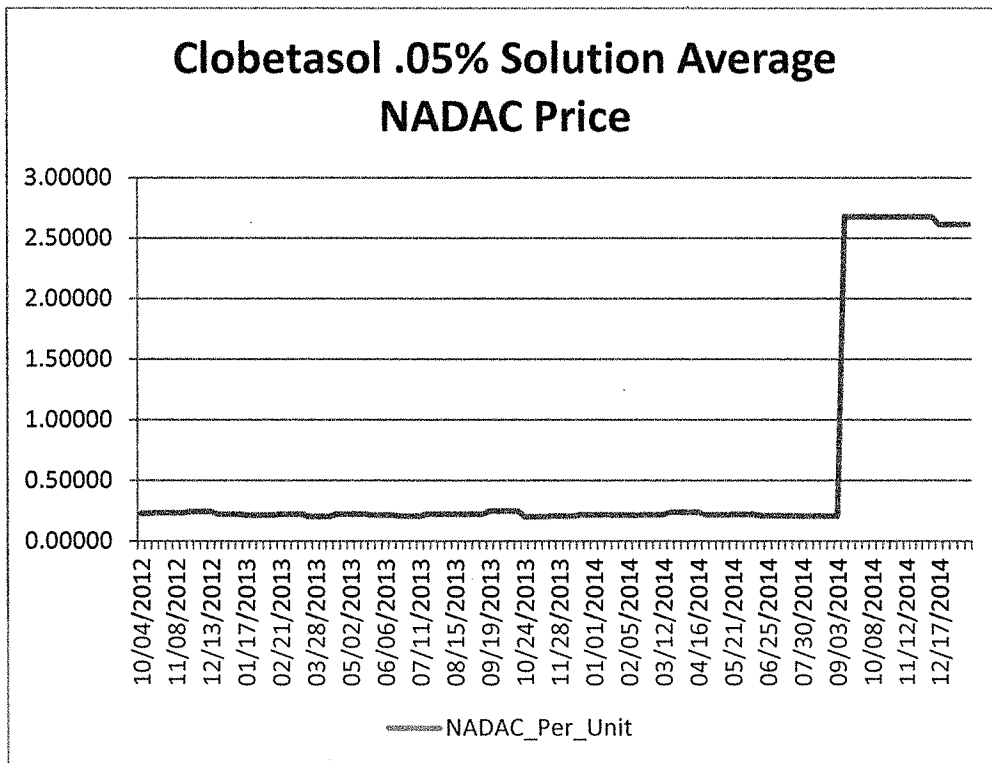
b. **Clobetasol 0.05% gel:** As shown by the chart below, the average price for Clobetasol 0.05% gel increased by 979% in September 2014.



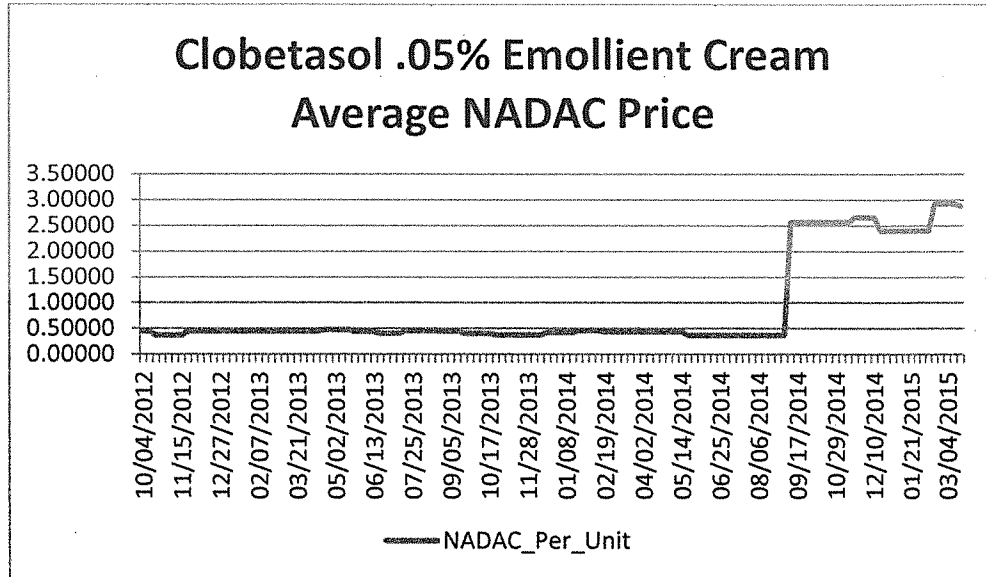
c. **Clobetasol 0.05% ointment:** As shown by the chart below, the average price for Clobetasol 0.05% ointment increased by 1852% in September 2014.



d. **Clobetasol 0.05% solution:** As shown by the chart below, the average price for Clobetasol 0.05% solution increased by 1204% in September 2014.



e. **Clobetasol 0.05% emollient cream:** As shown by the chart below, the average price for Clobetasol 0.05% emollient cream increased by 594% in September 2014.



63. From June to September 2014, Defendants collectively imposed price increases for generic Clobetasol of approximately 1,140%. As reported by the Boston Globe in November 2015, the price per gram for the drug rose from 26 cents to \$4.15 between 2013 and 2015; the price per 45 g tube went from \$2.89 in 2014 to \$198.64 in 2015. Further, in 2013, a 60-gram tube of Clobetasol cream cost \$15.60, and by 2015, the cost rose to nearly \$250.00.

64. Currently, the price of Clobetasol continues to be supracompetitive.

65. In Taro's Q2 2014 earnings call with industry analysts on November 10, 2014, Kal Sundaram, Taro's CEO stated: "Net sales for Q2 were \$251 million, up 22% over Q2 last year. As we anticipated in last quarter's earnings release we are realizing the benefits of the previous quarter's price adjustments in the current quarter. Gross profit increased 24% to \$198 million year-on-year resulting in a 130 basis points expansion in our gross margins to 79%."

66. On September 14, 2016, the Economics Times of India reported that, "While Taro has been gaining approvals for its products, a significant portion of its revenue growth has come from price increases."

67. In Akorn's annual report for the period ended December 31, 2015, Akorn reported: "Our gross profit increased by \$334.7 million, an increase of 128.0% over gross profit of \$261.4 million in 2014. Our overall gross profit margin was 60.5% in 2015 compared to 47.1% in 2014." The company attributed the increased profit margin to the effects of "price changes."

68. In or about May 2016, Akorn told industry analysts that "63% of [its] growth in 1Q16 versus 1Q15 was driven by price."

69. In Akorn's Q2 2016 earnings call with industry analysts on August 4, 2016, Akorn's CFO, Duane Portwood, stated: "net revenue for the quarter ended June 30, 2016, was \$281 million, an increase of \$60 million or 27% over the prior-year quarter. The increase in revenue was driven by organic growth, with approximately two-thirds attributable to price."

70. Perrigo reported that gross profit grew by \$59 million from 2014 to 2015, primarily due in part to "pricing initiatives."

71. Clobetasol price increases had a negative effect on patients. On August 5, 2015, Norman Levine, M.D., a private practitioner in Tucson, AZ wrote in *Dermatology Times*, an online news magazine:

A patient with a minimally steroid-responsive dermatosis, vitiligo, recently contacted me to complain that he could no longer afford the medication that I had prescribed for him. I was puzzled when he informed me that a 60-gram tube of clobetasol cream would now cost him \$220, an amount that was far beyond his budget. The medication was no longer on his insurance plan's formulary, presumably because it had become too expensive for them as well. At first I was highly doubtful and assumed that the dispensing pharmacy had mistakenly substituted a name-brand product for the generic version I had prescribed. A quick survey of several local pharmacies confirmed that all were pricing clobetasol above \$200.

72. The cost or availability of raw materials does not justify the Clobetasol price increases. As generic manufacturers, Defendants did not incur the same costs, such as research

and development, as brand drug manufacturers in bringing their generic Clobetasol products to market. The increased prices were not associated with any related increase in manufacturing costs.

73. Drug shortage reports for the time period do not list Clobetasol as being in short supply.¹⁹

74. At all times during the class period, there were at least four or more separate manufacturers of generic Clobetasol. The active ingredient for the drug product, Clobetasol propionate has five approved holders of active Drug Master Files (“DMF”).²⁰

75. Under the well-accepted economics of generic competition, when there are that many generic versions of a drug available, all of which by definition are equally substitutable, prices should remain at highly competitive, historic levels, and would not increase as they did here, absent anticompetitive conduct.

76. Because there were no justifications such as supply shortages attributable to higher raw material costs, raw material shortages, or manufacturing bottlenecks (such as too few manufacturers to satisfy demand), competition among generic manufacturers of Clobetasol should have resulted in lower prices. Instead, prices increased after the Defendants met and unlawfully colluded to raise prices.

E. Government Investigations of Generic Drug Industry

¹⁹ See FDA Drug Shortages website, <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm#P>; American Society of Health-System Pharmacists, <http://www.ashp.org/shortages>.

²⁰ A Drug Master File, or DMF, is a regulatory document that contains the complete information for an active pharmaceutical ingredient (or API or drug substance), or a finished dosage form (the complete drug product, such as a tablet). The DMF contains information on the drug manufacture, stability, purity, chemistry, packaging and the good manufacturing practices that were used in the processes to make the product that is the subject of the DMF.

77. As noted above, Defendants' conduct in generic pharmaceutical pricing is the subject of federal government investigations by the U.S. Senate and DOJ, as well as state government investigations.

78. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Representative Elijah E. Cummings sent letters to fourteen drug manufacturers seeking information relating to the escalating prices of generic drugs (the "October Letters"). The October Letters state the following:

This dramatic increase in generic prices results in decreased access for patients. According to the National Community Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country "have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate" and "77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price." These price increases have a direct impact on patients' ability to purchase their needed medications. The NCPA survey found that "pharmacists reported patients declining their medication due to increased co-pays..."²¹

79. The October Letters were accompanied by a press release by Senator Sanders and Congressman Cummings, which stated,

"We 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," Sanders, chairman of a Senate health care subcommittee, and Cummings, ranking member of the House oversight committee, wrote in letters to 14 pharmaceutical companies.

...

Cummings and Sanders cited a survey that found pharmacies across the country "have seen huge upswings in generic drug prices that are hurting patients" and having a "very significant" impact on pharmacists' ability to continue serving

²¹ See, e.g., Letter from Senator Sanders and Representative Cummings to Erez Vigodman, President and CEO, Teva Pharmaceutical Industries Ltd., October 2, 2014, available at <http://www.sanders.senate.gov/download/letter-to-mr-vigodman-president-and-ceo-teva-pharmaceutical-industries-ltd?inline=file>.

patients. The study for the National Community Pharmacists Association also found some patients refused to fill needed prescriptions because of rising prices.

“It is unacceptable that Americans pay, by far, the highest prices in the world for prescription drugs. Generic drugs were meant to help make medications affordable for the millions of Americans who rely on prescriptions to manage their health needs. We’ve got to get to the bottom of these enormous price increases,” Sanders said.

“When you see how much the prices of these drugs have increased just over the past year, it’s staggering, and we want to know why,” said Cummings. “I am very pleased that Chairman Sanders has joined me in this bicameral investigation because in some cases these outrageous price hikes are preventing patients from getting the drugs they need.”²²

80. The U.S. Senate HELP Committee held a hearing on November 20, 2014, “Why Are Some Generic Drugs Skyrocketing in Price?”²³

81. During the Senate Hearing on generic drug prices, pharmacist Rob Frankil testified on November 20, 2014 that, “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.”²⁴

82. On February 24, 2015, Senator Sanders and Congressman Cummings sent a letter to the Office of the Inspector General (“OIG”) of the Department of Health and Human Services asking that the OIG “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

²² 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>.

²³ <http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes>.

²⁴ <http://www.help.senate.gov/imo/media/doc/Frankil.pdf>.

Medicaid programs.”²⁵ The OIG responded to the request on April 13, 2015 and stated that it planned to review quarterly average manufacturer prices [“AMPs”] for the top 200 generic drugs from 2005 through 2014, and would “determine the extent to which the quarterly AMPs exceeded the specified inflation factor.”²⁶ The OIG concluded that escalating generic drug prices have cost taxpayers \$1.4 billion in overpayment by Medicaid.²⁷ In a 2015 budget deal by Congress, legislation requires generic drug manufacturers to pay back the Medicaid program when their prices rise faster than inflation. Later in 2015, Senator Sanders and Representative Cummings proposed comprehensive legislation to address prescription drugs prices.

83. Subsequent congressional hearings concerning the dramatic rise of generic pharmaceutical prices were held in December 2015 and February 2016. At the U.S. Senate Special Committee on Aging’s December 9, 2015 hearing, Erin D. Fox, 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 healthcare, stating that “[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.”

84. The DOJ is conducting an ongoing investigation into generic drug pricing. Several leading generic drug manufacturers have been subpoenaed for information, documents and testimony relating to “communication or correspondence with any competitor in the sale of

²⁵ <http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file>.

²⁶ <http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file>.

²⁷ Office of the Inspector General, Average Manufacture Prices increased faster than Inflation for Many Generic Drugs, December 2015, available at <https://oig.hhs.gov/oas/reports/region6/61500030.pdf>.

generic prescription medications.”²⁸ Grand jury subpoenas have been issued to Defendants Taro USA and Sandoz.

85. On September 9, 2016, Defendant Taro Israel disclosed that on September 8, 2016, Defendant Taro, U.S.A. “as well as two senior officers in its commercial team, received grand jury subpoenas from the United States Department of Justice, Antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and pricing, communications with competitors and others regarding the sale of generic pharmaceutical products, and certain other related matters.”

86. Defendant Sandoz received a DOJ subpoena in March 2016 relating to the industry-wide investigation into generic drug pricing.

87. The fact that a grand jury subpoena was served on Defendants Taro USA and Sandoz is indicative that it has potentially violated antitrust law. According to the DOJ’s *Antitrust Division Manual*, “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.”²⁹ If a grand jury request memorandum is approved by the DOJ field office chief, “a grand jury request should be emailed to the ATR-CRIM-ENF [Antitrust Criminal Enforcement Division].”³⁰ “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

²⁸ See Impax Laboratories, Inc., Form 8-K, November 3, 2014.

²⁹ See *Antitrust Division Manual*, Chapter III, Section F.1 at III-82 (2015).

³⁰ *Id.*

jury investigation.”³¹ Then, “[t]he 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.”³²

88. As discussed above, the first indictments to result from the DOJ’s investigation of the generic drug industry were filed in the Eastern District of Pennsylvania in December 2016 against former executives of Heritage Pharmaceuticals, Inc., Jeffrey A. Glazer and Jason T. Malek. Glazer and Malek pleaded guilty to violating Section 1 of the Sherman Act in January 2017.

89. Further, as a result of the Connecticut Attorney General’s two-year investigation of the generic drug industry, the AG Complaint was filed in December 2016 and provides additional details on anticompetitive conduct in certain generic drug markets. According to the AG Complaint, “[i]n July 2014, the State of Connecticut initiated a non-public investigation into suspicious price increases for certain generic pharmaceuticals. The information developed through that 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.”³³

90. One of the targets of the DOJ investigation has reportedly applied for leniency. This is significant because the applicant must admit to participation in a criminal antitrust violation. As the DOJ notes on its web site:

³¹ *Id.* at III-83.

³² *Id.*

³³ *See* AG Complaint at ¶ 1.

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.³⁴

91. 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."³⁵

92. DOJ and state government investigations of Defendants' alleged price-fixing conduct in the generic pharmaceutical industry continue.

F. Order Denying Motion to Dismiss in *Propranolol Antitrust Litigation*

93. In another generic drug price-fixing case, *In re: Propranolol Antitrust Litigation*, the U.S. District Court for the Southern District of New York entered an Opinion and Order on April 6, 2017 denying a motion to dismiss direct purchasers' consolidated amended complaint. *See In re Propranolol Antitrust Litig.*, No. 16-cv-9901, -- F.3d --, 2017 WL 1287515 (S.D.N.Y. Apr. 6, 2017) (Rakoff, J.) ("Propranolol Order").³⁶ Plaintiffs in the *Propranolol* case alleged a

³⁴ Frequently Asked Questions Regarding the Antitrust Division's Leniency Program, Dept. of Justice (last visited Jan. 24, 2017), available at <http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program>

³⁵ *Id.*

³⁶ The *Propranolol* defendants are Actavis Elizabeth, LLC, Teva Pharmaceuticals USA, Inc., Pliva, Inc., Mylan Inc., Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc., Par

conspiracy among generic manufacturers to manipulate the market for generic propranolol, with facts similar to those alleged herein for the generic Clobetasol market.

94. In denying the defendants' motion to dismiss, Judge Rakoff found that *Propranolol* plaintiffs pled a plausible price-fixing conspiracy and that plaintiffs alleged market specific factors suggesting that defendants had an incentive to manipulate prices. See *Propranolol Order* at 11, 13, 24. Judge Rakoff noted that Plaintiffs' pleadings "set forth in detail a regulatory regime that has historically pushed the price of Propranolol downwards and gradually reduced defendants' profits, thereby giving them a common motive to conspire." *Id.* at 13. Further, Judge Rakoff found that plaintiffs' pleadings "allege a pattern of price fixing spanning several years and no clear mechanism through which the defendants could legitimately and consistently monitor each other's pricing activity." *Id.* at 15-16.

95. The *Propranolol* plaintiffs alleged the presence of four plus factors to plausibly establish that the defendants conspired to fix prices of Propranolol capsules and tablets in 2013 and 2015: "(1) defendants had a motive to increase prices because they operate in an oligopolistic market characterized by falling prices; (2) the price increases were against defendants' self-interest because in a competitive market, defendants should have tried to undercut each other's prices to increase their market share; (3) defendants frequently communicated at trade association meetings; and (4) there are ongoing state and federal investigations for price manipulation of generic drugs, including Propranolol." *Id.* at 10-11, 24.

96. As alleged herein, the same plus factors exist in the market for Clobetasol.

97. Judge Rakoff rejected defendants' explanations for Propranolol price increases. For example, "plaintiffs plausibly allege that because the FDA did not report a shortage of

Pharmaceutical, Inc., Heritage Pharmaceuticals Inc., Breckenridge Pharmaceutical, Inc., and Upsher-Smith Laboratories, Inc.

Propranolol capsules following Mylan's exit, there was no 'shift' in the total supply of Propranolol that would rationally increase prices." *Id.* at 17. In addition, "while it is true that defendants' price increases did not always align on a monthly basis, defendants consistently raised prices on a bi-monthly and quarterly basis, which is consistent with an illegal agreement." *Id.* (emphasis in original). Similar price increases for Clobetasol are shown in this complaint. *See infra.*

G. *In re: Generic Pharmaceuticals Pricing Antitrust Litigation*

98. On April 6, 2017, the U.S. Judicial Panel on Multidistrict Litigation entered a Transfer Order granting Rochester Drug Cooperative, Inc.'s motion to transfer ten generic drug price-fixing actions to the Eastern District of Pennsylvania for inclusion in *In re: Generic Digoxin and Doxycycline Antitrust Litigation*, MDL No. 2724 (E.D. Pa.). The MDL was renamed *In re: Generic Pharmaceuticals Pricing Antitrust Litigation* and now includes price-fixing allegations for eighteen generic drugs: (1) Doxycycline, (2) Digoxin, (3) Albuterol, (4) Clomipramine, (5) Desonide, (6) Pravastatin, (7) Divalproex, (8) Benazepril HCTZ, (9) Levothyroxine, (10) Propranolol, (11) Baclofen, (12) Glyburide, (13) Ursodiol, (14) Amitriptyline, (15) Lidocaine/Prilocaine, (16) Clobetasol, (17) Fluocinonide, and (18) Econazole.

99. This case has been filed as a related case to *In re Generic Pharmaceuticals Pricing Antitrust Litigation*, MDL No. 2724.

VII. THE GENERIC DRUG MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION

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

- (1) **High Degree of Industry Concentration** – As discussed above, a small number of competitors control a significant market share for generic Clobetasol, following consolidation in the industry. As discussed above, the Clobetasol market is highly concentrated and is dominated by Defendants Hi-Tech, Perrigo, Fougera, Taro, and Morton Grove. Defendants control nearly all of the market for generic Clobetasol topical ointment .05%; topical solution .05%; topical gel .05%; and topical cream .05%.
- (2) **Barriers to Entry** – Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry in the generic drug market. For example, while ANDAs are generally approved faster than NDAs, they may still take longer than a year to obtain approval and a majority of ANDAs are rejected. Barriers to entry increase the market's susceptibility to a coordinated effort among the dominant entities in the generic drug industry to maintain supra-competitive prices.
- (3) **Demand Inelasticity** – Generic Clobetasol is a necessary treatment for millions of patients. If a price change triggers a smaller proportionate change in quantity of the drug demanded, then the demand for the drug is said to be inelastic. If demand is inelastic, price increases result in limited declines in quantity sold or consumed in the market. For a cartel to profit from supracompetitive prices, demand must be inelastic at competitive prices such that cartel members are able to raise prices without triggering a decline in demand that would make a concerted price increase unprofitable. Because generic Clobetasol is considered a medical necessity for patients who purchase it regardless of an increase in price, it is particularly susceptible to collusive price fixing as price increases will directly translate into more revenue for cartel members, rather than less.
- (4) **Lack of Substitutes** – Patients are often unable to substitute other dermatological medications for generic Clobetasol. Clobetasol is often the only effective medicine for patients as it is a high strength topical corticosteroid. In 2015, generic Clobetasol was one of the two most utilized drugs for skin conditions.
- (5) **High Degree of Interchangeability** – Defendants' generic Clobetasol formulations are interchangeable, as are their generic Clobetasol products, as they contain the same chemical compounds made from the same raw materials. Thus, generic Clobetasol is standardized across suppliers and is highly interchangeable from one Defendant to the next.
- (6) **Absence of Competitive Sellers** – In the generic Clobetasol market, there is no practical threat that a group of competitive sellers will take market share from Defendants. Defendants have maintained supracompetitive pricing for generic Clobetasol throughout the Class Period. Thus, Defendants have oligopolistic market power in the generic Clobetasol market, which enables Defendants to increase prices without losing market share to non-conspirators.

(7) **Opportunities for Contact and Communication Among Competitors** – As discussed above, Defendants Hi-Tech Pharmacal, Perrigo, Taro U.S.A., Sandoz and Wockhardt increased Clobetasol prices after attending a June 2014 meeting of trade association GPhA. The DOJ is considering whether trade associations, such as GPhA, are potential avenues for facilitating collusion between different generic manufacturers as part of its ongoing investigation into the generic drug industry. GPhA provides and promotes opportunities for its members to communicate. The issuance of a grand jury subpoena to Defendant Taro U.S.A. also supports the potential for communication among Defendants on the pricing of generic Clobetasol.

101. Defendants' dominant market power has allowed them to substantially foreclose the market to rival competition, thereby impairing competition, maintaining and enhancing market power, and enabling Defendants to charge Plaintiff and the Class Members inflated prices above competitive levels for generic Clobetasol.

VIII. CLASS ACTION ALLEGATIONS

102. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(2) and (b)(3), Plaintiff brings this action on behalf of a class defined as follows:

All persons or entities that directly purchased generic Clobetasol from Defendants in the United States and its territories and possessions at any time during the period July 1, 2014 through the present (the "Class Period").

Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

103. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes that there are hundreds 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

104. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff's interests are 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.

105. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

106. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving alleged violations of antitrust law.

107. 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, thereby determining damages with respect to the Class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

108. The common legal and factual questions, which do not vary from Class member to Class member and which may be determined without reference to individual circumstances of any Class member, 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 artificially increase the prices of generic Clobetasol in the United States;
- (b) The duration and extent of the alleged contract, combination, or conspiracy;
- (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 Clobetasol in the United States during the Class Period;
- (e) Whether Defendants' conduct caused supracompetitive prices for generic Clobetasol;

- (f) Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiff 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.

109. 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 to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

110. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

IX. INTERSTATE TRADE AND COMMERCE

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

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

113. Defendants' and their co-conspirators' conduct, including the marketing and sale of Clobetasol, 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.

114. The conspiracy alleged in this Complaint has directly and substantially affected interstate commerce as Defendants deprived Plaintiff of the benefits of free and open competition in the purchase of Clobetasol within the United States.

115. Defendants' agreement to inflate, fix, raise, maintain, or artificially stabilize prices of Clobetasol, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing Clobetasol prices, were intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States and on import trade and commerce with foreign nations.

X. DEFENDANTS' ANTITRUST VIOLATIONS

116. Defendants' combination and conspiracy had the following anticompetitive effects in the market for generic Clobetasol:

- (a) Competition in the market for generic Clobetasol has been reduced;
- (b) Prices for generic Clobetasol have increased and have not followed the typical pricing patterns of generic drugs over time; and
- (c) U.S. purchasers have been deprived of the benefit of price competition in the market for generic Clobetasol.

117. During the Class Period, Plaintiff and Class Members directly purchased generic Clobetasol from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for generic Clobetasol than they would have and thus suffered substantial damages. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

118. Because Defendants' unlawful conduct has successfully eliminated competition in the market, and Plaintiff 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 damages will be calculated after discovery and upon proof at trial.

119. Defendants' misconduct reduced competition in the generic Clobetasol market, reduced choice for purchasers, and caused injury to purchasers.

120. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class continue to pay supracompetitive prices for generic Clobetasol.

XI. CLAIM FOR RELIEF

VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1

121. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

122. Defendants and their co-conspirators entered into, and engaged in, a contract, combination, or conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

123. 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.

124. Defendants' anticompetitive acts were intentional, were directed at the sales of Clobetasol in the United States, and had a substantial and foreseeable effect on interstate commerce by raising and fixing Clobetasol prices throughout the United States.

125. In formulating and effectuating their combination or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix, raise, maintain and/or stabilize the prices of generic Clobetasol, including: (1) participating in meetings to discuss their respective generic drug products; (2) agreeing to

coordinate and manipulate the prices and available supply of generic Clobetasol in a manner that deprived purchasers in the U.S. of price competition; and (3) providing pretextual justifications to purchasers and the public to explain any raises, maintenance or stabilization of the prices for Defendants' generic Clobetasol.

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, Plaintiff for Clobetasol were artificially raised, fixed, maintained, or stabilized at supra-competitive levels;
- b. Plaintiff was deprived of the benefits of free, open, and unrestricted competition in the sale of Clobetasol in the United States market; and
- c. Competition in establishing the prices paid for Clobetasol was unlawfully restrained, suppressed, or eliminated.

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

128. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Defendants entered into agreements with one another on the pricing of generic Clobetasol in the U.S. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

129. Each Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.

130. The conspiracy had its intended effect, as Defendants benefited from their collusion and the elimination of competition, both of which artificially inflated the prices of generic Clobetasol, as described herein.

131. As a result of Defendants' unlawful conduct, Plaintiff and Class Members have been injured in their business and property in that they have paid more for generic Clobetasol than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.

132. Defendants' unlawful conduct as alleged herein poses a significant, continuing threat of antitrust injury for which injunctive relief is appropriate under Section 16 of the Clayton Act.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Class Members pray for relief as set forth below:

A. Certification of the action as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;

B. Permanent injunctive relief that enjoins Defendants from violating the antitrust laws and requires them to take affirmative steps to dissipate the effects of the violations;

C. That acts alleged herein be adjudged and decreed to be unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;

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

E. By awarding Plaintiff and Class Members pre-judgment 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 the complaint in this action;

F. The costs of this suit, including reasonable attorney fees; and

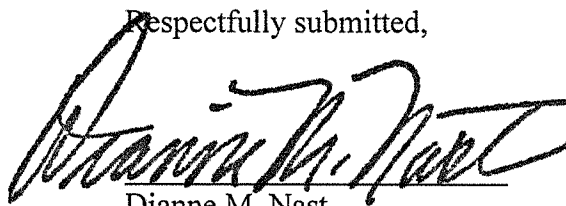
G. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

DATED: June 1, 2017

Respectfully submitted,



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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: 520 East Main Street, Gouverneur, NY 13642

Address of Defendant: See attached sheet

Place of Accident, Incident or Transaction: nationwide
(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

Does this case involve multidistrict litigation possibilities? Yes No

RELATED CASE, IF ANY:
Case Number: 16-MD-2724 Judge Cynthia M. Rufe Date Terminated: _____
16-CB-2724, 16-CB-27241

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
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 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
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

CIVIL: (Place 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. 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:

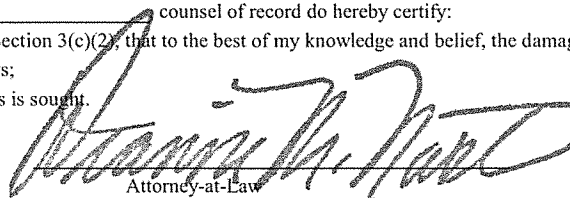
1. Insurance Contract and Other Contracts
2. Airplane Personal Injury
3. Assault, Defamation
4. Marine Personal Injury
5. Motor Vehicle Personal Injury
6. Other Personal Injury (Please specify)
7. Products Liability
8. Products Liability — Asbestos
9. All other Diversity Cases
(Please specify) _____

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: 6/1/2017


Attorney-at-Law

PA 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.# _____

Attachment to Designation Form

Addresses of Defendants

Fougera Pharmaceuticals Inc.
60 Baylis Road
Melville, NY 11747

Sandoz, Inc.
100 College Road West
Princeton, NY 08540

Novartis AG
Forum 1
Novartis Campus
CH-4056 Basel
Switzerland

Akorn, Inc.
1925 W. Field Ct.
Suite 300
Lake Forest, IL 60045

Hi-Tech Pharmcal Co., Inc.
369 Bayview Avenue
Amityville, NY 11701

Perrigo Company PLC
Treasury Building
Grand Canal Street Lower,
Grand Canal Dock,
Dublin 2
Ireland

Taro Pharmaceutical Industries Ltd.
14 Hakitor Street
PO Box 10347
Haifa Bay 2624761
Israel

Taro Pharmaceuticals USA, Inc.
3 Skyline Drive
Suite 120
Hawthorne, NY 10532

Wockhardt Ltd.
Wockhardt Towers
Bandra Kurla Complex, Bandra (East)
Mumbai 400051
Maharashtra, India

Morton Grove Pharmaceuticals, Inc.
6451 W. Main Street
Morton Grove, IL 60053

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

CASE MANAGEMENT TRACK DESIGNATION FORM

KPH Healthcare Services, Inc. : CIVIL ACTION
d/b/a Kinney Drugs, Inc. :
v. :
Fougera Pharmaceuticals, Inc. et al. : NO.

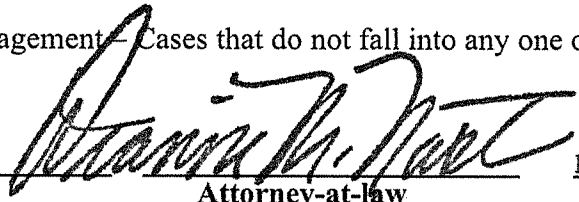
In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse 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. ()

6/1/2017

Date



Attorney-at-law

Plaintiff

Attorney for

215-923-9300

Telephone

215-923-9302

FAX Number

dnast@nastlaw.com

E-Mail Address

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.)

I. (a) PLAINTIFFS

KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc.

(b) County of Residence of First Listed Plaintiff St. Lawrence, NY (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) Dianne M. Nast, NastLaw LLC, 1101 Market Street, Suite 2801, Philadelphia, PA 19107, 215-923-9300

DEFENDANTS

Fougera Pharmaceuticals Inc., Sandoz, Inc., Novartis AG, Akorn, Inc., Hi-Tech Pharmacal Co., Inc., Perrigo Company PLC, Taro Pharmaceutical Industries Ltd., Taro Pharmaceuticals USA, Inc., Wockhardt Ltd., and Morton Grove Pharmaceuticals, Inc.

County of Residence of First Listed Defendant: Suffolk Co., NY

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- U.S. Government Plaintiff vs Federal Question (U.S. Government Not a Party)
U.S. Government Defendant vs Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff and Defendant citizenship: Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation.

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

Click here for: Nature of Suit Code Descriptions.

Large table with categories: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

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

- Original Proceeding, Removed from State Court, Remanded from Appellate Court, Reinstated or Reopened, Transferred from Another District, Multidistrict Litigation - Transfer, Multidistrict Litigation - Direct File

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

VI. CAUSE OF ACTION

Brief description of cause: Antitrust class action

VII. REQUESTED IN COMPLAINT:

X CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMANDS CHECK YES only if demanded in complaint: JURY DEMAND: X Yes 'No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Cynthia M. Rufe DOCKET NUMBER 16-MD-2724, 16-CB-27240, 16-CB-27241

DATE 6/1/2017 SIGNATURE OF ATTORNEY OF RECORD