16-cv-06698-CMR Document 1 Filed 12/30/16 Page 1 of 35

H400

Case 2

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

CÉSAR CASTILLO, INC., individually and on behalf of all those similarly situated,

Plaintiff,

11/2

v.

ACTAVIS HOLDCO U.S., INC.; FOUGERA PHARMACEUTICALS, INC.; PERRIGO COMPANY PLC; PERRIGO NEW YORK, INC.; SANDOZ, INC.; SUN PHARMACEUTICAL INDUSTRIES LTD.; TARO PHARMACEUTICAL INDUSTRIES, LTD.; and TARO PHARMACEUTICALS USA, INC., Civil Action No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Defendants.

Plaintiff César Castillo, Inc. ("Plaintiff") files this civil action pursuant to Section 1 of the Sherman Act, Section 4 of the Clayton Act, and Rule 23 of the Federal Rules of Civil Procedure, for damages, costs of suit, and other relief as may be just and proper, on behalf of itself and a class of those similarly situated ("Class" as defined below) against Defendants Actavis Holdco U.S., Inc. ("Actavis"), Fougera Pharmaceuticals Inc. ("Fougera"), Perrigo Company plc ("Perrigo Ireland"), Perrigo New York, Inc. ("Perrigo NY")¹, Sandoz, Inc. ("Sandoz"), Sun Pharmaceutical Industries Ltd. ("Sun"), Taro Pharmaceutical Industries, Ltd. ("Taro Israel"), and Taro Pharmaceuticals USA, Inc. ("Taro USA")², (collectively "Defendants"), for Defendants' conspiracy to artificially fix, raise, maintain and/or stabilize the prices of generic desonide ("Desonide"). Based upon personal knowledge, information, belief, and investigation of counsel, Plaintiff specifically alleges as follows.

INTRODUCTION

1. This is a civil antitrust action seeking treble damages arising out of the Defendants' unlawful scheme to fix, maintain, and stabilize the prices of generic desonide topical cream 0.05% and desonide topical ointment 0.05% ("Desonide").

2. Desonide is a widely prescribed topical corticosteroid that health care providers use to treat a variety of skin conditions, such as eczema and dermatitis. Because Desonide is a lower strength topical drug, physicians often prescribe it for pediatric patients or for adult patients to use in sensitive areas, like the eyelids.

3. Since at least 1994, manufacturers of generic drugs have had regulatory approval to market generic forms of Desonide. For much of that time, prices for generic

¹ Perrigo Ireland and Perrigo NY are together referred to as "Perrigo."

² Taro Israel and Taro USA are together referred to as "Taro."

forms of Desonide were low because generic manufacturers engaged in robust price competition, as typically occurs among generic drug manufacturers in the absence of collusion.

4. Recently, however, Defendants have substantially increased the price of Desonide, in unison.

5. Beginning in July 2013, shortly after two meetings of generic pharmaceutical manufacturers attended by Defendants Fougera, Perrigo, Sandoz, and Taro, Defendants acted in concert to raise the price of Desonide in unison by a dramatic margin.³ Although Actavis did not enter the Desonide market until November 2013, it too joined the conspiracy and implemented price increases. Those increases were the result of an agreement among Defendants to increase pricing and restrain competition for the sale of Desonide in the United States.

6. During a single week in July 2013, Defendants Fougera, Perrigo, Sandoz, and Taro collectively raised prices for Desonide more than six-fold, with certain product offerings increasing in price by more than 800%. Whereas, at the beginning of 2013, a 60-gram tube of Desonide cream cost \$26.75, as of December 12, 2013, the cost was nearly \$225.

7. Defendants' price increases were substantially in lockstep and Defendants' prices have stabilized at artificially high levels. As of December 2016, Desonide prices remain nearly more than 500% above their pre-July 2013 levels.

³ GAO, Report to Congressional Requesters, Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases (Aug. 2016), *available at* <u>http://www.gao.gov/products/GAO-16-706</u> and <u>http://www.gao.gov/assets/680/679022.pdf</u> at 37.

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 4 of 35

A report issued in August 2016 by the United States Government Accountability
 Office ("GAO") found that Desonide topical cream 0.05% and Desonide topical ointment 0.05%
 both "experienced an extraordinary price increase" from 2013 to 2014.⁴

9. Defendants' price increases were contrary to their respective unilateral selfinterests. Like any generic drug, Desonide is a commodity product. Therefore, absent a conspiracy or factors justifying a price increase, if any manufacturer substantially increased the price of Desonide, its competitors would not be expected to increase their prices by similar amounts, but would be expected seek to sell more Desonide to that manufacturer's customers. In other words, it would be contrary to any manufacturer's unilateral self-interest to substantially increase its price for Desonide unless it had agreed with the other manufacturers that they would do the same.

10. The only factors that would have justified such price increases would have been a significant increase in the costs of making Desonide, a significant decrease in the supply of Desonide, or a significant increase in demand for Desonide. None of those transpired in 2013. Absent these factors, substantial price increases would have been contrary to each Defendant's unilateral self-interest absent the existence of a cartel.

11. Inter alia, Defendants realized their conspiracy through private and public communications and meetings such as trade association meetings held by the GPhA. Given the small number of competitors and the high barriers to entry in the market for Desonide the market was ripe for collusion. Defendants recognized this and engaged in anticompetitive actions that allowed them to sustain their unlawful supracompetitive pricing.

⁴ Id.

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 5 of 35

12. Defendants' dramatic and unexplained price increases have resulted in extensive scrutiny by the United States Congress and federal and state regulators. In October 2014, Congress sent letters to the heads of several drug manufacturers, including Defendants Actavis and Sun as part of an investigation "into the recent staggering price increases for generic drugs used to treat everything from common medical conditions to life threatening illnesses."⁵

13. No later than November 3, 2014, the Antitrust Division of the United States Department of Justice ("DOJ") commenced a wide-ranging investigation into generic drug manufacturers' marketing and pricing practices.

14. These investigations have begun to reveal a reportedly broad, well-coordinated, and long-running series of schemes to fix prices, allocate markets, and rig bids for a number of generic drugs in the United States. These investigations have also revealed that Defendants' collusion on generic drug prices was centered around trade associations, such as the Generic Pharmaceutical Association ("GPhA"), customer conferences, and other industry gatherings. As part of these ongoing investigations, the DOJ convened a grand jury in this District. This grand jury has issued subpoenas and other requests for information to various generic drug manufacturers on a variety of generic drugs.

15. Defendants Taro, Fougera, Sandoz, Sun and Actavis have been subpoenaed by the DOJ's grand jury in this District as part of its ongoing investigation of anticompetitive practices in the generic pharmaceutical industry.

⁵ See e.g., Letter from Sen. Bernard Sanders and Rep. Elijah E. Cummings to Brenton L. Saunders, Chief Executive Officer and President, Actavis plc (Oct. 2, 2014), available at <u>http://www.sanders.senate.gov/download/letter-to-mr-saunders-ceo-and-president-actavis?inline=file</u>.

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 6 of 35

16. On December 14, 2016, the DOJ unsealed criminal informations against two former senior executives of generic drug manufacturer Heritage Pharmaceuticals Inc. for violations of Section 1 of the Sherman Act for their roles in conspiracies to fix prices, rig bids, and allocate customers for generic drugs Glyburide and Doxycycline Hyclate DR. *See United States v. Glazer*, No. 16-cr-506 (E.D. Pa.) and *United States v. Malek*, No. 16-cr-508 (E.D. Pa.). The DOJ is reportedly preparing additional cases involving other generic drugs.

17. On December 15, 2016, twenty states attorneys general also filed their first action (relating to the generic drugs Glyburide and Doxycycline) based on their investigation into generic drug pricing. *See State of Connecticut v. Aurobindo Pharma USA, Inc.*, No. 16-cv-2056 (D. Conn.) (the "State AG Action").

18. According to the complaint in the State AG Action, the information developed through the AGs' investigation (which is ongoing) uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for generic pharmaceuticals, beyond Glyburide and Doxycycline Hyclate DR. The complaint alleges that the conspiracies implicate numerous manufacturers.

19. As a result of Defendants' scheme to fix, raise, maintain, and stabilize the prices of Desonide, direct purchasers such as Plaintiff César Castillo, Inc., have paid and continue to pay supracompetitive prices.

20. Plaintiff César Castillo, Inc. brings this civil antitrust action on behalf of a proposed class of direct purchasers of (1) Desonide topical cream 0.05% and (2) Desonide topical ointment 0.05% (collectively, "Desonide"). Plaintiff seeks overcharge damages arising out of Defendants' agreement not to compete in the market for Desonide.

JURISDICTION AND VENUE

21. This action 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(a), and seeks to recover treble damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff and members of the Class resulting from Defendants' conspiracy to restrain trade in the United States. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

22. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because, during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of their activity that affected the interstate trade and commerce discussed below has been carried out in this District.

23. During the Class Period, Defendants sold and shipped Desonide in a continuous and uninterrupted flow of interstate commerce, including in this District. Defendants' conduct had direct, substantial, and reasonably foreseeable effects on interstate commerce in the United States, including in this District.

24. This Court has *in personam* jurisdiction over Defendants because each, either directly or through the ownership and/or control of its subsidiaries, *inter alia*: (a) transacted business throughout the United States, including in this District; (b) participated in the sale and distribution of Desonide throughout the United States, including in this District; (c) had and maintained substantial aggregate contacts with the United States as a whole, including in this District; or (d) was engaged in an illegal price-fixing conspiracy that was directed at, and had a direct, substantial, reasonably foreseeable and intended effect of causing injury to, the business or property of persons and entities residing in, located in, or doing business throughout the United States, including in this District. Defendants also conduct business throughout the United

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 8 of 35

States, including in this District, and they have purposefully availed themselves of the laws of the United States.

25. By reason of the unlawful activities alleged herein, Defendants substantially affected commerce throughout the United States, causing injury to Plaintiff and members of the Class. Defendants, directly and through their agents, engaged in activities affecting all states, to restrict output and fix, raise, maintain and/or stabilize prices in the United States for Desonide, which unreasonably restrained trade and adversely affected the market for Desonide.

26. Defendants' conspiracy and unlawful conduct described herein adversely affected persons and entities in the United States who directly purchased Desonide manufactured by Defendants, including Plaintiff and the members of the Class.

PARTIES

A. <u>Plaintiff</u>

27. Plaintiff César Castillo, Inc. is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business and headquarters located at Bo. Quebradas Arena, Rd. #1 Km. 26.0, Rio Piedras, Puerto Rico, 00926. During the Class Period, Plaintiff purchased Desonide directly from one or more Defendants. As a direct and proximate result of Defendants' collusion, manipulative conduct, and unlawful acts, Plaintiff was injured in its business or property.

B. Defendants

28. Defendant Actavis Holdco U.S., Inc. ("Actavis") is a Delaware corporation with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054. During the Class Period, Actavis sold Desonide in this District and throughout the United States.

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 9 of 35

29. Defendant Fougera Pharmaceuticals, Inc. ("Fougera") is a New York corporation with its principal place of business at 60 Baylis Road, Melville, New York 11747. Fougera markets and sells Desonide throughout the United States.

30. Defendant Sandoz, Inc. ("Sandoz") is a Colorado corporation with its principal place of business at 100 College Road, W, Princeton, New Jersey 08540. Sandoz is the United States affiliate of Sandoz International GmbH, a company organized and existing under the laws of Germany, with its principal place of business in Holzkirchen, Germany. Sandoz is responsible for the distribution of drugs developed and manufactured by Sandoz International GmbH. Together Sandoz and Sandoz International GmbH operate as the generic pharmaceuticals division of Novartis International AG, a global healthcare company based in Switzerland. In 2012, Novartis acquired Fougera for approximately \$1.5 billion.

31. Defendant Perrigo New York, Inc. ("Perrigo NY") is a Delaware corporation with its principal place of business at 1700 Bathgate Avenue, Bronx, New York 10457. Perrigo NY markets and sells Desonide through the United States.

32. Defendant Perrigo Company plc ("Perrigo Ireland") is a company organized and existing under the laws of Ireland with its principal place of business in Treasury Building, Lower Grand Canal St., Dublin 2, Ireland. Defendant Perrigo NY is a wholly-owned subsidiary of Defendant Perrigo Ireland.

33. Defendant Taro Pharmaceuticals USA, Inc. ("Taro USA") is a New York corporation with its principal place of business at 3 Skyline Dr., Ste. 120, Hawthorne, New York 10532. Taro USA markets and sells Desonide in the United States.

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 10 of 35

34. Taro Pharmaceutical Industries Ltd. ("Taro Israel") is an Israeli company with its principal place of business 14 Hakitor Street, PO Box 10347, Haifa Bay, 2624761, Israel. Defendant Taro USA is a wholly-owned subsidiary of Defendant Taro Israel.

35. Defendant Sun Pharmaceutical Industries, Inc. ("Sun") is an Indian corporation with its principal place of business located at 270 Prospect Plains Road, Cranbury, New Jersey 08512. In 2010, Sun acquired a controlling stake in Taro Israel.⁶

36. Various other entities and individuals currently unknown to Plaintiff may have also participated as co-conspirators in the acts complained of and/or performed acts that aided and abetted and/or otherwise furthered the conspiracy's objectives and unlawful conduct alleged herein.

37. The wrongful acts alleged to have been done by any one Defendant or co-

conspirator were authorized, ordered, or done by its directors, officers, managers, agents,

employees, or representatives while actively engaged in the management, direction, or control of

such Defendant's or co-conspirator's affairs.

CLASS ALLEGATIONS

38. Plaintiff brings this action on behalf of itself and, pursuant to Federal Rules of

Civil Procedure 23(a) and 23(b)(3), as representative of a class (the "Class") defined as follows:

All persons who or entities which purchased Desonide directly from any of the Defendants, or any current or former subsidiary or affiliate thereof, or any coconspirator, in the United States, during the period from and including June 4,

⁶ Rumman Ahmed, Sun Pharma Acquires Controlling Stake in Taro, THE WALL STREET JOURNAL (Sept. 22, 2010), available at

<u>http://www.wsj.com/articles/SB10001424052748704129204575507013304953260</u>. In May 2016, Sun's U.S. subsidiary received a grand jury subpoena from the Department of Justice Antitrust Division related to generic products and pricing. *See* Siddharth Vikram Philip, *Sun Pharma Says U.S. Unit Gets Subpoena in Antitrust Probe*, BLOOMBERG (May 28, 2016), *available at* <u>https://www.bloomberg.com/news/articles/2016-05-28/sun-pharma-says-u-s-unit-subpoenaed-in-antitrust-investigation</u>.

2013 through the present. Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

39. The Class Members are so numerous and geographically dispersed that joinder of all members is impracticable.

40. Plaintiff's claims are typical of the claims of the other Class Members. Plaintiff and other Class members have all sustained damage in that, during the Class Period, they purchased Desonide at artificially maintained, non- competitive prices, established by the Defendants' actions in connection with the violations alleged herein.

41. Plaintiff will fairly and adequately protect the interests of all Class Members. Plaintiff has purchased Desonide directly from at least one of the Defendants. Plaintiff has retained counsel competent and experienced in class action and antitrust litigation. Plaintiff's interests are coincident with, and not antagonistic to, the interests of the other Class Members.

42. Common questions of law and fact exist with respect to all Class Members and predominate over any questions solely affecting individual members. The common legal and factual questions, which do not vary among Class Members include, but are not limited to, the following:

(a) Whether and to what extent Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to fix, raise, maintain, or stabilize the prices of Desonide in the United States;

(b) The scope and duration of the contract, combination, or conspiracy, the identity of its participants, and the acts undertaken in its furtherance;

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

(d) Whether and to what extent Defendants' conduct resulted in supracompetitive prices for Desonide;

(e) Whether and to what extent Defendants' conduct injured Plaintiff and other Class Members; and

(f) The appropriate measure of damages sustained by Plaintiff and other Class Members.

43. A class action is superior to any other method for the fair and efficient adjudication of these issues, as joinder of all members is impracticable. The damages suffered by many Class Members are small in relation to the expense and burden of individual litigation, and therefore, it is highly impractical for such Class Members to individually attempt to redress the wrongful anticompetitive conduct alleged herein.

INTERSTATE TRADE AND COMMERCE

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

45. Desonide products are produced by or on behalf of Defendants or their affiliates in the United States and/or overseas.

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

47. 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.

48. Defendants and their co-conspirators' conduct, including the marketing and sale of Desonide, 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.

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

50. Defendants' agreement to inflate, fix, raise, maintain, or artificially stabilize prices of Desonide, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing Desonide 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.

FACTUAL ALLEGATIONS

A. <u>Overview of Generic Drug Market</u>

1. Generic drugs lead to lower prices

51. 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.⁷

⁷ FDA, Generic Drugs: Questions and Answers, available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 14 of 35

52. 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."⁸

53. Generic versions of brand drugs are priced significantly below the brand versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand product unless the doctor has indicated that the prescription for the brand product must be dispensed as written. States adopted substitution laws following the federal government's 1984 enactment of the Hatch-Waxman Act (discussed in more detail below).

54. The FDA has recognized that "[g]eneric competition is associated with lower drug prices[.]^{"9} A Federal Trade Commission study reached the same conclusion finding that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."¹⁰ Economic literature in the healthcare market further confirms that competition by generic products results in lower prices for consumers. 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 without the impact of competitive market forces. Once the first generic enters the market, however, a brand drug rapidly loses sales, on average 90% within a year.¹¹ As more

⁸ Id.

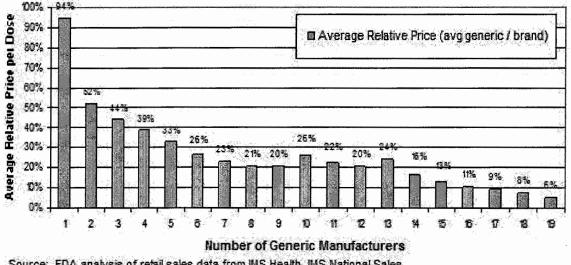
⁹ FDA, Generic Competition and Drug Prices, *available at* <u>http://www.fda.gov/AboutFDA/</u> CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

¹⁰ FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010), *available at*

https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-payoffs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

¹¹ Id.

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 drug to the corresponding generic accelerates as more generic options are available to purchasers:¹²



Generic Competition and Drug Prices

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

55. A mature generic market, such as the market for Desonide, has several generic competitors. Due to the fact that each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers.¹³ Over time, generics' pricing nears the generic manufacturers' marginal costs.

¹² See, e.g., Ernst R. Berndt et al., Authorized Generic Drugs, Price Competition, and Consumers' Welfare, HEALTH AFFAIRS, 26, no. 3 (2007):790-799.

¹³ 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."), *available at* <u>https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-</u>

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 16 of 35

56. Generic competition usually enables purchasers to (a) purchase generic versions of the brand drug at a substantially lower price than the brand drug, and/or (b) purchase the brand drug at a reduced price. Generic competition to a single blockbuster brand drug product can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and federal governments, and others. Indeed, one study found that the use of generic medicines saved the United States healthcare system \$254 billion in 2014 alone, and \$1.68 trillion between 2005 and 2014.¹⁴

2. How generic drugs come to market

57. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. § 355(a), (b).

58. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.¹⁵ Hatch-Waxman allows a manufacturer seeking approval to sell a generic version of a brand drug to file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA, and

effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-shortterm-effects-and-long-term-impact-report-federal-trade-commission.pdf; Congressional Budget Office, "How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" (July 1998), *available at* https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

¹⁴ Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.*, at 1 (2015), *available at* <u>http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf</u>.

¹⁵ See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 17 of 35

must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an "AB" rating.

59. Most drug companies that want to introduce a generic drug to the market file an ANDA with the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs. The only exception is for so-called "authorized generics," which are generics launched under the brand company's NDA but typically priced like other generics.

60. Generic drugs that are bioequivalent to a brand drug (sometimes called the "Reference Listed Drug" or "RLD") are assigned a Therapeutic Equivalence Code ("TE Code"). 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. Thus, generic drugs that are AB-rated to the brand share the same safety and efficacy characteristics and are the same dosage size and form.

B. <u>Consolidation of Generic Drug Market</u>

61. The global market for generic pharmaceuticals has undergone substantial consolidation since 2005. Generic pharmaceutical industry leader Teva Pharmaceutical Industries Ltd., for example, 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 Allergan Generics in 2016 for \$40.5 billion. Other major transactions that occurred during the same time period include Watson Pharmaceuticals' \$1.9 billion acquisition of Andrx Corporation in 2006; Daiichi Sankyo's purchase of a majority stake in Ranbaxy Laboratories, Ltd. in 2008; and Endo Pharmaceuticals' 2010 acquisition of Qualitest Pharmaceuticals for \$1.2 billion, Perrigo's acquisition of Paddock Laboratories, Inc. in 2011; and Sandoz's acquisition of Fougera in 2012.

62. Consolidation reduces the number of potential competitors, rendering the market ripe for collusion.

63. The consequence of the generic drug industry's consolidation and coordinated pricing activity has been higher prices for consumers. Market consolidation also has resulted in generic product lines being combined or discontinued, further reducing price competition.

64. Like the market for most generic drugs, the Desonide market is now highly concentrated. Defendants dominate the market for the generic forms of Desonide at issue here.

65. Thus, the Defendants' concerted actions have had the ability to, and did, impact pricing and output of Desonide in the United States.

C. Desonide Has Been Sold in the United States for Decades

66. Desonide is a low-potency topical corticosteroid that first came to market in the 1970s. Desonide is used to treat swelling, itching and redness caused by a variety of skin conditions. Because of its relatively low potency, Desonide is widely used to treat skin conditions in children and to treat sensitive areas and folds of the skin in adults.

67. Defendants Actavis, Fougera, Perrigo, and Taro have been the primary manufacturers of Desonide available for purchase in the United States. Defendant Sandoz acquired Fougera in 2012.

68. Since at least 1994, manufacturers of generic drugs have had regulatory approval to market generic forms of Desonide. For much of that time, prices for generic forms of Desonide were low because generic manufacturers engaged in robust price competition, as typically occurs among generic drug manufacturers in the absence of collusion.

D. <u>Desonide Prices Increased Dramatically During the Class Period Without</u> <u>Justification</u>

69. Prior to June 2013, the average price in the U.S. paid for Desonide was

remarkably stable. Beginning in June 2013, however, Defendants caused the price of Desonide to dramatically increase in unison. The chart below shows the nearly identical Defendant prices for each formulation of Desonide in September 2013, from one of the numerous industry reports of "runaway costs" and providing links to the NADAC files and price increase analyses:

NDC Description	National Drug Code	Brand or Generic	NADAC Per Unit	Units Per Packoge	Pricing Unit	Average Pharmacy Cost Per Package	Hatio of Recent Cost to Cost 1 Year Prior	Manufactures or Distributor	Effective (Sorvery) Date
DESONDE 0.05% CREAM	45602042237	G	4,13394	68.00	GM	\$248,64	9,27	PERFICO NEW YORK INC	09/19/2013
DESCRIDE 0.05% CREAM	51672128003	G	4,13294	60.00	GM	\$248.04	9.27	TARO PHARMACEUTICALS USA INC	09/19/2013
DESCRIDE 0.05% CREAM	45802942235	G	4.21352	15.00	GM	\$63.20	5.12	PERRIGO NEW YORK INC	69/19/2013
DESCRIDE 0.05% CREAM	51672128001	Ġ	4.21352	15.00	GM	\$63.20	5.12	TARO PHARMACEUTICALS USA NC	09/19/2013
CERCINCE O SEW LOTION	00168031002	G	3.72035	53.00	MIL.	\$219.50	2.33	E FOUGERA AND CO A DIVISION OF NYCOMED US BIC	09/19/2013
CESONDE 0.05% LOTION	00472080302	G	3,72035	57.10	ML.	5212.43	2.33	ACTAVIS MID ATLANTIC LLC	09/19/2013
desonde 0.95% loton	00168031004	G	2.51772	118.00	ML.	\$297.09	2.18	E FOUGERA AND CO A DIVISION OF NYCOMED US NC	09/19/2013
DESCRIDE 0.95% LOTION	00472080304	6	2.51772	114.10	Ma.	\$287.27	2.10	ACTAVIS MID ATLANTIC LLC	03/19/2013
DESCRIDE 0.55% ONTMENT	0168030960	6	3.09723	60.00	GM	\$185.83	8.51	E FOUGERA AND CO A DIVISION OF NYCOMED US INC	09/19/2013
DESCRIDE 6.95% ONTMENT	45802042337	G	3,09723	60.00	GM	\$185.83	9.51	PERRIGO NEW YORK INC	09/19/2013
DESONCE 0.05% ONTMENT	51572123103	Ģ	3.09723	60,00	GM	\$185.83	9.51	TARO PHARMACEUTICALS USA DIC	69/19/2013
DESONDE 0.05% ONTMENT	00158030915	G	3,15347	15.00	GM	\$47.30	4.96	E FOUGERA AND CO A DIVISION OF NYCOMED US INC	05/13/2013
DESCRIDE 9 35% ONTMENT	45802042335	G	3.15347	15,00	GM	\$47.30	4.96	PERRIGO NEW YORK INC	09/19/2013
DESONDE 0.05% ONTMENT	51672128101	9	3.15347	15.00	GM	\$47.30	4.96	TARO PHARMACEUTICALS USA INC	09/19/2013

See The Long Island Dermatological Society, Generic Drug Prices Climb, available at http://www.longislanddermatologists.org/default.asp?id=228&c002_ui=sa&c002_id=113

70. The National Association of State Medicaid Directors, National Average Drug Acquisition cost data ("NADAC") "is designed to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs."16

71. The NADAC data shows that between July 2013 and January 2014, Defendants increased their prices for Desonide in tandem by more than 600%, with certain products increasing by nearly 900%.

72. During a single week in July 2013, Defendants Fougera, Perrigo, Sandoz, and Taro collectively raised prices for Desonide more than six-fold, with certain product offerings increasing in price by more than 800%. Whereas, at the beginning of 2013, a 60-gram tube of Desonide cream cost \$26.75, by December 12, 2013, the cost was nearly \$225.

73. Additional NADAC data as of December 21, 2016 demonstrate that Defendants have maintained prices for Desonide in all of its relevant forms at supracompetitive prices. ¹⁷ As of December 2016, the cost of Desonide still remains nearly 500% higher than the cost prior to the June 2013 trade association meeting.¹⁸

74. There were no market-based justifications for these abrupt price increases, which were not necessitated by increased manufacturing costs, or research and development costs. There were no known raw material shortages affecting the manufacture of Desonide in the United States, nor did demand for Desonide suddenly increase.

¹⁶ See <u>https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf</u>.

¹⁷ See Survey of Retail Prices, available at <u>https://www.medicaid.gov/medicaid/prescription-drugs/survey-of-retail-prices/index.html</u>; and National Average Drug Acquisition Cost and NADAC Comparison Data available at <u>https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html</u>.

¹⁸ Available at <u>https://data.medicaid.gov/Drug-Prices/NADAC-as-of-2016-12-28/bg7x-n8ir</u>.

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 21 of 35

75. Federal law requires drug manufacturers to report potential drug shortages to the

FDA, along with the reasons for those shortages, and their expected duration. Defendants made no such reports with respect to Desonide during the Class Period.

76. In a report dated April 21, 2015, Sector & Sovereign Research concluded that:

"A plausible explanation is that generic manufacturers . . . 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."19

77. These price increases had a substantial impact on consumers. Letters from

members of Congress to generic drug manufacturers included the following:

This dramatic increase in generic drug 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," and "84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a 'very significant' impact on their ability to remain in business to continue serving patients."²⁰

E. Defendants' Opportunities for Collusion

78. The DOJ is reportedly looking closely at trade associations. According to an

intelligence report from Policy and Regulatory Report, a source that was given inside

information by someone with knowledge of the DOJ's investigation, the DOJ is looking closely

¹⁹ See US Generic Inflation Continues in 1Q15 (Apr. 21, 2015), available at <u>http://www.sector-sovereign.com/abccahmck-us-generic-inflation-continues-in-1q15/</u>.

²⁰ See e.g., Letter from Sen. Bernard Sanders and Rep. Elijah E. Cummings to Arthur P. Bedrosian, President and Chief Executive Officer, Lannett Company, Inc. (Oct. 2, 2014), *available at* <u>http://www.sanders.senate.gov/download/letter-to-mr-bedrosian-president-and-ceo-lannett-company-inc?inline=file.</u>

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 22 of 35

"at trade associations as part of their investigation as having been one potential avenue for facilitating the collusion between salespeople at different generic producers."²¹

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

80. At these conferences and trade shows, Defendants' representatives have opportunities to interact with each other directly, and discuss their respective businesses and customers. Organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities, are held concurrent with many of these conferences and trade shows, and provide further opportunities for conspirators to meet with competitors outside of the usual business setting. Generic drug manufacturer representatives who attend these functions use these opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers, among other competitively-sensitive information.

81. In addition to these conferences and trade shows, representatives of generic drug manufacturers gather separately, in smaller groups, allowing them to further meet face-to-face with their competitors and discuss their businesses. A large number of generic drug manufacturers, including several of the Defendants, have offices in close proximity to one another in New Jersey, eastern Pennsylvania, or New York, giving them more frequent

²¹ Eric Palmer, Actavis gets subpoena as DOJ probe of generic pricing moves up food chain, FIERCEPHARMA (Aug. 7, 2015), available at <u>http://www.fiercepharma.com/regulatory/actavis-gets-subpoena-as-doj-probe-of-generic-pricing-moves-up-food-chain</u>.

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 23 of 35

opportunities to meet and collude. In fact, high-level executives of Defendants gather periodically for what at least some of them refer to as "industry dinners."

82. As a result of these various interactions, Defendants' sales and marketing executives are well aware of their competition and, more importantly, each other's current and future business plans. This familiarity and these opportunities often lead to agreements among competitors to fix prices or to allocate given markets, so as to avoid price competition.

83. Defendants routinely communicate and share information with each other about their bids and pricing strategies. This can include forwarding bid packages received from their customers (*e.g.*, Requests for Proposal) to competitors, either on their own initiative, or at the competitor's request.

84. Defendants also share information regarding the terms of their contracts with customers, including terms relating to pricing, price protection and rebates. Generic drug manufacturers use this information from their competitors to impose higher prices or more onerous terms on their customers, to the ultimate detriment of consumers.

85. Before June 2013, the price of Desonide was stable. Following the June 2013 GPhA meeting, which was attended by executives from all of the Defendants, Defendants caused the price of Desonide to dramatically increase in unison beginning in at least August 2013. The increases were the result of a horizontal agreement among Defendants to increase pricing and restrain competition for Desonide. Defendants met at least twice in 2013 before implementing their price increases. These meetings occurred at GPhA events.

86. The GPhA describes itself as "the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry."

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 24 of 35

See <u>http://www.gphaonline.org/about/the-gpha-association/</u>. 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.

87. According to GPhA's website, "GPhA member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year." *See* <u>http://www.gphaonline.org/about/membership</u>. GPhA further claims 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." *Id*.

88. Defendants Perrigo Ireland and Sandoz sit on the GPhA's board of directors.

89. Defendants Actavis, Perrigo Ireland, Sandoz, Sun and Taro Israel attended the GPhA's Annual Meeting in Orlando, Florida on February 20, 21, and 22, 2013.

90. Defendants Actavis, Fougera, Perrigo Ireland, Sandoz, and Taro attended the GPhA's CMC Workshop in North Bethesda, Maryland on June 4 and June 5, 2013.

91. The meetings in February and June of 2013 provided Defendants with opportunities to collude.

92. Defendants also routinely gathered at non-GPhA sponsored events.

93. The meetings, among other contacts among Defendants, provided Defendants with opportunities to collude, and on information and belief, at these meetings Defendants agreed to increase pricing for Desonide.

94. As a result of Defendants' agreement, whenever certain Defendants raised their prices, others would soon follow. Plaintiffs analyzed certain Desonide sales data, which shows that the price hikes for Desonide generally occurred industry-wide.

F. Government Responses to Rising Generic Drug Prices

95. As noted above, Defendants' conduct in regards to generic drugs is under investigation by Congress, the DOJ, state attorneys general and others.

96. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Congressman Elijah Cummings sent letters to several Desonide manufacturers, including Defendant Actavis, as part of an investigation "into the recent staggering price increases for generic drugs used to treat everything from common medical conditions to life threatening illnesses" and requesting detailed sales, marketing and cost information for the Defendants' generic products.²²

97. On November 20, 2014, United States Senator Bernie Sanders' Senate Subcommittee on Primary Health and Aging held a hearing entitled "Why Are Some Generic Drugs Skyrocketing In Price?"²³

98. Most recently, in December 2016, the United States Senate Special Committee on Aging issued a lengthy report on drug pricing noting that its investigation "uncovered disturbing practices in pharmaceutical drug pricing."²⁴

²² See e.g., Letter from Sen. Bernard Sanders and Rep. Elijah E. Cummings to Jeffrey Watson, President, Apotex Corp., North America (Oct. 2, 2014), *available at* http://www.sanders.senate.gov/download/letter-to-mr-watson-president-apotex-corp?inline=file.

²³ See, e.g., U.S. Congress Press Release, Congressional Panel to Probe Generic Drug Price Hikes (Nov. 11, 2014), available at <u>https://democrats-oversight.house.gov/news/press-</u> releases/congressional-panel-to-probe-generic-drug-price-hikes.

²⁴ United States Senate Special Committee on Aging, Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S.

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 26 of 35

99. No later than November 3, 2014, as noted above, the DOJ opened a wide-ranging grand jury investigation into the marketing and pricing practices of generic drugs, which has resulted in the issuance of grand jury subpoenas several generic drug manufacturers, including all Defendants and/or their affiliates. The DOJ is now conducting a wide-ranging criminal investigation into collusion among generic drug companies. According to BLOOMBERG NEWS, the investigation encompasses more than 12 companies and at least 24 generic drugs. *See* <u>https://www.bloomberg.com/news/articles/2016-12-22/widespread-drug-price-increases-point-to-collusion-study-finds.</u>

100. A source at the Policy and Regulatory Report says "prosecutors see the case much like its antitrust probe of the auto parts industry, which has gone on for years and morphed into the department's largest criminal antitrust probe ever. Like in that case, prosecutors expect 'to move from one drug to another in a similar cascading fashion."²⁵

101. Some Defendants and other generic manufacturers have confirmed that they have been served with federal grand jury subpoenas and subpoenas issued by the Connecticut Office of the Attorney General.

102. On June 25, 2015 Actavis' parent Allergan plc disclosed in public filings that Actavis had received a subpoena from the DOJ "seeking information relating to the marketing and pricing of certain of the Company's generic products and communications with competitors about such products."

Health Care System (Dec. 2016), *available at* <u>https://www.collins.senate.gov/sites/default/files/DP%20Report.pdf</u>.

²⁵ Eric Palmer, *DOJ criminal probe takes a look at trade associations*, FIERCEPHARMA (Jul. 10, 2015), *available at <u>http://www.fiercepharma.com/regulatory/doj-criminal-probe-takes-a-look-at-trade-associations</u>.*

103. On September 9, 2016, Defendant Taro Israel disclosed that on September 8, 2016, Defendant Taro USA, "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."

104. Sandoz and Fourgera are also reported to be under DOJ investigation. According to a November 2016 BLOOMBERG report, "Novartis's Sandoz unit [including Fougera] got a U.S. Justice Department subpoena in March [2016] requesting documents related to marketing and pricing of copycat medicines."²⁶

105. The fact that these companies and/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.²⁷ 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." *Id.* at III-82. The staff request needs to be approved by the relevant field chief and is then sent to the Antitrust Criminal Enforcement Division. *Id.* "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

²⁷ See DOJ Antitrust Division Manual, *available at* <u>http://www.justice.gov/atr/public/divisionmanual/chapter3.pdf</u>.

²⁶ Manuel Baigorri, *Novartis Said to Hold Talk to Buy Generics Maker Amneal*, BLOOMBERG (Nov. 13, 2016), *available at <u>https://www.bloomberg.com/news/articles/2016-11-13/novartis-said-to-hold-talks-to-buy-u-s-generics-maker-amneal.</u>*

investigation." *Id.* at III-83. "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." *Id.* Thus, Defendants' and their representatives' receipt of federal grand jury subpoenas is an indication that antitrust offenses have occurred.

106. If there is a leniency applicant involved in the DOJ generic drug investigation, there is still greater indication that antitrust offenses have occurred. The DOJ notes on its website that the leniency applicant must admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter.

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.²⁸

107. 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.

108. The DOJ is poised to issue criminal indictments against various companies and individuals growing out this investigation and, as indicated above, issued its first two indictments

²⁸ Frequently Asked Questions Regarding The Antitrust Division's Leniency Program, available at <u>http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program</u>.

on December 12, 2016. On December 14, 2016, BLOOMBERG reported that "[t]he Justice Department accused two executives of colluding with other generic pharmaceutical companies to fix prices, the first criminal charges stemming from a sweeping two-year investigation. Jeffrey Glazer, a former chief executive officer of Heritage Pharmaceuticals Inc., and Jason Malek, an ex-president, were charged in Philadelphia on Wednesday, according to court filings."²⁹

109. Twenty states attorneys general also filed their first action (relating to the generic drugs Glyburide and Doxycycline) based on their investigation into generic drug pricing on December 15, 2016.³⁰ They have indicated that more actions are likely to follow, specifically alleging that they "have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the appropriate time..." The states attorneys general describe these conspiracies as "schemes to fix and maintain prices, allocate markets and otherwise thwart competition" and explain that they are carried out by generic companies through their senior executives who "exploit their interactions at various and frequent industry trade shows, customer conferences and other similar events, to develop relationships and sow the seeds for their illegal agreements. The anticompetitive agreements are further refined and coordinated at regular 'industry dinners', 'girls nights out', lunches, parties, and numerous and frequent telephone calls, emails and text messages."³¹

110. Connecticut's attorney general George C. Jepsen commented on the suit that it was "just the tip of the iceberg" and stressed that "our investigation is continuing, and it goes

²⁹ Tom Schoenberg, U.S. Generic Drug Probe Seen Expanding After Guilty Pleas, BLOOMBERG (Dec. 14, 2016), available at <u>https://www.bloomberg.com/news/articles/2016-12-14/u-s-files-first-charges-in-generic-drug-price-fixing-probe.</u>

³⁰ Complaint, *State of Connecticut v. Aurobindo Pharma USA*, 16-cv-2056-VLB (D. Conn. Dec. 15, 2016), ECF No. 1.

³¹ *Id.* at paragraphs 7-8.

way beyond the two drugs in this lawsuit" and "involves many more companies" than were named in the first complaint.³²

G. The Desonide Market is Conducive to an Effective Conspiracy.

111. Characteristics specific to the market for Desonide in the United States make it conducive to a price-fixing agreement.

112. The Market is Highly Concentrated: A concentrated market is more susceptible to collusion and other anticompetitive practices. The Desonide market is highly concentrated and is dominated by the Defendants. Therefore, elaborate communications, quick to be detected, would not have been necessary to enable pricing to be coordinated.

113. The Market has High Barriers to Entry: Conspiracies that raise product prices above competitive levels will, all things being equal, attract to the relevant market new firms seeking to benefit from supracompetitive prices. But when barriers to entering the market are significant, new firms are less likely to do so. Barriers to entry thereby facilitate the maintenance of a price-fixing conspiracy. Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry.

114. As the dominant players in the Desonide market, Defendants were able to fix, raise, and maintain their prices for Desonide without competitive threats from rival generic drug manufacturers.

115. **Demand for Desonide is Inelastic:** "Elasticity" is a term that describes the sensitivity of demand for a product to changes in its price. Demand is "inelastic" if an increase in its price results in a relativity small decline in demand for the product. Demand is inelastic in

³² Katie Thomas, 20 States Accuse Generic Drug Companies of Price Fixing, THE NEW YORK TIMES (Dec. 15, 2016), available at <u>http://www.nytimes.com/2016/12/15/business/generic-drug-</u> price-lawsuit-teva-mylan.html.

markets—such as the Desonide market—in which customers cannot readily substitute alternative products, or do without a product altogether.

116. For competitors to profit from colluding to raise prices above competitive levels, demand for their product must be relatively inelastic at competitive prices. Otherwise, increased prices would reduce their sales as customers abandoned their products. Inelastic demand thus facilitates collusion.

117. Demand for Desonide is highly inelastic. A meaningful increase in the price for Desonide would not induce purchasers to switch to another product in significant numbers, as the there is no reasonable substitute for Desonide available at a lower price.

118. **Desonide is a Fungible Product:** Because all Desonide is the same, price is the predominant factor driving customers' purchasing decisions. The interchangeability of Desonide products facilitated Defendants' conspiracy by enabling coordination on price that would be more difficult if Defendants sold products that varied in composition and/or performance.

119. Defendants Had Ample Opportunities To Meet and Conspire: Defendants had numerous opportunities to conspire in person under the guise of legitimate business meetings. In particular, Defendants are members of the GPhA, and attend other industry events and meetings, which provide opportunities to communicate. Defendants' representatives regularly attended meetings of GphA and meetings of other trade associations during the Class Period. The DOJ is reportedly investigating trade associations like GPhA as a potential avenue for facilitating collusion among generic drug manufacturers as part of its ongoing investigation into anticompetitive pricing activities in generic drug markets.

ANTITRUST INJURY

120. During the Class Period, Plaintiff and Class Members purchased Desonide directly from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for Desonide 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.

121. Because Defendants' unlawful conduct has successfully restrained competition in the market, 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.

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

CLAIM FOR RELIEF

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

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

124. 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.

125. 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.

÷

126. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Defendants entered into agreements with one another as to the output and pricing of Desonide 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.

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

128. The conspiracy had its intended effect, as Defendants benefited from their collusion and the restraint of competition, both of which artificially inflated the prices of Desonide, as described herein.

129. 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 Desonide 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.

130. 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.

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

Case 2:16-cv-06698-CMR Document 1 Filed 12/30/16 Page 34 of 35

laws and requires them to take affirmative steps to dissipate the effects of their 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: December 30, 2016

Respectfully submitted,

B.A.Ch

Linda P. Nussbaum Bart D. Cohen (PA Bar No. 57606) Bradley J. Demuth Peter E. Moran NUSSBAUM LAW GROUP, P.C. 1211 Avenue of the Americas 40th Floor New York, NY 10036-8718 (917) 438-9189 <u>Inussbaum@nussbaumpc.com</u> (917) 438-9198 bcohen@nussbaumpc.com . .

Juan R. Rivera Font JUAN R. RIVERA FONT LLC Ave. González Giusti #27, Suite 602 Guaynabo, PR 00968 (787) 751-5290 juan@riverafont.com

Counsel for Plaintiff César Castillo, Inc. and the Proposed Direct Purchaser Class

The JS 44 civil cover sheet and provided by local rules of court surpose of initiating the civil d	the information contained herein neither replace no. This form, approved by the Judicial Conference cocket sheet. <i>(SEE INSTRUCTIONS ON NEXT PAGE O</i>	or supplement the filing and servic of the United States in September F THIS FORM.)	e of pleadings or other papers 1974, is required for the use of	as required by law, except as the Clerk of Court for the	
I. (a) PLAINTIFFS Cesar Castillo, Inc.		Actavis Holdco U	S., Inc. (see attached lis	0	
(b) County of Residence (E	of First Listed Plaintiff San Juan, Puerto Ri ACCEPT IN U.S. PLAINTIFF CASES)	NOTE: IN LAND C	(IN U.S. PLAINTIFF CASES ON ONDEMNATION CASES, USE T OF LAND INVOLVED		
Barth Attometry (PST: Attiny Avenue of the Americas, 438-9198	No. 57606, Nussbaum Law Group, P.C., 40th Floor, New York, NY 40036 (917)	1211 Attorneys (If Known)			
II. BASIS OF JURISD	CTION (Place an "X" in One Box Only) 3 Foderal Question (U.S. Government Not a Party)	- 성별한 사업법 법정인 사업(방송) 가진 방송) 등	PRINCIPAL PARTIES	and One Box for Defendant) PTF DEF incipal Place 0 4 0 4	
J 2 U.S. Government Defendant	4 Diversity (Indicate Citizenship of Parties in Item III)		1 2 D 2 Incorporated and of Business In 1 3 D 3 Foreign Nation	Principal Place 🛛 5 🖸 5	
IV. NATURE OF SUIT	(Place an "X" in One Box Only)	FORFETTURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted	PERSONAL INJURY PERSONAL INJURY 310 Airplane 365 Personal Injury - 315 Airplane Product Product Liability Liability 367 Health Care/ 320 Assault, Libel & Pharmaceutical	Y G25 Drug Related Seizure of Property 21 USC 881 690 Other.	AUXAGENE V	 375 False Claims Act 376 Qui Tam (31 USC 3729(a)) 400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 	
Student Loans (Excludes Veterans) 53 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise	□ 340 Marine Injury □ 305 Assession Feinomia □ 345 Marine Product Liability Injury Product □ 355 Motor Vehicle □ 370 Other Fraud □ 355 Motor Vehicle □ 371 Truth in Lending Product Liability □ 380 Other Personal □ 360 Other Personal Property Damage □ 362 Personal Injury □ 385 Property Damage □ 362 Personal Injury Product Liability	LABOR	SoorAL SECURITY SoorAL SECURITY	 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 850 Securities/Commodities/ Exchange 890 Other Statutory Actions 891 Agricultural Acts 893 Environmental Matters 895 Freedom of Information Act 896 Arbitration 899 Administrative Procedure Act/Review or Appeal of Agency Decision 950 Constitutionality of 	
REAL PROPERTY. 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability.	CIVIT. RIGHTS PRISONER PETITION 440 Other Civil Rights Habeas Corpus: 441 Voting I 463 Alien Detaince 442 Employment I 510 Motions to Vacate 443 Housing/ Accommodations 530 General	0 791 Employee Retirement Income Security Act	 FEDERAL TAX SUFFS 870 Taxes (U.S. Plaintiff or Defendant) 871 IRS—Third Party 26 USC 7609 		
290 All Other Real Property	 ☐ 445 Amer. w/Disabilities - Employment ☐ 446 Amer. w/Disabilities - Other: ☐ 540 Mandamus & Other ☐ 540 Mandamus & Other ☐ 550 Civil Rights ☐ 448 Education ☐ 550 Civil Detainee - Conditions of Confinement 	Actions Actions Actions		Shate Statutes	
V. ORIGIN (Place an "X" iv C1 Original I 2 Rep Proceeding Sta	noved from I 3 Remanded from te Court Appellate Court	(specify,	r District Litigation Transfer		
/ VI. CAUSE OF ACTIC	Cite the U.S. Civil Statute under which you are 15 U.S.C. Section 1 Brief description of cause: Antitrust price fixing conspiracy in vio		tutes unless diversity):		
VII. REQUESTED IN COMPLAINT:	B CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.	an teal in the advantation of the second	CHECK YES only JURY DEMAND:	if demanded in complaint:	
VIII. RELATED CASE IF ANY	(See instructions): JUDGE Cynthia	ni ni ser neven de grandelik her tanis i sen anjene de	DOCKET NUMBER 2:1	6-cv-06662-CMR	
ATE 2/30/2016	SIONATORE OF ATT	ORNEY OF RECORD		UEL 30 201	
OR OFFICE USE ONLY					

CIVIL COVER SHEET ATTACHMENT

DEFENDANTS

Actavis Holdco U.S., Inc., Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054

Fougera Pharmaceuticals, Inc., 60 Baylis Road, Melville, NY 11747

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

Perrigo New York, Inc., 1700 Bathgate Avenue, Bronx, NY 10457

Perrigo Company plc, Treasury Building, Lower Grand Canal St., Dublin 2, Ireland

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

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

Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd, Cranbury, NJ 08512

UNITED STATES DIST Case 2:16 cv 06098-CMR Document 1-1 FOR THE EASTERN DISTRICT OF RENNSYLVANIA — DESIGNATION FORM to b assignment to appropriate calendar.	Filed 12/30/16 Page 3 of 5
	260, Rio Piedras, Puerto Rico 00926
Address of Defendant: (see attachment)	
United States and Puer	to Rico generally
Place of Accident, Incident or Transaction: (Use Reverse Side For A	dditional Space)
Does this civil action involve a nongovernmental corporate party with any parent corporation a	nd any publicly held corneration awning 10% or more of its stock?
(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))	그것 같은 것 같은 NTM 전에서
Does this case involve multidistrict litigation possibilities? RELATED CASE, IF ANY: Case Number: 2:16-CV-06662 Judge Cynthia M. Rufe	Yeso ND Date Terminated: <u>N/A</u>
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 ye	ar 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 st action in this court?	uit pending or within one year previously terminated
	Yes⊠ _{No} ⊡
3. Does this case involve the validity or infringement of a patent already in suit or any earlier n	지수수, 여러, 방법, 방법, 방법, 이번, 이번, 이번, 이번, 방법, 영법, 이번, 물물, 이번, 이번, 이번, 이번, 이번, 이번, 이번, 이번, 이번, 이번
terminated action in this court?	Yes No
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil right	선생활 관객 것 같아요. 이번 것 수는 여러 있는 것이 가지 않는 것을 많이
	Yes 🗖 No 🛱
CIVIL: (Place 🖌 in one category only)	n strengten im Billen in Billen in Billen in Strengt in Strengt in Strengt in Strengt in Billing of Strengt in Strengt
A. Federal Question Cases:	B. Diversity Jurisdiction Cases:
1. D Indemnity Contract, Marine Contract, and All Other Contracts	1. D Insurance Contract and Other Contracts
2. D FELA	2. 🗖 Airplane Personal Injury
3.7₽ Jones Act-Personal Injury	3. 🗆 Assault, Defamation
4. X Antitrust	4. 🗆 Marine Personal Injury
5. Patent	5. D Motor Vehicle Personal Injury
6. 📮 Labor-Management Relations	6. Other Personal Injury (Please specify)
7. Civil Rights	7. D Products Liability
8. 🗆 Habeas Corpus	8. Products Liability — Asbestos
9. □ Securities Act(s) Cases	그래, 말 그는 그는 그 것 같은 것을 알려요. 그는 것 것은 것은 것 같은 것 같은 것 같은 것 같은 것 같은 것 같은
0. □ Social Security Review Cases	9. 🗆 All other Diversity Cases
 I. □ All other Federal Question Cases (Please specify) 	(Please specify)
Bart D. Cohen (Check Appropriate Cat , counsel of record do hereby certify	(egory)
 X Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and be 150,000.00 exclusive of interest and costs; Relief other than monetary damages is sought. 	
12/30/2016 Sant Cohen	57606
Attorncy-at-Law NOTE: A trial de novo will be a trial by jury only if there	Attorney I.D.# thas been compliance with F.R.C.P. 38. DEC 30 2016
certify that, to my knowledge, the within case is not related to any case now pending or w xcept as noted above.	
그 같은 그 가지 않는 것 같은 것 같아요. 이렇게 가지 않는 것 같아요. 이렇게 하는 것 같아요.	몇 50 - 20 - 20 - 20 - 20 - 20 - 20 - 20 -
DATE: 12/30/2016 Bart Cohen	57606

:

DESIGNATION FORM ATTACHMENT

DEFENDANTS

Actavis Holdco U.S., Inc., Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054

Fougera Pharmaceuticals, Inc., 60 Baylis Road, Melville, NY 11747

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

Perrigo New York, Inc., 1700 Bathgate Avenue, Bronx, NY 10457

Perrigo Company plc, Treasury Building, Lower Grand Canal St., Dublin 2, Ireland

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

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

Sun Pharmaceutical Industries, Inc., 270 Prospect Plains Rd, Cranbury, NJ 08512

Ca		IN THE UNIT	TED STATES	DISTRICT CO		
				DESIGNATIO		
Cesar C	astillo, I	A de la constante de la consta	IENT IKACK	DESIGNALIU	경험에 가슴을 넣었다. 실험 이 방법 가지 것	
*						698
Actavis	V. Holdco U.	S., Inc.,	et :			030
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.)
- (f) Standard Management Cases that do not fall into any one of the other tracks.

12/30/2016

Date (917) 438-9198

Dart Lobe Attorney-at-law

(484) 223-3033

FAX Number

Attorney for bcohen@nussbaumpc.com

Cesar Castillo, Inc.

E-Mail Address

(Civ. 660) 10/02

Telephone

DEC 30 2016

()

)

)

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: <u>A Slew of Big Pharma Companies Face (More) Antitrust Litigation</u>