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

# IN RE: GENERIC PHARMACEUTICALS PRICING ANTITRUSTLITIGATION

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

**IN RE: DESONIDE CASES** 

THIS DOCUMENT RELATES TO:

ALL DIRECT PURCHASER ACTIONS

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

Plaintiffs,

v.

FOUGERA PHARMACEUTICALS INC., SANDOZ, INC., NOVARTIS AG, PERRIGO COMPANY PLC, PERRIGO NEW YORK, INC., TARO PHARMACEUTICAL INDUSTRIES, LTD., and TARO PHARMACEUTICALS USA, INC.,

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 generic Desonide ("Desonide") from Defendants Fougera Pharmaceuticals Inc., Perrigo Company PLC, Perrigo

16-DS-27241

16-DS-27240

**Civil Action No.** 

Jury Trial Demanded

New York, Inc., Sandoz, Inc., Taro Pharmaceutical Industries Ltd. ("Taro Israel"), and Taro Pharmaceuticals USA, Inc. ("Taro USA"), during the period from July 18, 2013 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 Desonide 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 Desonide 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 Desonide 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 Desonide.

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

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 3 of 37

Defendants' illegal conduct, Plaintiff and Class Members would not have paid supracompetitive prices for generic Desonide.

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 Desonide 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.<sup>1</sup> 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.

"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.).

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

- 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.<sup>2</sup> 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 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

<sup>&</sup>lt;sup>2</sup> 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.).

("the AG Complaint").<sup>3</sup> 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 Desonide 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.

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 Desonide throughout the United States,

<sup>&</sup>lt;sup>3</sup> See Connecticut et al. v. Aurobindo Pharma USA, Inc. et al, 3:16-cv-02056-VLB (D. Conn.).

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 Desonide 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. <u>PLAINTIFF</u>

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 Desonide from Defendants during the Class Period. For example, KPH's purchases from Defendants during the Class Period include Desonide .05% cream from Defendant Perrigo. As a result of Defendants' antitrust conspiracy, KPH paid supracompetitive prices for its generic Desonide purchases and KPH was injured by the illegal conduct alleged herein.

#### B. <u>DEFENDANTS</u>

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 Desonide 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

## Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 7 of 37

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 Desonide 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 Desonide to purchasers in this District and throughout the United States.

22. 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 plc'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 Desonide. During the Class Period, Perrigo plc sold generic Desonide through its U.S. subsidiaries to purchasers in this District and throughout the United States.

23. Defendant 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 the domestic Perrigo subsidiaries have been the same or have substantially overlapped during the Class Period.

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 8 of 37

24. 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 Desonide through its U.S. subsidiary, Taro USA, to purchasers in this District and throughout the United States.

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

26. 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

27. 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.

28. 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.

## Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 9 of 37

29. 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.

30. 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

31. 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.<sup>4</sup>

32. 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."<sup>5</sup>

33. 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

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

<sup>&</sup>lt;sup>5</sup> Id.

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 10 of 37

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)).

34. 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.<sup>6</sup> Generic 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.

35. 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

<sup>&</sup>lt;sup>6</sup> See, e.g., Ernst R. Berndt, et al., *Authorized Generic Drugs, Price Competition, And Consumers' Welfare*, Health Affairs 26, no. 3 (2007):790-799.

## Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 11 of 37

product can result in billions of dollars in savings to consumers, insurers, and other drug purchasers.

Drug companies that want to introduce a generic drug to the market file an 36. 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."<sup>7</sup> 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.<sup>8</sup> 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 bioequivalence has been established, the ANDA applicant may manufacture and market its generic drug in the U.S. as interchangeable with the RLD.

37. Generic drugs that are bioequivalent to an RLD are assigned a Therapeutic Equivalence Code ("TE Code").<sup>9</sup> An oral generic drug product will be coded "AB" if bioequivalence is demonstrated. The purpose of this coding is to allow users to determine

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

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

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

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 12 of 37

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.<sup>10</sup>

# B. Consolidation in the Generic Drug Industry

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

39. 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.

40. Consolidation in the Desonide market occurred in the years leading up to Defendants' price increases. In July 2012, Sandoz completed its acquisition of Fougera Pharmaceuticals, making Fougera the world's top manufacturer of generic dermatology medicines. As a result of the consolidation, Defendants Fougera, Perrigo and Taro dominate the market for Desonide in the U.S.

41. 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

<sup>&</sup>lt;sup>10</sup> <u>http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm.</u>

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 13 of 37

distributors were unable to negotiate lower prices with other generic manufacturers offering therapeutically equivalent drugs.

## C. Opportunities for Collusion

42. 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."<sup>11</sup>

43. 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.<sup>12</sup>

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

45. 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,

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

<sup>&</sup>lt;sup>12</sup> 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 <u>http://www.chaindrugreview.com/new-name-for-generic-pharmaceutical-association/</u>.

## Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 14 of 37

"[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."<sup>13</sup>

46. 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.<sup>14</sup>

47. 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.<sup>15</sup>

48. 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.

49. High-level executives of generic drug manufacturers meet periodically at industry dinners. For example, in January 2014, when certain generic drug prices were increasing exponentially, at least thirteen (13) high-ranking male executives of various generic drug manufacturers met at a steakhouse in Bridgewater, New Jersey.<sup>16</sup>

<sup>&</sup>lt;sup>13</sup> http://www.gphaonline.org/about/membership.

<sup>&</sup>lt;sup>14</sup> See AG Complaint at ¶ 50.

<sup>&</sup>lt;sup>15</sup> *Id.* at ¶ 51.

<sup>&</sup>lt;sup>16</sup> *Id.* at ¶ 55.

## Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 15 of 37

50. 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.<sup>17</sup> 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.<sup>18</sup>

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

# D. Generic Desonide Market and Pricing Information

52. Generic Desonide is a widely prescribed topical corticosteroid prescription drug used to treat skin conditions in children and to treat sensitive areas and folds of the skin in adults. Desonide first came to market in the 1970s.

53. Defendants Fougera, Perrigo and Taro have been the primary manufacturers of generic Desonide since June 2013.

54. Defendants Perrigo Ireland, Sandoz and Taro Israel attended the GPhA annual meeting in Orlando, Florida at the JW Marriott Orlando Grande Lakes on February 20-22, 2013.

55. On June 4-5, 2013, Defendants Fougera, Perrigo Ireland, Sandoz, and Taro attended the GPhA's CMC (Chemistry, Manufacturing, and Controls) Workshop in North Bethesda, Maryland.

56. The February and June, 2013 meetings provided Defendants with opportunities to collude.

<sup>&</sup>lt;sup>17</sup> *Id.* at ¶ 57.

<sup>&</sup>lt;sup>18</sup> *Id.* at ¶ 60.

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 16 of 37

57. Shortly after the June 2013 CMC Workshop, the price of generic Desonide increased by several hundred percent in a single week in July 2013. The price increase was a result of a horizontal agreement among Defendants to increase pricing and restrain competition for generic Desonide.

58. At the beginning of 2013, a 60-gram tube of generic Desonide cost \$26.75, and by December 12, 2013, the price was near \$225.00. As of September 2016, generic Desonide prices remained at more than 500% above pre-July 2013 prices.

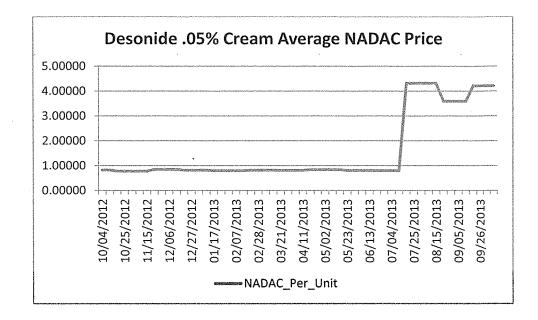
59. In August 2016, the U.S. Government Accountability Office found that generic Desonide topical cream 0.05% and generic Desonide topical ointment 0.05% "experienced an extraordinary price increase" from 2013 to 2014.

60. Defendants are alleged to have entered a horizontal price-fixing agreement to dramatically increase the price of generic Desonide, with more than a six-fold price increase.

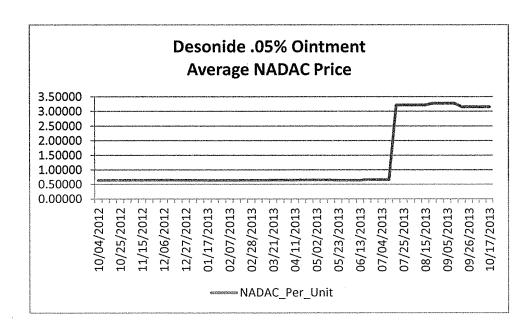
61. Draft National Average Drug Acquisition Cost ("NADAC") data shows that shortly after the GPhA CMC Workshop in early June 2013, prices for generic Desonide increased exponentially. NADAC is the National Association of State Medicaid Directors method of measuring the cost of drugs in order to set a single national pricing benchmark based on average drug acquisition costs. According to the Centers for Medicare and Medicaid Services, Draft NADAC price data is precise and accurate.

62. Soon after the GPhA CMC Workshop in early June 2013, NADAC data shows the following average price increases for Desonide products:

a. **Desonide 0.05% cream:** As shown by the chart below, between July 11, and July 18, 2013 the average price paid in the U.S. for Desonide 0.05% Cream increased by 442%.



b. **Desonide 0.05% ointment**: As shown in the chart below, between July 11, and July 18, 2013, the average price paid in the U.S. for Desonide 0.05% Ointment increased 390%.



63. Defendants' pricing for generic Desonide stabilized at supracompetitive levels.

64. Defendants' supracompetitive pricing of generic Desonide harmed patients.

According to February 3, 2015 article in Dermatology News by dermatologist Alan Rockoff,

MD:

Then this week it happened again. I prescribed hydrocortisone valerate 0.2% for a groin rash. The patient left a message asking me for an over-the-counter suggestion, since the prescription was going to cost him \$52.70 out of pocket. I asked my secretary to call the pharmacy to get a price for other generic steroid creams. Triamcinolone would cost \$14.70. Alclometasone would cost \$35.20. And desonide – generic desonide – would cost \$111.70. For a 15-g tube. \$111.70 for 15 g of a generic cream that's been on the market forever! Does that make any sense?

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There are no doubt economic reasons for such pricing anomalies. Maybe generic manufacturers have dropped out of making certain drugs because they don't make enough money on them, leaving the ones who remain in a position to charge whatever they can get away with. Maybe insurers or pharmacies cut deals with the makers of some drugs at the expense of others. I don't know. And that's the point. Because I have no way of knowing anymore which of the plain-vanilla generic drugs I've prescribed forever are going to be fine, and which are going to cost my patients an arm and a leg and encourage them to call back and yell at me- or else not bother to pick up the medication at all – I don't even know half the time what to recommend anymore. I certainly don't have the time to go shopping for every prescription I order. There are just too many drugs, too many prescriptions, too many patients, too many pharmacies, too many insurance contracts, each with its own formulary quirks.<sup>2</sup>

65. Defendants' profited from their unlawful scheme.

66. On February 10, 2014, Taro reported that, for the quarter ended December 31, 2013, there had been a 15% increase in net sales – in spite of a decrease in volumes – and an increase in gross profit as a percentage of net sales to 80.7%. And on May 27, 2014, Taro reported that, for the quarter ended March 31, 2014, net sales had increased 13.3% compared to the same quarter of the prior year, in spite of a decrease in volumes. 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

# Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 19 of 37

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%."

67. 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."

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

69. In Novartis's Q4 2013 earnings call on January 29, 2014, Novartis's Division Head of Sandoz stated that Fougera, which focuses on dermatology generics like Desonide, "is a business that has performed very well for us, with strong double-digit growth and very good margins given the limited competition nature of a lot of these markets."

70. Defendants substantially increased the price of Desonide in unison as a result of an agreement among Defendants to increase pricing and restrain competition for the sale of Desonide in the U.S.

71. Prices for generic Desonide increased without justification and in a departure from the usual industry practices. The cost or availability of raw materials does not justify the price increase. As generic manufacturers, Defendants did not incur the same costs, such as research and development, as brand drug manufacturers in bringing their generic Desonide products to market. The increased prices were not associated with any related increase in manufacturing costs.

# Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 20 of 37

72. At all times during the class period, there were at least three or more separate manufacturers of generic Desonide. The active ingredient for the drug product, Desonide has three approved holders of active Drug Master Files ("DMF").<sup>19</sup>

73. 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.

74. Drug shortage reports for the time period do not list Desonide as being in short supply.<sup>20</sup>

75. 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 Desonide 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

76. 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.

<sup>20</sup> See FDA Drug Shortages website,

<sup>&</sup>lt;sup>19</sup> 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.

<sup>&</sup>lt;u>http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm#P;</u> American Society of Health-System Pharmacists, <u>http://www.ashp.org/shortages</u>.

# Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 21 of 37

77. 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").

78. 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..."<sup>21</sup>

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 lifethreatening 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 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

<sup>&</sup>lt;sup>21</sup> 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 <u>http://www.sanders.senate.gov/download/letter-to-mr-vigodman-president-and-ceo-teva-pharmaceutical-industries-ltd?inline=file.</u>

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."<sup>22</sup>

80. The U.S. Senate HELP Committee held a hearing on November 20, 2014, "Why Are Some Generic Drugs Skyrocketing in Price?"<sup>23</sup>

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."<sup>24</sup>

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 Medicaid programs."<sup>25</sup> 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

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

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

<sup>&</sup>lt;sup>22</sup> Press release, Congress Investigating Why Generic Drug Prices are Skyrocketing, Oct. 2, 2014, available at <u>http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing</u>.

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

## Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 23 of 37

exceeded the specified inflation factor.<sup>26</sup> The OIG concluded that escalating generic drug prices have cost taxpayers \$1.4 billion in overpayment by Medicaid.<sup>27</sup> 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 generic prescription medications."<sup>28</sup> Grand jury subpoenas have been issued to Defendants Taro USA and Sandoz.

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

<sup>&</sup>lt;sup>27</sup> 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.

<sup>&</sup>lt;sup>28</sup> See Impax Laboratories, Inc., Form 8-K, November 3, 2014.

## Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 24 of 37

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."<sup>29</sup> 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]."<sup>30</sup> "The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation."<sup>31</sup> Then, "[t]he investigation should be conducted by a grand jury in a judicial

<sup>&</sup>lt;sup>29</sup> See Antitrust Division Manual, Chapter III, Section F.1 at III-82 (2015).

<sup>&</sup>lt;sup>30</sup> *Id*.

<sup>&</sup>lt;sup>31</sup> *Id.* at III-83.

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 25 of 37

district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred."<sup>32</sup>

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."<sup>33</sup>

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:

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

<sup>32</sup> Id.

<sup>&</sup>lt;sup>33</sup> See AG Complaint at  $\P$  1.

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.<sup>34</sup>

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."<sup>35</sup>

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").<sup>36</sup> Plaintiffs in the *Propanolol* case alleged a conspiracy among generic manufacturers to manipulate the market for generic propranolol, with facts similar to those alleged herein for the generic Desonide market.

<sup>35</sup> *Id.* 

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

<sup>&</sup>lt;sup>36</sup> The *Propranolol* defendants are Actavis Elizabeth, LLC, Teva Pharmaceuticals USA, Inc., Pliva, Inc., Mylan Inc., Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc., Par Pharmaceutical, Inc., Heritage Pharmaceuticals Inc., Breckenridge Pharmaceutical, Inc., and Upsher-Smith Laboratories, Inc.

## Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 27 of 37

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 Desonide.

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 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

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 28 of 37

raised prices on a <u>bi-monthly</u> and <u>quarterly</u> basis, which is consistent with an illegal agreement." *Id.* (emphasis in original). Similar price increases for Amitriptyline 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 pricefixing 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 Desonide, following consolidation in the industry. Defendants Fougera, Perrigo and Taro control nearly all of the market for generic Desonide topical cream .05% and topical ointment .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 Desonide is 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. If untreated, certain skin conditions normally treated with generic Desonide can rapidly worsen, leading to hospitalization, acute pain and discomfort, or other negative consequences. Because generic Desonide 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 Desonide. Desonide is often the only effective medicine for patients as it is a low-potency topical corticosteroid. Because Desonide is a wellestablished and commonly prescribed drug, health care providers have practical difficulty in prescribing other low-potency corticosteroids as alternatives to generic Desonide.
- (5) **High Degree of Interchangeability** Defendants' generic Desonide formulations are interchangeable, as are their generic Desonide products, as they contain the same chemical compounds made from the same raw materials. Thus, generic Desonide is standardized across suppliers and is highly interchangeable from one Defendant to the next.
- (6) Absence of Competitive Sellers In the generic Desonide 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 Desonide throughout the Class Period. Thus, Defendants have oligopolistic market power in the generic Desonide 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 Perrigo Ireland, Sandoz, and Taro Israel attended GPhA's annual meeting in Orlando, Florida on February 20-22, 2013. Defendants Fougera, Perrigo Ireland, Sandoz, and Taro attended GPhA's CMC Workshop in North Bethesda, Maryland on June 4-5, 2013, and increased Desonide prices shortly thereafter. 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 USA. also supports the potential for communication among Defendants on the pricing of generic Desonide.

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 Desonide.

## 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 Desonide from Defendants in the United States and its territories and possessions at any time during the period July 18, 2013 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.

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 31 of 37

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 Desonide 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 Desonide in the United States during the Class Period;
- (e) Whether Defendants' conduct caused supracompetitive prices for generic Desonide;
- (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.

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 32 of 37

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 Desonide 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 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.

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 Desonide within the United States.

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 33 of 37

115. 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.

# X. DEFENDANTS' ANTITRUST VIOLATIONS

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

(a) Competition in the market for generic Desonide has been reduced;

(b) Prices for generic Desonide 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 Desonide.

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

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.

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 34 of 37

119. Defendants' misconduct reduced competition in the generic Desonide 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 Desonide.

## 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 Desonide in the United States, and had a substantial and foreseeable effect on interstate commerce by raising and fixing Desonide 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 Desonide, 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 Desonide in a manner that deprived purchasers in the U.S. of price competition; and (3) providing pretextual justifications

#### Case 2:17-cv-02476-CMR Document 1 Filed 06/01/17 Page 35 of 37

to purchasers and the public to explain any raises, maintenance or stabilization of the prices for Defendants' generic Desonide.

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

- Prices charged to, and paid by, Plaintiff for Desonide 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 Desonide in the United States market; and
- c. Competition in establishing the prices paid for Desonide 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 Desonide 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 Desonide, 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 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.

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,

wC Dianne M. Nast

NastLaw LLC 1101 Market Street Suite 2801 Philadelphia, Pennsylvania 19107 Telephone: (215) 923-9300 Facsimile: (215) 923-9302 Email: dnast@nastlaw.com

Michael L. Roberts ROBERTS LAW FIRM, P.A. 20 Rahling Circle Little Rock, AR 72223 Telephone: (501) 821-5575 Facsimile: (501) 821-4474 Email: mikeroberts@robertslawfirm.us

## 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.			
Fougera Pharmaceuticals, et al.	Inc.,	:	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. § 22	241 through § 2255.	( )
	requesting review of a decisi mying plaintiff Social Security		( )
(c) Arbitration – Cases req	uired to be designated for arbi	itration under Local Civil Rule 53.2.	( )
(d) Asbestos – Cases invol- exposure to asbestos.	ving claims for personal injur	y or property damage from	( )
commonly referred to a	Cases that do not fall into trac s complex and that need spec side of this form for a detailed	ial or intense management by	(x)
(f) Standard Management	- gases that do not fall into an	ny one of the other tracks.	( )
6/1/2017	Tannu Malla	Plaintiff	
Date	Attorney-at-law	Attorney for	
215-923-9300	215-923-9302	dnast@nastlaw.com	·····
Telephone	FAX Number	E-Mail Address	

FAX Number

E-Mail Address

(Civ. 660) 10/02

#### JS 44 (Rev. 06/17)

# Case 2:17-cv-02476 CMPL Document SHEE Filed 06/01/17 Page 1 of 1

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.)* 

<ul> <li>I. (a) PLAINTIFFS</li> <li>KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc.</li> <li>(b) County of Residence of First Listed Plaintiff <u>St. Lawrence, NY</u></li> </ul>		<b>DEFENDANTS</b> Fougera Pharmaceuticals Inc., Perrigo Company PLC, Perrigo New York, Inc., Sandoz, Inc., Novartis AG, Taro Pharmaceutical Industries Ltd., and Taro Pharmaceuticals USA, Inc.			
(E.	XCEPT IN U.S. PLAINTIFF CA	(SES)	County of Residence (IN U.S. PLAINTIFF CA	of First Listed Defendant; Suf	ffolk Co., NY
(c) Attorneys (Firm Name, A Dianne M. Nast, NastI Philadelphia, PA 1910	Law LLC, 1101 Marke		NOTE: IN LAND CO THE TRACT Attorneys (If Known)	NDEMNATION CASES, USE TF OF LAND INVOLVED.	IE LOCATION OF
II. BASIS OF JURISDI	CTION (Place an "X" in O	ne Box Only)		RINCIPAL PARTIES	Place an "X" in One Box for Plaintif )
I U.S. Government Plaintiff	X' 3 Federal Question (U.S. Government)	Not a Party)	(For Diversity Cases Only) PT Citizen of This State '		
2 U.S. Government Defendant	<sup>4</sup> Diversity (Indicate Citizenshi	ip of Parties in Item III)	Citizen of Another State	of Business In A	Another State
			Citizen or Subject of a ' Foreign Country	3 ' 3 Foreign Nation	· 6 · 6
IV. NATURE OF SUIT		ly) RTS	FORFEITURE/PENALTY	Click here for: <u>Nature c</u> BANKRUPTCY	of Suit Code Descriptions.
<ul> <li>Ito Insurance</li> <li>Ito Insurance</li> <li>I20 Marine</li> <li>I30 Miller Act</li> <li>I40 Negotiable Instrument</li> <li>I50 Recovery of Overpayment &amp; Enforcement of Judgment</li> <li>I51 Medicare Act</li> <li>I52 Recovery of Defaulted Student Loans (Excludes Veterans)</li> <li>I53 Recovery of Overpayment of Veteran's Benefits</li> <li>I60 Stockholders' Suits</li> <li>I90 Other Contract</li> <li>I95 Contract Product Liability</li> <li>I96 Franchise</li> </ul> <b>REAL PROPERTY</b> 210 Land Condemnation 220 Forcelosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property	PERSONAL INJURY ' 310 Airplane ' 315 Airplane Product Liability ' 320 Assault, Libel & Slander ' 330 Federal Employers' Liability ' 340 Marine ' 345 Marine Product Liability ' 340 Marine ' 345 Marine Product Liability ' 350 Motor Vehicle ' 355 Motor Vehicle ' 355 Motor Vehicle ' 355 Motor Vehicle ' 360 Other Personal lnjury ' 362 Personal Injury- Medical Malpractice CIVIL RIGHTS ' 440 Other Civil Rights ' 441 Voting ' 442 Employment ' 443 Housing/ Accommodations ' 445 Amer. w/Disabilities - Employment ' 448 Education ' 448 Education	PERSONAL INJURY  PERSONAL INJURY  G 365 Personal Injury - Product Liability  G 367 Health Care/ Pharmaceutical Personal Injury Product Liability  A 368 Asbestos Personal Injury Product Liability  PERSONAL PROPERTY  G 370 Other Fraud  G 371 Truth in Lending  G 380 Other Personal Property Damage G 385 Property Damage Product Liability  PRISONERPETITIONS Habeas Corpus:  G 463 Alien Detainee S 510 Motions to Vacate Sentence S 530 General S 53 Death Penalty Other: S 540 Mandamus & Other S 550 Civil Rights S 555 Prison Condition S 60 Civil Detainee - Conditions of	<ul> <li>G 625 Drug Related Seizure of Property 21 USC 881</li> <li>G90 Other</li> </ul>	<ul> <li>422 Appeal 28 USC 158</li> <li>423 Withdrawal 28 USC 157</li> <li>PROPERTY RIGHTS</li> <li>820 Copyrights</li> <li>830 Patent</li> <li>835 Patent - Abbreviated New Drug Application</li> <li>840 Trademark</li> <li>SOCIAL SECURITY</li> <li>861 Black Lung (923)</li> <li>863 DIWC/DIWW (405(g))</li> <li>864 SSID Title XVI</li> <li>865 RSI (405(g))</li> <li>FEDERAL TAX SUITS</li> <li>870 Taxes (U.S. Plaintiff or Defendant)</li> <li>871 IRS—Third Party 26 USC 7609</li> </ul>	<ul> <li>OTTRISTATETES</li> <li>375 False Claims Act</li> <li>376 Qui Tam (31 USC 3729(a))</li> <li>400 State Reapportionment X 410 Antitrust</li> <li>430 Banks and Banking</li> <li>450 Commerce</li> <li>460 Deportation</li> <li>470 Racketeer Influenced and Corrupt Organizations</li> <li>480 Consumer Credit</li> <li>490 Cable/Sat TV</li> <li>850 Securities/Commodities/ Exchange</li> <li>890 Other Statutory Actions</li> <li>891 Agricultural Acts</li> <li>895 Freedom of Information Act</li> <li>896 Arbitration</li> <li>950 Constitutionality of State Statutes</li> </ul>
		Confinement		<u> </u>	
	moved from 3 ate Court	Appellate Court	Reopened Anothe (specify)		- Litigation - Direct File
VI. CAUSE OF ACTIC	N	tute under which you are fi use: Antitrust class action	ling (Do not cite jurisdictional statu	ttes unless diversity): 15 U.S.C. 1	1
VII. REQUESTED IN COMPLAINT:	C X CHECK IF TH	HS IS A <b>CLASS</b> ER RULE 23, F.R.Cv.P.	DEMAND S	CHECK YES only JURY DEMAND:	if demanded in complaint: X' Yes 'No
VIII. RELATED CASI IF ANY	E(S) (See instructions):	IA L	ufe DOCKETNUMBER <u>16-1</u>	MD-2724, 16-DS-27240, 16-D	S-27241
DATE 6/1/2017 FOR OFFICE USE ONLY	MARAN	SIGNATIONE OF ATTO	RNEY OF RECORD		
	MOUNT	APPLYING IFP	JUDGE	MAG. JUE	DGE

# Case 2:17-cv-02476-CMR Document 1-3 Filed 06/01/17 Page 1 of 1 UNITED STATES DISTRICT COURT

assignment to appropriate calendar.	used by counsel to indicate the category of the case for the purpose of		
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 Add	ditional Space)		
Does this civil action involve a nongovernmental corporate party with any parent corporation and (Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a))	d any publicly held corporation owning 10% or more of its stock? Yes디 No囚		
Does this case involve multidistrict litigation possibilities? RELATED CASE, IF ANY:	Yesy No <sup>D</sup>		
Case Number: <u>16-MD-2724</u> Judge Cynthia M. Rufe	Date Terminated:		
16-DS-2724, $16-DS-27241Civil cases are deemed related when yes is answered to any of the following questions:$			
1. Is this case related to property included in an earlier numbered suit pending or within one year	r 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 sui action in this court?			
3. Does this case involve the validity or infringement of a patent already in suit or any earlier nu	Yes好 No□ mbered case pending or within one year previously		
terminated action in this court?	Yes Not		
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		
	I G2 D INOK		
CIVIL: (Place 🖌 in ONE CATEGORY ONLY)			
A. Federal Question Cases:	B. Diversity Jurisdiction Cases:		
1. D Indemnity Contract, Marine Contract, and All Other Contracts	1. Insurance Contract and Other Contracts		
2. 🗆 FELA	2. 🗆 Airplane Personal Injury		
3. 🗆 Jones Act-Personal Injury	3. D Assault, Defamation		
4. 😰 Antitrust	4. 🗆 Marine Personal Injury		
5. 🗆 Patent	5. 🗆 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	9. 🗆 All other Diversity Cases		
10. □ Social Security Review Cases	(Please specify)		
11. □ All other Federal Question Cases (Please specify)	(		
ARBITRATION CERTII			
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 be	elief, 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	PA 24424 Attorney l.D.#		
<b>NOTE:</b> A trial de novo will be a trial by jury only if there	•		
I certify that, to my knowledge, the within case is not related to any case now pending or w	ithin one year previously terminated action in this court		

DATE: \_\_\_\_

CIV. 609 (5/2012)

Attorney I.D.#