

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI**

Elliot Conrad Dale, individually and on
behalf of all others similarly situated,

Plaintiff,

v.

GlaxoSmithKline PLC, and
GlaxoSmithKline LLC,

Defendants.

Case No. _____

CLASS ACTION

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

PARTIES

1. Plaintiff Elliot Conrad Dale is a citizen of Jackson County, Missouri and paid for part of the purchase price of Defendant's brand name inhalers Ventolin© and Arnuity Ellipta© during the Class Period.¹

2. Defendant GlaxoSmithKline PLC is a worldwide pharmaceutical company engaged in the development, manufacturing, marketing, and sale of pharmaceutical products. GlaxoSmithKline PLC is an English company having its principal place of business in Brentford, England.

3. Defendant GlaxoSmithKline LLC is a wholly-owned United States operating subsidiary of GlaxoSmithKline PLC, and is registered as a foreign entity in the State of Missouri (and together with GlaxoSmithKline PLC is referred to throughout this Complaint as "GlaxoSmithKline" or "Defendant"). GlaxoSmithKline may be served with process through its agent CSC-Lawyers Incorporating Service Company, 221 Bolivar Street, Jefferson City, Missouri 65101.

SUBJECT MATTER JURISDICTION

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(d) because this is a class action in which the aggregate amount in controversy exceeds \$5,000,000 (exclusive of interest and costs), the number of the members of the class exceeds 100, and at least one member of the putative Class is a citizen of a state different from that of one of the defendants. This Court also has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1337. The Court has supplemental jurisdiction over plaintiffs' pendent state law claims pursuant to 28 U.S.C. § 1367.

¹ Use of copyright symbols is discontinued hereafter.

5. This Court has personal jurisdiction over Defendant because Defendant is amenable to service of process, are co-conspirators, and each has minimum contacts with this District and has purposefully availed itself of the privilege of conducting business in this state.

ALLEGATIONS

6. Defendant manufactures and markets brand-name inhalers Ventolin and Arnuity Ellipta.

7. Inhalers are drug-device combination products.

8. Inhalers contain prescription medication that is sold together with the apparatus required for medication administration.

9. Inhalers are the mainstay treatment for asthma and chronic obstructive pulmonary disease.

10. Despite being on the market for several decades, inhalers remain expensive, representing approximately five percent of total net retail spending on prescription drugs in the United States.

11. Because of the complexities of producing drug-device combinations like inhalers, the Food and Drug Administration employs a special set of regulatory requirements when approving generic inhalers.

12. Specifically, when a brand-name manufacturer lists a patent for a product with the Food and Drug Administration (FDA), the FDA is prohibited from approving the generic version of that product until the patent protection expires or is challenged and overturned.

13. Patent protection lasts 20 years and can be extended under unique regulations governing pharmaceutical patents.

14. The FDA also issues non-patent related “exclusivities” pursuant to statutory and

regulatory authority.

15. Defendant schemed the FDA drug-device approval regimen to obtain patent protection and regulatory exclusivities on its brand-name inhalers Ventolin and Arnuity Ellipta with the goal of preventing generic inhalers from entering the market.

16. Defendant employed a scheme known as “device hopping.”

17. Device hopping works by retiring a branded inhaler but placing the same active ingredients into a new “follow on” branded inhaler with new patent and regulatory protection periods. *See generally*, Exhibit A, *Drug Pricing and Pharmaceutical Patenting Practices*, CONGRESSIONAL RESEARCH SERVICE (Feb. 11, 2020). Plaintiff hereby incorporates Exhibit A into this complaint.

18. Device hopping works because a generic version of a reference brand-name inhaler may only be approved for that specific brand-name inhaler.

19. A generic inhaler approved for an earlier version of a branded inhaler is not approved for the follow-on version of the branded inhaler.

20. Thus, device hopping prevents generics from ever having an unprotected brand name inhaler to reference for a generic.

21. By device hopping, Defendant manufactured over 60 years of uninterrupted patent and regulatory protection for its Ventolin inhaler line, thus prohibiting competition from generics. *See generally* Exhibit B, Feldman, William B., et. al., *Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020*, HEALTH AFFAIRS, Vol 40, No. 6 (May 19, 2022). Plaintiff hereby incorporates Exhibit B into this complaint.

22. By device hopping, Defendant manufactured over 35 years of uninterrupted patent and regulatory protection for its Flovent© and Arnuity Ellipta inhaler line, thus prohibiting

competition from generics. *See generally* Exhibit B, Feldman, William B., et. al., *Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986-2020*, HEALTH AFFAIRS, Vol 40, No. 6 (May 19, 2022).

23. Defendant used its unlawfully obtained market exclusivity to charge artificially inflated prices for inhalers.

24. The high cost of inhalers in the United States is now recognized as a significant public health concern.

CLASS ACTION ALLEGATIONS

25. **Nationwide Antitrust Class:** Pursuant to Federal Rule 23(b)(3) and (2), Plaintiff brings this suit on his behalf and on behalf of a proposed national class of all other similarly situated persons consisting of:

All persons or entities in the United States and its territories who purchased and/or paid for some or all the purchase price for Ventolin and Arnuity Ellipta inhalers, for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries, other than for resale, during the period January 1, 1986 through and until the anticompetitive effects of Defendant's unlawful conduct cease (the "Class Period"). For purposes of the Nationwide Antitrust Class definition, persons or entities "purchased" Ventolin and Arnuity Ellipta inhalers if they paid or reimbursed some or all the purchase price.

Excluded from the Nationwide Antitrust Class are:

- a. The Defendant and its officers, directors, management, employees, subsidiaries or affiliates;
- b. All governmental entities, except for government funded employee benefit plans;
- c. Fully insured health plans (*i.e.*, Plans that purchased insurance from another entity that covered 100% of the Plan's reimbursement obligations to its members);
- d. The judges in this case and any members of their immediate families;

- e. All persons who are presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and
- f. All persons who are currently incarcerated.

26. **State Antitrust Class:** Pursuant to Federal Rule 23(b)(3) and (2), Plaintiff brings this suit on his behalf and on behalf of a proposed class of all other similarly situated persons consisting of:

All persons or entities in the Indirect Purchaser States² who purchased and/or paid for some or all the purchase price for Ventolin and Arnuity Ellipta inhalers, for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries, other than for resale, during the Class Period. For purposes of the State Antitrust Class definition, persons or entities “purchased” Ventolin and Arnuity Ellipta inhalers if they paid or reimbursed some or all the purchase price.

Excluded from the State Antitrust Class are:

- a. The Defendant and its officers, directors, management, employees, subsidiaries or affiliates;
- b. All governmental entities, except for government funded employee benefit plans;
- c. Fully insured health plans (*i.e.*, Plans that purchased insurance from another entity that covered 100% of the Plan’s reimbursement obligations to its members);
- d. The judges in this case and any members of their immediate families;
- e. All persons who are presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and
- f. All persons who are currently incarcerated.

27. The Classes consists of millions of purchasers residing throughout the United States. Accordingly, it would be impracticable to join all Class Members before the Court.

28. Under Rule 23(b)(3), there are numerous and substantial questions of law or fact

² The Indirect Purchaser States are the states included in Count 2.

common to all the members of the Classes and which predominate over any individual issues.

Included within the common question of law or fact are:

- a. The definition of the relevant product markets;
- b. The Defendant's market power within the relevant product markets;
- c. Whether Defendant monopolized and continue to monopolize the relevant product markets using predatory behavior;
- d. Whether Defendant attempted to monopolize and continue to attempt to monopolize the relevant product markets using predatory behavior;
- e. Whether Defendant's conduct constitutes an unreasonable restraint of trade;
- f. Whether Defendant unlawfully maintained monopoly power through all or part of their overall anti-competitive scheme;
- g. Whether Defendant's anti-competitive scheme suppressed generic inhaler products or other competing products;
- h. Whether the Defendant's product hopping scheme, in whole or in part, has substantially affected interstate and intrastate commerce;
- i. The quantum of overcharges paid by the Classes in the aggregate; and
- j. Whether Defendant's were unjustly enriched by selling the Ventolin and Arnuity Ellipta inhalers at an inflated price.

29. Plaintiff's claims are typical of the claims of the respective Class Members, in that he shares the above-referenced facts and legal claims or questions with the Class Members, there is a sufficient relationship between the damage to Plaintiff and Defendant's conduct affecting Class Members, and Plaintiff has no interests adverse to the interests of other Class Members.

30. Plaintiff will fairly and adequately protect the interests of Class Members and has retained counsel experienced and competent in the prosecution of complex class actions including complex questions that arise in antitrust litigation.

31. A class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all Class Members is impracticable and no other group

method of adjudication of all claims asserted herein is more efficient and manageable for at least the following reasons:

- a. The liability claims presented in this case predominate over any questions of law or fact, if any exist at all, affecting any individual member of the Class;
- b. Absent certification of the Class, the Class Members will continue to suffer damage and Defendant's unlawful conduct will continue without remedy while Defendant profits from and enjoys its ill-gotten gains;
- c. Given the size of individual Class Members' claims, few, if any, Class Members could afford to or would seek legal redress individually for the wrongs Defendant committed against them, and absent Class Members have no substantial interest in individually controlling the prosecution of individual actions;
- d. When the liability of Defendant has been adjudicated, claims of all Class Members can be administered efficiently and/or determined uniformly by the Court; and
- e. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiff and Class Members can seek redress for the harm caused to them by Defendant.

32. Because Plaintiff seeks relief for the entire Classes, the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications with respect to individual Class Members, which would establish incompatible standards of conduct for Defendant.

33. Further, bringing individual claims would overburden the courts and be an inefficient method of resolving the dispute, which is the center of this litigation. Adjudications with respect to individual members of the Classes would, as a practical matter, be dispositive of the interest of other members of the Classes who are not parties to the adjudication and may impair or impede their ability to protect their interests. Consequently, class treatment is a superior method for adjudication of the issues in this case.

CLAIMS FOR RELIEF

COUNT I

Violation of Section 2 of the Sherman Act (on behalf of Plaintiff and the Nationwide Class)

34. Plaintiff repeats and re-alleges every relevant allegation above and below as if set forth in full herein.

35. Plaintiff brings this case under § 2 of the Sherman Act as amended to allow injunctive relief under § 16 of the Clayton Act (15 U.S.C. § 26) individually and on behalf of the Nationwide Class.

36. Defendant knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of competing inhalers.

37. The intended and accomplished goal of the scheme was to maintain their monopoly power using restrictive and exclusionary conduct to delay FDA approval of competing products. Such conduct injured plaintiff and the Nationwide Class.

38. It was Defendant's conscious objective to further its monopoly in the relevant market through the anticompetitive scheme. Defendant wrongfully and intentionally maintained monopoly power, with respect to its inhalers, in violation of § 2 of the Sherman Act (15 U.S.C. § 2). As a result of this unlawful maintenance of monopoly power, Plaintiff and members of the Nationwide Class paid artificially inflated prices.

39. Had manufacturers of competing inhalers entered the market and lawfully competed with the Defendant's inhalers in a timely fashion, Plaintiff and other members of the Nationwide Class would have substituted lower-priced competing products for the Defendant's higher-priced brand name inhalers for some or all of their requirements, and/or would have paid lower net prices on their remaining inhalers.

40. Nationwide Class members shall continue to suffer irreparable injury in the absence

of permanent injunctive relief.

41. Plaintiff and the Nationwide Class further seek equitable and injunctive relief pursuant to § 16 of the Clayton Act (15 U.S.C. § 26), and other applicable law.

42. Plaintiff and members of the Nationwide Class purchased substantial amounts of inhalers from Defendant.

43. Plaintiff and the Nationwide Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendant's conduct in seeking to prevent competition as described herein violates § 2 of the Sherman Act (15 U.S.C. § 2).

44. Plaintiff and the Nationwide Class further seek equitable and injunctive relief pursuant to § 16 of the Clayton Act (15 U.S.C. § 26), and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Defendant, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

COUNT II
Violation of the State Antitrust Statutes
(on behalf of Plaintiff and State Antitrust Class)

45. Plaintiff repeats and re-alleges every relevant allegation above and below as if set forth in full herein.

46. As to this count, "the Class" refers to the State Antitrust Class.

47. Plaintiff and State Antitrust Class members have suffered harm as a result of paying higher prices for Ventolin and Arnuity Ellipta inhalers than they would have absent Defendant's anti-competitive conduct and continuing anti-competitive conduct.

48. Defendant has knowingly engaged in an anti-competitive scheme designed to delay and block entry of generic competition to their Ventolin and Arnuity Ellipta inhalers. The intended and accomplished goal of the scheme was to use restrictive and exclusionary conduct to delay the

ability of generic manufacturers to launch competing, generic versions of their Ventolin and Arnuity Ellipta inhalers.

49. Plaintiff and State Antitrust Class Members have been injured in their business or property by Defendant's antitrust violation. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of the Ventolin and Arnuity Ellipta inhalers, and (2) paying higher prices for these products than they would have paid in the absence of Defendant's wrongful conduct. These injuries are of the type that state antitrust laws were designed to prevent, and flow from that which makes Defendant's conduct unlawful.

50. Plaintiff and State Antitrust Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendant's anti-competitive conduct. Attorneys' fees and costs are also proper.

51. Accordingly, Defendant has unlawfully restrained trade in violation of the following state antitrust statutes:

- a. Ariz. Rev. Stat. Ann. §§ 44-1402, *et seq.*
- b. Cal. Bus. & Prof. Code, §§ 16720, *et seq.*
- c. Conn. Gen. Stat. § 35-26, *et seq.*
- d. Haw. Rev. Stat. Ann. § 480-1, *et seq.*
- e. 740 Ill. Comp. Stat. Ann. 10/1, *et seq.*
- f. Iowa Code §§ 553.4 *et seq.*
- g. Kan. Stat. Ann. §§ 50-101, *et seq.*
- h. Me. Rev. Stat. tit. 10, §§ 1101, *et seq.*
- i. Md. Code, Com. Law §§ 11-201, *et seq.*
- j. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*

- k. Minn. Stat. §§ 325D.51, *et seq.*
- l. Miss. Code Ann. §§ 75-21-3, *et seq.*
- m. Mo. Ann. Stat. §§ 416, *et seq.*
- n. Neb. Rev. Stat. Ann. §§ 59-801, *et seq.*
- o. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*
- p. N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*
- q. N.M. Stat. Ann. §§ 57-1-1, *et seq.*
- r. N.Y. Gen. Bus. Law §§ 340, *et seq.*
- s. N.C. Gen. Stat. §§ 75-1, *et seq.*
- t. N.D. Cent. Code §§ 51-08.1-01, *et seq.*
- u. Or. Rev. Stat. §§ 646.705, *et seq.*
- v. 6 R.I. Gen. Laws Ann. §§ 6-36-4, *et seq.*
- w. S.D. Codified Laws §§ 37-1-3.1, *et seq.*
- x. Tenn. Code Ann. §§ 47-25-101, *et seq.*
- y. Utah Code Ann. §§ 76-10-3101, *et seq.*
- z. Vt. Stat. Ann. tit. 9, §§ 2453, *et seq.*
- aa. W. Va. Code §§ 47-18-4, *et seq.*
- bb. Wis. Stat. §§ 133.01 *et seq.*

COUNT III
Unjust Enrichment
(on behalf of Plaintiff and the Nationwide Class)

52. Plaintiff incorporates and realleges, as though fully set forth herein, only the relevant allegations set forth in the preceding paragraphs of this Complaint.
53. Plaintiff brings this claim under the common law of all 50 states.

54. By reason of its conduct, Defendant caused damages to Plaintiff and the Nationwide Class.

55. Defendant has benefitted from the monopoly profits on the sale of its Ventolin and Arnuity Ellipta inhalers resulting from the unlawful and inequitable acts alleged in this Complaint.

56. Defendant's financial benefit resulting from unlawful and inequitable conduct is traceable to overpayments for the Ventolin and Arnuity Ellipta by Plaintiff and the Nationwide Class.

57. Plaintiff and the Nationwide Class have conferred upon Defendant an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits to the economic detriment of Plaintiff and the Nationwide Class.

58. The economic benefit of overcharges and unlawful monopoly profits derived by Defendant through Plaintiff's and the Nationwide Class members' payment of supra-competitive and artificially inflated prices for Defendant's Ventolin and Arnuity Ellipta inhalers is a direct and proximate result of Defendant's unlawful practices.

59. The financial benefits derived by Defendant rightfully belong to Plaintiff and the Nationwide Class, as Plaintiff and the Nationwide Class paid anticompetitive and monopolistic prices during the Nationwide Class Period, inuring to the benefit of Defendant.

60. It would be inequitable under unjust enrichment principles in all 50 States for Defendant to be permitted to retain any of the overcharges for Ventolin and Arnuity Ellipta inhalers derived from Defendant's unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

61. Defendant is aware of and appreciated the benefits bestowed upon it by Plaintiff and the Nationwide Class.

62. Defendant should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Nationwide Class all unlawful or inequitable proceeds it received.

63. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendant traceable to Plaintiff and the Nationwide Class.

DEMAND FOR JURY TRIAL

64. Plaintiff respectfully demands a jury trial.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff respectfully requests the following relief:

- a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3) and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2) be given to the Classes;
- b. Require Defendant to pay for sending notice to the certified Classes;
- c. Appoint Plaintiff as Class Representatives and Plaintiff's counsel as Class Counsel;
- d. Issue an injunction to enjoin Defendant from engaging in the deceptive, unfair, unconscionable, and unlawful business practices alleged in this Complaint;
- e. Award further injunctive relief, as the Court deems appropriate;
- f. Award compensatory damages to Plaintiff and the proposed Class in an amount to be established at trial, or, alternatively, require Defendant to disgorge or pay restitution in an amount to be determined at trial;
- g. Award treble damages as permitted by law;
- h. Award pre- and post-judgment interest;
- i. Award punitive damages based on Defendant's reprehensible and deliberate conduct;
- j. Award reasonable attorneys' fees and costs; and,
- k. For all such other and further relief as may be just and proper.

Date: May 20, 2022

Respectfully submitted,
/s/ Sarah T. Bradshaw

Sarah T. Bradshaw MO #66276
SHARP LAW, LLP
4820 W. 75th Street
Prairie Village, KS 66208
Tel: (913) 901-0505
Fax: (913) 901-0419
Email: sbradshaw@midwest-law.com

CERTIFICATE OF SERVICE

I hereby certify that on this 20 day of May 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to parties and attorneys who are filing users.

s/ Sarah T. Bradshaw