UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

PAINTERS DISTRICT COUNCIL NO. 30 HEALTH AND WELFARE FUND, on behalf of itself and all others similarly situated,

Plaintiff,

v.

MERCK & CO., INC.; MERCK SHARP & DOHME CORP.; MSP SINGAPORE CO. LLC; GLENMARK PHARMACEUTICALS, LTD.; and GLENMARK GENERICS INC., U.S.A.,

Defendants.

Civil Action No. 2:18cv116

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Painters District Council No. 30 Health and Welfare Fund, on behalf of itself and all others similarly situated, brings this Class Action Complaint against Merck & Company, Inc., Merck Sharp & Dohme Corporation, MSP Singapore Company LLC, Glenmark Pharmaceuticals Limited, and Glenmark Generics Inc., U.S.A., and alleges as follows.

I. INTRODUCTION

1. This is a civil antitrust action on behalf of a proposed Class of end-payors who indirectly purchased, reimbursed, or otherwise paid for Zetia, a cholesterol drug that counteracts plaque development in arteries. Plaintiff seeks to recover damages incurred as a result of Merck and Glenmark's illegal agreement for Glenmark not to compete in the Zetia market.

2. Zetia's annual sales ranged from $1 billion to $2.6 billion between 2010 and 2016.

3. Merck, which developed Zetia in the early 1990s, obtained patent protection for it in a series of patents, including U.S. Patent No. RE37,721 (the "RE'721 patent").

4. Glenmark sought to bring a generic version of Zetia to market in October 2006. Merck sued Glenmark for infringement of the RE'721 patent, and Glenmark counterclaimed that the RE'721 patent was invalid and unenforceable. Glenmark cited evidence that key claims relating to patented compounds were invalid because Merck had disclosed them previously. Four of Glenmark's counterclaims—for anticipation, obviousness, double-patenting, and inequitable conduct—invoked similarities between the RE'721 patent and earlier Merck patents or patent applications. In a partial summary judgment order, the patent court invalidated four of the 13 claims in the RE'721 patent. Had the case proceeded to trial, Glenmark would have prevailed and obtained an order invalidating the remaining claims.

5. Merck and Glenmark settled the patent litigation on May 10, 2010, before trial. As part of the settlement, they stipulated to vacatur of the court's order invalidating four of the claims in the patent. Glenmark agreed to refrain from selling a generic version of Zetia for several years—until December 12, 2016. Merck, in exchange, agreed not to launch its own generic version of Zetia—an "authorized generic"—until 180 days after Glenmark entered the market. Under the Hatch-Waxman Act, because Glenmark was the first firm to receive FDA approval of generic Zetia, no other firm could sell generic Zetia during this 180-day period.

6. The parties thus traded monopoly for monopoly. Merck avoided patent invalidation and retained its lucrative Zetia monopoly until Glenmark entered with its generic product. Glenmark gained a 180-day monopoly over generic Zetia.

7. Defendants' transfer of wealth came at the expense of Zetia purchasers. Not until June 12, 2017, were competing generic versions of Zetia sold. Purchasers were harmed twice—first during the extended period of brand exclusivity Merck gained from Glenmark's agreement to postpone generic entry, and again during the six months in which Glenmark enjoyed generic exclusivity due to Merck's agreement not to launch an authorized generic version of Zetia.

8. Absent their agreement not to compete, Glenmark and Merck each would have launched a generic version of Zetia as early as December 6, 2011, and in any event well before December 12, 2016. Additional generics would have entered the market six months after that, well before June 12, 2017. The presence of multiple generic products would have caused Zetia prices to decline to competitive levels.

9. Merck and Glenmark's anticompetitive agreement injured the Class by causing Zetia end-payors to pay tens of millions of dollars in unlawful overcharges.

II. JURISDICTION AND VENUE

10. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, there are more than one hundred members of the Class, and at least one member of the proposed Class is a citizen of a state different from that of one of the Defendants.

11. This Court has personal jurisdiction over Defendants because they purposefully directed their business activities toward this jurisdiction and had substantial contacts with this jurisdiction.

12. Venue is properly laid in this district under 28 U.S.C. § 1391. At all relevant times, the Defendants transacted business in this district, and a substantial portion of the activity at issue in this case occurred in this district.

III. PARTIES AND RELEVANT NONPARTIES

A. Parties

13. Painters District Council No. 30 Health and Welfare Fund ("Painters Fund") is located in Illinois and is an employee welfare benefit plan providing benefits to active and retired painters, drywall finishers, and glaziers in the construction trade and to their dependents. As a third-party payor of pharmaceutical claims for its participants, Plaintiff is an end-payor of Zetia and was injured as a result of Defendants' violations. Plaintiff has purchased and/or provided reimbursement for Zetia during the Class Period, including in at least Illinois, South Dakota, Tennessee, and Washington.

14. Merck & Company, Inc. is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

15. Merck Sharp & Dohme Corporation is a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It is a subsidiary of Merck & Company.

16. MSP Singapore Company LLC is a Delaware company with its principal place of business at 200 Galloping Hill Road, Kenilworth, New Jersey 07033. MSP is a subsidiary of Merck & Company, Inc.

17. Merck & Company, Inc., Merck Sharp & Dohme Corporation, Schering-Plough Corporation, Schering Corporation, and MSP Singapore Company LLC are collectively referred to in this complaint as "Merck."

18. Glenmark Pharmaceuticals Limited is an Indian company with corporate offices in Mumbai, India.

19. Glenmark Generics Inc., U.S.A. is a Delaware corporation with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. It is a subsidiary of Glenmark Pharmaceuticals Limited.

20. Glenmark Pharmaceuticals Limited and Glenmark Generics Inc., U.S.A. are collectively referred to in this complaint as "Glenmark."

21. All of Defendants' actions described in this complaint were part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered and/or performed by Defendants' various officers, agents, employees, and other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and with the actual, apparent, and/or ostensible authority of Defendants.

B. Relevant Non-Parties

22. Schering-Plough Corporation was a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

23. Schering Corporation was a New Jersey corporation with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

24. In 2009, as part of Merck & Company, Inc.'s acquisition of Schering-Plough Corporation, Merck & Company, Inc. merged into Schering-Plough Corporation. Schering-Plough Corporation thereafter changed its name to Merck & Company, Inc., and the company formerly known as Merck & Company, Inc. changed its name to Merck Sharp & Dohme Corporation.

IV. CLASS ACTION ALLEGATIONS

25. Plaintiff brings this action under Federal Rules of Civil Procedure 23(a) and (b)(3), as representative of a Class of end-payors defined as follows:

> All persons or entities in the United States, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for branded or generic Zetia, other than for resale, at any time during the period December 6, 2011, through the date on which the anticompetitive effects of Defendants' challenged conduct ceased (the "Class Period").

26. The following persons and entities are excluded from the Class:

(a) the Defendants, their officers, directors, employees, subsidiaries, and affiliates;

(b) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans;

(c) all persons or entities who purchased Zetia for purposes of resale or directly from Defendants or their affiliates;

(d) fully insured health plans, i.e., plans that purchased insurance covering 100% of their reimbursement obligation to members

(e) any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of retail purchase price;

(f) pharmacy benefit managers; and

(g) all judges assigned to this case and any members of their immediate families.

27. Plaintiff's claims are typical of the claims of all Class members. Plaintiff's claims arise out of the same course of anticompetitive conduct that gives rise to the claims of the other Class members. Plaintiff and all Class members were harmed by the same wrongful conduct: They paid *supra*competitive prices for Zetia and were deprived of the benefits of competition as a result of Defendants' unlawful agreement alleged herein.

28. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are aligned with, and not antagonistic to, those of the Class.

29. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, with particular expertise in pharmaceutical matters.

30. Questions of law and fact common to the Class members predominate over any questions that may affect only individual Class members, and include:

a. Whether Defendants' pay-for-delay agreement violates the state laws set forth below;

b. Whether Defendants conspired to and did suppress generic competition to Zetia;

c. Whether Glenmark agreed to and did delay its entry into the generic Zetia market;

d. Whether Merck agreed not to—and, under that agreement, did not—introduce an authorized generic formulation of Zetia during Glenmark's 180-day period of exclusivity;

e. The length of the period of delayed entry Defendants' agreement caused;

f. Whether any legitimate procompetitive justifications for Defendants' agreement exist;

g. To the extent any procompetitive justifications exist, whether there were less restrictive means of furthering them;

h. Whether Defendants' scheme, in whole or in part, substantially affected intrastate and/or interstate commerce;

i. Whether Defendants' scheme, in whole or in part, caused antitrust injury in the form of overcharges paid by the Plaintiff and the members of the Class; and

j. The amount of overcharges paid by the Class.

31. Class treatment is a superior method for the fair and efficient adjudication of the controversy because, among other things, class treatment will allow the common claims of a large number of similarly situated persons to be prosecuted and adjudicated simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons and entities with a means of obtaining redress on claims that might not

be practicable to pursue individually, substantially outweigh any difficulties that may arise in the management of this class action.

32. Class treatment also is appropriate under Rule 23(b)(1) or (b)(2) because:

a. the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications which would establish incompatible standards of conduct for Defendant;

b. the prosecution of separate actions by individual Class members would create a risk of adjudication of their rights that, as a practical matter, would be dispositive of the interests of other Class members not parties to such adjudications or would substantially impair or impede other Class members' ability to protect their interests; and

c. Defendant has acted and refused to act on grounds that apply generally to the Class such that final injunctive relief or declaratory relief is warranted with respect to the Class as a whole.

V. BACKGROUND

A. Approval of a Branded Prescription Drug

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

34. When the FDA approves a brand pharmaceutical manufacturer's NDA, the manufacturer may list in the "Orange Book" (*Approved Drug Products with Therapeutic Equivalence Evaluations*) certain patents that the manufacturer asserts could reasonably be enforced against a manufacturer that makes, uses, or sells a generic version of the brand drug

before the expiration of the listed patents. After the FDA approves the NDA, the brand manufacturer may list such patents in the Orange Book. 21 U.S.C. §§ 355(b)(1), (c)(2).

35. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it lacks the resources and authority to verify the validity and applicability of the manufacturer's patents. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

36. When they do not face generic competition, brand manufacturers can usually sell the branded drug far above the marginal cost of production, generating profit margins in excess of 70% while making hundreds of millions of dollars in sales. The ability of a seller to charge *supra*competitive prices is called "market power."

B. Approval of a Generic Equivalent

37. Once lawful periods of patent exclusivity expire on branded drug products, generic manufacturers can seek FDA approval to market and sell generic versions of the branded drug. Under the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984)—commonly known as "Hatch-Waxman"—competitors wishing to sell a generic equivalent of a branded drug must file an abbreviated new drug application ("ANDA"), which relies in substantial part on the scientific findings of safety and efficacy contained in the branded drug manufacturer's NDA.

38. To gain FDA approval, generic drugs must be bioequivalent to their branded counterparts. Bioequivalence means that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the active ingredient of the brand. 21 U.S.C. § 355(j)(8)(B). Bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically

equivalent and may be substituted for one another. The FDA assigns an "AB" rating to generics that meet the necessary criteria in relation to their branded counterparts.

39. Because generic drugs are therapeutically equivalent to brand-name drugs, generic manufacturers compete by offering their drugs at low prices. According to the FDA and the Federal Trade Commission ("FTC"), the greatest price reductions occur when the number of generic competitors increases from one to two. A single generic on the market results in a near-term retail price reduction of approximately 10% as compared to the brand price. With two generic entrants, the near-term retail price reduction expands to roughly 50%. With more generic entrants, the price reduction grows to as much as 80% or more.

40. To benefit from these low prices, every state has adopted substitution laws requiring or permitting pharmacies to substitute AB-rated generic equivalents when filling branded drug prescriptions, unless the prescribing physician specifically directs otherwise. Due in part to these substitution laws, the launch of AB-rated generics causes a rapid price decline and shift from branded to generic drug sales. A generic often captures 80% or more of the market within the first six months of entry, regardless of the number of generic entrants. The effects of genetic entry are still more dramatic after a year. The FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and prices had dropped 85% with multiple generics on the market.[1]

[1] *See* Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-payoffs- cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

C. Periods of Regulatory Exclusivity for Brand and Generic Drugs

41. In addition to patent protection, regulatory exclusivities may prevent the FDA from approving an ANDA. Four exclusivities are relevant here: new chemical entity exclusivity, pediatric exclusivity, new indication exclusivity, and 180-day generic exclusivity.

1. New Chemical Entity Exclusivity

42. A "new chemical entity" is a drug that contains no active moiety—the part of the drug responsible for the physiological or pharmacological action of the drug—that the FDA has approved in another NDA. 21 C.F.R. § 314.108(a). Approval of an NDA with a new chemical entity provides a five-year exclusivity during which the FDA cannot approve an ANDA for a drug containing the same active moiety as the new chemical entity. 21 C.F.R. § 314.108(b)(2).

2. Pediatric Exclusivity

43. If the FDA believes that a drug may have a beneficial pediatric use, it may request that the brand manufacturer conduct pediatric studies. A brand manufacturer that satisfactorily completes the studies and timely submits them to the FDA is eligible to receive a pediatric exclusivity, which, among other things, prevents the FDA from approving an ANDA for an equivalent drug until six months after the drug patent expires. 21 U.S.C. § 355a(c).

3. New Patient Population Exclusivity

44. A brand manufacturer whose NDA has been approved may file a supplement with "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement . . . ." 21 U.S.C. § 355(j)(5)(F)(iv). This supplement provides the brand manufacturer a three-year exclusivity during which the FDA cannot approve an ANDA "rel[ying] on . . . information supporting a change approved in the supplemental new drug application." 21 C.F.R. § 314.108(b)(5)(ii).

45. This exclusivity is sometimes called a "new patient population exclusivity" because it often relates to applications for approval of the use of an already approved drug for a new medical indication, such as to treat a different patient population (e.g., a different age group). *See AstraZeneca Pharm. LP v. FDA*, 872 F. Supp. 2d 60, 64 (D.D.C. 2012), *aff'd*, 713 F.3d 1134 (D.C. Cir. 2013).

4. 180-Day Generic Exclusivity

46. A generic manufacturer cannot enter the market until all listed patents on a branded drug have expired, unless it can certify that its generic product does not infringe the listed patents or that those patents are invalid (a "paragraph IV certification"). Hatch-Waxman encourages potential generic entrants to submit paragraph IV certifications by affording the first generic manufacturer to file an ANDA with a paragraph IV certification a 180-day exclusivity period in which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same drug. 21 U.S.C. § 355(j)(5)(B)(iii). During this 180-day period, the first filer competes only with the brand manufacturer.

47. The 180-day exclusivity period can be extremely valuable to the first filer. In the absence of competition from other generics, a first-filing generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product during the initial 180-day period of exclusivity.

48. Because the first filer's generic drug typically is more affordable than the brand drug, the first filer typically takes substantial sales away from the brand manufacturer. Thus, the brand manufacturer, in accordance with its approved NDA, often introduces a cheaper version of its brand drug as its own generic drug to compete with the first filer's generic drug. A generic drug made and sold by the brand manufacturer is called an "authorized generic" or "AG".

49. Nothing prevents a brand manufacturer from selling an AG at any time. An AG is chemically identical to the brand but sold as a generic, typically through either the brand manufacturer's subsidiary (if it has one) or a third-party distributor. An AG is essentially the brand product in a different package.

50. Brand manufacturers sometimes begin selling AGs before the first-filer generic enters the market, to secure multi-year purchase contracts with direct purchasers and load the generic supply pipeline, thereby taking away sales from the first-filer generic.

51. Competition from an AG drives down drug prices and the revenues of the first-filing generic—especially during the 180-day exclusivity period. On average, an AG reduces the first filer's revenues by 50% because (i) the AG takes a large share of unit sales away from the first filer, and (ii) the presence of the AG in the market causes generic prices to decline.

52. Authorized generics therefore represent a significant source of price competition. During the first-filing generic's 180-day exclusivity period, they provide the only potential source of generic price competition.

D. Hatch-Waxman Patent Infringement Suits

53. If a generic manufacturer submits a paragraph IV certification, and the brand manufacturer has an objectively reasonable basis to claim that the generic drug will infringe the brand's valid patent, the brand manufacturer can sue the generic manufacturer for infringement. If the brand files such an action within 45 days after receiving notice of the paragraph IV certification, the FDA will *not* grant final approval until the earlier of (a) 30 months' passage, or (b) entry of a final judgment holding that the patent is invalid or not infringed by the generic formulation. 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii).

54. A generic manufacturer facing a claim of patent infringement may defend by counterclaiming that the patent is invalid or unenforceable. An issued patent may be held invalid or unenforceable for, among other reasons:

a. *Obviousness/Anticipation*: The patent is obvious in light of prior art or anticipated by prior art.

b. *Inequitable conduct*: The patent applicant committed inequitable conduct by making misrepresentations or omissions material to patentability with intent to mislead the Patent and Trademark Office ("Patent Office").

c. *Double-patenting*: The patent has a later expiration date than another patent but is not patentably distinct from the earlier-expiring patent.

55. In the pharmaceutical sector, these defenses often succeed. In Hatch-Waxman patent litigation cases, the generic manufacturer prevails in roughly three-quarters of cases adjudicated on the merits.

E. Pay-for-Delay or Reverse Payment Settlements

56. A brand manufacturer may attempt to settle its patent infringement claim against a generic manufacturer that has submitted a paragraph IV certification. In a "pay-for-delay" or "reverse payment" settlement, the brand manufacturer pays the generic manufacturer in exchange for the generic manufacturer's agreement not to enter the market for a specified amount of time. This structure is the opposite of a typical settlement structure because the plaintiff alleging infringement pays the defendant, rather than vice versa.

57. Reverse payments can be anticompetitive. *See FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). The brand manufacturer may offer to divide its monopoly profits with the generic manufacturer so that each makes greater profits under the brand's monopoly than either would make under competitive conditions. *Id*. at 154. In this way, even a brand manufacturer with a facially invalid patent can convince a generic manufacturer to settle because the value of the settlement to the generic manufacturer exceeds the value from winning the patent suit.

58. Reverse payments also can take the form of the brand manufacturer offering the generic manufacturer non-monetary consideration. As here, because the brand manufacturer is the only firm able to compete with the first-filing generic during the 180-day exclusivity period under Hatch-Waxman, the brand manufacturer can offer not to sell an authorized generic during that period. Such an offer, if accepted, allocates the entire generic market to the first-filing generic during the 180-day period. These "no-AG" agreements can be highly valuable: By avoiding competition from the brand manufacturer, the generic manufacturer can discount the drug less than it would if it were facing price competition from an authorized generic, thereby capturing more of the market.[2] Generally, because branded and generic drugs are identical except for pricing, a generic drug need only be priced at a small discount compared to its branded equivalent to make significant inroads in that market.

59. A collusive no-AG agreement causes purchasers to lose twice. First, they must pay the brand's price for longer than they would have had the patent suit proceeded and the generic manufacturer prevailed. Second, at a later time, purchasers paying for an alternative to the brand have no choice but to pay the first-filer's generic price—which is inflated because of the lack of competition from an authorized generic—for six months.

60. Even if the brand manufacturer's patent is invalid or unenforceable, a no-AG agreement diminishes other generic manufacturers' incentives to challenge the patent. The private agreement enables the first filer to retain the statutory 180-day period of exclusivity—the reward for proving patent invalidity. Even if a later-filing generic manufacturer could successfully defend

[2] Karen A. Goldman, et al., *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, Federal Trade Commission 142-49 (August 2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

a claim of patent infringement, it would thereby acquire only the right to enter the market at the same time as every other generic manufacturer. And in such a competitive market, profits are relatively low.

61. In short, a no-AG agreement allows a brand manufacturer whose patent is invalid or unenforceable to share some of its unjustified monopoly profits with a first-filer generic manufacturer. That sort of agreement violates antitrust law.

VI. FACTUAL ALLEGATIONS

A. Merck Developed Zetia.

1. Discovery of Ezetimibe and Related Compounds

62. High levels of cholesterol are associated with coronary heart disease and atherosclerosis. One treatment for high cholesterol inhibits the enzyme Acyl-CoA cholesterol acyltransferase (ACAT). In the early 1990s, Merck researched new ACAT inhibitors. Its scientists identified a lead compound, SCH-48461, and inherent metabolites and metabolite-like analogues of that compound, including SCH-58235 or "ezetimibe," which later became the active ingredient in Zetia.

63. SCH-48461 and ezetimibe share a central, core structure known as azetidinone (see Figures 1, 2, and 3 below). Unlike SCH-48461, however, ezetimibe has fluorine added to two of its phenyl rings (i.e., groups of carbon atoms bonded to each other and to hydrogen atoms in a cyclic pattern, shown as hexagons in Figures 2 and 3). Adding fluorine was not innovative in method or theory. The addition required only routine laboratory techniques. Moreover, its primary effect was to keep the compound in the body longer, and this effect from adding a halogen-like fluorine was well known in the scientific community before Merck's patent applications.

Figure 1. Azetidinone (core structure)

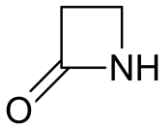


Figure 2. SCH-48461

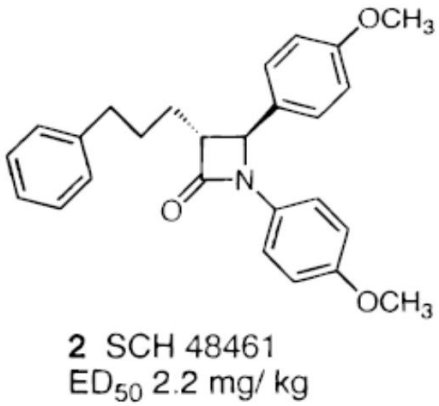
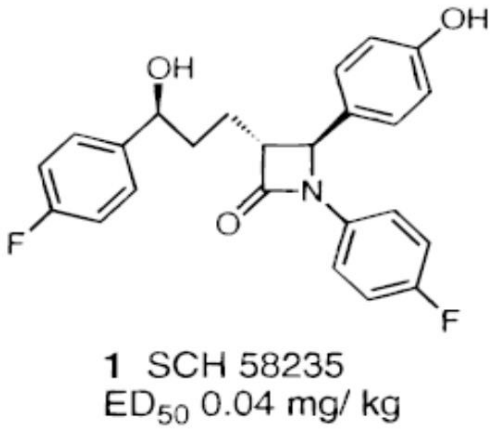


Figure 3. SCH-58235, Ezetimibe



64. Beginning in 1993, Merck filed a series of related U.S. patent applications regarding azetidinone compounds that can be used to reduce cholesterol.

2. The ’365 Patent

65. On September 21, 1993, Merck filed U.S. Patent Application 102,440. This application—entitled “Hydroxy-Substituted Azetidinone Compounds Useful As

Hypocholesterolemic Agents"—described the use of azetidinone compounds to reduce cholesterol.

66. Merck abandoned the '440 application. On June 9, 1994, however, Merck filed U.S. Patent Application 257,593 as a continuation-in-part of the abandoned '440 application.

67. On May 20, 1997, the '593 application issued as U.S. Patent No. 5,631,365. It was assigned to Schering Corporation and later conveyed to Merck Sharp & Dohme.

68. The '365 patent again described the use of azetidinone compounds to reduce cholesterol:

- It states that the "invention relates to hydroxyl-substituted azetidinones useful as hypocholesterolemic agents in the treatment and prevention of atherosclerosis . . . the invention also relates to a process for preparing hydroxyl-substituted azetidinones." Further, "[a] few azetidinones have been reported as being useful in lowering cholesterol and/or in inhibiting the formation of cholesterol-containing lesions in mammalian arterial walls."

- The specification notes, "We have found that the compounds of this invention lower serum lipid levels, in particular serum cholesterol levels. Compounds of this invention have been found to inhibit the intestinal absorption of cholesterol and to significantly reduce the formation of liver cholesteryl [sic] esters in animal models. Thus, compounds of this invention are hypocholesterolemic agents by virtue of their ability to inhibit the intestinal absorption and/or esterification of cholesterol; they are, therefore, useful in the treatment and prevention of atherosclerosis in mammals; in particular in humans."

69. The '365 patent has four claims, each relating to a process for preparing an azetidinone formulation (known as "formula I"). The summary of the invention describes cholesterol-reducing compounds of formula I or a pharmaceutically acceptable salt of those compounds. It states that the invention "relates to" all of the following:

- "[A] method of lowering the serum cholesterol level in a mammal in need of such treatment comprising administering an effective amount of a compound of formula I";

- "[A] pharmaceutical composition comprising a serum cholesterol-lowering effective amount of a compounds of formula I in a pharmaceutically acceptable carrier";

- "[T]he use of a hydroxyl-substituted azetidinone cholesterol absorption inhibitor of formula I for combined use with a cholesterol biosynthesis inhibitors [e.g., statins] . . . to treat or prevent atherosclerosis or to reduce plasma cholesterol levels"; and

- "[A] process for preparing certain compounds of formula I comprising [five steps]."

70. The specification states that "all isomers, including enantiomers . . . are contemplated as being part of this invention." The invention also "includes . . . racemic mixtures." The specification notes that compounds of the invention can exist in "pharmaceutically acceptable" salt forms, identifies at least two dozen salt forms, and describes how to prepare salt forms.

71. The '365 patent was never listed in the Orange Book; process patents are not eligible for listing.

72. The '365 patent expired on May 20, 2014.

3. The '115 Patent

73. On September 14, 1994, before the '365 patent issued, Merck filed a PCT/US94/10099 application, as a continuation-in-part of the '593 application. The PCT'099 application added two exemplar compounds (3L and 3M) in the specification as well as *in vivo* data for 3L, 3M, and 6A-1.

74. On March 18, 1996, the PCT'099 application entered the U.S. national stage as U.S. Patent Application No. 617,751 under 35 U.S.C. § 371. The specification for the '751 application was identical to the specification for the PCT'099 application.

75. On June 16, 1998, the '751 application issued as U.S. Patent No. 5,767,115.

76. The '115 patent had nine claims. Ezetimibe, the active ingredient in Zetia, falls within the scope of claims 1-3, 5, and 7. The specification designates ezetimibe as "6A" and describes it in Example 6 at column 31, and in claim 7 at column 40, lines 19-21.

77. The ’115 patent expired on June 16, 2015.

4. Reissue of the ’115 Patent as RE’721 with New Ezetimibe Claims

78. On June 15, 2000, Merck filed Reissue Application No. 09/594,996, asking the Patent Office to reissue the ’115 patent. Merck stated that it was filing the reissue application “to correct an error concerning the failure to appreciate the full scope of the invention by not including claims of narrower scope directed to one of the most preferred compounds disclosed in the specification,” namely ezetimibe. Merck sought to add claims 10-13. Claims 10 and 11 claimed ezetimibe. Claim 11 claimed a composition of ezetimibe. Claim 13 claimed a method of using ezetimibe to treat or prevent atherosclerosis or reduce plasma cholesterol levels.

79. In a declaration supporting Merck’s application, James R. Nelson, Staff Vice President and Associate General Counsel, Patents & Trademarks at Schering-Plough Corporation and Vice President at Schering Corporation, described the earlier error as “the failure to include a specific claim to one of the most preferred compounds,” later specified as ezetimibe.

80. On May 28, 2002, the RE’996 application issued as U.S. Patent No. RE37,721 with new claims 10-13. This was the patent at issue in the subsequent litigation with Glenmark.

5. The Zetia NDA

81. On December 27, 2001, while its application for reissue remained pending, Merck submitted NDA 21445 seeking FDA approval to market ezetimibe tablets for the treatment of hypercholesterolemia under the brand name Zetia.

82. The FDA requires applicants to identify all patents that claim their drug. Thus, Merck reviewed its patent portfolio while preparing its NDA for Zetia.

83. On October 25, 2002, the FDA approved the Zetia NDA and granted it a five-year New Chemical Entity exclusivity. Merck launched Zetia later that month. Zetia provided Merck

with immediate and growing profits. Annual U.S. sales of branded Zetia were about $1 billion in 2010, $1.4 billion in 2014, and $2.6 billion by 2016.

84. On December 12, 2002, after the Patent Office granted its reissue application, Merck—via James Nelson of Schering—requested a 497-day extension of the term of the reissued RE'721 patent based on the duration of the FDA's review of the Zetia NDA.

85. On January 17, 2006, the Patent Office granted the requested 497-day extension. As a result, the RE'721 patent was set to expire on October 25, 2016.

B. Merck Used Litigation to Thwart Competition to Zetia.

1. After Glenmark Filed the First ANDA for Generic Zetia, Merck Filed Suit.

86. On October 25, 2006, generic drug manufacturer Glenmark filed ANDA 78-560, seeking FDA approval to market an AB-rated generic version of Zetia.

87. Glenmark's ANDA contained a paragraph IV certification for each Zetia patent then listed in the Orange Book, including the RE'721 patent.

88. On or about February 9, 2007, Glenmark sent a letter to Merck (then Schering) notifying it of its ANDA filing and describing why the Zetia patents were invalid, unenforceable, and not infringed by Glenmark's product.

89. On March 22, 2007, Merck sued Glenmark in the District of New Jersey for infringement of the RE'721 patent. That was the only patent Merck claimed Glenmark's generic version of Zetia would infringe.

2. Glenmark Counterclaimed for Invalidity and Unenforceability.

90. On May 23, 2007, Glenmark answered, pleaded its affirmative defenses, and counterclaimed. Glenmark filed a corrected answer on June 7, 2007. On March 10, 2008, Glenmark filed a first amended answer and counterclaim.

91. Glenmark's counterclaim sought a declaratory judgment that the RE'721 patent was invalid or unenforceable, on the following bases:

- *Invalidity due to inherent anticipation.* Glenmark argued that at least two compounds claimed in the RE'721 patent are inherent metabolites of SCH-48461—i.e., when SCH-48461 is ingested, it is metabolized to form these two compounds. SCH-48461 was disclosed in an earlier Schering patent application, International Application No. PCT/US92/05972, filed on July 21, 1992, and published on February 4, 1993, as WO 93/02048.

- *Inequitable conduct for failure to disclose inherency.* Glenmark argued that Merck committed inequitable conduct while prosecuting the RE'721 patent by failing to disclose the inherency of these metabolites to the Patent Office. Nor did Merck disclose material publications describing the work its scientists had done to investigate SCH-48461, its metabolites, and its metabolite-like analogues.

- *Inequitable conduct regarding patent term extension.* Glenmark argued that Merck also committed inequitable conduct when seeking the RE'721 patent term extension, by knowingly failing to disclose that at least some claims were invalid due to inherent anticipation.

- *Invalidity due to lack of enablement.* Glenmark argued that the RE'721 patent does not teach one skilled in the art how to use ezetimibe to prevent atherosclerosis without further experimentation.

- *Failure to name inventors.* Glenmark argued that Merck failed to name all inventors in the RE'721 patent.

- *Lack of proper reissue.* Glenmark argued that reissue was improper, and hence the reissued claims were invalid, for failure to identify any error in the '115 patent of the type that reissue may properly correct.

- *Invalidity due to obviousness-type double patenting.* Glenmark argued that the subject matter claimed in the RE'721 patent was not patentably distinct from matter claimed in Merck's earlier-expiring '365 patent.

92. Only the claim of improper reissue was decided on the merits. On April 19, 2010, U.S. District Judge Jose L. Linares granted in part Glenmark's motion for partial summary judgment, finding that reissue of the '115 patent had been improper because Merck had not identified the sort of alleged error that reissue can correct. This ruling had the effect of nullifying

claims 10-13, which claimed ezetimibe expressly. Merck sought reconsideration of the court's order on April 30, 2010.

93. On April 24, 2009, while the patent suit was pending, the FDA granted tentative approval to Glenmark's Zetia ANDA. Glenmark thus gained first-filer status, securing the 180-day statutory period for exclusive generic sales. At that time, however, Hatch-Waxman's 30-month stay (running from February 9, 2007, the date of Glenmark's paragraph IV certification) prevented the FDA from granting final approval to Glenmark's Zetia ANDA.

3. Instead of Going to Trial on the RE'721 Patent, Merck and Glenmark Settled with a No-AG Agreement.

94. Trial before Judge Linares was scheduled to begin on May 12, 2010. On May 10, 2010, Merck and Glenmark settled their dispute.

95. To nullify an adverse judicial ruling on the RE'721 patent, Merck and Glenmark jointly requested that the court vacate its partial summary judgment invalidating claims 10-13. The court entered the parties' proposed order setting aside the partial summary judgment.

96. The parties further agreed, subject to certain undisclosed exceptions, that Glenmark would not market or sell its generic Zetia product until December 12, 2016.

97. The settlement agreement was not docketed with the court, nor have the parties publicly revealed any of its other terms. The parties' later behavior makes clear, however, what the key settlement terms were.

98. As a quid pro quo for Glenmark's agreement to drop its patent challenge and delay market entry for several years, Merck promised not to launch a competing authorized generic version of Zetia during Glenmark's 180-day exclusivity period.

99. This agreement can be inferred for two reasons. First, when Glenmark finally began selling generic Zetia, Merck did not launch an authorized generic despite the likelihood of

substantial profits had it done so and despite its track record of launching authorized generics. Other branded drugs for which Merck has sold authorized generic versions include Blocadren, Clinoril, Cozaar, Diprolene, Lotrisone, Nasonex, Singulair (Oral Granules), Temodar, K-Dur 10, K-Dur 20, and Lotrimin AF. The only economically rational explanation for Merck not launching an authorized Zetia generic is a no-AG agreement.

100. Second, Glenmark suggested publicly that it did not expect competition from an authorized generic. By May 2017, Glenmark's Zetia sales accounted for 58% of combined brand and generic Zetia sales. In that month, Glenmark informed its shareholders of its pre-launch estimate that it would ultimately control even more of the Zetia market than that. Typically, a generic entrant in competition with an authorized generic will take roughly 40% of the combined sales, whereas a generic entrant not facing competition will take roughly 80%. Glenmark's public statement makes sense only if it did not expect competition with an authorized generic.

4. The Consequences of the No-AG Agreement

101. Glenmark and Merck reached their no-AG agreement in May 2010. The agreement delayed Glenmark's generic entry until December 2016. Absent the agreement generic entry would have occurred much sooner than it did, and as early as December 6, 2011.

102. By December 6, 2011, the RE'721 patent stood as the only impediment to the prompt approval and launch of generic Zetia. Glenmark's ANDA had already received tentative FDA approval. Merck never asserted any other patent rights against Glenmark's Zetia formulation. Merck had performed a pediatric study for which, on June 5, 2008, it was granted a new patient population exclusivity and a pediatric exclusivity, but these and all other Zetia exclusivities expired as of December 6, 2011.

103. Merck and Glenmark could have settled their patent suit lawfully or proceeded to trial. A lawful settlement would have included a license for an earlier generic entry date

corresponding to the parties' respective views on the likelihood of patent invalidation. Because the RE'721 patent was very weak—and indeed had already been hollowed out at summary judgment—the negotiated entry date would have been as early as the expiration of the last relevant Zetia exclusivity, on December 6, 2011. Alternatively, had the patent suit been tried, Glenmark would have prevailed on the grounds discussed above. Glenmark then would have launched Zetia as early as the exclusivities expired—December 6, 2011. Either way, but for the no-AG agreement, Merck would have launched an authorized generic version of Zetia at or close to the time that Glenmark launched its generic version.

5. The Value of the No-AG Agreement to Merck

104. The known economics of the pharmaceutical industry permit an estimate of how much value the no-AG agreement provided to Merck and Glenmark.

105. The agreement enabled Merck to maintain its monopoly on Zetia from December 2011 to December 2016. Absent the agreement, Merck's revenue during that time would have been limited to the revenue it could have earned in a competitive Zetia market. It follows that the value to Merck of the no-AG agreement equals its branded Zetia sales during those five years minus the sales it would have made in a competitive market during that period.

106. In a competitive market, Merck would have derived revenue from its exclusive sales of the brand drug during the five years and its sales of the authorized generic during the first six months of generic competition. After other generic competitors entered the market, Merck's sales of its authorized generic would have been negligible.

107. But for the no-AG agreement, Merck's sales of the brand drug in each of the five years of competition would have equaled about 10% of its sales in its final year of exclusivity. Zetia sales in 2011 totaled $1.298 billion. So, in a competitive market, Merck could expect to

receive revenue of roughly $649 million ($1.298 billion × 0.1 [for annual branded sales] × 5 [for five years]).

108. Additionally, Merck's authorized generic and Glenmark's generic, combined, would have captured about 80% of total sales within the first six months after their entry, with generic sales divided between them (i.e., approximately 40% each). These generics would have sold at approximately 50% of the price of the brand. Under these estimates, Merck would have earned approximately $129.8 million from sales of authorized Zetia generics in the first six months after generic entry ($1.298 billion × 0.5 [half a year] × 0.8 [generic share of the market] × 0.5 [Merck's share of the generic sales] × 0.5 [generic price]).

109. Thus, absent the no-AG agreement, Merck reasonably could have expected Zetia revenues of approximately $778.8 million ($649 million [for brand sales] + $129.8 million [for AG sales in the first six months of generic competition]).

110. With the no-AG agreement, Merck reasonably could have expected to keep its branded sales at least at 2011 levels—$1.298 billion—for the next five years. It therefore reasonably expected Zetia revenue of at least $6.49 billion. In fact, Merck's actual revenue from branded Zetia from December 2011 to December 2016 totaled more than $9.1 billion.

111. Based on the foregoing, as a result of the no-AG agreement, Merck gained around $8.3 billion in additional sales. The value of the no-AG agreement to Merck greatly exceeded the litigation expenses Merck saved by settling with Glenmark.

6. The Value of the No-AG Agreement to Glenmark

112. The value of the no-AG agreement to Glenmark equals the sales it could have expected during its six-month exclusivity period in 2016 minus the sales it would have made during the first six months after entering a Zetia market that included an AG alternative.

113. As described above, under competitive conditions, Glenmark and Merck would have captured roughly equal sales of generic Zetia during the first six months of generic competition. Accordingly, Glenmark's revenue during this period would have about been the same as Merck's—approximately $129.8 million.

114. With the no-AG agreement, however, Glenmark could expect to earn more revenue. Free from no-AG competition, Glenmark could expect its generic to capture 80% of the market for Zetia at a price discounted only 10% from the brand's price. Under those anticompetitive conditions, Glenmark would (a) make 100% (not 50%) of generic sales during the first six months after generic launch (because no authorized generic would take market share); (b) be able to sell its generic Zetia during that time for about 90% (not 50%) of the branded price (because no authorized generic would reduce pricing); and (c) benefit from its generic Zetia entering a drug market after five-year delay period when demand would likely be greater.

115. By 2016, U.S. sales of Zetia totaled $2.6 billion. Thus, during its actual six-month exclusivity period in 2016—when there were no competing generic sales from Merck—Glenmark realized about $936 million in sales ($2.6 billion × 0.5 [half a year] × 0.8 [generic share of the market] × 0.9 [generic price]).

116. These estimates show that the agreement with Merck to delay Glenmark's launch of generic Zetia until December 2016 was worth approximately $806 million in additional sales to Glenmark, compared to sales it would have made beginning in December 2011 without the exclusionary effect of the no-AG agreement ($936 million minus $129.8 million).

117. Even if Glenmark did not anticipate the degree to which Zetia demand would increase during the five-year delay period, the no-AG agreement was still lucrative from Glenmark's standpoint when it entered into that agreement. If one were to assume that sales of

branded Zetia would remain at 2010 levels until Glenmark entered with its generic in 2016, the no-AG promise would still be worth an additional $225 million to Glenmark over what it would have made from launching its generic in December 2011 ($985,823,000 [2010 brand sales] × 0.5 [half a year] × 0.8 [generic share of the market] × 0.9 [generic price] = $354,896,280 [estimated Glenmark generic Zetia sales under 2010 market conditions with no-AG agreement] – $129,891,200 [estimated Glenmark generic Zetia sales under 2010 market conditions without no-AG agreement] = $225,005,080.)

118. The no-AG agreement, therefore, provided Glenmark with hundreds of millions in additional Zetia sales. The agreement caused Glenmark to gain more profits that it would have gained had it won the patent suit.

7. Reissue of the RE'721 Patent as RE'461

119. On June 9, 2010, within a month after setting with Glenmark, Merck applied to the Patent Office for reissue of the RE'721 patent.

120. Merck and its agents admitted that the RE'721 patent was at least partially invalid due to inherent anticipation, just as Glenmark had argued. In a declaration accompanying the reissue application, Mark Russell, legal director of patents for Schering Corporation, checked a box indicating that "the original patent [was] wholly or partly inoperative or invalid" because "the patentee claim[ed] more than he had the right to claim" in the patent. He elaborated:

> At least one error upon which reissue is based is described as follows: At least one claim of RE37,721 E is potentially inherently anticipated by International published patent application WO 93/02048, filed July 21, 1992 (PCT/US92/05972) and published February 4, 1993 ('the '048 PCT publication'). See also European patent application EP 0524595 A1. In infringement litigation involving RE37,721 E, defendants have alleged that the PCT'048 publication recites, in Example 9, a compound, that when administered to mammals, as also reported in the PCT'048 publication, metabolizes into one or more compounds that fall within the scope of at least claims 1 of RE37,721 E.

121. Attorneys Carl A. Morales and James F. Haley, Jr., of Ropes and Gray LLP, attorneys and agents for reissue applicants, made similar statements. To address these problems, they proposed to cancel claims 1-2 and 4-6 and amend claims 3 and 7-9.

122. On June 14, 2011, the RE'721 patent reissued as U.S. Patent No. RE42,461.

123. The RE'461 patent included only claims 8 through 13, as amended, and portions of claims 3 and 7, of the RE'721 patent at issue in the Glenmark litigation.

C. Merck Continued to Foreclose Competition with Infringement Suits and Settlements.

124. In or about April 2010, Mylan Pharmaceuticals, Inc. filed an ANDA for generic Zetia with a paragraph IV certification.

125. On June 16, 2010, Merck sued Mylan for infringement of the RE'721 patent. (Merck initially asserted infringement of another patent as well but later withdrew that claim.) Once the RE'721 patent reissued as the RE'461 patent, Merck substituted the RE'461 patent, asserting that Mylan infringed claims 10-13. The case was again assigned to Judge Linares.

126. Mylan counterclaimed, seeking a declaration that the RE'461 patent was invalid and unenforceable, and asserting antitrust claims for damages. Mylan raised many of the same arguments that Glenmark had raised in the settled case.

127. On August 22, 2011, the court denied Merck's motion for summary judgment on Mylan's defense of inequitable conduct for failure to disclose prior art to the Patent Office, holding that "Mylan has put forth sufficient indirect and circumstantial evidence from which a reasonable fact finder could conclude that Schering had knowledge of the materiality of the withheld prior art," and, "given that Schering does not appear to dispute that it had knowledge of the relevant prior art, a deliberate decision to withhold that information could likewise be reasonably inferred from the evidence already presented."

128. To reduce the triable issues, Mylan withdrew all defenses except inequitable conduct based upon misrepresentation of inventorship. The court held a bench trial on this issue in December 2011, and on April 27, 2012, found in favor of Merck. Mylan then unsuccessfully appealed to the Federal Circuit.

129. On August 7, 2013, the FDA tentatively approved Mylan's Zetia ANDA. To date, Mylan has not launched a generic version of Zetia in the United States.

130. The generic pharmaceutical companies Teva and Sandoz also filed Zetia ANDAs with paragraph IV certifications. Merck promptly sued each for infringement.

131. Both the Teva and Sandoz cases settled before the pleadings were closed. The court in each case entered a consent order prohibiting the defendant from selling generic Zetia before April 25, 2017. Additionally, each defendant stated that the RE'461 patent was valid and would be infringed by the proposed generic product. No other terms of either settlement were made public.

D. Glenmark Sold Generic Zetia for Six Months Without Facing Generic Competition.

132. The FDA granted final approval to Glenmark's ANDA 78-560 for Zetia on June 26, 2015. In doing so, the FDA confirmed that Glenmark was entitled to 180 days of generic market exclusivity upon launch.

133. From December 12, 2016, through June 12, 2017, Glenmark sold the only generic Zetia in the United States. Although it was entitled to do so by law, Merck did not launch an authorized generic version of Zetia during Glenmark's 180-day exclusivity period.

134. On or about June 12, 2017—the day Glenmark's exclusivity period ended—the FDA approved generic Zetia ANDAs previously filed by seven competing firms: Teva (ANDA 78-724), Sandoz (ANDA 203-931), Amneal (ANDA 208803), Apotex (ANDA 208332), Ohm

Laboratories (ANDA 207311), Zydus (ANDA 204331), and Watson Laboratories (ANDA 200831).

135. Five of these manufacturers—Teva, Sandoz, Amneal, Apotex and Ohm Laboratories—launched a generic Zetia product in June 2017, shortly after receiving FDA approval. Zydus launched its generic Zetia product in August 2017. Watson Laboratories did not launch a generic Zetia product because it sold its generic drug business to Teva before June 2017.

136. Aurobindo, which filed an eighth ANDA (ANDA 209838), received FDA approval in August 2017 and began selling generic Zetia that month.

137. The FDA approved a ninth ANDA, of Alkem Laboratories (ANDA 209234), in December 2017.

138. The average retail price of ezetimibe tablets dropped from $10 per pill before Glenmark's launch to less than $1 per pill as of December 1, 2017.

139. Merck has never sold a generic version of Zetia.

VII. INTRASTATE COMMERCE

140. Defendants' anticompetitive conduct has had substantial intrastate effects in that, among other things, it deprived retailers within each state of access to more affordable generic Zetia that they could sell to end-payors within each respective state. The delayed entry of generic Zetia, including of an authorized generic product of Merck, has directly affected and disrupted commerce for end-payors within each state.

141. During the relevant time period, Zetia was shipped into each state, and end-payors paid for Zetia in each state. Beginning in December 2016, an AB-rated generic version of Zetia was shipped into each state and paid for by end-payors.

142. Defendants' conduct as alleged in this complaint had substantial effects on intrastate commerce in each state. Zetia was sold to consumers and third-party payors in each state, and Defendants' agreement restrained trade in each state.

VIII. MARKET POWER AND MARKET DEFINITION

143. Until December 12, 2016, Merck had monopoly and market power over Zetia—broadly defined to include Zetia and its AB-rated generic equivalents—because Merck had the ability to maintain the price of Zetia at *supra*competitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Zetia.

144. From December 12, 2016, to June 12, 2017, Glenmark had monopoly and market power over the lesser-included market for generic Zetia because it had the ability to maintain the price of generic Zetia at *supra*competitive levels without losing substantial sales to other products prescribed and/or used for the same purposes.

145. A small but significant price increase for Zetia by Defendants would not have caused a significant loss of sales to drug products other than competing AB-rated generic versions of Zetia.

146. Defendants needed to control only the market for Zetia and its AB-rated generic equivalents, and for no other products, in order to profitably maintain Zetia prices at *supra*competitive levels. Only entry of a competing, AB-rated generic version of Zetia would have prevented Defendants from profitably maintaining *supra*competitive Zetia prices without losing substantial sales.

147. Defendants possessed, and exercised, the power to exclude and restrict competition over Zetia and its AB-rated generic equivalents.

148. Defendants sold Zetia at *supra*competitive prices far above competitive levels and well in excess of marginal costs, and enjoyed high profit margins as a result.

149. Defendants enjoyed high barriers to entry in the relevant product market due to asserted patent rights, other regulatory protections, and high entry costs.

150. Plaintiff alleges that the relevant market is Zetia (i.e., Zetia and its AB-rated generic equivalents).

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

152. Until December 12, 2016, Merck's market share in the relevant market was 100%, during which time it exercised monopoly power in the relevant market. From December 12, 2017, to June 12, 2017, Merck and Glenmark together held 100% of the relevant market and each exercised oligopoly power in it.

IX. EFFECTS ON COMPETITION; DAMAGES

153. Defendants' unlawful agreement delayed generic competition, enabled Merck to sell branded Zetia free from generic competition, and enabled Glenmark to sell generic Zetia free from competition from an authorized generic.

154. Merck's last regulatory exclusivity relating to Zetia ended on December 6, 2011. But for the unlawful agreement described herein, Glenmark would have entered the market on or shortly after that date, and in any event well before December 12, 2016.

155. But for Defendants' unlawful agreement, an authorized generic version of Zetia would have been available for purchase concurrent with the launch of Glenmark's generic or shortly thereafter.

156. Glenmark had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand.

157. As discussed above (*supra* paragraphs 39-40), generic entry reduces prices, and generics quickly capture market share. Entry of additional generics further reduces prices.

158. But for Defendants' unlawful agreement, competition in the Zetia market would have prevailed. End-payors like Plaintiff and the other Class members would have paid less for Zetia by (a) substituting purchases of less expensive AB-rated generic Zetia for their purchases of more expensive branded Zetia, and (b) purchasing generic Zetia at lower prices sooner. As a result of Defendants' illegal conduct as described herein, Plaintiff and Class members were forced to pay, and did pay, artificially inflated prices for Zetia.

159. During the relevant period, Plaintiff and Class members purchased substantial quantities of branded Zetia indirectly from Merck and substantial quantities of generic Zetia indirectly from Glenmark. Defendants' unlawful conduct deprived these end-payors of the benefits of competition that the antitrust laws were designed to ensure. Plaintiff and Class members sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

X. ANTITRUST IMPACT

160. *Supra*competitive prices for branded Zetia and AB-rated generic Zetia at a higher level of distribution resulted in higher prices at every level below.

161. Wholesalers and retailers passed on the *supra*competitive prices of branded Zetia and AB-rated generic Zetia to Plaintiff and members of the Class.

162. Defendants' anticompetitive conduct enabled them to raise, fix, maintain and stabilize prices to consumers and third-party payors far above the prices Defendants would have been able to charge absent such conduct.

163. The *supra*competitive prices Plaintiff and Class members paid are traceable to, and the direct, proximate, and foreseeable result of, Defendants' anticompetitive conduct.

164. The overcharges Plaintiff and Class members paid are traceable to, and the direct, proximate, and foreseeable result of, Defendants' *supra*competitive pricing.

XI. TOLLING OF THE STATUTE OF LIMITATIONS

165. Defendants, aware of their illegal scheme to monopolize the market for Zetia and its injurious effects on consumers, fraudulently concealed the scheme by failing to report it while reaping illicit profits from the *supra*competitive prices they charged.

166. Plaintiff and Class members could not have discovered that Merck had entered into a pay-for-delay settlement with Glenmark, with Merck agreeing not to launch an authorized generic, until (1) in December 2016, Glenmark introduced its generic Zetia product and (2) Merck refrained from introducing an authorized generic to compete with Glenmark's product.

167. Defendants disclosed little information about their settlement before December 2016. Defendants concealed both the existence of their no-AG agreement and the fact that it was intended to compensate Glenmark for dropping its patent challenge. Plaintiff and Class members did not discover, and exercising reasonable diligence could not have discovered, the facts underlying Defendants' violations or the harm they caused until 2017, at the earliest.

168. All applicable statutes of limitation were tolled during the period in which Plaintiff could not have reasonably discovered the facts constituting Defendants' violations.

XII. CLAIMS FOR RELIEF

CLAIM I—CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE IN VIOLATION OF STATE LAW

169. Plaintiff incorporates the above paragraphs by reference.

170. In or about May 10, 2010, Merck and Glenmark entered into a no-AG settlement agreement. This agreement is an illegal contract, combination, and conspiracy in restraint of trade under which Merck agreed to make a large and unjustified payment to Glenmark, in the form of a promise not to compete during Glenmark's 180-day exclusivity period, in exchange for Glenmark's agreement to delay bringing its generic version of Zetia to market. The purpose and

effect of this agreement were to: (a) delay and prevent the entry of more affordable generic versions of Zetia in the United States; (b) delay and prevent the introduction of an authorized generic version of Zetia during Glenmark's 180-day exclusivity period; (c) fix, raise, maintain, or stabilize the prices of Zetia products, even after generic entry; (d) allocate 100% of the U.S. Zetia market to Merck up until December 12, 2016; and (e) allocate 100% of the U.S. generic Zetia market to Glenmark during its 180-day exclusivity period.

171. Defendants implemented the terms of the agreement, and the agreement achieved its intended purpose. As a direct and proximate result of Defendants' anticompetitive conduct, alleged herein, Plaintiff suffered harm in the form of antitrust overcharges.

172. Defendants' agreement covered substantially all of the relevant market and harmed competition in that market.

173. There was and is no legitimate, non-pretextual, procompetitive justification for the reverse payment from Merck to Glenmark that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve that purpose.

174. By engaging in the foregoing conduct, Defendants entered a conspiracy and combination in restraint of trade in violation of the following state laws:

a. Ala. Code §§ 6-5-60, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Alabama by Class members and/or purchases by Alabama residents.

b. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Arizona by Class members and/or purchases by Arizona residents.

c. Cal. Bus. and Prof. Code §§ 16720, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in California by Class members and/or purchases by California residents.

d. D.C. Code Ann. §§ 28-4502, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in the District of Columbia by Class members and/or purchases by D.C. residents.

e. Fla. Stat. §§ 501.201, et seq., with respect to purchases of Zetia and AB-rated generic equivalents in Florida by Class members and/or purchases by Florida residents.

f. Haw. Code § 480-13, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Hawaii by Class members and/or purchases by Hawaii residents.

g. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Illinois by Class members and/or purchases by Illinois residents.

h. Iowa Code § 553.4 *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Iowa by Class members and/or purchases by Iowa residents.

i. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Kansas by Class members and/or purchases by Kansas residents.

j. Me. Rev. Stat. Ann. 10 § 1101, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Maine by Class members and/or purchases by Maine residents.

k. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Massachusetts by Class members and/or purchases by Massachusetts residents.

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Michigan by Class members and/or purchases by Michigan residents.

m. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Minnesota by Class members and/or purchases by Minnesota residents.

n. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Mississippi by Class members and/or purchases by Mississippi residents.

o. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Nebraska by Class members and/or purchases by Nebraska residents.

p. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Nevada by Class members and/or purchases by Nevada residents.

q. N.H. Rev. Stat. Ann. §§ 356:2, *et. seq*., with respect to purchases of Zetia and AB-rated generic equivalents in New Hampshire by Class members and/or purchases by New Hampshire residents.

r. N.M. Stat. Ann. §§ 57-1-2, *et seq*., with respect to purchases of Zetia and AB-rated generic equivalents in New Mexico by Class members and/or purchases by New Mexico residents.

s. N.Y. G.B.L. § 340, *et seq*., with respect to purchases of Zetia and AB-rated generic equivalents in New York by Class members and/or purchases by New York residents.

t. N.C. Gen. Stat. §§ 75-2.1, *et seq*., with respect to purchases of Zetia and AB-rated generic equivalents in North Carolina by Class members and/or purchases by North Carolina residents.

u. N.D. Cent. Code § 51-08.1-02, *et seq*., with respect to purchases of Zetia and AB-rated generic equivalents in North Dakota by Class members and/or purchases by North Dakota residents.

v. Or. Rev. Stat. §§ 646.725, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Oregon by Class members and/or purchases by Oregon residents.

w. 10 L.P.R.A. § 258, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Puerto Rico by Class members and/or purchases by Puerto Rico residents.

x. R.I. Gen. Laws §§ 6-36-4, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Rhode Island by Class members and/or purchases by Rhode Island residents.

y. S.D. Codified Laws Ann. § 37-1-3.2, *et seq*., with respect to purchases of Zetia and AB-rated generic equivalents in South Dakota by Class members and/or purchases by South Dakota residents.

z. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Tennessee by Class members and/or purchases by Tennessee residents.

aa. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Utah by Class members and/or purchases by Utah residents.

bb. Vt. Stat. Ann. 9 § 2453, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Vermont by Class members and/or purchases by Vermont residents.

cc. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in West Virginia by Class members and/or purchases by West Virginia residents.

dd. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Wisconsin by Class members and/or purchases by Wisconsin residents.

175. Plaintiff and Class members have been injured in their business or property by reason of Defendants' violations of the laws set forth above, in that Plaintiff and Class members (i) were denied the ability to purchase lower-priced generic Zetia, and (ii) paid higher prices for branded and/or generic Zetia than they would have paid but for the unlawful conduct. These injuries are of the type that the above laws were designed to prevent, and flow from that which makes the conduct unlawful.

176. Plaintiff and Class members accordingly seek damages and multiple damages as permitted by law.

CLAIM II—MONOPOLIZATION IN VIOLATION OF STATE LAW

177. Plaintiff incorporates the above paragraphs by reference.

178. Before Glenmark's 180-day exclusivity period began, Merck held monopoly power in the relevant market. Merck had the ability to control prices, prevent them from falling, and exclude competitors from the relevant market.

179. After generic entry, and through the 180-day exclusivity period, Glenmark and Merck together held monopoly power in the relevant market. Together, they had the ability to control prices, prevent them from falling, and exclude competitors from the relevant market.

180. By reason of the unlawful agreement alleged in this complaint, Merck and Glenmark exploited their monopoly power in the relevant market to block and delay market entry of generic Zetia, i.e., AB-rated generic versions of Zetia. The unlawful agreement: (a) allocated 100% of the market for branded Zetia to Merck; (b) delayed the availability of affordable generic Zetia products; (c) allocated 100% of the market for generic Zetia to Glenmark during its 180-day exclusivity period; and (d) gave rise to *supra*competitive prices for branded and generic Zetia, borne by the end-payors.

181. The objective, purpose, and effect of Defendants' unlawful agreement was to maintain and extend Merck's monopoly power for branded Zetia and to confer monopoly power in the generic Zetia market upon Glenmark during its 180-day exclusivity period. The agreement prevented and delayed generic competition to Zetia and enabled Defendants to charge high monopoly prices for branded and generic Zetia without a substantial loss of sales.

182. Defendants knowingly and intentionally conspired to maintain and enhance each other's monopoly power in the relevant market.

183. Defendants specifically intended that their unlawful agreement would barricade their monopoly power in the relevant market, injuring Plaintiff and the Class.

184. There is and was no legitimate, non-pretextual, procompetitive justification for Defendants' agreement that outweighs its harmful effects. Even if there were some conceivable justification, the agreement is and was broader than necessary to achieve such a purpose.

185. By engaging in the foregoing conduct, Defendants intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

a. Ariz. Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Arizona by Class members and/or purchases by Arizona residents.

b. Cal. Bus. and Prof. Code §§ 16720, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in California by Class members and/or purchases by California residents.

c. Cal. Bus. and Prof. Code §§ 17200, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in California by Class members and/or purchases by California residents.

d. D.C. Code Ann. §§ 28-4503, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in the District of Columbia by Class members and/or purchases by D.C. residents.

e. Fla. Stat. §§ 501.201, et *seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Florida by Class members and/or purchases by Florida residents.

f. Haw. Code § 480-9, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Hawaii by Class members and/or purchases by Hawaii residents.

g. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Illinois by Class members and/or purchases by Illinois residents.

h. Iowa Code § 553.4 *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Iowa by Class members and/or purchases by Iowa residents.

i. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Kansas by Class members and/or purchases by Kansas residents.

j. Me. Rev. Stat. Ann. 10 § 1102, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Maine by Class members and/or purchases by Maine residents.

k. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Zetia

and AB-rated generic equivalents in Massachusetts by Class members and/or purchases by Massachusetts residents.

l. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Michigan by Class members and/or purchases by Michigan residents.

m. Minn. Stat. §§ 325D.54, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Minnesota by Class members and/or purchases by Minnesota residents.

n. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Mississippi by Class members and/or purchases by Mississippi residents.

o. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Nebraska by Class members and/or purchases by Nebraska residents.

p. N.H. Rev. Stat. Ann. §§ 356:2, *et. seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in New Hampshire by Class members and/or purchases by New Hampshire residents.

q. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases in Nevada by Class members and/or purchases by Nevada residents.

r. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in New Mexico by Class members and/or purchases by New Mexico residents.

s. N.Y. G.B.L. § 340, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in New York by Class members and/or purchases by New York residents.

t. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in North Carolina by Class members and/or purchases by North Carolina residents.

u. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases in North Dakota by Class members and/or purchases by North Dakota residents.

v. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Oregon by Class

members and/or purchases by Oregon residents.

w. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Puerto Rico by Class members and/or purchases by Puerto Rico residents.

x. R.I. Gen. Laws §§ 6-36-7 *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Rhode Island by Class members and/or purchases by Rhode Island residents.

y. S.D. Codified Laws Ann. § 37-1-3.2, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in South Dakota by Class members and/or purchases by South Dakota residents.

z. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Tennessee by Class members and/or purchases by Tennessee residents.

aa. Utah Code Ann. §§ 76-10-3104, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Utah by Class members and/or purchases by Utah residents.

bb. Vt. Stat. Ann. 9 § 2453, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Vermont by Class members and/or purchases by Vermont residents.

cc. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in West Virginia by Class members and/or purchases by West Virginia residents.

dd. Wis. Stat. § 133.03, *et seq.*, of Zetia and AB-rated generic equivalents in Wisconsin by Class members and/or purchases by Wisconsin residents.

186. Plaintiff and Class members have been injured in their business or property by reason of Defendants' violations of the laws set forth above, in that Plaintiff and Class members (i) were denied the ability to purchase lower-priced generic Zetia, and (ii) paid higher prices for branded and/or generic Zetia than they would have paid but for the unlawful conduct. These

injuries are of the type that the above laws were designed to prevent, and flow from that which makes the conduct unlawful.

187. Plaintiff and Class members accordingly seek damages and multiple damages as permitted by law.

CLAIM III—UNFAIR METHODS OF COMPETITION, AND UNFAIR AND DECEPTIVE ACTS, IN VIOLATION OF STATE CONSUMER PROTECTION LAWS

188. Plaintiff incorporates the above paragraphs by reference.

189. The Defendants engaged in unfair methods of competition and unfair, unconscionable, and deceptive acts or practices to wrongfully perpetuate their concerted conduct to restrain trade in the Zetia market. As a direct and proximate result of Defendants' unfair, unconscionable, and deceptive conduct, Plaintiff and Class members were denied the opportunity to purchase generic Zetia and forced to pay higher prices for branded Zetia. Also as a direct and proximate result of Defendants' unfair, unconscionable, and deceptive conduct, Merck refrained from selling a competing authorized generic when Glenmark began selling generic Zetia, which forced Plaintiff and Class members to pay more for generic Zetia than they would have absent Defendants' unfair and oppressive acts.

190. The gravity of harm from the Defendants' wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and Class members could not reasonably have avoided injury from Defendants' wrongful conduct.

191. There was and is a gross disparity between the price that Plaintiff and Class members paid for Zetia and the value they received. Much more affordable, bioequivalent generic versions of Zetia would have been available sooner and in greater quantity, and prices for Zetia would have been far lower, but for the Defendants' unfair, unconscionable, and deceptive conduct.

192. By engaging in such conduct, the Defendants violated the following state consumer protection laws:

a. Ark. Code §§ 4-88-101, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Arkansas by Class members and/or purchases by Arkansas residents.

b. Ariz. Code §§ 44-1255, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Arizona by Class members and/or purchases by Arizona residents.

c. Cal. Bus. & Prof Code §§ 17200, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in California by Class members and/or purchases by California residents.

d. D.C. Code §§ 28-3901, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in D.C. by Class members and/or purchases by D.C. residents.

e. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Florida by Class members and/or purchases by Florida residents.

f. Idaho Code §§ 48-601, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Idaho by Class members and/or purchases by Idaho residents.

g. 815 ILCS §§ 505/1, et seq., with respect to purchases of Zetia and AB-rated generic equivalents in Illinois by Class members and/or purchases by Illinois residents.

h. Kan. Stat. §§ 50-623, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Kansas by Class members and/or purchases by Kansas residents.

i. 5 Me. Rev. Stat. §§ 207, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Maine by Class members and/or purchases by Maine residents.

j. Mass. Ann. Laws, ch. 93A, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Massachusetts by Class members and/or purchases by Massachusetts residents.

k. Mich. Stat. §§ 445.901, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Michigan by Class members and/or purchases by Michigan residents.

l. Minn. Stat. §§ 325F.68, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Minnesota by Class members and/or purchases by Minnesota residents.

m. Mo. Stat. §§ 407.010, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Missouri by Class members and/or purchases by Missouri residents.

n. Neb. Rev. Stat. §§ 59-1601, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Nebraska by Class members and/or purchases by Nebraska residents.

o. Nev. Rev. Stat. §§ 598.0903, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Nevada by Class members and/or purchases by Nevada residents.

p. N.H. Rev. Stat. §§ 358-A:1, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in New Hampshire by Class members and/or purchases by New Hampshire residents.

q. N.M. Stat. §§ 57-12-1, et seq., with respect to purchases of Zetia and AB-rated generic equivalents in New Mexico by Class members and/or purchases by New Mexico residents.

r. N.Y. G.B.L. §§ 349, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in New York by Class members and/or purchases by New York residents.

s. N.C. Gen. Stat. §§ 75-1.2, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in North Carolina by Class members and/or purchases by North Carolina residents.

t. Or. Rev. Stat. §§ 646.605, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Oregon by Class members and/or purchases by Oregon residents.

u. 73 Pa. Stat. Ann. §§ 201-1, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Pennsylvania by Class members and/or purchases by Pennsylvania residents.

v. R.I. Gen. Laws §§ 6-13.1-1, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Rhode Island by Class members and/or purchases by Rhode Island residents.

w. S.D. Code Laws §§ 37-24-1, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in South Dakota by Class members and/or purchases by South Dakota residents.

x. Tenn. Code §§ 47-18-101, *et seq.*, with respect to purchases of Zetia and

AB-rated generic equivalents in Tennessee by Class members and/or purchases by Tennessee residents.

y. Utah Code §§ 13-11-1, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Utah by Class members and/or purchases by Utah residents.

z. Va. Code Ann. §§ 59.1-196, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Virginia by Class members and/or purchases by Virginia residents.

aa. Vt. Stat Ann. 9, § 2453, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in Vermont by Class members and/or purchases by Vermont residents.

bb. W. Va. Code §§ 46A-6-101, *et seq.*, with respect to purchases of Zetia and AB-rated generic equivalents in West Virginia by Class members and/or purchases by West Virginia residents.

193. On behalf of itself and the Class, Plaintiff seeks all appropriate relief provided for under the foregoing statutes.

CLAIM IV—UNJUST ENRICHMENT

194. Plaintiff incorporates the above paragraphs by reference.

195. Defendants have reaped and retained substantially higher profits due to their wrongful scheme to monopolize the market for Zetia.

196. Plaintiff and Class members have conferred an economic benefit upon the Defendants: their profits derived from Zetia sales.

197. Defendants' financial gain from their wrongful conduct is traceable to overpayments for Zetia by Plaintiff and Class members.

198. Plaintiff and Class members have no adequate remedy at law.

199. It would be futile for Plaintiff and Class members to seek relief against the intermediaries in the distribution chain from which they directly purchased Zetia.

200. The financial benefits Defendants derived from charging *supra*competitive prices for Zetia directly and proximately resulted from their unjust practices described herein. Those benefits rightfully belong to Plaintiff and Class members.

201. It would be wrongful and inequitable, under the laws of all states and jurisdictions within the United States, except for Indiana and Ohio, for Defendants to be permitted to retain any of their ill-gotten gains from their scheme to foreclose competition to branded and generic Zetia.

202. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiff and Class members all proceeds that they inequitably derived from their scheme, and a constructive trust should be imposed upon such sums.

XIII. PRAYER FOR RELIEF

203. WHEREFORE Plaintiff, on behalf of itself and the proposed Class, respectfully requests that this Court:

a. Determine that this action may be maintained as a class action under Fed. R. Civ. P. 23(a), (b)(1), (b)(2), and (b)(3), direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and appoint the Plaintiff as named representative of the Class;

b. Enter joint and several judgments against Defendants and in favor of Plaintiff and the Class;

c. Award damages to the Class in an amount to be determined at trial, plus interest in accordance with law;

d. Award Plaintiff and the Class their costs of suit, including reasonable attorneys' fees, as provided by law; and

e. Enter such other and further relief as may be just and proper.

XIV. JURY DEMAND

204. Plaintiff demands a trial by jury on all issues so triable pursuant to Rule 38 of the

Federal Rules of Civil Procedure.

Dated: February 28, 2018

Respectfully submitted,

FURNISS, DAVIS, RASHKIND AND SAUNDERS, PC

By */s/ James A. Cales, III*
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Attorneys for Plaintiff

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Painters District Council No. 30, Health and Welfare Fund on behalf of itself and all others similarly situated,

(b) County of Residence of First Listed Plaintiff Kane Co., IL
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Alan Brody Rashkind, Esquire 12658; James A. Cales III, Esquire 41317
Furniss, Davis, Rashkind and Saunders, PC, 6160 Kempsville Cir. Ste 341B, Norfolk VA 23502 757-461-7100

DEFENDANTS

Merck & Co., INC; Merck, Sharp & Dohme Corp.; MSP Singapore Co. LLC; Glenmark Pharmaceuticals, LTD.; Glenmark Generics Inc., USA

County of Residence of First Listed Defendant Union Co., NJ
(IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys *(If Known)*

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

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☒ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

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

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☐ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 376 Qui Tam (31 USC 3729(a))
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	☐ 400 State Reapportionment
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander			☐ 820 Copyrights	☒ 410 Antitrust
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	☐ 368 Asbestos Personal Injury Product Liability		☐ 830 Patent	☐ 430 Banks and Banking
☐ 151 Medicare Act	☐ 340 Marine	PERSONAL PROPERTY	LABOR	☐ 835 Patent - Abbreviated New Drug Application	☐ 450 Commerce
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 840 Trademark	☐ 460 Deportation
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 371 Truth in Lending	☐ 720 Labor/Management Relations	SOCIAL SECURITY	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	☐ 861 HIA (1395ff)	☐ 480 Consumer Credit
☐ 190 Other Contract	☐ 360 Other Personal Injury	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	☐ 862 Black Lung (923)	☐ 490 Cable/Sat TV
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 790 Other Labor Litigation	☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
☐ 196 Franchise			☐ 791 Employee Retirement Income Security Act	☐ 864 SSID Title XVI	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS		☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	Habeas Corpus:	IMMIGRATION	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 462 Naturalization Application	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 895 Freedom of Information Act
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence	☐ 465 Other Immigration Actions	☐ 871 IRS—Third Party 26 USC 7609	☐ 896 Arbitration
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General			☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 535 Death Penalty			☐ 950 Constitutionality of State Statutes
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	Other:			
	☐ 448 Education	☐ 540 Mandamus & Other			
		☐ 550 Civil Rights			
		☐ 555 Prison Condition			
		☐ 560 Civil Detainee - Conditions of Confinement			

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C. s 1332(d)

Brief description of cause:
Pharmaceutical Antitrust Matter

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Smith DOCKET NUMBER 2:18cv23; 2:18cv35

DATE
02/28/2018

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE