UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UFCW LOCAL 1500 WELFARE FUND, on behalf of itself and all others similarly situated, Plaintiff, v. MERCK & CO., INC.; MERCK SHARP & DOHME CORP.; SCHERING-PLOUGH CORP.; SCHERING CORP.; MSP SINGAPORE CO. LLC; GLENMARK PHARMACEUTICALS, LTD.; and GLENMARK GENERICS INC., U.S.A., Defendants.	Civil Action No. _____ **DEMAND FOR JURY TRIAL**

CLASS ACTION COMPLAINT

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1. Plaintiff UFCW Local 1500 Welfare Fund brings this class action, on behalf of itself and all others similarly situated, for claims under federal and state antitrust, consumer protection, and unjust enrichment laws to recover damages and obtain injunctive and equitable relief for injuries caused by Defendants Merck & Company, Inc., Merck Sharp & Dohme Corporation, Schering-Plough Corporation, Schering Corporation, and MSP Singapore Company LLC (collectively, "Merck"), and Glenmark Pharmaceuticals Limited and Glenmark Generics Inc., (collectively "Glenmark"). Plaintiff's claims stem from Defendants' anticompetitive scheme to unreasonably restrain competition in the market for Zetia® and its AB-rated generic equivalents sold in the United States. Plaintiff's allegations are made on personal knowledge as to Plaintiff and Plaintiff's own acts and upon information and belief as to all other matters.

I. NATURE OF THE ACTION

2. ***Merck develops Zetia***. In the early 1990s, following its success with statins, Merck sought to identify new compounds that could reduce cholesterol and prevent the buildup of plaques in arteries. Merck turned to a class of drugs first developed forty years earlier: ACAT inhibitors. Ultimately, Merck developed a compound called "ezetimibe." Merck later obtained three patents purportedly covering its new compound, one of which was U.S. Patent No. RE37,721 (the "RE'721 patent"). Beginning in late 2002, Merck marketed ezetimibe as the blockbuster drug Zetia.

3. ***Glenmark was the first filer status, earning 180 days of generic exclusivity***. In 2006, Glenmark became the first generic manufacturer to seek FDA approval to market generic Zetia. As the first filer, Glenmark earned the right to keep other generic companies off the market for 180 days. Significantly, though, Glenmark could not keep Merck from selling or licensing its own generic (referred to as an "authorized generic" or "AG"). Brand companies frequently launch or license authorized generics, particularly during a first filer's so-called 180-

day exclusivity period, in an effort to prevent the massive loss of revenue attending generic entry. The brand's authorized generic typically takes up to 50% of generic sales away from the first filer. In effect, an authorized generic lets the brand hold on to sales that it otherwise would lose to the first-filer generic.

4. ***The RE'721 patent is invalid and/or unenforceable***. In its Abbreviated New Drug Application ("ANDA") for generic Zetia, Glenmark included a Paragraph IV certification, claiming that the RE'721 patent was invalid, unenforceable, or not infringed. Specifically, in a patent infringement action concerning Zetia, Glenmark argued that Merck had committed inequitable conduct by intentionally (and deceptively) failing to tell the U.S. Patent and Trademark Office ("PTO") that compounds claimed in the RE'721 patent were inherent metabolites of compounds Merck publicly disclosed years earlier. Merck also withheld references that would have, at minimum, caused the examiner to ask questions about metabolites and inherency. Glenmark also argued that—separate and apart from inequitable conduct—this inherency rendered the RE'721 patent invalid for anticipation. (Indeed, Merck knew well the dangers of inherency and later conceded the invalidity of the RE'721 patent.) Had the case resulted in a decision on the ultimate merits, Glenmark likely would have prevailed.

5. ***Merck sues to enforce its patent***. Following the filing of Glenmark's ANDA, Merck sued Glenmark for patent infringement of the RE'721 patent. The parties litigated the patent infringement suit for over three years.

6. ***Unlawful pay-for-delay agreement***. Rather than proceed to trial and risk losing its patent protection and monopoly over Zetia, Merck decided to settle with Glenmark. However, as part of the settlement, Merck agreed pay Glenmark to stay out of the ezetimibe market for almost five years. Merck's payment took the form of an agreement not to launch its own "authorized

generic" version of Zetia. Merck's no-authorized-generic ("no-AG") promise was worth an $800 million in additional sales to Glenmark during its 180-day exclusivity period that would have otherwise gone to Merck had it launched an authorized generic.

7. ***Earlier generic entry***. In the absence of Merck's large and unjustified payment, Glenmark and Merck would have each 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 launched six months later, after Glenmark's 180-day exclusivity period expired. These additional generic competitors would have continued to drive prices down to the benefit of all drug purchasers.

8. ***Injury to the Classes***. As a result of Defendants' unlawful pay-for-delay agreement, Merck continued to sell Zetia at supracompetitive prices without competition for an additional five years. Drug purchases have likely paid hundreds of millions in overcharges as a result of Merck and Glenmark's unlawful agreement. In the absence of this unlawful agreement, Glenmark would have entered the market earlier than December 2016, ending Merck's monopoly and bringing competition and lower prices to consumers of ezetimibe, as well as third party payors who reimburse all or part of the purchase price of ezetimibe. To redress the injury to the ezetimibe market, Plaintiff brings this action on behalf of two classes: (1) a nationwide injunctive class seeking to restrain Defendants' lawful conduct, as well as other equitable relief; and (2) a state law damages class consisting of class members who purchased or reimbursed part or all of the purchase price of Zetia or its AB-rated generic equivalents.

II. THE PARTIES

A. Plaintiff

9. Plaintiff UFCW Local 1500 Welfare Fund is an employee welfare benefits fund with its principal place of business at 425 Merrick Avenue, Westbury, New York. Local 1500

provides nearly 23,000 members with health and welfare benefits and is the largest grocery union in New York. During the Class Period, Plaintiff indirectly purchased and paid for some or all of the purchase price of brand or generic Zetia. As a result of the alleged pay-for-delay agreement, Plaintiff was injured in its business or property by reason of the violations of law alleged below.

B. Defendants

10. Merck & Company, Inc. is a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. It is or was the parent company of Defendants Merck Sharp & Dohme Corporation and MSP Singapore Company LLC.

11. Merck Sharp & Dohme Corporation is a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. It is a subsidiary of Merck & Company, Inc. and the assignee of patents relevant to this lawsuit.

12. Schering-Plough Corporation was a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey.

13. Schering Corporation was a corporation organized and existing under the laws of the state of New Jersey, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. It was a wholly owned subsidiary of Schering-Plough Corporation and the original assignee of the relevant patents.

14. 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 subsequently changed its name to Merck & Company, Inc., and the company

originally known as Merck & Company, Inc. changed its named to Merck Sharp & Dohme Corporation.

15. MSP Singapore Company LLC ("MSP") is a company organized and existing under the laws of the state of Delaware, with its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey. MSP is a subsidiary of Merck & Company, Inc. and was the exclusive licensee of the relevant patents.

16. 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**."

17. Glenmark Pharmaceuticals Limited is a company organized and existing under the laws of India, with its corporate office at Glenmark House, B. D. Sawant Marg, Andheri (E), Mumbai 400 099, India, and its registered office at B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai 400 026, India.

18. Glenmark Generics Inc., U.S.A., formerly known as Glenmark Pharmaceuticals Inc., U.S.A., is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 750 Corporate Drive, Mahwah, New Jersey. It is a wholly-owned subsidiary of Glenmark Pharmaceuticals Limited.

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

20. All of Defendants' wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or 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/or with the actual, apparent, and/or ostensible authority of Defendants.

III. JURISDICTION AND VENUE

21. This Court has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed class exceeds $5,000,000, and at least one Class Member is a citizen of a state different from that of one of Defendants.

22. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 16 of the Clayton Act, 15 U.S.C. § 26, because this action arises under the federal antitrust laws. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

23. Venue is appropriate within this district under 15 U.S.C. § 15(a) (Clayton Act), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. §1391(b) (general venue provision). Defendants resided, transacted business, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

24. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY FRAMEWORK

25. Generic competition allows purchasers at all levels of the pharmaceutical chain of distribution to purchase generic drugs at prices lower than those drugs' brand counterparts. Generic competition to a single brand drug can provide potentially billions of dollars in savings to consumers, pharmacies, and other drug purchasers, as well as to private health insurers or state Medicaid programs, both of which reimburse the cost of drug purchases by covered individuals.

26. The FDA sets the standards for the approval of generic drugs. Upon satisfaction of FDA regulations governing, among other things, safety, efficacy, and labeling, the FDA confers upon a generic drug an "AB" rating. The AB rating signifies that the generic version is, for all intents and purposes, bioequivalent to its brand counterpart. As defined in the regulations, bioequivalence is:

> the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.[1]

27. The AB rating permits the generic drug to be substituted for the brand drug at a pharmacy counter. All States permit—and indeed, some States require—pharmacists to substitute an AB-rated generic drug for the corresponding brand drug, unless the prescribing healthcare provider has specifically stated that the brand drug is to be used.

28. Many health insurers and other third-party payors have adopted policies to encourage the substitution of AB-rated generic drugs for their brand name counterparts. For example, many third-party payors implement a tiering system that places certain drugs on different benefit tiers. A drug that is placed on one tier may receive only partial reimbursement, while a drug placed on another tier may receive full reimbursement. Typically, branded drugs are

[1] 21 C.F.R. § 320.1(e).

placed on a different tier than their corresponding generic. Furthermore, branded drugs with a generic equivalent are usually subject to smaller reimbursements or higher co-pays, while generic drugs will be given total (or near total) reimbursement with a limited, or no, co-pay.

29. As a result of these policies, healthcare professionals are incentivized to prescribe generics so that they can receive higher reimbursements. In addition, these policies also incentivize end users to request generic drugs because of the cost savings they may receive with respect to their co-pay.

30. Because both healthcare professionals and end-users are economically incentivized to prefer generic drugs, AB-rated generics are usually able to capture a substantial portion of the market.

31. The first AB-rated generic is typically priced at a discount to its brand counterpart. As additional AB-rated generics obtain FDA approval to enter the market, the resulting increase in competition causes prices of both the first generic and the brand counterpart to drop dramatically.

32. Empirical studies show that within a year of generic entry, generics will have obtained about 90% of the market, *i.e.*, pharmacists fill 90 of every 100 prescriptions for the compound with an AB-rated generic. Indeed, an FTC study found that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[2]

A. FDA New Drug Approval Process

33. The Federal Food, Drug and Cosmetic Act (the "FDCA") and its accompanying regulations set the standards for the approval of any new drug compound that is to be marketed, sold, or distributed in the United States. Drug manufacturers seeking to gain FDA approval for a

[2] FTC Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at 8 (Jan. 2010), available at http://emmanuelcombe.org/delay.pdf.

new drug must file a New Drug Application ("NDA"). Applicants filing an NDA are required to provide a host of information demonstrating the safety and efficacy of their drug, including, but not limited to: (1) information and studies regarding the chemistry of the drug substance, which includes information concerning how the drug is manufactured; (2) information and studies regarding nonclinical pharmacology and toxicology for the new drug; (3) information and studies regarding the human pharmacokinetics and bioavailability; and (4) information and data from clinical studies on human subjects.[3]

34. Upon satisfying FDA regulations concerning efficacy, safety and labeling, the FDA will approve the NDA, permitting the applicant to market, sell, and distribute the approved drug to the U.S. public.

35. In addition, upon receiving FDA approval, the brand manufacturer will list any patents it believes cover the approved drug in a publication called the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is more commonly referred to as the "Orange Book."[4]

36. However, only drug substance patents (active ingredient), drug product patents (formulation and composition), and method-of-use patents qualify for listing in the Orange Book.[5] Thus, for example, process patents covering a new drug are not eligible for listing (although they may be asserted in a future patent litigation against any allegedly infringing product).

[3] *See* 21 C.F.R. § 314.50(c)-(d).

[4] 21 U.S.C. § 355(j)(7)(A)(iii).

[5] 21 C.F.R. § 314.53(b).

37. In listing patents in the Orange Book, the FDA acts in a ministerial capacity. It does not verify whether the patents listed in the Orange Book are properly listed and instead relies on the accuracy and truthfulness of the NDA applicant.

38. In addition to the protection conferred by patents covering the brand manufacturer's drug, NDA applicants are afforded additional statutory protections for a drug containing a new active ingredient. NDAs for drugs containing a new active ingredient are given up to five years of marketing exclusivity before any generic drug manufacturer may file an application for the approval of a generic formulation.[6]

B. The Hatch-Waxman Act Encourages and Facilitates the Approval of Generic Drugs

39. In 1984, Congress amended the FDCA with the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), more commonly known as the "Hatch-Waxman Act."

40. The Hatch-Waxman Act simplifies the regulatory hurdles that generic drug manufacturers have to clear prior to marketing and selling generic drugs. Instead of filing a lengthy and highly costly NDA, the Hatch-Waxman Act allows generic drug manufacturers to obtain FDA approval in an expedited fashion through the filing of an Abbreviated New Drug Application ("ANDA").

41. If an ANDA applicant shows that the generic drug is bioequivalent to the brand drug, then the ANDA applicant may rely on scientific and other data compiled in the brand drug NDA it references concerning, among other things, safety and efficacy.[7] The ability to rely on the scientific data published in the referenced NDA obviates the need for duplicative and

[6] 21 U.S.C. § 355(j)(5)(F)(ii).

[7] 21 U.S.C. § 355(j)(2)(A).

expensive experimentation and clinical trials, which in some instances can result in out-of-pocket costs of upwards of $130 million.[8] The FDA must approve an ANDA unless the information submitted in the ANDA is insufficient to meet the requirements under the Hatch-Waxman Act.[9] In sum, the streamlined approval process under the Hatch-Waxman Act makes it easier for generic drug manufacturers to bring competing and cheaper generic products to market.

42. Although the Hatch-Waxman Act seeks to facilitate generic competition, the brand manufacturer retains the right to enforce any patents associated with its brand drug. As part of its ANDA, the applicant must certify that the generic drug will not infringe any of the Orange Book patents because: (1) no patents exist on the brand drug; (2) the patents have expired; (3) the patents will expire by the time the generic product comes to market; or (4) the patents are invalid, unenforceable, or will not be infringed by the sale of the generic product.[10] When a generic drug manufacturer certifies that the patents covering the referenced brand drug are invalid, unenforceable, or will not be infringed, it known as a "Paragraph IV certification."

43. When a generic drug manufacturer files a Paragraph IV certification asserting that one or more patents listed in the Orange Book are invalid, unenforceable or will not be infringed, it must serve notice of its certification to both the brand manufacturer and the owner(s) of the patent.

44. The issuance of a Paragraph IV certification creates an "artificial act" of patent infringement, permitting the patent owner to file a patent infringement suit against the ANDA applicant making the Paragraph IV certification(s).[11]

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[8] *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1564 n.36 (2006).

[9] 21 U.S.C. § 355(j)(4).

[10] 21 U.S.C. § 335(j)(2)(A)(vii)(I)-(IV).

[11] 35 U.S.C. § 271(e)(2)(A).

45. If the brand manufacturer files a patent infringement suit against the ANDA applicant within 45 days of receiving the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of: (a) 30 months, running from the date the when the Paragraph IV notice was served on the patentee; or (b) a court ruling that the patent is invalid, unenforceable, or not infringed by the ANDA.[12] During the 30-month stay, the FDA may grant "tentative approval" of an ANDA if the FDA determines that the ANDA would otherwise qualify for final approval, but for the 30-month stay.

46. Despite the threat of a patent infringement suit and a 30-month stay, the Hatch-Waxman Act creates powerful incentives for generic drug manufacturers to file ANDAs. Specifically, the Hatch-Waxman Act grants a 180-day period of market exclusivity to the first applicant (the "first filer") to file a substantially complete ANDA containing a Paragraph IV certification.

47. During the 180-day period of market exclusivity, the first filer only competes against the brand manufacturer and potentially any AG marketed under the brand manufacturer's NDA; all other generic ANDA applicants must wait until either the expiration of the 180-day exclusivity period or a court order finding that each of the patents that are the subject of a Paragraph IV certification are invalid, unenforceable, or not infringed.

48. Because all other ANDA generics are barred from the market during the first filer's 180-day exclusivity period, the first-filing ANDA applicant is able to price its generic version at a price that is around 20%-30% below the brand drug's price. This allows the first filer to gain market share, while simultaneously taking advantage of the price umbrella created by the

[12] 21 U.S.C. § 355(j)(5)(B)(iii).

brand manufacturer's pricing. Indeed, during the first-filer's 180-day exclusivity period, the first-filer can capture over 80% of branded and generic unit and dollar sales.

49. However, once the first filer's 180-day exclusivity period expires, all other FDA-approved ANDA filers can begin to market their generic equivalents, driving down prices substantially and reducing the profitability of both the branded drug and the first filer's generic.

C. Brand Manufacturers and First Filers Manipulate the Regulatory Structure to Delay the Emergence of Generic Competition

50. Because the Hatch-Waxman Act automatically stays the approval of an ANDA when a brand manufacturer files an infringement suit against an ANDA applicant, the brand manufacturers have an incentive to liberally (and sometimes wrongfully) list in the Orange Book all patents potentially covering the brand drug. Upon a generic drug manufacturer's filing of an ANDA with a Paragraph IV certification, the brand manufacturer will then sue on one or more of those Orange Book patents to trigger the stay.

51. Frequently, patent infringement suits arising from Paragraph IV certifications result in settlements. In some of these settlements, the brand manufacturer will offer the generic drug manufacturer some form of consideration (*i.e.*, payment) in exchange for the generic drug manufacturer agreeing to delay entry of its generic product. These settlements commonly are referred to as "pay-for-delay agreements."

52. These pay-for-delay agreements have the practical effect of permitting the settling brand manufacturer to retain a significant portion of its monopoly profits while only ceding a relatively small portion of those profits to the settling generic drug manufacturer in exchange for the generic drug manufacturer's agreement to delay market entry.

53. The incentive to create these types of agreements is particularly acute between a brand manufacturer and the first-filing ANDA applicant. In these agreements, the brand

manufacturer seeks to delay generic entry and preserve its monopoly for as long as possible. Typically, a generic drug manufacturer will want as early an entry date as possible, if only for the higher present value of earlier sales.

54. However, unlike other generic drug manufacturers, a first-filing ANDA applicant has the potential benefit of 180 days of marketing exclusivity where it can reap substantial revenues as potentially one of two products in the relevant drug market. A first-filing ANDA applicant's continued litigation against the brand manufacturer runs the risk that the court will find the patent(s) at issue valid, enforceable, and/or infringed by the first filer's ANDA. A finding of validity, enforceability, and/or infringement by a court would negate the first filer's Paragraph IV certification and disqualify that generic drug manufacturer from receiving the benefit of 180 days of marketing exclusivity. Thus, the first filer has an acute interest in settling the patent infringement lawsuit as a means of guaranteeing its 180-day exclusivity period, and, in turn, the economic bounty associated with it.

55. With the promise of substantial revenue during its generic exclusivity period secure, the first filer cares little about date of ultimate launch sought by the brand manufacturer—that is so long as the brand name manufacturer sufficiently compensates the first filer for the delay in launching its generic.

56. Moreover, brand manufacturers are willing to pay substantial sums to the first filer for any delay in generic launch in exchange for the promise that the first filer will not enter before a certain date. This is because the value of monopoly profits is so great that the brand manufacturer is willing to pay more to ensure the first filer's acquiescence to the later launch date. The generic drug manufacturer's acquiescence to a later entry date, in turn, preserves a

substantial portion of the brand manufacturer's monopoly profits in the period prior to the first filer's agreed-to launch date.

57. In essence, by settling with the brand manufacturer, the first filer receives a double bonus in the form of: (1) a substantial payment from the brand manufacturer to forgo early entry; and (2) the guarantee of substantial revenues as the only generic on the market (absent an authorized generic) during that first filer's 180-day exclusivity period. Under such circumstances, the first-filing ANDA applicant has limited incentive to continue the patent litigation for purposes of securing a judgment of non-infringement, invalidity, or unenforceability—and thus, a potentially earlier entry date—because it still retains the economic bounty associated with its statutory 180-day exclusivity period.

58. Such pay-for-delay agreements also create powerful disincentives for subsequent ANDA filers to continue defending their ANDAs in patent infringement litigations against the brand manufacturer. Specifically, once it becomes apparent that the brand manufacturer and the first filer have settled their patent litigation, subsequent ANDA filers usually will not pursue litigation aggressively, and, often times, settle as well.

59. Subsequent ANDA filers are unlikely to continue litigating because obtaining a judgment that the patents subject to Paragraph IV certifications are invalid, unenforceable, or not infringed provides little pay-off to them. For example, prior to the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"), Pub. L. No. 108-173, 117 Stat. 2066, a judgment of patent invalidity or unenforceability would not cause the first filer to lose its 180-day exclusivity period; rather, the subsequent filer's success in litigation would only accelerate the start of the first filer's exclusivity period. The subsequent ANDA filer must still wait until the first filer's 180-day exclusivity period expires, and only at that point can

other FDA-approved ANDA applicants enter the market as well. Thus, these pay-for-delay agreements effectively "park" exclusivity and cause a bottleneck in the timing of full generic entry.

60. More recent legislation has not alleviated the problems caused by pay-for-delay agreements. MMA attempts to make the incentives underlying pay-for-delay agreements less attractive by enumerating a series of forfeiture events that, if triggered, will deprive a first filer of its 180-day exclusivity period.

61. One of the key forfeiture events under the MMA is if the first filer fails to obtain tentative approval within 30 months of submitting its ANDA.[13]

62. While noble in purpose, scholars have found the MMA's "use it or lose it" provision to be woefully inadequate in deterring anticompetitive agreements to delay generic competition for two reasons. First, market acceleration clauses, which are standard components of pay-for-delay agreements, allow the first filer to accelerate its entry into the market ahead of the later date agreed to with the brand manufacturer in its settlement should a subsequent generic challenger prevail in the courts.

63. Second, brand manufacturers can avoid triggering a potential forfeiture event by only suing on some, but not all, of the patents subject to the first filer's Paragraph IV certifications. Because a subsequent filer needs to obtain a judgment of invalidity or non-infringement with respect to *all* patents that are the subject of a first filer's Paragraph IV certification in order to trigger the forfeiture event, the brand manufacturer need only sue on a few of the patents to avoid that scenario.

[13] 21 U.S.C. § 505(j)(5)(D)(i)(I).

64. The lengthy and expensive nature of patent litigation makes it such that subsequent filing generic drug manufacturers typically do not have the stomach to pursue litigation to the end. Indeed, by the time a generic drug manufacturer secures the judgments necessary, "the clock [will] simply run[] out on the subsequent generic filers fighting to open the market earlier than the date agreed to by the first filer in its 'parked' exclusivity settlement."[14]

D. No-Authorized Generic Agreements

65. Pay-for-delay agreements can be augmented by including terms in which the brand manufacturer agrees not to launch an authorized generic to compete with the first filer during its 180-day exclusivity period.

66. As a threshold matter, a first filer's 180-day exclusivity period does not prevent a brand manufacturer from marketing its own authorized generic during that period of generic exclusivity. Authorized generics are chemically identical to the branded drug and are marketed under the brand manufacturer's NDA. An authorized generic can be marketed either through a generic drug division of the brand manufacturer or through a third-party generic drug manufacturer.

67. Competition from an authorized generic during the first filer's 180-day exclusivity period substantially reduces the first filer's profit margins and increases price competition that ultimately benefits consumers and other purchasers of the branded drug and the first filer's generic equivalent.

68. In a 2011 study titled, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (the "FTC 2011 Report"), the FTC found that authorized generics capture a

[14] Letter from Michael Carrier, Rutgers School of Law, to Sen. Tom Harkin, at 3 (Apr. 21, 2011), *available at* http://www.hpm.com/pdf/blog/LIPITOR%20-%20Balto-Carrier%20Ltr.pdf.

significant number of generic drug sales, reducing the first filer's revenues by between 40 percent and 52 percent on average during the 180-day exclusivity period.

69. Although first filers make significantly less money when they are forced to compete with an authorized generic during the first 180 days, consumers benefit from the lower prices caused by competition between the authorized generic and the first filer.

70. In light of the substantial negative effects on a first filer's bottom-line that can be caused by the presence of an authorized generic, a promise by a brand manufacturer to not launch, or license, an authorized generic confers significant monetary value to a first filer. The value conferred to a first filer is tantamount to a payment for agreeing to delay generic entry and competition.

V. DEFENDANTS' UNLAWFUL CONDUCT

A. A short primer on cholesterol-lowering drugs.[15]

71. Cholesterol is essential in constructing and maintaining membranes in animal cells. However, in humans, high cholesterol is associated with coronary heart disease and atherosclerosis. Atherosclerotic coronary heart disease is a major cause of death and cardiovascular morbidity in the Western World.

72. In the 1950s, scientists developed several drugs thought to lower cholesterol levels. In 1953, scientists in France reported that phenylacetic acid and its analogues—fibrates—lowered cholesterol levels. This discovery led to the approval of ethyl ester clofibrate in the U.S. in 1967; it was later found to have unacceptable side effects and was replaced with other fibrates.

[15] *See, e.g.*, C. Robin Ganellin, *Discovery of the Cholesterol Absorption Inhibitor, Ezetimibe, in* C. Robin Ganellin, Stanley Roberts & Roy Jefferis, *Introduction to Biological and Small Molecule Drug Research and Development* (2013) (reviewed by Dr. Stuart B. Rosenblum, one of the inventors of ezetimibe).

73. In the 1970s and 80s, scientists discovered a group of cholesterol-lowering drugs known as statins. Statins lower cholesterol levels by inhibiting the enzyme that regulates the production of cholesterol in the liver, HMG-CoA reductase. In 1987, Merck launched the first statin: lovastatin. Merck later launched a second statin: simvastatin. Statins, as a class, were for many years the most profitable drugs in pharmaceutical history.

74. However, the 1990s saw a renewed interest in fibrates as (1) cholesterol lowering drugs had become big business, (2) their mechanism of action became better understood, and (3) clinical trials demonstrated the efficacy of fibrates on cardiovascular events. Scientists had discovered that fibrates inhibited the enzyme Acyl-CoA cholesterol acyltransferase (ACAT), which blocked the absorption of cholesterol in the intestine (and may also inhibit cholesterol deposited within vascular walls). And clinical data showed that fibrates worked. So while statins had become first line treatments, fibrates were widely prescribed.

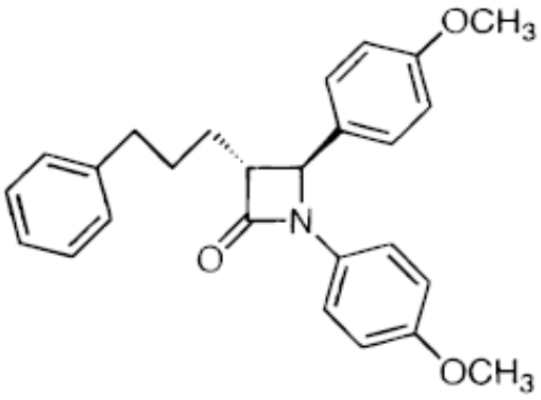
B. Early 1990s: Merck develops hydroxyl-substituted azetidinone compounds useful as hypocholesterolemic agents.

75. In the early 1990s, Merck embarked on a broad research program to discover novel ACAT inhibitors. Scientists for Schering began developing azetidinone compounds that, hopefully, would be useful in reducing cholesterol levels in humans. Those scientists included Stuart B. Rosenblum, Sundeep Dugar, Duane A. Burnett, John W. Clader, and Brian McKittrick.

76. In lab experiments conducted over several years, these scientists identified a lead compound, SCH48461, and inherent metabolites and metabolite-like analogues of that compound, including SCH58235 or "ezetimibe." (Ezetimibe would eventually become the active ingredient in Zetia.)

77. SCH 48461 is (3R,3S)-1,4-bis-(4-methoxyphenyl)-3-(3-phenylpropyl)-2-azetidinone.[16] It is pictured in Figure 4 below. The negative enantiomer possesses significantly greater *in vivo* activity.

Figure 4. SCH 48461



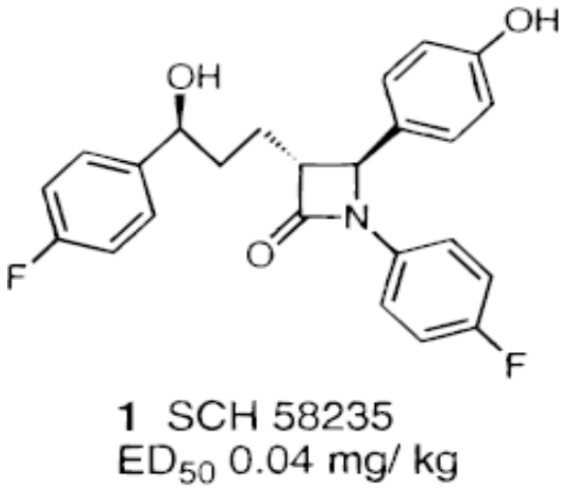
2 SCH 48461
ED_{50} 2.2 mg/ kg

78. SCH 58235 is 1-(4-fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3s)-hydroxypropyl]-(4S)-(4-hydroxypheyl)-2-azetidinone.[17] The use of halogen to block sites of metabolism was then well known. To create SCH 58235, Merck scientists used routine laboratory techniques to add fluorine to the two phenyl rings, in order to lessen the likelihood of hydroxylation (and thereby keep the compound in the body longer). It is pictured in Figure 5 below.

[16] See Brian G. Salisbury, *Hypocholesterolemic Activity of a Novel Inhibitor of Cholesterol Absorption, SCH 48461*, 115 Atherosclerosis 45 (1995); Duane A. Burnett et al., *2-Azetidinones as Inhibitors of Cholesterol Absorption*, 37 J. Med. Chem. 1733 (1994).

[17] Stuart B. Rosenblum, *Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH 58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption*, 41 J. Med. Chem. 973 (1998).

Figure 5. SCH 58235, Ezetimibe



79. Upon discovering these and other useful compounds (and their metabolites), and recognizing their potential to be developed into lucrative prescription drugs down the road, Merck set out to obtain broad patent protection.

80. Merck knew that publishing journal articles about its research and development could potentially undermine its ability to patent its inventions. So while its discoveries occurred in the early 1990s, its scientists did not publish their discoveries until after the first patent application was filed and, in some instances, only wrote about the development process over a decade later.[18]

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[18] See John W. Clader, *Ezetimibe and other Azetidinone Cholesterol Absorption Inhibitors*, 5 Current Topics Med. Chem. 243 (2005); John W. Clader, *The Discovery of Ezetimibe: A View from Outside the Receptor*, 47 J. Med. Chem. 1 (2004); Stuart B. Rosenblum et al., *Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2- azetidinone (SCH58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption*, 41 J. Med. Chem. 973 (1998); Margaret Van Heek et al., *In Vivo Metabolism-Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH58235, in the Rat and Rhesus Monkey through the Identification of the Active Metabolites of SCH 48461*, 283 J. Pharmacology & Experimental Therapeutics 157 (1997); Sundeep Dugar et al., *Metabolism and Structure Activity Data Based Drug Design: Discovery of (-) SCH 53079, an Analog of the Potent Cholesterol Absorption Inhibitor (-) SCH 48461*, 11 Bioorganic & Med. Chem. Letters 1271 (1996); John W. Clader et al., *2-Azetidinone Cholesterol Absorption Inhibitors: Structure-Activity Relationships on the Heterocyclic Nucleus*, 39 J. Med. Chem. 3684 (1996); Brian A. McKittrick et al., *Stereoselective Synthesis and Biological Activity of* Cis *Azetidinones as Cholesterol Absorption Inhibitors*, 16 Bioorganic & Med. Chem. Letters 1947 (1996); Brian G. Salisbury et al.,

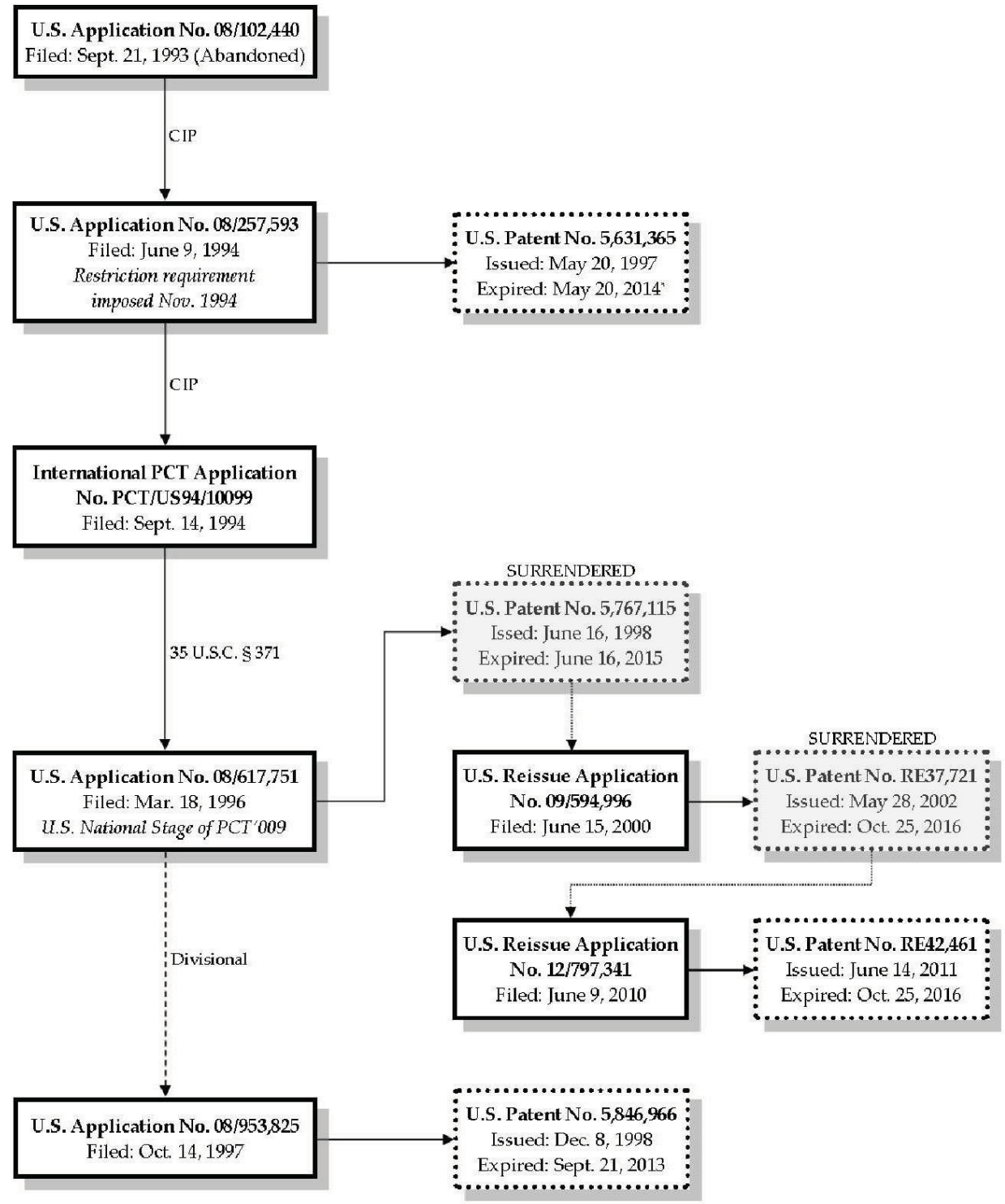
C. 1993-1998: Merck applies for, and obtains, the original azetidinone patents (the '365, '115, and '966 patents).

81. Beginning in 1993, Merck filed a series of related U.S. patent applications addressing hydroxyl-substituted azetidinone compounds useful as hypocholesteremic agents. (All of the patent applications and communications with the PTO described herein were done by Schering Corporation and its agents, unless otherwise noted.) Three issued as patents; one of these then reissued twice.

82. For shorthand, we refer to the family of patents resulting from Merck's efforts here as "the azetidinone patents." The azetidinone patents include the '365 patent, the '115 patent, the '966 patent, the RE'721 patent, and the RE'461 patent.

Hypocholesterolemic Activity of a Novel Inhibitor of Cholesterol Absorption, SCH 48461, 115 Atherosclerosis 45 (1995); Sundeep Dugar et al., *Gamma-Lactams and Related Compounds as Cholesterol Absorption Inhibitors: Homologs of the ?-Lactam Cholesterol Absorption Inhibitor SCH 48461*, 24 Bioorganic & Med. Chem. Letters 2947 (1995); Stuart B. Rosenblum et al., Abstract, *Discovery of SCH 58235: A Potent Orally Active Inhibitor of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995); Duane A. Burnett et al., *2-Azetidinones as Inhibitors of Cholesterol Absorption*, 37 J. Med. Chem. 1733 (1994).

Figure 6. The Azetidinone Patents



*All expiration dates are calculated without pediatric exclusivity extensions.

1. 1993-1994: Merck files two patent applications addressing hydroxyl-substituted azetidinone compounds useful as hypocholesteremic agents.

83. On September 21, 1993, Merck filed U.S. Patent Application 102,440, entitled "Hydroxy-Substituted Azetidinone Compounds Useful As Hypocholesterolemic Agents." Merck abandoned the application. Then, on June 9, 1994, Merck filed U.S. Patent Application 257,593 as a continuation- in-part of the abandoned '440 application.

84. Both the '440 application and the '593 application disclosed that the inventions described were useful as hypocholesterolemic agents in the treatment and prevention of atherosclerosis—the hardening and narrowing of the arteries due to build-up of fats and cholesterol on artery walls. These applications explained that the liver is the major organ responsible for cholesterol biosynthesis and is the prime determinant of plasma cholesterol levels. When intestinal cholesterol absorption is reduced, less cholesterol is delivered to the liver, which makes less hepatic lipoprotein and clears more plasma cholesterol (mostly LDL). As Merck put it, "[T]he net effect of inhibiting intestinal cholesterol absorption is a decrease in plasma cholesterol levels."

85. Merck went on to prosecute the '593 application for about three years, from June 9, 1994 until May 20, 1997.

2. 1994-1996: Merck files a third and fourth patent application addressing hydroxyl-substituted azetidinone compounds.

86. On September 14, 1994, Merck filed the PCT/US94/10099 application as a continuation-in-part of the '593 application. The PCT'099 application added two example compounds in the specification, 3L and 3M, as well as in vivo data for 3L, 3M, and 6A-1.

87. On March 18, 1996, the PCT'0099 application "entered the national stage" in the United States under 35 U.S.C. § 337 as U.S. Patent Application No. 617,751. The specification for the '751 application, as filed, was identical to the specification of the PCT'0099 application.

88. Merck prosecuted the '751 application for a little over two years.

3. Early 1997: Merck obtains its first azetidinone patent, covering processes (the '365 patent).

89. On May 20, 1997, the '593 application—Merck's second azetidinone patent application—issued as U.S. Patent No. 5,631,365. The '365 patent was the first-issued Merck azetidinone patent.

90. The inventors of the '365 patent are Drs. Rosenblum, Dugar, Burnett, Clader, and McKittrick. All worked for Schering.

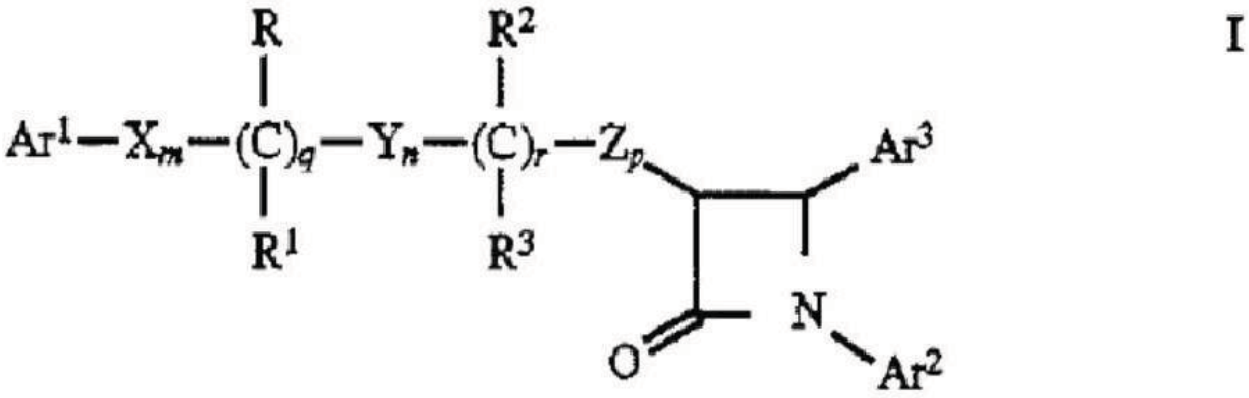
91. The '365 patent was originally assigned to Schering Corporation. In 2012, Merck Sharp & Dohme became the assignee of the '365 patent by means of a conveyance from Schering Corporation.

92. The '365 patent states that "the present 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." It observes that "[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," citing U.S. Patent No. 4,983,594; Ran, *Indian J. Chem*. (1990); European Patent Publication No. 264,231; European Patent No. 199,630; and European Patent Application No. 337,549.

93. The summary of the invention describes hypocholesterolemic compounds of formula I (Figure 7) or a pharmaceutically acceptable salt of those compounds. It also 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 specific steps]."

Figure 7. Hypocholesterolemic Compounds of Formula I



I

94. The specification confirms that the invention includes both enantiomers and racemic mixtures, and that one enantiomer may lead to greater cholesterol inhibition than another: "all isomers, including enantiomers . . . are contemplated as being part of this invention . . . including racemic mixtures." "Isomers can be prepared using conventional techniques, either by reacting chiral starting materials or by separating isomers of a compound of formula I."

"Those skilled in the art will appreciate that for some compounds of formula I, one isomer will show greater pharmacological activity than another isomer."

95. 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.

96. The specification notes that "[c]ompounds of formula I can be prepared by known methods, for example those described below and in WO93/02048" and then describes several methods of preparation. It further discloses that many, if not all, of the "starting compounds" used are "either commercially available or well known in the art and can be prepared via known methods."

97. The specification also 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.

It goes on to describe the procedure used to determine the in vivo activity of the compounds of formula I, using the "Hyperlipidemic Hamster."

98. The '365 patent has four claims, all of which claim a process of preparing a compound of formula I. Claims 1 and 3 are independent claims; Claims 2 and 4 depend on claims 1 and 3, respectively.

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

4. Late 1997: Merck files a fifth patent application addressing azetidinones, this one addressing combination use with statins.

100. On October 14, 1997, Merck filed U.S. Patent Application 953,825—titled "combinations of hydroxyl-substituted azetidinone compounds and HMG CoA reductase inhibitors"—as a continuation-in-part of the '751 application.

5. Mid-1998: Merck obtains a second azetidinone patent covering compounds, a composition, and a method of treating atherosclerosis (the '115 patent).

101. On June 16, 1998, the '751 application issued as U.S. Patent No. 5,767,115. The '115 patent had nine claims. Claims 1-7 covers compounds, claim 8 covers a pharmaceutical composition for the treatment or prevention of atherosclerosis (or for the reduction of plasma cholesterol levels), and claim 9 covers a method of treating or preventing atherosclerosis (or reducing plasma cholesterol levels) comprising administering to a mammal in need of such treatment an effective amount of a compound of claim 1.

102. Ezetimibe (the active ingredient in Zetia) is within the scope of claims 1-3, 5, and 7 of the '115 patent. Ezetimibe is designated "6A" and is described in Example 6 at column 31, lines 1-10 of the specification and in claim 7 at column 40, lines 19-21.

103. According to Merck, the '115 patent expired on June 16, 2015.

6. Late 1998: Merck obtains a third azetidinone patent for use in combination with statins (the '966 patent).

104. On December 9, 1998, the '825 application issued as U.S. Patent No. 5,846,966.

105. All claims in the '966 patent refer to a hydroxyl-substituted azetidinone used *in combination with* an HMG CoA reductase inhibitor—i.e., a statin. Claim 1 refers to hydroxyl-substituted azetidinone compounds used in combination, claims 2-5 refer to compositions of those compounds used in combination, and claim 6 refers to methods of treating or preventing atherosclerosis or reducing plasma cholesterol levels in combination with statins. Claim 8

explicitly refers to simvastatin (the active ingredient in Merck's Zocor) and atorvastatin (Pfizer's Lipitor).

106. As a result of this limitation, any generic version of Zetia that was only being used as a monotherapy (as opposed to the combination therapy described in the '966 patent) would not infringe the claims of the '966 patent.

D. 2000: Merck asks the PTO to reissue the '115 patent with new ezetimibe claims.

107. In early 2000, Merck—through its predecessor, Schering Corporation—was preparing a New Drug Application for Zetia. Merck closely reviewed the existing patent portfolio, knowing, as all sophisticated pharmaceutical manufacturers do, that the FDA would require them to identify the patents that claim the Zetia product (or a method of using it) by listing them in the Orange Book.

108. On June 15, 2000, Merck filed Reissue Application No. 09/594,996, asking the PTO to reissue the '115 patent. In preliminary remarks, Merck stated that the reissue application was filed "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 (described as 1-(4-fluoro[phenyl)-3(R)-[3(S)-(4 fluorophenyl)-3-hydroxypropyl)]-4(S)-(4-hydroxyphenyl)-2-azetidinone). Merck proposed adding claims 10-13, claiming the ezetimibe compound (in both prose and graphic form, claims 10 and 11), a pharmaceutical composition for the treatment or prevention of atherosclerosis or the reduction of plasma cholesterol levels (claim 12), a method of treating or preventing atherosclerosis or reducing plasma cholesterol levels (claim 13), and a method of use thereof.

109. Merck submitted a declaration in support of reissue signed by James R. Nelson, Staff Vice President and Associate General Counsel, Patents & Trademarks at Schering-Plough

Corporation and Vice President at Schering Corporation. Nelson described the error as "the failure to include a specific claim to one of the most preferred compounds."

E. 2001-2002: Merck obtains approval for Zetia, the RE'721 patent, and a corresponding 16-month patent term extension.

1. 2001: Merck files an NDA for Zetia.

110. On December 27, 2001, while the application for reissue was pending, Merck submitted NDA 21445 seeking FDA approval to market ezetimibe tablets in the United States under the brand name Zetia for the treatment of hypercholesterolemia.

2. 2002: The PTO reissues the '115 patent as the RE'721 patent.

111. On May 28, 2002, the RE'966 application issued as U.S. Patent No. RE37,721 with new claims 10-13. These included the compound ezetimibe (claims 10-11), a composition of ezetimibe (claim 12), and a method of using ezetimibe to treat or prevent atherosclerosis or reduce plasma cholesterol levels (claims 13).

3. 2002: The FDA approves Zetia.

112. 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 quickly became a steady source of profits for Merck, with annual U.S. sales of about $1 billion in 2010, $1.4 billion in 2014, and $2.6 billion by 2016.

4. 2002: Merck seeks a 16-month patent term extension for the RE'721 patent.

113. On December 12, 2002, Merck requested an extension of the patent term of the RE'721 patent based on the duration of the FDA's review of the Zetia NDA (pursuant to 35 U.S.C. § 156 and 37 C.F.R. §§ 1.710-1.791). Merck asked that an additional 497 days of patent term be added.

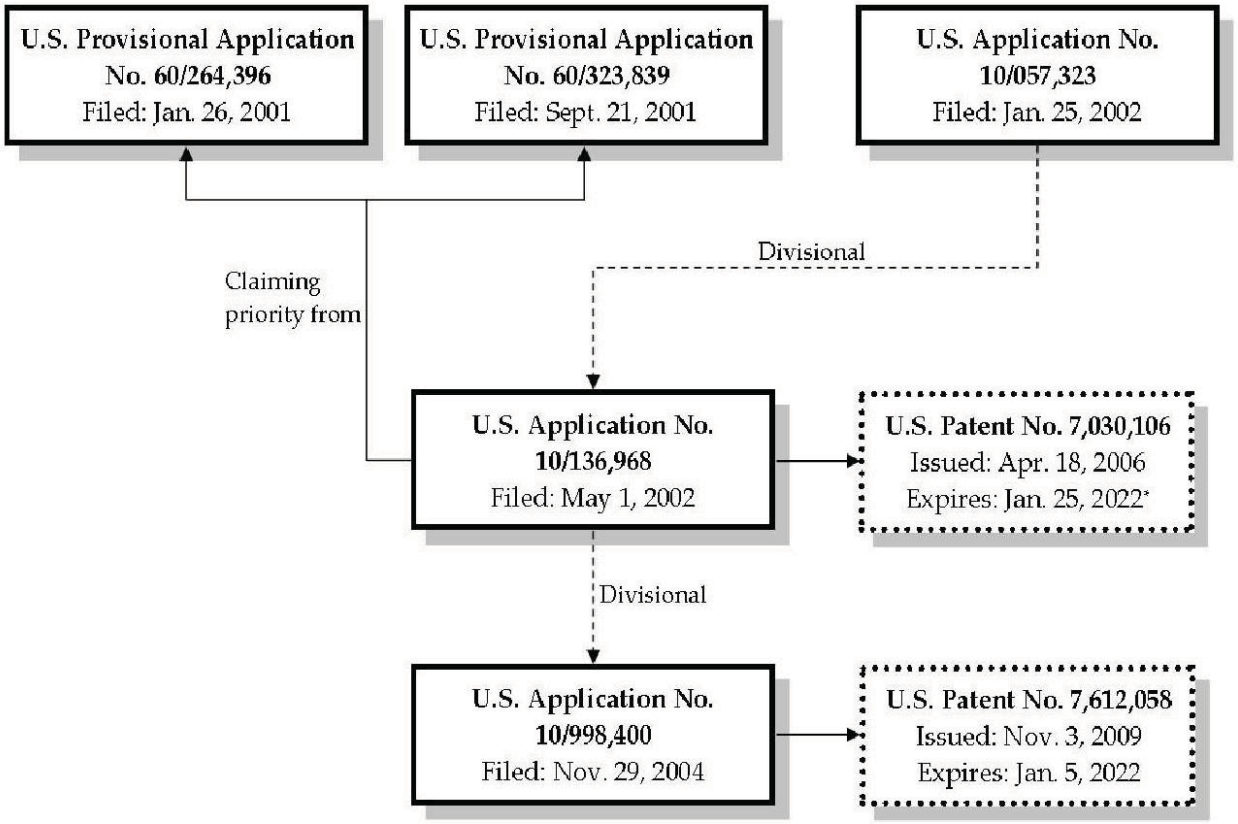
114. Ultimately, on January 17, 2006, the RE'721 patent was extended through October 25, 2016. The PTO, relying on information obtained from Schering and confirmed by the FDA, determined that the RE'721 patent was eligible for a patent term extension of 497 days due to the applicability of the 14-year exception of 35 U.S.C. § 156(c)(3). With this extension, granted in 2006, the RE'721 patent was set to expire on October 25, 2016.

F. 2006: Merck obtains its first "sterol non-absorption" patent (the '106 patent).

115. After Merck filed its NDA, but before it was approved, Merck sought to extend its patent protection for Zetia by filing a series of patent applications relating to compounds that inhibit sterol absorption and methods for treating specific conditions with those compounds. Two issued as patents (the '106 patent and the '058 patent). For shorthand, we refer to this family of patents as "the sterol non-absorption" applications and patents.

116. The sterol non-absorption applications did not claim priority to, or derive from, the azetidinone applications. Nor did they share any inventors.

Figure 8. The Sterol Non-Absorption Patents



*All expiration dates are calculated without pediatric exclusivity extensions.

117. On January 25, 2002, Merck filed Utility Application No. 10/057,323. The '323 application claimed priority to two provisional applications, filed in January 26, 2001 and September 21, 2001, respectively. It did not claim priority to, nor was it related to, the azetidinone patents described above. On May 1, 2002, Merck filed Application No. 10/136,968 as a divisional of the '323 application. The '323 and '968 applications purported to address compounds and compositions that inhibited sterol absorption.

118. On April 18, 2006, Merck's Application No. 10/136,968 issued as U.S. Patent No. 7,030,106. The '106 patent was Merck's first sterol non-absorption patent. It has two claims. The inventor is Wing-Kee Philip Cho. The assignee was originally Schering Corporation.

119. According to Merck, the ’106 patent originally was set to expire on January 25, 2022 but received a pediatric extension and is now set to expire on July 25, 2022.

120. The ’106 patent specification says that “the present invention relates to therapeutic combinations of peroxisome proliferator-activated receptor (PPAR) activator(s) and sterol absorption inhibitor(s) for treating vascular conditions (including atherosclerosis).”

121. But neither of the claims in the ’106 patent refers to combination use. Both claim pharmaceutical compositions of ezetimibe that were earlier disclosed in the RE’721 patent. Given this and other earlier disclosures, the ’106 patent is, and clearly was at the time of its issuance, invalid as obvious and/or for obviousness-type double patenting.

122. By this time, Merck/Schering had listed in the Orange Book the RE’721 azetidinone patent, the ’966 combination-with-statins patent, and the ’106 sterol non-absorption patent. The ’365 process patent was not listed in the Orange Book, likely because process patents—unlike product or method of use patents—are not eligible for listing.

G. 2006: Glenmark files the first ANDA for generic Zetia.

123. On October 25, 2006—one year prior to the expiration of the five-year NCE exclusivity and therefore the first day for would-be generic makers of Zetia to file an ANDA for that product—generic drug manufacturer Glenmark filed ANDA 78-560, seeking FDA approval to market an AB-rated generic version of Zetia.

124. Glenmark’s ANDA included a paragraph IV certification attesting that all of the patents then listed in the Orange Book—the RE’721 azetidinone patent, the ’966 combination-with-statins patent, and the ’106 sterol non-absorption patent—were invalid, unenforceable or not infringed. Because the ’365 process patent was not listed in the Orange Book, Glenmark did not need to certify to it in its ANDA.

H. 2007-2008: Merck sues first filer Glenmark; Glenmark counterclaims.

1. Early 2007: Merck sues Glenmark for infringing the RE'721 patent (only).

125. On or about February 9, 2007, Glenmark notified Merck of its ANDA filing and provided a detailed account of why the patents were invalid, unenforceable, or not infringed by Glenmark's ANDA product ("Glenmark's paragraph IV letter").

126. On March 22, 2007, Merck sued Glenmark in the District of New Jersey. Merck alleged that Glenmark's ANDA infringed the RE'721 patent. Merck did not sue Glenmark, in this suit or any other, for infringing the two other Orange Book listed patents (the '966 and the '106). Merck could not realistically expect to win a lawsuit asserting that Glenmark's generic ezetimibe product would infringe the '966 combination-with-statins azetidinone patent or the '106 sterol non- absorption patent because those patents were inapplicable, invalid, or not infringed. First, Glenmark could not infringe the '966 patent because Glenmark's product did not include a statin. Second, the '106 patent was, and is, invalid as obvious, as described above.

127. Under the Hatch-Waxman Act, Merck's filing of the RE'721 lawsuit—irrespective of its prospects of success—triggered a 30-month stay, running from the date Glenmark notified Merck of its paragraph IV certification. This stay prevented the FDA from granting final approval of Glenmark's ANDA until the earlier of (i) the expiration of the 30-month stay, or (ii) entry of a final judgment that the RE'721 patent was invalid, unenforceable, or not infringed.

128. Glenmark represented early on that "[t]he amount at issue in this case is at least $1 billion, representing the anticipated sales by Glenmark of its generic product (and the corresponding loss of sales by [Merck])."

2. Spring 2007: Glenmark counterclaims, alleging that the RE'721 patent is invalid and unenforceable.

129. On May 23, 2007, Glenmark answered; pleaded numerous affirmative defenses; and counterclaimed, seeking a declaratory judgment that the RE'721 patent was invalid and/or unenforceable. Glenmark asserted that the RE'721 patent was invalid for double patenting, anticipation, obviousness, a lack of enablement, and inventorship issues. Glenmark also asserted that the RE'721 patent was unenforceable due to inequitable conduct and that Merck was estopped or precluded from asserting infringement by reasons of actions taken and statements made to the PTO during its prosecution of the application(s) that led to the RE'721 patent. Glenmark refined these arguments as the litigation progressed, including adding in its March 10, 2008 first amended answer and counterclaims, a claim asserting that the 497-day patent term extension Merck received for the RE'721 patent was invalid.

130. *Invalid for inherent anticipation*. Glenmark argued that at least two compounds claimed in the RE'721 patent are inherent metabolites of a hypercholesterolemic compound (SCH48461) disclosed in an earlier Schering patent application. Merck had disclosed two compounds claimed in the RE'721 patent in an earlier patent application: International Application No. PCT/US92/05972, filed on July 21, 1992 and published on February 4, 1993 as WO 93/02048 (the "PCT'048 publication"). Upon ingestion, at least one of these earlier disclosed compounds, SCH48461 (disclosed as Example 9), is metabolized to form two hydroxyl-substituted compounds that are both claimed in the RE'721 patent. These metabolites inherently anticipate the claims of the RE'721 patent.

131. Indeed, after Merck settled its patent infringement suit with Glenmark, Merck acknowledged that RE'721 was inherently anticipated. On June 9, 2010, approximately one month after the settlement, Merck applied to the PTO for reissuance of the RE'721 patent. To

obtain reissue, the applicant must identify an error and attest, under oath, that the original patent is wholly or partly inoperative or invalid. Merck admitted that the RE'721 patent was invalid, citing inherent anticipation as the reason (as Glenmark argued in the infringement action).

132. In the required declaration accompanying its reissue application, Schering Corporation's legal director of patents, Mark Russell, attested to an error and conceded that Glenmark's inherent anticipation argument was correct:

- "I have reviewed and understand the content of the above identified specification, including the claims . . . ."
- "I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below . . . by reason of the patentee claiming more than he had the right to claim in the patent."
- "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."
- "I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed."

133. Further, in preliminary remarks, Merck's attorneys Carl A. Morales and James F. Haley, Jr. of Ropes and Gray LLP, attorneys/agents for reissue applicants, made similar statements about inherent anticipation and invalidity being the basis for seeking reissue and proposed amendments to the claims that ostensibly addressed these problems, namely cancelling claims 1- 2 and 4-6 and amending claims 3 and 7-9.

134. *Inequitable conduct for failure to disclose inherency*. Merck committed inequitable conduct during prosecution of the RE'721 patent by not disclosing the inherency of these metabolites to the PTO. Merck knew based on existing precedent that inherently anticipated metabolites are not patentable subject matter.

135. Indeed, Merck (through its predecessor Schering) itself had unsuccessfully litigated a same issue around time the time it was prosecuting the RE'721 patent. On August 8, 2002—a few days prior to instituting the reissue preceding before the PTO—the District of New Jersey in *Schering Corporation v. Geneva Pharmaceuticals, Inc.*, held that Schering's patent covering the drug Claritin was invalid due to inherent anticipation. There, the court found that the metabolite claimed by the patent was inherently anticipated because the "natural, inevitable production of [the metabolite] upon human ingestion of [Claritin] . . . demonstrates that this process is an 'inherent characteristic or functioning' of the use of [Claritin], the subject of the '233 patent." *Schering Corp. v. Geneva Pharms., Inc.*, 275 F. Supp. 2d 534, 542 (D.N.J. 2002). This ruling was affirmed a year later by the Federal Circuit in *Schering Corp. v. Geneva Pharms*., Inc., 339 F.3d 1373 (Fed. Cir. 2003).

136. As result of this precedent, Merck knew that if it disclosed the inherency of the metabolites to the patent examiner, the patent examiner would not grant the reissue patent. So rather than obey its duty of candor to the PTO, it simply omitted that fact during the prosecution of the reissue patent.

137. In support of its inherency argument, Glenmark also identified several publications demonstrating that Merck scientists understood that the metabolites described in RE'721 were inherently anticipated. Merck never disclosed these publications to the PTO during prosecution of the RE'721 patent. Glenmark argued that these publications would have been

material to the PTO when examining the RE'721 patent. That Merck withheld them, and the key information they contained, reflects deceptive intent.[19] These publications included:

- Margaret Van Heek et al., Abstract, *Isolation and Identification of the Active Metabolite(s) of SCH48461 and Possible in Vivo Mechanism of Action for their Inhibition of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Van Heek 1995 abstract");

- Harry R. Davis, Jr. et al., Abstract, *The Hypocholesterolemic Activity of the Potent Cholesterol Absorption Inhibitor SCH 58235 Alone and in Combination with HMG CoA Reductase Inhibitors*," Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Davis 1995 abstract");

- Stuart B. Rosenblum et al., Abstract, *Discovery of SCH 58235: A Potent Orally Active Inhibitor of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Rosenblum 1995 abstract");

- Margaret Van Heek et al., *In Vivo Metabolism-Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH58235, in the Rat and Rhesus Monkey through the Identification of the Active Metabolites of SCH 48461*, 283 J. Pharmacology & Experimental Therapeutics 157 (1997) (the "Van Heek 1997 publication");[20]

- Stuart B. Rosenblum et al., *Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption*, 41 J. Med. Chem. 973 (1998) (the "Rosenblum 1998 publication").[21]

138. *Inequitable conduct re patent term extension*. Glenmark argued that, by not disclosing that at least some claims were invalid due to inherent anticipation, Merck further committed inequitable conduct when seeking the RE'721 patent term extension. Merck sought to extend the term of the RE'721 patent claims after *Schering Corporation v. Geneva*

[19] Rather than repeat the details of Glenmark's discussion of these publications here, Plaintiff incorporates by reference ¶¶30-171 of Glenmark's First Amended Answer and Counterclaims (*Schering Corp. v. Glenmark Pharm., Inc., USA*, No. 07-cv-01334 (D.N.J. Mar. 10, 2008), ECF No. 54).

[20] Received for publication on February 13, 1997. Accepted for publication on June 30, 1997. Included in the October 1997 issue.

[21] Submitted October 16, 1997.

Pharmaceuticals Inc. was decided, knowing that claims it sought to extend were invalid under the doctrine of inherent anticipation.

139. *Invalidity for 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, which renders claims invalid for lack of enablement.

140. To be enabled, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. Articles published after a patent application's filing date can establish a lack of enablement.

141. *Failure to name inventors*. Glenmark argued that Merck may have failed to name all inventors, and took discovery on the issue. On May 10, 2006, the industry group Pharmaceutical Research and Manufacturers of America ("PhRMA") presented the Discoverers Award for contributions to the discovery of ezetimibe to three individuals: Harry R. Davis, Jr., Dr. Margaret Van Heek, and Kevin B. Alton. Merck had nominated all. None were listed as inventors on the RE'721 patent.

142. *Lack of proper reissue*. Glenmark argued that reissue was improper, and thus the reissued claims were invalid, for failure to identify an error in the '115 patent of the type that may be properly corrected through reissue.

143. *Invalidity for 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 issued (and earlier expiring) '365 patent. As a result, at least some claims of the RE'721 patent were alleged to be invalid for obviousness-type double patenting.

I. Spring 2009: Glenmark receives tentative approval, and Merck receives new regulatory exclusivities.

144. On April 24, 2009, the FDA gave tentative approval to Glenmark's ANDA for generic Zetia. This meant that the FDA considered Glenmark's ANDA fully approvable, but for the existence of the 30-month stay. Notably, Glenmark's receipt of tentative approval occurred within 30-months of filing its ANDA, thereby ensuring that Glenmark would not forfeit its first-filer 180-day exclusivity.

145. Also in 2009, Merck obtained pediatric exclusivities, the last of which expired on December 6, 2011.

J. Summer 2009: Glenmark seeks partial summary judgment on two discrete legal issues.

146. With a trial date in May 2010, in July 2009, Glenmark filed motions for partial summary judgment on two discrete legal issues as to which it did not believe there to be any disputed issues of facts.

147. *First,* Glenmark argued that the RE'721 patent was invalid for Merck's failure to identify an error of the type that may be properly corrected in reissue. Glenmark argued that the '115 patent was not, as issued, wholly or partly invalid and that therefore it could not be properly reissued under 35 U.S.C. § 251.[22]

148. *Second,* Glenmark argued that 12 of the 13 claims in the RE'721 patent were invalid by reason of obviousness-type double patenting, in light of Merck's earlier issued '365 patent.

149. On April 19, 2010, the Honorable Jose L. Linares of the U.S. District Court for the District of New Jersey issued opinions addressing each of Glenmark's motions for partial

[22] A subsequent Federal Circuit decision, *In re Tanaka*, 640 F.3d 1246, 1251-52 (Fed. Cir. 2011), effectively overturned this decision.

summary judgment. First, the court granted Glenmark's motion on invalidity, agreeing with Glenmark that reissuance of the '115 patent had been improper because Merck had failed to identify the kind of purported error that can be corrected in reissue. This functionally threw out claims 10-13, which claimed ezetimibe expressly and had been added in reissue. Merck moved for reconsideration of this order on April 30, 2010.

150. On the same day, the court denied Glenmark's second motion for partial summary judgment (obviousness double patenting), concluding that disputed issues of fact as to whether, at the time of the '365 patent, alternative processes for making the claimed azetidinone compounds existed. The court did not hold that there was no double patenting. Rather, the court simply concluded that the issue of double patenting should be resolved by the finder-of-fact at trial, based on a full evidentiary record.

K. Fall 2009: Merck obtains the second sterol absorption patent (the '058 patent).

151. On November 29, 2004, Schering filed Application No. 10/998,400 as a divisional of the '968 application, seeking another inhibition of sterol absorption patent.

152. On November 3, 2009, while the Glenmark summary judgment motions were pending, Merck's Application No. 10/998,400 issued as U.S. Patent No. 7,612,058, Merck's second sterol non-absorption patent.

153. The '058 patent is subject to a terminal disclaimer. According to Merck, it originally was set to expire on January 25, 2022 but, with its pediatric extension, will expire on July 25, 2022.

154. The '058 patent includes 10 claims. All cover methods of treating conditions associated with high cholesterol (*e.g.*, atherosclerosis, diabetes, obesity) comprising administering a pharmaceutical composition consisting of the same compound and routine

pharmaceutical additives described in the '106 patent (Formula II, ezetimibe). The '058 patent was at the time it was issued, and at all times thereafter, invalid for the same reasons as the '106 sterol non-absorption patent.

L. Summer 2010: Merck and Glenmark settle with a reverse payment.

1. Two days before trial, Merck and Glenmark agreed to settle by providing a payment for delay to Glenmark.

155. Trial was scheduled to begin on May 12, 2010. At issue were Glenmark's affirmative defenses and counterclaims, including its assertion that claims 1 through 9 were unenforceable because of Merck's intentional failure to disclose to the PTO either (1) compounds claimed in the RE'721 were naturally occurring metabolites of SCH46481 (and therefore inherently anticipated by earlier disclosures), or (2) the disqualifying prior art publications by Merck's own scientists that had been hidden from the PTO.

156. On May 10, 2010, two days before the scheduled start of trial, Merck and Glenmark entered into an agreement that settled the patent infringement lawsuit but, as later events would show, also unlawfully allocated the market for ezetimibe.

157. Merck and Glenmark agreed to entry of a consent judgment. In order to ensure there were no adverse rulings concerning the RE'721 patent as a result of the litigation, a condition of the settlement included that the parties seek to have the court vacate its partial summary judgment invalidating claims 10-13 for improper reissue. The parties gave the court a proposed order, along with the consent judgment vacating the partial summary judgment order on claims 10-13.

158. The proceedings on entry of the consent judgment revealed that the parties had agreed that, subject to certain unpublished caveats, Glenmark would not enter the market with its generic Zetia product until December 12, 2016.

159. Although the consent judgment made reference to the settlement agreement, the settlement was not docketed. The parties did not publicly reveal any of the remaining terms of that agreement at the time of the settlement nor have the other terms of that agreement ever been made public.

160. Nevertheless, subsequent events revealed certain aspects of the agreement. Upon information and belief, as a quid pro quo for Glenmark's agreement to drop its patent challenge and delay market entry for over five years, Merck promised not to launch a competing authorized generic version of Zetia during Glenmark's eventual 180-day exclusivity period (the "no-AG agreement"). The existence of a no-AG agreement is evidenced by the following facts:

- Merck previously admitted that marketing an authorized generic is often in its economic interest. For example, speaking about another blockbuster drug, Fosamax, a Merck executive acknowledged that Merck's "authorized generic strategy" will "maximize the value of the franchise" after entry by generic competitors.[23]

- Merck had a well-established history of launching authorized generics in the face of generic competition. Other branded drugs for which Merck or Schering has launched authorized generic versions include Blocadren, Clinoril, Cozaar, Diprolene, Lotrisone, Nasonex, Singulair (Oral Granules), Temodar, K-Dur 10, K-Dur 20, and Lotrimin AF.

- Zetia was a blockbuster drug, with sales in the billions at the time that a generic eventually launched in 2016. Absent Glenmark's reciprocal agreement to delay entering the market, launching an authorized generic would have been in Merck's financial interest.

- When Glenmark launched its generic on December 12, 2016, it issued a press release describing its generic Zetia as "the first and *only* generic version" of Zetia in the United States, which made it clear that it knew that Merck was not launching its own authorized generic.

- When Glenmark eventually launched generic Zetia in late 2016, Merck did not launch an authorized generic during Glenmark's 180-day ANDA-exclusivity period. The absence of an authorized generic in late 2016 and the first half of 2017 is perhaps the strongest evidence that Merck had made a contractual

[23] Merck & Co., Inc., 4Q 2007 Earnings Conference Call (Jan. 30, 2008).

agreement with Glenmark not to launch such a product because during this time period Merck stood to earn hundreds of millions of dollars from an AG launch.

- Glenmark reported to its shareholders in May 2017 that it had expected before launching the product that it would take well more than 58% of the combined brand and generic Zetia sales. Such a statement to investors would be misleading if had not secured a no-AG pact from Merck because, if Merck launched an authorized generic, Glenmark could realistically only expect to take a 40% of sales during its exclusivity period (one half of the standard 80% erosion rate).

161. Given Merck and Glenmark's decision to conceal the terms of their unlawful agreement, the absence of an AG launch for generic Zetia could be publically learned only at the time that Merck failed to undertake such a launch—late December 2016 and the first six months of 2017. Short of some disclosure of the confidential settlement agreement, existence of the no-AG agreement could not have been known until Glenmark launched its generic in 2016 and Merck failed to launch an AG product.

162. The no-AG agreement was a payment to Glenmark from Merck worth substantially more than Glenmark could have earned if it had come to market with generic Zetia in 2011. Glenmark could not have obtained a no-AG agreement even had it won the patent infringement litigation. By delaying generic entry for more than five years, and thereby obtaining the no-AG agreement from Merck, Glenmark was ensured six months of exclusive generic sales, free from competition from Merck's authorized generic or any other generic competitors.

163. For Merck, the benefits of the no-AG agreement were enormous. While it would forgo six months of profits on an authorized generic, in turn it would enjoy more than five years of monopoly profits selling much more expensive and profitable branded Zetia.

164. Absent the pay-for-delay agreement, generic entry would have occurred much sooner than it did, and as early as December 6, 2011, when all applicable pediatric exclusivities expired. At that time, other than the RE'721 patent, no other impediments existed to the prompt approval and launch of generic Zetia.

165. *First*, Glenmark's ANDA had already received FDA tentative approval. In effect, Glenmark had met all preconditions for FDA final approval other than the pendency of the 30-month stay.

166. *Second*, no other patents held by Merck would have prevented generic entry. The '966 patent had claims only to combination products, but generic Zetia is not a combination product, and Merck never enforced the '966 patent against Glenmark. The '106 and '058 sterol non- absorption patents were obvious in light of the RE'721 disclosures, and Merck never enforced those patents against Glenmark. The '365 patent was limited to the narrow processes set out in that patent, and Merck never enforced the '365 patent against Glenmark.

167. *Third*, no other exclusivity existed after December 5, 2011. The NCE exclusivity expired in 2007. Two other exclusivities—an indication exclusivity and a pediatric exclusivity—had expired by December 5, 2011.

168. Absent of the pay-for-delay agreement, Glenmark's earlier generic entry would have been possible under the following two scenarios: (1) an alternative settlement that would have permitted earlier entry, but without the unlawful payment; and (2) Glenmark's entry following success at trial during the patent litigation.

169. ***Alternative settlement without an unlawful payment to delay***. Absent the pay-for-delay agreement, reasonable, economically rational companies in the position of Glenmark and Merck may still have settled the litigation with an earlier agreed-to entry date but without the payment for delay. That agreed-to entry date would have been based on weakness of Merck's RE'721 infringement claims. As a result, an arms' length settlement between economically rational, law-abiding companies would have led to an agreed-to entry date occurring much

sooner than it did, and as early as the expiration of Merck's lawful exclusivities, *i.e.,* December 6, 2011.

170. ***Launch after success at trial.*** In the alternative, absent the pay-for-delay agreement, Glenmark would have won the trial scheduled to start in May 2010. A finder of fact would have concluded that (for the reasons described above) Merck failed to prove that Glenmark infringed a valid patent for one or more of the following reasons:

- Merck (through the inventors, agents, and others with a Rule 56 duty) committed inequitable conduct by intentionally and deceptively hiding the fact that the RE'721 claimed compounds that were naturally occurring metabolites of SCH 48461 (and therefore inherently anticipated by its earlier disclosure in PCT'048), which would render the entire RE'721 patent invalid or unenforceable);
- Regardless of whether Merck committed inequitable conduct, the claims of the RE'721 patent were invalid for inherent anticipation; and
- The RE'721 patent was invalid for obviousness-type double patenting over the '365 patent.

171. A reasonable, economically rational company in Glenmark's position would have launched generic Zetia soon after a district court ruling in its favor and after the expiration of any other, lawful exclusivity.

172. Without the large and unjustified payment, several additional generics would have come to market after Glenmark's 180-day exclusivity ended—as early as June 6, 2011, and in any event much earlier than June 12, 2017. Merck's last applicable regulatory exclusivity ran on December 6, 2011. By then, Glenmark would have resolved the RE'721 infringement claims by either winning at trial or settling on competitive terms (without a payment).

2. The value of the no-AG agreement to Merck.

173. After generic entry in December 2011, Merck would have lost at least 80% of its branded sales during the Glemark's 180-day exclusivity period. But without generic entry, Merck kept all those sales—and continued to enjoy those branded sales until the end of 2016.

174. Because Glenmark was the first ANDA filer, its agreement not to launch generic Zetia until December 2016 created a competition bottleneck wherein no other generic company could market a generic Zetia product until 180 days after Glenmark launched its generic product. In establishing a bottleneck using Glenmark, Merck maximized the potential for it to maintain its monopoly on Zetia for about five years longer than it otherwise would have.

175. Determining the value to Merck of the no-AG promise is a matter of estimating the additional branded sales it enjoyed during that five-year delay compared to the sales it would have made (a) from the reduced sales of branded Zetia, plus (b) the sales of its authorized generic during the first six months of generic competition starting in December 2011.

176. Sales of branded Zetia in 2011 totaled $1.298 billion. Based on well documented patterns of sales and pricing related to generic entry, Merck's authorized generic and Glenmark's generic, combined, would have captured at least 80% of the amount of branded sales in the first six months, with each of those companies splitting the generic sales 50/50 (therefore, 40% each of the brand share). Those generics would have sold at 50% of the price of the brand. Using these assumptions, the value of the authorized generic sales by Merck in the first six months following generic entry in December 2011 would have been about $129.8 million ($1.298 billion times 0.5 [for the first six months] times 0.4 [share of the generic sales] time 0.5 [generic price].[24]

177. Even with generic entry, Merck could still expect to sell some branded product—about 10% (or less) of its previous volume per year. So the revenues to Merck in the event of timely generic entry in, say, late December 2011, over the five-year time period reasonably would have been expected to be about $778.8 million ($1.298 billion baseline times 0.1 [for annual branded sales] times 5 [for five years] plus $129.8 [for AG sales in the first six months]).

[24] $1,298,000,000 × 0.50 (1/2 year) × 0.80 (generic penetration) × 0.50 (generic price) × 0.50 (split sales volume with Glenmark) = $129,891,200.

178. As a result of the no-AG agreement, however, Merck enjoyed full branded sales from December 2011 through December 2016 without competition from Glenmark's generic (or any other generic manufacturer). If one expected no growth in sales, then Merck would have about $6.490 billion in gross sales for Zetia over that five-year period (or about $5.7 billion more than it would receive under competitive conditions). Publically available information indicates that total sales for branded Zetia during this entire time period actually mounted to more than $9.1 billion (or about $8.3 billion more than it would receive under competitive conditions).

179. As a result of the no-AG agreement, Merck enjoyed between about $5.7 billion to about $8.3 billion in additional sales of branded Zetia, all at a cost of about $129.8 million in lost authorized generic sales during the first six months of generic entry.

3. The value of the no-AG promise to Glenmark.[25]

180. The value of the no-AG agreement from Glenmark's perspective is a matter of estimating the additional sales it made during its six month generic exclusivity period in 2016 compared to the sales it would have made in the first six months of generic competition starting in December 2011 when, without the benefit of the no-AG agreement, it would have faced competition from Merck's authorized generic.

181. Under competitive conditions, the calculation of Glenmark's sales during the first six months of generic competition starting in December 2011 is identical to the calculation for Merck's authorized generic during this period, because the same assumptions apply to

[25] Prior to the trial, on May 3, 2010, Glenmark entered into an exclusive licensing agreement with Par Pharmaceutical Companies (now a subsidiary of Endo International plc). Under the exclusive license Par paid Glenmark for the exclusive rights to market, sell and distribute ezetimibe in the United States, with the companies sharing the profits from the sales of Glenmark's generic product. *See* https://www.streetinsider.com/Corporate+News/Par+Pharma+%28PRX%29+and+Glenmark+Generics+Sign+Licensing+Agreement+for+Generic+Zetia/5586601.html. While the exact terms of the profit sharing agreement are not public, the presence of this profit sharing agreement does not negate the fact that Merck's no-AG promise was worth tens, if not hundreds, of millions of dollars to Glenmark.

Glenmark's generic as to Merck's. Thus the value of generic sales by Glenmark in 2011, facing competition from Merck's authorized generic, would have been approximately $129.8 million.

182. Under the anticompetitive conditions of the no-AG promise, however, Glenmark stood in a far better position financially. Glenmark would now (a) get 100% (not 50%) of the generic sales in the first six months of generic launch (because there was no authorized generic taking market share); (b) be able to sell that generic during those months for about 90% (not 50%) of the branded price (because there was no authorized generic driving down price); and (c) be able to have its generic product enter a market that had grown in size over the five-year delay period. Indeed, by 2016 annual sales of branded Zetia had grown to $2.6 billion.

183. Without competition from Merck's authorized generic, Glenmark's generic Zetia could expect to capture at least 80% of the sales of the branded product in 2016, and likely would have priced its generic product at about 90% of the brand's price. As a result, during its six-month exclusivity period in 2016, without competition from Merck's authorized generic, Glenmark's generic Zetia realized about $936 million in generic sales ($2.6 billion times 0.5 [1/2 year] times 0.8 [generic penetration] times 0.9 [generic price]).

184. Thus, the agreement with Merck to delay the launch of Glenmark's 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 benefit of the no-AG agreement ($936 million less $129.8 million). The no-AG payment from Merck to Glenmark made delayed generic entry quite lucrative for Glenmark.

185. Even if the parties did not foresee the meteoric rise in the sales of the branded product between 2011 and 2016, the no-AG promise was still a lucrative one for Glenmark from a 2011 perspective. If one assumes that the sales of branded Zetia remained flat at 2010 levels

(when the parties entered into their pay-for-delay agreement agreement) until Glenmark entered with its generic in 2016, the no-AG promise was still worth an additional $225 million to Glenmark over what it would have made launching its generic in December 2011.[26] Whether or not one assumes that the sales of branded Zetia would have remained flat at 2010 levels, the no-AG pact unlawfully delivered to Glenmark more than it could have obtained *even if it had won* the patent infringement litigation.

M. 2016: Glenmark launches a generic form of Zetia; Merck does not.

186. Glenmark's ANDA 78-560 received final FDA approval on June 26, 2015. In its final approval letter, the FDA reconfirmed that Glenmark was entitled to 180-days of market exclusivity upon launch.

187. On December 12, 2016, Glenmark launched its generic Zetia, which its press release of that date described as "the first and only generic version" of Zetia in the United States. Glenmark launched its generic product in partnership with Par Pharmaceuticals, an operating company of Endo International plc.

188. From December 12, 2016, through June 12, 2017, Glenmark's product was the only generic version of Zetia sold in the U.S. market.

189. Pursuant to the no-AG pact in the parties' unlawful agreement, Merck refrained from launching an authorized generic version of Zetia during Glenmark's 180-day exclusivity period. Merck also did not launch an authorized generic at the end of Glenmark's 180-day exclusivity in June 2017. This is likely because, once the exclusivity period ended, other generics flooded the market, thus driving the price for generic Zetia down significantly and leaving little margin left for Merck. This is in stark contrast to the price during Glenmark's exclusivity period

[26] $985,823,000 (2010 brand sales) × 0.5 (six months) × 0.8 (generic penetration) × 0.9 (generic price) = $354,896,280 - $129,891,200 = $225,005,080.

when a Merck authorized generic would have been one of only two generics on the market, taking at least half the sales at margins that would have yielded more than a hundred million dollars in profits.

N. 2017: 180 days later, five more generics launch.

190. On or about June 12, 2017—the day Glenmark's period of exclusivity expired—the FDA approved ANDAs for generic Zetia previously filed by seven competitor companies: 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).

191. 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 had sold its generic drug business to Teva before June 2017 and so did not launch a generic Zetia product.)

192. An eighth ANDA, filed by Aurobindo (ANDA 209838), was approved in August 2017 and launched the same month. A ninth ANDA, filed by Alkem Laboratories (ANDA 209234), was approved in December 2017.

193. Whereas only brand-name Zetia tablets were available to purchasers and consumers before December 2016, and only brand-name Zetia and Glenmark's generic tablets were available from December 2016 to June 2017, by July of 2017 there were six generics available to purchasers and consumers in addition to brand tablets, and by September of 2017 there were eight generics in addition to brand tablets.

194. This newly robust competition had the expected profound effect on prices: 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—a 90% decrease.

195. Absent the no-AG promise, Merck would have launched an authorized generic during Glenmark's 180-day exclusivity period, taking approximately 50% of Glenmark's generic sales and substantially lowering the price that drug purchasers paid for generic Zetia. Absent the no-AG promise, Glenmark would not have agreed to delay its launch until December 12, 2016 and instead would have entered the market much sooner than it did, as early as December 6, 2011. Additional generics would have entered the market six months later and further driven down prices.

196. The settlement with Glenmark enabled Merck to continue to receive monopoly profits until December 12, 2016 and enabled Glenmark to control the generic market for 180 days thereafter, with Glenmark sharing in the monopoly profits that the reciprocal non-competition pact made possible. The pay-for-delay agreement not only delayed Glenmark's own entry into the market, it also created a bottleneck that blocked all other would-be generic Zetia competitors by postponing the start (and thus also the conclusion) of Glenmark's 180-day first filer exclusivity period.

197. The Merck-Glenmark agreement was collusive and intended to maintain a monopoly and allocate the market.

O. The no-AG promise was a large payment.

198. The no-AG payment to Glenmark was large, estimated to be worth more than $800 million. It far exceeded any estimate of the litigation expenses Merck saved by settling the patent case with Glenmark which might have ranged from $3.7 million to $6.3 million.[27]

199. The value of the pay-for-delay agreement to Merck, estimated to be almost $9 billion, was far greater even than the value it conferred to Glenmark in the form of the no-AG agreement because the years-long delay in generic entry protected Merck's monopoly sales volume and pricing over that time.

200. Merck's payment to Glenmark guaranteed two distinct periods of non-competition: (a) the period before generic competition, during which Merck and Glenmark allocated 100% of the market to Merck; and (b) the 180-day exclusivity period after Glenmark's entry, during which Merck and Glenmark allocated 100% of generic sales to Glenmark. So drug purchasers were overcharged twice: before Glenmark's entry, they were forced to pay overcharges for branded Zetia; and during Glenmark's exclusivity period were forced to pay additional overcharges for branded Zetia and generic Zetia. And the unlawful agreement had the additional anticompetitive effect of delaying the entry of all of the other generic competitors.

201. Defendants have no procompetitive explanation or justification for the pay-for-delay agreement.

202. But for the pay-for-delay agreement between Merck and Glenmark, Glenmark could and would have entered the market much sooner than it did—and as early as December 6, 2011—with immediate competition from a Merck authorized generic and with full competition from other generics by approximately May 2012. Instead, Glenmark did not release its generic

[27] *AIPLA 2015 Report of the Economic Survey*, IPICS, http://www.patentinsuranceonline.com/wp-content/uploads/2016/02/AIPLA-2015-Report-of-the-Economic-Survey.pdf (last visited Jan. 25, 2018).

until December 12, 2016, without competition from Merck. Generic entry by other manufacturers would not occur until June 12, 2017.

VI. EFFECTS OF THE SCHEME ON COMPETITION AND INJURY TO PLAINTIFF AND MEMBERS OF THE CLASSES

203. Merck's U.S. sales of Zetia were approximately $1.3 billion in 2010, $1.4 billion in 2012, $1.5 billion in 2014, and $2.6 billion in 2016. These amounts represent billions of dollars more in sales than Merck would have achieved absent Defendants' unlawful scheme to impair generic competition. Generic Zetia products would have been priced at a fraction of the cost of brand Zetia and would have quickly captured the vast majority of the market for ezetimibe.

204. Merck's and Glenmark's unlawful agreement impaired and delayed the sale of generic Zetia in the United States, and unlawfully enabled Merck to sell its branded Zetia at artificially inflated prices, and then allowed Glenmark to sell is generic Zetia at artificially inflated prices. But for Merck's unlawful conduct, generic competitors would have been able to compete, unimpeded, with their own generic versions of Zetia at a much earlier date.

205. Were it not for Defendants' anticompetitive conduct, Plaintiff and members of the Classes would have: (1) purchased lower-priced generic Zetia, instead of the higher-priced brand Zetia, during the period when Glenmark delayed its entry to the market; (2) paid a lower price for generic Zetia products during Glenmark's 180-day exclusivity period; and (3) paid lower prices for generic Zetia products, as a result of the entry of generics at an earlier date, sooner.

206. As a consequence, Plaintiff and members of the Classes have 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.

VII. MARKET POWER AND MARKET DEFINITION

207. At all relevant times, Merck had substantial market power and/or monopoly power in the market for branded and generic versions of Zetia because Merck had the power to maintain the price of Zetia at supracompetitive levels without losing substantial sales to other cholesterol-lowering products.

208. A small but significant, non-transitory price increase for Zetia by Merck would not have caused a significant loss of sales to other cholesterol-lowering medications sufficient to make such a price increase unprofitable.

209. Zetia did not exhibit significant, positive cross-elasticity of demand with respect to price, with any cholesterol-lowering product other than AB-rated generic versions of Zetia.

210. Zetia is not reasonably interchangeable with any products other than AB-rated generic versions of Zetia.

211. The existence of non-Zetia cholesterol-lowering medications did not constrain Merck's ability to raise or maintain Zetia prices without losing substantial sales, and therefore those other drug products are not in the same relevant antitrust market with Zetia. Therapeutic alternatives are not the same as economic alternatives.

212. Functional similarities between Zetia and non-Zetia cholesterol-lowering products are insufficient to permit inclusion of those other cholesterol-lowering products in the relevant market with Zetia. To be an economic substitute for antitrust purposes, a functionally similar product must exert sufficient pressure on the prices and sales of another product, so that the price of that other product cannot be maintained at supracompetitive levels. No other cholesterol-lowering products apart from AB-rated generic versions of Zetia could have taken away sufficient sales from Zetia to prevent Merck from raising or maintaining the price of Zetia at supracompetitive levels.

213. Zetia is also not reasonably interchangeable with any products other than AB-rated generic versions of Zetia because both Zetia and its AB-rated generic equivalents have different attributes significantly differentiating them from other cholesterol-lowering products and making them unique. Zetia and its AB-rated generic equivalents are distinct from other cholesterol-lowering products, such as statins. Further, the FDA does not consider Zetia and its AB-rated generic equivalents interchangeable with other cholesterol-lowering products.

214. Price does not typically drive prescriptions for medications, including those for cholesterol-lowering products. The pharmaceutical marketplace is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including ezetimibe, to patients without a prescription written by a doctor. Patients and third-party payors have the obligation to pay for the pharmaceutical product, but it is ultimately the patients' doctors who choose which product the patient will buy.

215. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals. Moreover, even when they are aware of the costs, they are insensitive to prices because they do not pay for the products. The result is a marketplace in which price plays a comparatively smaller role in product selection.

216. Thus, unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the initial purchasing decision for prescription drugs, such as cholesterol-lowering products, is generally made by the physician, not by consumers of those products. Consequently, despite the existence of a number of different cholesterol-lowering products a physician could have started a patient on, or in theory could switch a patient to, once

the physician and patient find one that is effective and well-tolerated, it is unlikely that the patient will switch to a different cholesterol-lowering product based on variations of price.

217. Doctors generally select cholesterol-lowering products based on the clinical and pharmacological attributes of the drug and the relevant characteristics of the patient, rather than on the basis of price. For clinical reasons, among others, physicians and patients prefer Zetia to other cholesterol-lowering products.

218. The existence of other products designed to lower cholesterol has not significantly constrained Merck's pricing of Zetia.

219. Merck needed to control only Zetia and its AB-rated generic equivalents, and no other products, in order to profitably maintain supracompetitive prices for Zetia. Only the market entry of competing, AB-rated generic versions of Zetia would have rendered Merck unable to profitably maintain its prices of Zetia without losing substantial sales.

220. At all relevant times, Merck has sold Zetia at prices well in excess of the competitive price.

221. At all relevant times, Merck had, and exercised, the power to exclude and restrict competition in the market for branded and generic versions of Zetia.

222. At all relevant times, there were high barriers to entry with respect to competition in the market for branded and generic versions of Zetia in the form of patent and other regulatory protections, as well as high startup costs.

223. To the extent that Plaintiff may be required to prove market power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is the market for branded and generic versions of Zetia. During the relevant time, Merck has been able to profitably maintain the price of Zetia well above competitive levels.

224. Merck's market share in the market for branded and generic versions of Zetia, prior to generic entry, was 100%. Even upon generic entry, as one of only two competitors, during Glenmark's 180-day exclusivity period, Merck maintained substantial shares of the market for branded and generic versions of Zetia.

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

VIII. ANTITRUST IMPACT, MARKET EFFECTS, AND EFFECTS ON INTERSTATE AND INTRASTATE COMMERCE

226. Defendants' anticompetitive scheme had the purpose and effect of unreasonably restraining and injuring competition by protecting Zetia from generic competition. But for the pay-for-delay agreement, Glenmark would have entered the market upon earlier than December 2016.

227. But for Defendants' illegal conduct, generic competition would have forced decreases in the prices of Zetia, as price competition among the suppliers of branded and generic versions of Zetia would have been intense.

228. But for Defendants' illegal conduct, Plaintiff and members of the Classes would have paid less for branded and generic versions of Zetia. Defendants' conduct proximately caused Plaintiff's and the Classes' injuries because it forced them to pay hundreds of millions of dollars in overcharges on purchases of branded and generic versions of Zetia.

229. As a result of the delay in generic competition brought about by Defendants' anticompetitive scheme, Plaintiff and members of the Classes paid more for branded and generic Zetia than they would have paid absent Defendants' illegal conduct.

230. Upon entering the market, generic equivalents of brand name drugs are priced below the branded drug to which they are AB-rated. When multiple generic products are on the

market, prices for the brand drug and its generic equivalents fall even further because of the increased competition.

231. If generic competition for branded Zetia had not been unlawfully delayed, Plaintiff and members of the Classes would have paid less for both branded and generic versions Zetia by: (a) substituting their purchases of Zetia with less-expensive generic versions of Zetia; (b) purchasing generic Zetia at lower prices sooner; and (c) purchasing branded Zetia at a reduced price.

232. Defendants' efforts to restrain competition in the market for branded and generic versions of Zetia have substantially affected both interstate and intrastate commerce.

233. At all material times, Merck manufactured, promoted, distributed, and sold substantial amounts of branded Zetia in a continuous and uninterrupted flow of commerce across state lines and throughout the United States. Defendants' anticompetitive conduct had substantial intrastate effects in every state of purchase in that, among other things, retailers within each state were foreclosed from offering cheaper generic versions of Zetia to purchasers within each state, which directly impacted and disrupted commerce for consumers and third-party payors within each state.

234. At all material times, Defendants transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state lines in connection with the sale of branded and generic versions of Zetia.

235. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. Professor Herbert Hovenkamp explains that "[e]very person at every stage in the chain will be poorer" as a result of the

anticompetitive price at the top.[28] He also says that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."[29]

236. The institutional structure of pricing and regulation in the pharmaceutical drug industry ensures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of branded and generic versions of Zetia to Plaintiff and members of the Classes.

237. Defendants' pay-for-delay agreement enabled Merck to charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent the Defendants' unlawful actions.

238. These prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

IX. CLASS ACTION ALLEGATIONS

239. Plaintiff brings this action on behalf of itself and all others similarly situated as a class action under Rules 23(a) and 23(b)(2) of the Federal Rules of Civil Procedure, seeking equitable and injunctive relief on behalf of the following class (the "Injunctive Class"):

> All persons or entities in the United States and its territories that indirectly purchased, paid for, and/or provided reimbursement for some or all of the purchase price for brand Zetia or its AB-rated generic equivalents from Defendants, beginning at least as early as December 6, 2011 until the effects of Defendants' conduct cease (the "Class Period").

240. The following persons and entities are excluded from each of the above-described proposed Injunctive Class:

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[28] *See* Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice*, at 564 (1994).

[29] *Id.*

(a) Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

(b) All governmental entities, except for government-funded employee benefit 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 (plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members);

(e) Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs);

(f) Pharmacy Benefit Managers;

(g) All Counsel of Record; and

(h) The Court, Court personnel and any member of their immediate families.

241. Plaintiff also brings this action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages on behalf of the following class (the "Damages Class"):

> All persons and entities in the Indirect purchaser States that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of Zetia or its AB-rated generic equivalents from Defendants, beginning at least as early as December 6, 2011 until the effects of Defendants' conduct cease ("Class Period"), in the District of Columbia, Puerto Rico, or any of the following states and commonwealths: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island,

South Carolina, South Dakota, Texas, Tennessee, Utah, Vermont, West Virginia, Wisconsin, or Wyoming.

242. The following persons and entities are excluded from each of the above-described proposed Damages Class:

(a) Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

(b) All governmental entities, except for government-funded employee benefit 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 (plans that purchased insurance from another third-party payor covering 100 percent of the plan's reimbursement obligations to its members);

(e) Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs);

(f) Pharmacy Benefit Managers;

(g) All Counsel of Record; and

(h) The Court, Court personnel and any member of their immediate families.

243. The Injunctive Class and the Damages Class are referred to as the "Classes."

244. Members of the Classes are so numerous and geographically dispersed that joinder of all members of the Classes is impracticable. Plaintiff believes that there are thousands of members of both Classes widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The Classes are readily identifiable from information and records in Defendants' possession.

245. Plaintiff's claims are typical of the claims of members of the Classes. Plaintiff and members of the Classes were harmed by the same wrongful conduct by Defendants in that they paid artificially inflated prices for branded and generic Zetia and were deprived of the benefits of earlier and more robust competition from cheaper generic equivalents of Zetia as a result of Defendants' wrongful conduct.

246. Plaintiff will fairly and adequately protect and represent the interests of the members of the Classes. Plaintiff's interests are coincident with, and not antagonistic to, those of the members of the Classes.

247. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation and with experience in class action antitrust litigation involving pharmaceutical products.

248. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual members of the Classes because Defendants have acted on grounds generally applicable to the entire class, making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

249. Questions of law and fact common to the class include:

(a) Whether Defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

(b) To the extent such justifications exist, whether there were less restrictive means of achieving them;

(c) Whether direct proof of Defendants' monopoly power is available and, if so, whether it is sufficient to prove Defendants' monopoly power without the need to define the relevant market;

(d) Whether Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

(e) Whether Defendants' unlawful agreement, in whole or in part, caused antitrust injury through overcharges to the business or property of Plaintiff and the members of the Classes;

(f) Whether Merck and Glenmark conspired to delay generic competition for Zetia;

(g) Whether, pursuant to the pay-for-delay agreement, Merck's promise not to compete against Glenmark's generic product constituted a payment;

(h) Whether Merck's agreement with Glenmark was necessary to yield some cognizable, non-pretextual procompetitive benefit;

(i) Whether Merck's compensation to Glenmark was large and unexplained;

(j) Whether the pay-for-delay agreement a bottleneck to further delay generic competition for Glenmark;

(k) Whether the pay-for-delay agreement harmed competition;

(l) Whether, before December 12, 2016, Merck possessed the ability to control prices and/or exclude competition for Zetia;

(m) Whether, from December 12, 2016 through June 12, 2017, Merck and Glenmark possessed the ability to control prices and/or exclude competition for Zetia;

(n) Whether Defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB- rated generic Zetia;

(o) Determination of a reasonable estimate of the amount of delay Defendants' unlawful monopolistic conduct caused;

(p) The quantum of overcharges paid by the Damages Class in the aggregate; and

(q) The scope and nature of the equitable relief for the Injunctive Class.

250. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

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

X. PLAINTIFF'S AND THE CLASSES' CLAIMS ARE TIMELY

A. Defendants Have Engaged in a Continuing Violation

252. A cause of action accrued for Plaintiff and Damages Class Members each time Defendants sold a product to Plaintiff and Damages Class Members at a supra-competitive price made possible by their anticompetitive conduct. And each sale by Defendants of a product at a supra-competitive constituted another overt act in furtherance of their anticompetitive scheme. Accordingly, Plaintiff and the Damages Class Members are entitled to recover all damages on all

sales that Defendants made to Plaintiff and Damages Class Members at supra-competitive prices within four years of the filing of this lawsuit.

B. Defendants' Fraudulent Concealment of Wrongdoing Tolled the Statutes of Limitations for Plaintiff and Damages Class Members

253. Due to Defendants' concealment of their unlawful conduct, however, Plaintiff and the Damages Class Members are entitled to recover damages reaching back even beyond four years of the filing of this complaint. Merck's payment to delay Glenmark's generic launch was not discoverable until after Glenmark launched its generic ezetimibe in December 2016. At that time, Merck did not launch an authorized generic then or at any time during Glenmark's 180-day exclusivity period.

254. At the time of the settlement, Merck and Glenmark had disclosed only cursory information about the terms of the settlement. Plaintiff and the Damages Class Members had no knowledge of Defendants' unlawful scheme suppress competition in the market for brand and generic Zetia and could not have discovered it through the exercise of reasonable diligence more than four years before the filing of this complaint.

255. Defendants wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from Plaintiff and the Damages Class Members by, among other things:

(a) Concealing the fact of Merck's agreement not to launch a competing authorized generic Zetia product in exchange for Glenmark's agreement not to market its competing generic product until December 12, 2016;

(b) Concealing the fact that the purpose of the no-AG agreement was to provide compensation to Glenmark in connection with the settlement of the patent litigation and the December 2016 entry date for Glenmark's generic product; and

(c) Filing documents with the United States Securities and Exchange Commission that failed to disclose the existence or nature of the payments made.

256. Because the scheme and conspiracy was concealed by Defendants, Plaintiff and the Damages Class Members had no knowledge of the scheme and conspiracy more than four years before the filing of this complaint; nor did they have the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.

257. Plaintiff and the Damages Class Members also lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred. Reasonable diligence on the part of the Plaintiff and the Damages Class Members would not have uncovered those facts more than four years before the filing of this complaint.

258. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiff's and the Damages Class Members' claims have been tolled.

XI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Violation of Section 1 of the Sherman Act, 15 U.S.C. § 1
(on behalf of Plaintiff and the Injunctive Class against Defendants)

259. Plaintiff incorporates the preceding paragraphs by reference.

260. Defendants knowingly, intentionally, and cooperatively engaged in a contract, combination, or conspiracy in unreasonable restraint of trade, in violation of Section 1 of the Sherman Act. Specifically, Merck and Glenmark violated 15 U.S.C. § 1 by entering into an unlawful pay for delay agreement that restrained competition in the market for Zetia and its AB-rated generic equivalents.

261. On or about May 10, 2010, Merck and Glenmark entered into a pay-for-delay agreement, a continuing illegal contract, combination, and restraint of trade under which Merck

paid Glenmark substantial consideration in exchange for Glenmark's agreement to delay bringing its generic version of Zetia to the market, the purpose and effect of which were to:

(a) delay generic entry of Zetia in order to lengthen the period in which Merck's brand Zetia could monopolize the market and make supra-competitive profits;

(b) keep an authorized generic off the market during Glenmark's 180-day generic exclusivity period, thereby allowing Glenmark to monopolize the generic market for Zetia during that period and allowing Glenmark to make supra-competitive profits;

(c) allocate 100% of U.S. generic Zetia sales to Glenmark during the first 180 days of generic sales; and

(d) raise and maintain the prices that Plaintiff and the Injunctive Class Members would pay for Zetia at supra-competitive levels until at least June 12, 2017.

262. Defendants' illegal conduct constitutes a *per se* violation of the Sherman Act.

263. In the alternative, Merck and Glenmark are also liable for this pay-for-delay agreement under a "rule of reason" standard under the antitrust laws because there is no legitimate, non-pretextual, pro-competitive business justification for this pay-for-delay agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

264. As a result of Defendants' conduct, Plaintiff and the Injunctive Class Members have been harmed by having to pay higher prices for Zetia and its AB-rated generic equivalents than they would have paid in the absence Defendants' anticompetitive conduct.

265. Plaintiff and the Injunctive Class Members seek equitable and injunctive relief, including disgorgement of profits, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and

other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and other relief to ensure that the same or similar anticompetitive conduct does not reoccur in the future.

SECOND CLAIM FOR RELIEF
Conspiracy and Combination in Restraint of Trade under State Law
(against All Defendants on Behalf of the Damages Class)

266. Plaintiff incorporates the preceding paragraphs by reference.

267. Defendants entered into an unlawful pay-for-delay agreement that restrained competition in the market for Zetia and its AB-rated generic equivalents. Their agreement is and was a contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

(a) delay generic entry of Zetia in order to lengthen the period in which Merck's brand Zetia could monopolize the market and make supra-competitive profits;

(b) keep an authorized generic off the market during Glenmark's 180-day generic exclusivity period, thereby allowing Glenmark to monopolize the generic market for Zetia during that period and allowing Glenmark to make supra-competitive profits;

(c) allocate 100% of U.S. generic Zetia sales to Glenmark during the first 180 days of generic sales; and

(d) raise and maintain the prices that Plaintiff and the Damages Class Members would pay for Zetia at supra-competitive levels until at least June 12, 2017.

268. Defendants' unlawful agreement harmed Plaintiff and the Damages Class Members as set forth above.

269. There is no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effect.

270. Defendants' conduct violated the following state antitrust laws:

(a) Ala. Code § 6-5-60, with respect to purchases in Alabama by the Damages Class Members;

(b) Ariz. Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by the Damages Class Members;

(c) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in California by the Damages Class Members;

(d) D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by the Damages Class Members;

(e) Hawaii Code § 480, et seq., with respect to purchases in Hawaii by the Damages Class Members;

(f) 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the Damages Class Members;

(g) Iowa Code §§ 553 et seq., with respect to purchases in Iowa by the Damages Class Members;

(h) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by Damages Class Members;

(i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by the Damages Class Members;

(j) Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to purchases in Michigan by the Damages Class Members;

(k) Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by the Damages Class Members;

(l) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Damages Class Members;

(m) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by the Damages Class Members;

(n) Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by the Damages Class Members, in that thousands of sales of branded and generic versions of Zetia took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct;

(o) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by the Damages Class Members;

(p) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by the Damages Class Members;

(q) N.Y. Gen. Bus. L. §§ 340, et seq., with respect to purchases in New York by the Damages Class Members;

(r) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by the Damages Class Members;

(s) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by the Damages Class Members;

(t) Or. Rev. Stat. §§ 6.46.705, et seq., with respect to purchases in Oregon by the Damages Class Members;

(u) S.D. Codified Laws Ann. §§ 37-1, et seq., with respect to purchases in South Dakota by the Damages Class Members;

(v) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by the Damages Class Members, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of Zetia at Tennessee pharmacies;

(w) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by Damage Class Members who are either citizens or residents of Utah;

(x) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by the Damages Class Members;

(y) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by the Damages Class Members; and

(z) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by the Damages Class Members, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Zetia at Wisconsin pharmacies.

271. Plaintiff and the Damages Class Members have been injured in their business or property by Defendants' antitrust violations. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of Zetia, and (2) paying higher prices for branded and generic versions of Zetia than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

272. Plaintiff and the Damages Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

273. Defendants are jointly and severally liable for all damages suffered by Plaintiff and the Damages Class Members.

THIRD CLAIM FOR RELIEF
Monopolization and Monopolistic Scheme under State Law
(against Merck on Behalf of the Damages Class)

274. Plaintiff incorporates the preceding paragraphs by reference.

275. Merck has knowingly engaged in an anticompetitive scheme designed to delay and block entry of AB-rated generic equivalents of Zetia. The intended and accomplished goal of the scheme was to use exclusionary conduct to delay the ability of generic manufacturers to launch competing, generic versions of Zetia. Merck's exclusionary conduct maintained Merck's monopoly over branded and generic Zetia until at least December 2016.

276. Plaintiff and the Damages Class Members have suffered harm as a result of paying higher prices for Zetia and/or its AB-rated generic equivalents than they would have absent Merck's anticompetitive conduct and continuing anticompetitive conduct.

277. Merck's conduct violated the following state antitrust laws::

(a) Ala. Code § 6-5-60, with respect to purchases in Alabama by the Damages Class Members;

(b) Ariz. Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by the Damages Class Members;

(c) Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in California by the Damages Class Members;

(d) D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by the Damages Class Members;

(e) Hawaii Code § 480, et seq., with respect to purchases in Hawaii by the Damages Class Members;

(f) 740 Ill. Comp. Stat. Ann. 10 / 3, *et seq.*, with respect to purchases in Illinois by the Damages Class Members;

(g) Iowa Code §§ 553 et seq., with respect to purchases in Iowa by the Damages Class Members;

(h) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by Damages Class Members;

(i) Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by the Class Members;

(j) Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to purchases in Michigan by the Damages Class Members;

(k) Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by the Damages Class Members;

(l) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Damages Class Members;

(m) Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by the Damages Class Members;

(n) Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by the Damages Class Members, in that thousands of sales of branded and generic versions of Zetia took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendant's conduct;

(o) N.H. Rev. Stat. Ann. §§ 356:1, et seq., with respect to purchases in New Hampshire by the Damages Class Members;

(p) N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by the Damages Class Members;

(q) N.Y. Gen. Bus. L. §§ 340, et seq., with respect to purchases in New York by the Damages Class Members;

(r) N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by the Damages Class Members;

(s) N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by the Damages Class Members;

(t) Or. Rev. Stat. §§ 6.46.705, et seq., with respect to purchases in Oregon by the Damages Class Members;

(u) S.D. Codified Laws Ann. §§ 37-1, et seq., with respect to purchases in South Dakota by the Damages Class Members;

(v) Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by the Damages Class Members, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of Zetia at Tennessee pharmacies;

(w) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by Damage Class Members who are either citizens or residents of Utah;

(x) Vt. Stat. Ann. 9, §§ 2453, et seq., with respect to purchases in Vermont by the Damages Class Members;

(y) W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by the Damages Class Members; and

(z) Wis. Stat. §§ 133.03, et seq., with respect to purchases in Wisconsin by the Damages Class Members, in that the actions alleged herein substantially affected the people

of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Zetia at Wisconsin pharmacies.

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

279. Plaintiff and the Damages Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Merck's anticompetitive conduct

FOURTH CLAIM FOR RELIEF
State Consumer Protection Violations
(on behalf of Plaintiff and the Damages Class against All Defendants)

280. Plaintiff incorporates the preceding paragraphs by reference.

281. Defendants engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and the Damages Class Members were deprived of the opportunity to purchase generic versions of Zetia and were forced to pay higher prices branded and generic versions of Zetia.

282. For years, there was a gross disparity between the price that Plaintiff and the Damages Class Members paid for the brand product when compared to the less expensive generic products, which should have been available.

283. By engaging in the foregoing conduct, Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the following state unfair and deceptive trade practices and consumer protection statutes:

Florida Deceptive & Unfair Trade Practices Act ("FDUTPA")
Florida Stat. §§ 501.201, et seq.

284. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Florida Stat. §§ 501.202(2).

285. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

286. Under Florida law, indirect purchasers have standing to maintain an action under the FDUTPA based on the facts alleged in this Complaint.

287. Defendants' conduct constitutes an unfair method of competition because Defendants restrained trade in the market for branded and generic versions of Zetia by unreasonably delaying the entry of cheaper, competing generic versions of Zetia for at least five years, beginning in December 2011 until at least December 2016.

288. This delay was the product of an unlawful pay-for-delay agreement, which resolved ongoing patent litigation between Merck and Glenmark. Under the agreements, Merck agreed not to launch a competing authorized generic version of Zetia during Glenmark's 180-days of marketing exclusivity.

289. Defendants' conduct preserved Merck's monopoly over Zetia for an additional five years and stunted the effectiveness of future generic competition. This in turn caused end-payor purchasers of branded and generic versions of Zetia in Florida to continue to pay

supracompetitive prices for those products. Further, Defendants sold branded and generic versions of Zetia in Florida and their conduct had a direct and substantial impact on trade and commerce in Florida.

290. Accordingly, such conduct falls within the prohibitions in Florida Stat. §§ 501.202(2).

Massachusetts Consumer Protection Act ("MCPA")
Mass. Gen. L. Ch. 93A, et seq.

291. The MCPA regulates trade and commerce "directly or indirectly affecting the people of this commonwealth." Mass. Gen. L. Ch. 93A § 9(1).

292. Under the MCPA, "[a]ny person, who has been injured by another person's use or employment of any method, act or practice" that constitutes "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. L. Ch. 93A §§ 2, 9(1). MCPA § 2(b) provides that these terms are interpreted consistent with Section 5 of the FTC Act (15 U.S.C. § 45(a)), which also prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce." Mass. Gen. L. Ch. 93A § 2(b); 15 U.S. § 45(a)(1).

293. Defendants' conduct constitutes an unfair method of competition because Defendants restrained trade in the market for branded and generic versions of Zetia by unreasonably delaying the entry of cheaper, competing generic versions of Zetia for at least five years.

294. This delay was the product of an unlawful pay-for-delay agreement, which resolved ongoing patent litigation between Merck and Glenmark. Under the agreements, Merck agreed not to launch a competing authorized generic version of Zetia during Glenmark's 180-days of marketing exclusivity.

295. Defendants' conduct preserved Merck's monopoly over Zetia for an additional five years and stunted the effectiveness of future generic competition. This in turn, caused end-payor purchasers of branded and generic versions of Zetia in Massachusetts to continue to pay supracompetitive prices for those products. Further, Defendants sold branded and generic versions of Zetia in Massachusetts, and their conduct had a direct and substantial impact on trade and commerce in Massachusetts. Accordingly, such conduct falls within the prohibitions in Ch. 93A § 2.

Missouri Merchandising Practices Act ("MMPA")
Mo. Rev. Stat. 407.020

296. Under Section 407.020, the MMPA prohibits "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce." Mo. Rev. Stat. 407.020.

297. The Missouri Attorney General has defined an "unfair practice" as:

> any practice which . . . [o]ffends any public policy as it has been established by the Constitution, statutes or common law of this state, or by the Federal Trade Commission, or its interpretive decisions; or . . . [i]s unethical, oppressive, or unscrupulous; and . . . [p]resents a risk of, or causes, substantial injury to consumers.

Mo. Att'y Gen. Reg., 15 CSR 60-8.02.

298. Defendants' conduct constitutes an unfair method of competition because Defendants restrained trade in the market for branded and generic versions of Zetia by unreasonably delaying the entry of cheaper, competing generic versions of Zetia for at least give years.

299. This delay was the product of an unlawful pay-for-delay agreement which resolved ongoing patent litigation between Merck and Glenmark. Under the agreements, Merck

agreed not to launch a competing authorized generic version of Zetia during Glenmark's 180-days of marketing exclusivity.

300. Defendants' conduct preserved Merck's monopoly over Zetia for an additional five years and stunted the effectiveness of future generic competition. This, in turn, caused end-payor purchasers of branded and generic versions of Zetia in Missouri to continue to pay supracompetitive prices for those products. Further, Defendants sold branded and generic versions of Zetia in Missouri, and Defendants' conduct had a direct and substantial impact on trade and commerce in Missouri. Upon information and belief, Defendants also directed advertising and marketing efforts for branded and generic versions of Zetia in Missouri. Accordingly, Defendants' conduct falls within the prohibitions in the MMPA.

FIFTH CLAIM FOR RELIEF
Unjust Enrichment
(on behalf of the Damages Class against All Defendants)

301. Plaintiff incorporates by reference the preceding allegations.

302. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

303. This claim is pled by Plaintiff and the Damages Class against all Defendants.

304. Defendants have financially benefited from overcharges on sales of branded and generic versions of Zetia, which resulted from the unlawful and inequitable acts alleged in this Complaint. These overcharges were borne by Plaintiff and the Damages Class Members who purchased and/or reimbursed all or part of the purchase price of branded and generic Zetia. The benefits conferred upon Defendants are substantial and measurable, in that the revenues Defendants have earned due to unlawful overcharges are ascertainable by review of both sales records and the unlawful pay-for-delay agreement itself.

305. Moreover, Merck's promise not to launch a competing authorized generic version of Zetia during Glenmark's 180-day marketing exclusivity period was inextricably linked to the overcharges that Plaintiff and the Damages Class Members were to pay and thus part of the enrichment of Defendants at the expense of Plaintiff and the Damages Class Members.

306. For years, there was a gross disparity between the price that Plaintiff and the Damages Class Members paid for Zetia, compared to what they would have paid for less expensive generic versions of Zetia, which should and would have been available but for Defendants' unlawful and inequitable conduct.

307. Defendants repeatedly and continuously received financial benefits at the expense of Plaintiff and the Damages Class Members through each sale of branded and generic versions of Zetia at an inflated price.

308. It would be futile for Plaintiff and the Class Members to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to any other person for any of the benefits they received indirectly from Plaintiff and the Damages Class Members.

309. It would be futile for Plaintiff and the Damages Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Zetia, as those intermediaries cannot reasonably be expected to compensate Plaintiff and the Damages Class Members for Defendants' unlawful conduct.

310. The financial benefits that Defendants derived rightfully belong to Plaintiff and the Damages Class Members which paid anticompetitive prices that inured to Defendants' benefit.

311. It would be inequitable under unjust enrichment principles of the states listed below for Defendants to retain any of the overcharges that Plaintiff and the Damages Class Members paid for branded and generic versions of Zetia which were derived from Defendants' anticompetitive, unfair, and unconscionable methods, acts, and trade practices.

312. Defendants should be compelled to disgorge all unlawful or inequitable proceeds received by them into a common fund for the benefit of Plaintiff and the Damages Class Members.

313. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received, which arise from overpayments for branded and generic versions of Zetia by Plaintiff and the Damages Class Members.

314. Plaintiff and the Damages Class Members have no adequate remedy at law.

315. By engaging in the foregoing unlawful or inequitable conduct, which deprived Plaintiff and the Damages Class Members of the opportunity to purchase lower-priced generic versions of Zetia and forced them to pay higher prices for branded and generic versions of Zetia, Defendants have been unjustly enriched in violation of the common law of various states and commonwealths, as outlined below:

Alabama

316. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Alabama at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Damages Class as a direct result of the unlawful overcharges, and have retained this money. Defendants have benefitted at the expense of the Damages Class from revenue resulting from unlawful overcharges for Zetia or its AB-rated generic equivalents. It is

inequitable for Defendants to accept and retain the benefits received without compensating the Damages Class.

Alaska

317. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Alaska at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefits bestowed upon them by the Damages Class. Defendants accepted and retained the benefits bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Arizona

318. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Arizona at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Zetia or its AB-rated generic equivalents. The Damages Class has been impoverished by the overcharges for Zetia or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Damages Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment and the Damages Class's impoverishment, because the Damages Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Damages Class has no remedy at law.

Arkansas

319. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Arkansas at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Damages Class as a direct result of the unlawful overcharges, and have retained this money. Defendants have paid no consideration to any other person in exchange for this money. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

California

320. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in California at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class as a direct result of the unlawful overcharges. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the Damages Class.

Colorado

321. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Colorado at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants have benefitted at the expense of the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Connecticut

322. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Connecticut at prices that were more than they would have been but for Defendants' actions. Defendants were benefitted in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants have paid no consideration to any other person in exchange for this benefit. Defendants retained the benefits bestowed upon them under inequitable and unjust circumstances at the expense of the Damages Class.

Delaware

323. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Delaware at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Zetia or its AB-rated generic equivalents. The Damages Class has been impoverished by the overcharges for Zetia or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Damages Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Damages Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Damages Class has no remedy at law.

District of Columbia

324. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in the District of Columbia at prices that were more than they would have been but for Defendants' actions. The

Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Damages Class. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits.

Florida

325. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Florida at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefits bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Georgia

326. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Georgia at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Hawaii

327. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Hawaii at prices that were more than they would have been but for Defendants' actions. The Damages Class has

conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Idaho

328. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Idaho at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit conferred upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Illinois

329. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Illinois at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Damages Class. It is against equity, justice, and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Iowa

330. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Iowa at prices that were more than they would have been but for Defendants' actions. Defendants have been

enriched by revenue resulting from unlawful overcharges for Zetia or its AB-rated generic equivalents, which revenue resulted from anticompetitive prices paid by d the Damages Class, which inured to Defendants' benefit. Defendants' enrichment has occurred at the expense of the Damages Class. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Damages Class.

Kansas

331. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Kansas at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Kentucky

332. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Kentucky at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit conferred upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Louisiana

333. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Louisiana at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Zetia or its AB-rated generic equivalents. The Damages Class has been impoverished by the overcharges for Zetia or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Damages Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Damages Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Damages Class has no other remedy at law.

Maine

334. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Maine at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Maryland

335. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Maryland at

prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Massachusetts

336. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Massachusetts at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit conferred upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Michigan

337. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Michigan at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants retained the benefits bestowed upon them under unjust circumstances arising from unlawful overcharges to the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Minnesota

338. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Minnesota at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated and knowingly accepted the benefits bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Mississippi

339. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Mississippi at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Damages Class as a direct result of the unlawful overcharges. Defendants retain the benefit of overcharges received on the sales of Zetia or its AB-rated generic equivalents, which in equity and good conscience belong to the Damages Class on account of Defendants' anticompetitive conduct. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Missouri

340. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Missouri at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants

appreciated the benefit bestowed upon them by the Damages Class. Defendants accepted and retained the benefit bestowed upon them under inequitable and unjust circumstances arising from unlawful overcharges to the Damages Class.

Montana

341. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Montana at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Nebraska

342. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Nebraska at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Damages Class as a direct result of the unlawful overcharges, and have retained this money. Defendants have paid no consideration to any other person in exchange for this money. In justice and fairness, Defendants should disgorge such money and remit the overcharged payments back to the Damages Class.

Nevada

343. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Nevada at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful

overcharges for Zetia or its AB-rated generic equivalents. Defendants appreciated the benefits bestowed upon them by the Damages Class, for which they have paid no consideration to any other person. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

New Hampshire

344. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in New Hampshire at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Under the circumstances, it would be unconscionable for Defendants to retain such benefits.

New Jersey

345. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in New Jersey at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Damages Class. Defendants have paid no consideration to any other person for any of the unlawful benefits they received from the Damages Class with respect to Defendants' sales of Zetia or its AB-rated generic equivalents. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Damages Class.

New Mexico

346. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in New Mexico at prices that were more than they would have been but for Defendants' actions. Defendants have knowingly benefitted at the expense of the Damages Class from revenue resulting from unlawful overcharges for Zetia or its AB-rated generic equivalents. To allow Defendants to retain the benefits would be unjust because the benefits resulted from anticompetitive pricing that inured to Defendants' benefit and because Defendants have paid no consideration to any other person for any of the benefits they received.

New York

347. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in New York at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Zetia or its AB-rated generic equivalents, which revenue resulted from anticompetitive prices paid by the Damages Class, which inured to Defendants' benefit. Defendants' enrichment has occurred at the expense of the Damages Class. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

North Carolina

348. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in North Carolina at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. The Damages Class did

not interfere with Defendants' affairs in any manner that conferred these benefits upon Defendants. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Damages Class. The benefits conferred upon Defendants are measurable, in that the revenue Defendants have earned due to unlawful overcharges are ascertainable by review of sales records. Defendants consciously accepted the benefits conferred upon them.

North Dakota

349. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in North Dakota at prices that were more than they would have been but for Defendants' actions. Defendants have been enriched by revenue resulting from unlawful overcharges for Zetia or its AB-rated generic equivalents. The Damages Class has been impoverished by the overcharges for Zetia or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Damages Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment, because the Damages Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Damages Class has no remedy at law. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Damages Class.

Oklahoma

350. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Oklahoma at prices that were more than they would have been but for Defendants' actions. Defendants received money from the Damages Class as a direct result of the unlawful overcharges, and have

retained this money. Defendants have paid no consideration to any other person in exchange for this money. The Damages Class has no remedy at law. It is against equity and good conscience for Defendants to be permitted to retain the revenue resulting from their unlawful overcharges.

Oregon

351. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Oregon at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be unjust for Defendants to retain such benefits without compensating the Damages Class.

Pennsylvania

352. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Pennsylvania at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Puerto Rico

353. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Puerto Rico at prices that were more than they would have been but for Defendants' actions. Defendants have

been enriched by revenue resulting from unlawful overcharges for Zetia or its AB-rated generic equivalents. The Damages Class has been impoverished by the overcharges for Zetia or its AB-rated generic equivalents resulting from Defendants' unlawful conduct. Defendants' enrichment and the Damages Class's impoverishment are connected. There is no justification for Defendants' receipt of the benefits causing their enrichment and the Damages Class's impoverishment, because the Damages Class paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. The Damages Class has no remedy at law.

Rhode Island

354. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Rhode Island at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

South Carolina

355. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in South Carolina at prices that were more than they would have been but for Defendants' actions. The benefits conferred upon Defendants were not gratuitous, in that they comprised revenue created by unlawful overcharges arising from arising from unlawful overcharges to the Damages Class. Defendants realized value from the benefit bestowed upon them by the Damages Class. Under

the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

South Dakota

356. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in South Dakota at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants were aware of the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable and unjust for Defendants to retain such benefits without reimbursing the Damages Class.

Tennessee

357. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Tennessee at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class. It would be futile for the Damages Class to seek a remedy from any party with whom they have privity of contract. Defendants have paid no consideration to any other person for any of the unlawful benefits they received indirectly from the Damages Class with respect to Defendants' sales of Zetia or its AB-rated generic equivalents. It would be futile for The Damages Class to exhaust all remedies against the entities with which the Damages Class has

privity of contract because the Damages Class did not purchase Zetia or its AB-rated generic equivalents directly from any Defendant.

Texas

358. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Texas at prices that were more than they would have been but for Defendants' actions. Defendants have received a benefit from the Damages Class in the nature of revenue resulting from the unlawful overcharges, which revenue resulted from anticompetitive prices that inured to the benefit of Defendants. Defendants were aware of or appreciated the benefit bestowed upon them by the Damages Class. The circumstances under which Defendants have retained the benefits bestowed upon them by the Damages Class are inequitable in that they result from Defendants' unlawful overcharges for Zetia or its AB-rated generic equivalents. The Damages Class has no remedy at law.

Utah

359. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Utah at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Vermont

360. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Vermont at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants accepted the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Virginia

361. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Virginia at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of the benefit bestowed upon them. Defendants should reasonably have expected to repay the Damages Class. The benefits conferred upon Defendants were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Defendants' illegal and unfair actions to inflate the prices of Zetia or its AB-rated generic equivalents. Defendants have paid no consideration to any other person for any of the benefits they have received from the Damages Class.

Washington

362. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Washington at

prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit conferred upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

West Virginia

363. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in West Virginia at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants were aware of or appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Wisconsin

364. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Wisconsin at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants appreciated the benefit bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

Wyoming

365. Defendants unlawfully overcharged Damages Class Members, who made purchases of or reimbursements for Zetia or its AB-rated generic equivalents in Wyoming at prices that were more than they would have been but for Defendants' actions. The Damages Class has conferred an economic benefit upon Defendants, in the nature of revenue resulting from unlawful overcharges to the economic detriment of the Damages Class. Defendants accepted, used and enjoyed the benefits bestowed upon them by the Damages Class. Under the circumstances, it would be inequitable for Defendants to retain such benefits without compensating the Damages Class.

XII. DEMAND FOR JUDGMENT

366. WHEREFORE, Plaintiff, on behalf of itself and the proposed Classes, respectfully demands that this Court:

(a) Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2), be given to the Classes, and declare Plaintiff as the representative of the Classes;

(b) Enter joint and several judgments against the Defendants and in favor of Plaintiff and the Classes;

(c) Grants Plaintiff and the Classes equitable relief in the nature of an injunction, disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

(d) Award the Damages Class damages, and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial;

(e) Award Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

(f) Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIII. JURY DEMAND

367. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed Classes, demands a trial by jury on all issues so triable.

Date: February 2, 2018

LABATON SUCHAROW LLP

By: */s/ Gregory S. Asciolla*

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