

**THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND**

**IN RE LOESTRIN ANTITRUST LITIGATION**

**THIS DOCUMENT RELATES TO:  
END PAYOR PLAINTIFF ACTIONS**

**MDL NO. 2472  
JURY TRIAL DEMAND**

**CONSOLIDATED CLASS ACTION COMPLAINT**

Third Party Payor (“TPP”) Plaintiffs City of Providence, A.F.of L. - A.C.G. Building Trades Welfare Plan, Allied Services Division Welfare Fund, Electrical Workers 242 and 294 Health & Welfare Fund, Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund, Laborers International Union of North America, Local 35 Health Care Fund, Painters District Council No. 30 Health & Welfare Fund, Teamsters Local 237 Welfare Benefits Fund, United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund (“TPP Plaintiffs” or “End-Payors”), and Consumer Plaintiffs Denise Log, Melissa Chrestmas and Mary Alexander (“Consumers” or “End Payors”) on behalf of themselves and all others similarly situated, file this Consolidated Class Action Complaint (“Consolidated Complaint”) against Defendants Warner Chilcott (US), LLC, Warner Chilcott Public Limited Company, Warner Chilcott Company, Inc., Warner Chilcott Company, LLC, Warner Chilcott Laboratories Ireland, Limited, Warner Chilcott Holdings Company III, Ltd, Warner Chilcott Corporation, Warner Chilcott Sales (US), LLC (collectively, “Warner Chilcott”), Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively, “Watson”), Lupin Ltd., and Lupin Pharmaceuticals Inc. (collectively “Lupin”)

(Watson and Lupin are collectively referred to as “Generic Defendants,” and Warner Chilcott and the Generic Defendants are collectively referred to as the “Defendants”), based upon personal knowledge as to facts pertaining to it, and upon information and belief as to all other matters, and allege as follows:

### **I. NATURE OF THE ACTION**

1. This is a civil antitrust action seeking treble damages arising out of Defendants’ scheme to unlawfully allocate the market for oral contraceptive comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1mg of norethindrone acetate and 20 mcg ethinyl estradiol) and 4 ferrous fumarate tablets (placebo), which Warner Chilcott sells under the brand- name Loestrin 24 Fe (“Loestrin 24”). This market is, hereafter, referred to as the market for “Loestrin 24 Fe and its generic substitutes.” As alleged below, Defendants’ market-allocation scheme injured Plaintiffs and the class of end-payor purchasers it seeks to represent (as defined below), causing them to pay overcharges.

2. Warner Chilcott has sold Loestrin-based oral contraceptive products in the United States since 1973. Although the basic method of using norethindrone acetate, ethinyl estradiol, and a placebo to prevent pregnancy has been known for decades, Warner Chilcott has continued to seek and obtain new patents on minor variations of those basic ingredients, using its massive sales force to serially encourage doctors to write prescriptions for the latest version of Loestrin. Warner Chilcott’s various formulation patents have been subject to challenge by generic manufacturers as invalid, unenforceable, and not infringed.

3. When faced with the prospect of imminent generic competition to its formulation known as Loestrin 24 Fe, Warner Chilcott paid the generic manufacturers, Defendants Watson and Lupin, to withdraw their challenges to the patent and delay entry into the market. Warner Chilcott then used that delay to switch as many Loestrin 24 prescriptions as possible to yet another new formulation of Loestrin – one that would not face generic competition for another several years.

4. Warner Chilcott sued for patent infringement the generic drug manufacturers that submitted applications to the FDA for approval to sell generic versions of Loestrin 24, asserting that the generics infringe Warner Chilcott's U.S. Patent No. 5,552,394 ("the '394 Patent"). Warner Chilcott filed these patent lawsuits without regard to whether or not they had legal merit. Its purpose in filing the lawsuits was not to win them, but to use them to delay the onset of generic competition. Under the applicable provisions of the Hatch-Waxman Act (discussed in detail below), the mere filing of these lawsuits prevented the FDA from approving the generic drug for 30 months, regardless of the merits of the lawsuit. To get the automatic 30 months of delay, Warner Chilcott did not have to win the patent cases, it only had to file them.

5. To avoid any risk that the '394 Patent would be found to be invalid or deemed not infringed, Warner Chilcott simply paid the first potential generic competitor, Defendant Watson to withdraw its challenge to the patent and delay generic entry into the market. In exchange for substantial payments from Warner Chilcott, Watson agreed to stay out of the

market until January 2014 – just six months before the '394 Patent expires.

6. Warner Chilcott repeated this ploy with the second potential generic competitor, Defendant Lupin. Again to avoid any risk that the '394 Patent would be found to be invalid or deemed not infringed, Warner Chilcott agreed to share some of the supracompetitive profits with its potential competitor. In exchange for substantial payments from Warner Chilcott, Lupin agreed to withdraw its challenge to the patent and delay entry until July 2014 – to the very end of the patent term.

7. Having literally bought itself more time without generic competition, Warner Chilcott used that time to impair generic competition even beyond the expiration of the '394 Patent in July 2014. Warner Chilcott used the time that it bought to convert prescriptions for Loestrin 24 Fe, which will face generic competition beginning in January 2014, to prescriptions for follow-on branded products, such as Lo Loestrin Fe (“Lo Loestrin”) and Minastrin 24 Fe, for which Warner Chilcott could claim patent protection or other practical or legal exclusivity beyond the expiry of the '394 Patent.

8. Absent the unlawful payments from Warner Chilcott to both Watson and Lupin to delay the launch of their generic version of Loestrin 24, Warner Chilcott would never have even begun selling either Lo Loestrin or Minastrin 24 Fe, or if it had, it would have made very few sales. It is well known in the pharmaceutical industry that if the generic version of the original brand product enters the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers.

Neither Lo Loestrin nor Minastrin 24 offers any such benefits. Warner Chilcott's ploy of switching prescriptions to the follow-on products depended on launching them before generic versions of Loestrin 24 were available. Absent Warner Chilcott's unlawful payments to Watson and Lupin, generic Loestrin 24 would have been available long before the Food and Drug Administration ("FDA") approved Lo Loestrin and Minastrin 24 for sale. Consequently, Warner Chilcott would not have launched Lo Loestrin or Minastrin 24 or, if it had, they would have made very few sales.

9. But for the anticompetitive scheme and agreements alleged herein, a generic version of Loestrin 24 would have been available to Plaintiffs and members of the Class in the United States as early as September 2009, when the FDA granted final approval to Watson's generic Loestrin 24 Fe. Other generic versions of Loestrin 24, including an authorized generic version marketed directly or indirectly by Warner Chilcott, would have subsequently entered, driving the generic prices to down near marginal cost. Plaintiffs and the members of the Class would have purchased those generic products. Moreover, absent the anticompetitive scheme and agreements alleged herein, Warner Chilcott would not have been able since January 2011 to substantially reduce the number of Loestrin 24 Fe prescriptions available for generic substitution.

10. Defendants' unlawful scheme and agreements were designed to and did in fact:

(a) delay the entry of less expensive generic oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets in the United

States; (b) fix, raise, maintain or stabilize the price of oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets products; and (c) allocate 100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets market to Warner Chilcott.

11. Plaintiffs bring this action as a class action on behalf of all consumers and third-party payors (collectively “End-Payor Class”) in the United States of America and Puerto Rico who indirectly purchased, paid or provided reimbursement for branded and/or generic Loestrin 24 Fe products, other than for re-sale, since September 2009 (*see* Class Definition below). Plaintiffs seek a judgment declaring that Defendants’ anticompetitive scheme and agreements, as further described below, are unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1. Plaintiffs also seek an injunction pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, enjoining the continuation of the anticompetitive scheme and agreements. Unless enjoined, Defendants’ unlawful conduct will continue unchecked and Plaintiffs and the End-Payor Class will continue to bear the financial brunt of Defendants’ antitrust violations.

12. Plaintiffs also assert claims for compensatory and/or treble damages and equitable relief for continuing violations of state antitrust and/or consumer protection laws, and for unjust enrichment and disgorgement under common law.

## II. PARTIES

### A. Plaintiffs

13. City of Providence, Rhode Island (“Providence”) is a municipal corporation with a principal address of 25 Dorrance Street, Providence, Rhode Island. Providence is a self-insured health and welfare benefit plan, and purchases, pays and/or provides reimbursement to its employees for some or all of the purchase price of prescription drugs, including Loestrin 24. Providence indirectly purchased, paid or provided reimbursement for Loestrin 24 in, *inter alia*, Connecticut, the District of Columbia, Florida, Illinois, Maryland, Massachusetts, Missouri, New York, New Jersey, Ohio, Pennsylvania, Rhode Island, South Carolina and Texas, other than for resale and (and will purchase the generic version other than for re-sale once it becomes available). Providence paid more for Loestrin 24 than it would have absent Defendants’ unlawful anticompetitive conduct and was injured as a result thereof. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic alternative rather than branded Loestrin 24.

14. A.F. of L. - A.C.G. Building Trades Welfare Plan, (“the A.F.L. Plan”) is a self-insured health and welfare benefit plan with its principal place of business in Mobile, Alabama. The A.F.L. Plan provides reimbursement to its members for some or all of the purchase price of prescription drugs including Loestrin 24. The A.F.L. Plan represents participants who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Loestrin 24 in, *inter alia*, Alabama, Mississippi, and Tennessee, other than for resale (and will purchase the generic version other than for re-sale once it becomes available). The A.F.L. Plan paid more for Loestrin 24 than it would have for Loestrin 24 absent Defendants’ unlawful anticompetitive conduct and was injured as a result thereof. If a

generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic alternative rather than branded Loestrin 24.

15. Allied Services Division Welfare Fund (“ASD”), is a health and welfare benefits fund with its principal place of business at 53 West Seegers Road, Arlington Heights, Illinois 60005, and is involved in the business of providing health and pension benefits, among others, to covered lives. Plaintiff has indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Loestrin 24, other than for re-sale (and will purchase the generic version other than for resale once it becomes available), at supracompetitive prices in California, Illinois, Kansas, and Ohio during the Class Period. ASD paid more for Loestrin 24 than it would have absent Defendants’ unlawful anticompetitive conduct and was injured as a result thereof. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic alternative rather than branded Loestrin 24.

16. Electrical Workers 242 and 294 Health & Welfare Fund (“EW 242/294”) is an employee welfare benefit plan. EW 242/294’s headquarters and office responsible for covering medical benefits, including benefits for prescription drugs, is located in Duluth, Minnesota. Plaintiff has indirectly purchased, paid or provided reimbursement for some or all of the purchase price for Loestrin 24, other than for resale (and will purchase the generic version other than for resale once it becomes available), in Minnesota and Virginia at supracompetitive prices during the Class Period, and has thereby been injured. EW 242/294 paid more for Loestrin 24 than it would have absent Defendants’ unlawful anticompetitive conduct and was injured as a result thereof. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic

alternative rather than branded Loestrin 24.

17. Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund (“FOP”) is a health and benefit fund operated for the benefit of present and retired workers of the union and their families. The Fund was established pursuant to a duly executed Trust Agreement for the purpose of providing health benefits, including prescription benefits, to its defined beneficiaries. The Fund maintains its principal place of business in Fort Lauderdale, Florida. The Fund indirectly purchased, paid and/or provided reimbursement for Loestrin 24 in, *inter alia*, Florida, Michigan, New Jersey, and Nevada other than for resale (and will purchase the generic version other than for re-sale once it becomes available). FOP paid more for Loestrin 24 than it would have absent Defendants’ unlawful anticompetitive conduct and was injured as a result thereof. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic alternative rather than branded Loestrin 24.

18. Laborers International Union of North America, Local 35 Health Care Fund (“Local 35”) is a health and welfare benefit fund and is involved in the business of providing health and pension benefits, among others, to covered lives. Plaintiff has indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Loestrin 24, other than for resale (and will purchase the generic version other than for resale once it becomes available), at supracompetitive prices in New York during the Class Period. Local 35 paid more for Loestrin 24 than it would have absent Defendants’ unlawful anticompetitive conduct and was injured as a result thereof. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic alternative rather than branded Loestrin 24.

19. Painters District Council No. 30 Health & Welfare Fund ("Painters Fund") is located in Aurora, Illinois. Painters Fund is an "employee welfare benefit plan" and an "employee benefit plan" within the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §§1002(1), 1002(3) and 1003(a). As such, Painters Fund is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. §1132(d). Painters Fund is a not-for-profit trust, sponsored by and administered by a Board of Trustees, established and maintained to provide comprehensive health coverage for its participants and beneficiaries. Painters Fund is an indirect purchaser of Loestrin (and will purchase its generic equivalent once it becomes available) during the Class Period and was injured by Defendants' unlawful conduct, as alleged herein. Painters Fund sustained injury when it purchased, paid and/or provided reimbursement for purchases of Loestrin. As alleged herein, Painters Fund is entitled to recover damages and under the equitable remedy of unjust enrichment for purchases made by members in Illinois. Painters Fund paid more for Loestrin 24 than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic alternative rather than branded Loestrin 24.

20. Teamsters Local 237 Welfare Benefits Fund ("Teamsters Local 237 Fund") is a trust fund administered pursuant to the requirements of the Taft-Hartley Act, 29 U.S.C. § 186, by an equal number of trustees appointed by labor representatives and union representatives. Plaintiff is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to § 302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. § 186(c)(5), and as defined by § 1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C § § 1001, *et seq.* As such, Plaintiff is a legal entity entitled to bring

suit in its own name pursuant to 29 U.S.C. § 1132(d). Plaintiff's office is located in New York. During the relevant period, Plaintiff indirectly purchased, paid and/or provided reimbursement for its members' Loestrin 24 purchases in, *inter alia*, Connecticut, New York and New Jersey, other than for resale (and will purchase the generic version other than for resale once it becomes available). Teamsters Local 237 Fund paid more for Loestrin 24 than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic alternative rather than branded Loestrin 24.

21. United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund ("UCFW") maintains its principal place of business at 3031-A Walton Road, Plymouth Meeting, Pennsylvania 19462. Plaintiffs have indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Loestrin 24, other than for re-sale (and will purchase the generic version other than for re-sale once it becomes available), in Florida, New Jersey, Delaware, and Pennsylvania at supra-competitive prices during the Class Period, and has thereby been injured. UCFW paid more for Loestrin 24 than it would have absent Defendants' unlawful anticompetitive conduct and was injured as a result thereof. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic alternative rather than branded Loestrin 24.

22. Denise Loy is an adult, individual consumer, residing in Indian Harbor Beach, Florida. Plaintiff Loy has indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Loestrin 24, other than for resale (and will purchase generic

Loestrin 24 other than for resale once it becomes available), at supracompetitive prices during the Class Period, and has thereby been injured. Plaintiff Loy purchased and took Loestrin 24 from approximately June 2011 through the present. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic alternative rather than branded Loestrin 24.

23. Melissa Chrestmas is an adult, individual consumer, residing in Goodlettsville, Tennessee. Plaintiff Chrestman has purchased or paid for some or all of the purchase price of Loestrin 24, other than for resale (and will purchase generic Loestrin 24 other than for resale once it becomes available), at supracompetitive prices during the Class Period, and has been injured. Plaintiff Chrestman purchased and took Loestrin 24 from at least November 2012 through the present. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic alternative rather than branded Loestrin 24.

24. Mary Alexander is an adult, individual consumer, residing in Granite Quarry, North Carolina. Plaintiff Alexander has purchased or paid for some or all of the purchase price of Loestrin 24, other than for resale (and will purchase generic Loestrin 24 other than for resale once it becomes available), at supracompetitive prices during the Class Period, and has been injured. Plaintiff Alexander purchased and took Loestrin 24 from at least April 2011 through the present. If a generic alternative to Loestrin 24 had been available during the Class Period, Plaintiff would have purchased the less expensive generic alternative rather than branded Loestrin 24.

**B. Defendants**

25. Warner Chilcott (US), LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 100 Enterprise Drive,

Rockaway, New Jersey 07866.

26. Warner Chilcott Public Limited Company is a company organized and existing under the laws of Ireland, having its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland L2 00000.

27. Warner Chilcott Company, LLC is a limited liability company organized and existing under the laws of the Commonwealth of Puerto Rico, having its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico. This Defendant holds an approved New Drug Application from the FDA for a formulation of oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets, which it sells throughout the United States under the brand name Loestrin 24 Fe. This Defendant is a wholly owned subsidiary of Warner Chilcott PLC.

28. Warner Chilcott Holdings Company III, Ltd. is a privately-owned, for-profit company organized and existing under and the laws of Bermuda, having its office and principal place of business located at 100 Enterprise Drive, Rockaway, New Jersey 07866.

29. Warner Chilcott Laboratories Ireland Limited is a company organized and existing under the laws of the Republic of Ireland, having its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

30. Warner Chilcott Company, Inc., is a company organized and existing under the laws of the Commonwealth of Puerto Rico, having its principal place of business at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

31. Warner Chilcott Sales (US), LLC is a Delaware limited liability company with its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

32. Warner Chilcott Corporation is a Delaware corporation with its principal place

of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

33. The foregoing defendants are collectively referred to herein as “Warner Chilcott.”

34. Actavis, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054. Effective on or about January 24, 2013, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc.

35. Watson Pharmaceuticals, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 400 Interplace Parkway, Parsippany, New Jersey 07054. Effective on or about January 24, 2013, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc.

36. Watson Laboratories, Inc. is a company organized and existing under the laws of Nevada, having its principal place of business at 311 Bonnie Circle, Corona, California 92880. Watson Laboratories, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., which is now Actavis, Inc.

37. Actavis, Inc., Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. are collectively referred to herein as “Watson.” Watson is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district.

38. Lupin Ltd. is a company organized and existing under the laws of India, having its principal place of business at B/4 Laxami Towers, Branda Kurla Complex, Bandra (East), Mumbai, Maharashtra 400051, India.

39. Lupin Pharmaceuticals Inc. is a corporation organized and existing under the

laws of Virginia, having its principal place of business at Harbor Place Tower, 111 South Calvert Street, 21st floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals Inc. is a wholly-owned subsidiary of Lupin Ltd.

40. Lupin Ltd. and Lupin Pharmaceuticals Inc. are collectively referred to herein as “Lupin.” Lupin is engaged in the worldwide marketing, production and distribution of generic pharmaceutical products, including in this judicial district.

41. All of Defendants’ actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done 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**

42. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action in which the aggregate amount in controversy exceeds \$5,000,000 and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

43. This Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331 and 1337 in that Plaintiffs bring claims under Section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy Defendants’ violations of Section 1 of the Sherman Antitrust Act, 15 U.S. C. § 1. The Court has supplemental jurisdiction over Plaintiffs’ pendent state law claims pursuant to 28 U.S.C. § 1367.

44. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §1391(b) and (c), because Defendants transact business within this

district and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district.

#### **IV. INDUSTRY BACKGROUND**

##### **A. Characteristics of the Prescription Pharmaceutical Marketplace**

45. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

46. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Loestrin 24, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

47. Warner Chilcott and other brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs,

they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

48. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand – the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

**B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs**

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

50. When the FDA approves a brand manufacturer’s NDA, the manufacturer may list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may list in the Orange Book within thirty days of issuance any patents issued after the FDA approved the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

51. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

**1. The Hatch-Waxman Amendments**

52. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98- 417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

53. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

54. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

55. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled \$21.6 billion; by 2009 total prescription drug revenue had soared to \$300 billion.

## **2. Paragraph IV Certification**

56. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

57. If a generic manufacturer files a Paragraph IV certification, a brand

manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification (“Paragraph IV Litigation”), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer’s ANDA. Until one of those conditions occurs, the FDA may grant “tentative approval,” but cannot authorize the generic manufacturer to market its product. FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

58. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs). This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the

market; generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

59. Brand manufacturers can “game the system” by listing patents in the Orange Book (even if such patents are not eligible for listing) and suing any generic competitor that files an ANDA with a Paragraph IV certification (even if the competitor’s product does not actually infringe the listed patents) in order to delay final FDA approval of an ANDA for up to 30 months. That brand manufacturers often sue generics under Hatch-Waxman simply to delay generic competition—as opposed to enforcing a valid patent that is actually infringed by the generic—is demonstrated by the fact that generic firms have prevailed in Paragraph IV Litigation, by obtaining a judgment of invalidity or non-infringement or by the patent holder’s voluntary dismissal, in cases involving 73% of the drug products studied.

60. The first generic applicant can help the brand manufacturer “game the system” by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity, a tactic called exclusivity “parking.” This tactic creates a “bottleneck” because later generic applicants cannot launch until the first generic applicant’s 180-day exclusivity has elapsed or is forfeited.

61. On December 8, 2003, Congress enacted the Medicare Prescription Drug,

Improvement, and Modernization Act of 2003 (“MMA”) in order to make it more difficult for brand and generic manufacturers to conspire in order to delay the start of the first-filer’s 180-day period of generic market exclusivity. The MMA outlines a number of conditions under which an ANDA applicant forfeits its eligibility for 180-day exclusivity, making way for other ANDA filers to launch their generic products. For example, forfeiture occurs if the first ANDA applicant fails to obtain tentative approval from the FDA within 30 months from filing a substantially complete ANDA, unless the failure is caused by a change in or review of the approval requirements. Forfeiture under the MMA most commonly occurs for failure to obtain tentative approval within the requisite 30 months.

62. Under the “failure to market” provision, a first ANDA applicant forfeits 180-day exclusivity if it fails to market its generic drug by the later of: (a) the earlier of the date that is (i) 75 days after receiving final FDA approval; or (ii) 30 months after the date it submitted its ANDA; or (b) the date that is 75 days after the date as of which, as to each of the patents that qualified the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV certification), at least one of the following has occurred: (i) a final decision of invalidity or non-infringement; (ii) a settlement order entering final judgment that includes a finding that the patent is invalid or not infringed; or (iii) the NDA holder delists the patent from the FDA Orange Book.

63. Brand manufacturers and first-filing generics can structure their settlements in order to intentionally skirt these forfeiture provisions. For example, manufacturers subvert the

failure-to-market provisions and keep the 180-day exclusivity bottleneck in place by, for example, settling their litigation before a final judgment of invalidity or non-infringement can be entered with respect to each of the patents for which the first applicant submitted a Paragraph IV certification, or seeking a consent judgment that does not include a finding that all of the patents for which the first applicant submitted a Paragraph IV certification were invalid or not infringed. When that happens, in order to trigger forfeiture and gain access to the market, subsequent ANDA applicants are forced to obtain a judgment that all patents for which the first filing generic company filed Paragraph IV certifications are invalid or not infringed. This may require the subsequent ANDA applicant to initiate a declaratory judgment action concerning patents that the brand manufacturer did not assert against it in a Paragraph IV litigation.

64. In addition, brand and generic manufacturers can structure their settlements in a way that grants 180 days of exclusivity to the generic even where it is likely that the generic has forfeited that exclusivity under one of the applicable MMA forfeiture provisions, *e.g.*, the failure to obtain tentative approval within 30 months of submitting a substantially complete ANDA. This results in a windfall to the generic and a subversion of the regulatory scheme. Because FDA will not typically make a formal 180-day exclusivity determination until another generic applicant has received final approval and is ready to launch, settlements that retain de facto exclusivity – even where it should be forfeit de jure under the MMA – dissuade subsequent generic applicants from trying to obtain a court judgment of invalidity and/or infringement that would trigger the start of the 180 day period; because the lion's share of the

generic revenues will perceivably go to the first filer, subsequent filers have less incentive to litigate to judgment.

### **C. The Benefits of Generic Drugs**

65. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between generic and brand name drugs is their price: generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission (“FTC”) estimates that about one year after market entry, the generic version takes over 90% of the brand’s unit sales and sells for 15% of the price of the brand name product. As a result, competition from generic drugs is viewed by brand name drug companies such as Warner Chilcott as a grave threat to their bottom lines.

66. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by

writing “dispense as written” or similar language on the prescription).

67. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generics than on brands. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic products for more expensive branded ones. Health insurers are contractually obligated to pay for the bulk of their members’ prescriptions, whether filled with branded or generic drugs, so they offer their members lower copays for generic drugs in order to encourage the use of generics. Members also face the threat of increased health insurance premiums if branded prescription drug costs continue to rise.

68. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

69. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. As a result, brand manufacturers, who are well aware of generics’ rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the Agreements at issue here.

#### **D. The Impact of Authorized Generics**

70. The 180-day marketing exclusivity to which first-filer generics may be entitled

does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during that 180-day period. Such an “authorized generic” is chemically identical to the brand drug, but is sold as a generic product through either the brand manufacturer’s subsidiary (if it has one) or through a third-party generic manufacturer. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the first-filer’s revenue, and substantially reduces drug prices for consumers.

71. In its recent study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011) (the “FTC Study”), the FTC found that authorized generics capture a significant portion of sales, reducing the first-filer generic’s revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because: (1) the authorized generic takes a large share of unit sales away from the first filer; and (2) the presence of an additional generic in the market causes prices to decrease.

72. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, consumers and other drug purchasers such as Plaintiffs and the End-Payor Class benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

73. Given the significant negative impact of an authorized generic on the first-filing generic’s revenues, a brand manufacturer’s agreement not to launch an authorized generic has tremendous value to the generic manufacturer. Brand manufacturers have used such

agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive consumers and other drug purchasers such as Plaintiffs and the End-Payor Class of the lower prices resulting from two forms of competition: (1) among the branded and the generic products; and (2) between the generic products.

**V. THE ANTICOMPETITIVE SCHEME:  
SUE GENERICS, THEN PAY THEM TO DELAY ENTRY**

**A. Warner Chilcott Files Paragraph IV Litigation Against Watson**

74. Unlike traditional oral contraceptives that contain 21 active tablets and 7 placebo tablets, Loestrin 24 contains 24 active tablets (containing 1 mg of norethindrone acetate and 20 mcg of ethinyl estradiol) and 4 placebo tablets (containing ferrous fumarate). Warner Chilcott markets Loestrin 24's longer, 24-day active tablet regimen as providing an effective low dose birth control associated with shorter, lighter periods with less bleeding. Other oral contraceptives are not AB-rated to Loestrin 24, cannot be automatically substituted for Loestrin 24 by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Loestrin 24, and thus are not economic substitutes for, nor reasonably interchangeable with, Loestrin 24.

75. On April 15, 2005, Warner Chilcott submitted NDA 21-871 seeking FDA approval to market what became known as Loestrin 24. The FDA approved the NDA on February 17, 2006.

76. In connection with its Loestrin 24 NDA, Warner Chilcott listed the '394 Patent in the FDA Orange Book as covering Loestrin 24 or a method of using Loestrin 24. The

purported invention described in the '394 Patent is a method of female contraception which is characterized by a reduced incidence of breakthrough bleeding which comprises administering the claimed combination of estrogen and progestin for 23-25 consecutive days of a 28-day cycle. Warner Chilcott is the fifth owner of the '394 Patent, which issued in September 1996 to the Eastern Virginia Medical School ("EVMS"). EVMS sold the application that became the '394 Patent to Warner Lambert, which was acquired by Pfizer in 2000. Galen Holdings PLC (which acquired Warner Chilcott PLC in 2000), acquired the '394 Patent from Pfizer in March 2003. In July 2004, Galen Holdings, PLC changed its name to Warner Chilcott. Loestrin 24 is the purported commercial embodiment of the '394 Patent.

77. The active ingredients in Loestrin 24, the hormones norethindrone acetate and ethinyl estradiol, are not protected by any patent. In fact, norethindrone and ethinyl estradiol have served as the active ingredients in oral contraceptives dating back to at least the early 1970s. For example, Warner Chilcott's Loestrin Fe 1/20 product—which contains tablets identical to those used in Loestrin 24 Fe—was approved by the FDA on April 30, 1973. The only difference between the '394 Patent (and the corresponding Loestrin 24 product) and Loestrin Fe 1/20—which has been on the market for close to forty years—is that the '394 Patent claims require 23-25 days of tablets whereas the Loestrin 1/20 product was packaged in units of 21 active tablets.

78. Because the '394 Patent claims only a narrow method of using active ingredients that have been used for decades as an oral contraceptive to prevent pregnancy, generic manufacturers were eager to apply for FDA approval to market generic versions of

Loestrin 24 before the expiration of the '394 Patent. The generic manufacturers believed that they could obtain a court ruling that the '394 Patent was invalid and unenforceable.

79. On or about April 17, 2006, Generic Defendant Watson notified Warner Chilcott that Watson had filed ANDA No. 78-267, seeking to market a generic version of Loestrin 24. Watson's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic Loestrin 24 product would not infringe any valid claim of the '394 Patent.

80. On July 28, 2006, Warner Chilcott filed suit in the United States District Court for the District of New Jersey pursuant to Hatch-Waxman, alleging that Watson's generic Loestrin 24 product would infringe the '394 Patent.

81. Warner Chilcott filed the patent infringement case against Watson without regard to the merits of the case. Simply by filing the case, Warner Chilcott obtained automatic exclusion of Watson from the market for 30 months. Warner Chilcott's purpose in filing the case was to get the 30-month hiatus from generic competition, regardless of whether it ultimately won the case. In fact, had the case proceeded to a litigated conclusion, Warner Chilcott was very likely to have lost.

82. During the litigation, Watson conducted discovery supporting a host of defenses focusing on: (1) the enforceability of the '394 Patent; (2) the validity of the '394 Patent; and (3) the strength of Warner Chilcott's infringement allegations.

83. On January 23, 2008, Watson submitted an Amended Answer and Counterclaim asserting that the claims of the '394 Patent are invalid under one or more of 35

U.S.C. §§ 102, 103 and 112. Watson asserted, for example, that the only difference between Loestrin 24 and Warner Chilcott's prior art product Loestrin Fe 1/20—23 to 25 days of active tablets versus 21 days of active tablets—was trivial, particularly given that doctors routinely advised women using oral contraceptives to take more than 21 tablets in a row in order to delay the onset of menses that might otherwise occur at an inconvenient time. According to Watson, the claims of the '394 Patent were invalid because simply extending the regimen of a well-known prior art product by several days, as is taught in the literature and as practiced by women, was obvious.

84. Watson also alleged in its Counterclaim that the '394 Patent was unenforceable under equitable doctrines, including inequitable conduct, common law fraud and unclean hands. Watson alleged, *inter alia*, that the applicants for the '394 Patent intentionally: (1) concealed from the PTO an invalidating public use of the claimed invention that occurred more than one year before the application filing date; (2) made false statements and withheld material information; and (3) withheld prior art teaching an extended regimen of oral contraceptives (more than 21 days).

85. For example, one product, Loestrin Fe 1/20, which was known prior to the '394 patent and thus was prior art, was known to be associated with a high incidence of breakthrough bleeding and an unacceptable failure rate, problems that the prior art suggests can be alleviated by extending the number of days per cycle during which active pills are administered. Loestrin Fe 1/20 was administered for only 21 days, but suggested 23-25 days

in the claims of the patent. Loestrin Fe 1/20 further suggested that in low-dose oral contraceptives, the 7-day pill free period leads to follicular development, which may lead to pregnancy. Loestrin Fe 1/20 suggested that to provide improved suppression of follicular development by using a 24-day regime of active pills in oral contraceptive products while increasing the progestogen. One of ordinary skill in the art would have been motivated to administer Loestrin Fe 1/20 for additional days to alleviate the known problems associated with its administration over 21 days. Accordingly, the '394 patent was very vulnerable to challenge as obvious in view of the prior art.

86. To prevent generic entry using just the '394 Patent (rather than pay-offs), Warner Chilcott would have had to defeat each of Watson's arguments regarding invalidity and unenforceability and prove that Watson infringed the '394 Patent. To avoid any risk that a court would find the '394 Patent invalid or not infringed. Warner Chilcott decided to protect its supracompetitive profits by impermissibly paying Watson to withdraw its challenges to the validity and enforceability of the '394 Patent and delay its introduction of generic Loestrin 24. And that is precisely what it did, in concert with Watson.

**B. Warner Chilcott and Watson Enter an Exclusion Payment Agreement**

87. Having obtained the goal of the patent case – the 30-month stay – Warner Chilcott decided to end the case. On or about January 12, 2009, just one month before the 30-month stay was to expire, Warner Chilcott and Watson entered into an Exclusion Payment Agreement. Pursuant to that Agreement, Warner Chilcott ended its '394 Patent litigation against Watson, and Watson dropped its Counterclaims against Warner Chilcott. At the time of

the unlawful agreement, the court hearing the patent case had not issued any substantive rulings regarding the merits of the case.

88. Under the Exclusion Payment Agreement, Watson agreed to delay launching its generic Loestrin 24 product until the earliest of: (1) January 22, 2014; (2) 180 days before a date on which Warner Chilcott granted rights to a third party to market a generic version of Loestrin 24 in the United States; or (3) the date on which another generic version of Loestrin 24 entered the market.

89. As the *quid pro quo* for Watson's agreement to drop its challenge to the '394 Patent and to delay entry of its generic Loestrin 24 Fe product, Warner Chilcott agreed to pay Watson substantial sums. Warner Chilcott's payments to Watson under the Agreement took at least six forms.

90. *First*, the Agreement prohibits Warner Chilcott from launching an authorized generic version of Loestrin 24 during Watson's first 180 days of marketing. The Agreement expressly prohibits Warner Chilcott or its affiliates from marketing or supplying, or granting any third party rights to launch, an authorized generic during the 180-day period. Absent the Agreement, Warner Chilcott had the incentive and ability to launch an authorized generic version of Loestrin 24. Warner Chilcott has marketed authorized generic versions of other of its branded drugs, including its oral contraceptive, Dovonex. This aspect of the Agreement provides substantial compensation to Watson, which can expect to make approximately double the unit sales, at a much higher price, absent an authorized generic in the market. These higher

prices come at the expense of Plaintiffs and the End-Payor Class.

91. *Second*, Warner Chilcott agreed to grant to Watson a license to market Loestrin 24 *everywhere in the world* beginning January 22, 2014. The license to market Loestrin 24 outside the United States as well as inside the United States has substantially more value to Watson than a license to market the product only in the United States. But that license for foreign marketing has no value to consumers in the United States.

92. *Third*, the Agreement provides that Warner Chilcott will pay Watson annual fees and a percentage of net sales above a specified level in connection with Watson's co-promotion of Femring, a Warner Chilcott hormone therapy product, beginning in 2009.

93. *Fourth*, the Agreement gives Watson the exclusive right to earn highly profitable brand sales of a Warner Chilcott oral contraceptive that was in late-stage development at the time of the Agreement. Watson now markets that product under the brand name Generess Fe, a chewable oral contraceptive. Watson has already earned tens of millions of dollars selling Generess Fe in the United States since its launch in May 2011.

94. *Fifth*, Warner Chilcott agreed not to grant a license to any other manufacturer to enter with a generic version of Loestrin 24 until at least 180 days after Watson entered the market. Warner Chilcott thus guaranteed to Watson a period of 180 days of exclusivity as the only generic Loestrin 24 on the market, absent another generic manufacturer outlasting a 30-month stay or obtaining a court order permitting such entry. Watson, however, likely forfeited its entitlement to 180-day exclusivity under the Hatch-Waxman Act because it failed to obtain tentative FDA approval to market generic Loestrin 24 within 30 months of first submitting its ANDA in April 2006. Thus, the contractual exclusivity granted by Warner Chilcott had

substantial value to Watson, again at the expense of Plaintiffs and other End-Payors.

95. *Sixth*, Warner Chilcott agreed to permit Watson to enter the market earlier than January 22, 2014 in the event that another manufacturer entered the market with generic Loestrin 24 Fe before then. This “acceleration clause” was of substantial value to Watson because it guaranteed that no other generic manufacturer could enter the market before Watson, and it also deterred those other manufacturers from attempting to enter before January 22, 2014 because they knew that they could obtain a period of time in which they were the sole generic or one of only two generics on the market.

96. All of these payments had substantial value to Watson, and Watson could not have obtained any of these payments even if it had won the patent litigation against Warner Chilcott.

97. Warner Chilcott made these payments in exchange for Watson’s agreement to delay generic competition to Loestrin 24 for more than four years (or earlier under certain circumstances). Absent Watson’s agreement to delay entry into the market with generic Loestrin 24, Warner Chilcott would not have agreed to make these payments. Warner Chilcott paid Watson for delayed market entry of generic Loestrin 24.

**C. Warner Chilcott Files Paragraph IV Litigation Against Lupin**

98. As the first-filer, Watson had an opportunity to earn 180 days of exclusivity under the Hatch-Waxman Act. That circumstance created an economic incentive for other generic manufacturers to delay filing their own challenges to the ‘394 Patent while Watson litigated against Warner Chilcott. If Watson had obtained an order finding the patent invalid or

unenforceable, other generic manufacturers would have benefitted from that ruling without having to incur the costs of patent litigation.

99. On or about July 2009, six months after the announcement of the Warner Chilcott/Watson agreement, Lupin notified Warner that it had filed ANDA No. 091398, seeking to market generic versions of Loestrin 24. Lupin's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic product would not infringe any valid and enforceable claim of the '394 Patent.

100. On or about September 9, 2009, Warner sued Lupin for infringement of the '394 Patent in the United States District Court for the District of Delaware (Civil Action No. 09- 00673). Lupin answered the complaint on October 21, 2009, and alleged special defenses, including invalidity of the '394 Patent and non-infringement.

101. Warner Chilcott filed the case against Lupin without regard to its merits. Simply by filing the case, Warner Chilcott obtained automatic exclusion of Lupin from the market for 30 months. Warner Chilcott's purpose in filing the case was to get the 30-month hiatus from generic competition, regardless of whether it ultimately won the case. In fact, had the case proceeded to a litigated conclusion, Warner Chilcott was very likely to have lost.

102. During discovery, Lupin, like Watson before it, uncovered facts supporting a host of defenses that cast serious doubt on: (1) the enforceability of the '394 Patent (2) the validity of its claims; and (3) the strength of Warner Chilcott's infringement allegations.

103. To prevent generic entry using just the '394 Patent (rather than pay-offs),

Warner Chilcott would have had to defeat each of Lupin's arguments regarding invalidity and unenforceability and prove that Lupin infringed the '394 Patent. Warner Chilcott instead decided to protect its supracompetitive profits by paying Lupin to withdraw its challenges to the validity and enforceability of the '394 Patent and delay its introduction of generic Loestrin 24. And that is precisely what it did, in concert with Lupin.

**D. Warner Chilcott and Lupin Enter an Exclusion Payment Agreement**

104. To avoid the risk that the court would find the '394 Patent invalid and/or not infringed, Warner Chilcott unlawfully paid Lupin too, pursuant to the Exclusion Payment Agreement, to drop its patent challenge and stay out of the market until after Watson was permitted to enter the market under Watson's unlawful agreement with Warner Chilcott.

105. On or about October 10, 2010, before the close of fact discovery and before the court could issue any substantive rulings, Warner Chilcott entered into a non-competition agreement with Lupin, whereby Warner Chilcott agreed to pay Lupin substantial sums in exchange for Lupin's agreement to delay marketing its less expensive generic version of Loestrin 24 Fe until July 22, 2014, the month that the '394 Patent is set to expire. Pursuant to that Agreement, Warner Chilcott ended its '394 Patent litigation against Lupin, and Lupin dropped its Counterclaims against Warner Chilcott.

106. As the *quid pro quo* for Lupin's agreement to drop its challenge to the '394 Patent and to delay entry of its generic Loestrin 24, Warner Chilcott agreed to pay Lupin substantial sums. Warner Chilcott's payments to Lupin under the Agreement took at least two forms.

107. *First*, the agreement granted to Lupin a non-exclusive license covering Femcon Fe, another branded oral contraceptive manufactured by Warner Chilcott, which permitted Lupin to begin marketing an authorized generic version of Femcon Fe, supplied by Warner Chilcott, in the United States beginning on the earlier of (i) 180 days after the date that Teva Pharmaceutical Industries, Ltd (the “first-filer” with respect to Femcon Fe) entered the market with a generic equivalent to Femcon Fe, or (ii) January 1, 2013. Pursuant to the agreement, Lupin in fact entered the market with generic Femcon Fe, marketed as WYMZYA Fe, in October 2011, and since that time has made substantial sales of that product. But for this settlement, Lupin could not have begun making Femcon FE sales until the end of the 30 month stay in February 2012, assuming that Lupin would have entered at risk at that time.

108. *Second*, the agreement gave Lupin the right to purchase and sell in the United States a generic version of Asacol 400 mg (a branded treatment for inflammatory bowel disease), to be supplied by Warner Chilcott, if a generic version of the Asacol 400 mg product is launched by another generic manufacturer in the United States.

109. These payments had substantial value to Lupin, and Lupin could not have obtained any of these payments even if it had won the ‘394 patent litigation for Loestrin 24 Fe against Warner Chilcott. Warner Chilcott made these payments in exchange for Lupin’s agreement to delay generic competition to Loestrin 24 for more than two years (unless another generic entered the market first, which Warner Chilcott prevented through additional agreements described elsewhere in this complaint). Absent Lupin’s agreement to delay entry into the market with generic Loestrin 24, Warner Chilcott would not have agreed to: (a) grant to Lupin the non- exclusive license to make or sell generic Femcon Fe; (b) grant to Lupin the license to make or sell, under certain circumstances, a generic version of Asacol 400 mg;

and/or (c) grant the price and/or other terms that it did under those provisions of the agreement. Warner Chilcott paid Lupin for delayed market entry of generic Loestrin 24.

110. As described more fully below, Warner Chilcott delayed generic entry in order to both protect its Loestrin 24 supracompetitive profit and buy time to permit it to switch prescriptions to a follow-on branded version of Loestrin before generic Loestrin 24 became available.

#### **VI. THE ANTICOMPETITIVE SCHEME: SWITCH PRESCRIPTIONS FROM LOESTRIN 24 TO LO LOESTRIN**

111. In order to continue to exploit the market "disconnect" and maintain as many supracompetitive sales and profits as possible, it was necessary for Warner Chilcott to defeat the successful entry of generic Loestrin. In response to this anticipated competitive threat, Warner Chilcott devised a "life cycle management" or brand maturation strategy plan which involved (among other things) the rote filing of patent infringement cases regardless of their merit, unlawful pay-offs to generic manufacturers, and modifications to the Loestrin product – modifications that deliver no benefits to patients but that effectively shield substantial Loestrin sales from generic competition.

112. Using the time that it obtained by automatically filing patent litigation in order to obtain 30-month stays, and by paying off generic manufacturers to delay entry, Warner Chilcott modified the chemical composition of its Loestrin product so generic versions of Loestrin, when they finally did enter the market, would not be substitutable for branded Loestrin. This would protect as many Loestrin sales as possible from generic competition.

113. The follow-on products to which Warner Chilcott switched its marketing

efforts are Lo Loestrin 24 and Minastrin 24. These products are not medically superior to Loestrin 24 Fe. Warner Chilcott designed the products not in order to deliver a superior product to consumers, but to impair competition from generic Loestrin 24 Fe.

114. It was essential to Warner Chilcott that it launch and convert as many Loestrin 24 prescriptions as possible to Lo Loestrin and Minastrin 24 before generic versions of Loestrin 24 were available in the market. Beating the generics onto the market would allow Warner Chilcott to effect the switch at a time when no competing manufacturer had the incentive or ability to counter Warner Chilcott's marketing message to doctors.

115. It is well known in the pharmaceutical industry that if generic versions of the original brand product enter the market before the branded follow-on product, the latter will make very few sales unless it offers substantial, demonstrable medical benefits to consumers. For example, one brand manufacturer estimated that it would make ten times more sales of its branded follow-on product if it beat generic versions of the original product onto the market. In a detailed inquiry into the pharmaceutical industry, the European Commission concluded that "it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity." European Commission, Final Report, p. 356 (8 July 2009), available at [http://www.europa-nu.nl/id/vi6wcj7amsx3/pharmaceutical\\_sector\\_inquiry\\_fianl?start-006-00c=10](http://www.europa-nu.nl/id/vi6wcj7amsx3/pharmaceutical_sector_inquiry_fianl?start-006-00c=10). Industry analysts in the United States echo that conclusion, warning brand manufacturers that "it is essential that the brand holder switch their patients to the new formulation prior to generic

launch.” Stephen Perrett, *The Modified-Release Drug Delivery Landscape: The Commercial Perspective*, in II MODIFIED-RELEASE DRUG DELIVERY TECHNOLOGY 1, 3 (Michael J. Rathbone et al. eds., 2d ed. 2008).

116. Consequently, Warner Chilcott’s ploy of switching prescriptions to Lo Loestrin and Minastrin 24 depended on launching those products before generic versions of Loestrin 24 Fe were available. Absent Warner Chilcott’s unlawful payments to Watson and Lupin, generic Loestrin 24 Fe would have been available long before the FDA approved Lo Loestrin or and Minastrin 24or, if it had, it would have made few sales.

117. Due to Warner Chilcott’s anticompetitive scheme and unlawful payments to Watson and Lupin to delay entry, by the time generic Loestrin 24 is available in January 2014, the prescription base for Loestrin 24 will have been very substantially eroded.

## **VII. ANTICOMPETITIVE EFFECTS OF THE SCHEME**

118. Warner Chilcott’s scheme and payments to suppress generic competition to Loestrin 24 have delayed and substantially diminished the sale of generic Loestrin 24. By delaying the onset of generic competition and reducing the prescription base, Defendants deprived would-be generic versions of the most efficient means of distribution under the governing statutory and regulatory regime.

119. Warner Chilcott’s overarching anticompetitive scheme, and the Generic Defendants’ participation in it, delayed and substantially diminished the sale of generic Loestrin 24 in the United States, and unlawfully enabled Warner Chilcott to sell Loestrin 24 at artificially inflated prices. But for Defendants’ illegal conduct, generic manufacturers would

have been able to enter the market unimpeded and compete on the merits against Loestrin 24. Generic competitors would also have been able to compete earlier, as early as September 2009, and additional generic competitors would have entered the market thereafter. Defendants' conduct unlawfully prevented purchasers of Loestrin 24 from obtaining the benefits of unimpaired generic competition.

120. Defendants' scheme and unlawful payments harmed Plaintiffs and the End-Payor Class by depriving them of: (1) a market in which manufacturers and distributors of generic drugs make their decisions about challenging patents and entering markets free from the influence of unlawful payments; and (2) the most cost efficient means of distribution. Contrary to the purpose of the Hatch-Waxman Act, the anticompetitive scheme and payments have enabled Defendants to: (1) delay the entry of less expensive generic versions of Loestrin 24 in the United States; (2) fix, raise, maintain or stabilize the price of Loestrin 24; (3) allocate 100% of the U.S. market for an oral contraceptive comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets to Warner Chilcott.

121. But for the anticompetitive scheme: (1) Watson would have begun selling AB-rated generic versions of Loestrin 24 on or shortly after receiving final FDA approval of its generic Loestrin 24 ANDA on September 1, 2009; and (2) an increasingly competitive market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets would have emerged; and (3) Warner Chilcott would not have developed or marketed Lo Loestrin or Minastrin 24 and switched a substantial portion of

sales to those products and/or generic Loestrin 24 would have entered the market before Loestrin and Minastrin 24, and Warner Chilcott would have been able to switch few prescriptions to those products.

122. Defendants' unlawful conduct has delayed and diminished the sale of generic Loestrin 24 in the United States, and unlawfully enabled Warner Chilcott to sell Loestrin 24 at artificially inflated, supracompetitive prices. But for Defendants' illegal conduct, generic competition to Loestrin 24 would have occurred already, because, at a minimum, Watson would have already launched its generic version of Loestrin 24 and Warner Chilcott or its designee would have entered the market with an authorized generic version of Loestrin 24.

123. As a consequence, Plaintiffs and other members of the Class 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.

### **VIII. CLASS ACTION ALLEGATIONS**

124. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a), 23(b)(2), and (b)(3), as representative of an End-Payor Class defined as follows:

All persons or entities in the United States and its territories who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for Loestrin 24 Fe and/or its AB-rated generic equivalents in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class" or the "End-Payor Class"), other than for resale, during the period September 1, 2009 through and until the anticompetitive effects of Defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased"

Loestrin 24 Fe or its generic equivalent if they indirectly purchased, paid and/or reimbursed for some or all of the purchase price.

125. The following persons or entities are excluded from the proposed End-Payor

Class:

- a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;
- b. All federal or state governmental entities, excluding cities, towns or municipalities with self-funded prescription drug plans;
- c. All persons or entities who purchased Loestrin 24 Fe or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates;
- d. Fully insured health plans (*i.e.*, Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);
- e. Any "flat co-pay" consumers whose purchases were paid in part by a third party payor and whose co-payment was the same regardless of the retail purchase price;
- f. Any "brand loyalist" consumers or third-party payors who purchased Loestrin 24 Fe and who did not purchase any AB-rated generic equivalent after such generics became available; and
- g. The judges in this case and any members of their immediate families.

126. Members of the End-Payor Class are so numerous that joinder is impracticable.

Plaintiffs believe that the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

127. Plaintiffs' claims are typical of those of the members of the End-Payor Class.

Plaintiffs and all members of the End-Payor Class were damaged by the same wrongful

conduct of Defendants, *i.e.*, they paid artificially inflated prices for Loestrin 24 Fe and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Loestrin 24 Fe as a result of Defendants' wrongful conduct.

128. Plaintiffs will fairly and adequately protect and represent the interests of the End-Payor Class. The interests of the Plaintiffs are coincident with, and not antagonistic to, those of the End-Payor Class.

129. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience in class action antitrust litigation involving pharmaceutical products.

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

131. Questions of law and fact common to the End-Payor Class include, but are not limited to:

- a. whether Defendants conspired to suppress generic competition to Loestrin 24 Fe;
- b. whether Defendants Warner Chilcott and Watson entered into an unlawful agreement in restraint of trade;
- c. whether, pursuant to the agreement, Watson agreed to delay its entry into the market with generic Loestrin 24 Fe;

- d. whether, pursuant to the agreement, Warner Chilcott compensated Watson;
- e. whether Warner Chilcott's compensation to Watson was for a purpose other than delayed entry of generic Loestrin 24 Fe;
- f. whether Warner Chilcott's compensation to Watson was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;
- g. whether the agreement is illegal under the rule of reason;
- h. whether Defendants Warner Chilcott and Lupin entered into an unlawful agreement in restraint of trade;
- i. whether, pursuant to the agreement, Lupin agreed to delay its entry into the market with generic Loestrin 24 Fe;
- j. whether, pursuant to the agreement, Warner Chilcott compensated Lupin;
- k. whether Warner Chilcott's compensation to Lupin was for a purpose other than delayed entry of generic Loestrin 24 Fe;
- l. whether Warner Chilcott's compensation to Lupin was necessary to yield some procompetitive benefit that is cognizable and non-pretextual;
- m. whether the agreement is illegal under the rule of reason;
- n. whether, absent the delay caused by Defendants' unlawful payments, Warner Chilcott would have launched and marketed Lo Loestrin;
- o. whether Warner Chilcott introduced, priced, and marketed Lo Loestrin and Minastrin 24 in order to diminish the prescription base of Loestrin 24;
- p. whether the law requires definition of a relevant market when direct proof of market power is available and, if so, the definition of the relevant market;
- q. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- r. whether, and to what extent, Defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiffs and the members of the Class; and
- s. the *quantum* of aggregate overcharge damages to the Class.

132. 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.

133. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

#### **IX. INTERSTATE AND INTRASTATE COMMERCE**

134. At all material times, Warner Chilcott manufactured, marketed, promoted, distributed, and sold substantial amounts of Loestrin 24 in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

135. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Loestrin 24 and/or AB-rated bioequivalents.

136. In furtherance of their efforts to restrain competition in the market for Loestrin 24 and its generic equivalents, Defendants employed the United States mails and interstate and

international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of and have substantially affected interstate commerce.

137. Defendants' anticompetitive conduct has substantial intrastate effects in that, *inter alia*, retailers within each state are foreclosed from offering less expensive generic Loestrin 24 to end-payors inside each respective state. The foreclosure of generic Loestrin 24 directly impacts and disrupts commerce for end-payors within each state.

#### **X. MARKET POWER AND MARKET DEFINITION**

138. At all relevant times, Warner Chilcott had market power with respect to oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets because it had the power to maintain the price of the drug it sold as Loestrin 24 at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable.

139. A small but significant, non-transitory price increase above the competitive level for Loestrin 24 by Warner Chilcott would not have caused a loss of sales sufficient to make the price increase unprofitable.

140. At competitive price levels, Loestrin 24 does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Loestrin 24.

141. Some formulations of oral contraceptives have higher failure rates in certain classes of women, and they differ widely in their safety and side-effect profiles. The differing

efficacy, safety and side effect profiles of different oral contraceptives play a critical role in doctors' selection of the most appropriate oral contraceptive for a particular patient. The FDA does not consider these products bioequivalent, and there is variation in the dosage of the active ingredients.

142. Even though there may be a number of different oral contraceptive pills 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 well-tolerated, it is very unlikely that the patient will switch to a different oral contraceptive based on variations of price of 10% or less. Doctors generally select an oral contraceptive for their patients based on the clinical and pharmacological attributes of the drug and the relevant characteristics of the patient, rather than on the basis of price.

143. For clinical reasons, among others, physicians and patients prefer Loestrin 24 to other products designed to prevent pregnancy. Due to, among other reasons, its use and varying ability to prevent pregnancy while causing shorter, lighter periods, Loestrin 24 is significantly differentiated from all products other than AB-rated generic versions of Loestrin 24.

144. The existence of other products designed to prevent pregnancy has not significantly constrained Warner Chilcott's pricing of Loestrin 24. At all relevant times, Warner Chilcott's price for Loestrin 24 has been at least 60% above its marginal cost of production, and at least 40% above its marginal cost including marketing costs. Warner

Chilcott has never lowered the price of Loestrin 24 in response to the pricing of other branded oral contraceptives (or the generic versions of those other branded oral contraceptives).

145. Warner Chilcott needed to control only Loestrin 24 and its AB-rated generic equivalents, and no other products, in order to maintain the price of Loestrin 24 profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Loestrin 24 would render Warner Chilcott unable to profitably maintain supracompetitive prices for Loestrin 24.

146. Warner Chilcott knew that entry of a generic version of Loestrin 24 would be a uniquely significant market event. The entry of other branded oral contraceptives (or generic versions of those other brands) did not take substantial sales from Loestrin 24 or cause Warner Chilcott to lower its price. But Warner Chilcott predicted that entry of generic Loestrin 24 would immediately cause branded Loestrin 24 to lose well more than half of its unit sales. Likewise, Watson estimated that its generic version of Loestrin 24 would take essentially all of its sales from branded Loestrin 24 and few if any sales from other branded oral contraceptives (or generic versions of those other brands). Lupin predicted the same with respect to its generic version of Loestrin 24.

147. Warner Chilcott, Watson, and Lupin predicted that the competitive impact of a generic version on branded Loestrin 24 would be substantial. Among other things, all three Defendants predicted that entry of generic Loestrin 24 would deliver hundreds of millions of dollars of savings to consumers.

148. At all relevant times, Warner Chilcott has sold Loestrin 24 at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

149. Warner Chilcott had, and exercised, the power to exclude and restrict competition to Loestrin 24 and AB-rated bioequivalents.

150. Warner Chilcott, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

151. To the extent that Plaintiffs are legally required to prove market power circumstantially by first defining a relevant product market, Plaintiffs allege that the relevant product market is oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets (*i.e.*, Loestrin 24 and its AB-rated generic equivalents). During the relevant time, Warner Chilcott has been able to profitably maintain the price of oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets well above competitive levels.

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

153. At all relevant times, Warner Chilcott's market share in the relevant market was and remains 100%, implying a substantial amount of market power.

## **XI. MARKET EFFECTS AND DAMAGES TO THE CLASS**

154. But for the anticompetitive conduct alleged above, Watson would have entered the market with its generic Loestrin 24 as early as September 1, 2009, the date its ANDA 78-

267 received final FDA approval. Warner Chilcott would have launched an authorized generic version of Loestrin 24 at that same time. Lupin and other generic manufacturers would have entered the market with additional generic version of Loestrin 24 thereafter.

155. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Loestrin 24 from generic competition.

156. Watson and Lupin have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products, manufacturing commercial launch quantities adequate to meet market demand, and, where appropriate, paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

157. Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of Loestrin 24, has caused Plaintiffs and the Class to pay more than they would have paid for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets absent Defendants' illegal conduct.

158. Typically, generic versions of brand drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, end- payors rapidly substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a

drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand drug loses even more of its market share to the generic versions of the drug. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices, and/or (b) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

159. But for Defendants' anticompetitive conduct, end-payors, such as Plaintiffs and members of the Class, would have paid less for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets by: (a) substituting purchases of less-expensive AB-rated generic Loestrin 24 for their purchases of more-expensive branded Loestrin; (b) receiving discounts on their remaining branded Loestrin 24 purchases; and (c) purchasing generic Loestrin 24 at lower prices sooner.

160. Moreover, due to Defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in (a) developing generic versions of Loestrin 24, and/or (b) challenging the validity or infringement of the '394 patent in court.

161. During the Class Period, Plaintiffs and other members of the Class purchased substantial amounts of Loestrin 24. As a result of Defendants' illegal conduct as alleged herein, Plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for oral contraceptives comprising 24 norethindrone acetate/ethinyl

estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets. Plaintiffs and the other Class members paid prices for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic Loestrin 24 instead of expensive brand Loestrin 24; and (2) Class members paid artificially inflated prices for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets.

162. As a consequence, Plaintiffs and other members of the Class 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.

163. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

## **XII. ANTITRUST IMPACT**

164. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of brand Loestrin 24 indirectly from Defendants and/or purchased substantial amounts of AB-rated Loestrin 24 bioequivalent generic indirectly from Defendants or others. As a result of Defendants' illegal conduct, members of the End-Payor Class were compelled to pay, and did pay, artificially inflated price for their oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets requirements. Those prices were substantially greater than the prices that

members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand Loestrin 24 Fe was artificially inflated by Defendants' illegal conduct, (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Loestrin 24, and/or (3) the price of AB-rated Loestrin 24 generic was artificially inflated by Defendants' illegal conduct.

165. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

166. Overcharges at a higher level of distribution generally result in higher prices at every level below.

167. Wholesalers and retailers passed on the inflated prices of Loestrin 24 and AB-rated generic Loestrin 24 to the End-Payors defined herein.

168. Defendants' anticompetitive conduct enabled them to indirectly charge consumers and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

169. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

170. The inflated prices the End-Payor Class paid are traceable to, and the foreseeable result of, the overcharges by Defendants.

### **XIII. CLAIMS FOR RELIEF**

#### **FIRST CLAIM FOR RELIEF**

#### **For Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Defendants' Violations of Section 1 of the Sherman Act (Asserted Against Warner Chilcott and Watson)**

171. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

172. The Exclusion Payment Agreement between Warner Chilcott and Watson involves: (a) a payment from Warner Chilcott to Watson; and (b) an agreement by Watson to delay marketing its generic Loestrin 24 Fe until January 22, 2014 (or earlier in certain circumstances). The payments from Warner Chilcott to Watson under the Agreement were the *quid pro quo* for Watson's agreement to delay marketing its generic version of Loestrin 24 Fe for over four years. Absent the payments, Watson would not have agreed to delay marketing its generic version of Loestrin 24 Fe until January 22, 2014.

173. The purpose and effect of the unlawful Exclusion Payment Agreement between Warner Chilcott and Watson was to allocate 100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets to Warner Chilcott; delay the sales of generic Loestrin 24 Fe products for up to over four years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets at the higher, branded price.

174. The Exclusion Payment Agreement covered a sufficiently substantial

percentage of the relevant market to harm competition.

175. The Exclusion Payment Agreement constitutes a continuing contract, combination and conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The Exclusion Payment Agreement is a horizontal market allocation and price fixing agreement between actual or potential competitors that is unlawful under the rule of reason standard. The purpose and effect of the payments flowing from Warner Chilcott to Watson under the Agreement was to delay generic competition to Loestrin 24 Fe and there is and was no legitimate, non-pretextual, precompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

176. At all relevant times, Warner Chilcott possessed market power in the relevant market. Warner Chilcott possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

177. The goal, purpose and/or effect of the Exclusion Payment Agreement was to prevent and/or delay generic competition to Loestrin 24 Fe and enable Warner Chilcott to continue charging supracompetitive prices for Loestrin 24 Fe without a substantial loss of sales. By means of the Warner Chilcott's payment to Watson, the Defendants shared the supracompetitive profits that their unlawful agreement made possible.

178. Defendants each committed at least one overt act in furtherance of the conspiracy.

179. As a direct and proximate result of Defendants' unlawful restraint of trade

Plaintiff and members of the Class were harmed as described herein.

180. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a) hereby seek a declaratory judgment that Defendants' conduct as described herein violates Section 1 of the Sherman Act.

181. Plaintiff and the Class further seek equitable and injunctive relief 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 the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not occur in the future.

**SECOND CLAIM FOR RELIEF**  
**For Conspiracy and Combination in Restraint**  
**of Trade Under State Law**  
**(Asserted Against Warner Chilcott and**  
**Watson)**

182. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

183. The Exclusion Payment Agreement between Warner Chilcott and Watson involves: (a) a payment from Warner Chilcott to Watson; and (b) an agreement by Watson to delay marketing its generic Loestrin 24 Fe until January 22, 2014. The payments from Warner Chilcott to Watson under the Agreement was the *quid pro quo* for Watson's agreement to delay marketing its generic versions of Loestrin 24 Fe over four years. Absent the payments, Watson would not have agreed to delay marketing its generic versions of Loestrin 24 Fe until January 22, 2014.

184. The purpose and effect of the payments flowing from Warner Chilcott to Watson under the agreement was to delay generic competition to Loestrin 24 Fe and there is

and was no legitimate, non-pretextual, precompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

185. The purpose and effect of the unlawful Exclusion Payment Agreement between Warner Chilcott and Watson was to allocate 100% of the market for Loestrin 24 and its generic equivalents in the United States to Warner Chilcott; delay the sales of generic Loestrin 24 Fe products for over four years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for Loestrin 24 and its generic equivalents at the higher, branded price.

186. The Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

187. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiffs and members of the Class paid artificially inflated prices for Loestrin 24 and its generic equivalents as described herein, and were harmed as a result.

188. By engaging in the foregoing conduct, Defendants have violated the following state laws:

- a. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases of Loestrin 24 Fe in Arizona by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Loestrin 24 Fe in California by members of the Class.
- c. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of D.C. Code Ann.

§§ 28-45031, *et seq.*, with respect to purchases of Loestrin 24 Fe in the District of Columbia by members of the Class.

- d. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Loestrin 24 Fe in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.
- e. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Kansas by members of the Class.
- f. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Maine by members of the Class.
- g. Defendant have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Loestrin 24 Fe in Massachusetts by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Loestrin 24 Fe in Michigan by members of the Class.
- i. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Loestrin 24 Fe Minnesota by members of the Class.
- j. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in Mississippi by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nebraska by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Nev. Rev. Stat.

Ann. § 598A, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nevada by members of the Class, in that thousands of sales of Loestrin 24 Fe took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.

- m. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in New Mexico by members of the Class.
- n. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of New York General Business Law § 340, *et seq.*, with respect to purchases of Loestrin 24 Fe in New York by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in North Carolina by members of the Class.
- p. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchases of Loestrin 24 Fe in North Dakota by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Loestrin 24 Fe in Oregon by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of R.I. Gen. Laws §§ 6-36-5, *et seq.* with respect to purchases of Loestrin 24 Fe in Rhode Island by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in South Dakota by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Loestrin 24 Fe in

Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee with thousands of end-payors in Tennessee paying substantially higher prices for Loestrin 24 Fe at Tennessee pharmacies.

- u. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Loestrin 24 Fe in Utah by residents of Utah who are members of the Class.
- v. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Loestrin 24 Fe in Vermont by members of the Class.
- w. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in West Virginia by members of the Class.
- x. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Wis. Stat. § 133.01, *et seq.*, with respect to purchases of Loestrin 24 Fe in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Loestrin 24 Fe at Wisconsin pharmacies.

189. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Loestrin 24, and (2) paying higher prices for branded Loestrin 24 than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

190. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

**THIRD CLAIM FOR RELIEF**  
**For Declaratory and Injunctive Relief Under**  
**Section 16 of the Clayton Act for Defendants'**  
**Violations of Section 1 of the Sherman Act**  
**(Asserted Against Warner Chilcott and**  
**Lupin)**

191. Plaintiffs repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

192. The Exclusion Payment Agreement between Warner Chilcott and Lupin involves: (a) a payment from Warner Chilcott to Lupin; and (b) an agreement by Lupin to delay marketing its generic Loestrin 24 Fe until July 22, 2014 (or earlier in certain circumstances). The payments from Warner Chilcott to Lupin under the Agreement was the *quid pro quo* for Lupin's agreement to delay marketing its generic version of Loestrin 24 Fe for over four years. Absent the payments, Lupin would not have agreed to delay marketing its generic version of Loestrin 24 Fe until July 22, 2014.

193. The purpose and effect of the unlawful Exclusion Payment Agreement between Warner Chilcott and Lupin was to allocate 100% of the United States market for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets to Warner Chilcott; delay the sales of generic Loestrin 24 Fe products for up to over four years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets at the higher, branded price.

194. The Exclusion Payment Agreement covered a sufficiently substantial

percentage of the relevant market to harm competition.

195. The Exclusion Payment Agreement constitutes a continuing contract, combination and conspiracy in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The Exclusion Payment Agreement is a horizontal market allocation and price fixing agreement between actual or potential competitors that is unlawful under the rule of reason standard. The purpose and effect of the payments flowing from Warner Chilcott to Lupin under the Agreement was to delay generic competition to Loestrin 24 Fe and there is and was no legitimate, non-pretextual, procompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

196. At all relevant times, Warner Chilcott possessed market power in the relevant market. Warner Chilcott possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

197. The goal, purpose and/or effect of the Exclusion Payment Agreement was to prevent and/or delay generic competition to Loestrin 24 Fe and enable Warner Chilcott to continue charging supracompetitive prices for Loestrin 24 Fe without a substantial loss of sales. By means of the Warner Chilcott's payment to Lupin, the Defendants shared the supracompetitive profits that their unlawful agreement made possible.

198. Defendants each committed at least one overt act in furtherance of the conspiracy.

199. As a direct and proximate result of Defendants' unlawful restraint of trade Plaintiffs and members of the Class were harmed as described herein.

200. Plaintiffs and the Class, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. § 2201(a) hereby seek a declaratory judgment that Defendants' conduct as described herein violates Section 1 of the Sherman Act.

201. Plaintiffs and the Class further seek equitable and injunctive relief 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 the unlawful conduct of Defendants, and other relief so as to assure that similar anticompetitive conduct does not occur in the future.

**FOURTH CLAIM FOR RELIEF**  
**For Conspiracy and Combination in Restraint  
of Trade Under State Law  
(Asserted Against Warner Chilcott and  
Lupin)**

202. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

203. The Exclusion Payment Agreement between Warner Chilcott and Lupin involves: (a) a payment from Warner Chilcott to Lupin; and (b) an agreement by Lupin to delay marketing its generic Loestrin 24 Fe until July 22, 2014. The payments from Warner Chilcott to Lupin under the Agreement was the *quid pro quo* for Lupin's agreement to delay marketing its generic versions of Loestrin 24 Fe for over four years. Absent the payments, Lupin would not have agreed to delay marketing its generic versions of Loestrin 24 Fe until July 22, 2014.

204. The purpose and effect of the payments flowing from Warner Chilcott to Lupin

under the agreement was to delay generic competition to Loestrin 24 Fe and there is and was no legitimate, non-pretextual, precompetitive business justification for the payment that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve such a purpose.

205. The purpose and effect of the unlawful Exclusion Payment Agreement between Warner Chilcott and Lupin was to allocate 100% of the market for Loestrin 24 and its generic equivalents in the United States to Warner Chilcott; delay the sales of generic Loestrin 24 Fe products for over four years; and fix the price at which consumers and other End-Payor Plaintiffs would pay for Loestrin 24 and its generic equivalents at the higher, branded price.

206. The Exclusion Payment Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

207. As a direct and proximate result of Defendants' unlawful restraint of trade, Plaintiffs and members of the Class paid artificially inflated prices for Loestrin 24 and its generic equivalents as described herein, and were harmed as a result.

208. By engaging in the foregoing conduct, Defendants have violated the following state laws:

- a. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Arizona Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases of Loestrin 24 Fe in Arizona by members of the Class.
- b. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Cal. Bus. Code §§ 16700, *et seq.*, and Code §§ 17200, *et seq.*, with respect to purchases of Loestrin 24 Fe in California by members of the Class.

- c. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of D.C. Code Ann. §§ 28-45031, *et seq.*, with respect to purchases of Loestrin 24 Fe in the District of Columbia by members of the Class.
- d. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.*, with respect to purchases of Loestrin 24 Fe in Florida by members of the Class, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.
- e. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Kansas by members of the Class.
- f. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Maine by members of the Class.
- g. Defendant have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, *et seq.*, with respect to purchases of Loestrin 24 Fe in Massachusetts by members of the Class.
- h. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Mich. Comp. Laws Ann. §§ 445.771, *et seq.*, with respect to purchases of Loestrin 24 Fe in Michigan by members of the Class.
- i. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Minn. Stat. §§ 325D.52, *et seq.*, with respect to purchases of Loestrin 24 Fe in Minnesota by members of the Class.
- k. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in Mississippi by members of the Class.
- l. Defendants have intentionally and wrongfully engaged in a contract,

combination or conspiracy in restraint of trade in violation of Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nebraska by members of the Class.

- m. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Nev. Rev. Stat. Ann. § 598A, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nevada by members of the Class, in that thousands of sales of Loestrin 24 Fe took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- n. Defendants have intentionally and wrongfully engaged in a contract, combination and conspiracy in restraint of trade in violation of N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in New Mexico by members of the Class.
- o. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of New York General Business Law § 340, *et seq.*, with respect to purchases of Loestrin 24 Fe in New York by members of the Class.
- p. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in North Carolina by members of the Class.
- q. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchases of Loestrin 24 Fe in North Dakota by members of the Class.
- r. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases of Loestrin 24 Fe in Oregon by members of the Class.
- s. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of R.I. Gen. Laws §§ 6-36-5, *et seq.* with respect to purchases of Loestrin 24 FE in Rhode Island by members of the Class.
- t. Defendants have intentionally and wrongfully engaged in a contract,

combination or conspiracy in restraint of trade in violation of S.D. Codified Laws Ann. § 37-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in South Dakota by members of the Class.

- u. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payers in Tennessee paying substantially higher prices for Loestrin 24 Fe at Tennessee pharmacies.
- v. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Utah Code Ann. §§ 76-10-911, *et seq.*, with respect to purchases of Loestrin 24 Fe in Utah by residents of Utah who are members of the Class.
- w. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Vt. Stat. Ann. 9, § 2453, *et seq.*, with respect to purchases of Loestrin 24 Fe in Vermont by members of the Class.
- x. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in West Virginia by members of the Class.
- y. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Wis. Stat. § 133.01, *et seq.*, with respect to purchases of Loestrin 24 Fe in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payers in Wisconsin paying substantially higher price for Loestrin 24 Fe at Wisconsin pharmacies.

209. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Loestrin 24, and (2) paying higher prices for branded Loestrin 24 than they would have paid in the absence of

Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

210. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

**FIFTH CLAIM FOR RELIEF**

**For Conspiracy and Combination in Restraint of Trade Under State Law  
(Asserted against all Defendants)**

211. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

212. By entering the Exclusion Payment Agreements, Warner Chilcott engineered an agreement with, between and among itself and the Generic Defendants not to compete with each other and to delay generic entry, which constituted a continuing illegal contract, combination and conspiracy in restraint of trade.

213. In or about January 2009 and at times before the formal execution thereof, Warner Chilcott and Watson entered into the Warner Chilcott/Watson Exclusion Payment Agreement under which Warner Chilcott agreed to make substantial payments to Watson in exchange for its agreement to delay bringing its generic version of Loestrin 24 Fe to the market. As part of that conspiracy, Warner Chilcott agreed, among other things, that: (1) it would not license any other generic manufacturer to enter the market until 180 days after Watson entered; and (2) if any other generic manufacturer entered the market before January

22, 2014, Watson's entry date would be accelerated accordingly.

214. During the negotiation of its Exclusion Payment Agreement with Warner Chilcott, Lupin was aware of these two terms (among others) of the Warner Chilcott/Watson conspiracy. Lupin joined that ongoing conspiracy by, among other things, agreeing not to enter before January 22, 2014, which would have triggered earlier entry by Watson, and by accepting an entry date, pursuant to the terms of the conspiracy initiated by Warner Chilcott and Watson, that was 180 days beyond the specified entry date for Watson.

215. The purpose and effect of the conspiracy was to: (1) allocate to Warner Chilcott 100% of the market for the oral contraceptive comprising of 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets and its generic equivalents in the United States; (2) delay or impair the market entry of generic versions of the oral contraceptive comprised of 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets, i.e., AB-rated generic versions of Loestrin 24 Fe; and (3) fix at supracompetitive levels the price that end-payors would pay for the oral contraceptive comprised of 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets.

216. There are and were no legitimate non-pretextual, procompetitive business justifications for this unlawful conspiracy that outweigh its harmful effects.

217. As a direct and proximate result of Defendants' concerted illegal conduct, contract, combination and conspiracy in restraint of trade as alleged herein, Plaintiffs and

members of the Class paid artificially inflated prices for Loestrin 24 Fe as described herein and were harmed as a result.

218. By engaging in the foregoing conduct, Defendants have intentionally and wrongfully engaged in one or more combinations and conspiracies in restraint of trade in violation of the following state laws:

- a. Arizona Rev. Stat. §§ 44-1402, et seq., with respect to purchases in Arizona by members of the Class.
- b. Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in California by members of the Class.
- c. D.C. Code Ann. §§ 28-4502, et seq., with respect to purchases in the District of Columbia by members of the Class.
- d. Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.
- e. 740 Ill. Comp. Stat. 10/3, et seq., with respect to purchases in Illinois by members of the Class.
- f. Iowa Code § 553.2 et seq., with respect to purchases in Iowa by members of the Class.
- g. Kan. Stat. Ann. §§ 50-101, et seq., with respect to purchases in Kansas by members of the Class.
- h. Mass. Gen. L. Ch. 93A, et seq., with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for delayed-release esomeprazole magnesium in actions and transactions occurring substantially within Massachusetts.
- i. Me. Rev. Stat. Ann. 10, § 1101, et seq., with respect to purchases in Maine by members of the Class.
- j. Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to purchases in Michigan by members of the Class.
- k. Minn. Stat. §§ 325D.51, et seq., with respect to purchases of in Minnesota by

members of the Class.

- l. Miss. Code Ann. §§ 75-21-3, et seq., with respect to purchases in Mississippi by members of the Class.
- m. Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class.
- n. Nev. Rev. Stat. Ann. § 598A.060, et seq., with respect to purchases in Nevada by members of the Class, in that thousands of sales of Loestrin 24 Fe took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.
- o. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the Class.
- p. New York General Business Law § 340, et seq., with respect to purchases in New York by members of the Class.
- q. N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the Class.
- r. N.D. Cent. Code § 51-08.1-02, et seq., with respect to purchases in North Dakota by members of the Class.
- s. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class.
- t. 10 L.P.R.A. § 251, et seq., with respect to purchases in Puerto Rico by members of the Class.
- u. R.I. Gen. Laws §§ 6-36-5, *et seq.* with respect to purchases in Rhode Island by members of the Class
- v. S.D. Codified Laws Ann. § 37-1-3.2, et seq., with respect to purchases in South Dakota by members of the Class.
- w. Utah code Ann. §§ 76-10-911, et seq., with respect to purchases in Utah by residents of Utah who are members of the Class.
- x. Tenn. Code Ann. §§ 47-25-101, et seq., with respect to purchases in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Loestrin 24 Fe and AB-rated generic

equivalents at Tennessee pharmacies.

- y. Vt. Stat. Ann. 9, § 2453, et seq., with respect to purchases in Vermont by members of the Class.
- z. W.Va. Code §§ 47-18-3, et seq., with respect to purchases in West Virginia by members of the Class.
- aa. Wis. Stat. § 133.03, et seq., with respect to purchases in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Loestrin 24 Fe at Wisconsin pharmacies.

219. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic the oral contraceptive comprising of 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets, and (2) paying higher prices the oral contraceptive comprising of 24 norethindrone acetate/ethinyl estradiol (1mg/20mcg) tablets and 4 ferrous fumarate tablets than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

220. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

**SIXTH CLAIM FOR REVIEW**  
**For Unfair or Unconscionable Acts and**  
**Practices Under State Law**  
**(Asserted Against All Defendants)**

221. Defendants engaged in unfair competition or unfair or unconscionable, practices in violation of the state consumer protection statutes listed below. As a direct and

proximate result of Defendants' anticompetitive, unfair, or unconscionable, conduct, Plaintiffs and class members were deprived of the opportunity to purchase a generic version of Loestrin 24 Fe and forced to pay higher prices. By engaging in the foregoing conduct, Defendants have engaged in unfair competition in violation of the following state laws:

- a. Defendants have engaged in unfair competition or unfair acts or practices in violation of Ala. Ala. Code §8-19-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in Alabama by members of the Class.
- b. Defendants have engaged in unfair competition or unfair acts or practices in violation of Cal. Bus. & Prof. Code § 17200, *et seq.*, with respect to purchases of Loestrin 24 Fe in California by members of the Class.
- c. Defendants have engaged in unfair competition or unfair acts or practices in violation of D.C. Code §§ 28-3901, *et seq.* with respect to the purchases of Loestrin 24 Fe in the District of Columbia by members of the Class.
- d. Defendants have engaged in unfair competition or unfair acts or practices in violation of Fla. Stat. § 501.201, *et seq.*, with respect to purchases of Loestrin 24 Fe in Florida by members of the Class.
- e. Defendants have engaged in unfair competition or unfair acts or practices in violation of 815 ILCS § 505/1, *et seq.*, with respect to purchases of Loestrin 24 Fe in Illinois by members of the Class.
- f. Defendants have engaged in unfair competition or unfair acts or practices in violation of Idaho Code §§ 48-601, *et seq.* with respect to purchases of Loestrin 24 Fe in Idaho by members of the Class.
- g. Defendants have engaged in unfair competition or unfair acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*, with respect to purchases of Loestrin 24 Fe in Maine by members of the Class.
- h. Defendants have engaged in unfair competition or unfair acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases of Loestrin 24 Fe in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for Loestrin 24 Fe in actions and transactions occurring substantially within Massachusetts.

- i. Defendants have engaged in unfair competition or unfair acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nebraska by members of the Class.
- j. Defendants have engaged in unfair competition or unfair acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*, with respect to purchases of Loestrin 24 Fe in Nevada by members of the Class.
- k. Defendants have engaged in unfair competition or unfair acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*, with respect to purchases of Loestrin 24 Fe in New Mexico by members of the Class.
- l. Defendants have engaged in unfair competition or unfair acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*, with respect to purchases of Loestrin 24 Fe in North Carolina by members of the Class.
- m. Defendants have engaged in unfair competition or unfair acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*, with respect to purchases of Loestrin 24 Fe in Tennessee by members of the Class.
- n. Defendants have engaged in unfair competition or unfair acts or practices in violation of 9 Vt. § 2451 *et seq.*, with respect to purchases of Loestrin 24 Fe in Vermont by members of the Class.
- o. Defendants have engaged in unfair competition or unfair acts or practices in violation of West Virginia Code § 46A-6-101, *et seq.*, with respect to purchases of Loestrin 24 Fe in West Virginia by members of the Class.
- p. Defendants have engaged in unfair competition or unfair acts or practices in violation of Wisconsin Code § 100.2, *et seq.*, with respect to purchases of Loestrin 24 Fe in Wisconsin by members of the Class.

222. Plaintiffs and members of the Class have been injured in their business and property by reason of Defendants' anticompetitive, unfair acts alleged in this Claim. Their injury consists of paying higher prices for Loestrin 24 Fe than they would have paid in the absence of these violations. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

**SEVENTH CLAIM FOR RELIEF**

**Unjust Enrichment**

**(Asserted Against All Defendants)**

223. Plaintiffs hereby incorporate each preceding and succeeding paragraph as though fully set forth herein.

224. Defendants have benefited from splitting the monopoly profits on Warner Chilcott's Loestrin 24 Fe sales resulting from the unlawful and inequitable acts alleged in this Complaint.

225. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Loestrin 24 by Plaintiffs and members of the Class.

226. Plaintiffs and the Class have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiffs and the Class.

227. It would be futile for Plaintiffs and the Class to seek a remedy from any party with whom they had privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from Plaintiffs and the Class.

228. It would be futile for Plaintiffs and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which it indirectly purchased Loestrin 24 Fe, as they are not liable and would not compensate Plaintiffs for unlawful conduct caused by Defendants.

229. The economic benefit of overcharges and unlawful monopoly profits derived

by Defendants through charging supracompetitive and artificially inflated prices for Loestrin 24 Fe is a direct and proximate result of Defendants' unlawful practices.

230. The financial benefits derived by Defendants rightfully belongs to Plaintiffs and the Class, as Plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendants.

231. It would be inequitable under the laws of all states and jurisdictions within the United States, except for Indiana and Ohio, for the Defendants to be permitted to retain any of the overcharges for Loestrin 24 Fe derived from Defendants' unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

232. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs and the Class all unlawful or inequitable proceeds received by them.

233. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to Plaintiffs and the Class.

234. Plaintiffs and the Class have no adequate remedy at law.

#### **XIV. DEMAND FOR JUDGMENT**

WHEREFORE, Plaintiffs, on behalf of themselves and the End-Payor Class, demands judgment for the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a), 23 (b)(2) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class and declare the Plaintiffs representative of the End-Payor Class;

B. Declare that the conduct alleged herein is in violation of Section 1 of the Sherman Act, of the other statutes set forth above, and of the common law of unjust enrichment under the laws of all states and jurisdictions within the United States;

C. Enjoin Defendants from continuing the illegal activities alleged herein;

D. Enter joint and several judgments against Defendants in favor of Plaintiffs and the End-Payor Class;

E. Grant Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

F. Award the End-Payor Class damages and, where applicable, treble, multiple, punitive, and/or other damages, in an amount to be determined at trial, including interest;

G. Award Plaintiffs and the End-Payor Class their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grant such other further relief as is necessary to correct for the anticompetitive market effects caused by the unlawful conduct of Defendants, and as the Court deems just.

#### **XV. JURY DEMAND**

Pursuant to Fed. Civ. P. 38, Plaintiffs on behalf of themselves and the proposed Class demand a trial by jury on all issues so triable.

/s/ Marvin A. Miller

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